***Autoimmunity: The Impacts of Multilateral Free Trade Agreements on Global Health***

Free trade agreements are treaties between two or more countries designed to facilitate trade and eliminate trade barriers. Most nations of the world are members of the free trade agreements regulated by the World Trade Organization ("WTO"), such as the United States-Mexico-Canada Agreement ("USMCA") and, before that, the North American Free Trade Agreement ("NAFTA"). The idea behind these agreements is to create an open and competitive international marketplace and, in turn, improve the economic prospects of both the consumers and the businesses of all countries involved.[1]

However, whether such improvements have actually taken place in all industries and for all parties is up for debate.[2] This paper will advance the idea that, in particular, the healthcare industry and, as a result, the health of the global populace have been weakened by free trade agreements. Rather than reduce costs and augment innovation, free trade agreements' articles on pharmaceuticals have provided protection for pharmaceutical giants and, by doing so, negatively impacted both consumers the world over and manufacturers of generic pharmaceuticals in developing countries.

The General Agreement on Trade and Tariffs ("GATT"), the predecessor to the WTO, first codified the regulation of trade relations around the globe. As per Article V, the purpose of agreements under the rules of GATT is "provid[ing] for the absence or elimination of substantially all discrimination" in trade between its member nations.[3] This is qualified in the same section, and it

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[1] GATT 1994: General Agreement on Tariffs and Trade 1994, 15 Apr 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1867 U.N.T.S. 187, 33 I.L.M. 1153 (1994) [hereinafter GATT].

[2] *See* Robert W McGee, "The Philosophy of Trade Protectionism, its Costs and its Implications" Policy Analysis 10 (1996) *contra* Gary Gereffi & Stacey Frederick, "The Global Apparel Value Chain, Trade and the Crisis: Challenges and Opportunities for Developing Countries" World Bank Policy Research Working Paper No 5281 (2016).

[3] GATT.

is stated that "flexibility shall be provided" in cases "where developing countries are parties to an agreement".[4] Further, Article XIV (General Exceptions) provides a litany of cases in which the rules are malleable, including the provision that discriminations would not be deemed in violation if they were "necessary to protect human, animal or plant life or health".[5]

The pharmaceutical industry, though technically producing manufactured goods, primarily revolves around an economy of intellectual property, with patents, research and development, and the availability of generics to the consumer all playing pivotal roles. While our society's Lockian conception of property rights over material goods is largely concerned with mitigating the inefficiencies produced by scarcity, no such problem exists for intellectual property.[6] Intellectual property, by its very nature, creates an artificial scarcity by limiting production. This is done specifically to reward creativity and thus incentivize the creation of knowledge. Arguments around the applicability of intellectual property law, therefore, have many times focused on the definition of knowledge creation, such as reckoning with the difference (or lack thereof) between creating knowledge and consolidating knowledge,[7] and even creating knowledge and recording knowledge.[8]

It is widely accepted that some price discrimination is necessary in the pharmaceutical industry, at least in a free market economy.[9] The argument runs that without any length of intellectual monopoly, allowing for periods of steep profits for discoverers of new drugs, no pharmaceutical company would be incentivized to invest in the research and development that produces the discoveries. Whether the state should be charged with the research and

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[4] GATT.
[5] GATT.
[6] Salil K Mehra, "Competition Law for a Post-Scarcity World" 4 Tex A&M L Rev 1 (2016).
[7] Feist Pubs Inc v. Rural Tel Svc Co (1991 499 US 340)..
[8] International News Svc v Associated Press (1918 248 US 215)
[9] *See generally, e.g.,* David W Opderbeck, "Patents, Essential Medicines, and the Innovation Game" (1996); *see also* Anurada Chada, "Intellectual Property Rights Vis-A Vis Right to Health: A Critique" (2014).

development of pharmaceutical knowledge, either including or excluding firms operating on the free market, is the discussion topic of another paper. The arguments of this paper will concede the assumption that facilitating profit is to some extent necessary to incentivize investment in research and development in the pharmaceutical industry. The question, then, is to determine the appropriate extent, and whether the application of international trade law meets this standard.

The Trade-Related Aspects of Intellectual Property Agreement ("TRIPS", the "Agreement") is the major document governing the exercise of intellectual property law across international jurisdictions.[10] TRIPS, like GATT, applies to all member nations of the WTO. Its application requires nations to enact domestic law consistent with the standards of the international agreement.[11] Prior to the adoption of the Agreement, patent production in many developing countries was nonexistent.[12] In nations in which it did exist, it often featured provisions nullifying patent production for foreign companies.[13] Producers of generics in developing countries essentially had free reign.

