Voluntary Licensing of Pharmaceuticals: The Strategy Against Compulsory Licensing

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VOLUNTARY LICENSING OF PHARMACEUTICALS: THE STRATEGY AGAINST COMPULSORY LICENSING

Daniel D. Kim*

ABSTRACT

Whether in the World Trade Organization or through local courts, the pharmaceutical industry’s fighting against compulsory licensing is not working. The potential benefits for countries issuing and enforcing compulsory licenses far outweigh the potential risks for these countries. Though a number of strategies to mitigate the threat or potential damage of compulsory licensing have been explored by various pharmaceutical companies, perhaps the most successful strategy is the “voluntary licensing” model, most famously employed by Gilead Pharmaceuticals in India. By preemptively and voluntarily licensing brand name drugs, the licensor is better able to control the terms of the licensing agreement,

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and the scope of the market for which the licensees’ products can reach, while creating additional, low risk sources of revenue. Perhaps most importantly, the voluntary licensing model promotes cooperation between native generic manufactures and international parties wishing to protect their intellectual property rights, while promoting goodwill through better access to medicine, a hot-button issue recently of great concern to governments, citizens, and media. To ignore voluntary licensing as a strategy against compulsory licensing is to ignore one’s responsibility as legal counsel to a company concerned about intellectual property rights subject to compulsory licenses.

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INTRODUCTION

The media often depicts the pharmaceutical industry as villainous rogues profiting from disease. It is a simple picture; an easily digested story which fails to accurately highlight the importance of the industry. It does not seem to matter whether the story involves inaccessible drugs, increases in healthcare costs, imagined links to autism, or more real and lethal mistakes. Too many forget that innovations in pharmaceuticals and healthcare have saved “more lives than war [has] spent.”

Unfortunately, innovation in pharmaceuticals is slow. Biology and chemistry are complex sciences. Seemingly simple changes to pharmaceutical chemicals can have wildly unpredictable results upon the human body. It took forty-two years to discover a new colon cancer drug treatment after the initial Food and Drug Association’s approval of fluorouracil. Antibiotics become obsolete almost as

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2 Cf. e.g., Dr. Alexander Fleming, TIME MAG., May 15, 1944 (“penicillin will save more lives than war can spend”).

quickly as they are developed. Vaccines have to fight against evolving viruses, and there are millions of cancer patients still awaiting effective treatments. The price of innovation is expensive, too expensive for too many people. Thus, the high price of drugs raises serious concerns about availability. Too many people and too many countries cannot afford brand name drugs at brand name prices; some of these countries have resorted to compulsory licensing\(^4\) to fix this problem.

Though those most against the compulsory licensing of pharmaceutical patents may call it government sanctioned stealing\(^5\), most people would agree that the government’s first priority is towards the protection and well-being of its people.\(^6\) In regards to the pharmaceutical industry, this could mean the government should sacrifice the potential profits of the industry over concerns related to health or access to medicine. This holds particularly true if the country


does not directly benefit financially from the production or development of new drugs.

Pharmaceutical companies are obviously averse to this idea, and have tried to rally behind the threat of compelled, cheaper generic drugs leaking into protected markets that would negatively affect profitability.\(^7\) This threat, often called “divergence,” could create serious risks for pharmaceutical companies compelled to enter low-income markets with the potential of only a small reward.\(^8\)

Pharmaceutical companies could further cite the related threat to innovation that compulsory licensed generics would bring.\(^9\) After all, pharmaceutical companies are uniquely reliant on patents for innovation.\(^10\) Pharmaceutical

\(^7\) See Clair Cassidy, Transcript of Bayer CEO Marjin Dekkers quote at the December 3, 2013, FT Event, regarding India compulsory license of Nexavar, KNOWLEDGE ECOLOGY INT’L (Feb. 7, 2014), http://keionline.org/node/1924 (“But you know the risk in these situations is always spillover. If this generic Indian company is now going to sell this product, then South Africa [can], and then New Zealand . . . [a]nd that puts the whole industry and patent rights of an industry at risk.”).

\(^8\) See discussion infra section I.C (addressing the apparent threat of divergence).


\(^10\) Id.
companies could also address the threat of countries using compulsory licensing as a one-size-fits-all hammer to nail down the growing price of healthcare, a serious threat which even middle-income countries may soon employ with more frequency.\(^\text{11}\) However, so far these concerns are overshadowed by government concerns over the health of its citizens.

