ARTICLE 31(F): THE POLITICS, ECONOMICS, AND SHOWMANSHIP OF GIVING MEDICINE TO THE POVERTY-STRICKEN

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I. *Introduction*

Alexander Fleming's synthesis of penicillin is credited with saving between 80 million and 200 million lives.[1] It is one of the so called "holy grails" of innovation. Antiretroviral therapy is currently doing the same thing for HIV/AIDS. Genetic therapy may well be the breakthrough cure for cancer. Of course, the benefits inhering to medicine fall to waste if patients cannot actually take them. Herein lays the great tension in pharmaceuticals: balancing benefits for current patients with benefits for future patients, or in other words access versus innovation.[2] While public health may be reason enough for a government to invest its resources into the invention of medicine, it is certainly not a justification for pharmaceutical companies, which have fiduciary duties to generate profits for their shareholders. Intellectual property protection – especially patents – is one of the economic tools that attempt to reconcile this tension. By providing a period of exclusive rights, governments sanction the creation of novel pharmaceuticals because inventors have a guaranteed monopoly, through which they can recoup their original investment and collect a profit, which will both subsidize future investment and reward past investment.[3] When the economics are properly calibrated, the patent system will reliably churn out innovative products with minimal (though palpable) impediments to access.

Unfortunately, there is a caveat to all this. In countries with high income inequality, pharmaceutical companies face an economic incentive to price their drugs high so that they can take advantage of demand inelasticity.[4] This pricing strategy necessarily eliminates access to medication for vast swaths of the lower income parts of the population as the drug companies price their drugs high, selling at high profit margins but low volume.[5] Notably, the economics of demand inelasticity have not gone unnoticed, even in the United States:

> "I probably would have raised the price higher [than the 5,000% we already raised it by] …I think healthcare prices are inelastic. I could have raised it higher and made more profit for our shareholders, which is my primary duty – and again – no one wants to say it, no one's proud of it – but you know this is a capitalist society,

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[1] Carmel Fisher, *We've Never Had It So Good*, THE NEW ZEALAND HERALD (Sept. 30, 2016), http://m.nzherald.co.nz/personal-finance/news/article.cfm?c_id=12&objectid=11717552.
[2] *See generally*, Sean Flynn, Aidan Hollis, and Mike Palmedo, *An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries*, JOURNAL OF LAW, MEDICINE & ETHICS (Summer 2009).
[3] *Id*., at 4.
[4] *Id*., at 3-4.
[5] *Id*. Note that drug companies could pursue a high volume, low margin strategy. However, as income inequality widens, the population at the lower end of the economic spectrum may not even be able to afford startlingly low, unprofitable prices.

capitalist system and capitalist rules, and my investors expect me to maximize profits."[6]

II. *The History of Article 31(f) of the TRIPS Agreement*

For the purposes of this discussion, the Trade Related Intellectual Property Rights Agreement (TRIPS Agreement) requires the 162 World Trade Organization member countries to ensure patent rights of at least twenty years under Article 33.[7] The current economic and legal approach to the tension between access and innovation is found in Article 31 of the TRIPS Agreement.[8] The inspiration for Article 31of the TRIPS agreement in 1995 probably came from the Canadian "license of right."[9] Under this program, any company could apply for a license to manufacture a patented pharmaceutical. If the license was granted, the company could distribute the generic at competitive prices and would pay a royalty of four percent to the brand name manufacturer.[10]

The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement authorized the use of compulsory licenses for pharmaceuticals in January of 1995 under Article 31.[11] A compulsory license is an authorization made by a government for a company to produce a patented product or replicate a patented process without the patent owner's approval.[12] The compulsory patent holder/licensor does still retain their patent rights, including the right to payment for authorized copies of their products.[13]

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[6] *One-on-One with Pharma's Provocateur,* FORBES (Dec. 8, 2015), http://www.forbes.com/video/4650565743001/. Martin Shkreli, former CEO Turing Pharmaceuticals, speaking at the Forbes Health Care Summit in 2015, in response to the question if he would have done anything differently in hindsight after the backlash to the 5,000% increase in price of Daraprim.

[7] WTO, AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS [hereinafter TRIPS].

> "Article 33
> Term of Protection
> The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date[.]"

