Competitiveness and Death: Trade and Politics in Cars, Beef, and Drugs

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Competitiveness and Death: Trade and Politics in Cars, Beef, and Drugs

Gary Winslett

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Abstract: Cross-national differences in regulation have become the most significant barrier to international trade. My dissertation attempts to explain why states sometimes choose to reduce these regulatory trade barriers but at other times choose to maintain or increase them. To do this, I examine the international negotiation over regulatory trade barriers in three in-depth case studies, one from each of the three main areas of the international trade in goods: manufacturing, agriculture, and high-technology. The first investigates consumer safety, labor-related domestic content, and environmental regulations in the trade in automobiles in North America and the European Union. The second analyzes mad-cow safety regulations and the trade in beef between the United States and Japan. The third examines intellectual property regulations and the trade in pharmaceuticals between the United States and India.

I contend that the best way to explain this variation is by examining the motivations of three sets of actors (businesses, activists, and government officials) and the political bargaining between those three groups. Businesses seek to reduce regulatory barriers when those barriers raise production costs or inhibit market access. They may however choose to end that pursuit if those regulations are cheap to comply with or pursuing their reduction carries major reputational risk. Activists defend regulatory barriers when they perceive those regulations to be the sole effective means to address a societal problem they are concerned about. They may accept a reduction in regulatory barriers if those barriers have low salience or their opposition is bought out through private standards, corporate social responsibility, or some other arrangement in which businesses are not directly regulated by government. Government officials choose whether to side with businesses or activist groups based on their relative prioritization of trade and regulatory independence, their staffing, and whom they identify as their core constituency.

Businesses are likely to succeed at reducing a regulatory trade barrier when they can link their desire for that reduction with broader concerns about economic competitiveness while activist organizations are likely to succeed at defending regulatory trade barriers when they can link their desire for maintaining or increasing that barrier with preventing needless death.

This dissertation thus adds to the current understanding of international political economy by demonstrating that multinational corporations have less political power than is commonly assumed and by augmenting traditional explanations of trade politics based on economic cleavages through analyzing activists’ engagement in trade politics now that trade politics significantly affects regulations.
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Chapter 1: Introduction- The Centrality of Regulation to Trade Politics

Airbags, Antibiotics in Pork, and the Newest Generation of Cancer Drugs

American and European airbags are different.\textsuperscript{1} European airbags are tested based on the assumption that vehicle occupants are wearing their seat belts. If occupants are wearing seat belts, automakers know where the occupant’s head will be in a crash. This assumption leads to a smaller, more focused airbag. Conversely, given that many Americans do not wear their seat belts, American airbags are tested based on the assumption that the occupants are \textit{not} wearing seat belts. This assumption necessitates a larger airbag. For most automakers, it is prohibitively costly to design an airbag that meets safety requirements in both places. Thus automakers must have two production lines for airbags or have only one production line but forgo sales in a major market.

Another regulatory difference involves what is known as the baby head test.\textsuperscript{2} In the United States, safety specifications revolve around just one idea: protect the people inside the vehicle. In the EU however, because they have denser cities and a much higher percentage of accidents involve pedestrians, automobiles must be designed and tested to reduce injury both to the vehicle’s passengers and any pedestrian struck by the vehicle. One test within the constellation of regulations that accompany this goal involves launching a ball into the hood of a car to simulate a small child being struck by the car, i.e. the baby head test. The United States does not have such a test. These differences mean that vehicles have to be produced one way for one market and a different way for another. Here then are two regulatory differences that drive up the cost of trade for automakers in the two most lucrative auto markets in the world.

\textsuperscript{1} National Public Radio. “Why Cars From Europe and the US Just Can’t Get Along.” April 18, 2014.
\textsuperscript{2} Ibid.
\textsuperscript{3} The Economist. “Empire of the Pig.” December 20, 2014.
The amount of pork that Chinese consumers eat is staggering. The average Chinese person consumes nearly 90 pounds of pork per year, with the country as a whole consuming nearly half a billion pigs annually, and the number is growing as living standards and demand for meat expand. U.S. pork producers are some of the most efficient in the world, producing 23 billion pounds of pork annually, and would love to gain significant market share in this most lucrative of export opportunities. But many of them cannot. American pork producers give their swine ractopamine, an antibiotic that has the side effect of promoting accelerated growth; China bans ractopamine. Here then is a regulatory barrier inhibiting trade between the world’s most prolific pork eaters and the world’s most efficient pork producers, which just so happen to also be the two states with the most important economic relationship in the twenty-first century.

Pharmaceutical research has now advanced to the point where medications can be made not just from synthetic components but also from living cells. These new drugs called ‘biologics’ represent some of the most cutting-edge research in the pharmaceuticals industry and may soon lead to medicines for maladies that currently have little or no effective treatment. Just one kind of biologic drug, PD1 inhibitors, has generated huge excitement in the medical community due to its heightened efficacy in fighting certain cancers. These drugs are a generational leap forward from their

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predecessors and may do for cancer therapy what AZT did for HIV. PD1 inhibitors like Merck’s Keytruda are miracles in pill form; they are also wildly expensive. Biologics, even more than other drugs, can come with astoundingly high costs.  

Promoting innovation while controlling costs is the central dilemma of intellectual property regulation in pharmaceuticals. Trade-related intellectual property rules have generally only applied to synthetic chemical compounds and so covering biologics with intellectual property regulations requires new rule-making efforts at the international level. Pharmaceutical companies, for obvious reasons, are highly reluctant to produce drugs in, or import drugs into, countries in which their intellectual property rights will not be upheld. Differences in regulation on intellectual property thus have the power to impede the international trade in pharmaceuticals. The tension over these regulatory barriers has played out between the United States and other states in the Trans-Pacific Partnership (TPP) negotiations. The United States wanted to maximize the regulatory protections on biologics by granting twelve years of data exclusivity while other states wanted five years or less. The disagreement over that regulatory protection was perhaps the most contentious issue on the entire TPP docket and the very last issue resolved in the

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8 Most Americans who became infected with HIV just a few years before Magic Johnson have unfortunately no longer been with us for two decades now. Many U.S. citizens who became infected around the time Magic Johnson did (1991) have been able to continue leading productive, fulfilling lives. The sea change occurred as a result of the invention and approval of the first highly effective treatment for HIV. That drug was AZT.


In other words, the single biggest regional trade deal every negotiated hinged on states’ ability to find agreement on a regulatory trade barrier in pharmaceuticals.

The Practical Significance of Regulatory Trade Barriers

The difference in air bag rules, the disagreement over ractopamine in pork, and the negotiations over biologics data exclusivity are just three of the many examples of cross-national differences in regulation constituting significant impediments to international trade. These regulatory trade barriers are everywhere. They affect $5 trillion worth of traded goods annually and influence a wide range of policy areas. Regulatory and other non-tariff trade barriers are becoming so important that the WTO’s 2012 Trade Report was entirely dedicated to them; the WTO Director-General stated that these non-tariff measures “will not follow a path of diminishing relevance like tariffs have done. They will not shrink in importance. Regulatory interventions…with inevitable consequences for trade flows and investment are here to stay.”

Not only are regulatory barriers important for trade, they also affect nearly everyone’s daily lives. Everyone eats; a large portion of the food a person eats has been traded internationally before it is consumed. The differences in national regulations affect how safe that food is and how much it costs. Everyone wears clothes; the connection between the international trade in

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textiles and labor standards affects the conditions under which millions of people are employed and what it costs a consumer to be properly clothed. Many people take medications; including intellectual property regulations in international trade agreements influences how quickly innovative new drugs come on to the market as well as whether poor people in developing countries have access to needed medicines. Many people drive automobiles; the safety and environmental regulations on automobiles affect the chances of a person surviving an accident as well as the speed with which global warming progresses. In virtually all industries, by inhibiting or promoting firms’ ability to sell their goods in multiple markets, regulatory trade barriers impact businesses’ profit margins and in turn workers’ pay packets. Regulatory trade barriers have real world consequences for just about everyone. This book explains the politics that surrounds those regulatory trade barriers.

**The Question and My Answer**

When the differences between countries’ domestic regulations impede international trade, the states involved have three basic options. They can reduce those regulatory barriers, they can increase them, or they can do nothing. This dissertation asks when are states more likely to do each of these and why.\textsuperscript{15} I argue that regulatory trade barriers are most likely to be reduced when businesses are able to link their desire for that reduction with broader societal concerns about economic competitiveness while activist organizations are likely to succeed at increasing regulatory trade barriers when they can link their desire for maintaining or increasing that barrier with preventing needless death.

\textsuperscript{15} Note that reducing regulatory trade barriers may not be the same thing as reducing regulations. If regulations are harmonized upward, that is still a reduction in a trade barrier.
How This Study of Regulatory Trade Barriers Advances IPE Scholarship

Improving on Cleavage-Based Explanations

Trade politics no longer operates the way that it used to. David Ricardo famously argued that trade benefits countries by allowing them to specialize production in the goods in which they have the greatest comparative advantage and then trade that good for products in which they do not have a comparative advantage. Heckscher-Ohlin and then Stolper-Samuelson built on this logic and argued that trade would help the owners of a society’s abundant factor as that abundance is what drives a country’s comparative advantage. Therefore, trade would benefit the owners of capital in a capital-intensive country like the United States. The political corollary to that is that the owners of a society’s abundant factors will be in favor of trade liberalization while the owners of a society’s scarce factors are likely to seek trade protection. Thus, in the United States the owners of capital are likely to advocate free trade while low-skilled laborers are likely to oppose free trade.

Two of the most famous works on trade politics, Ronald Rogowski’s *Commerce and Coalitions* and Michael Hiscox’s *International Trade and Political Conflict* both build their arguments on the basis of these kinds of cleavages. Rogowski assumed that there are three political groups in society: land-owners, laborers, and capital owners. Let is say that in a given society, capital and labor are relatively abundant but land is relatively scarce. An expansion of trade will help laborers and capital owners as they are the holders of the abundant resources but hurt landowners as they are the holders of

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scarce resource. The capital owners and laborers will form a political coalition to push for
greater trade while landowners will advocate for protectionism. That society will thus
have an urban-rural political cleavage. Likewise, labor and land being abundant but
capital being scarce leads to a Red-Green coalition against the capitalists. Michael Hiscox
added greater nuance to this framework by showing that under conditions of low factor
mobility (i.e. high asset specificity), these cleavages are more likely to be between
different industry sectors rather than different social classes. This cleavage-based
framework has also been employed by others as well. At its core, these cleavage-based
explanations assert that trade generates economic benefits for some slice of society,
shrinks the benefits that go to other sectors of society, and the political struggle over trade
amounts to a fight between the economic winners and losers from trade.

As helpful as these theories are in explaining the trade politics that are unrelated
to regulation, they struggle to explain the politics of regulatory trade barriers. Because
they tend to focus on the economic implications of trade, they tend to ignore those
societal actors that have an interest in trade but are motivated by non-economic policy
goals. As trade increasingly impacts regulations, these actors have proliferated.
Additionally, in many disputes over regulatory barriers, some actors such as consumers
have acted in ways that are at odds with their apparent economic interests, which
according to the cleavage-based explanations should be the driver of their preferences. It
would also imply that firms seeking to limit trade would advocate for greater regulatory

19 Gourevitch, Peter. 1986. Politics in Hard Times: Comparative Responses to International Economic
trade barriers but, as I mentioned earlier, at least since the 1980s, they have not tended to do that.

An additional reason the cleavage-based framework struggles to explain regulatory trade barrier developments is that it either ignores the role played by government officials or depicts them as the mouthpiece of firms located in their state. That is problematic. Understanding the intersection of trade and the environment, for example, requires examining environmental NGOs as well as government officials’ preferences on environmental regulation.

Cross-national differences in regulation have become the most prominent issue in international trade politics and continue to grow even more important. Thus, the failure to explain regulatory trade barriers constitutes a large and expanding blind spot for these cleavage-based explanations. Now that trade is inextricably bound up with regulation, the politics that surround it are fundamentally new and require a new set of explanations. This study provides one of those explanations.

**A Hard Case for Resisting Globalization**

One of the aspects of this study that is unique is that it demonstrates the limitations of the power of globalization to compel policy adjustment in areas in which that power should be at its strongest. Globalization-driven policy convergence is especially likely to be the case in those policy areas that tangibly and significantly affect other states’ commercial opportunities. These impacts on foreigners lead to greater pressure from those foreigners on that state to amend its policies to reduce that commercial curtailment.

This is why trade-related regulations present such an interesting test case for the power of globalization. In some ways, it is not surprising that governments’ social
welfare, infrastructure, and defense spending policies do not show much convergence. In each of these cases, there are powerful reasons for governments to jealously guard their autonomy, there are limited commercial gains to that state from adjusting to be more like other countries, and there are relatively small commercial impacts on foreigners which generates relatively little objection to that policy autonomy.

Trade-related policies are a different matter. When a given policy affects another state’s commercial opportunities in that country, it very much does lead to pressure to adjust that policy. Moreover, because trade liberalization generally gets done reciprocally, adjusting that policy holds out the promise of benefiting from greater access to that state’s market. As I show in chapter 2, domestic regulations have become the central issue in trade politics. Unlike with those policies that generally do not directly affect foreigners, the incentives to adjust those regulations ought to be immense. Additionally, the generally low salience of most regulations means that making these changes should be relatively easy when compared to altering policies in areas like the level of social spending. If business-driven globalization dominates anywhere, it ought to be in the area of regulatory trade barriers, but even here, the extent of policy stickiness is striking.

In IPE scholarship, there has been a long-running debate between those who see globalization as exerting a great deal of pressure on governments to adjust their policies in ways that make them more similar to those in other countries and those who argue that states are likely to maintain their policy differences despite the pressures globalization
exerts.\textsuperscript{20} This study lands squarely in the second camp though suggests some circumstances under which the first camp may at times be correct.

\textit{Case Selection - A Practically Significant Set of Puzzles}

The choice of which cases to analyze in this study emerged from a dual set of motivations: practical significance and the analytic leverage created by empirical puzzles.

\textbf{Practical Significance}

First, the automotive, beef, and pharmaceuticals industries all have a great deal of practical significance. They are all large, important industries in their own right and merit attention simply on that consideration.\textsuperscript{21} As of 2014, the total value of the annual international trade in automotive products, food, and pharmaceuticals was $1.4 trillion, $1.5 trillion, and $550 billion respectively.\textsuperscript{22} Each of these industries, at a global level, affects millions of workers and billions of consumers.

Second, they are varied. Had I chosen three agriculture-related industries, any patterns I found might simply have been due to some idiosyncrasy in within that field. I wanted to have one industry from agriculture, one from manufacturing, and one that was more technologically advanced as those collectively comprise three of the most important kinds of internationally traded goods. Given how varied these three industries are, it is safe to say that they are at least fairly representative of the types of goods that are traded


\textsuperscript{22} \textit{World Trade Organization}. Statistics Database. Merchandise Trade by Commodity. Accessed May 1, 2016. This data is for 2014.
internationally. Moreover, each of them is a quintessential industry in its sector. If one wants to know how regulatory barriers affect manufacturing, the automotive industry is an excellent place to start. The same is true for beef in agriculture and pharmaceuticals in high technology.

Furthermore, each of the three industry studies has their own additional advantages. The automotive industry was one of the earliest sectors to be highly affected by regulatory barriers and so findings from that industry may preview the dynamics that we are likely to see in other sectors as they too become entangled in these barriers.

Examining the auto industry also allows for an investigation into one of the most fundamental trends in international trade: the rise of regionalism. Trade in automobiles is one of the clearest manifestations of this trend; almost three-quarters of the international trade in automobiles is intra-regional. Analyzing this industry thus helps illuminate why trade liberalization, at least as it pertains to regulation, has progressed at the regional but not global level.

The beef industry case involving mad-cow regulations and the U.S.-Japan beef trade has not yet been thoroughly analyzed by trade scholars. The trade disputes surrounding growth hormones and genetically modified organisms (GMOs) have already received large amounts of scholarly attention. If we as scholars want to learn something

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that we do not already know, and we believe the already-examined cases were adequately analyzed, then the most fruitful intellectual route is to study cases that have not already been exhaustively investigated. Chapter 5 does exactly that.

The pharmaceuticals case is useful because it tackles regulatory barriers such as compulsory licensing that are becoming increasingly prevalent and significant. As countries grow older and wealthier, the health care sector is likely to become that much more important. Additionally, intellectual property is one of the regulatory areas that most clearly pits developing versus developed countries and so examining that issue area allows for an exploration of that dynamic as well.

**A Set of Puzzles**

As Daniel Drezner points out, the paucity of good data appropriate for testing hypotheses on regulatory trade barriers make statistical analysis all but impossible; this means that case studies and process tracing are the most fruitful research method and are thus what I employ throughout this book.\(^{26}\) This work is thus also broadly consistent with the ‘analytic narratives’ research methods employed by James Shoch in his analysis of political parties’ influence on U.S. trade policy in the 1980s and 1990s and with the ‘grounded theory’ approach employed by Margaret Keck and Kathryn Sikkink in their
examination of civil society activists.\textsuperscript{27} Within the case studies, I rely upon any existing public information that I can find; these primarily consist of industry and NGO statements, the congressional record, government reports, newspaper articles, and other secondary sources.\textsuperscript{28}

Each case also constitutes an empirical puzzle for existing explanations of trade politics. The automobile case is centered on the puzzle that regulatory trade barriers were reduced within Europe and within North America but not reduced between them. The explanations that could be used to elucidate the intra-regional reduction such as economies of scale or factor-price differences would have predicted inter-regional reduction and yet that did not happen.\textsuperscript{29} Conversely, explanations that could be used to illuminate the lack of inter-regional reduction such as differences in regulatory strategy should have prevented intra-regional reduction and yet that did not happen either.

The beef industry case is centered on the puzzle that even though a number of factors that scholars consider important for explaining trade politics outcomes remained static throughout the time period examined (2003-2013), the was still significant movement in the extent to which regulatory differences impeded the trade in beef between the United States and Japan. First, the institutional context these negotiations


\textsuperscript{28} Again, in terms of style but not content, I am following in Drezner’s footsteps. The majority of the material he used for \textit{All Politics is Global} was publicly available information. This was also the case for Büthe and Mattli’s \textit{The New Global Rulers} and Shoch’s \textit{Trading Blows} as well as Susan Aaronson’s two books. Drezner. 2007. \textit{All Politics is Global}. Büthe and Mattli. 2011. \textit{The New Global Rulers}. Shoch. 2001. \textit{Trading Blows}. Aaronson. 1996. \textit{Trade and the American Dream}. Aaronson. 2001. \textit{Taking Trade to the Streets}.

took place in remained the same throughout this time period.\textsuperscript{30} Examining cases where the institutional context is constant does however allow for a more accurate examination of non-institutional factors.\textsuperscript{31} I am not arguing that institutions have no importance, only that they are not the sole entities that matter; there are a number of other non-institutional factors that also may augment or attenuate trade barriers. Second, the market power of each state also did not significantly shift over this time.\textsuperscript{32} As with institutions, choosing a case where this remains constant allows for a clearer examination of other factors.

\textsuperscript{30} At the global level, the entirety of this case takes place after the World Trade Organization’s Sanitary and Phytosanitary Agreement comes into force in 1995. The SPS is the international agreement that governs trade regulations on agricultural products. The central idea behind the SPS is that states have a right to set regulations to protect the health of their citizens and the safety of their food supply but the use of these regulations as a surreptitious means of protecting domestic producers is unacceptable. The SPS has three central provisions. First, if a state bases a regulation on the international standard as defined by a designated international non-governmental organization such as the Codex Alimentarius or the World Animal Health Organization (OIE), that regulation is considered WTO-compliant. Second, if a state sets regulations that are different from the international standard, those regulations must have a scientific basis. Third, states’ must use policies that are not more trade-restrictive than is necessary to achieve their regulatory goals. At the domestic level, there were no institutional transformations that could account for these changes in regulatory trade barriers.


The pharmaceuticals industry case is centered on the puzzle that despite similar power asymmetries between developing and developed countries throughout the time period analyzed, there are highly varied outcomes in the movement of regulatory trade barriers. They were significantly reduced in the TRIPS Agreement, reinforced in the Doha Declaration, and then a political draw in subsequent WTO negotiations as well as in India’s use of TRIPS flexibilities. Additionally, it was also somewhat puzzling that developing states agreed to TRIPS in the first place, given that TRIPS was not in their interests, and puzzling that the United States backed down in the negotiations over the Doha Declaration despite its economic and diplomatic power.

In addition to constituting an analytically useful set of puzzles, these three cases also provide leverage to study the politics of regulatory barriers because the outcomes vary both between cases and within cases. Between the three industry chapters, there are 11 subcases analyzed in automobiles, 8 in beef, and 4 in pharmaceuticals. The between case comparisons generate insights that can be applied to other industries while the within case variation allows for detailed process tracing and empirical depth.

**How Regulation Became Central to Trade Politics**

In Chapter 2, I explain how national regulations became the central to international trade politics. By the 1970s, six round of GATT negotiations had reduced tariffs to a fraction of what they were in the 1940s. As tariffs receded, non-tariff barriers (NTBs) became more significant. The Tokyo Round launched in 1973 was the first round to address these NTBs. The expansion of trade and national regulations combined with the increased sophistication of traded products and the heightened level of intra-industry trade further raised the significance of regulatory trade barriers. In the 1980s, states

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33 The Tokyo Round however did not compel GATT members to abide by the codes that were designed to curtail these NTBs.
becoming more concerned with their export performance and Western businesses pushed for trade rules in new areas added to this as well.

The Uruguay Round further constrained NTBs, which made regulatory barriers more apparent and more important, placed new rules on states’ use of regulations that had trade implications, and brought these new rules under a more robust dispute settlement process. As trade agreements increasingly impacted regulations, labor unions, environmentalists, consumer safety activists, and access to medicine advocates that previously were not interested in trade but were interested in regulations became more engaged in trade politics. These activists have pushed for specifically national regulations that can function to impede trade. Businesses on the other hand have sought to reduce these regulatory trade barriers. Finding agreement on these regulatory barriers has been impossible in the Doha Round, which has fueled the proliferation of regional and bilateral trade deals.

**Summary Preview of My Argument**

In Chapter 3, I present my main argument in full. I assert that businesses seek to reduce regulatory trade barriers when those barriers raise production costs or inhibit market access. They may however choose to end that pursuit if those regulations are cheap to comply with or pursuing that reduction carries major reputational risk. Activist groups defend regulatory barriers when they perceive those regulations to be the sole effective means to address a societal problem they are concerned about. They may accept a reduction in regulatory barriers if those barriers have low salience or their opposition is bought out through private standards, corporate social responsibility, or some other arrangement in which businesses are not directly regulated by government. Government officials choose whether to side with businesses or activist groups based on their relative
prioritization of trade and regulatory independence, their staffing, and whom they identify as their core constituency. Concerns about economic competitiveness stack these factors in favor of reducing regulatory trade barriers. Concerns about needless death stack these factors in favor of maintaining or increasing those barriers. This pattern can be seen throughout the cases analyzed in chapters four, five, and six.

**Cars**

In Chapter 4, I examine environmental, labor, and consumer safety regulations and the international trade in automobiles in North America and Europe. I ask why intra-regional regulatory trade barriers were reduced in Europe and North America but the regulatory trade barriers were not reduced between those regions.

**Europe**

In Europe from 1983 to 1988, environmentalists demanded an increase in emissions standards in some EC states as they saw that as the most effective means of alleviating the increasingly salient environmental degradation in their states. Automakers opposed an increase in emissions standards in these EC states because those standards would have amounted to regulatory trade barriers that would have raised their production costs and inhibited their market access. Government officials in Denmark and the Netherlands sided with environmentalists but officials in France and Italy as well as the EC level were more concerned with promoting economic competitiveness and so sided with the automakers. These regulatory barriers were thus not allowed to be raised.

In Europe in 1989 and 1990, higher emissions standards became much cheaper for automakers to comply with and so their opposition to those standards softened. Environmentalism had continued to politically strengthen and so the amount of political force pushing for higher standards had increased. Government officials still prioritized
advancing the single market and so agreed to prevent regulatory trade barriers related to emissions by raising emissions standards to the highest feasible level.\textsuperscript{34}

\textit{North America}

In the United States in the early 1980s, the United Auto Workers’ Union felt that domestic content regulations were the only way to address rising unemployment in the auto industry and so pushed for domestic content legislation. Domestic content regulations would have raised automakers’ production costs and so they opposed. They linked their opposition to concerns about American competitiveness. The Republican-controlled Senate and White House stood with automakers in opposing domestic content regulations and so those regulatory barriers were never raised.

In Mexico in the early 1980s, domestic content regulations were making Mexican cars uncompetitive in exports markets. This became a much more acute problem as a result of the Latin American debt crisis. Automakers lobbied the government to reduce them. Additionally, as a result of changes in the Mexican economy, businesses that were in favor of trade liberalization became much more powerful over the course of the decade. The new leaders of the Mexican government, President de la Madrid and President Salinas, had much tighter connections to these businesses than their predecessors had been and were willing to marginalize Mexican labor unions from the trade policymaking process. This led to the reduction of domestic content regulatory barriers.

In Canada, businesses also became more favorably disposed toward trade liberalization. The MacDonald Commission Report recommended greater trade with the United States as an alleviation of Canada’s economic malaise. This gave intellectual and

\textsuperscript{34} This is a good example of a regulatory trade barrier being reduced in such a way that it did not reduce the overall level of regulation.
political cover to Brian Mulroney, the Conservative Prime Minister, to pursue a free trade agreement with the United States even though that contradicted decades of Canadian trade policy. Canadian labor unions sat out of those free trade negotiations and so facilitated the government and businesses working together to reduce domestic content regulatory barriers as part of the free trade deal with the United States. These dynamics in all three states continued into the early 1990s, which led to NAFTA entirely removing domestic content regulatory barriers between the three states.

Meanwhile, environmentalists saw NAFTA as an opportunity to embed environmental regulations into trade negotiations. Businesses on the other hand were determined to prevent environmental regulatory trade barriers from raising their production costs. Unlike with organized labor, Mexican and U.S. officials in both countries were at least somewhat sympathetic to the policy goals of environmentalists. To prevent the emergence of environmental regulatory barriers, government officials in these two states increased enforcement of Mexico’s domestic environmental regulations and added language to NAFTA that sanctions states for not enforcing its own environmental regulations.

Automakers have not called for reduced regulatory differences between the United States and Mexico related to consumer safety because those differences have not only cheap to comply with, they have actually been a source of profit. Mexican Consumers have not pushed for increased regulations either because they are more concerned with maintaining access to affordable automobiles that in ensuring that vehicles abide by the full range of American safety standards. Given that neither societal
interest has become engaged on the issue, government officials have not incentivized to attempt to reduce that regulatory difference.

Consumer safety advocates in the United States however did become alarmed at the difference in safety between American trucks and Mexican trucks that would be allowed to enter the United States as a part of NAFTA. Consumer safety advocates were able to portray these Mexican trucks as a potentially lethal threat. U.S. officials, persuaded by this argument, banned Mexican trucks. It was only after American consumer safety advocated were satisfied with Mexican trucks and after American businesses hurt by retaliatory sanctions began lobbying on the issue and arguing that this regulatory trade barrier was undermining their competitiveness in the Mexican market, that U.S. officials lifted that ban.

**Inter-Regional**

Consumer safety-related regulatory differences between the United States and the European Union raised production costs for automakers and so they initially attempted to convince government officials to reduce those regulatory differences. Consumer safety advocates and national government officials in both place however held that their specific regulations were saving lives and were unwilling to potentially jeopardize that for the sake of trade and so resolutely opposed the automakers on these regulatory barriers. Consumer safety advocates won because they were able to portray those regulatory barriers as preventing needless death.

**Beef**

In Chapter 5, I analyze mad-cow related consumer safety regulations and the trade in beef between the United States and Japan. After the first case of bovine spongiform encephalopathy (BSE), a.k.a. mad-cow disease, was found in the United States, Japan’s
more stringent safety regulations applied to imports of beef from the United States. American cattlemen did not want to abide by these regulations because that would raise their production costs, but refusing to abide by them cost them access to the Japanese market. Japanese consumer safety advocates viewed those anti-BSE regulations as the only way to ensure the safety of beef and so robustly defended those regulations. American officials at the USDA and at the USTR had strong mandates to promote meat industry sales and American exports respectively. At the USDA in particular a number of high-ranking officials had direct personal connections with the meat industry as well. U.S officials thus sided with American cattlemen and attempted to get Japan to reduce those regulatory barriers. Japanese officials at the Ministry of Agriculture and Ministry of Health had badly botched the response to Japan’s first case of BSE in 2001 and so needed to win back credibility with consumers on the issue and so resisted reducing those regulatory barriers.

In negotiations from May 2004 to December 2005, Japanese consumer safety activists and American cattlemen continued to hold their respective positions. The Japanese and U.S. governments eventually settled on a deal in which U.S. beef exports would not have to undergo universal BSE testing as long as those exports were from cattle 20 months old or younger at the time of slaughter and all specified risk material was removed. This deal nevertheless took some time to reach because these regulations were highly salient for Japanese consumer safety advocates who took the details of these regulations very seriously and because much of the decision-making process was located in an institution, the Food Safety Commission, which was receptive to consumer advocate’s arguments.
After a U.S. producer made a serious safety mistake in January 2006, Japanese consumer groups were re-energized to push for more stringent BSE regulations. U.S. producers and U.S. officials opposed that. Japanese officials ultimately allowed the resumption of U.S. beef imports but agreed to new requirements promoted by those consumer activists.

In 2007, after the World Animal Health Organization improved the United States’ risk classification, U.S. beef producers sought to remove all age restrictions on non-universally tested exports. Japanese consumer groups opposed their removal. Some kind of compromise or buy-out might have been possible but U.S. beef producers and the U.S. government rejected that approach. Consequently, Japanese government officials sided with the consumer activists and so maintained the regulatory barriers.

In 2009 the Democratic Party of Japan came to power and, after having harshly criticized the Liberal Democratic Party for being too eager to compromise with the U.S. on these regulatory trade barriers, could not afford to be seen as doing the same thing, especially once a basing dispute over Okinawa became a more contentious issue. This combination of factors ensured that the Japanese government would continue to stand with the consumer activists and so the regulatory barriers were maintained.

Beginning in 2010, the Japanese government took some initial steps to join the Trans-Pacific Partnership (TPP), which brought exporters into the negotiations over Japan’s regulatory barriers on U.S. beef. The United States had concluded a free trade deal with South Korea that same year. Japanese businesses feared that this trade agreement would make them less competitive in the American market relative to their South Korean rivals if they did could not enter into a free trade agreement with the
United States. They therefore lobbied the Japanese government to enter into the Trans-Pacific Partnership (TPP) negotiations.

Additionally, once regulatory barriers in beef became embedded in a larger constellation of trade issues, the Ministry of Industry (MITI), which has traditionally been less protectionist than the Ministry of Agriculture (MAFF), became the leading player in formulating Japan’s trade policy rather than MAFF.

As importantly, the mood in Japan regarding the country’s BSE countermeasures had begun to shift. The number of BSE cases worldwide had fallen from 37,000 to just 29. By this time, most middle class urban consumers were accepting of American beef. The diminishing consumer hostility to relaxing the regulatory trade barriers on American beef imports was essential in giving the Japanese government the political space to agree to those relaxations. Even with Japanese export-oriented businesses pushing for the TPP, the government would have found it very difficult to relax those regulatory trade barriers on beef had the general public still been aroused in opposition. In 2013, the Japanese government announced that it would increase the age-exception to universal testing to 30 months, which in effect greatly reduced the regulatory barriers impeding American cattlemen’s access to the Japanese market.

**Drugs**

In Chapter 6, I analyze intellectual property (IP) regulations and the trade in pharmaceuticals involving the United States and India. As developing countries’ IP regulations became more injurious to Western drug firms’ interests, they became much more highly motivated to reduce those regulatory trade barriers in IP. Activists, who might have fought against these firms’ efforts, were not yet significantly engaged in IP

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politics. With businesses promoting the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), and with activists largely silent, government officials in the United States and India faced one-sided incentives and so gave businesses what they were asking for: significantly reduced regulatory trade barriers related to intellectual property.

In the second half of the 1990s, the AIDS epidemic grew into a public health nightmare, especially in sub-Saharan Africa. Given the relative newness of the disease, practically all of the effective HIV drugs were patented and thus expensive. Poor people were dying of a disease for which effective medicines existed but which were far too expensive for them to afford. Public health advocates began to take a much closer look at the connection between IP regulations and the cost of medicines and concluded that the high IP regulations mandated by TRIPS were the main drivers behind the expense of the medicines and thus complicit in widespread death. Drug companies compounded this imagery when they sued the South African government over measures it had taken to stem the AIDS crisis. Even after the drug companies dropped the suit, developing countries and access to medicine advocates wanted states to have more flexibility under TRIPS to institute different IP regulations. For a variety of reasons, the U.S. government, which normally would have been expected to oppose any increase in regulatory barriers on IP in pharmaceuticals, relented and accepted the Doha Declaration which strengthened developing states ability to implemented different IP regulations, most notably compulsory licenses.36

36 The United States did this because: 1) the relationship between U.S. government officials was highly strained at the time, albeit temporarily, 2) the 2001 anthrax scare led the U.S. to threaten to use a compulsory license to protect public health, which rhetorically undermined their arguments against developing countries doing the same thing, 3) the United States government was determined to launch a
The Doha Declaration was a big victory for access to medicine advocates and developing countries but it did not settle three issues: 1) which diseases a compulsory license could be issued for, 2) what kind of exceptions to make for states that did not have production capacity, and 3) whether non-violation complaints could move forward. On which diseases to cover, the language in Doha was never clarified to either side’s benefit. On states’ without production capacity, the same but no greater flexibilities were granted to them as to other states. On non-violation complaints, there has been a rolling temporary moratorium. In sum, the regulatory barriers on these issues remained static through a mix of constructive ambiguity and stalemate.

Under the provisions of TRIPS, India had to implement TRIPS-compliant IP regulations beginning in 2005. India has found a number of creative policy means to relax their IP regulations. They used a narrow set of patentability requirements and gave greater policy access for patent opponents and so limited which drugs could get patented. They also employed novel injunction policies as well as compulsory licenses to control drug prices. All of these measures made India’s IP regulations differ significantly from the high IP standards that the U.S. wanted. All of these measures were also technically TRIPS-compliant. Still, India has been judicious in its use of these measures, employing them much less than they otherwise could have in order to maintain amicable relations with U.S. drug firms and U.S. businesses more generally.

Implications of This Work For Businesses, Activists, and Government Officials

In Chapter 7, I discuss six broader implications this study has for International Political Economy scholarship. It questions cleavage-based explanations. It qualifies the new trade round at Doha to demonstrate continued American resolve after 9/11, 4) the heightened salience of the connection between IP and public health had led other U.S. government agencies, which often had a less pro-IP position than the USTR, to become involved in the issue.
California Effect.\textsuperscript{37} It highlights the growing importance of national courts in international trade politics. It helps explain the rise of regionalism. It clarifies the trade policy options that developing countries have moving forward. It underscores activists’ political power. Finally, it points to emerging vectors in the U.S.-China relationship. I then apply lessons from these cases to other cases and other industries.

I offer political recommendations for the businesses, NGOs, and government officials examined in this work based upon the political trajectory seen in the case studies. In automobiles, U.S. automakers should accept the limited currency provisions in the Trans-Pacific Partnership (TPP) as good enough while using that deal’s provisions to challenge Japan’s investment and distribution regulatory trade barriers but should delay, if not refrain altogether from, challenging Japan’s consumer safety regulations in automobiles. Consumer safety advocates in automobiles should emphasize sovereignty concerns and highlight the differing safety levels created by disparate regulatory regimes, thus emphasizing how each jurisdiction’s regulations prevent unnecessary deaths. Environmentalists should seek regulatory improvements that have low compliance costs and should emphasize how higher environmental regulations can actually boost economic competitiveness frame to promote their goals. Labor unions should challenge businesses’ use of the competitiveness frame and be creative in their efforts related to personnel and institutional jurisdiction. Auto regulators in Europe and the United States should work to establish safety equivalency on as many auto parts as they can and reduce regulatory barriers on an ad-hoc basis where they find such equivalency.

\textsuperscript{37} The California Effect is David Vogel’s argument on how trade, rather than creating a race to the bottom, can encourage states to raise their environmental and consumer safety standards. The California Effect is discussed in more detail on pages 102-104.
Food activists should broaden their scope beyond GMOs and also focus on the meat industry’s affect on heart disease, its climate change impact, and its systemic exploitation of workers. For their part, meat industry firms should improve their business practices sooner rather than later. The USDA should assist the meat industry in making these reforms and adopt a more pro-consumer stance.

Pharmaceutical firms should emphasize their contribution to economic competitiveness and should use personal stories in order to utilize the preventing needless death frame to advance their goals. They should also set up a pharmaceuticals bar association to internally clamp down on the most flagrantly greedy behavior in order to protect the reputation of the industry as a whole. Access to medicine advocates should try to demonstrate that a system not based on stringent intellectual property rights can actually promote innovation. They should also attempt to drive a wedge between drug companies and other businesses by arguing that the high cost of patented prescription drugs undermines their competitiveness. Finally, officials in the United States Trade Representatives Office should become more transparent and more inclusive by bringing NGOs as well as businesses into their negotiating process and by making negotiating texts public during negotiations. That could make the entire policymaking process, and trade policy as a whole, more legitimate in the eyes of the public. Given the centrality of regulation to international trade politics today and the public’s sensitivity on many regulations, maintaining that legitimacy is more vital now than ever.
Chapter 2: How Regulations Became the Crux of Trade Politics
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Introduction
Today, the principal barrier to trade is the difference between states’ regulations. The Trans-Pacific Partnership, Transatlantic Trade and Investment Partnership, and most other contemporary trade deals are about those regulatory barriers more than anything else. That was not always the case. The centrality of regulation in trade negotiations is a relatively new phenomenon, emerging only over approximately the last quarter century. Since they emerged, scholars have analyzed a myriad of economic, legal, and political aspects of this important developing trend. There is no dearth of scholarship on this issue. Still, to date and perhaps surprisingly, there is not an article-length political history explaining how cross-national differences in regulation became the primary barriers to trade and the central focus of contemporary trade agreements. This chapter contributes to IPE scholarship by doing just that. While it does not deeply delve into any single aspect of regulatory trade barriers, many of which are well covered in other works, it does provide a concise, unified explanation of how regulatory trade barriers came to be so important. It thus provides IPE scholars, political scientists, economic historians, international law scholars, economists, and public officials with a brief, useful account of how the trade world we live in came to be. Tracing this political history helps illuminate not only how we arrived at our current state of affairs but also how incorporating regulation changes trade politics and how increasing trade influences states’ regulations.

The 1970s- Trade Politics Starts to Move Past Tariffs
By the 1970s, six rounds of GATT negotiations reduced tariffs to a small fraction of what they were in the 1940s. As tariffs receded, non-tariff barriers (NTBs) became more significant. The Tokyo Round launched in 1973 continued to reduce tariffs but also
addressed many of these NTBs. It established a series of ‘codes’ that bound signatories’
use of NTBs. GATT members were not compelled to sign these codes. Explicating codes
but making them optional was an attempt to promote trade without undermining
countries’ policy flexibility. While understandable in theory, in practice not forcing states
to accept the codes as the price of GATT membership meant the Tokyo Round agreement
amounted to ‘follow these rules…..unless you don’t want to.’ Not surprisingly, many
states, especially developing ones, did not follow them. Many developed states did sign
on to these agreements however. That they were following these codes but developing
states were not was part of developed states’ rising cries of unfair trade in the 1980s.

The inclusion of NTBs in trade negotiations, even in a less than universally
binding way, led the U.S. Congress to demand greater review of those negotiations.
When only tariffs were involved, Congress specified a range in which the Executive was
allowed to reciprocally reduce tariffs with other states; once trade negotiations had the
potential to limit non-tariff barriers, Congress wanted to place greater checks on
Presidential prerogative. Congress did this for three reasons. First, negotiating NTBs,
especially those related to regulation, requires trade-offs that are less straightforward than
when the main agenda item is tariffs. When the agenda involves non-tariff barriers it
becomes less clear what an equivalent concession even is. Does Country A cutting its
subsidies to industry X fully compensate Country B for relaxing its rules on item Y? This
made it more difficult for Congress to know beforehand what the United States would be
conceding and so made them more reluctant to give the president carte blanche at the
outset. Second, negotiating NTBs meant potentially negotiating away domestically
agreed upon law. This too increased Congressional reluctance to take an institutional
backseat because a new trade deal would affect domestic law. Third, Congress received
the request for negotiating authority on NTBs during the Watergate scandal in 1974. It
goes without saying that in that context Congress was not eager to expand Executive
authority. These considerations led Congress to demand, and win, influence at both the
front end (giving the President fast-track authority) and at the back end (the ability to
vote up or down on the implementing legislation) in the Trade Act of 1974. In other
words, the inclusion of non-tariff barriers in trade negotiations is the principal reason why
we have the fast-track procedure that governs American trade policymaking today.

Meanwhile, for the first time, developing countries were gaining meaningful
involvement in trade negotiations. While they were given special treatment in previous
GATT rounds, they had little voice in the negotiations and so liberalization excluded
agriculture and textiles, two sectors where developing countries had their greatest
comparative advantage. The erosion of tariffs on manufactured goods made this
exclusion increasingly glaring. The inclusion of NTBs in trade negotiations threatened to
constrain these states development policies; subsidies, local content rules, and
government procurement policies were at the heart of developing countries’ efforts to
support their infant industries. Angry at the exclusion of their voice and priorities from
the negotiations and worried by the potential limits to their policy autonomy that trade
rules on NTBs might impose, developing states blocked the ratification of the Tokyo
Round until richer countries agreed to relax the agreement’s requirements and pass the
‘enabling clause’, which allowed developed countries to create preferential trading
schemes with developing countries.¹

The Expansion and Changing Relationship Between Trade and Regulation

By the early 1980s, trade was increasing at a remarkable pace. As trade accounted for more of the global economy, more firms were now engaging in trade and thus more firms had an interest in other states’ regulations. Meanwhile, as states grew richer, they engaged in health, environmental, and safety regulation to a greater extent. Later, developed states’ attempts to promote greater competition in their economies required more rather than less regulation. Moreover, the champions of deregulation tended not to focus on health and safety regulations they perceived to be particularly valued by society. For example, Thatcher’s deregulation program did not take aim at consumer protection policies. Increasing trade created greater demand for regulation as a cushion against social dislocations generated by that increased trade.

Changes in the nature of traded products meant the expansions of regulation and trade began to intertwine. In earlier periods, basic commodities like wheat and steel were the primary traded goods. When trade primarily involved commodities, the ability to sell that good was mostly a matter of cost. Tariffs were central to costs. As traded products grew more complex, considerations beyond costs and thus beyond tariff levels took on added significance.

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Regulatory Trade Barriers are Particularly Troublesome for Intra-Industry Trade

Over the course of the 1970s and 1980s trade became less inter-industry and more intra-industry. The shift to intra-industry trade meant firms engaged in intra-industry trade were both exporters and importers and so would oppose tariffs because they would raise production costs by making imported inputs more expensive.

Among NTBs, cross-national differences in regulation are particularly harmful to intra-industry trade because they undermine both factors that generate the benefits of intra-industry trade: product differentiation and economies of scale. One of the primary ways intra-industry trade benefits consumers is by expanding the array of available products. By making it impossible to purchase products that are available elsewhere, regulatory trade barriers limit consumers’ choices. For example, European carmakers would like to sell certain models of subcompact cars they believe would be popular among urban drivers in America but are prevented from doing so by regulatory differences between the U.S. and EU. Furthermore, by forcing producers to maintain multiple production lines to meet different states’ standards, regulatory differences also reduce businesses’ ability to leverage economies of scale and raise costs for consumers.

Regulatory barriers also posed problems for intra-firm trade. Global supply chains meant firms’ production must abide by multiple states’ regulations. If the costs of complying with these different rules outweigh the savings from locating production steps in disparate locales, global supply chains stop making economic sense.

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Europe Leads the Way in Splicing Trade and Regulation

The combined implications of increasing intra-industry trade and the Bretton Woods Compromise tensions first emerged in Europe.\(^9\) By the late 1960s, intra-continental tariffs had been eliminated and so EC authorities began to target NTBs, including regulatory barriers; throughout the 1970s, that diplomatic effort continually crashed on the rocks of national regulatory differences.\(^10\) Moreover, expansion of regulations meant the obstacles seemed to be ever increasing.\(^11\)

In the same year that the Tokyo Round moved the GATT toward a framework for dealing with NTBs (1979), the EC made a significant advance in dealing with regulatory barriers: the *Cassis de Dijon* decision and subsequent expansion of mutual recognition. One of the plethora of regulatory differences between European states was a German rule mandating all liqueurs have at least twenty-five percent alcohol; the idea was that lower alcohol beverages facilitated excessive consumption (beer and wine were exempted from this rule).\(^12\) A French producer of a twenty percent alcohol liqueur known as *Cassis de Dijon* wanted to export to Germany but was blocked from doing so, and so in 1979 the French government took the case to the European Court of Justice, which ruled in France’s favor. What made this ruling important was not that it untangled specialized liqueur sales across the Rhine but instead that it established the doctrine of mutual recognition. Rather than force the European Community to elaborate innumerable and politically impossible common rules on all traded products, European states were now obliged to allow the importation of any product that had been legally produced in another

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\(^9\) The Bretton Woods Compromise was the idea that economic liberalization should be promoted but only to the extent that it did not impinge on states’ sovereignty in economic policymaking.


\(^11\) Ibid. p. 28-29.

\(^12\) This paragraph draws on Vogel. 1995. *Trading Up.* p. 30-35.
member state. Exceptions would only be made if the regulatory barrier was instituted to achieve a legitimate public policy objective and that it used the available regulatory means that least restricted trade.13

Mutual recognition was supplemented by the ‘new approach’ to regulation, which augmented EU states’ and citizens’ confidence in their neighbors’ regulations by adding agreed-upon minimum requirements.14 The hope was that mutual recognition along with the new approach would promote trade without forcing states to alter their policies. Despite the innovativeness of mutual recognition, differences in regulation continued to dog intra-European trade relations throughout the early 1980s.

To alleviate these regulatory barriers, EC states signed the Single European Act in 1986, setting 1992 as a goal for completing the common market. The SEA helped remove regulatory barriers by changing requirements for EC-wide rulings from unanimous to a qualified majority and by expanding the EC’s regulatory authority into consumer safety, health, and environmental policy.15 After the SEA, and certainly after the Maastricht Treaty (1992), regulation was primarily Brussels’ prerogative. To the extent that regulation is made on a continent-wide basis, regulation stops being an intra-continent trade barrier. Thus, European integration represents one end of the spectrum in dealing with regulatory trade barriers: delegate regulatory authority to a supra-national government to the benefit of trade at the cost of sovereignty.

While it reduced regulatory barriers between EC states, integration did nothing to reduce regulatory barriers European firms faced abroad. In fact, because it raised

regulations, in many ways it served to increase regulatory barriers between Europe and the rest of the world. To expand global exports, a more comprehensive attenuation of regulatory barriers was needed. Firms in other states, and thus those states’ governments, were increasingly paying attention to these barriers. For a variety of reasons, states had long sought to export more than they imported; this desire took on greater significance in the 1980s and thus elevated the importance of regulatory trade barriers.

_Everybody Wants to Be An Exporter_

Since the 1950s, East Asian states had made export promotion a core component of their development strategies. By the 1980s, other developing states were turning away from the ISI development model and starting to follow the example of those East Asian states. This export-oriented development strategy could work only if their goods could be purchased in developed countries. Thus, developed countries’ growing product regulations, by threatening to cut off market access, presented a portentous hurdle to those countries’ attempts to develop.

Western businesses and governments were also becoming more interested in exports. Much as the increasing interconnections of global markets undermined ISI, forcing developing states, particularly in Latin America, to seek export led-growth, it also contributed to the crisis of Keynesianism in Europe and so pushed those governments to promote exports. By the late 1970s, leading businesses had become so internationally oriented that when faced with an economic downturn, their response was not to push for protectionism as their forebears had done in the late 1920s but instead push for greater trade liberalization.\(^\text{16}\) Instead of attempting to solidify their domestic market share, they

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pursued increased sales in foreign markets. The perceived need to win global market share and the increasing interconnections of the global economy gave American businesses a powerful rhetorical tool in their quest to alter regulations: competitiveness. The language of competitiveness allowed businesses to argue that the U.S. government should do more to aid American businesses and that domestic regulations had to be reduced, not just because they hurt firms’ profits but also because they were making America itself sclerotic in the global economy. In Great Britain and Germany, the deregulatory aspects of competitiveness also fell on receptive ears in the Thatcher and Kohl administrations.

That the U.S. was experiencing higher trade deficits than its policymakers considered healthy aided this framing’s persuasiveness; in addition to promoting a greater use of trade protectionism, a second perceived solution was to promote exports to states where American firms had not traditionally had much market share. This was especially the case apropos Japan for two reasons. First, imports from Japan were rising, contributing to the U.S. trade deficit, and were particularly salient in economically and culturally important sectors such as automobiles. Second, the Japanese government often used regulations to exclude foreign firms. Their Agriculture Minister’s claim that American beef was inappropriate for Japanese consumers because they have longer

intestines is something of a classic example in Japanese trade obstructionism.\(^{23}\) Japan’s liberalization of other trade policies such as quotas and tariffs made these regulatory barriers more significant and more apparent.\(^{24}\) The increased preoccupation with exports meant businesses and the governments that represented them wanted to ensure they had full access to other countries’ markets and thus had a greater interest in the extent to which those countries’ regulations inhibited market access.\(^{25}\)

**Western Business Pushes for Trade Rules in New Areas, Developing Countries Resist**

With the extent to which regulation limited trade becoming obvious to businesses and governments inclined to consider other states’ regulations protectionist, businesses began to pressure their governments to attempt to reduce those regulatory barriers. Monsanto was one of the first corporations to recognize how its revenue was being hurt by foreign regulations. In the late 1970s, Monsanto was losing millions of dollars annually because Hungary was violating its patents.\(^{26}\) At first, Monsanto’s attempts to insert intellectual property into U.S. trade policy met with limited success. According to Jim Enyart, the Monsanto representative who was the point man in this effort, “at the time everyone said ‘oh gee, patents are highly technical, very esoteric things. What do they have to do with trade’…the minute you would say ‘patents’ everybody’s eyes would glaze over.”\(^{27}\) Still, Monsanto was able to resolve its Hungarian difficulties with Congressional help and, joined soon thereafter by Pfizer and IBM, was able to bring intellectual property into U.S. trade policy and get it onto the Uruguay Round agenda in

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\(^{27}\) Ibid. p. 48.
These three companies found allies among other corporations based in the United States and Europe. U.S. and European corporations also wanted to see liberalization in services and investment. The array of national regulations in banking and services constituted an enormous trade barrier for them. Developing countries had a decidedly different perspective on bringing these new policy areas, and thus negotiations over sensitive domestic regulations, into trade talks.

Developing countries’ involvement in the Uruguay Round (1986-1994) was considerably deeper than it had been in previous rounds, including the Tokyo Round. On the one hand, many developing states were hostile to including services, investment, and intellectual property rights in a new GATT Round and were concerned that NTB rules would become obligatory. On the other hand, if a new GATT round could liberalize agriculture and textiles and the services and investment provisions could be watered down, then perhaps a more institutionalized and open trading system would benefit them. They also feared that if a multilateral agreement could not be reached, Western countries, and especially the United States, would pursue trade liberalization bilaterally and regionally, thus denying those developing countries the benefits of increased market

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28 Ibid. p. 49-58.
31 For space reasons and to maintain the focus on goods, I shall avoid discussing trade rules in services and investment except where they explicitly connect with trade in goods.
32 While I have bifurcated states’ positions into developed and developing for simplicity’s sake, there were some disagreements within these two blocs. On these divisions see Deese, David. 2008. World Trade Politics. p. 95-121.
access; likewise, they hoped that a stronger WTO could curtail the United States’ increasing penchant for using unilateral trade sanctions such as anti-dumping measures.\textsuperscript{34}

The Uruguay Round negotiations (1986-1994) that created the WTO produced an ambitious agreement built upon compromises between developed and developing countries. Developing countries won concessions in the reduction of export subsidies and quantitative restrictions in agriculture, abolition of the Multi-Fiber Arrangement in textiles, tighter rules on safeguards measures, and softening of trade-related investment rules. Developed states won inclusion of services under the GATS Agreement, inclusion of intellectual property based on developed-country standards under the TRIPS Agreement, and strengthening of the dispute settlement mechanism and greater compulsion to follow GATT/WTO rules such as the Tokyo Round agreements on NTBs. The final Uruguay Round Agreement (the Marrakesh Agreement) also fundamentally changed how trade and national regulation coexisted.