This was not the case in North America, where NAFTA had already covered the intellectual property of its signatories under Chapter Seventeen.[14] It did so in effectively the same manner TRIPS has since then.[15] Both agreements are products of the nineties, in the sense that they "were negotiated at a time when the internet was in its infancy and trade secrets were given little attention internationally".[16] When USMCA was signed, it was equipped with

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[10] TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 Apr 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS].
[11] TRIPS.
[12] Lee C Moerman & S L van der Lan, "TRIPS and the pharmaceutical industry: Prescription for profit?" Critical Perspectives on Accounting 17(8) (2006).
[13] *Id.*
[14] NAFTA, The North American Free Trade Agreement: a Guide to Customs Procedure,. Washington, DC, Dept of the Treasury, US Customs Service (1994) hereinafter NAFTA].
[15] NAFTA.
[16] David A Gantz, "USMCA Provisions on Intellectual Property, Services, and Digital Trade" (2020) at 2.

additional ideas about the fair enforcement of international intellectual property law which respond to our changing world,[17] but relating to pharmaceuticals, the agreement mostly just made small modifications, such as an alteration (to ten, from eight) to the number of years data protection for biologics would be enforced.[18] TRIPS is still the law.

TRIPS is both large in scope as well as binding legally. The Agreement is the most comprehensive multilateral intellectual property agreement in history and it has mandated since 1995 that WTO member states institute patent protections of twenty years, and make patents available for all producers, with the caveat that enforcement dates vary based on the countries' levels of development.[19]

TRIPS states explicitly that its objective is to "contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare".[20] It also states that there is "a balance of rights and obligations" that coexist with intellectual property protections.[21] In no area are these obligations more important than pharmaceuticals, a market where intellectual property protections can limit the production and dissemination of medicine that can be lifesaving. The WTO acknowledges as much in the 2001 Doha Declaration on the TRIPS Agreement and Public Health ("Doha Declaration"), adopting a statement declaring that "the TRIPS Agreement does not and should not prevent members from taking measures to protect public health."[22] They further expressed that "'the Agreement can and should be interpreted and implemented in a manner

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[17] *Id.*
[18] *Id.*
[19] TRIPS.
[20] TRIPS.
[21] TRIPS.
[22] World Trade Organization, Ministerial Declaration of 14 No 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 ILM 746 (2002) [hereinafter Doha].

supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all."[23]

This declaration bears resemblance to the sentiment extolled in the United Nations' much publicized[24] Sustainable Development Goals ("SDGs"). SDG 3.8 advocates for a transition to a global society of "universal health coverage" by urging the world's nation-states to strive for a world with "access to safe, effective, quality and affordable essential medicines and vaccines for all".[25] The goal's agreed upon indicators are both binary statistics: whether a person can afford their essential health services, and whether a person's actual expenditures on health constitute an undefined "large" proportion of total household expenses.[26]

Problem

At the time it was passed, TRIPS was considered to be "a major change to international market regulation".[27] However, not much has changed to the balance of powers since it was adopted.[28] Those advocating for more property protection "aggressively pushed their agendas through bilateral, regional, and plurilateral negotiations"[29] and as a result of this our world has been left with a system where drug prices are higher than ever, a few pharmaceutical giants are more powerful than ever, and access to essential medicines around the world is increasing at what can only be termed as a crawl.[30] The last factor cannot be overstated. While the AIDS crisis in Africa is not still at its most devastating, 25% of South Africans still die of complications of AIDS,[31] and most perish in ways that are preventable or mitigatable with greater access to prescription drugs.

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[23] Doha.
[24] United Nations <https://www.un.org/sustainabledevelopment/sustainable-development-goals/>.
[25] *Id.*
[26] *Id.*
[27] Susan K Sell, "TRIPS: Fifteen Years Later" J of IP L 18:2 (2001) at 2.
[28] *Id.*
[29] *Id.*
[30] *See* discussion *infra* in text.
[31] *See* US National Library of Medicine <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1172985/>.

Since the adoption of TRIPS, the promotion of access to affordable essential medicines has been the source of disagreement between developing countries and their developed counterparts.[32] Generally speaking, developed countries, many of the larger and even midsized of which typically have thriving pharmaceutical manufacturing industries,[33] want greater patent protection to create greater profit for its industry members, the protection which they maintain will "provide the necessary incentive for investment in research and development" and "best guarantee … access to essential medicines for all countries."[34] Developing countries counter this with the argument that the most important thing is allowing for the production of generic products so that access is more widespread to existing medications.[35]

Kevin Outterson describes the developed countries' rationale as being based on the idea "that the research and development enterprise must be nurtured by high prices to yield the next generation of breakthrough therapies".[36] This paper proposes that such logic is flawed for both practical and philosophical reasons. First, the majority of pharmaceutical profits do not get recycled into more research and development, but into more marketing. Thus, there is no causal connection between incentivizing research and producing new innovations.