[8] TRIPS

> "Article 31
> Other Use Without Authorization of the Right Holder:
> Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected[…]"

[9] *See* Jerome H. Reichman, *Comment: Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options*, JOURNAL OF LAW, MEDICINE & ETHICS (Summer 2009), at 252. "The Canadian compulsory approach was then formally prohibited by the intellectual property chapter in the North American Free Trade Agreement (NAFTA), whose provisions, in turn, became a blue-print for article 31 of the TRIPS Agreement."

[10] *Id.*

[11] WTO, *TRIPS and Health: Frequently Asked Questions, Compulsory Licensing of Pharmaceuticals* (2016), https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm

[12] *Id.*

[13] *Id.*

There are a number of conditions on these licenses. Most importantly, as negotiated in 1995, under Article 31(f)[14], the compulsory license must be *primarily for the domestic market*, and not for *export*.[15] Under normal conditions, pursuant to Article 31(b)[16], the company or person that is applying to a country for a compulsory license to produce a patented pharmaceutical must have first tried and failed to negotiate a voluntary license on reasonable commercial terms.[17] Also, under Article 31(b), in cases of national emergencies, other circumstances of extreme urgency, public non-commercial (or government) use the requirement to attempt negotiations for a voluntary license is waived.[18] Under Article (k), anti-competitive practices on behalf of the patent-holder are another justification to waive the negotiation requirement.[19] Once again, the patent holder still retains the right to payment under Article 31(h).[2021] The country issuing the compulsory license has the right to decide what amounts to "adequate payment," although the patent holder does retain the right to appeal within that country.[22] Article 31(d) requires that the use of the compulsory license be non-exclusive.[23]

Article 31(f) Waiver and Pending Amendment

Article 31(f), however, has changed as countries have begun to realize there may be circumstances in which a compulsory license should be granted *primarily for export*. As part of

[14] TRIPS, art. 31(f). "[A]ny such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use[.]"
[15] *Supra*, note 9.
[16] TRIPS, art. 31(b).

> "[S]uch use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly[.]"

[17] *Supra*, note 9.
[18] *Id*.
[19] TRIPS, art. 31(k).

> "Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur[.]"

[20] TRIPS, art. 31(h). " [T]he right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization[.]"
[21] *Supra*, note 9
[22] *Id*.
[23] TRIPS, art. 31(d).

the Doha Development Round, countries realized that Article 31(f) functionally served no purpose for nations that lacked the capacity to even produce a pharmaceutical. On August 30, 2003, the World Trade Organization agreed to a *waiver* (also known as the "*paragraph 6* d*eclaration*') for compulsory licenses allowing countries to grant licenses when they are unable to manufacture their own pharmaceuticals.[24] The pharmaceuticals would be produced by another country that has the capacity to produce, thus overcoming the 1995 limitation that compulsory licenses be issued primarily for the domestic market.[25]

On December 6, 2005, the WTO approved an amendment ("*Article 31 bis")* to make this waiver a permanent amendment, subject to a two thirds vote of approval.[26] On November 30, 2015, the General Council extended the deadline for acceptance of the amendment to December 31, 2017 or such later date as may be decided by the Ministerial conference.[27] As of October 18,

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[24] WTO, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Decision of the General Council of 30 August 2003* (Sept. 1, 2003), https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm.

> "…The obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out below in this paragraph[et. seq.]"

[25] *Id*.

[26] WTO, *Members OK Amendment to Make Health Flexibility Permanent, Press Release* (Dec. 6, 2005), https://www.wto.org/english/news_e/pres05_e/pr426_e.htm.

> The amendment is designed to match the 2003 waiver as closely as possible. Other procedures used in 2003 are also matched, including a statement read out by the General Council chair. In order to achieve this, delegations have been involved in intricate legal discussions aimed at ensuring that the legal meaning and weight, and the hierarchy of provisions, are preserved as exactly as possible….
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> ….Article 31(f) of the TRIPS Agreement says that production under compulsory licensing must be predominantly for the domestic market. The concern was that this could limit the ability of countries that cannot make pharmaceutical products from importing cheaper generics from countries where pharmaceuticals are patented.
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> As with the 2003 waiver, the permanent amendment will allow any member country to export pharmaceutical products made under a compulsory licence for this purpose. They may need to change their own laws in order to do so.
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> So far, Norway, Canada and India have informed the WTO that their laws are complete, while the Republic of Korea and the EU have said their new laws are on the verge of coming into force.
> A group of developed countries are listed as announcing that they will not use the system to import.
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> A number of other countries announced separately that if they use the system as importers it would only be for emergencies or extremely urgent situations. They are: Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey and United Arab Emirates….