\textit{What the Uruguay Round Did for Regulatory Trade Barriers}

The Uruguay Round was a watershed in setting the rules that govern trade and regulation. The GATT dispute mechanism lacked significant enforcement capabilities; one of the most conspicuous weaknesses was that panel rulings had to be unanimous meaning that even the state being accused of violating trade rules could veto adverse decisions. In contrast, the WTO dispute settlement understanding cannot be blocked by the accused, proceeds more quickly, possesses a greater ability to enforce decisions by sanctioning retaliation, and has more formalized panel proceedings.\textsuperscript{35} The WTO also more fully restricted the use of non-regulatory NTBs. This, combined with further reduction in tariffs, means trade barriers other than regulation are more stringently

\begin{flushright}
\textsuperscript{34} Deese, 2008. World Trade Politics. p. 108-110.  \\
\textsuperscript{35} Ibid. p. 112-147.
\end{flushright}
constrained and thus further raises the salience of regulatory barriers. In many ways, after the Uruguay Round, regulation became the last game in the trade barrier town. It was not silent on regulations either. While it did not mandate regulatory harmonization, it did strengthen the Tokyo Round codes pertaining to food and agriculture (SPS) and manufactured goods (TBT) by making them requirements of WTO membership.

The central idea behind the Sanitary and Phytosanitary Agreement (SPS) and the Technical Barriers to Trade Agreement (TBT) is that states have a right to set regulations for legitimate purposes, but the use of these regulations as disguised protectionism is unacceptable. The SPS and the TBT have three central provisions. First, if a state bases a regulation on the international standard as defined by a designated standard setting body such as ISO or the OIE, that regulation is considered WTO-compliant. Second, if a state sets regulations that differ from the international standard, those regulations must have a scientific basis. Third, states’ must use policies that are no more trade-restrictive than necessary to achieve their regulatory goals.

Once again, the framers of the global economic order were attempting to encourage trade while respecting national sovereignty. This was a laudable goal but meant there was enough policy wiggle room for states to continue enacting regulations that had profound impacts on trade and yet at the same time there was sufficient juridical structure in the WTO for other states to now challenge those regulations as illegal under international law if those regulations imposed costs on them. Up to this point, this chapter has been about how regulation became part of trade politics. This tension between policy space and trade promoting rules that came to a head with the creation of the WTO in 1994 is how trade became central to regulation politics.
Had the increasing connection between trade and regulation somehow gone unnoticed by civil society activists, the politics at the intersection of trade and regulation might have remained technocratic to the point of vapidity for all but the corporate lawyers and academic super-specialists, but that was not to be the case. While the Uruguay Round negotiations were indeed dominated by business, during roughly the same time period, non-business civil society actors started becoming interested in and involved in trade policy to a greater degree. Their attempt to gain greater influence over trade policymaking is one of the most important trends in global economic politics over the last three decades.

Prior to the 1980s, Western civil society groups had little interest in and little influence in trade policy. In the 1980s, these activists started viewing influencing trade as integral to achieving their policy goals. The idea that trade could be used for non-trade goals was not new; the central point of 17th and 18th-century mercantilism was that trade could be used to aggrandize the state. Even in modern times, governments sometimes attempted to use trade to advance geostrategic goals. What was new was that civil society groups more fully realized that they too could use trade to pursue their labor, environmental, and consumer safety policy goals.

**Labor Finds a Party and Starts to Focus to Regulations**

Organized labor was the first non-business civil society group to recognize the growing impact trade was having on regulations, specifically labor standards. In the United States, the political geography of the early 1970s dampened unions’ ability to gain

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36 As David Vogel points out, “of more than a score of books published by Ralph Nader and his associates during the late 1960s and early 1970s criticizing virtually every aspect of American health, safety, and environmental regulations, none examined trade policy. Consumer and environmental organizations played no role in the fierce debates surrounding American trade policy during the 1960s and 70s.” Vogel. 1995. *Trading Up.* p. 196.
trade protection. Import-competing industries and unionized workers were concentrated in the Midwest and Northeast and were generally represented by Republicans while export-oriented industries and less unionized workers were concentrated in Southern districts represented by Democrats.³⁷

The political upheaval of the 1960s and 1970s led the two parties to switch positions on trade. By 1980, Republicans’ geographic base was in the export-oriented South and interior West while Democrats largely controlled the protectionist Midwest and Northeast. This shift meant Republicans now favored trade expansion and labor regulation rollback. For unions, trade liberalization and deregulation were no longer separate battles but linked tools in the Reagan Administration’s arsenal for weakening labor. Furthermore, the ascendant rhetorical frame of competitiveness alarmed labor as much as it pleased business because it suggested that workers had to bear the costs of America adjusting to a post-industrial economic landscape.³⁸

Labor unions believed they were locked in a global contest for jobs with developing country workers and argued that the deplorable conditions that these workers were forced to work under constituted an unfair advantage for businesses that operated there and thus unfairly harmed American workers. In 1984, labor activists were able to use this rhetoric to get trade concessions for developing states linked to labor standards.³⁹ They feared that even if firms did not move operations to those countries, they could bully workers and governments into accepting their policy and wage preferences by

threatening to do so. Human rights activists joined labor unions in their crusade to link labor and trade, with the most dramatic example being their drive for trade sanctions against apartheid South Africa.\textsuperscript{40}

\textit{The Expansion of Consumer Skepticism}

Consumer activists too were becoming more skeptical of multinational firms. The modern consumer movement grew out of citizens’ perception that firms had failed to supply goods of sufficient quality and that governments had, at best, failed in their duty to regulate and, at worst, had colluded with business at consumers’ expense. The U.S. consumer movement won regulatory protections against what they saw as businesses’ depredations; their victories included the Fair Package and Labeling Act, the National Traffic and Motor Vehicle Safety Act, and the Consumer Product Safety Act as well as numerous local and state ordinances.\textsuperscript{41} The 1960s and 1970s also saw an expansion of consumer mobilization efforts in Europe that yielded significant political victories such as the establishment of the Office of Fair Trading and the National Consumer Council in Britain, implementation of quality contracts in France, and the establishment of an information-based consumer protection system in Germany.\textsuperscript{42} In Japan, though producer interests continued to dominate, consumer groups did gain more consistent influence in regulatory policymaking through the creation of consumer affairs divisions in government as well as the enactment of the Consumer Protection Basic Law.\textsuperscript{43}

\textsuperscript{40} This was of course not the first time that there was a link between trade and human rights.
In the 1980s, consumer groups began to recognize the extent to which trade policy impacted their regulatory goals. This added suspicion of imports to their already acute qualms about business. It was precisely these fears that led the European Community in 1985 to ban hormones in beef, a move that inhibited American beef exports to Europe; this was the first time consumer organizations’ political activism led to a trade dispute.\textsuperscript{44} The Single European Act (1986) further augmented the power of European consumer organizations by strengthening the European Parliament, which was more open to the concerns of non-business interests than the other major EC institutions.\textsuperscript{45} Meanwhile, consumer groups in Japan and the United States were gaining greater influence in their country’s trade policies as well.

Much of these groups’ demands rested upon a subtle distinction, that how a product is made is just as important as the characteristics of the product. One of the two principal pillars undergirding post-war trade rules was ‘national treatment’, the idea that a state could not treat an imported good differently than a domestic one. The legal language used by the GATT and later the WTO is that governments are not allowed to discriminate against ‘like products.’ For most of the GATT’s history, the definition of like products was based on characteristics of the product and thus straightforward; a soccer ball is a soccer ball. As civil society groups became more engaged in trade politics, they advanced a new definitional framework- process characteristics. To a labor standards activist, a soccer ball is \textit{not} a soccer ball if one of those balls is made by a worker toiling under deplorable conditions; because the process by which those two balls are made differ in

\textsuperscript{44} Vogel. 2012. \textit{Politics of Precaution}. p. 54-62.
\textsuperscript{45} Ibid. p. 238.
their consequences for labor rights, they are not ‘like products’ and so a state may
discriminate against the morally odious product. In the Tuna-Dolphin case, the GATT
established that, for the most part, only product-based regulatory barriers are legal.

**Environmentalists Become Interested in Trade Policy**

In the 1960s and 1970s, environmentalists in the U.S. and Europe focused
primarily on domestic issues. Even when the environment was discussed at the
international level, such as at the 1972 Stockholm Conference, the focus was on
organizing state action to combat pollution. In the late 1980s, these activists became
influential actors in trade politics.

European integration brought environmental activists into EC trade debates,
especially after the Single European Act.\(^46\) At roughly the same time, environmental
activists in the U.S. began to take a greater interest in trade policy based on three beliefs:
the potential efficacy of trade sanctions, the GATTzilla menace, and the race to the
bottom. The first belief was that, under the right conditions, trade sanctions could be used
to protect the environment. They could be applied unilaterally through regulations that
granted access to the U.S. market based on meeting environmental production standards
or could be used to enforce multilateral environmental treaties such as the Montreal
Protocol. The second belief was that, under the wrong circumstances, trade obligations
could run roughshod over states’ efforts to protect their environments. This fear was
stoked by the Tuna-Dolphin GATT case in 1991 that aided environmental activists in
depicting the GATT as a ‘GATTzilla’ come to eat Flipper and destroy the great
outdoors.\(^47\) Third, many environmentalists believed that even when not being pushed by

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\(^47\) On the reaction to the tuna-dolphin case, see Vogel. 1995. *Trading Up.* 112-117. For the advertisement
showing ‘GATTzilla’ crushing a dolphin while spreading DDT, see Esty, Daniel. 1994. *Greening the*
an institution like the GATT/WTO, trade could encourage a race to the bottom. The idea was that if environmental regulations placed costs on businesses and businesses were free to relocate, they would move to states with lax environmental regulations. This would create an incentive for states to relax their existing environmental rules, or at the very least give them pause before enacting new regulations. The efficacy of sanctions, the bias or not of international trade institutions, and the existence or not of races to the bottom are all beyond the scope of this work, but the important thing for the purposes of this discussion, is to recognize that these beliefs led environmental activists to engage in trade politics to a greater extent than they had before.

NAFTA and BSE Solidify Civil Society—Demanded Regulations as Trade Issues

The NAFTA debate was a pivotal moment for including labor and environmental rules in U.S. trade policy. For labor, the prospect of competing with developing country workers with little regulatory protection crystallized when the U.S. government began negotiating NAFTA, America’s first free trade deal with a developing country. For environmentalists, NAFTA’s implications were more ambivalent with some groups in support and others opposed. Both sets of activists were able to attract more attention to their trade priorities in NAFTA than in the simultaneously occurring Uruguay Round because NAFTA was more salient, involved neighboring countries, and was more intuitive; as the AFL-CIO Secretary-Treasurer put it, “GATT is something nobody

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*GATT: Trade, Environment, and the Future.* Petersen Institute for International Economics: Washington, D.C. p. 34 or the cover of Aaronson’s *Trade and the American Dream* (1996). The Dolphin-Tuna case was one of the major reasons why U.S. environmentalists were highly engaged in the politics surrounding NAFTA even though they had not been particularly engaged in the politics surrounding the Canada-U.S. Free Trade Agreement.

understands and NAFTA is something everybody understands.”

Much of the opposition to NAFTA was not explicitly protectionist per se, only concerned that NAFTA could undermine Americans’ regulatory preferences. Ecological economists Hermann Daly and Robert Goodland summarized this point best saying “protecting hard won social gains from blind standards lowering competition, that is what we are interested in- not the protection of some inefficient entrepreneur who wants to grow mangoes in Sweden.”

Labor and environmental activists succeeded in expanding the scope of what was considered a ‘trade’ issue. They forced Presidents Bush and Clinton to accept that labor and environmental standards had to be part of NAFTA negotiations. These groups were able to put their concerns at the center of the opposition to NAFTA. NAFTA did eventually include side agreements on the environment and labor standards that were stringent enough to gain at least some support from environmental groups though still not enough to satisfy labor.

The inclusion, or not, of these kinds of side agreements in future negotiations became a point of contention between the two parties. Republicans and their business allies resented that these policy areas, which they still did not consider to be ‘real’ trade issues, had been included in NAFTA and were determined to prevent them from contaminating future trade deals. Democrats, conversely, considered their inclusion the new normal; they would take a dim view of any future agreements that did not include such provisions. Thus, adding regulation to the trade policy mix activated the partisan polarization that was starting to ossify American politics more broadly. Though NAFTA

50 Ibid. p. 177.
indelibly added environmental and labor regulations to the trade policy docket, it did not raise consumer protection regulations to the same level of trade salience. It took an epic governmental failure two years later across the Atlantic to do that.

In March 1996, the British government announced that, contrary to what it had been saying for nearly a decade, bovine spongiform encephalopathy (BSE) also known as mad-cow disease which had been found in a large number of British cows, could in fact be transmitted to humans and cause a deadly, incurable virus, variant Creutzfeldt-Jakob Disease. Europeans who had consumed British beef in the previous 5 years, the disease’s incubation period, could potentially have been infected. A political firestorm ensued. Fear and indignation were widespread. Because the UK government so spectacularly failed in its obligations to protect consumers, and because the increase in trade engendered by European integration had exposed consumers across Europe to potentially fatal British beef, the mad cow crisis badly damaged the notion that Europeans were better off federalizing regulation and trade policy. The collective experience of the mad cow crisis was so searing that trade liberalization in regards to food safety became viewed with deep suspicion. The fallout from the BSE crisis directly contributed to European consumers’ rejection of allowing BST, a hormone given to milk cows, and genetically modified crops from being sold in Europe. Both of these

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decisions created serious trade disputes with the United States because both of those products were allowed in America.

**Civil Society and Trade: The Current State of Play**

Consumers protection groups do not have the same financial resources as businesses associations. Nevertheless, when they become engaged on an issue, they can be a powerful lobbying force because they deliver legitimacy by disseminating trusted information and representing respected broad-based groups. Consumer groups have an image of defending ordinary citizens. Who, aside from cat-stroking Bond villains, could possibly be against protecting consumers? This framing is so powerful that when businesses oppose consumer advocates’ demands, they are forced to justify their position as being better for consumers than the consumer advocates’ position.\(^{56}\)

Developed-country consumer advocates contend that without government regulation, international businesses will make substandard products to increase profits. Moreover, developed states and their citizens generally view developing countries’ regulations as flimsy, non-existent, or unenforced.\(^{57}\) They demand products sold in developed-country markets meet their standards, not the standards used in developing countries. Those demands and the regulations that emanate from them can inhibit trade. The difficulty in resolving the tension between consumer protection and trade is exemplified by an increasingly employed regulation: labeling requirements.

Labeling requirements have long been one of the main thrusts of consumer protection regulation. In the 1980s, these labels began to have significant trade impacts. GATT rules meant states were bound to employ regulatory means that least distorted

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\(^{57}\) For example, when asked what percentage of Chinese imports they believed violate American safety standards, the mean U.S. citizen’s guess was 45 percent. Gallup Poll, August 2007. Retrieved Nov-24-2014 from the iPOLL Databank, Roper Center for Public Opinion Research, UConn.
trade. GATT panels have often cited labeling as a preferred option because it is presumed to be less protectionist than an outright ban. On the one hand, it could be said that governments began to use labels as means of encouraging consumption of domestically produced items over imports; for example, the German government used its labeling requirements to compel a British sausage manufacturer to label their product not as sausage but as “pork-filled offal tubes.” Conversely, governments can respond that they are merely helping consumers. Parsing out which is the real motivation can be difficult. Consumer advocates and governments think they are protecting the public; foreign export-oriented producers think this kind of consumer advocacy is a smokescreen for protectionism.

As with consumer advocates’ wishes, the intent and appropriateness of trade demands made by labor activists is deeply contested. Amongst the American public, respondents generally favor more rather than less inclusion of labor standards in trade agreements. Every major piece of trade legislation since NAFTA has been accompanied by a debate on whether and how to attach such standards to trade deals. In 2007, Republicans and Democrats settled on a set of basic principles on environmental, labor, and intellectual property rights in trade negotiations known as the May 10th Agreement; still, on the details, there remains significant disagreement between the parties.

Notwithstanding this disagreement, the parties have been able to collaborate in using trade sanctions to punish other states’ human rights abuses. Human rights

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continue to be the primary emphasis in the trade-labor rights positions taken by the EU.\textsuperscript{61} While Europe and the United States have tried to connect labor standards and trade, developing countries have adamantly opposed it.\textsuperscript{62} Low-cost labor is frequently their primary comparative advantage and so they tend to see these connections as protectionism dressed in new rhetorical garb.

Finally, the growing recognition of climate change heightened the salience of the connection between trade and the environment. Environmentalists remain concerned by the impact increased trade may have on environmental protection but that does not mean that they oppose all trade liberalization; for most activists, the challenge is not to limit trade but instead to ensure that trade accommodates environmental goals. The European Union has sought to include environmental standards in its trade positions.\textsuperscript{63} In the United States, inclusion of environmental provisions in trade agreements has divided the parties in a similar way to labor rules. Underlying all of these demands for trade-encompassing protections for consumers, laborers, and the environment is a strong preference for domestic rather than international regulation; not only do developed states’ citizens not trust developing countries’ regulations, they also consistently prefer their own country’s regulations over those of other developed countries.\textsuperscript{64}

\begin{itemize}
\item \textsuperscript{64} On American and German citizens’ preference for their own country’s regulations, see Pew Research Center. “Support in Principle for U.S.-E.U. Trade Pact: But Some Americans and Germans Wary of TTIP Details.” April 9, 2014.
\end{itemize}
International Businesses Want International Rules

Multinational corporations on the other hand want just the opposite, international standards rather than a new rule for every state. Since the 1980s, international businesses have pushed their governments to reduce the extent to which national regulations inhibit their ability to profit from trade. Again, it was in Europe where this trend took place first. Businesses formed the vanguard in reducing regulatory barriers, both with respect to promoting mutual recognition and the Single European Act.65

Internationally-oriented European and American businesses worked together to promote the Uruguay Round. They were the main supporters of strengthening procedures used to address NTBs. The new SPS Agreement for example was a boon for international firms in three ways. First, it promoted the use of international standards set by organizations such as the Codex Alimentarius. The rule that regulations matching Codex standards would be considered WTO-compliant generated a powerful incentive for states to adopt Codex standards. The more states that adopt Codex standards, the more uniform regulations are across different states, and thus the fewer regulatory barriers blocking businesses from lucrative trade. Second, by forcing regulations that differed from standards set by these bodies to be based on science, the new SPS and TBT Agreements constrained states’ ability to create blatantly protectionist regulatory barriers.66 They also helped export-oriented businesses by alleviating the acute difficulties that regulatory barriers present for intra-industry trade. Third, business controls the lion’s share of representation at Codex; the more decisions that can be made at a forum dominated by business, the more influence business has over those regulations.67

66 Obviously, where the science is contested, this mechanism is weaker at reducing regulatory barriers.
Internationally-oriented businesses have been the leading proponents of preferential trade agreements. They seek these reductions to take advantage of economies of scale and the efficiency gains from locating disparate production steps in different states. The Canadian debate over a free trade agreement with the United States pitted environmental and consumer activists opposed to what they saw as American regulatory imperialism against Canadian businesses eager to gain access to the massive U.S. market.\textsuperscript{68} North American businesses strongly supported the successor of the Canada-United States Free Trade Agreement, NAFTA.\textsuperscript{69}

In all of these cases, international firms pushed back against labor, consumer protection, and environmental activists opposed to trade liberalization. Businesses have not \textit{en masse} rushed to locations with lower environmental and consumer protection regulations nor have they uniformly pushed for reduced standards in their home states.\textsuperscript{70} Instead, they fought against those groups’ demands for specifically national regulations that force firms to maintain two production lines at great cost or forgo sales in a lucrative market. Businesses like to portray these regulatory differences as unnecessary red tape. When they push for regulatory trade barrier reduction, they find examples of seemingly pointless regulatory differences such as Canada’s unique deodorant rules that force Proctor and Gamble’s North Carolina factory to maintain separate production just for the Canadian market, and ask, tongue in cheek, whether “Canadian underarms [are] so

\textsuperscript{70} Porter, Michael. 1998. \textit{The Competitive Advantage of Nations}. MacMillan: NY. Vogel. 1995. \textit{Trading Up}. There are a number of other works that also demonstrate the rarity of businesses fleeing to jurisdictions with more lax standards. For a review of these, see Drezner. 2007. \textit{All Politics is Global}. p. 14-17.
different that we need two sets of regulations?" Civil society groups respond with examples of national regulations that must be maintained to protect the citizenry.

The new, more robust WTO rules have heightened the drama of this regulatory struggle between businesses and advocacy groups by raising the stakes for all parties with an interest in the connection between trade and regulation. Under the GATT, even if a state was found to have violated GATT rules, the lack of enforcement capabilities meant such a ruling could often be prevented from having any material costs on that state. In contrast, the new WTO rules can force a state to change its regulations or face retaliation.

**Developing Countries and the WTO**

The WTO and its rules were far-reaching in their implications for developing countries. The Uruguay Round left them disillusioned with trade rules. Though there was agricultural liberalization, developing countries- with sound justification- believed that agriculture in the Global North received far too much protection. They perceived the new WTO rules, especially the TRIPS, GATS, and TRIMS agreements, as limiting their regulatory flexibility to an even greater extent than they had initially feared and also believed that developed states were implementing their concessions in agriculture and textiles as slowly as possible. Given their belief that the Uruguay Round resulted in an agreement biased against them, and given that they were facing greater domestic difficulty in implementing it than they expected, developing countries were reluctant to agree to another WTO round that would expand still further the list of regulatory areas.

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where they would be constrained by trade.\textsuperscript{74} Thus, in 1999 when President Clinton announced that labor and environmental regulations should be part of the trade regime and that sanctions should be used to enforce high standards in those areas, developing countries walked out, refusing to allow the launch of another WTO round.

Despite this rebuff, developed countries hoped to launch a new round in order to realize further trade gains. They recognized that agriculture remained highly protected and so agreed that a new round, the Doha Round launched in 2001, should focus on agriculture and other development-related issues. In return for concessions on these issues, the EU, and to a lesser degree the United States, demanded further regulatory constraints in four areas known as the Singapore issues: government procurement, investment, competition policy, and trade facilitation. Developing countries refused to include the first three in the negotiations.\textsuperscript{75} Given this blockage, the EU and Japan perceived that they would receive almost nothing in return and so had little incentive to make difficult agricultural reforms.\textsuperscript{76} The Doha Round has dragged on for over 14 years thus far and shows little sign of reaching a breakthrough on any issue other than the Bali Agreement on relatively minor trade facilitation rules. A major reason the Doha Round has failed is that it attempted to reduce regulatory trade barriers at a global level.

\textit{Regulation and Trade Regionalism}  

The increasing centrality of regulation in trade negotiations thwarts multilateralism and thus promotes regionalism. In the post-Cold War era, regional trade agreements have proliferated at a remarkable rate. Given the glacial pace of progress in

the Doha Round, developed states have pursued trade liberalization at the bilateral and regional levels. By not diluting their bargaining power in the way that a multilateral negotiation would, bilateral and regional agreements provide states with large markets a greater opportunity to graft their regulatory preferences onto smaller states. The regulatory changes that these smaller states have been coaxed into making are more stringent than those mandated by WTO stipulations and so are often referred to as WTO-plus or TRIPS-plus. Regulation is more central to these trade negotiations than it has been for any previous iteration of trade agreements, regional or multilateral. Two of the most significant manifestations of regulatory barrier negotiation combining with trade regionalism are the current negotiations taking place regarding the Trans-Pacific Partnership (TPP) and the Transatlantic Trade and Investment Partnership (TTIP).

The politics of the TPP primarily revolve around regulation. To wit, public health advocates have squared off against tobacco producers over Southeast Asian states’ regulation concerning tobacco. Unions remain skeptical that the labor standards components of the final agreement will meet their expectations. There is serious concern that the TPP would undermine various countries’ financial regulations. In Malaysia, there is apprehension over whether the TPP’s government procurement chapter will invalidate the country’s efforts to assist underprivileged minorities. Consumer groups worry that food safety regulations will be weakened. The intellectual property

provisions that have been made public reflect the regulatory preferences of the pharmaceutical and entertainment industries, to the dismay of access to medicine advocates.\textsuperscript{81} Conversely, business organizations argue that regulatory harmonization is amongst the TPP’s biggest benefits.\textsuperscript{82}

The U.S. Chamber of Commerce highlights regulatory convergence as the single largest benefit of the Transatlantic Trade and Investment Partnership (TTIP).\textsuperscript{83} Civil society groups are more ambivalent toward TTIP than toward the TPP. Organized labor is more receptive to the TTIP than it is to the TPP.\textsuperscript{84} Some consumer advocates contend that regulatory cooperation is acceptable, especially if harmonization is upward, while others remain concerned that mutual recognition will lower standards.\textsuperscript{85} This greater comfort with the TTIP than the TPP can be accounted for with two explanations. First, TTIP negotiations are not as far along as the TPP and thus have not reached the same level of salience. Second, the U.S. and the EU are at similar level of development and generally have the same level of regulatory protection; the same cannot be said for many of the United States’ TPP negotiating partners. American labor and consumer activists trust European regulations far more than they trust Vietnamese regulations.


Conclusion

As tariffs and other non-regulatory measures secularly fell, the extent to which cross-national differences in regulation impeded trade became more clearer, especially to multinational firms. Once regulations became the subject of trade negotiations in the 1980s, civil society groups with a vested interested in those regulations became involved in trade politics to a greater degree than ever before. Cross-national differences in regulation are the centerpiece issues in trade politics today. This is likely to continue being the case for the foreseeable future.

This political history reveals several dynamics that drive the international negotiation over regulatory trade barriers. First, the erosion of non-regulatory trade barriers has made regulatory trade barriers more apparent and more significant. Second, there have been significant divisions between developed and developing states regarding trade and regulation. Developed countries have often led the way in pursuing regulatory trade barrier reductions but developing countries have been wary of being locked into adopting developed countries’ regulatory preferences. Third, businesses have been a major driving force behind efforts to reduce regulatory trade barriers. Fourth, the incorporation of politically sensitive domestic regulations into trade negotiations led environmental, labor, and consumer advocacy groups to engage in trade politics to a greater extent. Fifth, the sensitivity of these regulations made reaching agreement in multilateral trade agreements more difficult and so contributed to the trend toward regionalism that has become so prevalent in global trade politics. Sixth, the intent of a regulatory trade barrier is often in the eye of the beholder; one group’s vital domestic regulation meant to protect citizens is another’s disguised protectionism meant to coddle underperforming but politically connected businesses.
Chapter 3- Competitiveness and Death: Explaining the Negotiations over Regulatory Trade Barriers

Introduction
When the differences between countries’ domestic regulations impede international trade, the states involved have three basic options. They can reduce those regulatory barriers, they can increase them, or they can do nothing. This chapter explains when states are more likely to do each of these and why. My explanation involves examining the motivations of and interactions between three sets of actors: businesses, activist groups, and government officials. I argue that businesses are likely to succeed at reducing a regulatory trade barrier when they can link their desire for that reduction with broader concerns about economic competitiveness while activist organizations are likely to succeed at increasing regulatory trade barriers when they can link their desire for maintaining or increasing that barrier with preventing needless death.

In this chapter, I explain why the negotiations around regulatory trade barriers are in essence bargains between businesses and activists. I first discuss why businesses seek to reduce regulatory trade barriers and what can get them to end that pursuit. I then examine why activist groups seek to increase or defend regulatory barriers and what can get them to accept a reduction in those regulatory barriers. I investigate government officials’ two primary roles in regulatory trade bargaining, that of the champion and that of the marginalizer. I then discuss which political entities are likely to prevail in this bargain and why and in so doing lay the theoretical expectations for later chapters.
Business

Why They Seek to Lower Regulatory Trade Barriers

Businesses’ initial growth occurs within a specific regulatory context. \(^1\) Successful businesses learn how to operate profitably within the rules that define that context. \(^2\) As firms grow still further, they increasingly seek out foreign markets and conduct business internationally. As they do this, they begin operating in regulatory contexts that may differ significantly from the one they are accustomed to. The multiplicity of regulations can be burdensome even if they are skilled at handling regulation. In pharmaceuticals, for example, the need to separately file for market access in disparate countries can add hundreds of millions of dollars in costs and consume valuable patent time, thus depriving the firm of significant revenue. \(^3\) The skills that firms have built to meet their home government’s regulatory demands may no longer be very useful in meeting their host government’s demands. Those businesses have stopped running a regulatory race and have started competing in a regulatory decathlon.

These regulatory barriers may threaten to deny businesses access to a lucrative market, thus undermining their global competitiveness. At the very least, these barriers can force firms to have multiple production lines. Sometimes these regulatory barriers can force businesses to engage in bizarre, efficiency-destroying behaviors. For example, a combination of tariff barriers and regulatory differences forces Mercedes-Benz and

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\(^2\) Since this project is concerned with businesses’ approach to regulatory trade barriers, it largely bypassed the voluminous literature on corporate political activity more broadly except where it specifically relates to regulatory barriers. For a useful review of that corporate political activity literature, see Hillman, Amy, Gerald Keim, and Douglas Schuler, 2004. “Corporate Political Activity: A Review and Research Agenda.” Journal of Management. 30:6. p. 837-857.

Freightliner to build their cargo-vans in Germany, take them off the assembly line, test drive them in Germany, partially disassemble them, ship them to the United States, and then reassemble them there.\(^4\) Obviously, there is zero business rationale for constructing a vehicle twice before it goes to the dealer.

This is not to say that business leaders see themselves as having no social responsibilities, but even the most responsible businessman will become frustrated when faced with a dizzying array of rule differences. There is no need to assume bad faith or dastardly motives on the part of business to recognize that, if given the choice, they would rather meet one standard than six.

For different reasons, both socially responsible and socially irresponsible businesses worry about the effects different standards can have on their competitiveness and so want one standard. The responsible ones want it to be a single high standard so that less scrupulous businesses do not gain a competitive advantage as well as to generate greater confidence in their particular industry and their firm.\(^5\) For example, European businesses that were forced to maintain public disclosure statements on environmental protection fought for and won requirements through the International Organization for Standardization (ISO) that forced non-EU businesses to maintain similar statements as well.\(^6\) Less responsible firms want a single standard set at a low level in order to avoid increased production costs. For example the shipping firms that value costs over safety, labor, and environmental standards have supported a flag-of-convenience system that


amounted to a very low level of regulation. They may disagree on whether it should be a high or low standard, but both kinds of businesses want a single standard.

Businesses’ desire to reduce regulatory trade barriers has grown over the last several decades. As noted in Chapter 2, regulatory barriers have become the central impediment to international trade, and the extent to which they raise costs for businesses has increased. Both large and small businesses’ competitiveness can be undermined by regulatory trade barriers.

Firms in many industries have grown larger and more multinational as evidenced by expanding global value chains and production networks, increased foreign direct investment, and more extensive intra-firm trade. This in turn means they have a greater interest in multiple states’ regulations. As firms have come to rely on greater economies of scale and cumulative learning effects, the ability to gain access to many national markets became more important. These regulatory barriers also hamper small firms because the cost of complying with regulations often comprises a greater percentage of their overall costs. This is why, when the U.S. government created greater regulatory trade barriers in toys with the Consumer Product Safety Improvement Act of 2008, some smaller foreign toymakers were forced to pull out of the United States completely.

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The increasingly capital-intensive nature of businesses’ production investments as well as the increasing imperative to market differentiated products further heightens the importance of economies of scale in trade and thus regulatory trade barriers.\(^{11}\) High multinational asset specificity (i.e., possessing resources that are multinational in character but specifically geared toward one kind of economic endeavor) also pushes firms to press for reducing regulatory trade barriers.\(^{12}\) The increasingly international nature of commerce, the greater need for economies of scale, and the more extensive capital-intensity mean that more businesses have exactly this kind of high multinational asset specificity.

Additionally, unlike their more nationally-based predecessors from earlier periods that, when faced with economic headwinds, sought protectionism from governments, contemporary businesses, due to their much more extensively international character, are instead more likely to ask for government assistance in gaining access to foreign markets.\(^{13}\) A good example of this was when Kodak, which was facing stiff competition from its Japanese archrival Fuji, instead of pushing for the U.S. government to grant it trade protection to help it strengthen its grip on the U.S. market, instead chose to lobby the U.S. government to reduce trade barriers that were impeding its ability to compete in the Japanese market.\(^{14}\) This same dynamic played out in the semiconductor trade as

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The upshot to this approach is that businesses in the contemporary era pressure their home governments to get other countries to reduce regulatory barriers instead of pressuring that home government to increase its own regulatory barriers.

Finally, even when import-competing business seek protectionism, they are much more likely to ask for non-regulatory means of protectionism because those measures offer the same benefit without limiting businesses’ flexibility as new regulations would. For example, when American sugar producers demand protection from Australian competition, they do not ask Congress for a special regulation on how sugar must be produced but instead lobby to maintain a trade scheme built on tariff rate quotas and market allotments.16

When faced with regulatory differences, businesses have been in the vanguard in reducing regulatory barriers. Food industry firms have been the primary supporters of the Codex Alimentarius’ efforts to reduce regulatory barriers in food.17 The Motion Picture Association of America has been the biggest promoter of coordinating international copyright regulations.18 Pfizer led the charge to harmonize international regulations on intellectual property in pharmaceuticals.19 A timber firm, the Ecological Trading Company, and B&Q, the British version of Lowes, were the early business leaders pushing for green certification schemes and the creation of the Forestry Stewardship

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Council, which has coordinated international regulations on timber.\textsuperscript{20} Chemical companies like Dow and Dupont have consistently pushed for reducing regulatory barriers in the chemicals.\textsuperscript{21} These are just of few of the many examples of this trend.

In sum, many modern firms have operations in many states, have large economies of scale, are capital intensive, and have high multinational asset specificity. They therefore push for a reduction in regulatory trade barriers because those barriers make them less competitive by A) raising production costs and B) inhibiting market access.

\textit{The Considerations That May Provoke Business Apathy on Regulatory Trade Barriers}

Though businesses have often pursued reduced regulatory barriers, they have not done so always and everywhere. Several considerations may convince them to simply accept a difference in regulation that raises the cost of trade. The regulation may be easy to handle. The Canadian requirement that new cars come with owners’ manuals in English and French is straightforward, reasonable, and cheap to comply with. Attempting to reduce these kinds of regulatory differences is a waste of resources and risks making that business appear implacable and extreme. Also, the consequences of regulatory changes in the context of international trade are often unclear.\textsuperscript{22} If a business cannot confidently say that a regulatory change will improve its competitiveness, there is no

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reason for it to pursue that change. This may be especially true for large multinational firms as a regulatory change may help one aspect of its business while hurting another.²³

Pushing for a reduction in a regulatory trade barrier also risks generating a backlash if that reduction is seen to be undermining a highly valued public policy goal. Given firms’ growing reliance on brands to differentiate and sell their products, reputational damage is becoming a profound risk for businesses.²⁴ Similarly, businesses may view a particular regulation as so firmly entrenched that political resources expended in trying to reduce that regulatory barriers are wasted. There is no point in attempting the impossible.

Sometimes, the existing regulatory framework, even if not the ideal solution from a business perspective, is good enough to elicit acceptance from business.²⁵ An example of this is the Safe Harbor Arrangement that governed early iterations of e-commerce between the United States and Europe; while American businesses would have preferred regulatory harmonization based on U.S.-law, the Safe Harbor Arrangement was acceptable to U.S. businesses because it reduced data privacy regulatory barriers, just on a firm-by-firm basis.²⁶

All of these factors mean that in many instances, businesses will lead the charge to reduce regulatory trade barriers but in many other instances they will remain undecided or apathetic when faced with trade-impeding cross-national regulatory

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differences. To summarize, firms choose not to push for regulatory barrier reduction because A) those regulatory differences are cheap to comply with or B) attempting to reduce those barriers would have severe reputational consequences.

Business Motivations for Seeking Reduced Regulatory Barriers

1. Raises Production Costs
2. Inhibits Market Access

Factors That Weaken Businesses’ Motivation to Seek Reduced Regulatory Barriers

1. Cheap Compliance
2. Reduction Attempts Would Have Reputational Consequences

Activist Groups

Why They Seek to Raise Regulatory Trade Barriers

Just as businesses grow in specific political and regulatory contexts, the same is true for activist organizations. What gets many citizens to advocate for greater environmental protection is the sense that the air and water around them need cleaning up. These kinds of concerns were central to promoting the environmental movements in the United States and Europe in the 1960s and 1970s. What gets many citizens involved in consumer advocacy is the perception that some product they have purchased endangered them, and did so because the company that made it was malfeasant. It was that kind of concern that facilitated the rise of the consumer movements in the U.S. and Europe in the 1960s and 1970s. Labor unions focus on local and national grievances. Activist organizations exist to lobby the government for greater regulatory protection.

National governments’ leadership in regulatory matters means that citizens who care about a given regulation, or lack thereof, have an incentive to organize nationally.

The smog in Los Angeles in the 1960s was so thick that it was practically chewy. The Cuyahoga River in Cleveland was so polluted that it literally caught on fire multiple times. The entity with the power to do something about those problems was the U.S. federal government. Environmental protection in other states also tends to be built on national-level laws. The same is true for regulation on consumer protection and labor. This dynamic is not a product of a bygone era. As new technologies arise today they create similar calls for regulation. Almost as soon as firms started employing nano-scale particles and compounds in the first decade of the 21st century, activist groups became concerned about the risks they posed and lobbied governments to tightly regulate them.

The chief environmental, consumer, and labor regulations that exist are not promulgated by the United Nations or other supranational organizations. Contrary to the visions of black helicopters that populate some American conservatives’ nightmares, the UN and other international organizations have little power to regulate on the ground except where they have the cooperation of national governments. States take the lead in regulation. This means that the chief targets of regulation-promoting activist groups are national-level government officials. Even when activists go ‘beyond borders,’ their

32 In the EU, these may also be EU-level given that many regulations are promulgated at that level.
primary aims are usually to change national laws. For example, when European and Japanese environmentalists wanted to increase regulatory barriers on tropical timber to protect the rainforest, their primary target was the Malaysian government.

This is a crucial point: given national government’s central place in modern politics, activist groups that exist to promote regulation do so largely at the national level. Each of these state’s laws are different. This means that even though these activist groups are not really trying to create trade barriers, that is de facto exactly what they do as a byproduct of their demand that those national government officials increase regulation.

Four factors increase the extent to which these activist-promoted regulations impede international trade.

1) Regulations are often the most effective, enforceable means for activists to promote their causes. Consumer information campaigns rely on a series of assumptions: that consumers will receive the information, that they will understand the information, and that they will act on that information. All of these assumptions can, and quite often do, fail. Very few consumers are willing to pay more for goods produced in socially responsible ways. Activists also generally lack the resources to monitor or enforce firms’ compliance with civil regulations and private standards. Campaigns to get consumers to punish irresponsible firms via the market may work in some cases, but the

33 See Keck, Margaret, and Kathryn Sikkink. 1998. *Activists Beyond Borders: Advocacy Networks in International Politics*. Cornell University Press: Ithaca. p. 12-13. There are of course exceptions to this such as when these organizations lobby the UN directly.


rarity of that success means that activists often need to get government officials to force businesses to change their behavior if they want to see that change occur.

2) Activists are generally suspicious of business. They led the opposition to Multilateral Agreement on Investment precisely because they feared that it would empower businesses and that businesses would use that power to advance their interests in profit over the wellbeing of citizens.\(^{38}\) Consumer watchdog organizations exist to ferret out the incompetencies and misdeeds of businesses.\(^{39}\) Some environmental activists have adopted adversarial positions against business, focusing on naming and shaming rather than collaboration.\(^{40}\) Doctors Without Borders and other access to medicine advocates contend that pharmaceutical companies are so obsessed with profit that they will readily sacrifice the lives of millions of poor people.\(^{41}\) If business cannot be trusted to behave ethically on its own, then it logically follows that it must be forced to do so through government enforced regulation.

3) Raising the level of regulatory protection by emulating the state with the highest protection or convincing multiple states to adopt the same regulations would not create as many regulatory barriers, but this happen infrequently. That is because activists tend to distrust foreign standards at least as much, if not more than, those of their own country.\(^{42}\) For example, most Americans want to ban unpasteurized milk even though


Europeans generally accept it, and Europeans want to ban hormones in beef that raise considerably less alarm in the U.S. This consumer distrust extends to other regulations as well. When asked about U.S. and German regulations in data privacy, food safety, environmental protection, and automobile safety, citizens of both states trusted their own country’s regulations more than the others.

Citizens of developed countries are especially mistrustful of the rules in developing countries. Developed country citizens’ views on China are a good example of this. When asked what percentage of Chinese imports they believed violate U.S. safety standards, the mean U.S. citizen’s guess was 45 percent, and 74 percent of respondents reported being very or somewhat concerned about the safety of food imports from China. This skepticism toward China can be found in Europe as well.

This dynamic is one of the reasons, though certainly not the only one, why OECD countries tend to liberalize trade among themselves, especially intra-industry trade, to a greater extent than they do with the Global South.

4) Activists often do not prioritize trade expansion or believe that threatening to curtail trade is an effective way to promote their policy goals. Environmentalists have often associated trade liberalization with environmental degradation even though the

evidence on that association is mixed.\textsuperscript{49} When they have advocated for linking trade with environmental goals, they have generally tried to use the threat of trade reduction as leverage to compel compliance with those goals.\textsuperscript{50} Examples of this include the Convention on the International Trade in Endangered Species agreement, the International Whaling Commission, and the Montreal Protocol.\textsuperscript{51} Activists have successfully inserted human rights clauses in the EU’s trade agreements.\textsuperscript{52} Unions, labor activists, and consumer organizations have employed similar tactics.\textsuperscript{53}

An activist group’s trade views also play a role. If a group generally views trade positively, then a small attenuation in a regulation may seem to be a reasonably small price to pay. If a group already views trade negatively however, reducing that regulatory trade barrier is a foolhardy sacrifice that serves only to facilitate an additional hardship in the form of liberalized trade.

Consumer groups are a particularly interesting manifestation of activist organizations not valuing trade because they generally represent a group that, at least superficially, should support trade liberalization. After all, one of trade’s biggest benefits is that it lowers prices, which benefits consumers. Why then do consumer groups often advocate for greater regulation at the cost of trade? This paradox can be explained by


Gunnar Trumbull’s research on narratives. Trumbull argues that consumer advocacy groups rely on two main kinds of arguments: ‘narratives of access’ that call on the state to increase consumers’ access to certain goods and ‘narratives of protection’ that call on the state to protect consumers from the dangers posed by certain goods.  

Consumer advocacy organizations have historically rested on a foundation of affluence and have been primarily concerned with those issues that motivate their relatively well-off members. For these consumers, their affluence means that access to goods is generally less of a perceived problem that the potential dangers of substandard goods. Given this, with regards to international trade, consumer advocacy groups tend to be much more interested in narratives of protection than narratives of access. These narratives of protection lead them to ask for more specifically national regulation.

These factors lead activists to seek specifically national, or in the case of the EU, regional regulations regardless of the consequences for trade. To give just a few examples, U.S. consumer groups have demanded country-of-origin labeling which in effect, even if not in intent, disproportionately harms Canadian meat suppliers.

Greenpeace’s campaign against phthalates (chemicals that make plastic toys softer) led to

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the creation of more stringent toy safety regulations in Europe, which created regulatory barriers in the toy industry between the U.S. and EU. Greenhouse gas regulations backed by European environmentalists have created regulatory trade barriers in refrigerators. American renewable and low-carbon fuel standards act as a regulatory barrier against Canadian energy exports derived from oil sands.

To summarize, activist organization push for a regulatory barrier increase because A) they perceive a need to redress some societal problem and cannot achieve their goals through non-regulatory means, or B) they prefer to use trade curtailment over trade liberalization to promote their policy goals.

**The Factors That May Provoke Activist Apathy on Regulatory Trade Barriers**

Like businesses, activist groups’ positions on regulatory barriers are shaped not only by their material interests, but also by their historical memories, their ideologies, and the way they define themselves. Activist groups often seek increased regulatory barriers but sometimes they choose to not care about a particular regulatory barrier. One reason they may do this is if that issue has low salience. Anthony Downs’ view that “most people are almost totally uninformed about most public issues” is bleak, but that does not make it entirely untrue.

Activist groups have limited resources. If few of their members care about an issue or it does not fit the group’s mandate, then that group is unlikely to expend

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60 Polczer, Shaun. “Minister: Oilsands Must Be Cleaned Up; Improve Record or Face ‘Green Protectionism,’ Prentice Says.” Times Colonist (Victoria, British Columbia) September 17, 2010.
resources defending that barrier. For example, prior to the 1970s, shipping regulations were not particularly salient for environmentalists and so they did very little lobbying on that issue. However, the growth in the size of ships as well as the increase in the number of ships combined with several high-profile spills elevated the salience of those regulations and so environmentalists began seeking more stringent shipping regulations.\textsuperscript{64} Similarly, the salience of labor standards gained greater salience with the expansion and heightened publicity of the anti-sweatshop campaign in the 1990s.\textsuperscript{65} In both cases, the extent to which activists demanded regulatory changes that amounted to trade barriers was connected to the salience of those regulations.

The salience of a regulation depends on how tangible the regulations are and how direct the connection is between ordinary citizens’ daily lives and the regulation in question. If citizens cannot easily understand the regulation and cannot easily estimate how that regulation might affect them, that regulation is likely to remain un-politicized. For example, when U.S. and EU-based stock markets moved to reduce the regulatory differences between their accounting standards, activist groups took little if any notice and said nothing, mostly because accounting standards regulations are almost incomprehensibly technical to those who do not already work for accounting firms.\textsuperscript{66}

This can be compounded when regulations are made at the international level. Because the process of making regulations in international forums is even further


removed from the public eye, the ability of a given regulation to gain salience may be undermined. On the other hand, some institutions that have traditionally not had much public involvement such as the *Codex Alimentarius* have been making special efforts over the last several years to more fully include NGOs in the policymaking process.

How an NGO and the society it is embedded in perceive risk can also affect which risks must be regulated against and which can be tolerated. NGOs and societies that adopt more group and hierarchy-based orientations are often more predisposed to risk mitigation through regulation than those that adopt more individualistic perspectives. Relatedly, much also depends on just how adversarial the particular NGO is to business. Friends of the Earth, Public Citizen, and Greenpeace have been much more adversarial toward business than the National Wildlife Federation and the Environmental Defense Fund. Some activist groups are willing to work with business. Other NGOs consider that approach ‘greenwashing,’ i.e. a thin public relations veil that delivers undeserved legitimacy to activities that are still fundamentally dirty.

An NGO’s acquiescence to regulatory trade barrier reduction can also be purchased. When businesses work with NGOs to promote reform through codes of conduct or private regimes, that often leads those NGOs to not press for government

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regulation.\textsuperscript{73} Indeed, what defines a private regime is that it is not state-enforced.\textsuperscript{74} These private regimes have grown considerably over the last two decades.\textsuperscript{75} Some examples of these kinds of NGO-business partnerships that avoid government-enforced regulations include the Fair Labor Association, the Marine Stewardship Council, and the Fairtrade Labeling Organization.\textsuperscript{76}

Importantly, it is activist pressure that pushes businesses to agree to these. Issue areas where there is significant NGO activity comprise a huge share of all private standard regimes.\textsuperscript{77} Firms that engage in self-regulation are similarly attempting to pre-empt state regulation.\textsuperscript{78} Sometimes the self-regulatory schemes are little more than flimsy shams designed to serve as public relations campaigns. One example of this was the chemical industry’s Responsible Care scheme after a major accident in Bhopal, India.\textsuperscript{79}


In other instances, such as in the self-regulation done by Body Shop and Levi-Strauss, self-regulation can actually be quite robust.80

Activists’ acquiescence can also be bought by business agreeing to accept a higher level of regulation in exchange for a unified standard. This kind of buy-out is especially likely to occur in areas where businesses care more about the multiplicity of regulation than the level of regulation and where what constitutes an upward movement in regulatory protection is clear to all parties. The movement in regulatory trade barriers on automobile emissions covered in the auto industry chapter later in this book demonstrates this kind dynamic.

Finally, activists’ acceptance may also be purchased through those activities that are referred to as corporate social responsibility (CSR). The CSR activities of today have moved beyond the philanthropic gestures of the past and have taken on a more political character in that firms now often provide public goods and contribute directly toward society’s achievement of regulatory goals.81 Importantly, as with private standards, in most cases these activities are not idealistic attempts to promote the common good. Scholars have found that it is activists’ demands that are the primary stimuli that provoke businesses into implementing CSR strategies.82 In other words, CSR is a way of buying off activist groups. One example of this was when Swedish food retailers were able to...

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prevent environmentalists NGOs from undermining their sale of imported seafood by agreeing to sell only those seafood products that had been caught in sustainable ways. It is also worth pointing out that a successful buy-out of activist organizations usually amounts to a de facto buy-out of government officials as well. Government officials respond to pressure. If environmentalists accept a regulatory barrier reduction, why should the EPA stop it?

Activists are able to demand these buy-outs by presenting businesses with a choice: accept regulatory changes that increase trade costs or face significant reputational damage. This is exactly what Global Witness, an NGO that works on resource extraction in war zones, was able to do to DeBeers. It was able to get DeBeers to accept responsibility for keeping conflict diamonds out of the supply chain rather that foist that responsibility onto regulators. By acquiescing to NGO demands, DeBeers was largely able to avoid severe reputational damage and was able to shape the regulatory agreement known as the Kimberley Process Certification Scheme in ways that alleviated the extent to which the agreement raised trade costs.

NGOs can also do this is by forcing firms to desist with some form of international commerce that the activist group, through a public relations campaign, has made too risky for their reputation. This is how the Free Burma Coalition, through a series of protests and lawsuits, was able to get Adidas and Costco to stop doing business

They can also pressure a company to join a certification scheme in which the firm’s reputation is safeguarded so long as it meets the requirements of a third party that will vouchsafe its good character.

All of these mechanisms rely on leveraging a firm’s concern for its reputation. These strategies are thus especially effective in situations where a company relies on its brand and where there is a direct connection between its production methods and consumption. A low-profile intermediate supplier may be somewhat less vulnerable, but a high-profile scandal involving a well-known brand can cost that firm a lot more than the cost associated with simply changing their production practices. Two of the most well-known chocolate brands are Hershey’s and Cadbury’s. When reports of forced child labor on cocoa farms in the Ivory Coast surfaced in 2000, they were quick to work with NGOs to end labor abuses in their industry. The absolute last thing Hershey’s and Cadbury’s want people thinking about when they purchase chocolate is a child in slavery harvesting their bars’ main ingredient.

Activist groups that employ these strategies in an attempt to win a buy-out are aided by the fact that attempting to silence activist groups can easily backfire. For example, when Boise Cascade Lumber Company tried to have the IRS revoke the tax-exempt status of the Rainforest Action Network (RAN) and then attempted to intimidate

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its funders with lawsuits, those moves only served to increase the profile and funding of the RAN.\(^9^0\)

On the other hand, activist organizations do have to give up total control over the regulatory process if they want businesses to participate. An early environmental labeling push (Green Seal) excluded businesses, which meant that Consumers Union loved it, but also meant that firms such as Proctor and Gamble openly opposed it.\(^9^1\)

The key point here is that businesses and activist groups may become politically engaged over a regulatory trade barrier but can also be convinced to remain politically inert on that issue. Should one of these sets of actors remain apathetic on a given regulatory issue, it becomes much easier for the other to dominate the policy entrepreneurship on that issue. To summarize, activist groups choose not to resist a regulatory trade barrier reduction because A) the regulatory barrier is of such low salience that it does not justify expending resources to defend it, or B) the activist group’s opposition is bought out by business through private standards, self-regulation, corporate social responsibility, or a higher international regulatory standard.

Activists’ Motivation to Defend Regulatory Trade Barriers

1. Perceive Problem That Cannot Be Addressed in Non-Regulatory Way
2. Prefer Trade Curtailment to Trade Liberalization as a Policy Tool

Factors That Weaken Activists’ Motivation to Defend Regulatory Trade Barriers

1. Low Salience
2. Acquiescence is Bought Off Through Private Standards, CSR, or Higher International Regulatory Standard

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Marginalizers and Champions- Government Officials in Regulatory Trade Politics

If government officials are involved in negotiations over a regulatory trade barrier, it means that business and activist groups both care about that barrier and were not able to reach agreement on some sort of private standard or other buy-out. At this point, business and activists are both likely to be lobbying the government for policy support. Each of them is attempting to convince government officials to marginalize the other. In fact, because activists and businesses are often so suspicious of each other, in many cases they would rather seek assistance from government first and cooperate with the other only as a last resort.\(^2\)

Faced with these cross-pressures, government officials have three basic choices. First, they can champion business and marginalize activists. Second, they can champion activists and marginalize business. Third, they can refuse to take sides and instead encourage a buy-out. Government officials may of course seek to promote the interests of domestic firms.\(^3\) It was for this very reason that the U.S. Federal Reserve supported more stringent capital regulations in the Basel Accord while the Securities and Exchange Commission opposed more stringent capital requirements on securities under the International Organization of Securities Commissions.\(^4\) On the other hand, government officials may oppose businesses, even powerful domestic firms, if defending that business has severe reputational consequences. For example, even though Nestle is a

\(^{2}\) Not only do NGOs and businesses frequently mistrust each other, they face other risks from collaboration as well. Business may become more vulnerable to NGOs while NGOs risk being perceived as sell-outs. Abbott and Snidal. 2009. “The Governance Triangle.” p. 61, 71, 80.