But the concept is also poisonous ethically. It sacrifices the existence of living humans for potential future gains to society, and the parties eager to codify the sacrifice are both not the people who will experience the loss as well as most definitely the people who will experience the most significant gain. Only via the truly American pastimes of obsessing over some

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[32] Peter K Yu, "TRIPS and its Discontents" Marquette IP L Rev 10:369 (2006) at 370.
[33] *Id.*
[34] Erika George, "The Human Right to Health and HIV/AIDS: South Africa and South-South Cooperation to Reframe Global Intellectual Property Principles and Promote Access to Essential Medicines" Indiana J of Global L Studies 18(1):167 (2001).
[35] *Id.*
[36] Kevin Outterson "Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets" Yale J of Health Pol, L & Ethics (2004) at 194.

imaginary future at the expense of the living present[37] and insisting fundamentally on constant growth in every industry could this poisonous conception be stomached. In reality, the narrative written and the statistics that follow it tell a simple story: the Dispute Settlement Bodies ("DSBs") adjudicating disputes between member states have taken up the rationalization put forth by the developed world, and by and large sided with the party arguing in favour of greater patent protection,[38] and residents of developing countries are still woefully unable to access essential medicines. More than two billion people are without affordable access to the pharmaceuticals they need,[39] mostly in developing countries.[40]

But it is more than just populations of developing countries who are negatively impacted by obtrusive patent laws. Due to the applicability of patent protections varying across regions, drug prices comprise the antithesis of global consistency, and the residents of developed nations are often forced to go without lifesaving drugs due to high prices as well.[41] In fact, pharmaceuticals cost more in the United States than they do anywhere else in the world,[42] even for drugs that are of American origin,[43] with nearly 500 billion USD of the world's pharmaceutical spending last year taking place in the United States alone.[44]

In 2020, the United States is projected to account for a total of 41% of global expenditures on pharmaceuticals.[45] This is 6.8[46] times what Japan will spend, despite the United

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[37] For another example of this, consider the distinctly (in the developed world) American opposition to abortion rights.
[38] European Union v Canada, WT/DS114/13 (2000); European Union v Turkey, WT/DS583/4 (2020); United States v India, WT/DS50/10 (1999); United States v Pakistan, IP/D/2/Add.1 WT/DS36/4 (1997).
[39] The Guardian <https://www.theguardian.com/business/2014/nov/17/gsk-top-table-for-drugs-access-developing-coountries>
[40] *Id.*
[41] *See* discussion *infra* in text.
[42] <https://www.medbelle.com/medicine-price-index-usa>
[43] *Id.*
[44] World Health Organization <https://www.who.int/docs/default-source/documents/2019-uhc-report.pdf>
[45] <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/global-medicines-use-in-2020>
[46] *Id.*

States having only 2.6 times the population, and 3.2 times what the five most populated countries in the EU[47] will spend combined, despite the United States containing basically the number of persons. The failure of the system to keep drug prices down in the United States is borne out by the fact that Americans have the largest ratio of health expenses to total household expenses in the OECD.[48] As stated previously, the ostensible goals of free trade agreements include decreasing barriers to trade *between* nations, but if not technically an indication of an impeded world market, it at least serves as a dead canary in twenty-first century capitalism's coal mine of pharmaceuticals that the citizens of the world's richest nation cannot afford medicine at close to the same level as their peers due to trade barriers whose advocacy was taken up by that very nation.

Additionally, it does not appear to be easy for fledgling firms to enter the industry, especially in countries with emerging pharmaceutical manufacturing industries. The biggest pharmaceutical firms are by and large the same ones now as they were pre-TRIPS, and the firms that did grow the most since the turn of the millennium were from these developed countries, rendering the current list of largest pharmaceutical firms a collection of massive entities substantially representing the United States, Japan, Germany and Switzerland, and to a lesser extent the United Kingdom, France and Sweden.[49] Although there have been some success stories, the majority of the developing world does not produce its own lifesaving medicines.[50] The exceptions to this rule, including new firms from China and India, typically do not find much success unless they forge partnerships with established multinational giants,[51] meaning the pharmaceutical multinationals have all bases covered.

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[47] *Id.*
[48] <https://stats.oecd.org/Index.aspx?DataSetCode=SHA>
[49] *Compare* <https://www.pharmaceutical-technology.com/features/top-pharmaceutical-companies/> *with* <https://onlinelibrary.wiley.com/doi/abs/10.1002/9780470571224.pse127>
[50] Bryan C Mercurio, "TRIPs, Patents, and Access To Life-Saving Drugs In The Developing World" Marquette IP L Rev (2004).
[51] *Id.*

If drug prices are still prohibitively high for both developed and developing countries' consumers, and TRIPS has proved unhelpful for new firms in developing countries, one might by the process of elimination infer that the agreement benefits established firms in developed countries; that inference would be correct. Some of the companies which benefit the most from this are American and Swiss companies, as six pharmaceutical giants from the developed world account for more than a fifth of the industry's total revenues.[52]