[27] General Council. *Amendment of the TRIPS Agreement – Fifth Extension of the Period for the Acceptance by Members of the Protocol Amending the TRIPS Agreement, Decision of 30 November 2015*, WTO Doc. WT/L/965 (Dec. 2, 2015).

2016, 106 of the necessary 108 votes have been tendered, so long as the European Union is counted as a separate member and the Brexit situation does not nullify any of the United Kingdom's proxy WTO votes, previously cast through the European Union.[28]

III. *Specific Cases*

A. *Rwanda*

The only pair of countries to successfully use the paragraph 6 waiver provisions was Rwanda and Canada.[29] Canada created the Canada's Access to Medicine Regime (CAMR) in response to the paragraph 6 Doha Declaration provisions and immediately began coordinating with Rwanda. There was much concern at the time that Canada did not establish the CAMR for public health reasons, but instead for political reasons. In other words, Canada was not pursuing the most effective strategy to expand access to medicine, but instead pursuing the most visible strategy. Here is a contemporaneous evaluation from Cohen-Kohler, Esmail, and Cosio published in December of 2007:

> "CAMR is removed from the realities of developing countries and the pharmaceutical market….CAMR is symbolically meaningful but in practice, limited. The Rwanda case will be noteworthy in terms of the future of the legislation. To meet its intended international health objectives, this legislation needs to be better informed of developing country needs and global pharmaceutical market imperatives."[30]

The paragraph 6 waiver proceedings began innocuously enough. On July 17, 2007, Rwanda notified the WTO that it would make use of the 31(f) waiver under paragraph 6 of the Doha Declaration. [31] Canada then notified the WTO on October 4, 2007 that it would provide a compulsory license to Apotex, Inc. to produce Apo-TriAvir, which is an HIV antiretroviral

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[28] *See* WTO, *Members Accepting Amendment of the TRIPS Agreement* (Jun. 22, 2016), https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm; Peter Ungphakorn, *Analysis: WTO Amendment on Access to Medicines Faces EU Conundrum* (INTELLECTUAL PROPERTY WATCH, Apr. 14, 1016), http://www.ip-watch.org/2016/04/14/analysis-wto-amendment-on-access-to-medicines-faces-eu-conundrum/. (using both of the articles to complete the arithmetic).

[29] Stacey B. Lee, *Can Incentives to Generic Manufacturers Save the Doha Declaration's Paragraph 6*, 44 GEORGETOWN JOURNAL OF INT'L LAW 1387, 1399 (2012).

[30] Jillian C. Cohen-Kohler, Laura C. Esmail, and Andre Perez Cosio, *Canada's Implementation of the Paragraph 6 Decision: Is it Sustainable Public Policy?* BIOMED CENTRAL (Dec. 6, 2007), https://globalizationandhealth.biomedcentral.com/articles/10.1186/1744-8603-3-12.

[31] Council for Trade-Related Aspects of Intellectual Prop. Rights, *Notification Under Paragraph 2(A) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTO Doc. IP/N/9/RWA/1 (Jul. 19, 2007) https://www.wto.org/english/tratop_e/trips_e/ta_docs_e/3_ipn9rwa1_e.pdf.

combination of three patented medications.[32] At the time Rwanda sought the compulsory license there were about 150,000 people living in Rwanda with HIV.[33] The majority of Rwandans earned less than $0.43 per day or $157 per year.[34] The cost of generic treatment ranged from $88 - $261 per year, while the cost of brand name treatment was $10,000 or more per year.[35] The situation of extreme poverty combined with the prohibitively priced drugs created an emergency situation under Article 31(b) of the TRIPS agreement.[36]

This process, unfortunately, did not go smoothly. For example, one of the obstacles was an enhanced negotiation requirement, above and beyond what TRIPS required. Canada's Access to Medicine Regime (CAMR) placed requirements for Rwanda to certify that they had attempted to negotiate with the manufacturers on reasonable terms and conditions, and that those efforts were not successful.[37] While the CAMR requirement may have been well-intentioned, it allowed the pharmaceutical companies to make offers to negotiate (without making much progress during the negotiations) and thus stall the process.[38] It cannot be stressed enough how much self-interest pharmaceutical companies have in any tactic that can delay competition and protect their economic rights to patent exclusivity. Apotex informed the brand name manufacturers (Shire, GlaxoSmithKline, and Boehringer Ingelheim) that it intended to produce Apo-TriAvir for purely humanitarian reasons and to sell the drug at zero profit for exactly $0.40 per pill.[39] The pharmaceutical companies refused to give Apotex a voluntary license and only relented after Rwanda informed the WTO that negotiations had stalled.[40]