\(^{4}\) Ibid. p. 545-549.

The relative political power of business and NGOs can have a significant impact on the incentives faced by a government official. Summarizing the literature on business representation in Washington, Coen, Grant, and Wilson note that “no group in the United States- certainly not the groups such as unions or public interest groups- that might be expected to clash with business commands anything like equal resources.”\footnote{Coen, David, Wyn Grant, and Graham Wilson. 2010. “Political Science: Perspectives on Business and Government” in The Oxford Handbook of Business and Government. Coen, David, Wyn Grant, and Graham Wilson (eds.) Oxford University Press: New York. p. 10-11.} On the other hand, activist groups provide information, deliver legitimacy, and in some cases mete out electoral rewards and punishment. Still, despite these pressures, government officials are more than just blind ropes following wherever they are tugged hardest. There are four major sources of government officials’ agency: institutional indeterminacy, competing imperatives, expertise and staffing decisions, and government officials’ beliefs about their role and the proper approach to regulation.

**Domestic Institutional Indeterminacy**

Government officials are not locked in place by their institutions.\footnote{This paragraph draws Mattli and Woods. 2009. “In Whose Benefit? See especially p. 15-16.} Institutional arrangements characterized by opaque and closed decision-making forums seem tailor-made for industry capture. On the other hand, should government officials want to marginalize businesses, these kinds of institutions provide a means to do that. Promoting regulatory governance through networks is particularly prone to this given that those
networks tend to also inhibit broader policy participation. Conversely, institutional arrangements characterized by transparent decision making and open access are assumed to be friendlier to NGOs. However, many access points may in fact give businesses more opportunities to shape regulations to their benefit.

Domestic institutions vary in other ways that may hinder or promote reducing regulatory barriers. First, they vary in their ability to provide timely information to key stakeholders, which affects how effective those stakeholders, usually businesses, can be in attempting to shape regulations being forged in international regulatory organizations such as ISO. This is helpful in explaining why firms whose home states have hierarchical institutions are generally more successful when lobbying standards bodies, but it does not explain whether government officials will be actively helpful to them in their attempt to reduce regulatory trade barriers or will oppose them. Second, there is the issue of equality in institution’s regulatory capacity. When one state has a highly developed regulatory capacity it is more likely to impose its regulations on products from other states that do not, but more likely to engage in regulatory cooperation with other states that have a similar level of regulatory capacity.

Competing Imperatives

One of the reasons why government officials’ behavior in regulation and trade cannot be easily predicted is that, within the realm of regulatory trade politics, they are often attempting to balance imperatives that run headlong into each other. South African

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officials for instance have struggled with how to best balance the need to attract foreign capital in order to promote employment growth and black economic empowerment while also increasing labor standards.\textsuperscript{102}

Within governments there are often contradictory impulses toward business. American politicians have routinely advocated reducing the regulatory burden on business and yet the tradition of adversarial legalism pushes the entire governing structure towards conflict with businesses over regulations.\textsuperscript{103} Another example of these impulses is the desire within many industrialized countries to both promote market competition but accompany that promotion with even more detailed and comprehensive regulations to govern commercial activity within those markets.\textsuperscript{104}

**Expertise and Staffing Decisions**

Bureaucracies may develop their own systems of information gathering and expertise creation apart from the regulated interest.\textsuperscript{105} The type of people that a bureaucracy hires has significant implications for this. The U.S. Forest Service generally hires and promotes scientists whereas the U.S. Park Service hires few scientists; this

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difference leads those two departments to have different cultures and take dissimilar positions on how best to manage wilderness areas.\(^{106}\)

Hiring practices can have significant implications for government agencies’ positions on trade. A good example is the USTR’s staffing on issues that relate to intellectual property. The USTR hires people from IP-intensive businesses while those same businesses hire USTR alumni in what appears to be an epitome of a revolving door.\(^{107}\) The two lead negotiators of the intellectual property provisions in the 2004 US-Australia Free Trade Agreement both received senior positions with pharmaceutical companies within three months after the agreement was signed.\(^{108}\)

Perhaps the best demonstration of this revolving door is Kira Alvarez.\(^{109}\) Alvarez was the lead intellectual property negotiator for the USTR in the US-Chile Free Trade Agreement, the US-Morocco Free Trade Agreement, and the Central America Free Trade Agreement (CAFTA). Alvarez then worked for the pharmaceutical company Eli Lilly implementing their government affairs strategy on intellectual property. She then worked for Time Warner and later was the U.S. Chamber of Commerce’s co-chair on global intellectual property. She then went back to the USTR to be its chief negotiator on intellectual property enforcement. After that, she went back to the pharmaceutical industry again, taking a job with AbbVie.

The policy access given to IP-intensive businesses reinforces these hiring practices. For example, when the USTR held a meeting on Intellectual Property within


\(^{109}\) All of this information on Kira Alvarez can be found on her LinkedIn page.
the TPP negotiations at 11am on February 1, 2011 in Winder Room 305 of its headquarters, the attendees included Shawn Brown, Matthew McGrath, Ralph Ives (via phone), Claude Burcky, Trevor Gunn, Doug Nelson (all representatives of IP-intensive businesses) but did not include any representatives of access to medicines activists or public health organizations.\footnote{Lee, Timothy. “Emails Show Cozy Relationship Between Obama Trade Negotiators and Industry.” The Washington Post. November 29, 2013.}

The practice of ‘cleared advisers’ on this issue shows a similar pattern. Cleared advisers are people who are allowed to view confidential negotiating documents. Firms have had many of their representatives named cleared advisers; however, when asked about cleared advisers from non-business groups, a USTR spokesperson could not name a single cleared adviser from a public interest group or activist NGO.\footnote{This list of attendees was emailed from Trevor Gunn to the other meeting participants email accounts with his gphaonline.org email account on Saturday, January 22, 2011 6:43 PM. This email was released under a FOIA request made by IPWatch.} There is nothing illegal or corrupt in this relationship between the USTR and IP-intensive firms but it is without question a cozy relationship. It is not surprising then that the policy preferences of these firms enjoy serious clout within the USTR.

Beliefs and Self-Identity

How government officials define their role can have a great deal of influence in terms of which constituencies they value most, who is supposed to be helped by a regulation, and what the proper relationship between business and government ought to be. Compared to their Swedish counterparts, American officials in the Occupational Safety and Health Administration tend to be much more legalistic and have a much more adversarial relationship with business.\footnote{Wilson. 1989. Bureaucracy. p. 295-296.}
They also can define for themselves what their job actually is. USDA officials for example resisted being put in charge of nutritional assistance programs, i.e. food stamps.\textsuperscript{113} In the 1980s European Court of Justice judges sought to include themselves in adjudicating disputes over intra-European non-tariff trade barriers.\textsuperscript{114} These role definitions can be significant drivers of government officials’ decisions on regulatory trade barriers.\textsuperscript{115} The USTR for example has generally had a culture that prized free trade and so has been more apt to promote the interests of American exporters than look for ways to create barriers to foreign imports.\textsuperscript{116}

Government officials may choose to do businesses’ bidding if they believe that pleasing business is a prerequisite for the economic well being of their constituents.\textsuperscript{117} They may also simply have an ideological commitment to free trade.\textsuperscript{118} There is an international component to this as well. The internationalization of epistemic communities through networks and interpersonal communication can promote common understandings of regulatory issues and thus lead government officials to work toward reducing regulatory trade barriers.\textsuperscript{119} On the other hand, cross-national differences in

\textsuperscript{115} There may also be jurisdictional concerns that play into this as well. Regulators may seek to promote regulatory cooperation to safeguard their turf and prevent disputes that would bring politicians in the issue area. Damro, Chad. 2011. “Regulators, Firms, and Information: The Domestic Sources of Convergence in Transatlantic Merger Review.” \textit{Review of International Political Economy} 18:4. p. 409–435.
institutional arrangements and cultural beliefs about the underlying regulatory issues can thwart efforts to reduce regulatory barriers even in areas such as software patents where other considerations suggests there should be policy convergence.\footnote{Eimer, Thomas. 2008. “Decoding Divergence in Software Regulation: Paradigms, Power Structures, and Institutions in the United States and the European Union,” Governance: An International Journal of Policy, Administration, and Institutions. 21:2. p. 275-296.}

To summarize, government officials side with business and marginalize activists from the policymaking process on that issue if A) they care more about commercial expansion than regulatory independence, B) their staffing favors business, and/or C) they identify business as a core constituency. On the other hand, government officials side with activists if A) they care more about regulatory independence than trade generation, B) their staffing favors activists, and/or C) they identify NGOs as a core constituency.

What Motivates Government Officials to Side With Businesses

1. Care more about trade than regulatory independence
2. Staffing and expertise favor business
3. Identify business as a core constituency

What Motivates Government Officials to Side With Activists

1. Care more about regulatory independence than trade
2. Staffing and expertise favor activists
3. Identify NGOs as a core constituency

Table 3.1 - Summary of Motivations

<table>
<thead>
<tr>
<th>Set A: Business- Seek Reduction</th>
<th>Set B: Business- Inert</th>
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</thead>
<tbody>
<tr>
<td>1. Raise Production Costs</td>
<td>1. Reputational Consequences</td>
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<tr>
<td>2. Inhibit Market Access</td>
<td>2. Firm Culture and Leader Values</td>
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<tr>
<th>Set C: Activists Seek Increase</th>
<th>Set D: Activists- Inert</th>
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<tbody>
<tr>
<td>1. Perceived Regulations as Sole Means</td>
<td>1. Low Salience</td>
</tr>
<tr>
<td>2. Prefer Trade Leverage Over Expansion</td>
<td>2. Acquiescence Purchased</td>
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</tbody>
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<table>
<thead>
<tr>
<th>Set E: Govt. Officials W/ Business</th>
<th>Set F- Govt. Officials W/ Activists</th>
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</thead>
<tbody>
<tr>
<td>2. Staffing Favors Business</td>
<td>2. Staffing Favors Activists</td>
</tr>
<tr>
<td>3. Identify Business as Core Constituency</td>
<td>3. Identify NGOs as Core Constituency</td>
</tr>
</tbody>
</table>

**The Sequencing of Regulatory Trade Barrier Negotiations**

On many occasions, the political negotiation over a given regulatory trade barrier is begun by business. In these scenarios, if the Motivation Set A outweighs Motivation Set B, businesses will seek to reduce regulatory trade barriers. Once businesses seek to do this, activist groups’ motivations determine whether they will resist this reduction or not. If Motivation Set D is equal to or greater than Motivation Set C, activist groups will not resist the regulatory barrier reduction. If Motivation Set C outweighs Motivation Set D, they will resist that regulatory trade barrier reduction. If that happens, at this point, government officials’ position becomes the determining factor. If Motivation Set E outweighs Motivation Set F, government officials will side with business and reduce the regulatory barrier. If Motivation Set F outweighs Motivation Set E, government officials will side with the activist groups and maintain the regulatory barrier. If government officials hold the two Motivation Sets roughly equal to each other, they will promote a buy-out between business and activists. On other occasions, the political negotiation over a given regulatory trade barrier is begun by activists. In these scenarios, the ordering of businesses and activists is simply reversed. These series of choices and the regulatory
trade barrier outcomes associated with those choices are encapsulated by the following flow-charts.

If Business Moves First - Figure 3.1

![Flow Chart Image]

- **A ≤ B**: RTB Stasis - Mexican Auto Safety Regs, NA-EU Safety Regs Period 2
- **A > B**: Seek RTB Reduction
- **C ≤ D**: RTB Decrease - RTB Decrease - Mex. Trucking, Period 2; Negotiation of TRIPS, BSE 10/11-03/13
- **C > D**: Resistance
- **E > F**: RTB Decrease - Dom. Content: Canada, Mex., and NAFTA
- **E = F**: Buy-Out - Japan-U.S. BSE 05/04-10/05, 09/10-10/11
- **E ≤ F**: RTB Stasis - NA-EU Safety Standards Period 1; WTO IP Decisions; Japan BSE 12/03-05/04, 05/07-08/09, 08/09-09/10
Figure 3.2-When Activists Move First

Activists

C≤D

RTB Stasis

C>D

Seek RTB Increase

Businesses

A≤B

RTB Increase- Mex. Trucking, Period 1; Negotiation of TRIPS; Japan BSE Regs 2001-2003

A>B

Resistance

Govt. Officials

E>F

RTB Stasis- US Dom. Content, EU Emissions Regs 83-88; US FTAs; IP

E=F

Buy-Out- EU Post-88, Mexico Environmental Regulations; India TRIPS Flex; BSE 2006-04/2007

≤F≥ F

RTB Increase- 2001 Doha Declaration
*Competitiveness and Death: Explaining Who Wins and Why*

Businesses are likely to succeed at reducing a regulatory trade barrier when they can link their desire for that reduction with broader concerns about economic competitiveness. Activist organizations are likely to succeed at increasing regulatory trade barriers when they can link their desire for maintaining or increasing that barrier with preventing needless death. The reason each of these is true is that they augment that group’s motivation to engage in the political fight, weaken the other side’s resolve, and present government officials with a situation in which the overwhelming majority of incentives and ideas flow in one direction.

*Competitiveness*

As I discussed earlier, businesses become motivated to lobby on regulatory trade barriers when those barriers raise production costs and/or inhibit market access, both of which directly undermine businesses’ competitiveness. The factors that reduce this motivation, cheap compliance and reputational concerns are also related to competitiveness. Cheap compliance means that regulatory barrier has little to no effect on that firm’s competitiveness while reputational concerns mean that despite the financial costs of a particular regulatory barrier, attempting to reduce that barrier could besmirch that firm’s reputation and thus do even more damage to that business’ competitiveness. In other words, those regulatory barriers related to competitiveness are the ones on which businesses will lobby the hardest.

This pattern occurs throughout the cases that are analyzed in the following chapters. In the early 1980s, the Big Three auto firms (Ford, GM, and Chrysler) fought hard to reduce labor-backed domestic content regulatory trade barriers precisely because those regulatory barriers were making them less competitive vis-à-vis Japanese
automakers. In Europe, the companies like Fiat and Peugeot that specialized in small cars fought hard against increased environmental regulatory barriers because those barriers threatened to annihilate their competitiveness in states like Denmark, the Netherlands, and Germany. They relaxed their opposition only after a series of developments made increasing environmental regulations no longer a throttle on their competitiveness. In the mid-2000s, U.S. beef producers stridently resisted Japanese safety-related regulatory barriers on beef because those barriers effectively prohibited them from competing in the Japanese market and because acquiescing to Japanese demands could have made their products less price-competitive against other forms of meat such as chicken and fish. Western pharmaceuticals firms became highly engaged in attempting to reduce developing countries’ intellectual property-related regulatory barriers precisely because those barriers were corroding their international competitiveness.

Crucially, competitiveness concerns are also significant drivers of government officials choosing to side with business in reducing regulatory trade barriers. When businesses can link their request for reduced regulatory barriers with broader concerns about the competitiveness of the country as a whole, reducing those barriers no longer appears to be a favor to business. Instead, it is a proactive, jobs-creating, economy-boosting decision. Not only does it smoothly portray doing what is best for business as doing what is best for country, it also rhetorically delegitimizes opposing that reduction. If a regulatory barrier is perceived to be a matter of competitiveness, defending that barrier makes the country less economically competitive. No one wants their country to be less competitive.
An additional reason why the narrative of competitiveness is effective is that many people, including government officials, continue to see economics as a fundamentally competitive activity. Economists would disagree, pointing to the innumerable ways in which economic activity is a positive-sum endeavor. That does not change the fact that many people, including government officials, find the language of competitiveness with regards to international economics to be intuitively appealing.

Furthermore, when competitiveness gains salience on the political agenda, it is often during a time of acute economic distress. Concerns about competitiveness during these times thus take on an air of crisis that government must do something about. Relatedly, government officials are more capable of reducing regulatory barriers during these times because moments of economic distress create policy windows in which altering trade policy becomes easier.  

The case studies analyzed in subsequent chapters demonstrate this pattern as well. Worries about continued economic malaise were a significant driver of European Community officials’ attempt to reduce intra-continental regulatory barriers in automobiles in the 1980s. Concerns that Korean firms would gain a competitive edge over Japanese firms in terms of exports to America was one of the reasons why Japanese government officials were willing to reduce the regulatory barriers in the U.S.-Japan beef trade in 2013. U.S. government officials connected stringent intellectual property rights with American firms’ competitiveness during the negotiation of the Uruguay Round and so were eager to reduce the regulatory barriers between developed and developing countries. These same competitiveness-based motivations led U.S. government officials to work with the Big Three automakers to marginalize labor unions and reduce domestic

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content regulatory barriers. The most significant reductions in regulatory trade barriers in the cases analyzed in this book were all accompanied by competitiveness concerns. That, more than anything else, explains when regulatory trade barriers get reduced.

Death
As I discussed earlier, activist groups may remain inert on a particular regulatory trade barrier if that regulatory barrier has low salience or their opposition can be bought off through private standards, corporate social responsibility, or some other arrangement in which businesses are not directly regulated by government. When activist groups perceive a regulation as being necessary to prevent needless death, neither of those is likely. To state the obvious, death grabs attention and concerns citizens as few, if any, other things do. Death raises the salience of an issue. It is clear. It is tangible. It motivates people. This is especially the case when the timeline and the casual connection between the regulatory mistake and the needless death are short.

Death does not just motivate activist groups. It also shifts the political terrain in ways that fundamentally increase activists’ chance of lobbying success. Not only does death motivate activists, it can cow businesses by presenting them with severe reputational risks and so weakens the political force that might oppose activists’ call for greater regulatory barriers.

At a basic level, the government’s core responsibilities all revolve around prevent unnecessary deaths among the population. It is why we have armies, health care systems, government-funded cancer research, policemen, firemen, food inspection, building codes, water treatment facilities, a National Weather Service, bridge standards, and consumer safety warnings. Preventing death is what government does. The birth of modern regulation in the late nineteenth and early twentieth centuries centered on food and drug
safety because business ineptitude, and in some cases mendacity, led to people dying.
Activist groups, and citizens more generally, are unlikely to accept the notion that the
government should stand by and do nothing when, through regulation, it could prevent
needless death.

Government officials are people too. At least in decently run places, those
officials do not want their citizens to die needlessly either and so their motivation to
maintain those regulations is also increased. The pressure that activists can bring to bear
on these issues is unlikely to be lost on those government officials. Furthermore, on
regulations that pertain to preventing death, those government officials are more likely to
value regulatory independence over trade and, given the engagement of activist groups,
are more likely to identify NGOs as their core constituency. In summation then, when a
regulatory trade barrier is perceived to pertain to preventing needless death, activists get
motivated, businesses get quiet, and government officials get involved.

The case studies analyzed in subsequent chapters bear out this pattern. Regulatory
barriers in automobiles were reduced within Europe and within North America. However,
the primary barriers that were reduced were related to emissions in the case of Europe
and domestic content in the case of North America. Neither of those had to do with
preventing death. The primary regulatory barriers between the regions, safety differences,
have been maintained. They have everything to do with preventing death. Consumer
advocacy groups and government officials on both sides of the Atlantic have fought to
maintain those regulatory barriers.

Bovine spongiform encephalopathy, also known as mad-cow disease, is a
neurological disease in cows. When humans consume beef from cows infected with BSE,
they may get variant Creutzfeldt-Jakob’s Disease (CJD). CJD is fatal and has no known cure. When Japanese consumer groups were defending Japan’s stringent anti-BSE countermeasures, they were doing so to prevent needless deaths. It was only when BSE became more fully contained, and the concerns about BSE and needless death subsided that Japanese consumer groups and government officials were more willing to reduce regulatory trade barriers in the U.S.-Japan beef trade.

The AIDS crisis in sub-Saharan Africa was death on a massive scale. Access to medicine advocates held that stringent intellectual property regulations as enforced by the TRIPS Agreement were making drugs too expensive for AIDS victims and so causing needless death. These activists along with developing country officials fought vigorously to solidify policy space in the Doha Declaration and so increase regulatory trade barriers related to intellectual property by increasing international regulatory diversity in the policy area.

In the cases analyzed in this book, the most resilient stasis in regulatory trade barriers and the most significant increases in those barriers were distinguished by serious concerns that relaxing those regulatory barriers would lead to needless death. That, more than anything else, explains when regulatory trade barriers get maintained or increased.

**Alternative Explanations**

**Cleavage-Based Theory**

There are of course a number of theories that already exist which seek to explain trade politics, however; they all struggle to fully capture the dynamics that surround regulatory trade barriers. As I discussed in Chapter 1, the cleavage-based explanations struggle to explain trade politics that involve regulations. As I have showed in chapter 2, cross-national differences in regulation have become the most prominent issue in
international trade politics and continue to grow even more important. Thus, the failure to explain regulatory trade barriers constitutes a large and expanding blind spot for the standard cleavage-based explanations.

**Business Dominates**

Second, there is the prominent explanation that large corporations that are able to effectively lobby governments drive international trade policy.\(^{122}\) We might call this the business dominates hypothesis. The imagery of a businessman puppeteering government officials to deliver special privileges through protectionism goes back to one of the earliest political science works on trade, Schattschneider’s *Politics, Pressures, and the Tariff*.\(^{123}\) In its modern manifestations, especially among anti-globalization activists, this explanation ignores the fact that government officials are capable of telling business ‘no’ when they want to.\(^{124}\) This argument has also been cast in a class-based context by some scholars who argue that the business class has effectively imposed its neoliberal views and promoted commerce over non-commercial public policy goals.\(^{125}\)

In many instances, government officials do adopt positions that help business, but it is an unhelpful exaggeration of businesses’ political power to assume that must happen.

This is especially the case because activist organizations can exert significant pressure on


government officials as well. One example of this was in the collapse of the Multilateral Agreement on Investment (MAI). Businesses wanted the MAI very much but the trade negotiators from the United States and European Union were forced to abandon the MAI when activist organizations were able to successfully portray it as a giveaway to big business.\footnote{On the MAI, see Devereaux, Charan, Robert Lawrence, and Michael Watkins. 2006. 

In some ways, regulatory barriers might even be seen as an easy case for this hypothesis because businesses are often seen as the primary drivers of regulatory politics as well.\footnote{This idea was perhaps most famously summarized by George Stigler’s widely cited argument that “as a rule, regulation is acquired by industry and is designed and operated primarily for its benefit.” Stigler, George. 1971. “The Theory of Economic Regulation.” *Bell Journal of Economic and Management Science.* p. 3.} Because regulatory trade barriers should be an easy set of cases for the business dominates hypothesis, its failure to adequately explain them, as I will show in the case studies to come, constitutes particularly damaging counter-evidence against it.

**Disguised Protectionism**

public safety justification, are one of the few efficacious tools of trade protectionism that governments have left.

This line of argument is quite common because it comports with the mildly cynical view of the political process held by many people. Government officials delivering protectionism to favored local constituencies and then pretending they were motivated by nobler and less parochial goals sounds like exactly the kind of thing we expect politicians to do.

Despite its intuitive appeal, there are several reasons to be skeptical of this argument. First, regulations limit businesses’ flexibility in ways that other means of trade protection do not. Countervailing duties for instance do not tell a business how it must conduct its affairs in the way that labor, environmental, or safety regulations do. Given this, when import-competiting business seek protection from foreign competition, they are much more likely to ask for non-regulatory means of protectionism.

Second, there is also the fact that trade rules are much more effective at preventing this sly protectionism than they once were. Regulation as disguised protectionism did occur in the 1970s and 1980s. Indeed, many of the most famous examples of transparently protectionist regulations are from this period. For instance, in an effort to boost Japan’s nascent ski equipment industry, the Japanese government attempted to ban foreign ski equipment on the grounds that Japanese snow was “special” and that this “special” snow fell on every mountain in Japan.\textsuperscript{129} Ontario’s environmental rules on bottles were designed more for the purpose of curtailing American beer imports that protecting nature; what made this goal transparent was that those rules were not

applied to soda. New WTO rules under the Tokyo and Uruguay Rounds largely curtailed that. John Braithwaite and Peter Drahos explain this change well and are worth quoting at length:

“Under the old regulation of national sovereignty, it would be common for South Korea, for example, to do the regulatory bidding of Hyundai in a smoke-filled room when Hyundai wanted a new non-tariff barrier. The national sovereign would not be required to provide good reasons; there was no risk that its reasoning might become known to consumer groups, let alone excoriated by their critiques. The post-1980 global regulatory order no longer works this way. South Korea will have to give reasons for the regulation, in Geneva. These reasons will be exposed to critique by hostile foreign firms, by independent professionals from non-manufacturing states or from the Society of Automotive Engineers, and by consumer advocates. If the standard is a spurious one, the South Korean public will find out by Consumers International passing the information to Korean consumer groups. South Korea will risk a WTO complaint and panel hearing over the non-tariff barrier and it may jeopardize type approval of its vehicles in states that have performance standards which are deliberately defensible.”

Given that businesses in the contemporary context are unlikely to demand regulatory protectionism and that government officials are far less capable of granting that protectionism than they once were suggests that the sneaky protectionism argument may not be a particularly helpful explanation despite its intuitive appeal.

The California Effect

Fourth, David Vogel argues that trade, rather than creating a race to the bottom, can encourage states to raise their environmental and consumer safety standards. This

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explanation was called the California Effect after an eponymous example in his book. California set high auto emissions standards, German automakers manufactured their cars to meet those standards, and then, because they did not want to maintain two production lines or be disadvantaged in competition with domestic-only firms, successfully lobbying the German government to raise its emissions standards to the California level.133

There were three central elements to the California Effect.134 First, businesses will support stricter regulations when those stricter regulations make them more competitive. Second, richer states with higher standards force producers in other states to raise their standards in order to export to them and so de facto raise foreign standards. Third, trade agreements give richer states with higher standards leverage to pressure other states to raise their standards to the richer states’ level. Nevertheless, discrepancies between the expectations of the California Effect and empirical realities have shown that Vogel’s explanation though quite good, was incomplete.

The California Effect largely ignores government officials’ beliefs. That is problematic given that those officials are the people who write the regulations and who do the negotiating over international trade agreements. Government officials must evaluate the utility of raising regulations, the utility of promoting commerce, and the relationship between those two goals. If government officials believe that raising regulations and liberalizing trade are mutually reinforcing rather than conflicting goals, that is likely to have a huge impact. If they believe that potential increases in regulation are wrong-headed and/or represent an unacceptable curtailment of commerce, that too is likely to matter a great deal. Can societal actors persuade government officials on various

matters, provide useful information, and exert political pressure on those officials? Of course, but that does not imply that those officials do not have ideas or that those ideas have not influence.

The California Effect also largely under-theorizes the construction of a state’s regulatory trade preferences. Why is exactly is a greener state greener? Within the case material covered in *Trading Up*, this often gets addressed, but within the California Effect theory itself, it is nowhere to be found. The demands on the state for stricter regulations come from somewhere and that somewhere needs to be explained. By ignoring activist organizations, the California Effect discards a variable that may be critical to explaining which regulations a state wants to raise and on which regulations it is willing to compromise for the sake of trade liberalization.

Finally, the California Effect overemphasizes the role of market power in regulatory trade politics. In the California Effect, as well as other explanations discussed below, it is asserted that market power matters because it gives states leverage in the form of threatening to deny another state and its businesses access to that lucrative market. The underlying thrust of that argument is that a smaller state, even if it wants to fight hard on its regulatory preferences, will eventually yield to the richer state’s demands because access to that richer state’s market presents such an enormous economic opportunity for the poorer state’s exporters. Undoubtedly, there is some truth to this argument. Trade agreements do present exporters with significant market access.

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135 Vogel’s California Effect is not the only trade politics explanation that relies on power and leverage to do much of its analytical lifting. Beth Simmons for example has argued that market power gives some states a dominant position that allows them to promulgate regulatory innovations that other states must respond to. Relatedly, it allows that state to graft its regulatory preferences on to smaller states. Simmons, Beth. 2001. “The International Politics of Harmonization: The Case of Capital Market Regulation.” *International Organization*. 55:3. p. 589-620.
opportunities and those exporters are likely to press their governments to pursue that access. Still, the market power argument overestimates the pliability of states’ regulations.

Labor, environmental, and consumer regulations are often sensitive topics. Changing them within a trade context may sometimes have the backing of activist organizations, as it did when Mexican environmentalists supported changes in their countries environmental regulations under NAFTA. In many other contexts though, attempts to change regulations within a trade context may run into strident opposition. Government officials changing these regulations for the sake of trade promotion risks being labeled a sell-out or a lackey.

The market power argument also assumes that government officials prize promoting commerce over maintaining regulatory independence. Again, that may be the case, but it is far from automatic. Finally, one must keep in mind that there are limitations to just how much the state with stricter regulations is willing and able to demand from other states within a trade negotiation. If a state with higher standards in one issue wants to complete a trade agreement with a state that has lower standards in that area, will it really be willing to jeopardize the success of that trade negotiation over a disagreement on a regulation in that policy area? The California Effect cannot answer this.

Even the United States, the country with the most market power leverage, is constrained in its ability to deploy that power. That is not to say that market power has no significance. It clearly does. But it does not have the significance that Vogel and others claim. In summation then, the California Effect can be improved upon by adding government officials’ beliefs to the analytic mix, by building a more substantial
explanation of state preferences in regulatory trade politics, and by shrinking though not eradicating the emphasis placed on market power.

**State-Centric Explanations**

Fifth, Stephen Krasner and Joseph Grieco depict the intersection of trade and regulation as a distributional conflict with the winner determined by political power. In this depiction, states spar to see who can write the rules with the winning state framing them in such a way as to benefit itself directly or at least benefit its businesses. In this depiction, societal actors can be ignored and the state’s preferences can be assumed.

This state-centric depiction is parsimonious, but it assumes away many factors which may have a profound effect on the ultimate outcome of an international negotiation at the intersection of trade and regulation. If a state is assumed to have only one overarching objective in mind, win the struggle to write the rules, then it logically follows that the state will pursue that objective single-mindedly. To make that assumption, it helps tremendously to speak of country A wanting X and country B wanting Y, and in so doing, assume away the cacophonous debates that accompany political decision-making. Assuming that each of multiple unitary states wants to “win” almost inescapably leads to the conclusion that the winner is determined by who is stronger.

At the intersection of trade and regulation these assumptions befog more than they illuminate. At that intersection, states do not have one primary goal, win; they have two,

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economic benefits and social regulation autonomy.\textsuperscript{138} States want both the economic benefits that derive from trade and the autonomy that comes with being able to set regulations completely independently. These two goals are frequently in tension. Agreeing to reduce regulatory trade barriers with another state delivers economic benefits at the cost of having specifically national regulations that can be changed on a political whim. Erecting regulatory trade barriers creates greater regulatory independence at the cost of trade-related economic benefits. States have these multiple goals because they have multiple actors in their societies who make disparate and often contradictory demands on government officials. This multiplicity of demands means that states’ international behavior, and thus international negotiation outcomes, are likely to vary with the intensity and effectiveness of the societal demanders as well as the proclivities of the governmental demandees.

This state-centrism is shared by Dan Drezner’s revisionist theory of international regulatory outcomes. Drezner argues that the distribution of great power preferences and the distribution of preferences between the great powers, the United States and the European Union, and other international actors, smaller states and NGOs, are the key independent variables in explaining regulatory outcomes.\textsuperscript{139} For Drezner, domestic actors are important only insofar as they raise the adjustment cost to regulatory coordination. In Drezner’s telling, on a given issue, government considers pursuing regulatory coordination and domestic actors become important only to the extent that they make


\textsuperscript{139} Drezner. All Politics is Global. p. 72.
government pay a price for pursuing that coordination. This fits with his approach of
generally dismissing societal actors’ importance. He specifically argues that he believes
that NGOs and businesses “function as intervening variables, not as underlying causes”
and that the accurate causal story on regulatory outcomes is one in which “corporations
and transnational activist networks do not appear.”

On this point, Drezner’s view is flawed. The business community is an important
domestic constituency. When it cares about an issue, its preferences matter. Indeed, in a
review of international regulatory schemes, Kenneth Abbott and Duncan Snidal find very
few instances in which businesses’ preferences were not significant factors. Though
they are often but not always outgunned by business interests, activist organizations such
as consumer groups and environmental advocacy NGOs matter as well. An explanation
of trade and regulation requires taking into account the preferences and political
strategies of those groups who are directly affected by that regulation. Ignoring societal
actors is unhelpful as it leads to a serious under-theorization of state’s preferences.

Conclusion
To summarize, businesses seek to reduce regulatory trade barriers when those
barriers raise production costs or inhibit market access. They may however choose to end
that pursuit if those regulations are cheap to comply with or pursuing their reduction
carries major reputational risk. Activist groups defend regulatory barriers when they
perceive those regulations to be the sole effective means to address a societal problem.

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140 Drezner. All Politics is Global. p. xii-xiii.
Institutions and the Shadow of the State” in The Politics of Global Regulation. Mattli, Walter and Ngaire
142 Martha Derthick and Paul Quirk provide strong evidence against the notion that corporations are all
powerful in their examination of how businesses were unsuccessful in defending regulations that limited
competition to their benefit. Derthick, Martha, and Paul Quirk. 1985. The Politics of Deregulation. The
they are concerned about. They may accept a reduction in regulatory barriers if those barriers have low salience or their opposition is bought out through private standards, corporate social responsibility, or some other arrangement in which businesses are not directly regulated by government. Government officials choose whether to side with businesses or activist groups based on their relative prioritization of trade and regulatory independence, their staffing, and whom they identify as their core constituency. Concerns about competitiveness stack these factors in favor of reducing regulatory trade barriers. Concerns about needless death stack them in favor of maintaining or increasing those barriers.
Chapter 4- Automobiles and Regulatory Regionalism in North America and Europe

Introduction

By almost any measure, the automotive sector is massive in scale and significance. It accounts for three trillion dollars of global economic output per year.\(^1\) Auto manufacturing employs close to a million people in the United States without even counting dealers and mechanics.\(^2\) A car is amongst the most important purchases many people make. Given the international nature of automobile production and the sheer volume of the trade in automobiles (1.3 trillion dollars in 2013), automobiles are inextricably bound up in trade politics.\(^3\) Automobiles are also highly regulated. From the horn’s decibel level to the exhaust’s content, essentially everything about a car is regulated in one way or another. The contrasting ways in which cars are regulated in different countries has significant implications for the trade in automobiles.

In the early 1980s, the European auto market sat atop a checkerboard of conflicting regulations that significantly impeded the intra-continental trade in vehicles. At that time, regulatory barriers also hampered the trade in cars between the three North American states. By 1996, regulatory trade barriers within both regions had been almost totally reduced. In Europe, environmental barriers were maintain in the first period from 1983 to 1988 but were then reduced in 1989-1990. In North America, domestic content regulatory barriers were reduced in both Mexico and Canada. Domestic content barriers were blocked from existing at all in the United States. They were then completely eliminated in NAFTA. In contrast to this intra-regional attenuation, consumer safety-related inter-regional regulatory barriers between North America and Europe have not

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been reduced. Herein lies the research enigma that motivates this chapter: why were regulatory trade barriers in the automotive sector reduced within Europe and North American but not reduced between those regions?

### Table 4.1- Regulatory Trade Barriers Outcomes In Automobiles

#### European Case
- Environmental 1983-1988---------> Maintained
- Environmental 1989-1990---------> Reduced via Buy-Out

#### North American Case
- Domestic Content Mexico--------> Reduced
- Domestic Content Canada--------> Reduced
- Domestic Content U.S.---------> Prevented
- Domestic Content NAFTA--------> Reduced
- Environmental Mexico/U.S.------> Prevented via Buy-Out
- Consumer Safety Mexico---------> Maintained
- Mexican Trucking ----------------> Maintained, then Reduced

#### Inter-Regional Case
- Consumer Safety 1996-1999-------> Maintained
- Consumer Safety Post-1999--------> Maintained

#### Environmental Regulatory Trade Barriers in Europe, 1983-1988

##### Background
During the 1970s, European businesses became increasingly regional and thus more frustrated by intra-European trade barriers. This was especially true in automobiles. After Ford began profitably selling its vehicles on a continental basis, other automakers followed suit; this served to create a continental vehicle market and made intra-regional regulatory barriers more important.

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While this development was occurring, the European Community (EC) began to regulate automobiles with an eye toward liberalizing the continental market in vehicles. Beginning in 1970 and then more robustly in 1972, the European Community began regulating air pollution from automobiles. EC 70/156 established a type-approval process for automotives and emphasized the imperative of promoting a common market. EC 70/220 established the first limits on carbon monoxide and hydrocarbons (environmentally-damaging emissions). EC 72/306 established the first emissions limits on diesel engines. These three directives set the basis for the EC’s automotive environmental regulations to come; future iterations of EC automotive regulations were amendments to these three foundational directives.

Organizing production continentally would aid automakers in achieving scale economies, which were becoming more important and more difficult to achieve. The minimum volume for a firm to survive in the auto industry leapt from 800,000 in the 1970s to two million in the early 1980s. Continental production would help this by

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8 In a type-approval regulatory system, automakers submits plans for a given auto design and the plans for that type of vehicle are either rejected or approved. The EU uses this kind of system. The other major auto regulation system is used primarily by the United States and Canada in which automakers self-certify that they have met government standards and then have vehicles recalled if they are found to be non-compliant.
9 Hydrocarbons are environmentally toxic compounds of hydrogen and carbon.
10 Diesel-engines are compression-ignition rather than positive-ignition engines and therefore were not covered under EC 70/220. EC 72/306 thus expanded the framework directive to also cover commercial trucks as well as the portion of automobiles that used diesel engines.
allowing for further specialization. Instead of having one production line for vehicle X in three markets, the automaker could have one of those lines produce vehicle X for all three markets and the other two lines produce vehicles Y and Z. Greater scale would also help reduce costs through standardizing output while increasing the variety of goods produced by facilitating components exchange. Greater scale could also assist modularization, which involved demanding that suppliers make more complex parts— for example, an entire seat rather than just the fabric— and deliver that part to the automakers within minutes of when it was needed, to curb inventory costs. For modularization and economies of scale to function, automakers needed to be able to organize production on a continental basis.

The movement toward EC trade liberalization that was gaining momentum in the late 1970s and early 1980s held out the promise of helping them achieve exactly that, which is why automakers formed the vanguard in promoting regional trade liberalization. In fact, the European Business Roundtable, the peak organization for the largest European businesses, originated from discussions in 1982 between Pehr Gyllenhammer, the chief executive of Volvo, and Etienne Davignon, the vice president of the European Commission. As trade liberalization was gaining momentum in the early 1980s, emissions regulations were becoming more politically salient.

Environmentalists and Emissions Regulations in Western Europe

At this time, environmentalists were gaining greater political strength in several European states. In March 1983, the West German Green Party for the first time

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surpassed the five percent threshold in federal elections needed for representation in the
Bundestag.\textsuperscript{15} The next year, environmental protection gained even greater salience as it
became clear that between one-third and half of the country’s forests were being badly
damaged by pollution and acid rain.\textsuperscript{16} One potential response, imposing speed limits on
the autobahn, was sure to be highly controversial and politically costly for the West
German government.\textsuperscript{17}

Separately, environmentalists pushed for emissions standards so high that they
could only be achieved by requiring all cars be equipped with catalytic converters, which
would have created a major regulatory barrier to automotive trade.\textsuperscript{18} At first, German
automakers did not join environmentalists in this effort but neither did they oppose them
as they did on speed limits.\textsuperscript{19} This political landscape incentivized the West German
government to unilaterally announce that it would make catalytic converters mandatory.\textsuperscript{20}
Only when West German automakers became concerned that other states’ retaliation
could hamper their exports did they push against environmentalists’ attempts to raise
these regulatory barriers.\textsuperscript{21} This pressure from German automakers convinced the West
German government to drop its unilateral approach.\textsuperscript{22}

\textsuperscript{15} Financial Times. “Germany Votes For Stability.” March 8, 1983. The Green Party was also making
October 31, 1984.
\textsuperscript{17} Drozdiak, William. “Push for Speed Limits Divides West Germans.” The Washington Post. October 19,
1984.
\textsuperscript{18} Cornwell, Rupert. “Bonn Faces Tough Fight Over Car Pollution Plan.” Financial Times. September 21,
1984.
\textsuperscript{19} Ibid.
\textsuperscript{20} Tomforde, Anna. “Bonn Flouts EEC With Early Date For Exhaust Control.” The Guardian. September
19, 1984.
\textsuperscript{22} Ibid. p. 70.
Like West Germany, Denmark had developed a strong environmental movement that wanted to raise emissions standards. Unlike West Germany, Denmark had no domestic automakers and so the Danish government never faced countervailing pressure against environmentalists’ pushing for increased regulatory barriers. The Netherlands too had a strong environmentalist movement and no indigenous manufacturers, making it another state willing to push strict environmental regulations even when Europe’s automakers opposed them.

There were no domestic automakers in Denmark or the Netherlands that would have benefitted from these regulatory trade barriers. Clearly, they were implemented not to protect some non-existent firm but to promote environmental goals. This undermines the notion that regulatory barriers are simply disguised means of protectionism.

These activists’ engagement in the politics surrounding trade and emissions regulations underscores the limitations of the cleavage-based explanations of trade politics. The cleavage here was not between a sector of society that profited from trade and a sector that lost. It was between a sector (automakers) that had an economic stake and a sector (environmentalists) that wanted to prioritize non-economic public policy goals. This is one example of how, by focusing exclusively on economic considerations, these cleavage-based explanations ignore the extent to which trade increasingly animates actors with normative concerns once regulations get added to the equation.

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25 Ibid. p. 90.
Emissions Standards and Competitiveness

The specter of mandatory catalytic converters constituted a nightmare for Fiat, Peugeot, and Renault. Catalytic converters work by rearranging the oxygen and hydrocarbon molecules in car exhaust into the less damaging chemicals carbon dioxide and water. At the time, they were a relatively new technology and somewhat costly, adding about 500 dollars to the price of a car. For a large luxury car such as a Mercedes Benz, that additional cost was relatively small as a percentage of the total cost of the car and could be absorbed more easily by those consumers affluent enough to own a Mercedes. But for the small cars that Fiat, Peugeot, and Renault specialized in, these converter’s additional cost was much portion of overall costs and could seriously crimp sales if they pushed those vehicles out of reach for less well-off consumers.

Moreover, vehicles equipped with catalytic converters required unleaded gasoline because lead makes catalytic converters malfunction. The problem for French and Italian automakers was that, unlike in Germany, Denmark and the Netherlands, unleaded gasoline was extremely difficult to find in their home countries. For Fiat, Peugeot, and Renault, mandatory catalytic converters thus meant producing vehicles that many of their customers could not afford and that no one would be able to drive as soon as the car needed its first gasoline refill.

This is why they could not accept emissions standards so high that they required catalytic converters as the basis for continent-wide regulations. They also could not countenance other governments’ unilaterally requiring catalytic converters, as that would

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28 Ibid.
prevent them from exporting their products to those countries. In other words, these automakers advocated lower standards precisely because higher standards constituted a significant regulatory barrier for them. At the same time, and again in contrast to West Germany, Denmark, and the Netherlands, the environmental movement in Italy and France was still quite weak. Government officials in these two states thus faced the exact opposite incentives in their domestic arena as their counterparts in West Germany, Denmark, and the Netherlands. Furthermore, by undermining domestic automakers, these regulatory barriers also threatened to undermine the overall national economic competitiveness of Italy and France as well. Given this, they sided with their domestic automakers in opposing what they called regulatory “blackmail.”

The trajectory of events here also undermines state-centric explanations of international trade politics. European governments’ stances were not independently designed. They only came about as a result of societal actors’ lobbying. The positions of Denmark and the Netherlands were a product of environmentalists’ strength there. The positions of France and Italy were a product of automakers’ strength there. One cannot explain these states’ position without first examining societal actors within those states.

With regards to EC officials, while they were not hostile to the call for environmental protection, at this point they saw creating a common market as their primary responsibility. The link between the national economies of Europe had grown

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30 Ibid. p. 67.
32 Ibid.
tighter over the course of the 1970s. Europe’s economic recovery in the mid-1980s was much weaker than the United States’ or Japan’s. Trade liberalization was seen as a way of boosting European companies’, and by extension European states’, competitiveness and thus ending Eurosclerosis.

High emission regulations that created intra-EC trade barriers were thus seen by EC officials not as an innocuous regulatory difference between states but as a throttle on European competitiveness and on EC officials’ ability to deliver prosperity through the advancement of the internal market. Thus, they sided with France and Italy. The 1985 agreement raised emission standards but excluded small cars to environmentalists’ chagrin, thus necessitating a future negotiation over those cars’ emissions. This agreement was vetoed by the Danish government which was still beholden to its environmentalists who wanted higher standards come what may in terms of trade.

Danish officials continued to face pressure from only one direction domestically and so continued to block the compromise. The Green Party made significant gains in local elections in November 1985, which made Danish officials even more convinced that caving on emission standards was out of the question. Denmark’s environment minister made it clear where the battle lines were drawn, saying, “Denmark will not

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36 Garrett and Weingast. 1993. “Constructing the European Community’s Internal Market.” p. 188.

In the meantime, the EC had passed the Single European Act in 1986, which set the end of 1992 as the goal of fully establishing a common market, codified environmental policy goals at the EC level for the first time, and changed the requirements for EC-wide regulatory rulings from being unanimous to a qualified majority.\footnote{On the negotiation of the Single European Act, see Moravcsik, Andrew. 1998. \textit{The Choice for Europe: Social Purpose and State Power From Messina to Maastricht}. Cornell University Press: Ithaca. p. 314-378.} In July 1987, this procedure was used for the first time by other EC states to pass the regulations agreed to in 1985 over the objections of Denmark.\footnote{Dawkins, William, and John Griffiths. “EC Agrees Car Exhaust Plan.” \textit{Financial Times}. July 7, 1987.} After the accord was reached, Denmark made it known that it planned to enact its own higher emission standards anyway, which was sure to invite a legal challenge from other EC states.\footnote{Dawkins, William. “EC Agrees Measures to Cut Car Pollution.” \textit{Financial Times}. December 4, 1987.} This had to be addressed, as did emissions regulations for the smaller vehicles excluded from the 1985 compromise. The start of small car emissions negotiations in January 1988 was not promising as France blocked any real discussion of toughening regulations on small cars.\footnote{The Globe and Mail. “Exhaust Plan Delayed.” January 22, 1988.} Jacques Calvet, the hardline chairman of Peugeot, attacked increased emission standards as a demagogic barrier to intra-EC trade.\footnote{Betts, Paul. “Greens Make Peugeot Car Chief See Red.” \textit{Financial Times}. July 14, 1988.}
subsequently abandoned a compromise deal of small car emissions that had been
tentatively worked out in June 1988.\textsuperscript{48}

\textbf{Emission Standards Harmonized, 1989-1990}

By 1989, it became apparent that two developments had altered the configuration of interests around emissions regulations. First, environmentalism had strengthened across Europe. Picking environmental fights with Brussels continued to be a political winner domestically in Denmark.\textsuperscript{49} Sweden’s election in 1988 demonstrated the continued growth of environmentalists there too.\textsuperscript{50} The Dutch government, which in 1988 was keener on environmental issues than at any time since 1982, defied the EC by going ahead with a tax scheme that incentivized the purchase of cars that emitted such low emissions that they required catalytic converters.\textsuperscript{51} Environmentalists also gained strength in countries where they had previously been relatively weak. In Italy, the salience of green issues had grown substantially.\textsuperscript{52} In the UK, environmental concerns became a much higher political priority.\textsuperscript{53} The strengthening of environmentalists made it politically dangerous for EC officials to be seen as insufficiently green. It also made it clear that reducing regulatory barriers at a common low level of emissions standards was infeasible.

Second, advances in technology led automakers to relax their resistance to higher emission standards. In 1984, the EC had mandated that by 1989 all EC states had to

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ensure the widespread availability of unleaded gasoline.\textsuperscript{54} By 1988, it was clear that states would meet their obligation to do that.\textsuperscript{55} It also became clear that other approaches to emissions could not match catalytic converters’ effectiveness.\textsuperscript{56} By 1988, as opposed to 1985, consumers were highly in favor of catalytic converters.\textsuperscript{57} The fear subsided that cars with catalytic converters would become useless once they needed a refill. Automakers and gasoline providers had achieved technological innovations that greatly reduced the performance penalties that had accompanied the use of catalytic converters a few years earlier.\textsuperscript{58} Catalytic converters also became cheaper to produce and install because automakers figured out how to replace the platinum in them with palladium which only cost one-tenth as much.\textsuperscript{59} Automakers specializing in small cars no longer perceived mandatory catalytic converters to be a revenue death knell.\textsuperscript{60} One-time opponents of catalytic converters such as Fiat and Renault had begun selling cars with converters in the Netherlands.\textsuperscript{61}

EC officials identified with environmentalists and automakers. They were thus eager to promote a buy-out arrangement between them. The European Parliament continually pushed for greater environmental protection.\textsuperscript{62} The EC’s Environment Commissioner Carlo Ripa Di Meana openly advocated for the adoption of higher

\textsuperscript{60} Vogel. 1995. \textit{Trading Up}. p. 74.
standards and was soon joined by Karel Van Miert, the EC Transport Commissioner.\footnote{Dickson, Tim. “Brussels Calls For Stricter Car Pollution Standards.” Financial Times. March 9, 1989.} It was not just these two. As one EC official noted, this Commission as a whole was “definitely a lot greener than the last.”\footnote{Dickson, Tim. “Green Issues On Centre Stage.” Financial Times. April 21, 1989.}

The common market was also of course a central mission of the EC and so preoccupied its officials at least as much as environmental protection. By this point, those officials badly wanted one standard, any standard as long as it was a common one. For them the 1992 deadline grew ever more looming with each passing month.\footnote{Vogel. 1995. Trading Up. p. 73.} It was clear that environmentalists and the states that sided with them were not backing down. With automakers wanting one standard and environmentalists wanting a high standard and given the advances made in catalytic converters, high uniform standards became a way to liberalize rather block trade.

In April 1989, the European Commission proposed new higher emission regulations that effectively mandated catalytic converters.\footnote{William Dawkins. “Strict EC Car Exhaust Limits Proposed.” Financial Times. April 6, 1989.} The EC Council voted to approve the new standards in the summer of 1989.\footnote{Dickson, Tim. “UK Reverses Position On Car Emission Standards.” Financial Times. May 24, 1989.} This reduction in emissions-based regulatory barriers opened the way for similar reductions in the other regulatory barriers. Automakers hoped for region-wide standards on these issues for the same reasons that they wanted uniform emissions standards. There is no evidence that activists objected to reducing these regulatory barriers.

EC officials were committed to completing the single market. Martin Bangemann, the EC Commissioner for the Internal Market, had previously been the leader of the Free
Democratic Party in Germany and the West German Economic Minister. In other words, the negotiation of technical standards was guided by a politician who had led a highly pro-trade party in a highly pro-trade country. It therefore is not surprising that he provided the political leadership to reduce these other intra-EC regulatory trade barriers. Thus, in June 1989, EC officials announced their intention to put forth a mandatory technical standards regime for the entire EC; this regime was agreed to in March 1990.68 This agreement, as part of the construction of the single market, effectively completed the regionalization of European auto production.

**Domestic Content Regulatory Trade Barriers in North America**

*Background*

Although there were differences in safety and environmental regulations among Canada, the United States, and Mexico in the 1980s, they did not generally constitute significant regulatory barriers. Automakers had to meet U.S. standards for vehicles destined for the United States but for vehicles produced for the Canadian and Mexican markets, they could meet either standard that state’s standard or the American standard at their discretion. The major regulatory barriers to continent-wide auto production were domestic content regulations.69

These regulations stipulated that a certain percentage of an automaker’s sales had to come from domestically produced parts and domestic labor. A domestic content requirement does not help firms because it limits their flexibility. Automakers prefer domestic content rules be eradicated because even when they seek protectionism, there

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69 On domestic content rules being the most significant barrier to the international trade in automobiles at this time, see Rob van Tulder and Denis Audet. 2004. “The Faster Lane of Regionalism.” in *Cars, Carriers of Regionalism?* Carrillo, Jorge, Yannick Lung, and Rob van Tulder (eds.) Palgrave MacMillan: New York. p. 34.
are a number of other non-regulatory means that achieve the same protectionist goal without limiting automakers’ flexibility. A domestic content requirement does help workers though by maintain domestic auto employment. Mexico and Canada had domestic content regulations but reduced them over the course of the 1980s and early 1990s. The United States never had them; labor unions wanted them but were rebuffed in that attempt.