The global pharmaceutical industry is simply massive. Revenues in 2018, the last year with available data, exceeded 1.2 trillion USD, and early estimates for 2019 suggest around 1.3 trillion USD in sales.[53] This is the culmination of years of massive increases since the turn of the millennium; in 2001, revenues did not even hit 400 billion USD.[54] While the improving numbers on access to health services in the developing world[55] might account for some of this change, it cannot possibly explain a growth rate 1.7 times the rate of inflation in the same time period.[56] Besides, as stated, the world's few largest developed countries account for the vast majority of pharmaceutical sales, with all G7 countries appearing among the world's ten largest pharmaceutical markets (along with China and Brazil, and another large developed nation, Spain), and the developed world was still the source of 63% of pharmaceutical expenditures last year.[57]

If one is inclined to take a step back and examine the political dynamics of the pharmaceutical industry, the source of the drug price inflation, especially in the United States, becomes more apparent. The largest American pharmaceutical manufacturers are all members

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[52] <https://www.proclinical.com/blogs/2019-3/the-top-10-pharmaceutical-companies-in-the-world-2019>
[53] <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/global-medicines-use-in-2020>
[54] <https://www.statista.com/statistics/263102/pharmaceutical-market-worldwide-revenue-since-2001/>
[55] World Health Organization <https://www.who.int/news-room/detail/13-12-2017-world-bank-and-who-half-the-world-lacks-access-to-essential-health-services-100-million-still-pushed-into-extreme-poverty-because-of-health-expenses>
[56] 3.09/1.83=1.69. *See* <https://data.worldbank.org/indicator/FP.CPI.TOTL.ZG?end=2018&start=2001&view=chart>
[57] *Id.*

of two trade organizations: Pharmaceutical Research and Manufacturers of America, and Biotechnology Innovation Organization. The two groups have extensive resumes: they lobby with respect to hundreds of pieces of legislation each year, devote enormous funds to Federal lobbying and information campaigns, and give millions of dollars to Presidential candidates (and more millions to Republicans than to Democrats).[58]

In 2003, the Medicare Prescription Drug Improvement and Modernization Act was passed, enabling pharmaceutical manufacturers to negotiate prices directly with Medicare, instead of with the federal government at its full resources.[59] The largest purchaser of essential medicines in the world, the United States government, has passed legislation banning itself from the price negotiations of those very essential medicines, at the urging of the lobbies of the very parties who will be selling those essential medicines. Giving this full consideration, it is unsurprising that the last two decades have seen an enormous growth of pharmaceutical costs and drug company profits.

There are however legal arguments that can be employed to address the problems caused by the current application of intellectual property law in the pharmaceutical industry. This paper will present potential constructive actions by developing countries drawing on both jurisprudential and practical justifications.

Antitrust Jurisprudence

TRIPS contains several references to antitrust protections.[60] This makes it all the more strange that, in all decisions regarding patent rights in developed and developing countries alike, decisions of the Dispute Settlement Bodies have yet to address attempts by, the possibility of, or even the idea of antitrust law in developing countries.[61] This suggests that such topics have not been extensively explored in practice, and that the body of antitrust law, calibrated with

[58] Washington Post <https://www.washingtonpost.com/wp-dyn/content/article/2007/01/11/AR2007011102081.html>
[59] Medicare Prescription Drug Improvement and Modernization Act
[60] *See* discussion *infra* in text.
[61] European Union v Canada, WT/DS114/13 (2000); United States v India, WT/DS50/10 (1999).

a robust interpretation of the Agreement's language on competition, is ripe for argumentation. First it is necessary to examine the phrasing of the antitrust provisions in TRIPS.

Two sections contain qualifying statements about adhering to a system of fair competitive practices in limitation of certain patent protections. Article 8(2) allows for measures that "may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology."[62] Article 31, when reading various subparts in concert, makes clear that "a practice determined after judicial or administrative process to be anti-competitive" cannot be remedied by the utilization of certain other parts of the article, normally suitable for limiting the exploitation of patents by those other than rights holders.[63]

The section explicitly dedicated to antitrust provisions, however, is article 40. It states that:

> "1. Members agree that some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology.
>
> 2. Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market."[64]

[62] TRIPS.
[63] TRIPS.
[64] TRIPS.

While the beginning of article 40 is "strikingly philosophical" in that it waxes on "the rationale under which the international community may approve of … intervention to restore competition" rather than "the behaviour … subject to antitrust scrutiny",[65] the common law tradition of interpreting statutory language in its plain and ordinary meaning is justification for interpreting the text logically and literally. Doing so, it is made clear that the "transfer and dissemination" of a type of medical technology, which has already taken place elsewhere in the world, has been impeded in developing countries where lack of universal healthcare is still widespread and access to pharmaceuticals is irregular. The impediment to actual human health is proof of the impediment experienced technologically.