In May of 2008, Rwanda was finally able to accept Apotex's bid to supply Apo-TriAvir. Rwanda received two shipments of the drug in 2008.[41] CAMR, however required Apotex to file a new application to renew its compulsory license in 2009; at this point Rwanda received its second delivery of two shipments of Apo-TriAvir in September, 2009.[42] These were the only two deliveries.[43] Although Rwanda wanted to double the order from Apotex, there was no efficient way to do so under the CAMR requirements and Rwanda and Apotex were unable to pursue an expansion.[44] In addition to the regulatory hurdles, the paragraph 6 waiver faced another critical barrier. Because the CAMR limited Apotex to only producing 15,600,000 tablets

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[32] Council for Trade-Related Aspects of Intellectual Prop. Rights, *Notification Under Paragraph 2(C) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTO Doc. IP/N/10/CAN/1 (Oct. 8, 2007), https://www.wto.org/english/tratop_e/trips_e/ta_docs_e/3_ipn10can1_e.pdf.
[33] *Supra*, note 29.
[34] *Id*.
[35] *Id*., at 1400.
[36] *See supra*, note 16.
[37] *Supra*, note 29 at 1401.
[38] *Id*.
[39] *Id*. at 1403.
[40] *Id*.
[41] *Id*.
[42] *Id*.
[43] *Id*. at 1404.
[44] *Id*. at 1405.

over a two year period, Apotex was never able to recover its initial investment through cost savings in economies of scale.[45] The final dagger to the Paragraph 6 procedure was the decision of Cipla, a generic Indian pharmaceutical company that approached Rwanda during the CAMR procedure.[46] It offered to sell its own version of the generic antiretroviral Apotex was producing for $0.26.[47] In addition to being $0.14 cheaper per tablet, the Cipla generic drug would not trigger any problems under TRIPS.[48]

B. *Thailand*

> *Thailand, in contrast to Rwanda, is a country that has the capacity to produce pharmaceuticals. Therefore, it does not need to rely on the paragraph 6 waiver exception. This capacity can make a tremendous difference in the outcome of compulsory license proceedings.*

While Rwanda's use of the waiver provisions of 31(f) exposed the futility of coordination between the different stakeholders (i.e., the importing country, the exporting country, the brand name pharmaceutical companies, and the generic pharmaceutical companies), Thailand, in contrast, exposed the weaknesses of 31(f) as it applies solely to compulsory licensing for domestic uses.

Just two months after a military coup, in November of 2006, Thailand decided to issue its first compulsory license for efavirenz (from Merck's Stocrin), an HIV antiretroviral drug.[49] Upon assuming power, Thailand's new military government had immediately eliminated the fee for universal health care coverage.[50] The government stated that the high prices of drugs were undermining universal health care coverage.[51] While this problem is accurate, the means to correct the problem appear disingenuous. Thailand pursued an aggressive scheme to issue Moreover, there was a legitimate problem with access to medicine. As of 2009, close to 90,000 people were receiving antiretroviral therapy in Thailand.[52] Thailand publicly expressed its desire to lower the price of Kaletra, an antiretroviral drug manufactured by Abbott Pharmaceuticals, to 20% of Abbott's quoted price.[53] Thailand was unable to reach this goal of 20%.[54] Additionally,

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[45] *Id*. at 1403, 1405.
[46] *Id*. at 1404.
[47] *Id*.
[48] *Id*.
[49]Kristina M. Lybecker and Elisabeth Fowler, *Compulsory Licensing in Canada and Thailand: Comparing Regimes to Ensure Legitimate Use of the WTO Rules*, JOURNAL OF LAW, MEDICINE & ETHICS (Summer 2009), at 228.
[50] *Id*.
[51] *Id*.
[52] *Id*.
[53] *Id.* Lybecker and Fowler cite a 2002 statement from auditor general Jaruvan Maintaka saying the Government Procurement Office sold about 60% of its medical products above cost. Furthermore, the government pharmaceutical office in Thailand has had a seedy history of selling drug products above market price, sometimes by as much as 1,000%, calling into question the price sensitivity justification.