In 1981, the North American auto trade was stymied by these domestic content regulations and thus auto production was organized on a national basis. By the mid-1990s, domestic content regulations between the United States, Canada, and Mexico had been effectively eradicated and auto production was organized on a regional basis.

The origins of this shift began in the late 1970s when the Big Three faced growing labor disharmony, ballooning labor costs, new environmental and safety regulations, a string of public relations fiascos exemplified by exploding Ford Pintos, energy crises, and stagflation. None of these developments were popular in Detroit but what made them an existential crisis for the Big Three was that they intensified the competition American automakers faced from Japanese automakers. At the time, Japanese cars not only used less gasoline, they were also produced more efficiently (which meant they could be priced lower than American cars) and had fewer defects (which meant they lasted longer and needed fewer repairs). This was a dark moment for the Big Three. Chrysler almost collapsed while Ford and GM posted record losses.

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In response to this competition, American automakers needed to cut production costs and so began exploring the possibility of relocating labor-intensive production steps to Mexico where labor costs were 31 percent of those in the United States. In addition, automakers were having difficulty getting unions to accept new production methods such as modularization; moving abroad could help them get around that problem. They were also hoping to benefit from greater economies of scale for the same reasons as in Europe. Additionally, by pushing up the value of the dollar, Paul Volcker’s tight monetary policy made producing a good abroad and importing it more profitable. The problem for the Big Three in this endeavor was the set of regulations on domestic content.

**U.S. Domestic Content Rules, 1982-1984**

The confluence of factors hurting U.S. automakers in the late 1970s and early 1980s hit auto industry employees particularly hard. Employment in auto assembly plummeted from 760,000 in 1978 to 490,000 in 1981. A Buy American campaign sprung up among the UAW’s rank-and-file, but did little to stem the rising tide of Japanese imports, and so the UAW began pushing for Congressional action to mandate a de facto Buy American regulation in auto production: domestic content rules. These proposed regulations mandated that all models with sales over 100,000 vehicles had to have at least 25 percent of their content made in the United States and employed a sliding scale that called for all models with sales over 500,000 to have 90 percent domestic

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75 Ibid. p. 162-171. Cite here the increase in imports from Japan.
In 1981-1982, domestic content legislation in the auto industry was the top priority of the UAW and the AFL-CIO but was opposed by automakers.

Ford and GM were just as much a target of these UAW-proposed regulations as Japanese automakers; UAW President Doug Fraser argued that “content legislation not only will address the savaging of the American economy by the Japanese….it will also confront the exporting of American jobs and capital by General Motors and Ford.”

Even a cursory look at management behavior makes it easy to see why autoworkers resented their bosses. In 1982, the same day that GM convinced workers to accept wage freezes and fewer holidays, the executives were rewarded with bigger bonuses. Into the late 1980s, GM persisted with the antagonizing practice of having segregated bathrooms for hourly workers versus management. When Ford’s bosses bought an enormous Persian rug for their executive suite that was too large to install because it could not fit in any of the building’s elevators and then, rather than return the rug or not purchase such an extravagance in the first place, they had windows temporarily removed so that the rug could be installed via helicopter. Little wonder that unions saw management as just as much their enemy as foreign competition.

Though the UAW wanted domestic content requirements, American automakers decidedly did not. GM and Ford testified against the bill when it was before the House of

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80 Ibid. p. 9.
81 Ibid. p. 94.
Representatives. Thomas Atkinson, a GM executive, succinctly summarized the automaker’s position on them saying “we wish these laws had never been invented, and would not like to see them increased or created in countries where they don't exist now.” Opposition to the domestic content bill was placed on a rhetorical foundation that it would make American-made cars less competitive. This provides evidence for a point that I made in Chapter 3, that when business want to seek protection, they are unlikely to ask for regulatory protectionism because those regulations limit those firms’ flexibility in ways that non-regulatory trade barriers do not. This is what automakers did here. The protectionism they sought was in the form of a quota-based voluntary export restraint agreement with the Japanese, not regulations on domestic content.

In the meantime, Paul Volcker’s tight monetary policy was driving up interest rates which made the value of the dollar increase and so made American exports that much more expensive; this only compounded concerns about U.S. competitiveness. As evidence of how serious U.S. officials were taking these competitiveness concerns, both the Senate and the White House set up special commissions on economic and industrial competitiveness.

To the delight of the Big Three and the infuriation of the UAW, the Reagan Administration was resolutely opposed to domestic content regulations. John Danforth (R-Missouri), the chairman of the lead Senate committee on trade, attested that many

members of the Senate viewed the domestic content legislation as “perfectly ridiculous” while U.S. Trade Representative William Brock called it “the worst piece of economic legislation since the 1930s.” Mr. Brock was no fan of government intervention in markets in general; earlier in his Congressional career he had voted against the minimum wage, Medicare, and civil rights legislation. He was a dyed-in-the-wool free trader and was so stoutly hostile to labor unions, that in Reagan’s second term, he was appointed Secretary of Labor. With no support from the USTR’s office or anywhere else in the Executive Branch, the domestic content bill died in the Republican-controlled Senate. In sum, labor unions attempted to create a significant new regulatory barrier to the trade in automobiles but were defeated by the combined efforts of the automakers and government officials who opposed the erection of those barriers.

**Mexican Domestic Content Rules, 1982-1989**

The Latin American debt crisis, which started in Mexico in August 1982, augmented automakers’ opposition to Mexico’s domestic content rules. The dramatic decrease in demand for automobiles meant that the attraction of building in Mexico just for the domestic market had all but evaporated. To be profitable, vehicles produced there had to be competitive on the international market, and that could not happen without changes in Mexican policy. Ford was particularly aggressive in lobbying the Mexican government for changes in the domestic content and ownership regulations; one group of scholars even argues that the policy changes adopted by Mexico were a direct result of

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90 Ibid. p. 279-303.
Ford’s lobbying.\(^{92}\) At the very least, it would be fair to say that Ford was pushing hard for reduced regulatory trade barriers.

At this point, the American-based automakers were joined by Mexican businesses from other sectors organized under the Business Coordinating Council (CCE), a newly constructed super-lobby that had united CONCANACO and CONCAMIN, the two oldest and most prestigious business confederations in Mexico. They collectively pushed the Mexican government to take a less active role in the economy and to adopt policies that would help exporters.\(^{93}\)

The debt crisis softened Mexican officials’ support for the domestic content regulations. They no longer had the same leverage over automakers but wanted to maintain manufacturing jobs and to promote exports to improve the country’s trade balance. To emerge from this debt crisis, their manufactured goods had to be competitive in export markets. One positive side effect of the crash was that it devalued the peso which made labor even cheaper and thus made exports more attractive, though again the domestic content regulations stood in the way.

Given these developments, in 1983 the Mexican government took its first steps away from ISI and toward promoting exports.\(^{94}\) The Border Industrialization Program, also known as the maquiladora program, was reformed and expanded, and the Trade and Industry Ministry which had long been protectionist was reorganized and given a staff

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dedicated to trade liberalization. The expansion of the maquiladora program allowed firms to import goods tariff-free if they were used in to make products that were then exported, and it allowed automakers to have less domestic content on cars produced for export. The number of auto maquiladoras consequently increased from 51 in 1984 to 129 in 1988. A Ford executive cited the decree as “a major reason” for the company’s decision to construct a new half-billion dollar facility in Hermosillo that year.

Given that domestic demand had collapsed, for a Mexican business to survive, much less thrive, it had to find markets abroad for its products. During this period, the major businesses organizations grew more assertive toward the government in general and more eager to push the Mexican government to pursue further liberalization in particular. This was a major shift for business; less than a decade earlier, the composition of the business lobby was much more protectionist and had successfully blocked Mexico’s accession to the GATT. There was also a shift in the relative power of businesses in different regions of Mexico. Businesses in northern Mexico, given their proximity to the United States, had traditionally been more liberal in their trade preferences than businesses in central Mexico that owed their ascendancy to state-led ISI policies. The collapse of ISI weakened the latter group to the benefit of the former.

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Additionally, starting around 1986, trade liberalization had created its own vested interest among the business community that wanted still more liberalization.\textsuperscript{102} Compared to earlier periods, business leaders in the mid-1980s had both a greater commitment to free trade and greater access to like-minded government officials.\textsuperscript{103} Labor unions remained either repressed or co-opted and controlled by the government through the Confederation of Mexican Workers (CTM). They were in no position to offer meaningful resistance to reducing domestic content requirements, especially in the auto industry.

The Mexican government was now headed by President de la Madrid, a man who had never been elected to office before but who had nearly unanimous backing from big business.\textsuperscript{104} De la Madrid stacked his cabinet with free traders.\textsuperscript{105} That coincided with the rise of what came to be known as the ‘technoburocrata,’ the cadre of younger, more pro-market officials within the government.\textsuperscript{106} In 1984, the Mexican government sold its shares in Renault and VAM, meaning it no longer had a vested interest in protecting the two least competitive producers in Mexico.\textsuperscript{107} This made government officials even more willing to listen to calls for reductions in regulatory barriers. Given this configuration of interests, Mexico moved rapidly toward trade liberalization, deciding to join the GATT in 1985 and signing the Tokyo Round non-tariff barrier (NTB) codes in 1987.\textsuperscript{108}

\textsuperscript{103}Thacker. “Private Sector Trade Politics in Mexico.” p. 179.
\textsuperscript{104}Story, Dale. 1986. \textit{Industry, the State, and Public Policy in Mexico}. University of Texas Press: Austin.
These moves accelerated the growth of export-oriented auto manufacturing in Mexico. For the period from 1983-1987 compared to 1978-1982, even though production for the domestic market fell 36 percent, auto production for export markets increased 184 percent. Exports from Mexico at first were mostly parts, but then automakers realized that they could actually produce sophisticated components in Mexico with the same level of quality as in the United States. Trade liberalization was key to this because it meant that steel of higher quality than that produced in Mexico could be imported; this was critical in making feasible some of the most quality-dependent and capital-intensive processes. After this discovery, the Big Three began lobbying the Mexican government to adopt a new Auto Decree that would reward the production of more sophisticated components. The 1989 Auto Decree completed Mexico’s abandonment of ISI and reduced local content requirements. While Mexico’s auto industry had been transforming, the politics of regulatory barriers had been unfolding in Canada as well.

**Canadian Domestic Content Rules, 1982-1988**

The 60 percent domestic content regulations impeding trade in automobiles between the U.S. and Canada in the early 1980s were a result of the 1965 Auto Pact between them. Like their Mexican counterparts but for different reasons, Canadian businesses in the early 1980s were far more eager to push for trade liberalization than

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111 Ibid. p. 205.

112 Ibid. p. 173-174. By the late 1980s, the Big Three had moved from advanced components to whole vehicles for export. Ibid. p. 178.


they had been just a few years prior. In the Tokyo Round that ended in 1979, in addition to the round’s NTB reforms, Canada was forced to accept a tariff reduction on industrial goods that most other countries had taken in the Kennedy Round; this led to a surge of imports thereafter.\textsuperscript{115}

Faced with this import penetration, businesses needed greater export market access and so began to more vigorously lobby their government for greater trade liberalization, especially with the U.S.\textsuperscript{116} The global recession that took place in 1981-1982 hit Canada especially hard and thus augmented this change in attitude.\textsuperscript{117} Moreover, the Canadian dollar, which was worth one dollar in 1976, traded at around 80 cents in 1982; this made Canadian exports more competitive in the U.S. and Canadian importers less vulnerable to competition from American exports.\textsuperscript{118}

Canadian businesses also preferred to pursue an explicitly liberal, business friendly trade regime rather than bring labor into the fold to form some kind of societal grand alliance.\textsuperscript{119} The Canadian Manufacturers Association (CMA), the Business Council on National Issues (BCNI), and the Canadian Chamber of Commerce began calling for a free trade agreement with the United States.\textsuperscript{120} It also was not just that their position had changed; their political power had also grown substantially through more effective

political organization.\footnote{Langille. 1987. “The Business Council on National Issues.”} These business leaders were slightly ahead of their government counterparts in their turn toward trade liberalism but would not have to wait long to be joined by them.

What makes the turn in Canadian trade policy in the 1980s so interesting is that it flew in the face of almost every bit of Canadian trade policy to that point. The Canadian government had historically adopted a consistently protectionist line going as far back as the late nineteenth century. Indeed, high tariff barriers were essential in early Canadian political development. The 1879 National Policy was the Canadian government’s attempt to economically unify Canada by promoting domestic East-West trade rather than international North-South trade with the United States.\footnote{On the 1879 National Policy, see Williams. 1994. \textit{Not For Export}. p. 26-33. Smiley, Donald. 1975. “Canada and the Quest for a National Policy.” \textit{Canadian Journal of Political Science}. 8:1. p. 42-44.} Prior to this, it was much easier for a businessman in Winnipeg to conduct business with Minneapolis than with Ottawa, and so Canadians often had closer connections with Americans than with each other. High tariffs changed that.

When Wilfrid Laurier, a Prime Minister who had held power since 1896, pursued greater trade with the United States in 1911, he was quickly chased from office; “the lesson that emerged was clear and lasting, free trade was a political nonstarter in Canada.”\footnote{Lusztig. 2004. \textit{The Limits of Protectionism}. p. 108.} Even in the 1960s and 1970s, Canadian support for GATT trade rounds was more about multilateralism than a deep-seated love of free trade.\footnote{For a thorough treatment of Canadian trade policy during the 1960s and 1970s, see Hart, Michael. 2002. \textit{A Trading Nation: Canadian Trade Policy From Colonialism to Globalization}. UBC Press: Vancouver. p. 233-338.} With regards to the U.S. in particular, the Liberal government under Pierre Trudeau advocated a Third Option policy that took an economically nationalist line even to the point of antagonizing
the behemoth to the south. The clearest example of this was the 1979 National Energy Program which, in an attempt to subsidize energy in Ontario and Quebec, curtailed energy exports to the U.S. at the exact moment it was suffering from an energy crisis.\textsuperscript{125}

As late as 1983, Brian Mulroney, the leader of the Conservative Party who would later champion the Canada-U.S. Free Trade Agreement said the following: “Don’t talk to me about free trade, that issue was decided in 1911. Free trade is a danger to Canadian sovereignty, and you’ll hear none of it from me now during this leadership campaign or at any other time in the future.”\textsuperscript{126}

But the utility of greater trade with the United States was starting to percolate through the Canadian bureaucracy and many Canadian government officials were beginning to seriously question the protectionist policy orientation. Ed Lumley and then later Gerald Regan, two trade ministers sympathetic to both trade reforms and business interests, conducted a stem-to-stern review of Canadian trade policy; their final analysis, which was released in August 1983, advocated for greater trade and also somewhat unexpectedly signaled that bilateral negotiations with the United States might be an option in addition to Canada’s traditional commitment to the GATT.\textsuperscript{127} This report and the media attention it received sparked the most open trade discussion Canada had seen in a very long time.\textsuperscript{128} In many ways, it laid the groundwork for what would become the most consequential report in Canadian trade policy, probably ever.

In its encapsulation of the political zeitgeist and intellectual defense for a policy response to a problem fixating the nation, the Macdonald Report was as important for

\begin{thebibliography}{99}
\bibitem{Hart1994a} Hart. 1994. \emph{Decision At Midnight}. p. 17-20.
\bibitem{Hart1994b} Hart. 1994. \emph{Decision At Midnight}. p. 21.
\end{thebibliography}
Canadian trade policy in the 1980s as George Kennan’s writings were for American policy toward the Soviets in the 1940s. In 1982, the Canadian government set up a Royal Commission to diagnose Canada’s economic malaise. Its mandate was the economy in general; there was little expectation that it would focus on trade policy.\textsuperscript{129} The Report harshly criticized Trudeau’s policies that shifted political and economic attention away from the U.S. relationship, arguing that it contributed to Canada’s poor economy.\textsuperscript{130} The Report’s signature recommendation was for Canada to assertively pursue freer trade, especially with the U.S.\textsuperscript{131} When it was released in 1985, it delivered instant intellectual and political cover for a politician who wanted to unlearn the lesson of 1911.

The year before the Macdonald Commission Report, the Conservatives led by Brian Mulroney defeated the Liberals who had been the champions of leftist nationalism. Mulroney’s political base economically was the business community and geographically was the Western provinces, both of which wanted trade liberalization.\textsuperscript{132} His political instincts were to improve relations with the United States and trade, almost by definition, had to be a major part of that.\textsuperscript{133} After months of political planning, consultation with business leaders, and the release of the Macdonald Report, in September 1985 Mulroney announced his intention to seek a free trade agreement with the United States.\textsuperscript{134}

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\item[131] Inwood. 2005. \textit{Continentalizing Canada}. p. 91-96. It is worth noting that the one representative of organized labor on the Macdonald Commission was its strongest opponent. Hart. \textit{Decision At Midnight}. p. 35.
\item[132] The Western provinces hoped to profit from greater energy exports to the United States that would likely accompany trade liberalization.
\item[133] Canadian-American trade is more significant than most Americans realize. Canada is the leading export market for 36 of the 50 states and is in the top three in all but four states. Hussain and Dominguez. 2015. \textit{North American Regionalism and Global Spread}. p. 21.
\end{footnotes}
Once the negotiations for the Canada-U.S. Free Trade Agreement (CUSFTA) got under way, what to do on automobiles became an enduring subject given its importance to both economies. The automakers wanted an end to Canada’s domestic content regulations. The lead negotiators also believed the domestic content regulations were expendable. Organized labor formed the vanguard of the opposition to CUSFTA and argued vociferously against reducing those domestic content requirements in the media.

While businesses had been growing in political strength during this period, Canadian labor, much like their American counterparts, had seen their political power wither due to a decline in unionization, a fragmentation of the union’s overarching organizational structure, and the transition to a more service-oriented economy. Contributing to this weakness, they made a major strategic error during the negotiations. Fearing their participation would give CUSFTA legitimacy, labor refused to participate in the negotiations even after being specifically invited by the government, and so undermined their own role and influence. In the end, the automakers and government officials got what they wanted. CUSFTA, signed in 1987 and in effect by 1989,

eliminated Canada’s domestic content requirements; content could now originate in Canada or the U.S and the level of required content was lowered to fifty percent.\(^{141}\)

In all three of these states, the state-centric approach fails to explain why these states took the positions they did. This is further evidence that to understand states’ policies on regulatory trade barriers, societal actors must be examined.

**NAFTA and Domestic Content**

As I showed earlier, by the late 1980s Mexico was even more predisposed to pursue trade liberalization than it had been earlier that decade. The firms most committed to protectionism had been smashed by the economic crisis.\(^{142}\) The major business associations were in favor of even greater liberalization.\(^{143}\) Also, for the first time, they were joined by small businesses.\(^{144}\)

President Salinas, who took office in 1988, was just as much of a free trade advocate as his predecessor. This was especially the case vis-a-vis the United States after he received tepid interest from European businesses and government officials when he pursued a trade deal with the European Community.\(^{145}\) In addition to his sympathy with the trade policies advocated by business, Salinas also had an electoral incentive to pursue liberalization, as that would help the PRI by appealing to pro-liberalization business


forces that had defected to the National Action Party (PAN). Salinas also had tapped a Kimberly-Clark executive as his special economic adviser, while at the same time arresting a longtime union boss. In 1990, business and government leaders created the Coordinating Body of Foreign Trade Business Associations (COECE) to be the link between them in the formation of Mexican trade policy.

During the NAFTA negotiations, Mexican officials and businessmen worked so closely together that during the talks they would meet before and after each session; business representatives were even allowed to set up shop in the adjacent room with a computerized system that allowed them to monitor what was being said by whom. Government-business collaboration during this period was frequent and close. This relationship was reflected in autos. One Mexican official admitted that the Big Three were just as influential in guiding Mexico’s negotiating positions as they were for the Canadian and American teams. Clearly, business and government officials were cooperating to marginalize labor.

The government-affiliated Confederation of Mexican Workers (CTM) followed the government dictated line and dutifully endorsed NAFTA. Another labor organization, the Revolutionary Confederation of Workers and Peasants (CROC) took an ambivalent approach; they welcomed the agreement because they believed it would

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generate more employment and better wages but also lobbied for special treatment for labor in the deal.\textsuperscript{153} Other labor unions, along with nationalists, were opposed to NAFTA, but were systematically marginalized by the coalition of business and government leaders pushing for trade liberalization.\textsuperscript{154}

With content regulations combined for Canada and the United States, the final step to creating a regional production network for automobiles was folding Mexico’s domestic content into the regional content with the other two states. For automakers, the NAFTA negotiations were a fortuitous window for pushing exactly this kind of regulatory alteration.\textsuperscript{155} Canadian and U.S. negotiators closely consulted with the Big Three throughout the NAFTA negotiations.\textsuperscript{156}

U.S. and Canadian unions advanced proposals that would reinforce domestic content requirements in all three countries, essentially taking the region back to where it was in 1982.\textsuperscript{157} These proposals had no chance of gaining support from automakers or the respective government officials. The Canadian and U.S. autoworkers’ unions knew that were NAFTA to pass, the regionalization of content requirements would be an inevitable result (along with manufacturing relocating to Mexico). Their hope was to stop NAFTA altogether. Given that everyone knew the unions would oppose practically any agreement that came out of the negotiations, their policy preferences carried little weight within those negotiations.\textsuperscript{158} Unions were further hampered, and business further helped, by the

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fact that the Conservatives were in power in Canada and the Republicans were in power in the United States, both of which were ideologically sympathetic to business and ideologically hostile toward labor. With business advocating for reduced regulatory barriers and governments in all three countries aligning with business and marginalizing labor, NAFTA replaced domestic content with regional content. With content regulations organized on a regional level, they no longer impeded intra-regional trade.

Environmental Trade Barriers in North America Pre-Empted

NAFTA also dealt with environmental regulations that had the potential to create trade barriers. If access to the American market were conditioned on meeting certain environmental production standards that were not achievable at Mexican plants, those plants could no longer be used, and the entire regionalization strategy would no longer deliver the cost savings that were its reason for being. This was not beyond the realm of possibility. American environmentalists had recently done exactly that to the tuna industry. Environmentalists were concerned that Mexico’s more lax regulations would badly pollute the border region. They worried that they would attract industries eager to exploit lax environmental standards.

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160 Even when foreign companies could not meet those regional content requirements, they were not excluded from the market in the way that automakers had been under Mexico and Canada’s earlier rules. They were simply subjected to fairly low tariffs of 2.5 percent on cars. Thus, automakers’ defense of regionalized content was simply a way of maintaining those tariffs. In contrast to cars, truck tariffs are 25 percent due to the ‘chicken tax.’ In the 1960s, U.S. frozen chicken began dominating the German market and so to protect its poultry farmers, Bonn levied new tariffs on frozen chicken. At the time, Volkswagen sold the majority of trucks in America and so the U.S. retaliated with a 25 percent tariff on trucks. National Public Radio. “The Chicken Tax.” Planet Money Episode 632. June 12, 2015.


Mexican environmentalists saw NAFTA as a way to strengthen their country’s environmental rules.\footnote{Vogel. 1995. \textit{Trading Up}. p. 236.}


The American and Mexican governments were willing to accept the addition of some environmental language to the agreement so long as that language did not create trade barriers.\footnote{Maggs, John. “US Yields on ‘Green’ Language in Proposed N. America Trade Pact.” \textit{Journal of Commerce}. June 18, 1992.}

Unlike with organized labor, Mexican and U.S. officials in both countries were at least somewhat sympathetic to the policy goals of environmentalists. William Reilly, the EPA administrator, was a major proponent of linking environmental and trade issues and was able to use his personal contacts with U.S. Trade Representative Carla Hills to advance that position even though the EPA is usually not a central player in trade
Hills also appointed the leaders of the National Wildlife Federation, the National Audubon Society, the National Resource Defense Council, and the Nature Conservancy to key trade advisory committees.\textsuperscript{172}

Additionally, over 200 Congressmen signed a letter in support of linking trade and environmental goals.\textsuperscript{173} Mexican officials also had little problem with their domestic NGOs’ desire for greater environmental protection.\textsuperscript{174} Given the imperative to liberalize trade, their sympathy towards environmentalists, and the cheapness of improving environmental protection practices, Mexican officials hoped to satisfy environmentalists first and resort to marginalization attempts only if that did not work.

To achieve this, the U.S. and Mexican governments needed to emphasize Mexico’s commitment to the environment, especially among the maquiladoras, and demonstrate to the American public that Mexico was neither sending pollution across the border nor attempting to attract firms with lax regulations. To accomplish that, they increased inspections and shutdown non-compliant maquiladoras in the lead-up to NAFTA.\textsuperscript{175} They also announced in January 1991 a plan to clean up the border.\textsuperscript{176} These were not long-standing practices. The Mexican government rarely inspected its industrial plants prior to the NAFTA debate but conducted more than 11,000 such inspections in


\textsuperscript{173}Vogel. 1995. \textit{Trading Up}. p. 239.


1992 and 1993, which suggests that satisfying environmentalists was the main impetus for those inspections.\(^{177}\)

The heart of environmentalists’ complaints about Mexican environmental regulations was not that they were poorly written but that they were largely unenforced.\(^{178}\) Given this, the major thrust behind NAFTA’s environmental provisions was not to change their regulations but to ensure enforcement. The primary sanctions mechanism under the NAFTA environmental side agreement thus occurs when a state repeatedly fails to enforce its own environmental regulations.\(^{179}\)

This approach alleviated trade impediments while respecting Canadian and Mexican sensitivities. Even though business leaders and government officials in those two countries had shifted to seek increased trade with the United States, that did not mean that their concerns over America imposing its regulatory will had evaporated. It was not politically possible for Canada and Mexico to accept the United States hegemonically setting regulatory standards for all three states in order to fully integrate the North American market, nor was it at all likely that the United States would cede much real authority to an EU-style supranational institution.\(^{180}\)

Thus, in liberalizing North American regional trade, there was a greater need to minimize the number of regulatory alterations. This is why the environmental side agreement leaves so much room for interpretation. Article I stipulates that the whole point of the side agreement is to avoid new trade barriers while Article III stipulates that

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the three states can set their own regulations as long as they ensure high levels of environmental protection. These side agreements satisfied a significant portion, though not all, of American environmental NGOs and thus they supported NAFTA. By satisfying at least some of the environmental groups, business interests and government officials prophylactically stopped the emergence of new regulatory trade barriers. Environmental regulations were not allowed to interrupt the intra-regional trade in automobiles. Once again, the proposed environmental regulatory trade barriers were sought for normative reasons by activists, not by businesses that wanted trade protection. This is yet more evidence that regulatory trade barriers are generally not disguised protectionism.

**Consumer Safety Regulations in North America**

**The Absence of a Mexican Ralph Nader**

Whereas domestic content regulations were regionalized and regional environmental regulations were formulated to encourage environmental protection along with trade liberalization, consumer safety regulations did not change. The degree of difference between the United States and Mexico was as great in the late 1990s as it was in the early 1980s. Even today, Mexican automobiles are not required to have safety features such as anti-lock brakes and electronic stability controls that Americans take for granted; this is almost certainly one of the main reasons why adjusted for miles traveled, the automobile fatality rate in Mexico is more than three and a half times higher than it is

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183 Though it did not mandate harmonization of the content of regulations in the three countries, it did encourage Mexico to improve its environmental performance. Beginning in 1994, as a result of NAFTA Mexico raised its air quality regulations to bring them closer to the US and began cooperating with US authorities on air quality to a greater extent and significantly increased maquiladoras compliance with environmental regulations. Kirton. 1998. “The Impact of Environmental Regulation.” p. 198, 202.
184 Canadian regulations are generally aligned with U.S. regulations.
in the United States.\textsuperscript{185} This lack of convergence in regulations is interesting because the need for two production runs to satisfy different standards is often used by business as a primary justification for reducing regulatory trade barriers. Why then aren’t the automakers producing their cars for Mexico in the same way they are producing cars for the United States and Canada? Why haven’t regulatory standards converged as they did with environmental standards in Europe? In other words, why was there no California Effect?\textsuperscript{186}

They have not done so because firms were not advocating for reduced regulatory differences nor, as was the case with European emission standards, nor were activists pushing for increased standards, which might have lead to regulations being harmonized but at a higher level. For the U.S.-based automakers, these regulatory differences have been a source of profit rather than a barrier to trade. Even though it requires a different production process, not including these features in vehicles boosts the automakers’ profit since they sell their less safe Mexican versions at the same price point as their American versions.\textsuperscript{187} There was no indigenous Mexican automaker for which the regulatory difference constituted a barrier to the U.S. market. There was no company that was meeting the American standard but being undermined by a purely domestic competitor. In other words, the regulatory difference did not pose a regulatory barrier for the Big Three even though it likely would have posed a barrier for the hypothetical Mexican firm. This demonstrates an important point. A cross-national regulatory difference may be a trade barrier for one firm but not for another even if they are in the same sector.


\textsuperscript{186} See Chapter 3 for an explanation of the California Effect.

\textsuperscript{187} \textit{Santa Fe New Mexican}. “Regulations Matter: Just Look At Mexico.” December 9, 2013.
Furthermore, whereas there were environmental activists pushing for higher regulations in Europe, there was no such group trying to increase Mexican safety standards. There has been no political entrepreneur like Ralph Nader able to make a political issue out of safety standards. Additionally, consumers have actually been resistant to more safety regulations due to a widespread perception that such standards would make cars unaffordable.\(^{188}\) This is in marked contrast to Japanese consumer groups’ approach to safety standards involving beef that will be discussed in Chapter 5. Here again is an area where Gunnar Trumbull’s narratives of access and narratives of protection argument helps explain consumer groups’ political behavior.\(^{189}\) Whereas Japanese consumers were more concerned with being protected from the potential harm of American beef, Mexican consumers were more concerned with ensuring continued access to affordable cars.

The Mexican government has been reticent to fight for higher safety regulations because it does not want to throttle a sector that generates significant employment and revenue.\(^{190}\) Had consumer groups effectively mobilized around the issue, then perhaps government officials may have felt pressured to improve Mexico’s safety regulations, but that has not happened.

**Safety Standards Differences and Mexican Trucking**

The one area where there has been a regulatory movement on safety standards involved an issue on which American activists and government officials were eager to increase regulatory trade barriers and leave it up to Mexican businesses to meet them.


The NAFTA agreement, for the first time, allowed Mexican trucks access to the U.S. As the 1995 opening date drew closer, highway safety advocates and state officials in Texas and California began loudly criticizing the safety of Mexican trucks.\textsuperscript{191} No American businesses would be negatively affected in the immediate term if these trucks were barred from the road and so there was no countervailing force arguing against these critics. Moreover, given the potential for fatal auto accidents to happen even when safety rules are being followed, there was a real chance that these trucks could become a public relations nightmare for the Clinton Administration; as one official put it, “all we need is one big environmental disaster, or one of these trucks plowing into a school bus, and all of a sudden NAFTA is going to look like a pretty disastrous idea.”\textsuperscript{192} Those deaths, had they happened, would have been seen as preventable. President Clinton thus banned Mexican trucks from traveling farther than 26 miles from the border.\textsuperscript{193}

After the dispute dragged on for over a decade, Mexico began leveling retaliatory tariffs on 2.6 billion dollars worth of American products in August 2010, thus hurting their export competitiveness in Mexico; this got those exporters as well as a number of Congressmen to quickly and strongly push in favor of reducing regulatory trade barriers.\textsuperscript{194} Meanwhile, a pilot safety program from 2007 to 2009 had shown that by that time Mexican trucks were just as safe as American trucks.\textsuperscript{195} In 2011, less than a year after the Mexican tariffs were levied, with businesses screaming for a reduction of these regulatory barriers and highway safety advocates largely satisfied with Mexican trucks,

\textsuperscript{192} Ibid.
\textsuperscript{195} Ibid. p. 5-6.
the U.S. and Mexico agreed to allow access for Mexican trucks in exchange for removal of those tariffs.\textsuperscript{196} When the regulatory barriers surrounding Mexican trucks were a matter of preventing needless death those barriers were maintained. When that fear subsided and when those barriers were a matter of competitiveness, they were reduced.

\textit{Consumer Safety Regulatory Barriers in the Transatlantic Auto Trade}

\textit{Background}

By 1996, for all intents and purposes, North America and Europe were each unified regions in terms of regulation and trade. For the previous decade and a half, the trajectory of automobile market organization bent toward greater and greater scale and internationalization. At that point, reducing the regulatory trade barriers that inhibited trade between Europe and North America seemed like the next logical step, and at first automakers adopted a strategy that suggested this was exactly what they believed. Carmakers, and especially Ford, attempted to create so-called ‘world cars’ that could satisfy consumers in multiple markets.\textsuperscript{197} At least initially, this seemed like a real possibility. Non-tariff barriers had been greatly reduced, as had domestic content regulations. American and European environmental standards were now much closer than they had been. The problem for these automakers was the bevy of consumer safety related regulations and the extent to which those regulatory differences inhibited trade.

Safety standards for automobiles first appeared in Europe in the late 19\textsuperscript{th} century. The first set of automotive regulations was Britain’s 1896 mandate that cars have lights at night and a bell or horn.\textsuperscript{198} European safety standard recommendations began to be

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\item \textsuperscript{196} Ibid. p. 7.
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promulgated on a regional level in the late 1950s under the aegis of the United Nations Economic Commission for Europe (UNECE) Working Party 29. In 1970, under EC Council Directive 70/156, the EC established a type-approval under which the automaker would submit plans for a given design and the plans for that type of vehicle would be either rejected or approved. Using the EC 70 type approval system and coordinating work on technical standards under the WP 29 helped European standards alleviate potential regulatory trade barriers that might arise from different safety rules and attract extra-regional adherents as well. This system carried through to the 1990s.

The United States never joined that system. In the lead up to the creation of the NHTSA, Congress believed that European regulations were insufficient and so decided that the United States should develop its own set of standards. The United States moved toward a self-certification system under which automakers certify that they have met government standards and then automobiles are recalled if they are found to be non-compliant with those standards. Interestingly, the NHTSA did initially use a system of rule promulgation similar to type-approval from its inception in 1966 to 1974. This proved too difficult given the United States’ penchant for adversarial legalism. A recall-based approach was much easier to implement and uphold in court when challenged by automakers. In fact, the NHTSA lost half of the cases that were brought to court under

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the rule system but only a single case under the recall system. As with Europe, this approach persisted into the 1990s. These different systems meant that safety standards in the two markets developed independently from one another. By the 1990s and even up to today, there are numerous differences in how automobiles are regulated in the two markets. The two photos below give a small sampling of the dizzying array of regulatory differences.

Figure 4.1: U.S.-EU Regulatory Differences

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204 Ibid. p. 273-274.
Starting in 1995, businesses on both sides of the Atlantic came together to create the Transatlantic Business Dialogue (TABD), an international lobby to push for greater trade liberalization. Automakers were major players in the TABD. Some estimates claimed that harmonizing regulations could save $3,000 on the production cost of a car. Regulatory cooperation in automobiles was a core pursuit of the TABD starting with their first meeting in Seville. In 1996, with the support of the TABD, automakers called for their governments to “eliminate completely the barriers to trade resulting from unwarranted differences in vehicle regulation.” As a start toward this, they proposed harmonizing regulations for five parts (windshield wipers, defrosters, seatbelts, head restraints, and headlamp encasings) that they felt would be particularly easy to align regulations on. To their surprise, the regulators did not agree to make any changes to any of the requirements for any of those parts.

This happened because the other interested parties chose to stridently resist businesses’ attempts to reduce regulatory barriers. American consumer groups, who were accustomed to extensive access during regulation comment periods and public hearings

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207 Alex Trotman, the CEO of Ford, was the co-chair of the TABD in 1996. Lelyveld, Michael. “Panel Aims to Abolish Non-Tariff Barriers; Business Forum on Mission to Harmonize Standards, Spur Trans-Atlantic Talks.” *Journal of Commerce*. May 21, 1997.
in the U.S., were angry that the discussions going on under the auspices of the TABD systematically excluded them. European regulators chafed at automakers appearing to call the shots saying that European, and particularly French officials, “don't accept that businessmen can sit down and set policy.”

Amongst the loudest critics of the TABD’s efforts was Ricardo Martinez, the head of the National Highway Transportation Safety Administration (NHTSA). He argued that the TABD was too willing to sacrifice the public’s safety for the sake of trade saying “I have great concerns that the perspective is not broad enough to respect the real issues of safety and health…the dialogue so far has been very much one way.” Martinez was not a former auto executive. He was a former ER doctor who frequently had to deal with the consequences of car accidents.

This lack of industry background for the head of the NHTSA was not an anomaly for the NHTSA. A previous NHTSA chief was Joan Claybrook, a former chief executive of Public Citizen, the advocacy group founded by Ralph Nader. The NHTSA’s relationship with automakers is in many ways the diametric opposite of the USDA’s relationship with beef producers discussed in Chapter 5. Whereas the USDA sees its mandate as both protecting public safety and promoting meat industry sales, the NHTSA sees it mission as protecting consumers, full stop. The NHTSA was set up in 1966 in order to monitor automakers precisely because those automakers were perceived to have valued profits over passenger safety. The NHTSA’s early decision to staff its agency

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214 Ibid.
215 Ibid.
216 Ibid.
primarily with engineers, rather than economists or industry representatives, created an institutional outlook at the NHTSA that promoted the use of design specifications, i.e. safety regulations, with little if any regard for automakers’ profit margins.\textsuperscript{218} This stance carried into the 1990s and meant that the NHTSA remained skeptical of automakers’ attempts to harmonize regulations to boost trade.

Moreover, changing those regulations would have required them to turn their backs on regulations they believed were just fine. Robert Zoellick, the former head of the World Bank explained it this way, “a lot of the regulatory authorities are sensitive to their prerogatives. They think ‘we are doing it the right way, and why should we change?’\textsuperscript{219} Indeed, when asked about specific regulations such as airbag size, American and European regulators each insist that their standard is superior and saves lives.\textsuperscript{220} American and European regulators both fervently believe the regulations that they have laid out are necessary and effective; for them to believe otherwise would be tantamount to admitting to being bad at their jobs, and that is something most human beings just do not do. As hard as it is to find someone who will admit to being a bad driver, it may be harder still to find a bureaucrat who admits to regulating poorly.

Yet again, these regulatory barriers were promoted by activists for normative reasons and were not means of disguised protectionism. The cleavage-based explanations, by ignoring these actors engaged in trade politics but for normative rather than economic reasons, would not have been able to explain the politics surrounding

these environmental regulations and trade. Furthermore, this case also demonstrates that business’ political power is more limited than is often estimated. As with the consumer-safety related regulatory barriers related to mad-cow disease analyzed in the next chapter, these barriers seemed like the kind of technical, low-salience issues that should allow for easy cooperation between governments, especially when business interests are pressuring them to do so. Nevertheless, when these regulatory barriers take concrete form and seem to be protecting lives, consumer safety advocates can effectively defeat large businesses.

**Consumer Safety Regulatory Trade Barriers, Post-1999**

As it was becoming more clear to automakers that they would face greater resistance to reducing transatlantic regulatory barriers than they originally believed, automakers also realized that the gains from transitioning their production from region-based to globally-based were not likely to produce the level of benefits that they had envisioned. This realization centered around three considerations. First, economies of scale often have a diminishing marginal return. At a certain point, the fixed costs that drive economies of scale become smaller and firms encounter diseconomies of scale where increased size hurts profits. These diseconomies can emerge from a host of issues ranging from specialization getting too narrow to organizational decision-making becoming sclerotic and unwieldy. Automakers had already reached an effective size at the regional level to achieve helpful economies of scale. They did not need to reorganize globally to get those, and if they did attempt that, they might encounter costly diseconomies of scale.

Second, the just-in-time inventory systems pioneered by the Japanese firms in the 1970s and adopted by other automakers and the 1980s and 1990s required that supplier

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networks and automakers’ production processes be at least somewhat near each other.\textsuperscript{222} To state the obvious, just in time inventory is much easier when there is not an ocean in the way. In addition, shipping finished vehicles is very expensive given their size and the need to handle them with care, which motivates firms to build vehicles at least in the general vicinity of where they will be sold.\textsuperscript{223}

Third, consumer preferences between the two regions were so different that attempting to create a single vehicle for both markets might be a losing proposition even without being held up by regulatory trade barriers. Differences in consumer tastes between North America and Europe obviously did not begin in the 1990s, although they did become more significant over the course of that decade. In Japan, sales of mini-cars grew rapidly.\textsuperscript{224} In North America, light trucks and sport utility vehicles became highly popular; they grew from 30 percent of the market in 1990 to around 50 percent in 2001.\textsuperscript{225} In Europe, diesel cars increased from 19 percent market share in 1990 to 42 percent in 2001 whereas their share of the market in North America remained close to zero.\textsuperscript{226} Attempts at ‘world cars’ such as the Ford Mondeo had a habit of being successful in one region and tanking in the other.\textsuperscript{227}

As it became more apparent that changing from a regional to a global orientation would be less lucrative and more difficult to achieve, automakers stopped expending political energy advocating for reduced regulatory trade barriers. There were no serious

\textsuperscript{223} Rubenstein. 2001. Making and Selling Cars. p. 94, 322.
\textsuperscript{225} Ibid.
\textsuperscript{226} Ibid.
efforts to harmonize regulations after 1999. Businesses had stopped advocating for reduced regulatory barriers while consumer organizations and regulators were ready to push against them if they started to do so again.

Some discussion of renewed regulatory cooperation in automobiles has accompanied the Transatlantic Trade and Investment Partnership (TTIP) that started being negotiated in 2013. Automakers hope that these talks will reduce regulatory trade barriers in their industry. They should not hold their breath. Those negotiations are languishing. The Obama Administration has its eye on the TPP ball, which it has accurately perceived to be further along than TTIP. European economic governance seems continually mired in the Greek debt crisis and may soon have to deal with Brexit, which could be a catastrophe that demanded all political and economic attention.

Even when U.S. and EU officials can find the attention to discuss transatlantic trade, mutual skepticism towards each other’s regulations impedes progress. German consumer groups went berserk when they found out that the TTIP could potentially lead to imports of American chicken that, unlike German chicken, is put through a series of chlorinated rinses. American consumer groups likewise worry about the areas in which

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230 Both German and American consumers trust the other’s standards much less than their own country’s on a number of issues including auto safety, data privacy, environmental regulations, and food safety standards. Pew Research Center. “Support in Principle for U.S.-E.U. Trade Pact: But Some Americans and Germans Wary of TTIP Details” April 9, 2014. The margins are especially profound for German citizens.
European standards are lower than in the U.S.\textsuperscript{232} These sorts of dynamics would likely arise in auto regulations if and when more negotiating progress were made on TTIP.

It would be foolhardy to try to predict exactly which car-related regulation consumer groups would latch on to, but given that car regulations have life-and-death consequences, it is not difficult to envision those groups finding some regulatory change in a proposed TTIP that they consider to be a public safety sacrifice in the name of trade expansion. Here’s one plausible scenario. Child safety restraint regulations are different in the United States and Europe.\textsuperscript{233} It would not be too difficult to imagine a policy entrepreneur with a blog convincing a slice of American parents that regulatory trade barrier reductions in a TTIP deal would make it more likely that their children die on the way to soccer practice. NHTSA officials would not-so-quietly mutter in op-ed pieces that these parents had a point, adding further fuel to the criticism that the USTR was getting. The only way to circumvent this criticism would be to have all of the harmonization go upward, but unlike in the environmental regulations, in safety regulations the various regulators and consumer groups cannot agree on what upward even means or whose regulations are higher than whose. Unless automakers can find some way of mollifying or marginalizing consumer advocacy groups as well as regulators, reducing safety-related regulatory trade barriers in the transatlantic auto trade seems unlikely.

This too undermines the disguised protectionism thesis as well as the state-centric and cleavage-based explanations. The regulatory differences were not promoted by


automakers as a way to reduce competition. Far from it, they wanted these differences significantly reduced. Once again, the purely state-centric explanations, by ignoring societal actors, and the cleavage-based explanations, by ignoring those with normative motivations, fail to explain the politics behind the negotiations over these regulatory trade barriers.

**Concluding Remarks: Wealth Generation and Regulatory Sovereignty**

The generation of wealth is a worthy goal for societies. Many of societies’ other goals depend on its accomplishment. Trade liberalization helps accelerate that. That is why concerns about competitiveness are so instrumental in reducing regulatory trade barriers. Competitiveness links businesses’ particular interest with society’s broader goal of wealth generation. Still, wealth generation is not the only goal societies have. They also want to protect their environments, their laborers, and their consumers. Pursuing those goals leads states to jealously guard their regulatory autonomy. This will especially be the case when the potential or actual removal of a regulatory barrier has clear negative consequences as it relates to government protecting its citizens. Preventing unnecessary death links activists’ particular interest with society’s broader goal of protecting people.

As long as regulation and trade intersect, regulatory trade barriers will continue to affect societies’ attempts to generate wealth and their attempt to protect citizens. The politics surrounding regulatory barriers in the automobiles trade has been about these two imperatives since the 1980s and is likely to continue be so for the foreseeable future.
**Chapter 5- Catching Roadrunner:**
*Mad-Cow Regulations and the U.S.-Japan Beef Trade, 2003-2013*

**Introduction**

Beef exports are a lucrative business for American cattlemen. The single largest export market for American beef is Japan. Of the $6.5 billion in beef the U.S. exported in 2014, 1.4 billion of that went to Japan.¹ Beef exports have not just been remunerative. They have also been highly variable. The value of U.S. beef exports to Japan was $1.2 billion in 2003, just 80 million in 2004 and 2005 combined, 439 million in 2008, and 1.3 billion in 2013.²

Figure 5.1. U.S. Beef Exports to Japan³

The tariffs and other non-regulatory trade barriers faced by U.S. exporters remained constant throughout this period. The changes in regulatory trade barriers faced by U.S. beef exporters however were a major driver of this variability. At times those

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² Ibid.
³ Figure 4.1 is based monthly data from the U.S. Meat Export Federation. https://www.usmef.org/news-statistics/statistics/ Accessed March 8, 2016. Note: The negotiations over regulatory trade barriers are responsible for the overall trajectory seen in this graph but the individual peaks and valleys are due to the fact that overall demand for beef in Japan is higher in summer months.
regulatory barriers were increased, while at other times they were reduced, and at other times stayed the same. This chapter explains the political negotiations that drove that variation in regulatory trade barriers.

In the wake of discovering bovine spongiform encephalopathy (BSE), also commonly referred to as mad-cow disease, in their country in September 2001, the Japanese government instituted the world’s strictest beef safety regulations. They did not apply those regulations to beef imports from countries that had never had a case of BSE. At the time, that included the United States. Once the first case of BSE was discovered in the United States in December 2003 however, Japan’s strict regulations did apply to beef that U.S. producers wanted to export to Japan. These regulations were markedly tougher than the regulations those producers were accustomed to operating under in the United States. Because U.S. beef producers could not or would not abide by these Japanese regulations, depending on the phrasing one wants to use, this cross-national difference in regulations constituted a major regulatory trade barrier for U.S. beef. Negotiations between the United States and Japan in 2004-2005 resulted in a buy-out in which U.S. beef producers regained some market access but could only ship certain kinds of beef (only from cows under 20 months old and with all specified risk materials removed). A U.S. producer’s major safety mistake in 2006 led to a renewed ban and subsequently to another round of negotiations in which those producers regained access for a second time, but with even more regulatory strings attached. A 2007 OIE decision led the United States to take a more hardline stance; the two sides could not reach an agreement and so the regulatory trade barriers remained in place. Just when a compromise seemed within reach, the LDP was replaced by the DPJ, which was much less willing to compromise on
the issue. The Japanese government’s initial steps to join the TPP led to some softening on the issue but was halted by farmer protests and the need to focus on recovering from the 2011 tsunami/nuclear disaster. Finally, negotiations that stretched from the fall of 2011 to March of 2013 led to a nearly full re-opening of the Japanese market for U.S. beef producers almost a decade after that access had been originally shut.

Table 5.1- Regulatory Trade Barriers Outcomes In the U.S-Japan Beef Trade

<table>
<thead>
<tr>
<th>Event Description</th>
<th>Outcome</th>
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<tbody>
<tr>
<td>BSE Emerges in Japan (2001-2003)</td>
<td>Increase</td>
</tr>
<tr>
<td>Self-Tied Hands and the DPJ (August 2009-September 2010)</td>
<td>Stasis</td>
</tr>
<tr>
<td>30-Month Rule is Implemented (October 2011-March 2013)</td>
<td>Decrease</td>
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I explain this variation by examining the political bargaining between U.S. beef producers, Japanese consumer advocacy groups, and government officials in both states. The reaction of Japanese consumers to the spread of BSE in Japan and then the United States was so strong that Japanese officials had no choice but to increase regulatory differences between the U.S. and Japan despite the protests from U.S. cattlemen and U.S. government officials. These Japanese consumer advocacy groups were motivated enough and strong enough to ensure that any compromises made that allowed renewed market access for American beef came with significant regulatory commitments. Only when those consumer groups became less animated by this issue and when the TPP brought Japanese producer interests into the negotiations, did American cattlemen regain nearly full market access.

**Cultural, Historical, and Scientific Background**

In Japanese culture, the customer has traditionally been considered to be socially superior to the retailer; this has fostered high service standards but also encouraged
consumers to be detail-oriented and relatively unforgiving of merchants’ mistakes. Post-war Japanese businesses, by advocating consumer education and promoting greater information provision as a means of protecting consumers without adding costs to themselves, amplified this trend. The upshot of this strategy was that by the 1970s, strict regulations had become foundational to Japanese consumer protection policies. The behavior and demands of Japanese consumer advocacy organizations remains embedded within this cultural and regulatory dynamic.

In terms of political activity, the stereotypical view of Japanese consumers is that they are either docile accomplices of producers or bullied into submission by the combined political strength of business interests in league with the powerful Japanese bureaucracy. By the early 2000s though, this depiction had grown far less accurate. Japanese consumer groups had been highly concerned by and engaged in food safety as far back as the 1970s and 1980s. An augmenting factor behind this concern was that newspapers often covered food safety-related stories because they involved issues that readers could easily digest, thus making good copy.

Moreover, because consumer groups had far fewer avenues for recompense and protection through the court system than their American counterparts, they were much

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more reliant on protection through government regulation.\textsuperscript{10} In line with this, the Japanese regulatory system is designed to prevent defects beforehand whereas the American system often relies on compensating victims after the fact.\textsuperscript{11} For these reasons, Japanese consumers have generally been more concerned with food safety regulations than their American counterparts.\textsuperscript{12}

They have aggressively lobbied in favor of stringent labeling requirements and against the use synthetic food additives and post-harvest pesticides, both commonly used in the United States.\textsuperscript{13} That contaminated blood from the United States was one of the major sources of the spread of AIDS in Japan only compounded Japanese suspicions of imports from America.\textsuperscript{14} Japanese consumer groups have also tended to assert that safety inspections, even based on similar regulations, will not be carried out as carefully in other states as they would be in Japan.\textsuperscript{15} These groups have favored stricter regulations even when that limits the variety of products available to them.\textsuperscript{16}

Japanese consumer groups’ political strength grew still further in the 1990s. The Liberal Democratic Party’s (LDP) loss of power in 1993, its first such loss since the 1950s, greatly weakened producers’ stranglehold on the political process, and relatively strengthened consumer activists by creating a greater number of access points and leading

\begin{itemize}
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to augmented consumer protection laws.\textsuperscript{17} Consumer groups have effectively punished political parties, especially the LDP, for perceived mistakes on several other occasions as well.\textsuperscript{18} Compared to other Japanese civil society groups such as environmentalists, the consumer movement is organizationally strong and politically influential.\textsuperscript{19}

This organizational strength was, and continues to be, supplemented by the great extent to which government officials have dreaded the public outrage that can ensue from a scandal; as one minister put it, “we have to be very careful to prevent incidents because the newspapers really go after you when you slip up.”\textsuperscript{20} Businesses were still well represented in the halls of Japanese power, but by 2000, they no longer dominated the political process to the exclusion of consumer groups in the manner they once did, especially with regards to food safety regulations. As this change was occurring, Japan was also rapidly increasing its imports of U.S. beef.

Western food became prevalent in Japan in the 1970s and 1980s.\textsuperscript{21} Beef was a significant part of that trend. Japan began importing large amounts of U.S. beef in the late 1970s but these imports were subjected to a highly protectionist quota system.\textsuperscript{22} In 1991, these quotas were replaced with tariffs, which were further reduced in the Uruguay Round negotiations that created the WTO in 1995.\textsuperscript{23} Consequently, Japanese imports of U.S. beef significantly increased in the early 1990s and then surged again in the late

1990s. This increase notwithstanding, even though imported foods were once highly prized, by the 2000s domestically produced foods had become associated with higher quality and safety.