Simply, if the same impediment were to be experienced in Canada, Germany or Japan, there is no way that either the citizenries or the governmental bodies of those countries would accept the protection and enforcement of property rights of foreign multinationals as a valid reason for the experience. Thus, the only non-hypocritical contention that an appropriate "transfer and dissemination" has actually taken place requires implying that what is widely accepted as a human rights violation in developed countries is acceptable in their still developing peers, a position of some moral difficulty, or at least an antiquated (lack of a) conception of equality.

The segment of article 40 quoted above also contains key language near the end. The context of the particular "relevant market" is noted, suggesting that there is no general solution applicable to all developing countries, but that individual developing countries can enact legislation of their choosing in response to their unique condition. It is almost axiomatic but bears noting that there is nobody more appropriate, qualified or aptly positioned to judge a country's unique condition than representatives of the country itself.

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[65] Marco Ricolfi, "Is there an Antitrust Antidote against IP Overprotection within TRIPs?" Marquette IP L Rev 10(2):305 (2006) at 310.

Other parts of the Agreement, without referring directly to competition law, use language that can be drawn upon to further facilitate the presentation of a broad and permissive method of identifying antitrust practices. Article 63(1), though unrelated to competition law itself, parenthetically defines the "subject matter of this Agreement" as "the availability, scope, acquisition, enforcement and prevention of the abuse of intellectual property rights".[66] The inclusion of a method of "prevent[ing] … abuse of … property rights" in a description of the Agreement paints a picture of anticompetitive practices concordant with the United States Federal Trade Commission ("FTC") description of monopolization, or prohibited single firm conduct. According to section 5 of the FTC Act, "unfair methods of competition" are prohibited.[67] On their website, the FTC is less platitudinal, defining a firm guilty of monopolization, or prohibited single firm conduct, as "a firm with market power [that] act[s] to maintain or acquire a dominant position by excluding competitors or preventing new entry", yet still, only if such acts are a manifestation of "unreasonable methods".[68]

It has been suggested that developed countries could argue that the "enabling rather than mandatory" antitrust provisions of the Agreement are insufficiently severe to justify the level of patent exclusion proposed.[69] But if what is enabled is a function of permissive, wide-ranging policy, then mere enabling is enough. TRIPS is an international agreement, but the kind of improvements for which this paper advocates include those to domestic legislation, especially in the case of anticompetition practices.

It can reasonably be regarded as an uphill battle to utilize the antitrust provisions of a WTO-backed agreement like TRIPS if, as a whole, such an agreement ostensibly contemplates patent violations as the particularly egregious barrier to trade in international intellectual

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[66] TRIPS.
[67] Federal Trade Commission Act.
[68] *Id.*
[69] Ricolfi at 316.

property markets. But examining the Preamble elucidates that reality features more grey area than that. The text of the Agreement makes it clear that its purpose is not just to "promote effective and adequate protection of intellectual property rights" but also "to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade".[70] The preamble further clarifies that "the underlying public policy objectives" behind the Agreement "includ[e] developmental and technological objectives".[71] Not only does TRIPS contemplate the notion of patent exclusion being necessary to maintain fair trade, but it stresses that maintaining fair trade is not the only goal of the Agreement and, indeed, the domestic developmental goals of developing countries do not take second fiddle to structuring international markets. This sentiment is repeated in the body of the Agreement. Article 8(1) allows parties to "adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance".[72]

It is an important first step to determine that the antitrust protections embedded in TRIPS can be applied, and should be applied in the current situation. However, it is still necessary to determine what this application should look like. TRIPS is built "on an architecture based on authorization plus reticence" in that it has an overarchingly enabling conception to it.[73] This enabling, as opposed to mandatory, conception implies that individual nations are emboldened to construct antitrust provisions independently, with much latitude and authority.[74] That does more than just provide the opportunity to make laws that succeed, but also the opportunity to make laws that fail. And, according to Marco Ricolfi, "emerging economies do have a number of reasons to be cautious in embracing antitrust."[75] He later states:

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[70] TRIPS.
[71] TRIPS.
[72] TRIPS.
[73] Ricolfi at 317.
[74] *Id.*
[75] Ricolfi at 337.

> "[Developing countries'] political and academic elites tend to see antitrust as a body of rules originating from developed nations and hardly adaptable to their widely different economic and social environments, in which State intervention and action by public enterprises tends to be extensive. … [T]he case has often been made that most appropriate timing for implementing competition policy should be selected on the basis of the stage of economic development in which each economy finds itself."[76]

That being said, almost two decades have passed since the Doha Declaration and universal healthcare is still far from manifested in several developing countries. A notion to trust in the goodwill of developed countries and the global pharmaceutical companies that call such countries home has not been fruitful. Attempts at taking on developed countries according to the WTO's dispute resolution mechanism have been met with failure. New options are needed.