the antiretroviral drugs for HIV were available from non-governmental organizations (NGO's) for a lower price than the Kaletra target, anyways, had Thailand decided to purchase drugs through the NGO's in the first place.[55]

In fact, between coming to power in September 2006 and January 2008, Thailand issued 32 compulsory licenses.[56] At this point, it becomes necessary to evaluate the real reasons behind Thailand's compulsory licensing regime and not merely the public relations statements:

> "It is then worth probing whether the decision is a supply issue. Is domestic production necessary to Thailand in order to maintain a reliable supply of the drug? Certainly this could justify the government's action and be the objective behind the compulsory licenses. However, examination of the Thai Procurement rules suggests no. The sole license to manufacture the compulsorily licensed drugs was granted to the [Government Pharmaceutical Organization (GPO)]. The Thai government has denied private Thai manufacturers procurement contracts while simultaneously claiming that universal coverage can only be assured through compulsory licenses for the multiple drugs selected. An increased supply of drugs and enhanced security of a reliable supply through multiple producers does not appear to be the government's motivating objective."[57]

Lybecker and Fowler go on to argue that in addition to violating 31(d)[58] by only giving licenses to the GPO, Thailand is not using the compulsory license program for a permissible use[59] but, instead, overtly chasing financial profit.[60] For example, in 2003, the GPO made a profit of 642 million baht and that level rose to 1 million baht in 2005.[61] Moreover, "[t]he GPO plan[ned] to double its 2005 revenue to 10 billion baht by 2010[.]"[62] They further question the disease indications for compulsory licenses, noting that while HIV/AIDS (antiretrovirals: generic efavirenz and Abbot's drug Kaletra) is a legitimate public health emergency, high cholesterol (Bristol Myers Squibb and Sanofi Aventis' drug Plavix) are not.[63]

C. *Revisiting Thailand*

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[54] *Id*.
[55] *Id*.
[56] *Id*. at 229.
[57] *Id*., at 228-229.
[58] *Supra*, note 23.
[59] *Supra*, note 16.
[60] *Supra*, note 49 at 232.
[61] *Id.*
[62] *Id*., quoting P. Stevens, Will Compulsory Licenses Improve Treatment for Patients: The Case of Thailand, International Policy Press, London U.K., May 2007, available at http://www.fightingdiseases.org/pdf/Stevens_thailand_web.pdf (last visited April 7, 2009) at 5.
[63] *See* i*d*., at 233. *C.f.*, Lawrence O. Gostin, Global Health Law (2014) (discussing repeatedly the exportation of lifestyles that lead to non-communicable diseases like heart disease, cancer, and diabetes).

Even though Thailand appears to circumvent the *intent* and the *procedure* for issuing compulsory licenses, there is another perspective: Thailand is prioritizing access to medication. Abbot, despite initial denouncements, really did end up reducing the price of its antiretroviral drug, Kaletra.[64] In fact, Abbot announced on April 10, 2007 that it would reduce the price of its drug in not just Thailand, but in low and medium-income countries to $1,000 per patient per year.[65] This 55% reduction in price effectively made Kaletra more affordable than any generic already on the market.[66]

Additionally, in a remarkable set of negotiations, Novartis decided to distribute its breakthrough cancer drug, Glivec (imatinib) for free after Thailand commissioned a study to determine whether to issue a compulsory license on the drug.[67] Glivec is indicated in treating chronic myeloid leukemia and gastric stromal tumors; the drug stood to benefit 1,000 Thai patients each year.[68] A treatment regimen would have cost approximately 1.31 million baht per year ($39,800.00), while a generic, produced under a compulsory license, would have cost 54,750 baht per year ($1,642.50).[69] The negotiations, themselves, lasted for months with Novartis initially only committing to provide free drugs to 79.1% of the Thai population.[70]

The rationale for the pharmaceutical companies to swiftly end negotiations and reduce the prices of their drug products is decidedly overt. According to Teera Chakajnarodom, president of the Pharmaceutical Research and Manufacturers association, which is a pharmaceutical industry trade group in Thailand: "We don't want Thailand to be used as a springboard for other countries to do the same."[71] Conversely, the bargaining position of the Thai government is equally conspicuous: "People told us, 'It's useless to negotiate with them unless you start to announce that you want to go for compulsory licensing," said Suwit Wibulpolprasert, a senior adviser on disease control at the Thai Ministry of Public Health. 'Then they start to talk to you.'"[72] Observers speculate that because Thailand has not started production on many of the compulsory licenses it has issued, Thailand's real purpose for compulsory license is not to produce pharmaceuticals, *per se*, but instead to acquire leverage to persuade companies to lower the prices they are charging on those drugs.[73] In a demonstration of solidarity, the Thai approach