Amidst this increase in beef imports, in 1996 bovine spongiform encephalopathy (BSE) gained international notoriety, especially in Europe, and led to calls for regulatory action to prevent its spread. BSE, also commonly referred to as mad-cow disease, is a neurological disease that may infect cattle. If a person consumes meat from a cow infected with BSE, even if the meat is cooked thoroughly, that person can contract variant Creutzfeldt-Jacob Disease (vCJD), which is fatal within one to two years after onset and has no known cure. BSE is highly correlated with a cow’s age. That is why many of the regulations designed to combat BSE have an age component. The disease clusters in the cow’s brain and spinal cord which is why these parts are deemed “specified risk materials” that should be removed from cattle that are slaughtered after they reach 30 months of age according to the World Animal Health Organization (referred to as the OIE), the international standard-setting body for regulations used in the meat industry.

**BSE in Japan But Not in the United States: September 2001-December 2003**

In September 2001, the first case of BSE was discovered in Japan. The Japanese government, especially the Ministry of Agriculture, Forestry, and Fisheries (MAFF) and the Ministry of Health, Labor, and Welfare (HLW) were widely perceived to have badly

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27 For an encyclopedic coverage of BSE, see the OIE’s official website on BSE. http://www.oie.int/animal-health-in-the-world/bse-portal/ Accessed March 8, 2016.

botched their response because the infected cow had inadvertently been processed into bone meal and distributed to pork and chicken farmers. Pigs and chickens cannot contract BSE but this still alarmed consumers and created a perception of an ineffective safety system. As one Japanese consumer said, “I don’t think there is any concrete logic to say that meat is safe, when you hear that the cow was not actually destroyed, what can you believe?” The MAFF was also criticized for not banning meat-and-bone meal (MBM) being fed to cattle as the OIE had recommended. The Ministry of Health, Labor, and Welfare (HLW), which was the ministry responsible for conducting the BSE tests, also came under severe criticism because it was that ministry’s officials who contributed to the slow response by forgetting to actually inform their counterparts in the Ministry of Agriculture (MAFF) that a BSE case had been found.

The opposition party, the Democratic Party of Japan (DPJ) condemned the ruling Liberal Democratic Party’s (LDP) handling of the situation and engaged in a bit of rhetorical outbidding, advocating for a total ban on the use of MBM, even for pigs and poultry because if it was allowed to be fed to chicken and pigs, it would be very easy for farmers to give potentially infected MBM to cattle either mistakenly or as a cost-saving

30 Ibid.
31 Ibid.
32 The Nikkei Weekly. “Mad-Cow Disease Plagues Beef Industry.” October 1, 2001. MAFF did ban the practice after the first BSE case was discovered but by then over 2,000 cows had consumed the infected bone meal that had been imported from Europe. Ibid. Though this practice was banned in the United States, a December 2001 investigation by the FDA found that at least 264 American beef producers were violating that ban and a GAO review of that study suggested that FDA was probably undercounting the number of non-compliant businesses. Hesman, Tina. “Mad Cow Defenses are Inadequate, GAO Says; But Agriculture Departments Says Report is Flawed.” St. Louis Dispatch. February 7, 2002.
33 Yomiuri Shimbun. “Full Disclosure on BSE Needed.” October 14, 2001. Yomiuri Shimbun is referred to as Japan News in the LexisNexis Database should the reader want English language copies of their articles. Note: I do not speak or read Japanese and have used LexisNexis’ English translations of Yomiuri Shimbun.
maneuver without the government knowing.\textsuperscript{34} Shortly thereafter, it came to light that the Japanese government had not just ignored but actively suppressed a report on the risk of BSE coming into the Japanese market via meat-and-bone meal imports from Europe.\textsuperscript{35} The discovery of that suppressed report only added to consumer groups’ outrage.\textsuperscript{36}

A series of scandals shortly after the discovery of BSE involving domestic meat firms further reinforced Japanese consumer groups’ belief that strict regulations were needed to prevent beef producers from engaging in unsavory behavior. One company had falsely labeled imported beef as domestic and had sold meat to the government well past its expiration date in order to take advantage of a government insurance program, a maneuver that a MAFF official called “heinous beyond imagination.”\textsuperscript{37} Subsequent investigations revealed that at least two other major meat companies had falsified information regarding their products as well.\textsuperscript{38} A number of smaller scale frauds accompanied these revelations and convinced consumer advocates that these deceptions were “only the tip of the iceberg.”\textsuperscript{39} These episodes fueled calls for greater traceability and more exacting labeling requirements for meat and some of these calls directly accused the government bureaucracies of being too cozy with producers.\textsuperscript{40}

\textsuperscript{39} Kashiwagi, Akiko. “Scandals Cause Japanese to Lose Their Appetite; Once Revered Local Food In Doubt.” March 25, 2002.
These events, though not directly related to U.S. beef producers, had two major consequences for the regulatory trade barrier negotiations that would occur later. First, they convinced consumer activists that stringent regulations were absolutely necessary and so made them more rigid in defending Japan’s BSE countermeasures. This conviction also helped give birth to a traceability system in which shoppers could view the cow’s breeding history, their inspection certificate showing they were free of BSE, their species, breed, sex, slaughter date, the packaging plant they came from, the name of the meat inspector, and even a photograph of the farmer who sold the animal to the slaughter facility.41 Once Japanese consumers considered that level of transparency the norm, the argument made by U.S. beef producers a few years later that they should not have to keep records of or identify a cow’s actual age - the factor most strongly correlated with BSE - struck those consumers as unreasonable and flippant.

Second, these scandals so thoroughly embarrassed the Ministry of Agriculture that it became highly incentivized to aggressively pursue and enforce food safety regulations in order to win back credibility in the eyes of the public. After these incidents, Agriculture Minister Takebe said that the MAFF would begin implementing regulations “from the standpoint of the consumer.”42 Demonstrating the extent to which this issue was being taken seriously across the Japanese government, the Fair Trade Commission,

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though it was not the central target of consumers’ ire, also said that it to would take a stronger stand on consumer protection regulations.43

In order to re-establish its credibility on food regulation and reassure consumers of the safety of Japanese beef, the government implemented the world’s most stringent BSE counter-measures. All cattle entering the food supply would be tested for BSE and all specified risk materials had to be removed.44 Later, in 2003, when the OIE recommended the vertebrae also be considered a specified risk material, Japan changed its regulations to match the OIE’s guidance, which suggests that the Japanese government was not as contemptuous of international standards as the U.S. would later claim.45 These regulations were not applied to beef imported from states that had never had a case of BSE. Therefore, beef imports from the United States, which still had not had a BSE case, were not subjected to these regulations. This counts as strong evidence that the Japanese government was not attempting to use BSE regulations as a disguised means of protectionism. If a government were using regulations as a sneaky form of protectionism, it would not exempt imported products from the regulations imposed on domestic producers.

Also during this time, U.S. beef producers, through the U.S. Meat Export Federation, organized a promotional campaign to extol the safety of American beef.46 They ostentatiously labeled their products as imported from the United States and even had U.S. Agriculture Secretary Ann Veneman tour the country, giving cooking lessons

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prominently featuring American beef to Japanese schoolchildren.\textsuperscript{47} By May 2003, Japanese beef consumption had returned to 86 percent of its pre-BSE level and so as long as the U.S. could remain BSE-free, U.S. beef producers could resume their billion dollar-plus level of annual exports to Japan.\textsuperscript{48} That did not happen.

**The Discovery of BSE in the U.S. and Initial Reactions: December 2003-April 2004**

In December 2003, the first case of BSE was discovered in the United States. In response, Japan suspended U.S. beef imports until an investigation could be undertaken, as is standard international practice when a country reports its first BSE case.\textsuperscript{49} That BSE discovery had two effects. First, it increased Japanese consumers’ skepticism of the adequacy of U.S. food safety regulations and the safety of U.S. beef.\textsuperscript{50} These concerns were especially acute because when that first BSE case was discovered, by the time the test results came back showing that the cow in question did have BSE, that cow had been slaughtered, its meat had been mixed with 10,000 pounds of meat from other cattle, and had been shipped to supermarkets in eight states.\textsuperscript{51} The BSE discovery raised considerably more alarm in Japan that in the United States.\textsuperscript{52}

Second, it meant that if U.S. beef producers wanted to regain market access, they now had to meet Japan’s strict BSE countermeasures. Notably, the Japanese government declared that U.S. producers would not have to implement a Japanese-style traceability


\textsuperscript{52} In contrast to the fallout in Japan in 2001-2002, the effect the BSE discovery in the U.S. had on Americans’ purchasing decision was tiny and lasted less than two weeks. Kuchler, Fred and Abebayehu Tegene. 2006. “Did BSE Announcements Reduce Beef Purchases?” USDA, *Economic Research Service*. Economic Research Report 34.
program and stated that by making this exception they were hoping to avoid erecting an unnecessary trade barrier, again suggesting they were not attempting to use regulations as disguised protectionism.\textsuperscript{53}

In the wake of the BSE discovery, U.S. beef producers fought against every regulatory change designed to curtail BSE on the grounds that those changes would be too expensive and successfully blocked a number of proposed regulations.\textsuperscript{54} The USDA did implement some new safety measures after the BSE discovery.\textsuperscript{55} For example, it stopped allowing downer cows (i.e. cows too sick or injured to walk) to be slaughtered and enter the food supply, and instituted a rule that if a cow was tested for BSE, that cow’s meat could not be sent to retailers until after the BSE test results came in.\textsuperscript{56} It did not however institute universal testing or specified risk material removal on all cows.

Consumer groups criticized the meat industry for adopting this approach and the U.S. government for acquiescing to industry demands but were no match for an industry with deep pockets and a direct interest in those regulations, especially since they were unable to galvanize the wider public.\textsuperscript{57} This situation resembled what James Q. Wilson has called entrepreneurial politics in which a diffuse interest squares off against a concentrated interest.\textsuperscript{58} For the diffuse interest to prevail, a successful political

\textsuperscript{56} Nesmith, Jeff. “New Rules Aim to Protect U.S. from Mad Cow.” The Atlanta Journal-Constitution. December 31, 2003. In 2008, the Humane Society released footage of “downer cows being shocked, prodded with forklifts, and blasted with water hoses to force them into standing long enough so that they could be certified for slaughter” which suggests that these downer cattle regulations have not always been rigorously enforced. The International Herald Tribune. “U.S. Beef Inspections Don’t Inspire Much Confidence.” June 12, 2008.
\textsuperscript{57} Farsetta, Diane. “The Cows Have Come Home.” CorpWatch. September 1, 2005.
entrepreneur must be able to garner attention and sympathy from the wider public. U.S. consumer groups were not able to do that.

The American regulatory changes were not enough for Japanese politicians or consumers, who saw no reason why American beef producers should not have to abide by the same safety regulations as Japanese producers. Prime Minister Koizumi stated that all beef imported from the United States had to pass “the same measures taken in Japan to secure safety and peace of mind such as removal of specified risk materials and inspection on all cows.”

The Japanese government did however introduce an exception to blanket testing. The youngest cow found to have BSE in Japan was 21 months old and so the Japanese government stated that beef from cows slaughtered at 20 months or younger did not have to be tested for BSE. Though any producer could theoretically take advantage of the 20-month age exception to universal testing, in practice only U.S. producers could use this carve-out. That was because, through intensive grain feeding, U.S. cattle are the only cattle that are raised and fattened quickly enough that they are ready for slaughter at or before 20 months. In contrast, Japanese cattle are not ready for slaughter until they are roughly four years old. This too counts as strong evidence that the Japanese government was not using BSE regulations as disguised protectionism. If the Japanese government had been doing so, the last thing they would have done would be to create an exemption to their regulations that only imported products could take advantage of.

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63 Obara, et. al. 2010. p. 18.
Despite this concession, U.S. producers still balked at Japan’s regulatory demands. They were less interested in assuaging Japanese consumers than in getting the Japanese government to allow them to sell their products under a regulatory framework more to their liking. As Roger Evans, the President of the Colorado Cattleman’s Association put it, “this thing has to be producer-friendly [and] I want it to be in the private sector that way someone is accountable to the producer.”\textsuperscript{64} Note the extent to which this cattleman did not understand, or did not care, that food safety regulations are usually thought of as being primarily for consumers’ benefit.

\textit{Explaining the Absence of a California Effect}

U.S. beef producers could have chosen to adopt the higher Japanese standards and lobby the U.S. government to raise U.S. standards accordingly, thus creating a California Effect. Had they done so, they would have immediately regained access to the Japanese market. Two factors made this California Effect even more likely. First, the Japanese market was the largest export market for U.S. beef producers. Market power is what gives states with high regulatory standards the ability to force foreign producers to raise their standards.\textsuperscript{65} If any foreign state had the market power to create a California Effect in U.S. beef, it was Japan. Second, the cost of changing these regulations was actually low, which is another factor that should encourage a California Effect.\textsuperscript{66} The direct costs of administering universal testing would only have been about a few cents per pound of beef and only took around six hours.\textsuperscript{67} U.S. producers could have implemented these

\textsuperscript{66} Vogel. 1995. \textit{Trading Up}. p. 257-258
\textsuperscript{67} The FAO estimated the costs of BSE testing at 50 dollars per head of cattle but an American rancher who wanted to universally test all of its product said that the costs were only around 20 dollars per head. In either case, the additional cost was only a few pennies per pound. McNeil, Donald. “Barred From Testing
regulations only for beef being exported to Japan but worried that would lead American consumers to demand the same elevated standards. In other words, U.S. beef producers were actively trying to prevent a California Effect, and seemingly so was the USDA.

One small producer, Creekstone Farms, did attempt to adopt universal testing. The USDA blocked it from doing so because it was concerned that one company testing all of its beef for BSE would lead to consumers demanding that all companies do the same, thus adding costs for major beef producers. In other words, the USDA was implementing its regulations with the express purpose of undermining consumer activism over those very food safety regulations.

The penetration of beef industry insiders at the highest levels of the USDA made it even more likely the USDA would identify with those producers. For example, Alisa Harrison, the spokeswoman for Agriculture Secretary Veneman, and Dale Moore, Veneman’s Chief of Staff, both worked for the National Cattlemen’s Beef Association prior to their time at the USDA. Previously, in 1994, when Michael Taylor (who did not have a connection to the meat industry) took office as head of the Food Safety and Inspection Service (FSIS) at the USDA, he recalls being perturbed that the phone in his new office already had two speed dials, both for beef producer organizations. As Taylor explains, there was “a culture [in the USDA] that has developed over the years at the

political level, the food safety program at the USDA thinking of the industry as the customer rather than the consumer, and thinking in terms of efficient inspection rather than protecting public health. Collectively, these examples strongly suggest that the USDA at this time defined its role as protecting beef industry profits.

Regardless of the USDA’s position, U.S. producers’ resolute opposition to adopting Japanese standards even though that refusal lost them access to their largest export market demands explanation. Two factors explain their intransigence. First, their rhetorical strategy for criticizing Japanese BSE regulations further hardened their position. Because they disagreed with Japan’s regulations, and because regulations need to be justified on scientific grounds, U.S. producers repeatedly impugned as Japanese BSE rules as “unscientific.” Over time, these derisions created an echo chamber among beef producers that reinforced rather than softened their position.

Not only were beef producers unwilling to incur even small cost increases, they also were philosophically opposed to regulation and government intervention in markets in general. This outlook is reflected in the fact that since 1990, three-quarters of their over 60 million dollars in campaign contributions have gone to Republicans; relatedly, of the 15 largest recipients of livestock industry campaign contributions in the 2014 cycle,

71 Ibid.
all 15 were Republican. Since the 1980s, the meat industry has also been rabidly anti-union. The meat industry as a whole at this time was not ideationally predisposed to accepting higher regulations it deemed unnecessary.

Second, universal testing would have required American beef businesses go against the primary strategy of their business model, aggressive cost cutting. The meat industry’s primary focus at that time was, as it is now, on cost-control and getting meat to market as cheaply as possible; every other consideration was of secondary importance. Adding costs, especially costs emanating from a regulatory approach they deemed unscientific, was simply not something beef producers were willing to do, even if such a stance lost them export business. Beef producers were not only in competition with each other; they were also in competition with the producers of all other foods, especially other forms of meat. Even if new testing requirements costs were spread evenly across beef producers thus ensuring that none of them gained a competition advantage, beef producers as a whole would still have lost out by having their product become more expensive relative to chicken, pork, and fish.

That the conditions for the California Effect were present and yet it still did not occur suggests a few caveats to the California Effect. First, while market power does matter, it does not automatically override other concerns. As much as American cattle producers were committed to regaining access to Japan’s market, they were even more committed to promoting a regulatory regime that operated on their policy terms. Second, unlike automakers in their interaction with environmental regulations discussed in Chapter 4, U.S. beef producers believed they had another option besides conforming with Japan’s stricter regulations and pressing the U.S. government to raise its standards to match them. As will be shown in the following section, they believed that they could get the U.S. government, and specifically the United States Trade Representative, to successfully pressure the Japanese government into allowing imports of U.S. beef under a special arrangement that exempted U.S. beef producers from Japan’s more onerous regulations.

That Japanese market power could not make U.S. producers adopt stricter regulations but U.S. political and economic power could tempt them into attempting to strong-arm the Japanese, which did not work either, suggests that economic and diplomatic power in this case impeded progress toward a settlement more than it helped. That power backfired in a situation where it arguably should have been effective suggests that power-based explanations may be less efficacious than is commonly assumed. It also suggests just how sensitive the domestic politics over regulation can be.


With U.S. beef producers refusing to accept either Japanese standards or permanent exclusion from the Japanese market, their only other option was to lobby the
U.S. government to pressure the Japanese government to allow U.S. beef imports under a special arrangement. Through the early fall of 2004, the U.S. government pressured the Japanese government to allow a resumption of American imports under regulatory terms that U.S. producers could accept, showing that it was not just the USDA siding with producers. Allen Johnson, the chief U.S. agricultural negotiator alluded to the United States potentially taking the case before the WTO and Senator Max Baucus as well as Vice President Cheney urged the Japanese government to reopen its market. In June, Agriculture Secretary Veneman and President Bush also implored Japanese Prime Minister Koizumi to re-establish market access for U.S. producers as soon as possible. These entreaties grew more insistent as the U.S. presidential election loomed closer. President Bush badly wanted to be able to declare victory on this issue in order to gain support in key swing states with large agriculture sectors such as Colorado, Missouri, and Florida.80

The lead negotiators throughout this case were in the office of the United States’ Trade Representative (USTR). Two dynamics combined to incentivize the USTR to vigorously defend the interests of U.S. beef exporters in this case. First, the USTR is strongly in favor of trade liberalization in its culture, its personnel, and its mission.81 Second, the USTR also generally wants good relations with Congress.82 In many cases, there is a tension between those two imperatives. Congressman X wants to protect the

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industries in their district while the USTR wants to promote trade, which may come at the expense of those industries. However, when a Congressman’s efforts to protect their constituent industry do not entail raising U.S. trade barriers but instead reducing another state’s trade barriers, the USTR’s two bureaucratic interests dovetail. Moreover, in this particular case, the trade barriers that the USTR would be trying to reduce were not part of some larger trade deal. Thus, they need not worry that some other Member of Congress would object to the USTR’s backing of the beef industry while not demonstrating the same fealty to an industry in their district. Additionally, the USTR had no bureaucratic or ideational interest in the content of America’s domestic beef regulations. This dispute with Japan over beef regulations provided the USTR with a rare opportunity to simultaneously pursue trade liberalization and good relations with Congress, and there was no countervailing interest mitigating those incentives.

Meanwhile, MAFF and HLW officials worried that a resumption of U.S. imports under looser regulations than those imposed on domestic beef would be perceived as the government sacrificing public health in order to appease the United States.\(^\text{83}\) By October 2004, it was clear that Japan, at least for the time being, would not back down from its final offer of a 20-month age exemption from universal testing and removal of specified risk materials from all cattle.\(^\text{84}\) U.S. negotiators had already accepted a plan very close to this as an acceptable first step, so it seemed as though the United States and Japan were very close to re-opening at least some market access for U.S. beef producers.\(^\text{85}\)

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The only real difference between the U.S. and Japanese plans was how to measure the age of the cattle to ensure they were not older than 20 months. Japan wanted the United States to institute a cattle tracking system like its own. The United States wanted to be allowed to estimate the cattle’s age based on the cow’s skeleton even though that method had a greater margin for error than Japanese regulators were comfortable with.\(^8^6\)

The Bush Administration decided to accept the Japanese terms and declare trade victory less than two weeks before the presidential election.\(^8^7\) It presumed that the age-verification details could be worked out later and that in any case this was only a temporary agreement that would be superseded after the United States won still greater access to the Japanese market.\(^8^8\) The timing of the agreement led the main opposition party, the DPJ, and a number of consumer groups to mistrust the reopening of imports as they saw the agreement as Prime Minister Koizumi’s political gift to President Bush.\(^8^9\)

To the consternation of U.S. beef producers, the dispute over age verification and thus the exclusion of U.S. beef from the Japanese market dragged into and throughout most of 2005. The MAFF and HLW accepted new U.S. proposals for age-verification in February 2005 but they did not have final say on the matter.\(^9^0\) To implement the agreement with the United States, an official end of the universal testing policy as well as the acceptability of the U.S. age verification system had to be recommended by the Food Safety Commission, an independent, politically insulated panel of experts that was


created in July 2003 to make scientific judgments on food safety.\textsuperscript{91} It was created for the express purpose of making neutral decisions on food safety. MAFF and HLW officials argued, probably correctly, that any attempt on their part to force the commission to expeditiously make the decision MAFF/HLW wanted would likely have generated a storm of outrage that once again the government was not adequately protecting public health.\textsuperscript{92}

After the Japanese government had publicly stated its intention to create the 20-month exemption, the Food Safety Commission came under intense pressure from consumer groups to maintain universal testing.\textsuperscript{93} These consumers groups also argued that the Food Safety Commission should not allow a resumption of U.S. imports because safety procedures at U.S. meat processing facilities did not meet Japanese standards.\textsuperscript{94} In March 2005, Japanese restaurants that needed specifically American beef started lobbying the government to find some way to expedite the Food Safety Commission’s decision.\textsuperscript{95} This was the first time that the Japanese government received significant business lobbying in favor of reducing the regulatory barriers.

U.S. beef producers and government officials believed the October 2004 agreement amounted to a Japanese commitment to allow a resumption of U.S. beef imports and that the continued delay was at the very least intentional foot-dragging if not a wholesale reneging on that agreement.\textsuperscript{96} U.S. officials became much more overt and


aggressive in their diplomatic pressure. Beef industry organizations and Congressmen began demanding that retaliatory sanctions be leveled against Japan if it did not allow imports of U.S. beef.\textsuperscript{97} This pressure made any relaxation seem to be a response to U.S. demands. In their zeal of pushing sanctions, members of Congress actually made reducing these barriers more difficult by delegitimizing Japanese government officials’ attempts to change their country’s regulations in ways that would have facilitated greater imports of American beef. Here too power backfired more than it helped.

Despite these threats, filing suit before the WTO on behalf of beef producers was never a real option for the U.S. government. A ruling in favor of the U.S. could have created a perception that Japan was being forced to accept imports of unsafe beef. That perception, besides generating diplomatic tension, could lead consumers to shun U.S. beef, thus negating the regained market access. This points to a potentially significant limitation to the power of the WTO’s dispute settlement mechanism as it pertains to regulatory barriers. Exporters benefit when the WTO rules against a particular trade barrier such as an unfair subsidy. However, the political sensitivity of states’ domestic regulations means that an exporter cannot make a WTO case out of that regulatory barrier because forcing a state to change its domestically agreed upon rules risks destroying the exporter’s reputation, and thus profits, in the importing country.

Throughout 2005, consumer groups remained convinced that U.S. safety standards did not pass muster and said so loudly.\textsuperscript{98} The DPJ criticized the ruling LDP for

disregarding consumer safety and for seeming to kowtow to the United States.\textsuperscript{99} This was a particularly sensitive time for the DPJ to make such accusations because there was a general election scheduled for September 2005. Much as President Bush wanted a trade victory just before the November 2004 U.S. elections, Koizumi and the LDP wanted to avoid making a trade concession that would incur consumer groups’ wrath until after their elections.

After those elections, to get the Food Safety Commission to approve U.S. beef, the LDP-led government ordered the commission to perform its risk-assessment based on the assumption that U.S. producers would follow Japanese regulations.\textsuperscript{100} In October 2005, the Commission approved a resumption of U.S. imports under that assumption but noted, presciently, that they were skeptical that stringent adherence to Japanese standards would actually be carried out.\textsuperscript{101}

Throughout this period, contra to the expectations of IR theories that presume that security issues predominate, neither side sacrificed its position on regulatory trade barriers in beef to realize gains on other security-related issues such as Japan’s participation in the war in Iraq, talks with North Korea, China’s military growth, or basing issues in Okinawa.\textsuperscript{102} Relatedly, even though they were key security allies, neither side was willing to allow the other to have its way on this issue.\textsuperscript{103} In fact, the beef issue at certain points overshadowed security matters during bilateral talks.\textsuperscript{104} This pattern of

beef-related tensions predominating security concerns would be repeated at later points as well.\(^{105}\) That the United States could not get Japan to yield on these regulatory barriers suggests that the political economy-related leverage benefits gained from providing security benefits to a regional protégé are highly limited once regulations are involved.

This is a significant development. It has long been presumed that delivering those security benefits gained the United States diplomatic capital that it could spend in other policy areas. Indeed, throughout the Cold War, trade policy often was subservient to geopolitical concerns, but that was a time period in which trade policy generally did not impact regulations. In the post-Cold War era, trade policy very much does affect regulation. Given this, looking forward the United States should not presume that security assistance will coax other states into bending in negotiations over regulatory trade barriers.

In December 2005, U.S. beef was allowed to be exported to Japan.\(^{106}\) The regulatory standards under which U.S. beef producers regained access to the Japanese market (under 20 months age limit, removal of all specified risk materials) still constituted a significant regulatory barrier, but at least renewed access meant some access, and if U.S. producers could demonstrate the safety of their product then perhaps those regulatory barriers could be reduced still further.\(^{107}\) The resumption of imports was severely criticized by Japanese consumer groups.\(^{108}\) The notion that U.S. meat packaging facilities might not always abide by the rules was not a figment of Japanese

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consumer groups’ imagination; a USDA audit found 1,036 violations of specified risk material regulations from January 2004 to May 2005, and these rules were not even as strict as those contained in the U.S.-Japan agreement.¹⁰⁹ MAFF and HLW officials, as well as Prime Minister Koizumi and the LDP, had staked their reputations on public health policy on the safety of U.S. beef. As long as U.S. beef producers adhered to the regulatory requirements agreed to by the U.S. and Japan, they could regain sales with more potential revenue gains to come. U.S. beef producers however failed to follow those regulations, to put it very mildly.

**Careless, Stupid Mistakes And Diplomatic Clean-Ups- January 2006 to April 2007**

In January 2006, Japanese inspectors found a serious lapse in U.S. beef producers’ implementation of the safety protocols, which resulted in Tokyo suspending U.S. beef imports.¹¹⁰ In one of the boxes of U.S. beef, Japanese inspectors found vertebrae and a spinal cord.¹¹¹ It would be difficult to overstate just how much of blunder this was. Recall that BSE clusters in the cow’s nervous system, making the spinal cord an especially risky “specified risk material.” *The Aberdeen American News* of South Dakota, as pro-beef a publication as one is likely to find anywhere, called the inclusion of these materials “a careless, stupid mistake.”¹¹² Mike Johanns, the new U.S. Secretary of Agriculture rightly said it was “an unacceptable failure.”¹¹³

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Johanns’ contrition was undermined however by statements other American officials and suppliers were making. The National Cattlemen’s Beef Association downplayed the mistake, pointing out that the inclusion of spinal cords from cattle less than 30 months old was not actually illegal in the United States, as if somehow that obviated Japanese concerns and regulations.\(^{114}\) In a similarly thoughtless vein, Agriculture Undersecretary J.B. Penn compared the risk of contracting vCJD from eating American beef to the risk of being hit by a car on the way to purchase the beef.\(^ {115}\) From an actuarial standpoint, he may have been correct, but the remark was tone-deaf. In any case, comparing the consumption of one’s product to being struck by a vehicle does not conjure up images of safety and wholesomeness. The perception of insensitivity these comments engendered was compounded by Congressmen who immediately began calling for retaliatory sanctions after Japan’s re-imposition of the import ban.\(^ {116}\)

Meanwhile, Japanese consumer activists that had objected to allowing U.S. beef imports were apoplectic over the mistake and vindicated in their opposition. The Food Safety Citizen’s Watch declared their “great anger” and reminded everyone that they had “pointed out again and again…there is indeed a danger to us Japanese consumers [from U.S. beef].”\(^ {117}\) This mistake shook Japanese consumers’ trust in American beef as badly as, if not worse than, the original discovery of BSE in the U.S.\(^ {118}\) As one official put it “in

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\(^{115}\) *Yomiuri Shimbun.* “Penn's BSE Comment Raises Eyebrows.” January 26, 2006.


the opinion of the Japanese consumer, this is like a new scandal being revealed.”\textsuperscript{119} The DPJ party leadership pounced on the scandal, portraying it as indicative of the LDP’s insufficient concern for consumer safety and pointing out that it had opposed the market access agreement.\textsuperscript{120}

Consumer groups demanded that, at minimum, the U.S. should have to allow Japanese regulators to inspect and decide for themselves which facilities to approve and that Japanese inspectors should be allowed to accompany their U.S. counterparts when they conducted surprise inspections of American meatpacking facilities.\textsuperscript{121}

Japanese consumer groups demanded reinforced protection rather than continued access. What Gunnar Trumbull has called “narratives of access” (i.e. arguments in favor of using the state to increase consumers’ access to certain goods) were less powerful than “narratives of protection” (i.e. arguments in favor of using the state to protect consumers from the dangers posed by certain goods).\textsuperscript{122} Narratives of access had relatively little power to encourage relaxations of the Japanese regulations on American beef exports because consumers knew that their demand for beef could still be satisfied by other sources. A Japanese shopper interviewed after the spinal cord discovery argued that "the government should stop importing dangerous beef from the United States as (a supply shortage) could be averted with beef from Australia."\textsuperscript{123} For their part, Australian beef importers expressed astonishment at the maladroitness of this American blunder but were

\textsuperscript{122} On narratives of access and narratives of protection, see Trumbull. 2012. \textit{Strength in Numbers}. p. 26-29, 124-150.
nevertheless happy that their main competition, after fighting so hard to regain market access, had managed to fritter away that access so expeditiously.  

Japanese officials again faced a serious threat to their credibility on food safety. What made the matter all the more perilous for the MAFF and HLW was that the day before the spinal cord discovery, Japanese officials had, on camera, assured consumers of American regulatory effectiveness. Given the predicament these officials were in, in order to retain the public’s trust, they had no choice but to re-impose the ban on beef not universally tested for BSE and insist upon the two policy demands advanced by the consumer groups. As a Japanese abattoir owner pointed out, “MAFF took the USDA at its word and it let them down. Because they look foolish, it would be some time before trade resumes.” The MAFF also decided to increase inspection of U.S. beef at ports of entry should imports be resumed. If these policies meant trade friction with the United States, then that was Prime Minister Koizumi’s problem; MAFF had almost no choice but to insist on significant regulatory improvements from the Americans.

Koizumi thus needed to demand tougher rules on U.S. beef but also not start a trade row. He did not want to be seen as caving to U.S. pressure and so argued that the decision was in the MAFF’s hands. When asked when about U.S. imports, he said that “specialists are discussing this matter. I'll follow their opinion.” Importantly, by April MAFF officials were satisfied with the increase in safety rules being placed on U.S. producers. They also believed that Japanese consumers’ concerns had become

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overwrought; as one Food Safety Commission official said, “as specialists here at the ministry, we regard the consumers' reaction as extreme.”\textsuperscript{129}

The U.S. acceded to these demands and in May 2006 the Japanese and U.S. governments reached an agreement to restore U.S. beef producers’ access to the Japanese market starting in July.\textsuperscript{130} This restored access came with a stricter oversight regime that gave foreign regulators inspection rights over American firms located entirely within the United States, an uncommon arrangement to say the least. Moreover, the HLW also decided to begin inspecting every box of imported U.S. beef rather than just a random sample.\textsuperscript{131} Still, this agreement only restored market access to its December 2005 level, a level U.S. cattlemen were never satisfied with in the first place. U.S. beef had not yet even reached Japan before the American government was already pushing Japan to further reduce its regulatory barriers, specifically raising the age exception on universal testing to all cows 30 months and younger.\textsuperscript{132} This pressure continued into 2007.\textsuperscript{133}

It bears noting that throughout this period and into 2008, U.S. beef producers continued to make basic errors in complying with the U.S.-Japan beef export verification agreement. For example, they included unapproved thymus glands in one shipment, erroneously shipped beef that did not abide by Japan’s age limits on multiple occasions,


and included yet another spinal column.\textsuperscript{134} These mistakes did not make the Japanese more eager to alter their regulations to match American preferences. Still, Japanese officials believed that on the whole, U.S. safety standards were effective enough that in response to these mistakes, instead of imposing broader import restrictions as they had after the earlier spinal cord mistake, they chose to decertify the offending facilities individually.\textsuperscript{135} Additionally, in April 2007, the U.S. agreed to allow Japan to conduct more audits of American meat packing plants in exchange for the Japanese agreeing to loosen its policy of inspecting 100 percent of all beef boxes.\textsuperscript{136} The OIE would soon issue new estimates that encouraged Japanese regulators to have even more confidence in U.S. regulations.

**American Exceptionalism and Throttled Compromise: May 2007 to August 2009**

In May 2007, the World Animal Health Organization (OIE) reclassified the United States from being a country with ‘unidentified BSE risk’ to being a country with ‘controlled BSE risk.’ This decision, though non-binding in international law, officially endorsed U.S. BSE regulations as effective enough that it supported the United States’ ability to export beef regardless of age.\textsuperscript{137} In response to this ruling, and after an internal review and Diet elections in July, Japanese officials announced that they were willing to


In other words, Japanese officials were agreeing to implement the regulations that U.S. beef producers and policymakers had spent the previous three and a half years saying they wanted. All that the United States’ officials had to do was accept the offer and the confrontation over regulatory trade barriers in beef between the United States and Japan would have been over. Japan would have been able to maintain the regulations it preferred and U.S. beef producers would have had what in effect amounted to a 90 to 95 percent opening of the Japanese market as that is the percentage of American cattle that are slaughtered between the ages of 15 and 24 months.\footnote{Inside U.S. Trade. “USDA Asks Japan to Accept All U.S. Beef in Wake of OIE Finding.” Vol. 25. No. 22. June 1, 2007. Nakamura, Hiryuki and Toshihiko Yada. “OIE OK’s U.S. Beef Exports From Older Cows.” Yomiuri Shimbun. May 24, 2007.} That did not happen. American officials rejected the Japanese offer.

all the way up to President Bush pressured Japan to remove all of its age-related regulatory trade barriers. What made the American position transparently hypocritical, and thus easier for the Japanese to disregard, was that though the United States held up the OIE as the definitive ‘scientific’ international standard in this particular instance, it continued to ignore OIE standards on other matters related to beef regulations calling those recommendations ‘unscientific.’ The U.S. would not fully align its beef regulations with OIE recommendations until March 2012, over three years into the Obama administration.

Three principle reasons lay behind the U.S. government’s decision to reject the Japanese offer of a 30-month age limit. First, as was seen earlier in this case, USDA officials and American producers did not accept the legitimacy of the Japan’s regulatory preferences, dismissing them as “unscientific” and did not accept that they needed to bend at all. Second, the U.S. was attempting to fully open Japan’s beef market so that it could use that as a lever to open the South Korean market in the free trade agreement negotiations that were taking place between the United States and Korea.

Third, this maximalist approach fit the Bush administration’s modus operandi with regards to international negotiations. Bush administration officials tended to conflate anything that could be construed as compromise with capitulation. Christopher Hill, a career diplomat who has served in high-level positions under both Republican and

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Democratic presidents, argued at the time that, for Bush Administration officials, there was no need for the United States to give up anything in international negotiations; according to Hill, those policymakers’ negotiating positions on seemingly all issues were essentially “come out with your hands up.”\textsuperscript{147} A ‘come out with your hands up’ approach only works in Western movies, and even then only sometimes. When the other side is not surrounded, does not consider you the sheriff (even if that is how you imagine yourself), and does not consider itself an outlaw, the most likely result is continued non-movement, and that is exactly what happened here. It was for these reasons that the dispute between Japan and the United States dragged into 2008.\textsuperscript{148}

International standards bodies like the OIE, ISO, and the \textit{Codex Alimentarius} are often credited with facilitating cooperation, and indeed there is considerable evidence that they do exactly that.\textsuperscript{149} This part of the case study though suggests a potential limitation to that. When these bodies issue recommendations that support a particular claimant’s preferences, they can make that claimant more rigid in their position. In situations in which the willingness to compromise is more important than coordination difficulties, which is arguably a huge proportion of regulatory trade barrier disputes, making one party more immutable may hamper cooperation more than the recommendations facilitate that cooperation through the enunciation of potentially common standards.


In its own way, Barack Obama’s rhetoric also demonstrated that, like President Bush, Obama too saw his role on this issue as supporting American beef producers. Though he criticized the Bush Administration on almost all other issues, then-candidate Obama’s rhetoric on these beef regulations was remarkably similar to President Bush’s. He too chalked up the regulatory differences to simple protectionist chicanery saying that “you can’t get beef into Japan and Korea, even though, obviously, we have the highest safety standards of anybody, but they don’t want to have that competition from U.S. producers.”

Likewise, Austan Goolsbee, who would later be the Chairman of the Council of Economic Advisers, argued that

“two facts are not in dispute. Japan and Korea retain rules that prevent imports of U.S. beef, rules that other countries don’t have, and in countries that don’t have those rules, U.S. beef exports have returned to higher levels than before. So you’ve got to be highly suspicious at the outset.”

The Obama administration may have phrased its position on Japan’s beef regulations specifically, and foreign regulatory barriers broadly, in a more polite way than their Bush administration predecessors, but that position was still based on the same hubristic premise.

The underlying assumption behind Goolsbee’s and Obama’s statements as well as the Bush Administration’s position is that American businesses, and by extension America, are so unfailingly excellent that if they cannot effectively compete in a foreign market, the only logical explanation is that there must be some underhanded trade policy trick preventing them from doing so. In contemporary America, there is sometimes a tendency to see the two parties as diametrically opposed on everything and Democrats as more urbane in their foreign policy approach than Republicans, but in important ways in

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151 Ibid.
this case the two parties behaved in exactly the same manner. Both were eager to arrogate to the United States the role of final arbiter of scientific truth. Both were willing to indulge in the haughty trope of American exceptionalism.

When the National Cattleman’s Beef Association’s policy position on negotiating with Japan changed, so did President Obama’s. In January 2009, the NCBA asked its members to consider changing the association’s position to supporting an incremental approach vis-à-vis the Japanese.\(^{152}\) Instead of pushing for the removal of all age restrictions, as was their preference before, the beef industry representatives were willing to accept the 30-month position that Japan had signaled it would accept after the OIE’s 2007 ruling. In May 2009, that became the NCBA’s position and the U.S. Meat Export Federation joined them in promoting this incrementalism.\(^{153}\)

In the intervening period between January and May 2009, the Obama Administration’s position remained unchanged from the Bush Administration’s.\(^ {154}\) After the beef industry preference shift, the Obama Administration adopted that incremental approach; by July, even Congressional Republicans had adopted that position.\(^ {155}\) That the Obama administration’s position did not change immediately upon taking office but did shift after the beef industry’s position changed strongly suggests that this policy position adjustment was not simply a manifestation of campaign rhetoric being jettisoned in the face of the realities of governance. Rather, it was a manifestation of policymakers


defining their role as promoting the beef industry and taking their policy cues from them. That the GOP’s position changed too and aligned with the Obama administration’s further supports that explanation.

The problem for U.S. policymakers was that by this point, summer 2009, there was a Japanese general election fast approaching in August and the ruling LDP knew that it was in for a difficult election. They did not want to implement sensitive compromises then, better to wait until September.\textsuperscript{156} The LDP had been in power for all but 11 months since the 1950s, which is why Japan has often been held up as an exemplar of a single-party democracy, and so there was some sense that the issue could be dealt with after the election. Perhaps, had the LDP remained in power, there may have been some way for the two states to find agreement. The LDP’s loss of power to the DPJ in August 2009 buried any chance of that however.

\textbf{The DPJ and Beef Imports: August 2009-September 2010}

The DPJ had spent years castigating the LDP as too subservient to the United States and insufficiently protective of consumers.\textsuperscript{157} The DPJ had held up every concession that the LDP had made to the United States from 2005 to 2009 as indicative of the LDP’s craven diplomacy and had called for a much tougher approach to U.S. beef imports.\textsuperscript{158} Even if its leaders had wanted to compromise with the U.S. on regulatory trade barriers in beef, such a naked volte-face, at least in the near term, would have been a humiliating climb down with little domestic upside. Moreover, the divisions within the DPJ, which was created in 1998 as a merger of several smaller parties,

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continued to shine through on trade policy. Though the party had used the beef regulation dispute as a cudgel against the LDP and though some DPJ members opposed trade liberalization, other DPJ members were in favor of a broader trade agreement with the U.S. as a way to promote Japanese exports; these members were thus willing to consider a relaxation of Japan’s regulatory trade barriers against U.S. beef if it were part of a larger trade agreement. Though that created some potential room for compromise, it also meant that attempting to address this issue jeopardized splitting the already fractious party. Percolating disputes with the U.S. over other agenda items made the issue even more politically fraught for the DPJ.

In 2006, the LDP had signed an agreement with the United States to move the U.S. base at Okinawa, which was highly unpopular with local residents, from Futenma, a major urban center, to a less populated area of the island called Henoko. During the 2009 election, DPJ leader Hatoyama had promised to move the base off of the island of Okinawa completely. After the DPJ won, Okinawa residents believed that they would finally be rid of this foreign military base, which many of them despised. When the DPJ ultimately had to allow the base to remain on the island, large protests against leaving the base in Okinawa ensued. The public relations damage to the DPJ was so bad that DPJ leader Hatoyama was forced to resign.
Once again, trade considerations were not made subservient to security concerns; neither the Japanese nor the American government attempted to barter away their position on beef regulations to win concessions on the basing dispute. In fact, the Futenma basing dispute meant that the DPJ did not believe it could afford to be seen caving to American demands regarding an issue as sensitive as consumer safety. Not only did this basing controversy leave the DPJ with even less political room to be seen as compromising with the United States but it also led to leadership changes that added an additional hurdle to resolving the beef trade dispute.

The new Prime Minister, Naoto Kan, largely left the cabinet the same. However, one of the few changes he did make directly affected policy related to trade and beef regulations. Kan’s choice to head the MAFF was Masahiko Yamada, a devoutly protectionist beef farmer who had written a book titled *America Will Destroy Japan’s Food Industry* and a dystopian novel titled *The Japan-US Food War: When Japan Goes Starving*. Little else needs to be said about his policy outlook. The compartmentalization of Japanese policymaking meant that Yamada would play a major role in determining the extent to which the government compromised with the U.S. over BSE regulations and trade in beef as long as he was in office. Kan chose him because he had been close to Ichiro Ozawa, a long time power broker within the DPJ who had been forced to resign with Hatoyama, and Kan wanted to hold the various factions in his party together.

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Later that year, when Ozawa attempted to usurp Kan’s leadership of the DPJ, Kan was able to beat back the challenge to his leadership and consolidate his control over the DPJ. Soon thereafter, he sacked Yamada, replacing him with a free trade advocate and installing Akihiro Ohata, another proponent of trade liberalization, as the head of the Ministry of Economy, Trade, and Industry. U.S.-Japan discussions over the beef issue ensued directly after this shake-up, though nothing was agreed to in the immediate sense. The new Japanese leadership did signal its seriousness in considering relaxing the regulatory barriers by asking the United States to provide the data it would need to conduct an internal risk assessment that would be the first step in that process. The change in Japanese leadership and their tentative steps toward meaningful negotiation augured well for compromise on the beef trade issue. It was at this point that the nascent Trans-Pacific Partnership (TPP) began to gain salience in Japan. That increased salience brought hitherto uninvolved domestic actors into the negotiation of regulatory barriers in beef.

**The TPP, Farmer Protests, and the Triple Disaster: October 2010-October 2011**

The Trans-Pacific Partnership (TPP) began in 2005 as a free trade agreement between New Zealand, Brunei, Chile, and Singapore but by 2010 had been joined by Peru, Malaysia, Australia, Vietnam, and the U.S. and so had grown immensely larger in geographic and economic terms. To this point, the main actors in this case have been Japanese consumer organizations, Japanese policymakers, American beef producers, and American policymakers as they were the four groups that had an interest in beef.

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regulations and trade. The attenuations and increases in the regulatory trade barriers in beef were based on their respective positions. The TPP gave Japanese beef producers and Japanese export oriented businesses an interest in those regulatory trade barriers as well.

Japanese beef producers had never really entered the political contestation over these regulatory trade barriers. The reason they did not was because their competition was not U.S. beef imports in particular so much as imports period. As long as Australia and other states could provide beef to fill the lost American supply, Japanese producers’ incomes were not really affected by the regulatory trade barriers.\(^{171}\) Perhaps, had the Japanese regulations been disguised forms of protectionism that excluded all imports, Japanese beef producers would have been major defenders of those regulations. Given that these regulatory barriers did not erect tariff-like walls that affected all imports however, beef producers had to no reason to expend political capital on regulations. Instead they would save their organizational strength for the policy fights that did matter to them: tariffs and other non-regulatory trade policy, and it was exactly those kinds of policy fights that the TPP was creating.

Throughout this time period (2001-2010), whenever international negotiations over beef involved tariffs or other trade barriers not related to regulation, Japanese beef farmers loudly opposed any trade liberalization. For example, at the behest of Japanese beef farmers, the Japanese government chose not to end safeguard tariffs early despite the fact that they were generally considered unnecessary and were raising prices for consumers.\(^{172}\) In 2007, Japanese farmers had blocked trade liberalization talks with the


In 2008, they had also stood in the way of a free trade agreement with Australia. In these episodes, the negotiations over regulatory and non-regulatory trade were always kept separate. That would not be the case for the TPP.

These farmers understood that the U.S. would demand compromise on beef regulations as a price of Japanese entrance into TPP negotiations. In other words, Japanese beef farmers saw regulatory trade barrier relaxation in beef as paving the way for the TPP which would lower tariffs, thus reducing the costs of imports which in turn would threaten their livelihood. These farmers saw those regulatory trade barriers as a roadblock to that and wanted to ensure that roadblock stayed in place. Just days after Prime Minister Kan began to signal that the government was considering joining the TPP, thousands of farmers rallied in Tokyo against it.

Meanwhile, the conclusion of a free trade agreement in December 2010 between the U.S. and Korea gave Japanese businesses an augmented interest in getting Japan to join the TPP. 70 percent of Japanese and South Korean exports to the United States are in the same two commodities: cars and machinery. Japanese businesses, especially in these two areas, feared that the Korea-U.S. free trade agreement had given their Korean rivals a significant competitive advantage and that now they too needed a free trade agreement between the United States and their country in order to compete in the lucrative American market. Fortunately for them, the TPP presented just such an opportunity, if only they could get the U.S. government to acquiesce to Japan’s inclusion

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in the TPP. Like Japanese farmers, these businesses also recognized the extent to which the regulatory barriers in beef trade functioned as a roadblock to Japan’s entry to the TPP negotiations. Unlike those farmers though, they badly wanted this roadblock removed.

The addition of non-agricultural issues to the trade docket also had a significant impact on the Japanese government’s approach to these issues. In principal, the Ministry of International Trade and Industry (MITI) controls Japanese trade policy. However, when the trade policy at hand is agricultural, the Ministry of Agriculture (MAFF) is given primary responsibility in that negotiation. MAFF is generally more inclined toward protectionism than MITI. As long as the negotiations over regulatory barriers on beef remained isolated from other trade issues, MAFF controlled Japan’s position. Once regulatory barriers in beef became embedded in a larger constellation of trade issues, MITI became the leading player in formulating Japan’s trade policy.

Moreover, exchanging one trade concession for another did not generate the political blowback that exchanging agreement on the beef issue for non-trade concessions threatened to. This suggests something interesting about the nature of cross-issue linkages in trade negotiations. Which issues are getting cross-linked matters a great deal. How citizens and policymakers think about concessions is central to which concessions can be made. Linking other trade-related issues to the beef regulation dispute created greater space for compromise because both sides in a trade negotiation recognize that concessions are a prerequisite for the successful conclusion of the negotiation. Conversely, linking security-related issues was, at best, a non-factor in the negotiation over regulatory trade barriers, and at worst, made finding a resolution more difficult.

While the deliberations surrounding joining the TPP were occurring, in March 2011, Japan was struck by the triple disaster of an earthquake, tsunami, and subsequent nuclear crisis. Progress on compromise over these regulatory trade barriers in beef was slowed by the simple fact that the catastrophe understandably pushed all other agenda items to the margins while recovery and reconstruction began in earnest in the spring and summer of that year.

The 30-Month Compromise is Finally Reached: October 2011- March 2013

By fall 2011, Yoshihiko Noda had replaced Naoto Kan as DPJ leader and Prime Minister. His positions on trade were essentially the same as his predecessor’s. By this point, the mood in Japan regarding the country’s BSE countermeasures had begun to shift. *Yomiuri Shimbun*, Japan’s most widely circulated newspaper, which had opposed some earlier efforts to relax the beef regulatory trade barriers, now supported such a move.181 Later, *Yomiuri Shimbun* even specifically admonished consumer groups for continuing to oppose relaxation, thus providing political cover from Japanese political leaders who wanted to advance exactly that position.182 Moreover, public sentiment towards relaxed rules had softened as the total global number of cattle found with mad-cow disease had fallen to 29, which was an almost infinitesimally small fraction of the high-water mark of 37,000 cases.183

By this time, most middle class urban consumers were accepting of American beef.184 This is a critical point because the diminishing consumer hostility to relaxing the regulatory trade barriers on American beef imports was essential in giving the Japanese

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181 *Yomiuri Shimbun.* “Beef Import Limits Must Conform To Global Standards.” October 22, 2011.
government the political space to agree to those relaxations. Even with Japanese export-oriented businesses pushing for the TPP, the government would have found it very difficult to relax those regulatory trade barriers on beef had the general public still been aroused in opposition. This change suggests that not only were Japanese consumer organization critical in promoting the augmentation of regulatory trade barriers but were also key is allowing an attenuation of regulatory trade barriers through their acquiescence. It was in this context that in October, the Japanese government announced that it intended to revise its BSE regulations, which clearly signaled that it was strongly contemplating relaxing the age regulations on beef. Soon thereafter, the Japanese government formally announced its intent to join the TPP talks.

Relatedly, this case complicates the ‘business dominates’ hypothesis. Throughout this case, U.S. beef producers pushed for a relaxation of regulatory barriers. They enjoyed a cozy relationship with U.S. officials who adopted and fought hard for their policy positions. Still, time and again, in terms of international negotiation outcomes, they lost that policy fight. Despite their constant efforts, it took them a decade to regain full market access, at the cost of billions of dollars to themselves. At no point were they defeated by a competing business interest. Instead, their losses came at the hands of consumers groups, i.e. the interest most frequently held up as the exemplar of diffuse, weak interests. It was only when consumer fears had subsided that American businesses, i.e. the interests most frequently held up as the most powerful private interests in the world, were able to enact their policy preferences.

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Let us assume that U.S. beef exporters, over the time period of this case, had been able to maintain the same market access they enjoyed prior to December 2003. Beef exports to Japan averaged 118.2 million dollars per month for the first 11 months of 2003.\textsuperscript{187} The shaded region in Figure 4.2 represents those beef producers lost exports from December 2003 to March 2013. That lost revenue totals 9.2 billion dollars.\textsuperscript{188} If business dominates, it does not lose 9.2 billion dollars in revenue at the hands of the paragon of diffuse interests defending regulations those firms perceive to be illegitimate.\textsuperscript{189}

Figure 5.2: Revenues Losses for U.S. Beef Producers

The U.S. government politely welcomed the Japanese announcement but made it clear that in the context of TPP negotiations they expected actual movement on the regulatory barriers in beef, not just signals and promises of future movement.\textsuperscript{190} The next month, Tami Overby, the Vice President for Asia of the U.S. Chamber of Commerce,

\begin{figure}[h]
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\includegraphics[width=\textwidth]{us_beef_exports_to_japan.png}
\caption{U.S. Beef Exports to Japan}
\end{figure}

\begin{itemize}
\item\textsuperscript{187} As with the chart on page 1, the data this paragraph and chart are based on comes from monthly data collected by the U.S. Meat Export Federation. That data can be found at: https://www.usmef.org/news-statistics/statistics/ (Last Accessed April 28, 2016).
\item\textsuperscript{188} This figure was arrived at by subtracting actual monthly exports from the 118.2 million dollar monthly average for January-November 2003 and then summing those differences.
\item\textsuperscript{189} Figure 4.1 is based monthly data from the U.S. Meat Export Federation. https://www.usmef.org/news-statistics/statistics/. Accessed April 28, 2016.
\item\textsuperscript{190} \textit{Inside U.S. Trade.} “Marantis Visits Tokyo; Outlines U.S. Priorities on Autos, Beef, and Japan Post.” November 25, 2011.
\end{itemize}
echoed this saying that “now we need to see action. Not words, action” and specifically called on Japan to enact three “confidence-building measures” that would demonstrate Tokyo’s readiness to participate in TPP talks. The United States government, specifically the USTR, soon adopted this very position, even using the exact same ‘confidence building measures’ phrasing. With regards to beef regulations, the National Cattlemen’s Beef Association announced its support for Japan’s entrance to TPP negotiations contingent on Japan relaxing its regulatory barriers on U.S. beef.