Potential antitrust provisions in the international pharmaceutical market can be broadly confined to two main categories: innovation-oriented and dissemination-oriented.[77] Innovation-oriented competition rules aim to prevent and eliminate situations where monopolization has rendered a jurisdiction in lack of the benefits of an innovation, whereas rules of the dissemination-oriented variety aim to ensure that dissemination of new intellectual property takes place if that intellectual property is used in a jurisdiction.[78]

TRIPS contemplates the two possibilities differently, but both options have their benefits and drawbacks in the current context, irrespective of the extent to which they are facilitated or hindered by TRIPS. Innovation-oriented competition rules can aim to ensure that developing

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[76] Ricolfi at 338.
[77] *See* Ricolfi *generally*.
[78] *Id.*

countries experience the benefits of medical invention the same as their developed peers, but do not foster the involvement of domestic enterprise. While dissemination-oriented competition rules do ensure that knowledge is spread to domestic firms, as discussed *supra*, multinational pharmaceutical giants have a history of exploiting connections with domestic firms in developing countries' pharmaceutical industries.

This paper wishes to suggest that dissemination-oriented competition rules, which historically have been the choice of developing countries, are the weaker option of the two. The argument in favour of such rules is predicated on the value of emerging firms in developing countries getting their feet in the technological door. Such thinking fails to survive an idea explicated *supra*: when millions are dying of failure to afford medicine, the current economic structure of the pharmaceutical industry is a diseased system, whatever it is. Additionally, the argument places the value of favouring the pursuit of a thriving industry over achieving widespread access to healthcare, the very type of thinking that, on the international stage, has predicated the problem this paper seeks to address.

One potential issue with developing countries enacting antitrust legislation is posed by article 27(1) of the Agreement. This section states that "patents shall be available and patent rights enjoyable without discrimination as to ... whether products are imported or locally produced."[79] Thus, developing countries limiting the scope of monopolization availed to large pharmaceutical companies from developed countries may be forced to similarly place limits on large pharmaceutical companies from their own countries that they may not have intended to institute. Depending on the policy a developing country is taking with its domestic pharmaceutical market, this could be a significant negative.

Practical Solutions

[79] TRIPS.

There are several practical solutions available to developing countries, and they range from acute to entirely wide-reaching. One of the broader potential solutions is to enact a fair use policy for patents akin to that for copyrights. A rubric for measuring whether such a policy would be upheld by the WTO has been put forth by Maureen O'Rourke. She states that the "five factors relevant to a fair use finding" are:

> "(i) the nature of the advance represented by the infringement; (ii) the purpose of the infringing use; (iii) the nature and strength of the market failure that prevents a license from being concluded; (iv) the impact of the use on the patentee's incentives and overall social welfare; and (v) the nature of the patented work"[80]

This finding accords with article 30's prescription for the allowance of what would otherwise be considered a patent infringement: it is limited, it is not unreasonable, and it does not fatally prejudice the interests of patent holders, especially when considering the interests of third parties.[81] It also makes sense according to article 27, allowing exemptions for moral and health reasons.[82]

Crafting a fair use policy is thus a task that must be approached with these limitations in mind. They must not be so broad as to facilitate more than the widespread public dissemination of pharmaceuticals. Any attempt at strengthening domestic industry, and the entire "nature" and "purpose" of the infringement are modified.[83] The nature and severity of the market failure is contestable. Developed countries and their pharmaceutical giants, according to the claims they make, do not even believe that a market failure has taken place, as they are not prone to

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[80] Maureen A O'Rourke, "Toward a Doctrine of Fair Use in Patent Law" Columbia L Rev 100(5):1197 (2000).
[81] TRIPS.
[82] TRIPS.
[83] O'Rourke.

characterizing the global access to health crises as emergencies. Developed nations, simply by the numbers, have a reasonable counter, but that has not stopped parties from engaging in almost doublespeak by claiming that in fact more patent protections are necessary to produce more pharmaceutical knowledge to combat the lack of access to pharmaceuticals. But the lack of access is a product not of weak pharmaceutical science, but weak market science, and thus the pharmaceutical knowledge accrued is truly useless in fighting the source of the issue. The problem is not a lack of innovation, to be made in the future; it is a lack of distribution of the innovation that has already been made.

Another bold solution is to embolden regulatory agencies to invalidate, withdraw or limit patents on pharmaceuticals. While TRIPS is the product of a multilateral negotiation, the regulatory bureaucracies of developing countries are at the conjuring of domains strictly domestic. It is essential that developing countries imbue their patent process functions with the nation's general goals. Through hiring practices as well as general policy, developing countries can mold their patent offices in a healthy way.