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[64] Thomas Fuller, *Thailand Takes on Drug Industry, and may Be Winning*, N.Y. TIMES (Apr. 11, 2007), http://www.nytimes.com/2007/04/11/world/asia/11iht-pharma.4.5240049.html.
[65] *Id.*
[66] *Id.*
[67] Sinfah Tunsarawuth, *Thailand Avoids Compulsory License on Cancer Drug; 3 More Drugs Undecided*, INTELLECTUAL PROP.WATCH (Jan. 31, 2008), http://www.ip-watch.org/2008/01/31/thailand-avoids-compulsory-licence-on-cancer-drug-3-more-drugs-undecided/.
[68] *Id.*
[69] *Id.*
[70] *See id.*
[71] *Supra*, note 64.
[72] *Id.*
[73] *See id.*

has been lauded by global health organizations such Médecins Sans Frontières, the Clinton Foundation and UNAIDS.[74]

D. *Brazil*

Brazil is yet another country with independent manufacturing capacity.

Brazil shared a similar problem with Thailand as it also had high levels of HIV/AIDS, coupled with high prices on patented antiretroviral therapies.[75] Just as in Thailand, Merck had patents covering the antriretroviral drug, efavirenz. Brazil negotiated with Merck and Merck eventually offered a 30% reduction in the price per pill from $1.59/pill to $1.10/pill.[76] As Brazil was credibly able to threaten a compulsory license, possessing sufficient manufacturing capacity (and thus avoiding any Paragraph 6 waiver scenario), Brazil negotiated from a position of some leverage.[77] Brazil further cited Thailand's use of a compulsory license and the reduction in price on efavirenz to $0.65/pill.[78] Merck refused to lower its price any further, while Brazil did, in fact, issue a compulsory license and was able to successfully produce a generic version of efavirenz, both expanding access and saving $30 million in 2007 alone.[79]

During the failed negotiations with Merck, Brazil – perfectly mirroring Thailand – pursued a compulsory license on Abbot Pharmaceutical's, antiretroviral drug, Kaletra.[80] Abbot sold Kaletra in Brazil at $1.17/pill.[81] Brazil's compulsorily licensed generic would have cost $0.68/pill.[82] Abbott relented and priced Kaletra at $0.63/pill. Brazil was also able to procure 37% price reductions in Nelfinavir, Lopinavir, Tenofivir, and Atazanavir in January of 2004 after threatening compulsory licenses.[83]

On the other hand, the World Bank does categorize Brazil as an upper-middle income country.[84] Because Brazil has a higher per capita GDP than Thailand, trade advocates have criticized Brazil's unwillingness to accept Merck's offer and suggest that Brazil is negotiating disingenuously. They fear that Brazil may be jeopardizing pharmaceutical company's

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[74] *Id*.
[75] Shaira Bhanji, *Bullying the Boss? Compulsory Licensing for Antiretroviral Drugs in Brazil and Thailand*, HARV. COLL. GLOB. HEALTH REV. (Oct. 21, 2011), https://www.hcs.harvard.edu/hghr/online/bullying-the-boss-compulsory-licensing-for-antiretroviral-drugs-in-brazil-and-thailand/.
[76] *Id*.
[77] *See id*. (generally discussing Brazil's process of negotiations and subsequent production of efavirenz).
[78] *Id*.
[79] *Id*.
[80] Jennryn Wetzler, *Timeline on Brazil's Compulsory Licensing*, PROGRAM ON INFO. JUSTICE AND INTELLECTUAL PROP. (Aug. 2007), (updated by Ana Ayala in Apr. 2008).
[81] *Id*.
[82] *Id*.
[83] *Id*.
[84] *Supra*, note 75. Thailand is also an upper-middle income country according to the World Bank.

willingness to market their products in Brazil as pharmaceutical products require exorbitantly high research and development budgets.[85]

The Merck case created a firestorm of international trade consequences and human rights controversy for Brazil.[86] The US Trade Representative filed a complaint with the WTO against Brazil on January 8, 2001, which came to be known as the "Merck" case.[87] While the complaint was ultimately withdrawn on June 25, 2001 after the US Trade Representative faced strong international condemnation, the US Trade Representative placed Brazil on its "Special 301" Report Priority Watchlist, subjecting Brazil to the corresponding trade sanctions that come with such a designation.[88]