In September 2012, the Japanese government took another procedural step toward altering its 20-month regulations on beef to 30-months, pleasing the U.S. Meat Export Federation (USMEF) as well as the USTR. The LDP, which took power after elections in December 2012, contained even fewer opponents of the regulatory alterations than the DPJ had. Interestingly, even though they did not oppose relaxing these regulatory trade barriers in beef, many LDP Diet members did oppose Japanese participation in the TPP as a whole because they did not want to see reductions in agricultural tariffs; they even specifically stated that their opposition stemmed from their concern for the farming sector, again undermining the idea that these regulatory trade barriers were sneaky forms

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of protectionism as well as contradicting the behavior we should have seen based on the expectations of the cleavage-based explanations.\textsuperscript{196}

In January 2013, the Japanese government announced that it was changing its regulations to the 30-month age limit.\textsuperscript{197} U.S. beef producers now had essentially 90-95 percent access to the Japanese market. They could finally resume their roughly billion dollar annual level of exports to Japan. Once the regulatory relaxation was fully implemented in March, the National Cattlemen’s Beef Association endorsed Japan’s involvement in TPP negotiations “as soon as possible.”\textsuperscript{198} After Japanese Prime Minister Abe officially announced that Japan would be seeking entrance to the TPP, the U.S. government, for the first time, supported Japan’s inclusion in the TPP.\textsuperscript{199}

**Conclusion: The Surprising Difficulty of Catching Roadrunner**

There was a certain Wile E. Coyote quality to the negotiations over these regulatory barriers. Just when U.S. and Japanese negotiators thought they had found a way to use an ACME rocket to catch Roadrunner (i.e. compromise on regulatory barriers in beef), the rocket would explode, obliterating their best-laid plans. To wit, the negotiators thought they had found agreement in fall 2004 but were stymied by something as technical and seemingly inconsequential as age-verification techniques. In January 2006, again the negotiators thought they were making progress only to be thwarted by slapdash producers allowing spinal cords to find their way into beef packages. In 2009-2010, hopes for agreement were first dashed by a stunning election result and then by an unrelated controversy over military base locations. The reason these

events had the power to block progress toward compromise on these regulatory barriers was because those barriers were embedded in sensitive domestic politics. Finding agreement on issues that affect consumers’ health and safety required engaging in a laborious and contentious process. Given that sensitivity, any number of trends and dynamics had the potential to act as a roadblock.

Relatedly, nesting the international negotiation over these regulatory trade barriers within a milieu of other issues undermined compromise on the regulatory barriers at least as often as it facilitated compromise. Adding issues to the negotiating agenda is often considered to be an avenue toward reaching a deal because it increases options and gives each side a greater ability to find some concession on an unrelated matter. The more issues that are the table, the easier it is to find some concession on issue Y that can be exchanged for movement on issue X. Indeed, this logic is what has traditionally underpinned conducting trade negotiations in a single undertaking, i.e. lots of issues negotiated on once. While that sort of tradeoff did occur within the context of Japan gaining access to the TPP in exchange for regulatory trade barrier relaxation, in other instances, additional agenda items such as the base dispute made compromise harder to reach because the Japanese government felt that it could not be seen as capitulating to the United States on two issues at once. This suggests that embedding multiple issues into a single undertaking, a maneuver that was quite effective at promoting trade liberalization in tariffs and other non-regulatory measures, may actually backfire when applied to some regulatory trade barriers.

At first glance, regulatory barriers seem like the kind of technical, low-salience issues that should allow for easy cooperation between governments, especially when
business interests are pressuring them to do so. Businesses move to reduce those regulatory trade barriers and think they will be able to do so easily because they perceive themselves as being the only entities interested in them. Governments, responding to these entreaties from business, explore international cooperation over those regulatory barriers and then find, to their surprise, that catching the compromise Roadrunner is not so easy because activists also care about those regulatory barriers. This process of policy deal exploration and then surprise opposition happens because most people do not get excited when they hear the word “regulation.” When talked about in the abstract, trade regulations seem remote and almost painfully boring, but when the regulations being discussed take concrete form and affect those citizens in a tangible, easy-to-understand way, some of those citizens get quite animated and when they do, they detonate the ACME rocket. Only when those activists can be prevented from doing so either through persuasion or political marginalization can negotiators pursue their policy prey unimpeded. This is why finding a mutually acceptable attenuation of regulatory trade barriers requires Sisyphean perseverance.
Chapter 6 - Small Details, Enormous Consequences: Regulation and the International Trade in Pharmaceuticals

Introduction

Perhaps more than any other product, pharmaceuticals distill the complex interplay between commercial interests and non-economic public policy goals that is at the center of regulation and trade politics. The global trade in pharmaceuticals is worth approximately $550 billion annually.¹ Drugs generate massive sales because they are indispensable in promoting the health of huge numbers of people around the world. Almost everyone will take some form of medication at some point in their lives. Governments have an interest in promoting the health of their citizens and thus have an interest in promoting access to safe, effective medications. This is why drugs were amongst the first products to be closely regulated by governments.²

Across the globe, societies are aging and developing, which means they are likely to spend greater shares of their GDP on health care.³ This means that the trade in pharmaceuticals is likely to continue growing larger and more geopolitically significant. Moreover, given the increasing extent to which different states’ disparate regulations on pharmaceuticals impact this global trade, the content of those regulations is also becoming a central issue in international trade negotiations. The very last issue resolved

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² While Upton Sinclair’s The Jungle and the filth of meatpacking lead the meat industry to garner most of the attention in the Progressive Era growth in regulation, the 1906 legislation that regulated new industries was in fact called The Pure Food and Drug Act. The public consequences of the proliferation in phony, or worse poisonous, tonics were as gruesome as the foulness of much food at the time. For an examination of early efforts to regulation drugs in the United States. Hilts, Philip. 2004. Protecting America’s Health: The FDA, Business, and One Hundred Years of Regulation. University of North Carolina Press: Chapel Hill. p. 3-55.
in the Trans-Pacific Partnership negotiations was what length of data exclusivity to give to patented biologic drugs.\(^4\)

Pharmaceutical companies are highly reluctant to produce drugs in, or import drugs into, countries in which their intellectual property will not be respected. Refusing to protect a firm’s intellectual property constitutes a trade barrier because it prevents that firm from reaping gains from trade and so effectively prohibits them from engaging in international trade. Differences in regulation on intellectual property thus have the power to impede the trade in pharmaceuticals and thus constitute regulatory trade barriers.\(^5\)

Those regulatory barriers are becoming the centerpiece issues in the geopolitical negotiations that surround the trade in pharmaceuticals.

The United States and India are two of the central players in the geopolitics of drugs and will likely continue to be so for the foreseeable future. The United States is home to some of the largest, most advanced drug companies in the world.\(^6\) It has been a leader in using regulation to promote a highly efficient pharmaceuticals sector.\(^7\) More controversially, it has attempted to get other countries to adopt intellectual property regulations similar to its own. It is the leader of the camp that wants intellectual property

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regulations set at high levels.\textsuperscript{8} Still, it is no exaggeration to say that without the United States and its drug firms, many of the miraculous drugs in existence today would not exist, and many millions of people would have had shorter, less fulfilling lives. For its part, India has been a leader in using intellectual property regulations to promote access to medicines for even the poorest of citizens. It has been the leader of the camp that wants intellectual property regulations set at lower levels. It too is no exaggeration to say that without India, many millions of people would have had shorter, less fulfilling lives, not because the drugs they needed did not exist, but because those drugs were too expensive.

The extent to which states’ regulations on intellectual property differ has varied over time. The negotiation of the Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS) in the 1980s and early 1990s significantly reduced those regulatory differences. The Doha Declaration in 2001 strengthened the flexibilities in the TRIPS Agreement and so gave states greater policy room to re-expand those regulatory differences. Subsequent WTO decisions from 2003 to 2015 amounted to a stalemate that preserved the policy space that allowed these regulatory differences. India also found ways after 2005 to creatively interpret TRIPS provisions to further increase those differences but selectively employed those flexibilities in ways that balanced the interests of activists and drug companies. This chapter explains that variation.

Table 6.1- Regulatory Trade Barriers Outcomes In Pharmaceuticals

<table>
<thead>
<tr>
<th>Regulator</th>
<th>Outcome</th>
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<tbody>
<tr>
<td>TRIPS</td>
<td>Decrease</td>
</tr>
<tr>
<td>Doha Declaration</td>
<td>Increase</td>
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<tr>
<td>WTO Decisions</td>
<td>Buy-Out</td>
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<tr>
<td>Indian Flexibilities</td>
<td>Buy-Out</td>
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\textsuperscript{8} For the purposes of this chapter, I am defining high regulations as those that increase the scope of intellectual property protection. Thus a 20-year patent and 12 years of data exclusivity are considered higher regulations than 15-year patents and 5 years of data exclusivity.
I explain this variation by examining the political bargaining between pharmaceutical companies, access to medicine advocates, and government officials. In the TRIPS negotiations, two factors were key to pharmaceutical companies and the U.S. government officials that identified with them being able to significantly reduce those regulatory differences. First, activists were still not engaged on the issue and so had the negotiating terrain to themselves. Second, pharmaceutical companies were able to successfully link their policy requests with broader societal concerns about economic competitiveness.

In the negotiations leading up to the Doha Declaration, activists were able to wage a highly successful public relations campaign and work with developing country government officials to force pharmaceutical firms and their allies in Western governments to accept an increase in those differences. They were able to do this by linking uniform intellectual property regulations with needless death, specifically the AIDS crisis in Sub-Saharan Africa.

In the WTO decisions that pertained to intellectual property and pharmaceuticals, the two sides fought to a draw and so the international legal architecture on intellectual property has largely remained the same. The Indian government has sought to pacify access to medicine advocates as well as multinational pharmaceutical firms and so has used TRIPS flexibilities in creative ways that uphold firms’ intellectual property much of the time but still curtail them often enough to please activists.

A Primer on Intellectual Property Regulations

The Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS) structures those intellectual property (IP) regulations that have significant trade implications. One set of those regulations concern patents and so shape the international
trade in pharmaceuticals. At their heart, the IP regulations that surround patents are an attempt to balance the desire to limit monopoly and at the same time limit free riding.

On the one hand, the intellectual work that goes into a given product has to be protected from being imitated before the creator can be appropriately compensated. Doing nothing to prevent this sort of free riding undermines the incentive to innovate and leaves society as whole worse off. This is particularly the case when there are significant up-front research and development costs. If it costs 2.5 billion dollars to develop a new drug but the marginal costs of producing every additional pill is one cent, a second company can come along, copy the drug, and profitably sell it for far less because it never incurred that $2.5 billion cost. Knowing this, the first company would be foolish to invest those $2.5 billion in that new drug unless there is some mechanism to prevent the second imitating company from undercutting it. That mechanism is a patent.

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9 TRIPS also deals with copyright, trademarks, and geographical indicators. Those three areas are not nearly as central to the trade in pharmaceutical products as patents and so this chapter will bypass them.

10 For a concise economic discussion of these two competing goals, see Winegarden, Wayne. 2014. “The Economics of Pharmaceutical Pricing.” Pacific Research Institute.

11 This number comes from one of the most widely used estimates for the cost of new drug development and takes into account the costs of drug failures and capital costs. DiMasi, Joseph, Henry Grabowski, and Ronald Hansen. “Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs.” Tufts Center for the Study of Drug Development. November 18, 2014. Access to medicine advocates contend that this number is too high and argue that R&D can be done for much less. Love, James. “KEI Comments on the New Tufts Study on Drug Development Costs.” November 18, 2014. Knowledge Ecology International. Others have noted that the Tufts Center is primarily funded by research-based drug companies and so has a clear incentive to arrive at a high estimate, which helps justify high drug costs. Their earlier estimates are also based on a sample of drugs that seems to have been intentionally selected to produce high estimates. Dukes, Graham. “Assessing the Empirical Evidence on the Costs and Benefits of Developing New Drugs- A Global Perspective.” Paper presented at ESF-IFW Conference: “The International Regulation of New Medical Technology: Health Technology Adoption in the European Union, North America, East Asia, and in the Developing World.” Salzau Castle, Germany. May 7-10, 2007. p. 3. Still, even if the 2.5 billion estimate is inflated, there is no doubt that developing a new drug is very expensive.

Patents give businesses the exclusive right to market their invention for a given period of time; in other words, it gives them a temporary monopoly.\textsuperscript{13} They are granted for new inventions that meet three criteria: novelty, non-obviousness, and usefulness.\textsuperscript{14} The stronger patent regulations are, that is the longer the patent lasts and the more effectively it prevents free-riding, the greater the commercial incentive will be to invest in new drugs. Pharmaceutical executives point to stunning improvements in the health outcomes for patients with diseases such as HIV and hepatitis C that used to be death sentences and contend the profitability of drugs for those diseases is the major incentive driving this innovation.\textsuperscript{15} And in fairness to the pharmaceutical companies, society now has in its possession a vast array of medicines that are highly effective and that, because they are now off-patent, are incredibly cheap. Yes, these medicines were expensive when they first came out and yes, pharmaceutical companies created them out of profit-seeking rather than philanthropic motives, but it can still be credibly argued that the stringent IP regulations that the United States employs built that storehouse of wonder drugs.

Pharmaceutical companies also contend that, despite the eye-popping costs of some drugs, they actually save the overall health care system money by preventing more expensive procedures such as transplants and extended hospital stays.\textsuperscript{16}

\textsuperscript{13} The length of that patent monopoly is of course a critical distinction.

\textsuperscript{14} As will be explained later, different states’ patent regulations define and apply these terms in different ways, which has significant implications for which drugs receive patents and which do not.


\textsuperscript{16} Anderson, Richard. “Pharmaceutical Industry Gets High on Fat Profits.” \textit{BBC News}. November 6, 2014. Ingram, Robert. “A Not-So-Transparent Attempt to Cap Drug Prices.” \textit{The Wall Street Journal}. July 19, 2015. It is also important to think about the difference between cost per dose and cost per cure. In 2010, hepatitis C drugs costs $50,000 and cured a little over one-third of patients so the cost per cure was about $140,000. Sovaldi is $85,000 but cures 95 percent of patients and so the cost per cure is actually about $50,000 less than previous treatments. Scannell, Jack. “Four Reasons Drugs Are Expensive, Of Which Two are False.” \textit{Forbes}. October 13, 2015.
Finally, because the catalogue of available medicines continues to improve, the benchmark that pharmaceutical companies must exceed to create new medicines continues to get higher. The first person to invent Tylenol could patent that. The second person had to invent something better than Tylenol, which was harder. The third person had to invent something that was better still, and so even more difficult. Every generation of scientists makes the next generation’s job that much harder. This is yet another reason why drug firms want patents to be as strong as possible. If it is getting ever harder to invent patentable products, they have an even greater incentive to ensure that those that do get patented are revenue bonanzas.

It is not just patent regulations though that pharmaceutical companies want expanded. They also want a high regulatory standard for what is known as data exclusivity, especially for biologics, today’s cutting edge medical products that cost far more to develop than traditional small-molecule drugs. When research-based pharmaceutical firms attempt to get their product approved by regulators such as the FDA, they must provide extensive amounts of data demonstrating the safety and efficacy of their drug. When the patent term on that drug expires, generic firms can make copies of that drug. Rather than repeat the costly and difficult tasks needed to replicate the data that demonstrated the drug’s safety and efficacy, the generic firm will simply use the first firm’s data. After all, if H₂O was safe to consume when it was sold by Prescott pharmaceuticals, it should be just as safe when sold by a different firm.

17 Scannell, Jack. “Four Reasons Drugs Are Expensive, Of Which Two are False.” Forbes. October 13, 2015. This is also one of the main reasons why drug firms’ research has moved toward more serious diseases because it is on those diseases that the inelasticities are greatest and the regulators are most willing to accept risks. Ibid.

Research-based firms argue that the generic firm using their data is still free-riding and that because they produced that data, they own it and should have exclusive rights to it.¹⁹ The government granting this data exclusivity effectively lengthens patent times by forcing the generics firm to repeat the trials that created that data, thus making it more difficult for a generic to enter the market.²⁰ Research-based firms base their arguments in favor of data exclusivity on the same incentives-promotion premises as their support for extensive patents.²¹ While there is certainly some validity in drug firms’ claims regarding IP regulations, one does have to take their position with a grain of salt given that it is clearly in their direct financial interests to promote high IP regulations.

While high intellectual property regulations do create powerful incentives for innovation, they are not without drawbacks. Monopolies, which are what patents effectively constitute, limit competition, thus raising prices for consumers. The very profits that create that incentive come from consumers, insurance companies, and the government. That incentive may have sparked innovation, but it is still astoundingly expensive. All told, the United States spent $374 billion on prescription drugs in 2014.²² There is also a great deal of profit making in that. The ten largest pharmaceutical firms had an average profit margin in 2013 of 19.6 percent.²³

²¹ Pharmaceutical Research and Manufacturers of America. “12 Years of Data Protection in TPP.”
One of the major drivers of these high profits is that medicines are the epitome of inelastic goods.\textsuperscript{24} When the extent to which a good is purchased varies more than a change in price, that good is elastic. So if the price of a good increases by 10 percent and its sales drop by 30 percent, that good is elastic. If that same 10 percent increase only leads to a 3 percent drop in sales, that good is inelastic. Elastic goods are typically those goods that are less necessary, have many substitutes, and for which purchases can more easily be postponed. Medications for serious diseases do not demonstrate any of these properties. The upshot of a good being inelastic is that the most sensible business strategy, from a purely revenue perspective, is to raise the price since the revenue increase from the raised price will overwhelm the revenue loss from the few people who stop purchasing the good.\textsuperscript{25} At a basic level, the source of drug firms’ massive profits is that they produce what might be the most inelastic goods in the world.\textsuperscript{26}

From a purely revenue perspective, it makes sense for pharmaceutical firms to charge as much as they can get for a product, but from a societal perspective, generating huge revenues for drug companies is not the point of IP regulation. The point of IP regulation is generating an incentive to innovate. Those who are opposed to higher levels of IP regulations, such as access to medicine advocacy groups like Oxfam International, argue that it is not obvious that prices and profits must be totally unbounded to produce

\textsuperscript{24} In this paragraph, I am referring to demand, rather than supply, elasticities.

\textsuperscript{25} For a look at the internal discussions pharmaceutical companies have to determine the price of a new drug, see Johnson, Carolyn and Brady Dennis. “How an $84,000 Drug Got Its Price: ‘Let’s Hold Our Position Whatever the Headlines.’” \textit{The Washington Post}. December 1, 2015.

\textsuperscript{26} This inelasticity, not the research costs, is primarily what determines a drug’s cost. As Peter Ubel, a doctor and professor of business at Duke University put it “if I’m the pricing person for something, I’m not looking at how much we spent making it. I’m looking at what I think the market will bear.” Stockton, Nick. “How Prescription Drugs Get So Wildly Expensive.” \textit{Wired}. September 23, 2015.
the same incentive. Gilead made 10.3 billion dollars on Sovaldi in 2014; would they really not have done research on a hepatitis C cure if Sovaldi were only going to net 4 billion dollars in revenue in 2014? Must pharmaceutical companies be allowed to charge whatever the market will bear for an adequate incentive to innovate to be present? Of course, drug companies would answer that question with a yes and access to medicine advocates would say no, but both answers come from sources with clear, vested interests in giving the answers they give. The correct answer, like so many answers in social science, is probably a combination of ‘we do not know’ and ‘it depends.’

Opponents of higher IP regulations also contend that they slow innovation by preventing researchers from borrowing certain ideas or working on certain projects. They also restrict the flow of information, which almost by definition slows scientific progress. For this reason, they are particularly critical of data exclusivity provisions and efforts to limit Bolar exemptions.

Relatedly, they are major proponents of compulsory licenses, which are a mechanism by which a state gives a license to a generic firm to manufacture copies of a patented medicine without the permission of the inventing firm. They are, in effect,

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Patent revocations and so bring drug costs down. As will be discussed below, there have been extensive negotiations over the conditions under which states may issue these compulsory licenses. Pharmaceutical firms want these conditions to be as constraining as possible while access to medicine advocates want them to be as permissive as possible. This concern with costs is also why access to medicine advocates want tight rules on what makes a drug patentable so as to prevent drug companies from profiting through ‘evergreening’, which is when those firms extend the life of a patent, and thus keep the cost of a drug high by making small changes to the product and re-patenting it.33 Those opposed to higher IP regulations do not want those regulations eliminated though they do want them relaxed.34 In a nutshell, they want shorter patent times, no data exclusivity, fewer curbs on Bolar exemptions, fewer strings on compulsory licensing, and tight rules on what qualifies as patentable. They also point out that drug firms’ poor mouthing about huge R&D costs is undermined by the fact that nine out of ten of the largest drug firms spend more on sales and advertising than they do on R&D.35 They also

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point out that the U.S. government, through NIH grants and tax credits, subsidizes much of the drug firms’ R&D costs. Thus, because the risks of that money being spent on a failed drug have been socialized, the benefit from a successful drug should also be socialized. Entirely privatized profits only makes sense if the risks too are entirely privatized and they are not. Most critically, those who oppose higher IP regulations argue that those regulations lead to drug prices so high that they make drugs unaffordable for poor people in developing countries.

**Background to the Cases**

Outside of Western developed countries, there have been few if any cultural traditions supporting stringent IP rights. Knowledge was considered a collective good and imitation was considered appropriate, possibly even a form of flattery. For the first two decades after World War II, the lack of patent protection in developing countries did not really concern Western pharmaceutical firms because their profits were much less dependent on patent protection than they are now. Indeed, until the 1960s, most developed countries also did not have extensive IP protections. Patents were often only on the process of producing a drug, not the drug itself, and so there was a significant

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amount of reciprocal reverse engineering which helped these states build large pharmaceutical infrastructures and keep drug prices down.\textsuperscript{42}

Even once they became more concerned with patents, there were few if any firms in those developing states that had the capacity to copy their drugs anyway.\textsuperscript{43} IP was also not really considered a trade issue at this time either. It had been left out of the GATT almost entirely.\textsuperscript{44} Developments from the late 1960s to the early 1980s however created tensions between Western drug firms’ commercial aims and developing countries’ IP regulations.\textsuperscript{45}

During the 1960s, India had some of the world’s highest drug prices despite its poverty and so its government redesigned its IP legal system to reduce the costs of drugs.\textsuperscript{46} In 1970, India passed a new patent law that prohibited patents on drugs.\textsuperscript{47} It only allowed patents on the process by which a drug was made.\textsuperscript{48} Allowing process patents but not product patents meant that generic drug makers were incentivized to make the same drugs as Western firms but to find ways to do so more cheaply.\textsuperscript{49} This led to Indian firms becoming highly skilled reverse engineers that excelled at producing drugs at very low

\textsuperscript{43} Drahos and Braithwaite. 2002. Information Feudalism. p. 67.
This new IP regime resulted in much lower drug prices. It also meant that Indian firms became major exporters to other developing states. India’s IP regulations were not just important because of what they did to the Indian market, but also because India was a leader among developing states in attacking stringent IP regulations.

**Pushing Against an Open Door: The TRIPS Negotiation**

As developing countries’ IP regulations became more injurious to Western drug firms’ interests, they became much more highly motivated to reduce those regulatory trade barriers in IP. Activists, who might have fought against these firms’ efforts, were not yet significant participants in IP politics. With businesses promoting the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), and with activists largely silent, government officials in the United States and India faced one-sided incentives and so gave businesses what they were asking for: significantly reduced regulatory trade barriers related to intellectual property.

**Business Efforts to Strength International IP Regulations**

By the late 1970s, the less stringent IP rules in the developing world, and in particular India, were starting to irritate Western pharmaceutical firms. Also, advances in technology combined with a lack of enforcement mechanisms had made violating IP

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53 India’s leadership role within the developing world was not just in pharmaceuticals. In the 1960s, India led developing countries in pushing for reforms to international copyright treaties because they saw that IP protection as inhibiting their ability to promote mass education. I. Olian. 1974. “International Copyright and the Needs of Developing Countries: The Awakening at Stockholm and Paris.” Cornell Journal of International Law. 7:2. p. 3-26.
54 PhRMA President Gerald Mossinghoff argued that there was “no country in the world where patent piracy of valuable patented medicines has been more rampant or unchecked than India.” Harrison, Christopher Scott. 2004. The Politics of the International Pricing of Prescription Drugs. Praeger: Westport, CT. p. 80.
easier and increasingly rampant. On drugs specifically, technological advances had made reverse engineering patented drugs easier and cheaper. Moreover, by the early 1980s, Western drug companies had become much more dependent on patents for their revenue stream. At about the same time, these firms in the United States were also honing their lobbying skills and forming effective, durable political coalitions with each other as they collectively fought for changes in U.S. patent regulation.

Reverse engineering was beginning to eat into their sales across the developing world. Additionally, pharmaceutical companies started to worry that the emergence of cheaper copies of drugs in the developing world might lead to developed country citizens wondering why they had to pay so much more for a drug than what people in developing countries paid. These firms also tended to view developing country arguments against stringent IP regulations as simply a smokescreen for their “real” motivation, giving an advantage to domestic businesses. If developing countries’ IP regulations were going to undermine these Western companies in both new markets as well as established ones, something had to be done about them.

U.S. drug companies like Pfizer, as well as other IP-intensive firms such as IBM, wanted an international IP-regime that had two characteristics. First, they wanted

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developing states’ IP regulations to be raised to match U.S regulations. Patents terms should be extended; all classes of products, including pharmaceuticals, should be patentable; and the means to break these patents should be greatly circumscribed. Second, they wanted this new regime to have strong enforcement capabilities to prevent those developing countries from backsliding or ignoring their own laws whenever it was convenient. At the time, the primary international organization for IP issues, the World Intellectual Property Organization (WIPO) had no real means of enforcement and no dispute settlement mechanism. Also, because it only dealt with IP issues, there was no possibility of cross issue linkage. Even worse, from the perspective of these firms, was that it had a one-country, one-vote structure, which meant it was dominated by developing states.

At first, these businesses attempted to achieve their policy goals through WIPO, but after being stymied, they began looking for a new forum. This is where the GATT, and explicitly linking IP with trade, enters the picture. Jim Enyart, Monsanto’s point man on intellectual property explained how these firms approached WIPO, saying this about a meeting with Arpad Bogsch, the head of WIPO, in Bogsch’s penthouse overlooking Lake Geneva:

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“He fed us a multicourse lunch from his private dining room. It was concluded with cognac and cigars…Finally we said to him, “Look, Mr. Bogsch, we have found WIPO to be not constructive in the protection of IP and we are going to do something about it. You are either going to help out or we are going to go right around you.” And he said, “Well you can’t do that, we are the only authorized organization.” And we said, “Well, we are going to do it. You’ve got your choice; you either get on board or get left in the dust.” It turned out, when the negotiations started in GATT, Mr. Bogsch became very friendly and said that there was a great deal of expertise in WIPO and how there ought to be a huge role for WIPO in the TRIPS agreement. You will notice that the TRIPS Agreement has a reasonably weak consultative role for WIPO.”

IP-intensive firms, led by the drug companies, argued that developing states’ lower IP-standards were essentially theft of their intellectual property and amounted to piracy. These businesses successfully sold the causal story that intellectual property rights lead to free trade and investment and so promote economic growth. Moreover, in the mid-1980s the perception of a loss of competitiveness was something of a policy crisis in the United States; these businesses successfully capitalized on that crisis by arguing that the best way to improve American competitiveness would be to force other states to cease and desist with this intellectual property theft. The best place to do that, according to the firms, was in trade policy.

According to them, linking IP with trade would have several advantages. First, through the Generalized System of Preferences (GSP), it meant that there was something that could be exchanged for a country agreeing to higher IP regulations. Second, the single undertaking of the Uruguay Round meant that states could not pick and choose

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73 The GSP is an American trade program dating back to 1974 that grants developing countries additional tariff reductions on items they export to the U.S. in order to promote poverty reduction.
areas of the agreement to sign. It thus created cross-issue linkage and so states that never would have countenanced more stringent IP rules in isolation could be bought off with concessions in other areas. Finally, the GATT, unlike WIPO, had a dispute settlement mechanism, albeit a relatively weak one (though it would get strengthened as part of the Uruguay Round).

The industry’s lobbying efforts to place IP regulations on the Uruguay Round agenda were considerable. According to one US trade negotiator, Edmund Pratt and John Opel, the bosses of Pfizer and IBM respectively “basically engineered, pushed, and cajoled the government into including IP as one of the topics for the negotiation.”

Edmund Pratt and other pharmaceutical executives repeatedly beseeched government officials to make increasing other states’ IP regulations a centerpiece of U.S. trade policy. To build an intellectual foundation for linking trade and IP they partnered with conservative think tanks like the Heritage Foundation that President Reagan was known to respect. To pressure their governments to take a stronger stand on IP regulations, they formed alliances with executives in Europe and Japan. To sustain the momentum behind these efforts they created organizations such as the Intellectual Property Committee (IPC), a coalition of representatives from IP-intensive industries.

**NGOs Remain Silent; Government Listens to Business**

In contrast to the concerted efforts by business, at this time, there was little if any push back from activists against using trade policy to reduce differences in trade-related

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76 Drahos and Braithwaite. 2002. *Information Feudalism.* p. 70.
intellectual property regulations. Prior to TRIPS coming into force in 1995, health advocates really did not engage in IP at all; it was not part of their agenda because it was not perceived to directly affect their goals.79 NGOs just were not part of most of the Uruguay Round negotiations on IP.80 James Love, a prominent activist on medicine and IP has admitted that even as late as 1994, much less in the 1980s, “there was virtually no awareness in the United States or European [NGO community] of the scope and importance of the trade effort to raise levels of patent protection on medicines.”81 They were not alone. Public health agencies also had little to no understanding of what was being negotiated and so also sat on the sidelines.82 With activists not taking part in the IP negotiations in the Uruguay Round, business was pushing against an open door.

U.S. government officials responded warmly to the arguments made by these businesses. Competitiveness was a major concern at the time and blaming America’s loss of competitiveness on thieving foreigners was a convenient argument to buy.83 The argument did have at least some merit. In 1984, the U.S. International Trade Commission estimated that America businesses lost between six and eight billion dollars due to other states’ more relaxed IP regulations.84 The language of piracy was highly effective at getting U.S. government officials to take a very hard line in favor of higher IP standards as it made it a moral issue with many fewer shades of grey.85

Even if they were not IP specialists, and in almost all cases they were not, Congressmen could not help but notice that the businesses animated by a desire for higher IP regulations were some of the most significant businesses in America and thus their districts.\(^{86}\) Once drug firms’ focus was foreign rather than domestic IP laws, the issue of drug costs became much less important to legislators.\(^{87}\) The pharmaceutical industry’s status as one of the few industries that maintained a trade surplus further augmented its political standing on Capitol Hill.\(^{88}\) Finally, the arcane character of IP meant government officials often relied on business for guidance.\(^{89}\)

The executive branch was receptive to these businesses too. The Reagan and Bush administrations deeply respected property rights and so framing high IP regulations as defending intellectual *property rights* was highly effective.\(^{90}\) The Reagan Administration was a major proponent of trade liberalization and was eager to spearhead a new GATT Round.\(^{91}\) USTR Bill Brock also saw IP as a way of bolstering business support for trade liberalization.\(^{92}\)

Since 1981, Edmund Pratt had headed the Advisory Committee for Trade Negotiations (ACTN), a key group charged with providing the business community’s

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\(^{86}\) Drahos and Braithwaite. 2002. *Information Feudalism.* p. 86.


trade policy advice to the Executive branch.\textsuperscript{93} Changes in US trade law in 1984 gave IP-intensive firms greater access to USTR officials. In 1985, the new USTR Clayton Yuetter created an assistant USTR position dedicated solely to promoting higher IP regulations globally.\textsuperscript{94} IP-intensive firms also began to employ former USTR negotiators which gave them special expertise in how the USTR operated and indirectly but strongly signaled the rewards that might accrue to USTR officials after they left their posts if they did the bidding of those firms.\textsuperscript{95} Given all of this, it is perhaps not surprising that the business community’s assessment of what IP-trade policy should be, which was titled “Basic Framework of GATT Provisions on Intellectual Property: Statement of Views of the European, Japanese, and the United States Business Communities” became the foundation of the USTR’s negotiating position in the Uruguay Round.\textsuperscript{96}

Some scholars such as Peter Drahos and John Braithwaite have criticized these officials’ willingness to act as lawyers for these businesses, portraying them as part-puppets, part-bullies bent on strong-arming developing countries into an agreement that benefitted corporate America, whatever the cost to public health. But given the incentives and information around these officials at the time, it would have been surprising for them not to have taken the actions they did.\textsuperscript{97} From an informational perspective, there were not yet any access to medicine advocates or other lobbying organizations providing analyses to government officials that would have countered IP-intensive businesses’

\textsuperscript{94} Devereaux, et. al. 2006. \textit{Case Studies in U.S. Trade Negotiations}. p. 53. The first person to occupy this position was a man named Harvey Bale, who would later work as a lobbyist for the pharmaceuticals industry.
\textsuperscript{95} Drahos and Braithwaite. 2002. \textit{Information Feudalism}. p. 96. As will be discussed below, this connection between USTR employment and employment with IP-intensive firms has been a consistent trend up to today.
\textsuperscript{96} \textit{Ibid}. p. 123-126.
claims. From an electoral perspective, backing the pharmaceutical companies was a high-reward, low-cost strategy. The resistance from developing countries was also pretty minimal. This was not a cabal or a conspiracy against poor, sick people. It was a lesson in what happens in the politics of regulation and trade when businesses show up for a policy fight and activists do not.

The trajectory of events here also undermines state-centric explanations of international trade politics.\textsuperscript{98} The American government’s stance was not independently designed. It only came about because businesses lobbied vigorously and successfully for it. Likewise, developing countries’ willingness to yield in these negotiations had everything to do with the fact that domestic actors within those societies were not particularly animated by TRIPS.\textsuperscript{99} One cannot explain these states’ positions without first examining societal actors within those states.

\textit{How the U.S. Government Promoted Higher IP Regulations in the Uruguay Round}

In 1984, the United States made IP regulations a major part of its bilateral trading relationships through a mechanism known as 301.\textsuperscript{100} The 1974 Trade Act had a provision in it called Section 301 that authorized the executive branch to retaliate against trade policies implemented by other states that either violated international trade treaties, discriminated against American products, or posed an unreasonable restriction on U.S. commercial interests. Section 301 retaliation could either be initiated by the executive


\textsuperscript{99} Discussed below.

branch, or more commonly, after a U.S. firm petitioned the executive branch to act on its behalf. It thus gave U.S. businesses a powerful institutional mechanism with which to seek reductions in other countries trade barriers.

The 1984 Trade Act amended this section by explicitly defining inadequately high IP regulations as an unreasonable restriction on U.S. commercial interests and thus meant that U.S. firms could now demand that the executive branch retaliate against states that had IP regulations those companies felt were insufficiently high. The Trade Act also made having high IP regulations a key criterion for receiving GSP benefits. GSP benefits were important to agriculture and, given agriculture’s importance to many least developed states’ economies, lost benefits could have serious social and political ramifications. This helps explain why 301 was so effective and powerful in the minds of developing country officials. The Reagan Administration also floated the idea of trying to make IP regulations a criterion for assistance from the IMF and the World Bank.

These mechanisms were further strengthened in the Trade and Competitiveness Act of 1988. That act erased the requirement that pharmaceutical firms demonstrate that a foreign set of regulations actually hurt them to petition the government for 301 action. It also created the mechanism known as Special 301. This provision charged the USTR with monitoring other states’ intellectual property regulations and annually

making a ‘naughty list’, known as the Special 301 Watch List, of those states whose IP regulations, by virtue of being lower than U.S. IP regulations, impeded American IP-intensive businesses. The USTR was, and continues to be, required to enter into negotiations with states on that list to raise their IP regulations. If that country does not raise its IP regulations, it can then be put on the Priority Watch List. The USTR will then issue a specific set of actions it wants that state to take. If that state does not take those actions, the USTR can then downgrade that state to the most serious level, Priority Foreign Country (PFC). A PFC faces an imminent threat of strong retaliatory sanctions.

The U.S. government assertively used these measures in its bilateral relationships to one-by-one get its trading partners to raise their intellectual property regulations. First, the USTR used 301 to get South Korea to raise its IP regulations. Then, it targeted Brazil over its lack of pharmaceutical patents; after retaliatory tariffs started to be imposed, it too raised its IP regulations. 301 also got Argentina to do the same. The U.S. used GSP to get developing countries like Thailand to raise their intellectual property regulations as well. This bilateral strategy had two benefits for the U.S. First,

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108 One of the most conspicuous weaknesses in the GATT’s enforcement was that panel rulings against a state had to be unanimous meaning that even the state being accused of violating international trade rules had the power to veto adverse decisions. On the GATT’s relatively weak dispute settlement process, see Davey, William. 1987. “Dispute Settlement in GATT.” Fordham Law Journal. 11:1. p. 51-109. Van Bael, Ivo. 1988. “The GATT Dispute Settlement Procedure.” Journal of World Trade. 22:4. p. 67-77. 301 was actually illegal under GATT rules but the same lack of enforcement in GATT proceedings that U.S. companies bemoaned were quite useful here because even though 301 was almost a violation of GATT rules, there was no real mechanism to punish the U.S. for using it. Trebilcock and Howse. 2005. The Regulation of International Trade, 3rd Edition. p. 407.
110 Ibid. p. 105.
111 Ibid. p. 105.
there were the direct benefits that would accrue to American IP-intensive firms doing business in those states. Second, it indirectly helped the U.S. at the multilateral level because now that state would not object to TRIPS because it had already raised its standard to what the U.S. wanted.113

While it was deploying 301 at the bilateral level, the United States had also been pushing to include an agreement on higher IP regulations in the Uruguay Round. The same aspects of WIPO that Western firms found so frustrating—its lack of enforcement mechanism and its one-country, one-vote model—made it quite popular with developing countries. They saw no reason why intellectual property should be handled by any institution other than the World Intellectual Property Organization.114 U.S. government officials however insisted that IP be put on the agenda and threatened to scuttle the whole round if it were not included. Developing countries got agricultural liberalization added to the agenda in exchange.115

Developing countries thought they had given away very little by agreeing to discuss IP in the Uruguay Round.116 At this point, those countries, as well as public health activists, had no idea what TRIPS would become. There was still a general perception that any IP provisions that got added to the GATT would be relatively weak, would likely only focus on counterfeit goods, and even if a state violated the rules, given the GATT’s institutional structure there would not be a mechanism to punish them.117

And so, in 1986, intellectual property was officially put on the agenda. All three of those beliefs turned out to be very wrong.

Over the next several years, the United States worked with European states and Japan in private, informal sessions to arrive at common positions so that a united front could be presented to developing countries. These states understood that much of the key negotiating was going on between developed countries and that forums they were invited to were mere formalities and so, according to one developing country negotiator, “we lost interest [in the TRIPS forums].”

Developing countries would later become highly engaged in the politics of IP, especially with regards to pharmaceuticals, but at this point, they did not consider TRIPS to be a big deal. Many developing countries, unlike the United States, had no IP experts on their trade negotiating teams. Many of them did not understand the details of what they were negotiating and so did not understand the full measure of their concessions.

Even if they had been more engaged on IP, developing states were far less well organized under the GATT than under WIPO. There was often little to no coordination between their trade negotiators in Geneva and national capitals. Lodging negotiators in Geneva is not exactly cheap and so many of these developing countries had tiny, poorly funded trade negotiation teams. These teams would simply get overwhelmed in negotiations with the U.S. team.


124 Deere. 2009. *The Implementation Game.* p. 120.
India was really one of the only developing countries that had the technical expertise to resist American demands on IP and so many developing states looked to them for leadership. Its leadership on the issue though was still quite spotty. Given the stakes, Indian drug companies did surprisingly little lobbying; like access to medicine advocates, they did not really get engaged with the issue until after TRIPS had been signed. India did not often engage with other developing states on this issue and skipped what was supposed to be a key meeting of those states to coordinate their negotiating position on IP regulations. When they did engage in negotiations, U.S. negotiators were prepared to beat back any argument they made; as Mike Hathaway, the lead U.S. negotiator on IP recalled, “we certainly had fun….beating down arguments made by India.”

Even if they had wanted to oppose the United States more forcefully, many of their key allies such as Argentina and Brazil had been peeled away. South Korea was attempting to gain admission to the OECD and so was more concerned with pleasing developed countries than with showing solidarity with Brazil and India. Additionally, other developing states such as the ASEAN members, badly wanted a deal to get done and believed that giving the United States what it wanted on IP was the required price and so they had little appetite for a fight over IP. Developing countries generally perceived services liberalization to be the biggest threat and TRIPS to be a lesser issue

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128 Ibid. p. 135.
and so reserved their energy for fighting on services rather than on IP.\textsuperscript{132} Also, India, like other developing countries, was attempting to liberalize its investment laws to attract foreign direct investment and raising IP regulations seemed to be consistent with that.\textsuperscript{133} The one area where India did fight hard was on compulsory licensing and there it was able to win more permissive language, which would have major ramifications later on.\textsuperscript{134}

Moreover, developing countries were not going home empty-handed. In exchange for acquiescing to the United States on IP, developing countries won concessions in two areas that were much more important to them, agriculture and textiles.\textsuperscript{135} An Argentinian negotiator said “they didn’t give a damn what was in the IP code as long as they got what they wanted in agriculture.”\textsuperscript{136} IP was perceived by developing country leaders to be part of broader bargain in which they would get investment and market access benefits in textiles and agriculture in exchange for increasing their IP regulations.\textsuperscript{137}

Developing states believed, inaccurately, that TRIPS would curtail America’s 301 unilateralism.\textsuperscript{138} Also, because these states were to be given a grace period to implement

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\bibitem{132} Ibid. p. 57.
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the new IP regulations, their governments lowered the extent to which they prioritized the costs of higher IP; the costs were far down the road and so just not as important. As myopic as this seems in hindsight, discounting future costs is basic human nature.

Finally, the Uruguay Round came with many other agreements and TRIPS was but one of them. These agreements collectively ran over 1,000 pages long and most developing state legislatures had little discussion of the impact TRIPS would have; it was only later when those impacts became more clear that these legislatures took more interest. In the U.S., it was an afterthought for the public as well. Unlike NAFTA, the completion of the Uruguay Round, including TRIPS, was not particularly controversial.

Developing states’ decision to accept TRIPS was understandable, but TRIPS, which came into force in 1995 with the birth of the WTO, nevertheless represented a major reduction in regulatory differences by requiring all signatories to adopt the higher IP regulations developed countries wanted. They all had to have patents that lasted 20 years. None were allowed to prohibit patents on drugs. The use of compulsory licenses was constrained. All states were required to stringently enforce IP regulations. Failure to do any of these could lead to that state being taken before a WTO dispute settlement mechanism, which was much more robust than the GATT’s had been.

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For a state to use a compulsory license under TRIPS, A) that state must have attempt to obtain use on ‘reasonable commercial terms’ B) the license must be non-exclusive C) the license must primarily be for the domestic market, not exports and D) adequate compensation must be given.

In contrast to the GATT dispute settlement, the WTO dispute settlement understanding cannot be blocked by the accused, proceeds more expeditiously, possesses a greater ability to enforce its decision by sanctioning retaliation, and has more formalized panel proceedings. On the WTO dispute settlement procedures, see Trebilcock and Howse. 2005. The Regulation of International Trade. p. 112-147.
The California Effect actually applies well to this case. There were three central elements to the California Effect. First, businesses will support stricter regulations when those stricter regulations make them more competitive. Second, richer states with higher standards force producers in other states to raise their standards in order to export to them and so de facto raise foreign standards. Third, trade agreements give richer states with higher standards leverage to pressure other states to raise their standards to the richer states’ level.

All three of those were present here. American IP-intensive businesses saw high IP regulations as a competitive advantage. The United States linked other states’ producers’ access to the U.S. market and used the Uruguay Round to pressure other states to raise their IP standards. This suggests that the California Effect may, at times, be applicable outside of the two regulatory areas (consumer safety and the environment) which Vogel originally intended.

TRIPS required little adjustment for the U.S. but came with very large adjustment costs for many developing countries such as India. All WTO members were now required to adopt the exact kind of IP regulations demanded by the United States. In the words of one pharmaceutical lobbyist, “we got 95 percent of what we wanted.” It would not be that long however before the connection between intellectual property regulations and trade became a white-hot international political issue.

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The Doha Declaration: Access to Medicine Activists Show Up…..and Win

In the second half of the 1990s, the AIDS epidemic grew into a public health nightmare, especially in sub-Saharan Africa. Given the relative newness of the disease, practically all of the effective HIV drugs were patented and thus expensive. Poor people were dying of a disease for which effective medicines existed but which were far too expensive for them to afford. Public health advocates began to take a closer look at the connection between IP regulations and the cost of drugs and concluded that the high IP regulations mandated by TRIPS were the main drivers behind the expense of the medicines and thus complicit in widespread death. Drug companies compounded this imagery when they sued the South African government over measures it had taken to stem the AIDS crisis. Even after they dropped the lawsuit, developing countries and access to medicine advocates wanted states to have more flexibility under TRIPS to institute different IP regulations. For a variety of reasons, the U.S. government, which normally would have been expected to oppose any increase in regulatory barriers in pharmaceuticals, relented and accepted the Doha Declaration which strengthened developing states’ ability to implement different IP regulations.

The HIV Crisis Gets Really Bad But Drug Firms, and the U.S. Government, Hold Their Ground

By the late 1990s, 25 million Africans had HIV/AIDS.148 In 1998, it killed more than two million people in Sub-Saharan Africa and life expectancy there had fallen by twenty to thirty years.149 Drug firms were reluctant to substantially lower their prices in developing countries because that would demonstrate just how low their marginal costs were and thus could lead government officials and citizens in wealthier states to ask why

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149 Ibid. p. 179.
they should have to pay so much more for the drug than it cost to make.\textsuperscript{150} With HIV rates soaring and drug prices out of reach for most of its HIV victims, in 1997 the South African government passed a law that permitted the parallel importing of generic drugs manufactured under compulsory licenses.\textsuperscript{151} In effect, the South African government said that the AIDS crisis justified ignoring drug companies’ patents on anti-retroviral drugs.\textsuperscript{152}

Western drug firms were irate over this policy. They believed that it amounted to “carte blanche for the wholesale abrogation of patent rights for all pharmaceuticals” in a $2.5 billion market.\textsuperscript{153} They worried that the South African legislation would set a precedent that other states would follow and implement on other diseases, which could lead to an unraveling of TRIPS altogether.\textsuperscript{154} Not only were they opposed to any weakening of TRIPS, they in fact had been wanting TRIPS strengthened still more through requirements that states grant patents on biological products, more limits on compulsory licensing, greater enforcement of TRIPS and more stringent data exclusivity provisions.\textsuperscript{155} They were not interested in finding a compromise solution. U.S. trade officials said that when they asked pharmaceutical representatives whether they could accept some concessions to South Africa, the companies “said no, we really just want you to hold the line and continue to pressure South Africa to terminate this law altogether.”\textsuperscript{156}

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\item Trebilcock and Howse. 2005. \textit{The Regulation of International Trade, 3\textsuperscript{rd} Edition}. p. 430.
\item Deere. 2009. \textit{The implementation Game}. p. 114-115. With some activists screaming for TRIPS to be gutted, that was not an entirely idle concern.
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These drug firms first attempted to intimidate the South African government into backing down. Merck threatened to leave the country altogether and take millions of dollars and thousands of jobs with it. Bristol-Myers Squibb, Pharmacia and Upjohn, and Eli Lilly all closed plants after the introduction of the bill. The International Federation of Pharmaceutical Manufacturers said the weakening of patents could lead to South Africa being denied access to any new HIV drugs that came on the market. That was an extremely serious and not-at-all veiled threat.

These firms continued to hold a privileged position in the U.S. trade policymaking process. The 1984 Trade Act required the USTR to consult with a range of businesses through the (IFAC-3), a group of 40 industry representatives that plays a key role in preparing the USTR’s annual Section 301 Reports as well as reports on trade agreement that go to the Executive branch and to Congress. IP-intensive businesses also continued to have the ear of Capitol Hill; 47 members of Congress signed a letter encouraging the USTR to fight the South African law. Congress also reduced foreign aid to South Africa over the law.

These government officials echoed the drug industry’s argument about the danger of a precedent being set. One Western official argued that

"if the Health Minister thought it was in the interest of public health that those $10,000 AIDS cocktails be cheaper, she could just rip off the patents and set up a factory in Cape Town to make them…..and if the Minister of

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Health says this is O.K., then the Minister of Education will be able to say, 'Well, affordable computers are in the interest of public education, but Windows is just too darn expensive, so we're going to buy knockoff copies.' It was not just about AIDS drugs. The way U.S. government officials saw it, the South African law was a direct challenge to the new, higher IP regulations embodied in TRIPS. They had fought to reduce those regulatory barriers and were in no mood to see their work undone.

U.S. government officials thus sallied forth in defense of the drug companies. In 1998, the USTR placed South Africa on the 301 Priority Watch List. IP regulations were the central issue at the US-South Africa Binational Commission meetings in August 1998. By the U.S. government’s own admission, multiple agencies and branches of the government colluded to put extraordinary diplomatic pressure on South Africa to scrap the 1997 Medicines Act.

The HIV Crisis Prompts Access to Medicine Advocates to Get Engaged in IP Politics

Meanwhile, public health activists had gotten seriously engaged in the politics of IP regulations in a way they never had during the TRIPS negotiation. The first big international meeting of NGOs on the relationship between IP and public health was in 1996, the year after TRIPS came into effect. The second meeting was hosted by the Indian National Working Group on Patents and also brought in government representatives and generic drug producers. The U.S. attempt to coerce South Africa to

168 Ibid. p. 78-79.
169 Ibid. p. 78.
repeal its allowance of compulsory licenses on HIV drugs in 1998 infuriated NGOs. As one of NGO leaders put it “this whole debate in 1998 woke people up. It really got the attention of the public health community, which really started to get engaged at this point. It was what paved the way for the Doha Declaration- it was Doha before Doha.”

These activists’ engagement in the politics surrounding trade and intellectual property regulations highlights the limitations of the cleavage-based explanations of trade politics. The cleavage here was not between a sector of society that profited from trade and a sector that lost. It was between a sector (pharmaceutical firms) that had an economic stake and a sector (access to medicine advocates) that wanted to prioritize non-economic public policy goals. By focusing exclusively on economic considerations, these explanations again miss how trade increasingly animates actors with normative concerns once regulations get added to the political equation.