Of course, regulatory decisions are subject to judicial oversight, and this will inevitably play itself out in domestic courts. It is not just the lawmakers of developed countries who need to change their approach, but judiciaries too. Courts must be activist in their fight for the human health of the countries they represent, and side against pharmaceutical patent holders where feasible and appropriate. Legislatures can help with this. Although they cannot directly influence judicial opinions, published guidelines on remedies for patent violations can gear the courts to create a jurisprudence in favour of those fighting for the free exchange of information for the sake of improving access to drugs.

Influencing judicial policy is always a tricky enterprise in an open democracy, but there is much benefit to enabling and ennobling courts to hold up the invalidations, withdrawals and

limitations of patent rights that their domestic regulatory bodies enact. It takes the battle to a venue over which the international community is not supposed to have domain. However, it also all but guarantees an international appeal stage. That is precisely what Canada found when its court system upheld the elimination of two of Eli Lilly and Company's pharmaceutical patents.[84]

Eli Lilly, under the terms of NAFTA (and, by the end of the dispute, USMCA) brought a claim of 500 million USD against the government of Canada.[85] Eli Lilly claimed that Canada's courts had acted improperly in upholding the Canadian bureaucracy's exclusion of Eli Lilly's patents.[86] They claimed that the law on which the Canadian courts had relied, "promise utility doctrine", was "new, arbitrary and discriminatory against pharmaceutical companies and products."[87] According to the international arbitrators that resolved the dispute, the substantive positions taken by Eli Lilly can be summarized as follows:

> "[Eli Lilly] argues that the promise utility doctrine is a radical departure from Canada's traditional utility standard and the utility standards applied by Canada's NAFTA partners, the United States and Mexico. It claims that for decades Canada applied the traditional utility test for which a "mere scintilla" of utility sufficed, and under that test, pharmaceutical patents were never found to lack utility until the advent of the promise utility doctrine in the mid-2000s."[88]

Eli Lilly based these suppositions on NAFTA articles 1105 and 1110. Article 1105 states that the countries "shall accord to investments of investors of another Party treatment in accordance

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[84] Eli Lilly v Canada, UNCT/14/2 (2017) [hereinafter Eli Lilly].
[85] *Id.*
[86] *Id.*
[87] *Id.*
[88] *Id.*

with international law, including fair and equitable treatment and full protection and security" and that they must practice "non-discriminatory treatment with respect to measures it adopts or maintains".[89] Article 1110 prohibits nations from "directly or indirectly nationaliz[ing] or expropriat[ing] an investment of an investor of another Party in its territory or tak[ing] a measure tantamount to nationalization or expropriation of such an investment".[90]

The tribunal did not adopt this argument. Instead, they found that Eli Lilly had "failed to establish the factual premise of its claims" by failing to meet the conditions prescribed by articles 1105 and 1100 of NAFTA.[91] The tribunal agreed with Canada that they had provided a "minimum standard of treatment" and that thus there had not been any "fundamental or dramatic change in Canadian patent law". They also indicated that Canada had not enacted any "arbitrary or discriminatory measure[s]". This grants nations a broad permission to make significant changes to their patent law (including changes that reassign formerly patented drugs as freely exploitable public goods) without risking violation of trade agreements, as long as they maintain a baseline. Directly impacting only two drugs, as Canada did in this case,[92] is neither arbitrary or discriminatory.

It does bear mentioning that in *Eli Lilly*, the one instance where patent rights were unequivocally struck down, the successful party was still a developed nation. While in an ideal world that would not matter, developed nations have both soft and hard power that would surely imbue on them a certain amount of arbitrational privilege in international dispute resolution arenas. Additionally, they typically have a greater wealth of legal experience and expertise at their command. The disadvantages faced by developing countries in the milieu of international dispute resolution, though noted, will not be explored in this paper.

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[89] NAFTA.
[90] NAFTA
[91] Eli Lilly.
[92] Eli Lilly.

Solutions do not have to be as ambitious as creating a new doctrine through which our global society will construe patent rights, or entrenching new regulatory and judicial guidelines or objectives. There are smaller changes that can be made to the domestic policies of developing countries. For example, interpreting the linguistic prescriptions of TRIPS more generously and translating this interpretation into advantageous policy is possible as well. The Agreement has been described as containing "constructive ambiguities"[93] or "policy space"[94] in which nations can display flexibility in interpreting the provisions of the Agreement as they pertain to policy drafting. But actually coming up with identifiable word changes that can be employed by developing nations in legislation drafting can be difficult, especially as many less developed countries' "experience with intellectual property protection" is still in its beginning stages.[95] One legislative idea, proposed by Susan Sell, is to focus the language of domestic pharmaceutical patent legislation in developing countries on bestowing "grants" instead of "rights" to pharmaceutical companies. As rights are often conceived as more inalienable than grants,[96] which can be given or withdrawn as a governing body sees fit, framing domestic patent protections as granted by developing countries makes it easier for these nations to scrap protections for a certain drug, as a health crisis or other situation may necessitate.