Following the trade consequences, NGO's rallied to support Brazil.[89] For example, on May 5, 2005, one hundred thirty eight civil society groups issued the "Declaration of Civil Society Regarding the Brazilian Negotiations for Voluntary Licenses for AIDS drugs," calling upon Brazil to both continue pursuing compulsory licenses within Brazil and to produce drugs for countries in need, with a special emphasis on African nations.[90] In a November 2007 hearing, the Human Rights Commission asked Brazil's parliamentary representatives to re-assess its intellectual property regime and bring its IP protection in line with its stated commitment to increase access to medicine throughout the country.[91] Harvard University has showered praise on Brazil's HIV/AIDS treatment regime: "Brazil has one of the developing world's largest, and arguably most successful, AIDS treatment programs."[92]

IV. *Recommendations*

The argument in favor of high drug prices is unequivocally that *research and development* is expensive; by charging high prices, pharmaceutical companies are able to both fund future research and recoup the investment already outlaid for successful drugs. This argument, however, while based on sound economics, has been corrupted by another line item in the pharmaceutical companies' budgets: *sales and marketing*.[93] In the United States in 2013, Johnson and Johnson & Johnson spent $8.2 billion on research and development and $17.5

[85] *Id*.
[86] *Supra*, note 80.
[87] *Id*.
[88] *Id*.
[89] *Id*.
[90] *Id*.
[91] *Id*.
[92] Amy Stewart Nunn, Elize Massard de Fonseca, Francisco I. Bastos, and Sofia Gruskin, *AIDS Treatment In Brazil: Impacts and Challenges*, HEALTH AFFAIRS, 1103, 1103 vol 28, n. 4 (Jul./Aug. 2009), available at http://diseaseriskindex.harvard.edu/pihhr/files/resources_and_publications/selected_articles/BrazilHealthAffairs.pdf.
[93] Ana Swanson, *Big Pharmaceutical Companies Are Spending Far More on Marketing Than Research*, THE WASH. POST (Feb. 11, 2015), available at https://www.washingtonpost.com/news/wonk/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-than-research/.

billion on sales and marketing.[94] Novartis spent $9.9 billion on research and development and $14.6 billion on sales and marketing.[95] Pfizer spent $6.6 billion on research and development and $11.4 billion on sales and marketing.[96] GlaxoSmithKline spent $5.3 billion on research and development and $9.9 billion on sales and marketing.[97] Merck spent $7.5 billion on research and development and $9.5 billion on sales and marketing.[98] Of the top ten United States drug manufacturers, only Roche spent more on research and development at $9.3 billion, compared to its sales and marketing budget of $9 billion.[99] To be fair, the United States under the First Amendment to the Constitution allows direct to consumer marketing.[100] This practice is only practiced in one other country, New Zealand.[101] However, the profit margins of pharmaceutical companies globally reveal that pharmaceutical companies do not have financial problems.[102] Forbes identified pharmaceuticals as the most profitable global industry in 2013, with Pfizer earning 42% profit margins and four other companies earning at least 20% in profits.[103] Compare these companies to carmakers, where the most profitable company earned 10% in profits.[104]

Thus rejecting the contention that exorbitant prices are necessary to generate research and development, we are forced to come to another, far more cynical conclusion for high drug prices. High prices are necessary for generating high profit. As mentioned earlier, pharmaceutical companies will, at times, price their drugs deliberately high in developing countries in order to exclude the sector of the population least able to provide profits.[105] The compulsory license was an attempt around this economic problem. It was originally contemplated to facilitate access to drugs in times of emergency, failed negotiations, and anticompetitive practices by pharmaceutical companies.[106] It was then expanded *vis-à-vis* the Paragraph 6 waiver, to include countries that lack the means to even issue a compulsory license because they cannot manufacture their own drugs.[107] Economics, for better or worse, explains why the Rwanda-Canada Paragraph 6 waiver partnership has widely been deemed a failure and not since repeated. Rwanda had no negotiating power. Rwanda was effectively a case study in charity, both for Canada's "flagship" CAMR program and for India's generic pharmaceutical industry.