In 1998, these activists went to the WHO and were instrumental in that organization crafting a Revised Drug Strategy that emphasized the need to prioritize public health over commercial interests and mandated that the WHO monitor trade agreements for their affect on public health. The next year, Doctors Without Borders launched its Access to Essential Medicines Campaign and began closely collaborating with other NGOs such as Health Action International, the Consumer Project on Technology, and Oxfam International. Doctors Without Border then won the Nobel

170 Ibid. p. 81.
171 Devereaux, et. al. 2006. Case Studies in U.S. Trade Negotiations. p. 80-81. US negotiators were not happy that the WHO was now taking part in IP discussion, which they believed belong exclusively to the WTO. Ibid. The World Health Organization’s governing body has a rotating board and so every third year the U.S. is not on that board. 1998 was one of those off years. This is what allowed activists to sidestep the U.S. Sell and Prakash. 2004. “Using Ideas Strategically.” p. 163.
Peace Prize for its efforts and used the prize money toward boosting its Access to Essential Medicines Campaign.\textsuperscript{173}

These activists also started to engage with key governments on a domestic basis. They get more involved in lobbying the U.S. government.\textsuperscript{174} Starting in 1996, the Indian Commerce Ministry set up a consultation process that involved industry representatives and NGOs.\textsuperscript{175} They repeatedly lobbied the USTR to take more relaxed positions on intellectual property regulations.\textsuperscript{176} USTR and European trade officials afterwards acknowledged that NGOs were crucial in bringing attention to the connection between IP and access to medicines.\textsuperscript{177} In June 1999, they stole the show at Al Gore’s announcement that he was running for president, and continued to dog his campaign.\textsuperscript{178} They also successfully lobbied key segments of the Democratic Party such as the Congressional Black Caucus.\textsuperscript{179} In May 2000, they successfully convinced the Clinton administration to back off threatened trade sanctions against South Africa.\textsuperscript{180}

This chain of events provides further evidence against the disguised protectionism argument.\textsuperscript{181} The primary defenders of regulatory barriers throughout this time period

\textsuperscript{174}Deere. 2009. \textit{The Implementation Game}. p. 118.
\textsuperscript{175}Ibid. p. 213.
\textsuperscript{179}“NGOs argued that high costs of patented pharmaceuticals made them unaffordable to most South Africans and only the affluent (predominately white) could afford them. Thus, the policy of compulsory licenses that the USTR was opposing was, in part, a challenge to medical apartheid. Such arguments resonated well with the U.S. Congressional Black Caucus, a key pillar of support for President Clinton.” Sell and Prakash. 2004. “Using Ideas Strategically.” p. 165.
were not businesses looking for protectionism; they were NGOs trying to maintain policy space. The same would continue to be true in the WTO stalemate and India’s use of flexibilities examined below.

As activists and developing countries fought to broaden that policy space by increasingly IP regulatory differences while businesses and the U.S. government stridently resisted, the relationship between the players on each side continued to grow more and more acrimonious. NGOs portrayed the drug companies as death merchants.\footnote{Sell and Prakash. 2004. “Using Ideas Strategically.” p. 165.}

Nkosozana Zuma, the South African Health Minister and the leading force behind the South African law, said of her critics “if they had their way, we would all die of AIDS.”\footnote{McNeil, Donald. “South Africa’s Bitter Pill for World’s Drugmakers.” \textit{The New York Times}. March 29, 1998.}

For their part, the drug companies saw the South African law as a smokescreen for a WHO plot to eradicate patents, a move by Indian generics firms to increase market share, and an ideological crusade against Western businesses by the South African ANC.\footnote{McNeil, Donald. “South Africa’s Bitter Pill for World’s Drugmakers.” \textit{The New York Times}. March 29, 1998. When the Indian firm Cipla offered to sell generic versions of HIV medicines to South Africa, Merck’s CEO was responded “they are stealing my intellectual property, and I cannot accept that.” Stolberg, Sheryl. “Africa’s AIDS War.” \textit{The New York Times}. March 10, 2001.}

They also argued that corruption and poor governance, rather than high IP regulations, were the real facilitators of the AIDS crisis.\footnote{Sell and Prakash. 2004. “Using Ideas Strategically.” p. 145, 165.}

This standoff built to a head in March 2001. The legal case between the drug firms and the South African government that had begun in 1998 had finally come before

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the South African High Court.\textsuperscript{186} The opening of the case was accompanied by a wave of anti-industry protests.\textsuperscript{187} Access to medicine advocates kept up the pressure for the next several weeks.\textsuperscript{188} These raised the salience of the access to medicines issue and threatened to badly damage drug companies’ image. The WHO and the EU publicly sided with South Africa.\textsuperscript{189} In April 2001, before the PR damage could get any worse, the drug companies dropped their lawsuit and agreed to pay the South African government’s legal costs.\textsuperscript{190} Beyond the immediate costs on AIDS, the pharmaceutical firms worried that the issue could spill over into a broader discussion of drug pricing in developed states that could have potentially disastrous implications for them.\textsuperscript{191} For them, it was better to concede defeat here than continue fighting on terrain this disadvantageous.

The AIDS crisis was tailor made for activists’ victory. As Keck and Sikkink point out, activism is more effective on “issues involving bodily harm to vulnerable individuals, especially when there is a short clear causal chain (or story) assigning responsibility.”\textsuperscript{192} The HIV crisis had all of those. AIDS is clearly bodily harm. Poor Africans are amongst the most vulnerable people anywhere. The story that activists told, that corporate greed was leading to needless death, provided a short clear causal chain assigning responsibility. Drug firms should have known that the public relations backlash against them would be intense. Somehow, they did not.

\textsuperscript{190} Ibid.
Activists Win A More Durable Victory at Doha

Drug firms dropping the lawsuit did not settle the matter though. Just because the pharmaceutical companies backed down this time did not mean that developing countries were free from worrying about being challenged in the future. What was and what was not TRIPS-compliant needed to be clarified and that was still a matter of considerable debate because Articles 30 and 31 of TRIPS, which covered exceptions to patent rights, were ambiguous and vague in terms of the conditions under which a compulsory license would be considered TRIPS-compliant.\(^{193}\) Developed country governments, and the Bush Administration in particular, had been pushing for a new trade round.\(^{194}\) With respect to IP, the most important issue demanding attention was under what circumstances compulsory licenses could be issued. Was AIDS sui generis and the sole permissible exception to strict patentability or did all diseases merit such consideration? Who got to choose which diseases made the lists, each national government, the WTO, the WHO, or would it be some independently negotiated text? The upcoming ministerial meeting seemed to be the arena at which these matters could get decided.

Several factors led developing states to punch harder and more effectively than they had during the original TRIPS negotiation. First, whereas they were in many ways in the dark about the connection between IP and access to medicine during the Uruguay Round, by 2000, they were quite aware of that connection. The AIDS crisis and the pharmaceutical companies’ suit against South Africa had ensured that. Every year starting in 1998, the G-77 developing countries issued a statement arguing for expanding

\(^{193}\) Article 30 of the TRIPS Agreement says that “Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.”

TRIPS flexibilities.\textsuperscript{195} Second, the year 2000 had been a deadline for many developing countries to become TRIPS compliant and so they were fully aware of how much policy adjustment TRIPS was requiring.\textsuperscript{196} Third, the benefits they were supposed to receive in exchange for TRIPS had been slow in coming. The concessions in textiles and agriculture were weaker and more delayed than anticipated.\textsuperscript{197} Fourth, though it was implied that TRIPS would lead to a reduction of America’s use of 301 and other unilateral measures, the United States had actually used them more after TRIPS than before it.\textsuperscript{198}

Access to medicine advocates augmented these developing countries’ efforts.\textsuperscript{199} These activists were much more well-organized at this point than they had been in the TRIPS negotiations.\textsuperscript{200} They worked directly with those countries’ governments to strengthen their negotiating performance.\textsuperscript{201} They encouraged developing countries to not limit their demands to AIDS in particular but to public health more broadly.\textsuperscript{202}

Developing states, led by India, had several policy demands. First, they wanted a new declaration that stated that TRIPS “does not in any way undermine the legitimate rights of WTO Members to formulate their own public health policies.”\textsuperscript{203} They wanted a
text focused on public health, which was broader than just access to medicines.204

Second, they wanted governments to have the right to decide what constituted a national emergency, which was important because it is only under conditions of national emergency that a state can issue compulsory licenses without prior consultation with the patent holder.205 Third, they wanted a moratorium on disputes against access to medicines policies.206 Fourth, they wanted developed countries, (i.e., the United States) to be prohibited from basing unilateral trade preferences on IP (i.e. 301).207 Finally, they wanted TRIPS flexibilities to cover as many diseases as possible, not just AIDS.208

Developed countries, led by the United States, had several concerns. First, they worried that developing countries would use compulsory licenses to promote industrial and economic concerns, instead of just access to medicine.209 U.S. officials believed that India’s involvement in particular was really just a smokescreen for them advancing their generics industry.210 Second, given that the declaration language developing countries wanted could cover practically any policy, it would have effectively eradicated TRIPS altogether.211 Third, even if that language were narrowed, a moratorium on disputes and trade preference linkage would take the enforcement teeth out of TRIPS and give states de facto impunity to violate it. Fourth, they wanted the list of diseases covered by these

206 Ibid.
flexibilities to be an agreed-upon list narrowly tailored to HIV/AIDS and other epidemics, not just whatever a developing country government decided constituted an emergency.\footnote{212} Finally, they wanted developing countries to implement policies designed to prevent re-importation, i.e. people buying drugs cheaply in a developing country and then sneaking them into a developed country where prices were higher.\footnote{213} Once again, contra to the state-centric explanations, both developed and developing states’ negotiating positions was based mainly on the demands being made by societal actors.

In November 2001, these states agreed to the Doha Declaration. It was largely based on developing states’ proposals.\footnote{214} It re-affirmed states’ rights to issue compulsory licenses under three conditions: 1) an attempt was made to obtain a voluntary license from the patent holder but was unsuccessful- this condition could be bypassed in a national emergency; 2) the patent holder was adequately compensated; and 3) it was predominately for the supply of the domestic market. It also said that states could determine for themselves what constitutes a national emergency.\footnote{215} Developing states now had a confirmed right to institute different IP regulations that could amount to a regulatory trade barrier. The Doha Declaration made it much more difficult, legal and politically, to challenge a developing country’s use of a compulsory license.\footnote{216} The side in favor of reducing regulatory barriers in IP by raising them to a high-level, which seemed so dominant during the TRIPS negotiation, had backed down. The U.S. government in particular had abandoned the maximalist positions it once held.

Why the United States Backed Down

Several factors led to this climb down. First, the relationship between the drug firms and the U.S. government had been damaged, albeit temporarily, by the South African episode. U.S. officials were greatly annoyed with drug representatives’ refusal to recognize that high drug prices were at least partially exacerbating the AIDS crisis in South Africa. Several Democratic Congressmen were not pleased with them either. After an amendment that would have prevented the U.S. from challenging sub-Saharan African countries’ access to medicine policies was stripped from a trade bill, Dianne Feinstein and Russ Feingold threatened to filibuster that bill.

Second, after anthrax was sent via mail shortly after 9/11, both Canada and the United States threatened Bayer with a compulsory license for the anthrax drug Cipro to get Bayer to lower its price. In other words, the U.S. had just threatened a company’s IP protection based on public health considerations. How could U.S. negotiators just a few months later at the Doha ministerial argue, with a straight face, that threatening IP to protect public health was inappropriate?

Third, after 9/11, the U.S. was determined to launch a new trade round at the Doha Ministerial to demonstrate its global leadership and wanted to attain that goal so badly that it was willing to accept language that developing countries were demanding to get that. Conversely, developing states prioritized public health over the start of a new round, especially since they were not entirely sure that the Uruguay Round had been good for them given the painfully slow implementation of the agricultural and textile

218 Ibid. p. 89.
219 Ibid. p. 98.
concessions that were supposed to benefit them. This shows that market power considerations, while important, can be overridden if the non-economic policy goals prioritized by activists have enough salience. It also implicitly critiques the bicycle theory of trade which argues that for trade liberalization to be maintain, there must constantly be forward momentum (i.e. a new round on the agenda); otherwise those actors opposed to trade can more easily promote protectionism. At this point, there was a new round on the agenda and that still was not enough to counter the power of activists’ lobbying.

Fourth, given the greater salience of the IP-medicine cost connection, a greater array of U.S. government agencies had taken interest in the subject and they often had a different perspective than the USTR. This is a reminder that just as trade increasingly impacting regulation brings more societal actors into trade politics, especially those with normative concerns related to those regulations, it also means that government agencies that are primarily interested in those regulations also take a greater interest in trade. If they generally side with those activists, then the USTR and other agencies that frequently side with businesses may find their control over trade policymaking greatly diluted.

If the TRIPS negotiation was a lesson in what happens when activists do not show up for a policy fight, the passage of the Doha Declaration is a lesson in the extent to which it actually is possible for a rag-tag crew of activists to beat some of the world’s most powerful corporations.

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222 A point made by a Washington Post article is insightful on this. “Inertia led trade regulators to treat generic AIDS medicine on the model they use for pirated music discs and computer games--as a threat to the profits of copyright-holders, to be suppressed. ‘You mean the U.S. Trade Representative doesn't know the difference between Barbie dolls, tennis rackets and AIDS drugs?’ one senior health official recalls asking incredulously during the interagency fight. ‘Well, the problem is, they didn't.’ Gellman, Barton. “A Conflict of Health and Profit: Gore at Center of Trade Policy Reversal on AIDS Drugs to South Africa.” *The Washington Post*. May 21, 2000.
Stalemate And Constructive Ambiguity at the WTO

The Doha Declaration was a big victory for access to medicine advocates and developing countries but it did not settle three issues: 1) which diseases a compulsory license could be issued for, 2) what kind of exceptions to make for states that did not have production capacity, and 3) whether non-violation complaints could move forward. On which diseases to cover, the language in Doha was never clarified to either side’s benefit. On states’ without production capacity, the same but no greater flexibilities were granted to them as to other states. On non-violation complaints, there has been a rolling temporary moratorium. In sum, the regulatory barriers on these issues remained static through a mix of constructive ambiguity and stalemate.

Three Outstanding Issues Left Over From Doha

While the Doha Declaration had affirmed developing states’ right to institute IP regulations that differed from what developed states wanted, several important details remained deeply contested. These details were the crux of the political wrangling over the next few years. On one level, they were deeply legalistic and technical, but on another level they were entirely political. They determined the extent to which less stringent IP regulations could get used and thus the extent to which different states’ use of these regulatory vehicles could constitute a barrier to trade. In other words, they were a fight over a potential regulatory trade barrier that had the power to determine the relative prioritization of commercial interests and public health.

The first and second issues related to compulsory licenses. The definition of a national emergency was of critical importance because it facilitated the issuance of compulsory licenses. Paragraph 5(c) of the Doha Declaration reads “Each Member has the right to determine what constitutes a national emergency or other circumstances of
extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.” The first clause seemed to give states a great deal of leeway but the second clause implies that states cannot just label anything a national emergency and hints at criteria but does not specifically enumerate what is a national emergency and what is not.

The first major vector of this wrangling was over which diseases counted as a national emergency. Activists wanted it to cover as broad of a disease spectrum as possible. Developing countries also held that the reference to AIDS in the Doha Declaration was non-exhaustive; they wanted no limits on the diseases covered.

Drug companies had politically lost on AIDS and wanted to limit their loss to just that disease. AIDS was undoubtedly an enormous crisis and if it were the only exception to TRIPS rules, they could live with that. At the very least, they had the public relations acumen to not try again to challenge a developing state as they had with South Africa. But if seemingly any disease could be labeled an emergency, that would quickly undermine drug companies’ overseas profit, and that was unacceptable. Letters from

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the U.S. Congress to the USTR on limiting diseases that could get TRIPS exceptions essentially repeated pharmaceutical industry talking points.\textsuperscript{229} The U.S. later somewhat expanded its list of acceptable diseases, even saying that it might consider all infectious diseases acceptable, but it still wanted a defined list.\textsuperscript{230} That was not good enough for developing countries.\textsuperscript{231} The EU tried to float a compromise but that too was shot down by African countries.\textsuperscript{232} The two sides have never resolved this disagreement. The United States refused to countenance developing countries’ position but did state that it would forgo pursuing disputes against states that were attempting to combat AIDS or other epidemics.\textsuperscript{233} The United States has never pursued a dispute against another state’s IP regulations based on the target disease and thus developing countries have never had the opportunity to challenge that dispute being brought forth. A dispute could lead the issue to be clarified but neither side can be sure it will not be clarified in ways that benefit the other side. Better to have a murky disagreement than a clear loss.

The second vector had to do with states that did not possess the domestic capability to make drugs.\textsuperscript{234} The original TRIPS Agreement had conditioned a state issuing a compulsory license on that license being primarily for the supply of the

\textsuperscript{229} \textit{Inside U.S. Trade.} “WTO Fails to Bridge Gaps on TRIPS and Health Deal, Sets New Deadline.” December 13, 2002.


domestic market. Paragraph 6 of the Doha Declaration recognized that this condition meant that states without the domestic wherewithal to manufacture generic medicines would have difficulty using a compulsory license as no other state would be able to make it for them since that would violate that condition.\textsuperscript{235} 

Until January of 2005, this did not in effect constitute much of a problem because it was not until that date that India had to abide by the terms of the TRIPS Agreement.\textsuperscript{236} Until that date it could supply these drugs for states without domestic manufacturing capacity, but that date was approaching quickly and India would be in clear violation of the letter of the TRIPS Agreement if it continued supplying those drugs after that date. Developing countries wanted a resolution to this issue before that January 2005 deadline. 

Activists argued that developing countries without domestic manufacturing capacity should be allowed to issue compulsory licenses and then import that drug from another state, most likely India.\textsuperscript{237} The Doha Declaration also mandated that states find a negotiated solution over this issue in order to help disease-stricken developing countries. 

Western pharmaceutical companies wanted to ensure that developing countries’ use of compulsory licenses did not undermine patent protections in richer countries. They were especially wary of two problems. First, they were concerned that drugs made for developing countries would get diverted away from those countries and into richer states where, given their significantly lower costs, they would undermine drug companies’

\textsuperscript{235} For India, this meant that even though it would not get entangled by condition 3 when it was producing drugs for its own citizens, it would run into difficulties when other developing countries could not make the generic and turned to India, which has often been called the pharmacy of the Third World, to make them. 


In order to reduce the chance of this happening, the United States wanted developing countries using this system to make the compulsory licensed drugs easily distinguishable by packaging and coloring. Given that this kind of packaging and distribution could increase the cost of producing and distributing those drugs, developing countries initially did not want to do this. Second, the pharmaceutical firms were worried that richer developing countries would also try to use the system even though they could better afford patent-protected medicines than the least developed countries.

The United States very much wanted to revive the flagging Doha Round of WTO negotiations at a Ministerial Meeting in Cancun scheduled for September 2003. The standoff over IP regulations and pharmaceuticals threatened to block that. As September 2003 got closer and closer, the United States became more and more willing to cut a deal while developing countries perceived that now was their best opportunity to exert leverage. Just two weeks before that meeting was scheduled to begin, WTO members agreed on a buy-out. Countries without domestic manufacturing capacity would be given a waiver from TRIPS rules to use compulsory licenses in much the same way as other developing countries, but to prevent diversion into richer countries, they had to implement “reasonable measures within their means proportionate to their administrative capacities.” This was another example of constructive ambiguity in this period.

Additionally, 44 developed and richer developing states agreed to forgo their use of this

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system or limit it only to serious epidemics. This waiver was made official in 2005 and has been renewed every two years since 2007 with the most recent renewal coming in December 2015.

Interestingly, this case contradicts what the California Effect would have predicted and suggests a possible caveat to it. Here, the United States, a rich country, wanted higher standards and was not able to use a trade agreement to raise other countries standards. It was not able to do so because it wanted a trade agreement much more eagerly than its negotiating partners. Given the relative size of the respective markets, it is presumed that the smaller country benefits from increased access to the larger market more than the other way round and this gives the country with the larger market the market power to leverage increases in the other states’ level of regulatory protection. But as we have seen in this chapter and the other cases, market power is far from the only factor at play. If those other factors lead the state with the larger market to more desperately want the trade deal than the country with the smaller market, the market leverage that it would normally enjoy evaporates. In those circumstances, the California Effect is much more likely to break down.

The third area of disagreement centered on non-violation complaints. These complaints basically argue that a member state has denied another state market access benefits even though its behavior is not outside the letter of the agreement. In October 2002, developing countries pushed for a prohibition on non-violation disputes. The

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United States did not want a permanent prohibition but was willing to agree to a moratorium on those complaints. Thereafter, the moratorium was renewed every two years with little disagreement until 2014. In that year, after American businesses continually complained about India’s IP policies (discussed below), the U.S. began opposing extending the moratorium on non-violation complaints.\textsuperscript{245} The TRIPS Council nevertheless extended the moratorium again in November 2015.\textsuperscript{246} Given that Switzerland is the only country that supports the U.S. in opposing the extension of this moratorium, it is likely to continue to be extended for the foreseeable future.\textsuperscript{247}

2015 was also notable for another development as well. The Sustainable Development Goals, the UN’s follow on efforts that aim to build upon the Millennium Development Goals, affirmed states’ right to use TRIPS flexibilities to promote access to medicines. Once again, developed countries led by the United States and developing countries led by India have not been able to agree to specifics and so the language has been left vague. On all of the details in this period, the result of negotiations at the WTO level was either an exercise in constructive ambiguity or a compromise. Now that both sides knew the stakes of the fight and were eager to show up, it was difficult for either to gain the upper hand.

**Legal Creativity: India’s Interpretation and Use of TRIPS Flexibilities**

Under the provisions of TRIPS, India had to implement TRIPS-compliant IP regulations beginning in 2005. India has creatively found a number of policy means to relax their IP regulations. They used a narrow set of patentability requirements and


greater policy access for patent opponents and so limited which drugs could get patented. They also employed novel injunction policies and compulsory licenses to control drug prices. All of these measures made India’s IP regulations differ significantly from the high IP standards that the United States wanted. All of these measures were also technically TRIPS-compliant. Still, India has been judicious in its use of these measures, employing them much less than they otherwise could have in order to maintain amicable relations with U.S. drug firms and U.S. businesses more generally.

**Flexibilities in India’s 2005 Patent Act**

The Indian government used administrative delays in the 1990s to lessen TRIPS’ impact. Still, by 2005, India would have to make its IP regulations TRIPS-compliant. The cost of patented drugs was a looming challenge. This was especially the case because drugs are a much larger share of health expenditures in India (44%) than in the United States (12%). To make matters worse, the paucity of health insurance in India means that the costs of drugs are borne almost entirely by the consumer in a manner that is much more salient than when the bill is being paid by an insurance company or the state. Even the tiny fraction of citizens that have health insurance have to pay for drugs themselves because health insurance in India does not cover drugs. 70 percent of Indian healthcare expenses are paid out of pocket. As discussed earlier, since the 1970s India had not allowed patents on drugs at all. The Indian government was also able to issue compulsory licenses for those drugs made and sold in India prior to 2005.

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252 Ibid.  
In 2005, in order to comply with TRIPS, the Indian government revised its IP regulations to allow for pharmaceutical patents as well as for the 20-year patent term and other TRIPS provisions. Drug cost concerns remained ever-present however and TRIPS was not as airtight of an agreement as its Western proponents believed. A number of the terms in TRIPS are quite vague such as that governments undertake ‘reasonable’ efforts to work with patent holders.\footnote{Kapczynski. 2009. “Harmonization and Its Discontents.” p. 1588.} What exactly counts as reasonable? Rather than reject TRIPS outright or seek an international dispute, India instead chose to interpret these provisions in highly creative ways.\footnote{Ibid. p. 1575.} They primarily did this in three areas: patentability, injunctions, and compulsory licenses.

While TRIPS undeniably forced many states to strengthen their IP regulations, which was exactly the point, it did leave a number of patent-related matters firmly in the hands of national government officials. For an applicant to receive a patent, their invention must be new, non-obvious, and useful; TRIPS gives national patent offices the power to define what exactly those terms mean and to determine what information must be disclosed in a patent application.\footnote{Deere. 2009. The Implementation Game. p. 80.}

During the domestic negotiation over India’s 2005 Patent Act, activists such as the Delhi Network of Positive People opposed the expansion of drug patents.\footnote{Kapczynski. 2009. “Harmonization and Its Discontents.” p. 1586.} Doctors Without Borders also opposed granting patents to new forms of known drugs, rather than an entirely new class of drug, and wanted extensive opportunities for opposition to the granting of patents in the approval process.\footnote{Doctors Without Borders. 2005. “Will the Lifeline of Affordable Medicines for Poor Countries Be Cut?” http://www.msfaccess.org/content/will-lifeline-affordable-medicines-poor-countries-be-cut-} Officials in the Indian Parliament cited
these activists in their arguments in the debate over the bill.\textsuperscript{259} The 2005 Patents Act reflected a number of these activists’ concerns.

First, the Indian government has, since the passage of the 2005 Patents Act, implemented a number of limitations on what subject matter can and cannot be patented.\textsuperscript{260} Second, India’s definition of what counts as non-obvious is also exceptionally high.\textsuperscript{261} Third, the biggest curtailment of patentable products is section 3(d) of the law which is aimed at preventing what is known as evergreening, which is when drug firms keep the cost of a drug high by making small changes to the product and repatenting it.\textsuperscript{262}

To prevent this, Section 3(d) says that to receive a patent, new forms of known drugs must enhance the drug’s efficacy, which is defined as healing effectiveness.\textsuperscript{263} This is in stark contrast to other states’ IP regulations. In the United States, a new chemical compound may receive a patent by being easier to store or being more easily absorbed by the body.\textsuperscript{264} That is not only a more forgiving standard; it is also a lot easier to prove. Proving therapeutic effectiveness is difficult and costly. Relatedly, India also does not allow patenting of combinations of known drugs.\textsuperscript{265} In the United States, even if drug A and drug B are not patented, a combination of them, drug AB, can be patented. That

\textsuperscript{261} On Section 3(d), see Liu, Jodie. 2015. “Compulsory Licensing and Anti-Evergreening: Interpreting the TRIPS Flexibilities in Section 84 and 3(d) of the Indian Patents Act.” Harvard International Law Journal. 56:1. p. 207-227.
\textsuperscript{263} Ibid. p. 1594.
cannot be done in India. India also does not grant data exclusivity.\textsuperscript{266} All of these exceptions can mean that India can make a drug that is patented in other states subject to generic competition without needing to issue a compulsory license.\textsuperscript{267} Importantly, none of these maneuvers to relax IP standards violate the letter of TRIPS.\textsuperscript{268}

It is not just the content of India’s IP regulations that limit patentability; it is also the procedure by which patenting decisions get made that helps activists and curtails drug firms. The opponents of a patent have three opportunities to make their case before the government: 1) at a pre-grant stage in front of the patent office or, 2) at a post-grant proceeding at the patent office or, 3) through revocation proceedings before India’s Intellectual Property Appellate Board.\textsuperscript{269}

The pre-grant stage is particularly important. In this stage, the Indian patent office allows activist organizations and generic drug makers to review pending patent applications to decide which ones they want to oppose.\textsuperscript{270} At this stage, any individual or activist organization, not just rival companies, may oppose a patent being granted.\textsuperscript{271} Indeed, NGOs have filed many of the pre-grant oppositions.\textsuperscript{272} Once again, this stands in marked contrast to the United States and other high-IP states that often have no mechanism whatsoever for pre-grant opposition.\textsuperscript{273}

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  \item \textsuperscript{266} Lalitha. 2013. “Access to Indian Generic Drugs.” p. 244-245.
  \item \textsuperscript{267} Kapczynski. 2009. “Harmonization and Its Discontents.” p. 1594.
  \item \textsuperscript{268} Ibid. p. 1595.
  \item \textsuperscript{270} Kapczynski. 2009. “Harmonization and Its Discontents.” p. 1602.
  \item \textsuperscript{272} Kapczynski. 2009. “Harmonization and Its Discontents.” p. 1599-1600.
  \item \textsuperscript{273} Kapczynski. 2009. “Harmonization and Its Discontents.” p. 1599. Having no opportunity for pre-grant opposition hurts opponents not just because it is a blocked opportunity in its own right but also because by the time they are opposing a patent it is after the patent has granted it and thus would make the patent office look bad if it were to win.
\end{itemize}
Once put in place, it did not take long for Western pharmaceutical companies to start to feel the bite of these less-friendly IP regulations. In 2006, despite protests from activists, Novartis filed for a patent in India on its new leukemia drug Glivec.\textsuperscript{274} Access to medicine activists immediately protested, pointing to Glivec as an example of evergreening.\textsuperscript{275} The Indian government denied that patent application because Glivec was a modification of an earlier drug (imatinib); the only change was that it was put into a salt format which Novartis claims makes it a patentable improvement since the salt form can be absorbed by the body 30% more easily.\textsuperscript{276} Novartis could not prove that Glivec had greater therapeutic efficacy and thus could not prove that it met the Indian patent office’s definitions of ‘new’ and ‘useful.’

To the delight of access to medicine advocates, this decision set the precedent for using therapeutic efficacy as a key criterion for patentability. In 2012, the Indian Intellectual Property Appellate Board appeared to uphold this standard when it revoked the patents on drugs made by Pfizer, Merck, and Roche because they were not sufficiently innovative over existing drugs.\textsuperscript{277} The Glivec case went to the Indian Supreme Court, which upheld the decision to not grant it a patent, further bolstering the precedent.\textsuperscript{278} The Indian government has also recently rejected a patent for Sovaldi- the hepatitis C cure that sells in the U.S. for $84,000- on similar grounds and thus has been able to keep the price of the drug at around $900, a roughly 99 percent discount.\textsuperscript{279}

\textsuperscript{276} \textit{The Economist}. “Taking Pains.” September 8, 2012.
\textsuperscript{279} \textit{The Times of India (Jaipur Edition)}. “Indian Generic at 1/100th the Cost, Saves Aussie’s Life.” August 21, 2015.
The Indian government has also begun using compulsory licenses to lower drug prices.\footnote{280}{On compulsory licensing in India, see Chopra, Madhavi. 2015. “Of the Big Daddy, the Underdog, the Mother Hen, and the Scapegoats: Balancing Pharmaceutical Innovation and Access to Healthcare in the Enforcement of Compulsory Patent Licensing in India, its Compliance With TRIPS, and Bayer v. Natco.” \textit{Santa Clara Journal of International Law.} 13:2. p. 333-374.} One of the advantages of a compulsory license is that it requires relatively few technical resources.\footnote{281}{Kapczynski. 2009. “Harmonization and Its Discontents.” p. 1633.} India issued its first compulsory license in March 2012 for Bayer’s drug Nexavar, which is used to treat kidney and liver cancers.\footnote{282}{On the Nexavar decision, see Srinivasan, S. “The Compulsory Licence for Nexavar: A Landmark Order.” \textit{Economic and Political Weekly.} April 7, 2012. Vol. 47, No. 14. Bajaj, Vikas and Andrew Pollack. “India Order Bayer to License a Patented Drug.” \textit{The New York Times.} March 13, 2012.} Bayer charged $5,500 per month for Nexavar; Natco, an Indian generics firm, sold a copy for $173 a month after the compulsory license was issued.\footnote{283}{Ward, Andrew and Amy Kazmin. “Bayer Loses Bid to Block Cheap Version of Cancer Drug in India.” \textit{Financial Times.} December 12, 2014.} The Nexavar compulsory license opened the possibility for India to issue compulsory licenses for at least four other patented drugs.\footnote{284}{Inside U.S. Trade. “U.S. Business Steps Up Fight Against Indian Trade Barriers Ahead of Election.” June 14, 2013. Vol. 31, No. 24.} There likely would have been more compulsory licenses issued had it not been for the fact that some drug companies, faced with imminent compulsory licensing decisions, have cut deals to allow local producers to make generic versions of their drugs.\footnote{285}{Kazmin, Amy. “Roche Drops Patent for Herceptin in India.” \textit{Financial Times.} August 16, 2013. Harris, Gardiner. “India’s Efforts to Aid Poor Worry Drug Makers.” \textit{The New York Times.} December 30, 2013.} Given the very high costs of many cancer medicines and given that the number of cancer cases in India is expected to double in the next two decades, it is possible that the Indian government will increase its use of compulsory licenses.\footnote{286}{Pulakkat, Hari. “Number of Cancer Cases in India Predicted to Double in Next 20 Years.” \textit{The Economic Times.} April 18, 2014.}

In addition to tight patentability requirements, a patent-granting process open to activists, and compulsory licenses, the Indian government also developed new policy measures related to injunctions, and ironically, received a major boost in this effort from...
the U.S. Supreme Court. Over the course of the 1990s and early 2000s, more and more companies found themselves being sued for patent infringement by shell firms that filed patents but never did anything with them. These shell companies were basically just waiting for someone else to infringe the patent so they could sue them and profit from settling out of court. These shell companies came to be known as patent trolls. This was especially a problem in the United States. In 2006 a case involving one of these patent trolls and eBay came before the U.S. Supreme Court.\(^{287}\)

When a plaintiff argued that their patent was being infringed, courts up to this point had generally issued injunctions, which forced the firm accused of infringing the patent to cease the activities involving the patent unless there was some sort of extraordinary circumstance. In their decision on this case, eBay v. MercExchange, the Supreme Court unanimously ruled that this automatic injunction was unwarranted and instead argued that a more balanced approach should be taken.\(^{288}\) According to the Supreme Court’s decision, for an injunction to be granted, the plaintiff (i.e. the patent holder) must show that 1) it suffered irreparable injury, 2) it could not be fairly compensated, 3) the balance of hardship between the two parties merits an injunction and 4) the public interest would not be disserved.\(^{289}\) This unanimous decision constitutes a powerful change to how patent infringement should be handled by the courts and by extension, the regulatory standards that dictate how much protection IP should receive if and when that intellectual property affects a tangible aspect of the public interest.


\(^{289}\) Ibid.
When Clarence Thomas was writing this opinion, and when the other eight justices were joining, they may or may not have been considering how it would affect the Indian government’s treatment of drugs, but their decision nevertheless handed the Indian government a powerful new legal justification for refusing to force a generic drug maker to cease making copies of patented drugs. This is exactly what they did. Shortly thereafter, the Indian Court cited the U.S. Supreme Court decision numerous times to defend its decision to not issue an injunction that would have forced Cipla (a generics firm) to stop making copies of a drug that Hoffman-La Roche held the patent to.  

In other words, an Indian court found against a foreign pharmaceuticals firm and based its decision on the U.S. Supreme Court. This was really clever. How could U.S. government officials in the USTR and Congress insist that the Indian court’s actions in denying injunctions were illegitimate and a denial of due process when they rested on legal foundations constructed by the U.S. Supreme Court? The U.S. Supreme Court has given the Indian government the legal means to grant patents but then selectively refuse to enforce those patents if they lead to higher prices, which is exactly what patents do. In fact, the non-use of injunctions may be an even more robust check on drug firms’ market exclusivity than compulsory licenses because they are less vulnerable to unilateral retaliation given the political insulation that judges often enjoy.

The pharmaceutical company representatives and government officials that were the primary authors of TRIPS never anticipated this kind of attack on stringent IP regulations via new injunction standards. TRIPS thus says absolutely nothing about this. No one foresaw this series of events. India thus has a TRIPS-compliant means of

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291 Ibid. p. 1632.
indirectly invalidating any patent it issues. Article 44.1 of TRIPS only gives judiciaries the authority to issue injunction.\textsuperscript{292} It never says that they must. This was not the only gap in TRIPS.

While TRIPS seemed to be a blowout victory for business supporters of stringent IP regulations, it was actually full of little holes that India has been able to exploit. These holes were not intentional. They were the result of a certain amount of sloppiness and lack of legal imagination on the part of the officials that negotiated TRIPS. Emory Simon, the director for IP at the USTR at the time, said that “the reality is that we do not spend a lot of time thinking about legal issues when we negotiate agreements in the GATT…the concerns that we have are with the commercial results of what a negotiated agreement is, rather than with the legal niceties of it.”\textsuperscript{293} If anyone should have been obsessed with the legal niceties of TRIPS, it should have been the director of IP at the USTR, but even he was not all that interested in the details. For whatever reason, Emory Simon and the other TRIPS negotiators simply did not appreciate the simple truth that details are sacred things that should never be ignored simply because big ideas are sexier.

In addition to the small but critical distinction that national judicial bodies could but did not have to issue injunctions, the TRIPS language on pharmaceuticals only covered small-molecule drugs and so enabled countries to deny patents on biologics.\textsuperscript{294} The TRIPS Agreement also never defines inventive step and that too gives India considerable leeway.\textsuperscript{295} States are also allowed to employ patent exemptions for non-

\begin{flushleft}
\textsuperscript{292} World Trade Organization. Agreement on Trade-Related Aspects of International Property Rights. Article 44, Clause 1. \\
\textsuperscript{293} Drahos and Braithwaite. 2002. Information Feudalism. p. 139. \\
\textsuperscript{294} Deere. 2009. The Implementation Game. p. 77. \\
\end{flushleft}
commercial use such as second use and what are referred to as Bolar exemptions.\textsuperscript{296} India has taken advantage of both of these exemptions.\textsuperscript{297} Finally, the TRIPS dispute settlement process does not allow for retroactive sanctions and so that means there is an incentive for developing countries to push the boundaries as far as they can.\textsuperscript{298}

The Checks on These Flexibilities

Despite what appear to be robust opportunities for India to implement IP regulations that would be far lower than those envisioned by TRIPS, the Indian government has been quite temperate in its use of these flexibilities. As Shri Anand Sharma, the Indian Commerce Minister has pointed out, the Indian government has still been granting many patents to Western pharmaceutical companies; the Glivec decision is not representative of the majority of cases.\textsuperscript{299}

On compulsory licenses, the Indian government has been careful to issue them only when necessary to further public health and to not issue them when it might violate international rules.\textsuperscript{300} There are number of factors behind this policy temperance.

First, many Indian generics firms have developed increasingly tight connections with Western research-based firms.\textsuperscript{301} Relatedly, TRIPS and the attendant reduction in IP regulatory barriers has led many of the largest Indian drug companies to make more of their money abroad than at home.\textsuperscript{302} For many of these companies, licensing foreign

\textsuperscript{296} Bolar exemptions are rules that allow a generic firm to use a patented product for testing purposes while it is still under patent. On Bolar exemptions see Deere. 2009. The Implementation Game. p. 80-81.
\textsuperscript{297} Deere. 2009. The Implementation Game. p. 79.
\textsuperscript{300} Business Line. “India Again on US IPR Priority Watch List; Govt Disappointed, But Not Worried.” May 1, 2015.
intellectual property, rather than copying it, is the more profitable route, but Western firms want effective IP protection to agree to giving a license to a firm based in a developing country. Western firms such as AstraZeneca, GlaxoSmithKline, Eli Lilly, Pfizer, and Novartis, and have also increasingly partnered with Indian firms to conduct clinical testing as this can achieve cost savings of 40-60 percent.

This means that Indian firms’ competitiveness would suffer if India were to become perceived as a pariah on protecting IP. This incentivizes the Indian government to loosen IP regulations where it can but not go so far as to make foreign investors skittish. Once again, the disguised protectionism argument would fail to correctly explain the source of this regulatory difference. Here too, it was activists, not businesses, that were clamoring for regulatory differences that could impede trade.

Second, rather than focusing exclusively on generics production, many Indian firms are increasingly involved in research and development, either on their own or in a partnership with foreign firms. India has a significant talent pool in chemistry and chemical engineering, two building blocks of pharmaceuticals research; 122,000 Indians annually graduate from Indian universities with degrees in those two subjects, and they work cheap. With research and development costs that are one-eighth of those in Western countries, India is highly competitive in this subfield. That R&D requires IP protection though. When Western companies believe that protection is not high enough,
they pull their investments. After initiating new investments in rural India in 2008, Novartis announced after the Indian Supreme Court’s Glivec decision in 2013 that it would no longer make any research and development investments in India.\textsuperscript{308}

Additionally, because the point of compulsory licensing is to bring down drug prices and because those licenses come with considerable scrutiny, many India firms increasingly perceive producing compulsory licensed drugs as not very profitable.\textsuperscript{309} Thus, Indian firms are much less enthusiastic about loose IP regulations than might first be assumed. India also has the world’s largest film industry and a sizeable software industry, both of which want strong copyright protection, which only adds to the volume of domestic voices calling for higher IP regulations.\textsuperscript{310}

Third, India does not want a WTO ruling against it and thus has been careful not to use these flexibilities in a potentially disadvantageous case. For example, it rejected a generic firm’s application for a compulsory license on AstraZeneca’s drug Saxagliptin, a diabetes medication, because substitutes are readily available and the generic firm was only going to be able to deliver relatively little cost savings given the already fairly low price of Saxagliptin.\textsuperscript{311} The Indian government knows that if it stretches the TRIPS Agreement to the point of clearly violating it, it would invite a dispute with a developed country, probably the United States. A WTO ruling against it could greatly constrain its space for policy flexibility.\textsuperscript{312} On the other hand, the United States may have lost a WTO

\textsuperscript{311} The Economic Times. “India Rejects Lee Pharma’s Compulsory License Plea.” August 18, 2015.
dispute panel over Nexavar had such a dispute materialized, and so the U.S. too is a bit gun-shy about starting WTO cases that could go against it and thus put India’s IP regulations on firmer legal grounds.\footnote{A WTO case involving the EU and Canada defined IP trade discrimination as ‘differential treatment without a reasonable justification.’ If the WTO panel decided that bringing down the high cost of Nexavar was a reasonable justification, the U.S. would have lost and the compulsory licenses would have been augmented.} As with the WTO stalemates discussed earlier, for both sides it is better to have a murky non-resolution than risk a clear loss.

Fourth, the United States has direct and indirect means of pressuring India to not go too far in its creativity. U.S. officials can employ Special 301, and under pressure from business, they came close to doing so after the Nexavar decision.\footnote{Inside U.S. Trade. “Business Coalition Seeks PFC Designation for India in Special 301 Report.” February 14, 2014. Inside U.S. Trade. “Special 301 Report Stops Short of Naming India PFC; Watch Lists Largely Unchanged.” May 1, 2014.} The American drug market is the world’s largest and so the Indian government views friendly cooperation with the United States, and the FDA in particular, as crucial towards protecting the export performance of its pharmaceuticals sector.\footnote{Inside U.S. Trade. “Leavitt Says Placing FDA Inspectors in India is a ‘High Priority for U.S.” March 21, 2008. Vol. 26, No. 12.} The Indian patent authorities have relatively few resources to push back against this pressure and at the same time their patent examiners generally receive their training in Western states and rely on their Western counterparts for guidance.\footnote{Kapczynski. 2009. “Harmonization and Its Discontents.” p. 1617-1627.}

Finally, the new government headed by Narendra Modi that assumed power in May 2014 has been especially keen to attract foreign direct investment from multinational corporations and so has been careful not to implement IP regulations that would make these businesses wary of investing in India. Modi has even suggested that he would like to see India change its IP laws to more closely match other states’ higher standards saying, "If we don't work towards bringing our intellectual property rights at
par with global parameters, then the world will not keep relations with us. If we give confidence to the world on IPR, then we can become a destination globally for their creative work.”

Modi has disbanded a cabinet-level subcommittee that was making compulsory licenses more likely to be approved, to the delight of international drug companies. He also set up a six-person think tank to review India’s IP regulations; of those six members, four were connected with large businesses that have an interest in raising India’s level of IP protection and none of them were from academia or access to medicine advocates.

In sum then, the Indian position on IP-regulations has been a compromise. It has patentability regulations that are much more restrictive than developed countries like the U.S. would prefer. It has procedures that allow NGOs to challenge patents at multiple stages. It has new, U.S. Supreme Court-backed policies related to injunctions. It has begun issuing compulsory licenses. All of these mean that India could have given an across the board resounding victory to access to medicine advocates. It instead opted for a middle ground approach. It did so for several reasons. Its drug firms often have close relationships with international drug companies and are increasingly involved in research and development. Also, firms in other industries want IP protection. Additionally, it is wary of a WTO ruling against it and is pressured by the U.S. government. Finally, its prime minister has prioritized attracting foreign direct investment.

Still, even taking into account Modi’s position and the other checks on India’s creative use of TRIPS flexibilities, India’s IP regulations stand as a model for other

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developing countries that want to maintain different regulations than those espoused by those states with high IP regulations. The Philippines in 2008 for example, added a patentability provision to their patent law that is modeled after India’s Section 3(d).  

**Conclusion**

Intellectual property, especially as it pertains to pharmaceuticals, is often held up as an exemplar of big business getting its way politically, and indeed the TRIPS agreement did largely reflect the wishes of IP-intensive firms. And yet the TRIPS negotiation is the only case analyzed here in which businesses were able to secure their preferences and even here, they were able to get their way only because they were able to link their policy requests with broader concerns about competitiveness and because NGOs did not take the field. In the negotiation of the Doha Declaration, access to medicine politically snookered pharmaceutical companies and won significant legal reinforcement for differing IP policies. In the latter two cases, businesses did not suffer resounding defeats but, because of the opposition of NGOs and developing country officials, neither were they able to fully achieve their policy preferences. Far from demonstrating business’ political power, the negotiations over intellectual property regulations and trade show just how contingent and limited business’ political power actually is.

These negotiations also demonstrate how important not knowing can be. Access to medicine activists did not get engaged in the TRIPS negotiation in the 1980s and early 1990s because they did not yet understand how significant IP regulations were to their overall goals. In the negotiation over the Doha Declaration in 2001, pharmaceuticals companies walked into a policy fight they had no chance of winning because they had no

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idea just how fierce the public relations backlash against them was going to be. India’s
creative use of TRIPS flexibilities only happened because the original authors of the
TRIPS Agreement did not understand how important the legal details were and did not
anticipate the extent to which clever, oppositional interpretations could exploit the holes
they left behind. When it comes to regulatory trade barriers, what you do not know will
hurt you.

One thing we do know is that people will continue to get sick. Some will get very
sick. Between 130 and 150 million people have hepatitis C.\(^{321}\) Cardiovascular disease
killed 17 million people in 2012.\(^{322}\) Close to ten percent of all adults now have
diabetes.\(^{323}\) The biggest challenge of all is cancer. Cancer has been called the emperor of
all maladies with good reason.\(^{324}\) 14 million new cases are diagnosed every year and the
number of new cases is expected to increase by 70 percent over the next twenty years.\(^{325}\)
The political fight over how best to help those dying from these diseases, and how to pay
for that help, is just starting. Trade-related intellectual property regulations, as dry and
technical as they may sound, are at the very center of that fight.

\(^{324}\) Mukherjee, Siddhartha. 2010. The Emperor of All Maladies: A Biography of Cancer. Scribner: New
York.
Chapter 7 - Conclusion: Regulation and Trade Politics in the 21st Century

The intersection of trade and national regulations has significant consequences for our contemporary world and is likely to continue to do so for the foreseeable future. In this chapter, I discuss the theoretical implications this work has for IPE scholarship. I then offer political recommendations for the businesses, NGOs, and government officials examined in this work. I finally discuss how lessons from these industries may apply to other industries as well.

Theoretical Implications for IPE Scholarship

This book has seven implications for IPE scholarship on trade. It calls for a more critical questioning of cleavage-based explanations. It qualifies the California Effect. It highlights the growing importance of national courts in international trade politics. It helps explain the rise of regionalism. It clarifies the trade policy options that developing countries have moving forward. It underscores activists’ political power. Finally, it points to emerging vectors in the U.S.-China relationship.

Questioning Cleavage-Based Explanations

As I discussed in Chapter 2, the increasing extent to which international trade negotiations involve national domestic regulations has fundamentally altered the politics of trade by bringing in activists that previously were uninterested in trade negotiations. As I pointed out repeatedly in all three case studies, the involvement of these actors and the importance of government officials’ stance on these regulatory trade barriers mean that the cleavage-based explanations of trade politics are no longer sufficient. In European emissions standards, the division was not between economic winners and losers but between a sector (automakers) that had an economic stake and a sector (environmentalists) that wanted to prioritize non-economic public policy goals. The same
was true for Japanese consumer organizations versus American beef producers and access to medicine advocates versus pharmaceutical companies.

Given the centrality of those explanations to our understanding of trade politics, that presents a major challenge but also a significant opportunity. It is a challenge because if those giant shoulders can no longer be stood upon, then new theories of trade politics must be constructed to take their place. It is an opportunity because it allows future researchers to critically question many of the assumptions made in 20th century scholarship and ask whether they still hold today.

For example, Rogowski divided society into three groups based on which factor of production they possessed: landowners, capital holders, and laborers. Hiscox then sharpened Rogowski’s work by adding another economic factor, asset specificity into the mix. As we’ve seen though, regulation brings whole new non-economic factors into play in trade politics. Given that, is this division based solely on economic factor endowments still the most useful way to conceptualize groups in society? It certainly continues to have some leverage and I do not mean to suggest otherwise (owners of mobile capital still have quite different interests from relatively immobile laborers), but perhaps regulation means we need to rethink how we conceptually divide society. In this work, I have divided in one particular way - businesses, activists, and government officials - but that is certainly not the only way actors in trade politics may be thought of.

Given the rise of the populist right in Europe and the United States that have propelled the Le Pen’s and Donald Trump and the political divisions that has highlighted, perhaps it may be useful to also think about society in terms of how people feel about the different fundamental components of trade. Trade, in its most basic sense, is business
conducted with foreigners under a set of international rules. Society then could be divided into four groups based on how they feel on the one hand about big businesses, which are the firms most closely associated with international trade and on the other hand how they feel about foreigners and international institutions.

The first group would be nationalists who mistrust big businesses as well as foreigners and international institutions. The second group would be leftists who mistrust big business but are more accepting of foreigners and international governance. The third group would be corporatists who mistrust foreigners and international governance. The fourth group would be globalists who support big business as well as foreigners and international governance. The division in the Republican Party over trade is in many ways a divide between the nationalists and the corporatists in that party. Conversely, the division in the Democratic Party may be thought of as a division between the leftists and the globalists. This is obviously somewhat speculative but what I mean to point out is that given the extent to which trade politics now touches upon a huge array of non-economic policies, our conceptualization of societal groups’ trade preferences also should take into account non-economic motivations.

**Qualifying the California Effect**

This work also offers qualifications to the California Effect. ¹ The cases analyzed in this work suggest three conditions under which the California Effect is more or less likely. First, the smaller state in the trade negotiation has to actually want the agreement more than the larger state. The key causal mechanism in the California Effect is market

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¹ As I explained in Chapter 3, there are three elements to the California Effect. 1) Businesses support stricter regulations when those stricter regulations make them more competitive. 2), richer states with higher standards force producers in other states to raise their standards in order to export to them and so de facto raise foreign standards. 3) Trade agreements give richer states with higher standards leverage to pressure other states to raise their standards to the richer states’ level. Vogel, David. 1995. Trading Up. Harvard University Press: Cambridge, MA.
size. The state with the larger market is able to use the potentially lucrative access to that market as leverage in the trade negotiation. Market size however is not the only potential political leverage that may exist. If the state with the smaller market is less eager to seal the agreement than the larger state, that smaller state has much more relative leverage. In the pharmaceuticals case, during the negotiations over the issues leftover from the Doha Declaration, developing countries were much less eager to revive the flagging Doha Round talks than the United States was. This resulted in the United States being less able to use its market size as leverage to raise intellectual property regulations and so short-circuited the market power causal mechanism that can create a California Effect.

Second, a California Effect is less likely to happen if the firms whose market access is being impeded by regulatory trade barriers believe they can get the state with the higher standards to lower those regulations. If that is the case, those firms may choose not to accept and then promote higher standards, but instead fight against them. This occurred in the beef case when U.S. producers believed that they could get the United States Trade Representative to pressure Japanese regulators to reduce Japan’s anti-mad cow regulations that were inhibiting their exports.

Third, a California Effect is less likely if narratives of access dominate narratives of protection. Calls for more stringent regulation generally flow from a desire to use those regulations to protect consumers from risky products. However, when consumers are more concerned with promoting access to a good, those who would normally be the most enthusiastic pursuers of higher regulations, consumer advocates, do not do so. It is because narratives of access predominated among Mexican automobile purchasers that there has not been a California Effect in consumer safety regulations in Mexico to match.
U.S. safety standards. Narratives of access have also predominated in developing countries on intellectual property and so have served to bolster resistance to higher IP regulations there as well.

**The Growing Importance of National Courts in International Trade Politics**

A third noteworthy implication for IPE scholars is the significance of national courts. Now that international trade negotiations involve national regulations, national courts, by affecting those regulations, can have indirect but nevertheless powerful effects on trade. In the beef chapter, the reduced ability of Japanese consumers to seek redress and recompense through their national courts relative to their American counterparts made them much more eager for strict regulations. That eagerness was the foundation of the resilience of the regulatory barriers that impeded imports of American beef. In the auto case, the inability of the NHTSA to use a type-approval system was rooted in the American tradition of adversarial legalism in the courts. This led to the NHTSA setting up a recall system. The differences between the European Union’s type approval systems and the United State’s recall system is the foundation of many of the consumer safety differences in automobiles between them. In the pharmaceuticals case, it was a United States Supreme Court cases on patent injunctions that bolstered India’s policy space to implement less stringent intellectual property regulations. So long as trade politics involves regulations, it de facto involves courts.

The upshot of this is that courts may be required to increasingly think about how other states have adjudicated a particular issue and about what effect their ruling may have on foreign jurisdictions. Indeed, U.S. Supreme Court Justice Stephen Breyer has

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2 For a look at the use of foreign law in the U.S. Supreme Court, see Parrish, Austen. “Storm in a Teacup: The U.S. Supreme Court’s Use of Foreign Law.” *University of Illinois Law Review*. p. 637-680. For a
recently argued that given the increasingly interconnected world in which we live and the centrality of national courts to juridical structure of that world, those jurists must now be constitutional diplomats, carefully weighing how international politics affect their decisions and how their decisions affect international politics.³

Courts, however, must be careful in this endeavor both not to over-involve themselves in international matters as that could both add to their already stuffed dockets and invite heightened international tensions. They must also be wary of their potential to be perceived as illegitimate lawmakers. Citizens already do not appreciate judiciaries behaving like activists judges; that would likely only grow worse if that activist judge operates from a foreign court.