Finally, it is important to remember that TRIPS and its application are not intractable. The enforcement of the bargain is an ongoing process; the conception of the terms of the Agreement can potentially be changed via further negotiations. Parties can redo agreements suddenly; the transformation of NAFTA into USMCA is proof of that. One possible area for improvement in future dealings is the lack of explicit user rights in TRIPS. Because of the nature of the pharmaceutical industry, making user rights as explicit as possible is key. Peter Yu explains:

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[93] Yu at 387.
[94] Reichman at 28.
[95] Yu at 388.
[96] Susan K Sell, Private Power, Public Law: The Globalization of Intellectual Property rights (2003) at 128.

> "While the lack of explicit rights might be less problematic in a system where intellectual property rights are the exception, rather than the rule, such a lack because a major problem in today's system where such rights are more the rule than the exception."[97]

It is imperative, in a system where developing countries have historically been at a power disadvantage,[98] that they find ways to translate their victories at the bargaining table into positive law in treaties.

Speaking broadly, when fighting for a recalibration of the Agreement, developing countries must advocate for a greater inclusion of the objectives and opinions of third parties whose stances are usually favourable to developing countries: "libraries, educational institutions, research institutes, or non-governmental organizations".[99] Groups like those can provide valuable third party perspectives on why and how the fundamental rights of developing countries are their citizens are being threatened by the current state of international patent law, as codified by TRIPS. However, during the initial negotiations of the Agreement, their input was nowhere to be found.[100]

## Conclusion

Merriam-Webster's medical definition of autoimmunity is a condition in which the body produces immunity in a response against its own constituents.[101] Immunity is the ability of the body to prevent and resist other conditions.[102] The global community of humans, and the geopolitical bodies that represent them as global citizens, have let its metaphorical autoimmunity in the form of trade barriers hinder its literal health. This is the textbook definition

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[97] Yu at 397.
[98] As evidenced by the state of affairs.
[99] Ruth L Okediji, "Public Welfare and the Role of the WTO: Reconsidering the TRIPS Agreement" Emory Intl L Rev 7 819 (2003) at 839.
[100] *Id.*
[101] <https://www.merriam-webster.com/medical/autoimmunity>
[102] <https://www.merriam-webster.com/dictionary/immunity>

of disease: the type of condition due to which our international pharmaceutical markets are currently not working.

Trade barriers are usually detrimental to the global economy. It is for this reason that their diminishment has been widely embraced, and met with success. But TRIPS is not an ordinary trade agreement, because it governs pharmaceuticals, which is not an ordinary industry. Thus TRIPS cannot be treated like the boilerplate of international trade agreements. And the way in which TRIPS is being enforced cannot sacrifice human health for economic growth.

This paper does not advocate for the position that the pharmaceutical industry should not feature patent protections, on the dual assumptions that a capitalist political economy cannot incentivize the creation of knowledge without granting some level of domain over the profits secured by exploitation of such knowledge, and that the world's international economy will remain essentially capitalistic, or at least aspirationally so, for the foreseeable future. Nonetheless, patent protections need to adequately balance the need for the world's economically lacking persons to access essential, lifesaving drugs.

The practical application of TRIPS has not weighed out this balance properly. The proof of this is not rooted in legal argumentation; simply, too many people are dying from a financial lack of access to medicine. It is the role of law to advance human progress, and the law must thus be considered in a manner different from the current state of interpretation, a reckoning which is debilitating humanity's ability to advance medically. It is incumbent on all stakeholders in human health to work together to combat preventable death. However, developing countries are by and large the victims of patent law gone amok, and developing countries are thus the ones most apt to be outfitted with arguments and strategies.

Creating a robust, but not overbroad, fair use policy for patents is one such strategy. The terms of TRIPS detail the extent to which such a policy can be enacted, and by meeting those prescriptions, developing countries can craft fair use policies devoted to facilitating the health-based eschewing of normally patentable innovations. By building regulatory agencies in such a manner so that they have the agency to invalidate, withdraw and limit patents on pharmaceuticals, developing countries can further strengthen their fair use policies. It is also incumbent on judiciaries to help nations approach their health objectives by holding up the aforementioned invalidations, withdrawals and limitations in court. The potential solutions are many.

Health is a human right, with no substitute goods, and the international law on the access to medicine cannot protect corporate interests for the sake of profit. But they currently do. And the autoimmunity of these self-debasing trade barriers is a disease that must be cured. The cure is good policy, and antitrust jurisprudence provides both proof of and justification for the relevant policy recommendations. By interpreting TRIPS in a manner which supports the international goal of working towards universal health, and acting in accordance with this interpretation, the legal framework of our international pharmaceutical industry can begin the necessary healing.