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[94] *Id.*
[95] *Id.*
[96] *Id.*
[97] *Id.*
[98] *Id.*
[99] *Id.*
[100] *See, e.g.*, C. Lee Ventola, *Direct-to-Consumer Pharmaceutical Advertising: Therapeutic or Toxic*, NCBI (Oct. 2011), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278148/.
[101] *Id.*
[102] *See* Richard Anderson, *Pharmaceutical Industry Gets High on Fat Profits*, BBC (Nov. 6, 2014), available at http://www.bbc.com/news/business-28212223.
[103] *Id.*
[104] *Id.*
[105] *See supra*, notes 2, 5 (discussing demand inelasticity in the developing world as it concerns drug pricing).
[106] *Supra*, note 16.
[107] *Supra*, note 24.

Economics also explains why Thailand and Brazil were able to obtain significant price concessions – including Novartis providing glivec for free – by using the *credible* threat of a compulsory license as leverage.[108] Both Brazil and Thailand actually issued these licenses, putting companies on notice that they may be next.

The only solution to an economic problem is an economic solution and we are wise to turn toward generic pharmaceutical producers. The target of the compulsory license is *patented drugs*. Moreover, the most troubling TRIPS provision is article 31(f). In cases where countries have capacity, the threat of a compulsory license is fairly effective. In other words, these countries do not need the Paragraph 6 waiver to partner with a second country to produce the drugs primarily for export. When a country lacks capacity, as in Rwanda, the Paragraph 6 waiver does not function effectively. The pending approval of the amendment for Article 31 bis is no more than symbolic.[109] India's production of generic Cipla for Rwanda was arguably more effective in creating access to medicine than any other trade related policy Rwanda could have pursued.[110] On a related note, Thailand's GPO (rightfully) received criticism for its execution, following its decision to issue a compulsory license on Kaletra.[111] Thailand's GPO was arguably compromised by its interest in profits (in addition to its very legitimate interest in expanding access to medicine).[112] Thailand could have procured antiretrovirals from NGO's at cheaper prices than the prices it received on compulsory licenses.

Therefore, this paper is proposing an increased reliance on coordination between NGO's and generic manufacturers. Moreover, because many patents on breakthrough antiretrovirals (and other essential drugs) are expiring or have already expired, coordination between manufacturers and NGO's presents a novel opportunity to address global health in a totally unprecedented manner.[113] Admittedly, this is a rather simple solution. Sometimes, however, the simplest solutions are actually the strongest. The reality of the TRIPS agreement and trade law based solutions, unfortunately, is that the TRIPS agreement really only helps countries that can manufacture their own drugs. For these countries, the compulsory license is genuinely effective. For countries that lack capacity, the TRIPS agreement, the 31(f) waiver, and the Article 31 bis amendment do nothing to alleviate the problems with access. Generic manufacturing and NGO's *demonstrably* and *significantly* increase access. The TRIPS agreement for all intents and purposes will not change. Article 31 was created in 1995; it is 2016 and a simple amendment

[108] *See supra*, notes, 67 and 83 (discussing Novartis' decision to distribute glivec for free in Thailand and Brazil's procurement of price concessions of 37% on four antiretrovirals in January of 2004).
[109] *Supra*, note 26
[110] *Supra*, notes 46 and 47.
[111] *Supra*, note 55.
[112] *Supra*, note 57.
[113] *See e.g.*, Michael Carter and Keith Alcorn, *Generic Antiretrovirals Could Save NHS £1.25 Billion Over 5 Years, Study Finds*, AIDSMAP (Nov. 4, 2016), available at http://www.aidsmap.com/Generic-antiretrovirals-could-save-NHS-125-billion-over-5-years-study-finds/page/2919016/; THE LANCET, *Monthly Cost of $1-2 per Person Could Ensure Access to Basic Package of 201 Essential Medicines* (Nov. 7, 2016) available at https://www.eurekalert.org/pub_releases/2016-11/tl-tlm110316.php.

has yet to be enacted after 13 years of consideration.[114] Global health policy must be pragmatic and work within the confines of observed reality. In closing, 46% of all adults living with HIV have access to treatment.[115] Globally, 19.7 million people do not have access to treatment.[116] 35 million people have died since the start of the epidemic.[117] We can do better.

[114] *Supra*, notes 24 and 28.
[115] UNAIDS Fact Sheet 2016, available at http://www.unaids.org/en/resources/fact-sheet (last accessed Nov. 10, 2016).
[116] *Id.*
[117] *Id*.