*The Rise of Regionalism*

In the post-Cold War era, regional trade agreements have proliferated at a remarkable rate.⁴ Economists have generally been skeptical of these agreements and have argued that the growth of regionalism is both inferior to multilateral liberalization and undermines multilateralism.⁵ As Greg Anderson points out, it is non-economic reasons that account for why regional trade liberalization is growing despite its inferiority to multilateralism in terms of efficiency.⁶ Anderson lists geopolitical imperatives, the desire to solidify partner states’ economic reforms, the desire to help developing countries and

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the increasing difficulty of collective action problems as negotiating groups grow larger as motivations that drive states to liberalize trade regionally.\(^7\)

To that list, we can add the ascending importance of regulatory trade barriers. In principle, it is almost always the case in any international negotiation that it is easier to reach agreement among a smaller group of states, but the greater sensitivity of regulation as opposed to tariffs, and the inclusion of once excluded domestic actors, make this an even more acute obstacle than would otherwise be the case. Exhibit A on this dynamic is the Doha Round. As I explained in Chapter 2, since the mid-2000s, it has been quite clear that the round would not result in substantive trade liberalization in the regulatory trade barriers that developed states would like to target. Thus, those developed states have pursued trade liberalization at the bilateral and regional levels. In other words, one of the central trends in international trade, the rise of regionalism, can be traced to the increasing importance of regulatory trade barriers and to the politics that surround them.

This work also suggests that it is unlikely that the trend toward regionalism, rather than multilateralism, is likely to reverse itself. As I argued throughout this book, businesses are at their most effective in seeking reduced regulatory trade barriers when they can connect their pursuit of that goal with broader concerns about competitiveness. That is more difficult to do at the multilateral level. The argument that a regional trade deal makes the states within that region more competitive vis-à-vis states outside the region has a certain intuitive appeal. It becomes much more difficult to make that

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argument if the deal is at the WTO level as such an agreement would include nearly all countries. Everyone cannot simultaneously become more competitive.\(^8\)

**Developing Countries’ Options**

In exchange for making further concessions on agriculture and textiles, developed states are likely to insist on greater regulatory constraints on developing countries. This was the basic exchange that developed states asked for in the Doha Round when they pushed for regulatory trade barrier reduction in the four Singapore Issues - investment, competition, government procurement, and trade facilitation. Once they could not get regulatory trade barrier reduction in those areas, developed states, and especially the European Union and Japan, refused to offer further concessions on agriculture and textiles. This has also been the basic bargain in regional trade deals. In the TPP, Malaysia and Vietnam are gaining greater market access in Japanese and North American agriculture and textile markets in exchange for agreeing to greater regulatory constraints in intellectual property, competition rules, investment, human rights enforcement, labor standards, environmental protection, and health and safety standards.

This means that for developing countries to achieve the agricultural liberalization they want, they have three basic options moving forward. First, they can continue to push for greater liberalization in agriculture and textiles through the WTO and accept movement on the Singapore Issues. That seems unlikely. The second option is to accept inclusion into regional trade deals involving developed states like the TPP. The third option would for developing countries, be to construct a new trade agreement amongst

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\(^8\) Paul Krugman, among others, has strongly criticized competitiveness as a way of thinking about international trade. His criticism is well founded and I do not dismiss it. Competitiveness is a flawed way of thinking about international trade. I have not and do not advance competitiveness as an accurate or helpful way to conceptualize trade. I merely argue that the rhetoric of competitiveness is particularly powerful from a political standpoint. For criticisms of competitiveness as a way of understanding trade, see Krugman, Paul. “Competitiveness: A Dangerous Obsession.” *Foreign Affairs.* March/April 1994.
themselves. Tariffs between developing countries remain much higher than between developed and developing countries. Much of the direct gains from trade liberalization are the result of tariff reductions. As they become more prosperous and more populous, the gains from trade between developing countries is likely to continue increasing.\(^9\) Additionally, reducing tariffs can promote economic growth in developing countries, especially in Sub-Saharan Africa, by helping those countries engage in greater intra-industry trade and global supply chains.\(^10\)

Furthermore, a Trade Agreement of the Global South (TAGS) that focused on tariff reduction would mean that developing countries could benefit from trade liberalization without having to undermine their regulatory flexibility. Importantly, the second and third options are not mutually exclusive. Developing countries could continue to join regional trade agreements when and where they choose, and at the same time, work toward greater trade liberalization between each other.

**Activists’ Political Power**

This work underscores just how much political power activists actually have. In popular conceptions of political lobbying, it is often presumed that well-financed business interests are the powerhouses and activists the underdogs. This book suggests that activists’ succeed in their opposition to business more often than that popular conception would imply.

In cars, European environmentalists were able to win major increases in emissions standards. In North America, they won significant environmental improvements in

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\(^9\) The United Nations estimates that by 2050, more than twice as many people will live in Africa as in Europe and North America combined (2.5 billion versus 1.1 billion). United Nations. 2015. “World Population Prospects: 2015 Revision.” Department of Economic and Social Affairs” Population Division.

Mexico via NAFTA. Consumer safety advocates were successful at raising the safety standards of Mexican trucks and at blocking transatlantic regulatory trade barrier reductions they opposed.

In beef, Japanese consumer safety advocates were able to promote strict anti-BSE countermeasures such as universal testing over 20 months and specified risk material removal on all cattle and were able defend those measures even against considerable diplomatic pressure from the United States. It is a testament to their strength that it was only when they were satisfied that regulatory barriers were reduced.

In pharmaceuticals, access to medicine activists achieved a sweeping success in the Doha Declaration, which clarified and bolstered states’ ability to use intellectual property regulatory flexibilities such as compulsory licenses to promote public health. They have successfully resisted attempts by drug companies to limit which diseases count as a national emergency and to use non-violation complaints. They have also effectively promoted creative, TRIPS-compliant regulatory flexibilities that have in effect relaxed intellectual property regulations in developing countries such as India.

Out of all 23 sub-cases analyzed in this book, only in the domestic-content regulations in the North American auto industry and the negotiation of the TRIPS Agreement in pharmaceuticals did businesses dominate. Everywhere else, activists’ had a meaningful amount of political power and at least some success at advancing their goals.

Perhaps this can be of comfort to both sides. Activists’ may take heart that their odds of success are not as long as they may fear. Activists are not the political weaklings that they are sometimes presumed to be. Businesses may find it useful to show that in reality they do not dominate the policy process anywhere nearly as much as is commonly
believed. Multinational corporations are not the evil overlords of global capitalism that they are sometimes depicted as.

**The U.S.-China Relationship**

The economic relationship between the United States and China is likely to be one of the most important dynamics in global politics for the next several decades. The scope and trajectory of that relationship could obviously be a whole series of books unto itself and I will not try to encapsulate all facets of it here, but the political negotiations over regulatory barriers in each of the three industries analyzed in this book points to a significant aspect of that relationship.

**Cars**

The auto industry highlights the potential rewards for successfully entering the Chinese market.\(^{11}\) The Chinese auto market is now the largest in the world.\(^ {12}\) From 2004 to 2014, the Chinese auto industry averaged 11.4 percent annual growth versus growth in North America, Europe, and Japan of 0.9, 1.4, and -0.5 percent respectively.\(^ {13}\) While China’s economic growth has slowed somewhat over the last year, the Chinese market is expected to grow another twenty percent to 30 million cars by 2020, which represents a significant portion of overall global growth.\(^ {14}\) China is where the expansion opportunity for automakers is.

The opportunity though comes with challenges, particularly in relation to differences in consumer tastes, and in the difficulties created by China’s regulations. In

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consumer tastes, in addition to the obvious differences such as Chinese car buyers’ greater preference for sub-compact cars, there are other less obvious differences that automakers should remain vigilant about. For example, surveys have shown that Chinese consumers are much more particular than their American counterparts about what smell fabrics and other interior materials in a new car should have.\textsuperscript{15} Recall that significant differences in consumer tastes were one of the key factors that undermined automakers desire to pursue regulatory convergence in safety standards between the United States and Europe. Here too, automakers may want to consider not pursuing regulatory convergence for the same reason.

Given the increasing number of cars on Chinese roads and the concomitant deterioration of air quality in Chinese cities, China’s emission regulations are likely to become much tougher, very soon. In fact, Ford CEO Mark Fields believes that at some point in the next five years China’s environmental regulations on cars will be the strictest in the world.\textsuperscript{16} Here automakers would do well to not resist an increase in emissions standards but instead simply ask for standards to be set in high, uniform way. If and when China does raise its emissions standards, that could be an excellent opportunity to promote a mega-sized California Effect.

These potential rewards and challenges can be seen in other industries as well. It is of course not just the auto industry that has grown. The wealth and size of the Chinese middle class is expanding quickly. In fact, there are now more people considered middle class in China than in the United States.\textsuperscript{17} The disposable income of urban Chinese

\begin{itemize}
\item \textsuperscript{17} Credit Suisse Research Institute. 2015. “Global Wealth Report.” p. 31. Middle-class in this reported is defined as those adults possessing between $50,000 and $500,000 wealth.
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consumers is expected to grow from $4,000 to $8,000 dollars from 2010 to 2020.\textsuperscript{18} And it is not just urban consumers in coastal China that global firms can reach. The share of the Chinese middle class that lives in inland China is expected to triple from 13\% to 39\% from 2010 to 2020.\textsuperscript{19} These consumers are a key target market for businesses selling everything from laptops to laundry softener.\textsuperscript{20} One of the major challenges for these companies however is China’s slough of regulatory barriers that at times impede companies’ ability to reach that market.\textsuperscript{21}

In other words, the single biggest commercial opportunity for countless firms boils down to the movement of regulatory trade barriers. As I have argued throughout this book, linking a reduction of regulatory barriers with economic competitiveness has been the most consistently successful means of winning a reduction in those barriers. Joint ventures between multinational corporations and Chinese firms as well as other means of more tightly intertwining the Chinese economy with the global economy may be the best way to portray reductions of those regulatory barriers as boosting Chinese competitiveness and thus may be the best way to convince Chinese leaders to reduce those barriers.\textsuperscript{22}

\textsuperscript{20} More laptops are now purchased in China than anywhere is the world. Meanwhile, laundry fabric softener sales there have grown twenty percent a year, every year, for the last five years. Barton, Dominic. “Half A Billion: China’s Middle Class Consumers.” \textit{The Diplomat}. May 13, 2013.
\textsuperscript{22} A good example of one such joint venture in the auto industry is Shanghai GM, which is a joint venture between General Motors and China’s SAIC Motor Corporation.
Beef

The trade in beef between the United States and China underscores how difficult it will be for the United States to impose its preferences on China. In December 2003, when the first case of mad-cow disease was discovered in the United States, China closed its market to imports of U.S. beef, just as Japan did. The difference is that whereas the Japanese market was gradually reopened to U.S. beef, the Chinese market was not. China refuses to end that prohibition until the United States puts in place a traceability system and as we saw in the Japan case, U.S. beef producers refuse put that kind of a system in place. The reduction in mad-cow cases and the relaxation of Japanese consumers was crucial to the reopening of the Japanese market but another important factor was that Japanese businesses were concerned about losing competitiveness in the American market relative to their Korean rivals and the United States was able to use that market power and the lure of the TPP to get those businesses to lobby for a reduction in those regulatory barriers in beef.

Should the TPP get ratified and should the Chinese government decide that it wants to join that agreement, the United States may gain leverage to convince Beijing to readmit American beef but at least for now it does not have that kind of leverage over the Chinese government. To the contrary, the fact that China’s rapidly increasing demand for beef gives it market leverage of U.S. beef producers. As a result of that market leverage, China has a much greater ability to set regulatory standards that differ from other states and still get businesses to comply. Australian beef producers for instance have been happy to abide by Chinese regulations to order to gain access to such a large and lucrative

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This trend can be seen in other sectors as well. Traditionally, the United States and the European Union have been the global powerhouses in regulation and trade. China is quickly becoming a third pole.

Drugs

The pharmaceuticals trade, and intellectual property more generally points to the tension between the two states being in competition with each other while also having some shared interests. In June 2012, the Chinese government amended the country’s IP regulations to facilitate a greater use of compulsory licenses, but only in cases of epidemics like SARS and Ebola, and has not actually issued a single compulsory license to date. China is determined to become a global leader in pharmaceuticals research; from 2004 to 2012, their annual research and development spending in pharmaceuticals increased ten-fold to 1.1 billion dollars. That is still quite small by Western standards and the Chinese pharmaceuticals industry still mostly specializes in drug ingredients rather than new medicines, but over the near and medium term futures China’s investments in pharmaceutical R&D is likely to grow even more and its companies will start to become more oriented toward advanced research and patented drugs. This means that Chinese firms will be the direct competitors of Western firms but it also means that they will want intellectual property protected and so China’s stance on IP is likely to increasingly complement rather than contradict America’s IP preferences.

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24 Australia’s dominance of the Chinese beef market is likely to further increase as a result of a recently signed free trade agreement between the two states. Inside U.S. Trade. “China Signals It Will Speed Review of Biotech Traits, Continue Beef Talks.” November 27, 2015.
That is of course not the only area in which China is trying to catch up to the United States as quickly as possible. In 2012, a group of Chinese national employed by agricultural companies in China was arrested as they tried to smuggle cutting edge genetically modified corn seeds being developed by Monsanto and DuPont out of the United States. They were attempting to steal those companies intellectual property, with the complicity of the Chinese government, so that China could increase its corn production without having to either compensate those American companies for the use of their technology or invest millions in research the way that Monsanto and DuPont had.

On the one hand, surely China and the United States both have an interest in the use of these hybrid seeds increasing so that China and other countries can more efficiently feed their growing populations. On the other hand, this was blatant corporate espionage.

Chinese companies haven’t just stolen American companies’ technology, they have also in many instances attempted to steal their branding. Nike and Apple, as well as many other firms, have had their branding copied by Chinese imitators. China’s firms that are imitating this intellectual property are in direct competition with the Western firms that want their IP rights upheld. This kind of competitive clash is also occurring in the automotive sector. The United States and China, via Tesla and BYD, are locked in fierce competition establish a market share edge in the fast growing, and potentially

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revolutionary, electric vehicle market.\textsuperscript{31} Across these and other areas, businesses in China and the United States- and by extension the two countries- are in direct competition.

Despite that competitive aspect however, China and the United States often have more in common in terms of intellectual property than is commonly assumed. Not very long ago, China was a capital-poor country that specialized in making cheap imitations of other countries’ innovation. That depiction becomes less accurate by the day; China is increasingly a hotbed of technological innovation in its own right.\textsuperscript{32} This not only increases the quality and performance of goods exported to other countries, it also is making it easier for entrepreneurs, programmers, and engineers to go work in China.\textsuperscript{33} As China become more innovation-centric rather than imitation-centric, its desire to protect intellectual property will become more aligned with the IP preferences of the United States. China and the United States are likely to be the two most economically and politically powerful states in the 21\textsuperscript{st} century. They may never be close allies but they both have an interest in a stable Middle East, a prosperous Africa, calm financial markets, and alleviating climate change to name just a few areas. How they handle intellectual property regulations and trade may be a good bellwether of how well they can handle other issue areas in which their interests somewhat, but do not entirely, overlap.

**Examining Cases Not Covered in This Book**

There are of course a number of other cases of international negotiations over regulatory trade barriers. The findings from the three industries analyzed in this work may help explain the outcomes in those negotiations. One of the first high-profile

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negotiations over a regulatory trade barrier concerned hormones in beef. The controversy started when Italian officials noticed heightened levels of developmental abnormalities in babies and linked that to hormones given to livestock that the babies then ate.\footnote{Vogel, David. 1995. *Trading Up: Consumer and Environmental Regulation in a Global Economy.* Harvard University Press: Cambridge. p. 154.} That link would later be discredited but at the time European consumers believed that banning hormones in beef protected children. Additionally, banning hormones would not make European beef more competitive because Europe already had a surplus of beef.\footnote{Vogel. 1995. *Trading Up.* p. 156.}

Genetically modified organisms (GMOs) have been banned in the EU but allowed in the United States.\footnote{On the politics of GMOs, see Pollack, Mark, and Gregory Shaffer. 2009. *When Cooperation Fails: The International Law and Politics of Genetically Modified Foods.* Oxford University Press: Oxford.} Activists pushed for that regulatory barrier because it came on the heels of a number of food safety crises including dioxin in Belgian meat and chocolate, contaminated Coca-Cola (again beginning in Belgium), and most seriously the peak of the mad-cow crisis.\footnote{Vogel, David. 2012. *The Politics of Precaution: Health, Safety, and Environmental Risks in Europe and the United States.* Princeton University Press: Princeton. p. 65, 76.} As I mentioned in Chapter 2, that crisis badly discredited the notion that regulatory harmonization combined with trade liberalization would improve Europeans’ quality of life. European consumers believed that the deaths that resulted from the mad-cow crisis were preventable and believed that a new expansion of trade in an agricultural product they were suspicious was another disaster waiting to happen; as David Vogel points out, “although there was no link between GNOs and the BSE crisis, European consumers connected the two.”\footnote{Vogel. 2012. *The Politics of Precaution.* p. 75. Pollack and Shaffer. 2009. *When Cooperation Fails.* p. 65.}
Moreover, the business most interested in trading in GMOs, Monsanto, was an American company and could not make a competitiveness-based argument.\footnote{Ansell, Christopher, Rahsaan Maxwell, and Daniela Sicurelli. 2006. “Protesting Food: NGOs and Political Mobilization in Europe” in \textit{What’s the Beef? The Contested Governance of European Food Safety}. Christopher Ansell and David Vogel (ed.) MIT Press: Cambridge. p. 104-105.} Furthermore, if GMOs raised agricultural productivity, the subsidies given to farmers under the EU’s Common Agricultural Policy would also have increased; EU officials did not want that.\footnote{Drezner, Daniel. \textit{All Politics is Global: Explaining International Regulatory Regimes}. Princeton University Press: Princeton. p. 155.} Interestingly and not coincidentally, the three areas where EU authorities made exceptions to their anti-GMO stance were in three internationally competitive European industries that wanted to use genetically modified enzymes, the cheese, wine, and beer industries.\footnote{The Economist. “GM Food and Trade: More Trouble.” July 3, 2003.}

In shipping, firms in states with high standards were able to significantly raise international shipping standards by arguing to government officials in those states that raised, uniform standards would created a balanced playing field in which their competitiveness would not be undermined by more unscrupulous shippers.\footnote{DeSombre, Elizabeth. 2000. \textit{Domestic Sources of International Environmental Policy: Industry, Environmentalists, and U.S. Power}. MIT Press: Cambridge.} Businesses have used similar arguments to reduce regulatory barriers in telecommunications.\footnote{Braithwaite, John and Peter Drahos. 2000. \textit{Global Business Regulation}. Cambridge University Press. p. 350.}

**Applying the Lessons From This Work to A Different Industry: The Case of Toys**

The dynamics surrounding the political negotiations over regulatory trade barriers discussed in this book hold lessons for other industries as well including but not limited to chemicals, textiles, coffee, diamonds, cocoa, minerals, gold, wood, cosmetics, electronics, and toys. Rather than discuss how this work applies to all of those, I will instead focus on just the last industry, toys.
The toy industry depends on economies of scale and product differentiation and is hampered by regulatory trade barriers that impede toymakers’ market access or raise their production costs. Lego’s CEO has spoken of his firm as “operating globally, on a vertical integration from basic manufacturing to global distribution” and that his firm wants “to see the world in three vertical regions: the Americas, Europe/the Middle East/Africa, and then obviously Asia so we’re looking to have a manufacturing hub in each of the three regions.” He is not alone in this. The U.S. Toy Industry Association is eager to pursue regulatory trade barrier reduction in the TTIP. Small firms in the industry are also likely to be concerned with regulatory barriers because the cost of complying with regulations often comprises a greater percentage of their overall costs. This is why, when the U.S. government created greater regulatory trade barriers in toys with the Consumer Product Safety Improvement Act of 2008, some smaller foreign toymakers were forced to pull out of the United States completely.

If toymakers want to reduce these regulatory barriers then they must engage their respective trade representative to negotiate those reductions, and the most effective rhetorical strategy that they are likely to have is that foreign regulatory barriers are making them uncompetitive globally. They should take care though to ensure that the reductions they call for cannot be construed to endanger child safety. Greenpeace was able to increase regulatory stringency in Europe on phthalates (chemicals that make

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Given the understandable sensitivity parents have regarding the safety of their little ones, if the toy industry wants to reduce regulatory trade barriers, it must be indisputable that reducing those barriers will have no negative consequences on children’s safety. This is likely to be especially important for firms such as Mattel that conduct much of their production in countries like China that have spotty records in safety standards.\footnote{Barboza, David and Louise Story. “Toymaking in China, Mattel’s Way” New York Times. July 26, 2007.} Additionally, it seems unlikely that government officials would marginalize consumer groups in toys to the extent that North American officials ignored labor unions in the auto industry case. Therefore, if toymakers want to reduce regulatory barriers, they must accommodate consumer groups in the manner that automakers in Europe and North America accommodated environmentalists.\footnote{Accommodating consumers was also critical in the beef case as well. In that case, regulatory barriers were reduced only after Japanese consumer groups were satisfied with the safety of American beef.}

For consumer advocates, one lesson would be that whatever they do, they should not refuse to participate in negotiations. That strategy did Canadian labor groups no favors in NAFTA. They should also remain uncommitted to a trade deal rather than implacably opposed. Being uncommitted helped American environmentalists get what they wanted in NAFTA. Being resolutely opposed contributed to labor getting ignored. These lessons transfer to other industries as well.

\textbf{Recommendations to Businesses, Activists, and Government Officials}

\footnote{\textit{Recommendations to Businesses, Activists, and Government Officials}}
In this book, I have analyzed the political behavior of businesses, activists, and government officials in three industries. In this section, I offer advice to each of these groups based on the research and analysis that I have undertaken.

**Cars**

**Automakers**

Automakers had perhaps the most unalloyed victory anywhere in this work when they convinced North American government officials to reduce domestic content regulatory trade barriers. They did that by connecting their interests to broader concerns about competitiveness. That is their strongest rhetorical tool. This kind of rhetoric could be effectively deployed on monetary rules to prevent currency manipulation and in fact, this is what the American Automotive Policy Council’s statement on the Trans-Pacific Partnership focuses on.\(^{50}\) The language of the side agreement on currency that came along with the TPP language does not make currency policy subject to any sort of dispute settlement mechanism and does not threaten tariff benefit suspension, but it does have some quite robust requirements in terms of data reporting and transparency.\(^{51}\) As small potatoes as that sounds, it may actually help prevent the most egregious attempts at currency manipulation.\(^{52}\) In any event, while accusing America’s TPP partners of currency manipulation might be rhetorically useful, it was never likely that America’s negotiating partners were going to agree to tightly limit their policy flexibility on something so central to national sovereignty as currency.

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\(^{51}\) Joint Declaration of the Macroeconomic Authorities of Trans-Pacific Partnership Countries.

Still, there are a number of other policy areas where other state’s differing regulations could be portrayed as unfairly harming U.S. automakers’ and by extension U.S. competitiveness. As the AAPC has pointed out, Japan has historically maintained an array of investment and distribution regulations that have made Japan the most closed auto market in the OECD. While the currency side deal does not match automakers’ previous proposals, the side agreement between Japan and the United States does give U.S. automakers the ability to challenge those non-tariff barriers that have kept the Japanese auto industry closed to them.

That agreement contains a tariff delay mechanism that allows the United States to delay phasing out its 25 percent tariff on trucks and 2.5 percent tariff on cars from Japan if a dispute settlement body finds that Japan is imposing a discriminatory non-tariff barrier, which is exactly what Japan’s investment and distribution regulations are. Moreover, this mechanism, unlike other similar trade provisions before it, allows the United States to retaliate at levels greater than the damage caused by that non-tariff barrier and is linked to the size of allowable retaliation to the size of the U.S. trade deficit in vehicles. This means that the United States under the TPP would have a powerful new lever with which to pry open the Japanese market to U.S. exports.

Portraying those investment and distribution regulations as curbs on competitiveness can be an especially effective way to make that happen. Targeting these distribution and investment regulations also has the added advantage that those

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regulations cannot easily be portrayed as saving lives and protecting consumers. Japanese activists are unlikely to consider these issues salient and thus unlikely to fight U.S. automakers attempt at reducing these regulatory barriers.

However, automakers should beware challenging Japan’s consumer safety regulations as non-tariff measures. It would be very easy for a Japanese consumer group to portray those regulations as preventing needless death. As this book’s beef chapter demonstrated, Japanese consumer safety advocates can be highly effective at defending regulatory barriers in these kinds of scenarios. That would put U.S. automakers on the back foot, forcing them to pre-emptively prove that the regulatory changes they seek will not harm anyone, which they cannot definitively prove at the outset. Of all of the regulatory barriers hampering their access to the Japanese market, these should be the very last ones automakers challenge, if they challenge them at all.

Consumer Safety Advocates
Conversely, consumer safety advocates, if they want to defend regulatory trade barriers such as those that exist between the United States and the European Union, must emphasize sovereignty concerns and the extent to which those regulatory differences save lives. In a few auto parts such as seat belt anchors, in which equivalency between U.S.-regulated parts and EU-regulated parts has been proven, there is no safety cost associated with mutual recognition or regulatory harmonization.\(^{56}\) However, in many other parts, there is not sufficient evidence to prove equivalency. In fact, tests done by a team of research centers based in the United States and the EU have shown that European-regulated vehicles are safer in side and front collisions but that U.S.-regulated vehicles

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\(^{56}\) Equivalency means that parts made under different regulatory regimes have been shown to be equally effective.
are safer in rollovers. It would not be difficult for European consumer groups to argue that reducing transatlantic regulatory barriers would endanger European drivers in collisions while American consumer groups argued that reducing those barriers would endanger Americans in rollover crashes.

Environmentalists

When environmentalists advocate raising some regulatory standard to promote environmental protection, they present automakers with a trade-off: compliance costs versus reputation. If that new regulatory standard comes with high compliance costs and you the environmentalists cannot convince automakers that opposing a new standard will significantly hurt their reputations, as happened with emissions regulations in Europe from 1983 to 1988, those automakers oppose it. If compliance is cheap and the reputational consequences severe, as they were in 1989 and 1990 in the European case, they accept the new standard and abide by it.

Environmentalists should not focus solely on the reputation half of that equation. Naming and shaming has been an effective strategy for environmentalists in a number of policy areas ranging from deforestation to global warming. However, naming and shaming is not the only effective strategy. Environmental activists have also been able to design and promote specific regulations. This gives them the ability to choose from a wide menu of different regulatory options. There is actually a great deal of evidence that

when they have designed standards that are cheaper to comply with, they have been much more effective at eliciting cooperation from businesses and thus protecting the environment.60

Environmentalists can also work to not only undermine arguments made by some businesses that compliance with environmental regulations makes them uncompetitive but also to steal the competitiveness frame altogether. Michael Porter has argued that businesses and the countries that they are based in can become more competitive if those businesses are pressured to innovate.61 Environmental regulations can do exactly that. By pressuring firms to innovate to meet higher standards, environmental regulations actually make those companies more internationally competitive, not less. This argument can be bolstered by the fact that overall environmental regulations can create more wealth than compliance of them costs. For example, by preventing millions of lost work and school days, by preventing premature deaths, and by reducing the amount that must be spent on maladies from bronchitis to asthma, the Clean Air Act is estimated to have created 12 trillion dollars in net economic benefits from 1990 to 2020.62

**Labor Unions**

The first recommendation for labor unions is in regards to which rhetorical strategy is most likely to bear policy fruit. The most politically powerful argument in defense of regulatory trade barriers, that their reduction would lead to needless death, is

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really not available to labor unions. Therefore, unions’ best strategy is a defensive one: undermine the competitiveness arguments made by businesses seeking to reduce those regulatory barriers. Automakers were successful in reducing domestic content regulatory barriers, which unions prized, because they successfully linked that reduction with larger societal concerns about competitiveness. To protect their interests, unions must be able to fight against arguments that suggest that they make firms uncompetitive. They can do this by emphasizing that there is strong evidence that worker involvement in decision-making through unions and works council boosts plant-level productivity and enhances the competitiveness of that plant and the company as a whole.63

The second implication for labor unions is that personnel decisions are policy decisions. Which government officials are involved in trade negotiations has a significant impact on the trajectory those negotiations take. Here, labor unions could learn from several of the turns in the beef chapter. In 2004 and 2005, the resilience of Japan’s position on BSE regulations was reinforced by the fact that the universal testing policy was overseen by the Food Safety Commission (an independent, politically insulated panel of experts) rather than by the Ministry of Agriculture or the Ministry of Health, both of which could more easily have been pressured to relent to U.S. demands. Later, one of the factors that promoted a reduction in the BSE-related regulatory barriers was that negotiations over those barriers became linked to other trade issues and so the Ministry of Industry and Trade (MITI), which is pro-liberalization, was in charge of the trade negotiations rather than the Ministry of Agriculture, which is more protectionist.

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Labor unions can learn from this by being strategically creative in terms of promoting differing jurisdictional understandings, specifically by getting the Department of Labor involved in trade negotiations. This would not be a totally unprecedented maneuver. A recent decision by the Department of Labor suggests a possible route that labor unions might take. For decades, financial advisers were not required to put their clients interests first when giving them financial advice and could instead guide them toward financial products based on incentives like bonuses and trips that were offered to those advisers. Consumer advocates pushed for a rule known as the fiduciary standard that financial advisers be required to give advice based on what is best for the client. The financial industry opposed this rule and the Securities and Exchange Commission (SEC), which traditionally has had a relatively close relationship with the financial services industry, refused to move forward. Recently the Department of Labor, which does not have that kind of cozy relationship with the financial industry, asserted that it too had jurisdiction on this matter and so instituted a fiduciary standard rule.64

Labor unions, as they are usually protectionist, typically do not find a favorable hearing before the United States Trade Representative, as it is pro-trade. If labor unions can convince the Department of Labor to insert itself into trade negotiations based on the idea that trade involves its jurisdictional prerogatives, then perhaps labor unions will have an ally in those trade negotiations. In politics, if you are not at the table, you are on the

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menu. If labor unions cannot find someone currently at the table who will fight for them, they need to find a way to change who sits at the table.

*Government officials in the NHTSA and Europe*

For regulators on both sides of the Atlantic, this work suggests that automakers will likely continue to request greater regulatory cooperation between the two polities but mutual recognition or regulatory harmonization will be a tough sell given the concerns of consumer safety advocates and the power of the rhetoric surrounding preventing needless death. The major implication of this is that part-by-part negotiations seem the best way forward. The current collaboration over the two part types where equivalency has been proven, seat belt anchors and visibility equipment, provide a model for the painstaking way in which regulatory cooperation should proceed.

**Beef**

*Activists Concerned About Food*

The biggest implication of this work for consumer advocates in food pertains to what they should focus on. In short, they need to stop concentrating on genetically modified organisms (GMOs) and instead focus on three other regulation-related aspects of the food industry: heart disease, climate change, and the exploitation of workers. First, consumer advocates need to get off GMOs. There is no scientific evidence that GMOs are harmful to humans.\(^{65}\) None.\(^{66}\) The idea that GMOs are dangerous to consume has no more basis in reality than climate change denial or refusing to vaccinate ones’ children.

\(^{65}\) Statement by the Association for the Advancement of Science Board of Directors on Labeling of Genetically Modified Foods. October 20, 2012.

\(^{66}\) To quote from the definitive EU-funded meta-study of GMOs: “the main conclusion to be drawn from the efforts of more than 130 research projects, covering a period of more than 25 years of research, and involving more than 500 independent research groups, is that biotechnology, and in particular GMOs, are not per se more risky than e.g. conventional plant breeding technologies.” European Commission. 2010. “A Decade of EU-Funded GMO Research, 2001-2010.” Food, Agriculture, Fisheries, and Biotechnology. p. 16.
Not all opinions are equally valid. Opposition to GMOs is a sincerely held and well-intentioned viewpoint, but that does not change the fact that it is objectively misinformed. Not only is opposition to GMOs factually wrong-headed, it also undermines the political effectiveness of the consumer food movement as a whole. The facts are not on their side, which makes it difficult to build a persuasive case and convince regulators to take their side. Relatedly, it is difficult to show a tangible way in which GMOs have actually hurt anyone. The reason that preventing unnecessary death is such a powerful rhetorical tool is that death is highly tangible and motivates risk aversion. All of the alleged risks associated with GMOs are hypothetical.

A focus on GMO opposition has unnecessarily narrowed the political appeal of the food consumer movement. GMO opposition springs from an instinctive mistrust of multinational corporations like Monsanto and is often tied to anti-commercialism, environmentalism, and vegetarianism, all of which are popularly associated with a certain kind of neo-hippie political liberalism. Conservatives see the types of liberals who form the core of GMO opposition and conclude that the food consumer movement does not reflect them or their interests. Re-orienting the food consumer movement to a less purely liberal political orientation could broaden the appeal of that movement and thereby strengthen it.

The first issue area that would provide the food consumer movement a more favorable opportunity to push for better regulation is in the connection between meat, especially beef, and public health. Meat consumption is directly connected with heart
disease, the number one killer globally. The causal chain between using regulations to reduce meat consumption and preventing needless death is clear and direct.

The second issue that consumer advocates should focus on is the connection between meat, again especially beef, and climate change. Livestock is responsible for fifteen percent of all greenhouse gas emissions worldwide, equivalent to the emissions of all vehicles combined. Beef is especially carbon intensive. Doing something about climate change is broadly supported in the United States and abroad. Environmental groups are wary that appearing to dictate people’s personal consumption might elicit backlash, but at the same time poll, respondents appear less reluctant to address climate change if businesses appear to be the ones bearing the costs. Pushing for regulations that require meat producers to minimize their carbon footprint could thus not only be good policy, but also good politics.

Third, the consumer food movement can raise public awareness of the extent to which the meat industry is built on systemic exploitation of vulnerable workers. To quote from a Human Rights Watch Report:

“Employers put workers at predictable risk of serious physical injury even though the means to avoid such injury are known and feasible. They frustrate workers' efforts to obtain compensation for workplace injuries when they occur. They crush workers' self-organizing efforts and rights of association. They exploit the perceived vulnerability of a predominantly immigrant labor force in many of their work sites. These are not

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occasional lapses by employers paying insufficient attention to modern human resources management policies. These are systematic human rights violations embedded in meat and poultry industry employment.”

For food activists, stories are more likely to be effective than statistics. At Hormel-subsidiary factories in Minnesota and Texas, undocumented employees were forced to work brain-removal devices at such speeds that it badly compromised basic sanitation needs and workers’ health - I will spare the reader the stomach-churning details. When those workers got so ill that they suffered long-term neurological damage, Hormel’s subsidiary fired them. This is but one example of the ways in which meat industry employees are mistreated. More examples of deplorable, abusive, and intimidating treatment can be found here, and here, and here, and here, and here. And I could keep going, but you get the picture.

Because they are often undocumented immigrants, these workers have little ability to seek redress over this systemic exploitation. They cannot go to the police because they fear deportation. If they complain to management or push for better conditions, management calls the local law enforcement authorities and informs them of...

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the location of illegal immigrants, who had to give management their address in order to work in the first place.

Farmers too get taken advantage of. The poultry industry is built on a contract farming system in which large poultry producers A) own the chickens, B) mandate the conditions under which the chickens are to be raised, and C) foist the costs of facility upgrades on to farmers by refusing to bring them new chickens or cutting their payments, which would force them into default on their loans and off of their farms. This contract farming system is rife with power asymmetries, indebtedness, fraud, and legalized brutality; it is sharecropping by another name.

If you are looking for the face of greed-driven corporate villainy, it is not the pharmaceutical companies; it is these guys, the meat industry corporations that, in an effort to squeeze every last penny of profit from the production process, have based their business model on abuse and intimidation. This is what exploitation in 21st-century America looks like.

Targeting these firms on a one-by-one basis may be activists’ most effective option. As I mentioned earlier, some activists have a reasonable concern that if they are perceived to be telling people what to do, they may face significant backlash. The best way around that is not to tell consumers that they should refrain from purchasing meat, but instead that they should refrain from purchasing meat from one or two particular

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companies. Tyson would be a good place to start as they are both visible and engaged in some of the most egregious abuses. What will likely help is that there are a number of meat industry firms, like Creekstone Farms discussed in Chapter 5, that are willing to implement higher standards in the production process than those currently used by much of the industry.

Activists will have difficulty making large numbers of people feel guilty for eating meat, but they can make large numbers of people feel virtuous for forgoing Tyson chicken. When that company has improved its production practices, activists can target a different company that is continuing with the abuse. Activists have gained traction in pushing firms to sell products devoid of antibiotics and hormones; they can succeed at pushing firms to sell products devoid of abuse. This strategy is also more likely to be successful because it includes a narrative of protection, i.e. that farmers and workers need to be protected from abuse, but is not vulnerable to a narrative of access because consumers will not lose the ability to purchase meat.

Once a critical mass of ‘clean’ firms has been reached, activists can also call for new labor standards as a requirement for the sale of meat products in the United States. That is likely to create regulatory trade barriers, and that may lead to a WTO dispute with a developing country and the United States may lose that dispute. Food activists are not likely to care, nor should they. Trade liberalization as a whole is a positive thing, but it cannot be allowed to override every other societal concern. Wealth creation is important, but so is protecting the vulnerable.

All three of these issues can be made politically salient for broad groups more easily than GMOs. In all three of them, the facts are on the consumer advocates’ side, the
consequences are direct and clear, and the policy victory is both attainable and prosperity enhancing. In sum, the consumer food movement can be a broad-based, politically powerful force for social good that promotes public health, alleviates environmental degradation, and protects workers, but in order to do that it first it has to stop focusing so much of its attention on GMO opposition.

*Meat Industry*  
Just over a century ago, the meat industry, by allowing repellant and abusive conditions to flourish in its midst, brought down upon itself the most comprehensive and most onerous set of regulations the U.S. government had issued to any industry to that point. That can happen again. If they want to avoid a new set of regulations, meat industry firms must improve the labor practices they use, the environmental impacts they have, and the policies they promote before the general public turns against them. If their abuses become more widely known and if consumers’ interest in how the products they consume are made continues to grow, meat companies will have no choice in whether to clean up their act; they will be compelled to do so by government regulation, and deservedly so.

*USDA*  
If the USDA wants to promote meat industry sales, as is their mandate, they need to help the meat industry institute the reforms discussed above. They should also adopt a more flexible position toward firms like Creekstone that want to institute standards that exceed federal requirements. Finally, they should also adopt a more consumer-centric perspective. Their stance on carbon monoxide in beef packaging is a good example of a policy that needs to change.
For years, American meat producers were losing a significant amount of sales because consumers were bypassing meat that, though still safe to eat, had lost its bright red color that people associate with freshness.\textsuperscript{83} One way to alleviate this problem was to inject the meat with carbon monoxide. In 2002, the use of carbon monoxide in beef for this purpose was approved.\textsuperscript{84} There are no requirements that packages of meat be labeled as being treated with carbon monoxide.\textsuperscript{85}

Carbon monoxide does not actually preserve the meat’s freshness, only its color; in fact, carbon monoxide may actually accelerate bacteria growth in the event that the meat is stored improperly.\textsuperscript{86} Carbon monoxide helps beef maintain its appetizing, bright red color for significantly longer than it would be able to hold that color otherwise.\textsuperscript{87} When ingested by humans in this way, carbon monoxide is not harmful in the way that it can be when it is inhaled; it will not cause cancer and does not, by itself, make the consumer ill.\textsuperscript{88} However, because the carbon monoxide will keep the meat appearing fresh even after it has spoiled, consumer groups fear that it may lead some buyers to eat spoiled beef, and that can make them very ill.\textsuperscript{89} Meat producers have responded that consumers will not inadvertently eat spoiled meat even if it is still red because they will

\textsuperscript{84}Weiss, Rick. “FDA is Urged to Ban Carbon-Monoxide Treated Beef.” \textit{The Washington Post}. February 20, 2006. The FDA and the USDA share jurisdiction in meat labeling.
abide by sell-by dates and that in any event, consumers are unlikely to care if the meat they purchase is treated with carbon monoxide.\textsuperscript{90} That is a dubious claim.

Even if it does not contribute to making people sick, and that’s an open question, the use of carbon monoxide in this manner is a deceptive business practice. It fools consumers into thinking meat is fresh when in fact it may not be. It is for this very reason that some retailers such as Wegman’s, Publix, Meijer, and Wal-Mart refuse to sell meat treated with carbon monoxide.\textsuperscript{91} While it is relieving that at least some businesses are forgoing this marketing sleight of hand, that abstention is not nearly as extensive as the USDA prohibiting the use of carbon monoxide on beef would be.

This also creates an unnecessary regulatory difference between the United States and Japan as well as the European Union. Japan and the EU ban this practice because it deceives consumers while the United States allows the practice because it protects industry profits.\textsuperscript{92} This is a policy in which the United States government can, in one stroke, adopt a more consumer-friendly position and reduce a regulatory trade barrier.

**Drugs**

*Pharmaceutical Companies*

This work suggests how pharmaceutical companies can more effectively defend high intellectual property regulations to the general public. Drug firms have a lot of work to do on this. If there were gold medals awarded for worst corporate public relations

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performance, the pharmaceuticals industry would have no competition. They did not have to gain the reputation they did. Cigarette companies profit from products that kill people. Drug companies make products that save lives. There was no preordained reason why pharmaceutical companies had to gain a villainous image. That happened as a result of a series of major strategic blunders. To reverse that, the pharmaceuticals industry should shift how it justifies high intellectual property regulations, emphasize the high-paying jobs it creates, highlight the cost savings it delivers, and police itself more thoroughly.

First, drug companies should justify their preference for high intellectual property regulations not through statistics and abstract logic regarding incentives to innovate but instead through personal stories. The preventing needless death argument works because it makes an issue clear and salient. This argument was used by access to medicine advocates to fight for lower IP regulations but it can also be used by pharmaceutical companies to defend higher IP regulations. Stories sell. Access to medicine advocates were able to paint drug companies as villainous because they were able to tell a story of drug company greed costing lives. To reverse that, drug companies need to be able to tell a story of their actions saving lives. The best way for them to do this is an advertising campaign featuring real people who would have died without that company’s drug and then assert that without stringent IP regulations, they would not have been able to invent those drugs and save those lives.

Second, the pharmaceuticals industry should emphasize the number of high-paying jobs and foreign direct investment that the industry brings to states. The reason that the competitiveness argument is so effective is that it comes with an implied promise of jobs and prosperity. No government official in the United States, India, or Europe
wants to be held responsible for costing their constituency lucrative jobs. All of them want to be able to brag about bringing in those jobs. The competitiveness argument was key to drug firms’ ability to defend their interest in the pharmaceuticals chapter. That is likely to remain the case. In 2008, the CEO of Pfizer encapsulated this kind of sales pitch to Washington in three short sentences: “the protection of intellectual property equals innovation. Innovation equals competitiveness. Competitiveness equals jobs.” Based on the cases studied in this book, that is a message that works and one that it is in the best interests of the pharmaceutical companies to keep repeating.

Third, the pharmaceuticals industry should also emphasize the amount of money it saves the healthcare industry and thus the overall economy. Prescription drugs account for just nine percent of all healthcare spending in the United States. By contrast, hospital care accounts for 32 percent. By preventing more expensive procedures such as transplants and extended hospital stays, drug companies actually save the overall system a great deal of money.

Relatedly, the pharmaceuticals industry should emphasize the extent to which it, not the access to medicine advocates or other NGOs, has built a storehouse of wonder drugs. One observer reckons that today, at very cheap generic-level prices, a person can buy a set of drugs that have more medical utility than all drugs, patented or generic, that existed in 1995. Did drug companies do that out of profit-driven rather than altruistic motives? Of course they did, but their motivations are irrelevant. The relevant fact is that

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95 Ibid.
they did it at all. Capitalism is a means of harnessing greed for social good. Perhaps no industry demonstrates how effective it can be at doing just that better than the pharmaceuticals industry.\footnote{It demonstrates the limits of that model as well. The current profit-driven system is very good at delivering innovative treatments for diseases that afflict people in developed countries. It is not nearly as good at creating new treatments that primarily afflict poor people in developing countries. Markets are good for those with the money to make them operate. Poor people in developing countries rarely have that kind of money.}

Fourth, the pharmaceuticals industry needs to police itself much more robustly than it has thus far. When pharmaceutical executives like Martin Shkreli radically increase the price of a monopoly-controlled generic drug like Daraprim, that makes the entire industry look bad.\footnote{Pollack, Andrew. “Once a Neglected Treatment, Now A Specialty Drug.” \textit{The New York Times}. September 21, 2015.} He is only the most visible example. Questcor Pharmaceuticals raised the price of a drug for multiple sclerosis from $40 to $28,000, a seventy thousand percent increase!\footnote{Herper, Matthew. “My Lunch With Shkreli: What We Should Learn From Pharma’s Latest Monster.” \textit{Forbes}. September 24, 2015.} Valeant Pharmaceuticals has engaged in similar behavior.\footnote{Rockoff, Jonathan, and Ed Silverman. “Pharmaceutical Companies Buy Rivals’ Drugs, Then Jack Up the Prices.” \textit{The Wall Street Journal}. April 26, 2015.} When drug firms adopt transparently anti-competitive strategies like pay-for-delay schemes, that too hurts the entire industry’s image.\footnote{Pay-for-delay is when a pharmaceutical company that has a drug that is about to lose its patent pays a generic drug maker not to produce this drug. This artificially extends the first companies monopoly and keeps the drug’s price high. It is pretty nakedly anti-competitive behavior. Fortunately, the U.S. Federal Trade Commission as well as other countries’ regulators are starting to crack down on this practice. Crow, David. “U.S. Watchdog Sues Over Pay-For-Delay Agreements.” \textit{The Financial Times}. April 1, 2016.} When drug companies engage in these behaviors they undermine public confidence in the high intellectual property regulations that are the source of their profit. As Ian Read, the CEO of Pfizer, put it in 2014, “unless we’re respected by society, unless we’re seen as good stewards of our resources, then we run the risk of losing both patents and losing the ability to price our medications.”\footnote{The Economist. “The New Drug War: Hard Pills to Swallow.” January 4, 2014.}
To clamp down on these kinds of actions, the pharmaceutical industry needs to create a mechanism to enforce good practices on all pharmaceutical manufacturers. In this matter, drug firms could learn from the legal profession and create a pharmaceutical equivalent of the bar. If a lawyer behaves in ways that violate what the bar has decided is acceptable practice, that lawyer can lose their ability to practice. This mechanism benefits the entire legal profession. Likewise, drug companies could form a pharmaceuticals bar association, and with the help of government, compel all drug firms to abide by a set of good practices including but not limited to no pay-for-delay schemes and no sudden price increases for generic drugs that have no substitute.

If the pharmaceuticals industry does not police itself better, at some point it will find that it loses even more esteem in the eyes of the public and rightly so. That esteem can only fall so far before the public stops believing that the intellectual property regulations that create drug industry profits are good for society rather than just a handout to a well connected but morally bankrupt industry. Should that happen, pharmaceutical companies may find that their ability to set prices becomes as constrained in the United States as it is in other developed countries.103

Access to Medicine Advocates

First, if access to medicine advocates want to reduce the stringency of intellectual property regulations, they must be able to demonstrate that new breakthrough medicines can be developed and guided through the entire approval process without the patent-based system the pharmaceuticals industry is built on. Through whatever means they choose, be it university funded basic research followed by prize pools for applied research followed by NGO leadership through the approval process or some other

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process, these advocates must be able to show that a non-patent based system can promote just as much innovation as the current system. Until they can do that, they will consistently run into the concern that reducing intellectual property regulations, as these activists want to do, will slow medical innovation and ultimately cost lives.

Second, access to medicine advocates may be successful in promoting a reduction of IP regulations on pharmaceuticals if they are able to drive a wedge between other businesses and pharmaceutical companies on drug costs. The average business’ annual contribution to a family health insurance plan now total $12,591. That is a major expense. If access to medicine advocates can convince businesses that the high cost of health insurance is at least in part due to the high cost of patented medicines, they may gain powerful political allies. They are likely to have even more success if they are able to paint high health insurance costs as undermining American businesses’ international competitiveness. The pharmaceutical companies’ most powerful rhetorical tool is that high IP regulations on drugs make American business more competitive. Access to medicine advocates are more likely to win if they can destroy the power of that narrative.

**Officials in the USTR**

The United States Trade Representative should make its policymaking processes more transparent and more inclusive. This means having a more diverse set of individuals as cleared advisers and means making negotiating texts public during those negotiations.

As I discussed in Chapter 3, cleared advisers are people who are allowed to view confidential negotiating documents. Firms have had many of their representatives named

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cleared advisers; however, when asked about cleared advisers from non-business groups, a USTR spokesperson could not name a single cleared adviser from a public interest group or activist NGO.\textsuperscript{106} Even to someone who accepts the need for strong intellectual property protection, the current revolving door between IP-intensive firms and the USTR reeks of cronyism.

That needs to change. The concern is that allowing activists to see negotiating texts would jeopardize trade talks because those activists cannot be trusted to not release those documents to the public. That concern can be alleviated by choosing cleared advisers from more moderate, less anti-business NGOs such as the National Resource Defense Council instead of Friends of the Earth. In IP, Doctors Without Borders is also fairly moderate. The Access to Essential Medicines Campaign leader Ellen ‘t Hoen has said that Doctors Without Borders “is not against patents and not against patent legislation. True innovation deserves to be protected and to be awarded. We advocate a balanced IP regulation.”\textsuperscript{107}

Excluding these groups makes enemies unnecessarily. Bringing them into the process could win them over and so dilute the opposition to trade deals. That is what happened with environmentalists in NAFTA. Allowing them access resulted in stricter environmental provisions in the agreement but won the support of some more moderate environmentalist organizations, which gave Democrats greater political cover to vote for NAFTA.\textsuperscript{108}


Bringing in activist groups might also help the reputation of the USTR by showing that the USTR often does take a balanced approach. For example, during the TPP negotiations, the USTR took the most pro-environment stance of any negotiating team.\(^{109}\) The reason that there are not more environmental provisions in the TPP is not because the USTR betrayed environmentalists; it is because developing countries such as Vietnam and Malaysia opposed those provisions.\(^{110}\)

Furthermore, the current secrecy and exclusivity surrounding negotiating positions and negotiating texts are not helping. They have led many observers, including Congressmen, to believe that the secrecy of the negotiations is meant to shroud nefarious intent.\(^{111}\) If the Trans-Pacific Partnership really is as good as U.S. Trade Representative Froman says it is, then why all the secrecy? Furthermore the public now expects much more transparency than it once did. The days of secrecy being tolerated are over. To alleviate this problem, the United States Trade Representative should make negotiating texts publicly available during trade negotiations. As Susan Aaronson has pointed out, there is no clear evidence that secrecy actually strengthens one’s negotiating position.\(^{112}\) In fact, transparency might be used to credibly signal that a government cannot abandon a hardline position without being hammered domestically.

There are actually some examples of transparency upgrades in other trade negotiation institutions. The World Intellectual Property Organization conducts its negotiations in full view of webcasts that are publicly available online and has given a


A wide variety of stakeholders unprecedented access. The European Union has published drafts of its negotiating positions in the Transatlantic Trade and Investment Partnership. Negotiating in broad daylight would certainly be different from the way things have traditionally been done but that does not mean it would be impossible.

Even if a given trade agreement does have net benefits, the USTR should only agree to and push for that trade agreement if it has broad societal buy-in and the legitimacy that comes with that. Including activists groups in trade negotiations and making those negotiations more accessible and transparent might make trade deals more difficult to conclude but it would make them more legitimate and more likely to be ratified.

**Concluding Remarks - Hidden in Plain Sight**

As states' economies grow more interconnected, regulatory trade barriers cannot help but grow in importance. The political negotiations that surround those regulatory trade barriers affect how safe the products we buy are and how much they cost. They affect how much we can export and so how many export-oriented jobs there are. They affect the extent to which trade helps or hurts the environment. They affect how workers get treated. All of these issues are hugely consequential and all of them are greatly affected by the politics of regulatory barriers.

At the beginning of this book, I mentioned the regulatory trade barriers that influence air bags, the U.S.-China pork trade, and PD1 inhibitors. These regulatory barriers affect the quality and affordability of the meat a Chinese family puts on its table. In the United States and Europe, they affect the health outcome of car crashes that

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involve air bag deployment. Around the world, they affect how quickly new cancer medicines can be created and how costly they will be. These regulatory trade barriers affect whether you personally survive a car crash or cancer. Regulatory trade barriers are everywhere around us, and once they stop being abstract and technical, once it becomes clear the central role they play in the global economy and in nearly everyone’s daily life, their significance becomes inescapable.
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