A concerned company may then wish to explore strategies against compulsory licenses. While other strategies to mitigate the potential harm of compulsory licensing have been explored, the best strategy may be simply preemptively and voluntarily licensing the drug patent to foreign generic manufacturers. Indeed, other strategies against compulsory often fail to achieve as desirable an outcome, instead acting mostly to create further animosity between the parties and unduly hurting the company.\(^\text{12}\)

By voluntarily licensing new drugs, the pharmaceutical company would encourage cooperation between itself, generic manufacturers, and governments, creating additional incentives for the enforcement of intellectual property rights;\(^\text{13}\) create additional sources of revenue, previously untapped due to the high price of brand name drugs;\(^\text{14}\) and could create additional goodwill towards the

\[\text{11 See discussion } infra \text{ section II.A (addressing the increased incentives for countries to employ compulsory licensing and how this could hurt the pharmaceutical industry).}\]

\[\text{12 See discussion } infra \text{ sections III. C – E (discussing the benefits of voluntary licensing when compared to other models).}\]

\[\text{13 See discussion } infra \text{ II.C (discussing the benefits of cooperation for corporations).}\]

\[\text{14 See discussion } infra \text{ section II.D (discussing the additional revenue available from voluntary licensing).}\]
pharmaceutical company.\textsuperscript{15}

I. LICENSING AFTER TRIPS

No company, organization, or person should be forced into a contract for which they have no wish to join;\textsuperscript{16} this is a fundamental tenet of contract law.\textsuperscript{17} Yet, the Agreement on Trade Related Aspects of Intellectual Property Rights


\textsuperscript{16} See, e.g. Robert Braucher, \textit{The Unconscionable Contract or Term,} 31 U. PITT. L. REV. 337, 339 (1969) (“[A] bargain was said to be unconscionable in an action at law if it was ‘such as no man in his senses and not under delusion would make on the one hand, and as no honest and fair man would accept on the other.” (citing \textit{Humes v. United States,} 132 U.S. 4406, 4411 (1889)) [hereafter “Braucher”].

\textsuperscript{17} Thomas A. Baker, \textit{Consent Theory as Possible Cure for Unconscionable Terms in Student-Athlete Contracts,} 22 MARQ. SPORTS L. REV. 619, 620 (2011) (“Lack of choice is contractually problematic because the essence of contract is volition” (citing \textit{JOHN E. MURRAY, JR., MURRAY ON CONTRACTS} 482 (3d. ed. 1990)).
an agreement required for participation in the World Trade Organization (WTO), provides countries with the very authority to force licensing agreements upon patent owners for issues related to public health. However unconscionable these compulsory licenses may seem, they are enforceable and undeniable for pharmaceutical companies. They may also soon grow in popularity.

A. Compulsory Licensing

Despite significant support from the U.S. Government, the pharmaceutical

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19 Governments are not strictly bound by their own unconscionable provisions. See NICHOLAS SEDDON, GOVERNMENT CONTRACTS: FEDERAL, STATE AND LOCAL 308 (4th ed. 2009) (“[I]f the purchase was for ordinary government purposes, it is not bound by [the unconscionable] provision because the purchase could not be said to be part of carrying on a business.”); see also LARRY DI MATTEO & MARTIN HOGG, COMPARATIVE CONTRACT LAW: BRITISH AND AMERICAN PERSPECTIVES 268 (2015) (“Despite the more highly contextual analysis used in government contract law, in fact, there are few successful claims of relief based upon claims of unconscionability in government contracts.”).

20 See discussion supra II.A (discussing the growing incentives for countries to employ more compulsory licenses).

industry was not able to obtain the full spectrum of intellectual property protection it might have wished for during the negotiations of TRIPS.\textsuperscript{22} The most pertinent example of this shortcoming is the inclusion of the compulsory licensing option on patents related to public health. Perhaps the industry hoped compulsory licensing would be a small nuisance, relegated only to emergencies or desperate need. Indeed, some initial observers claimed TRIPS applied strict standards for the enablement of compulsory licensing,\textsuperscript{23} but recent developments on the international scale have potentially proven otherwise.\textsuperscript{24}

Of course, the concept of compulsory licensing has existed well before TRIPS. Even before the official ratification of the WTO agreement, most countries had the option to compulsory license a patent.\textsuperscript{25} For the most part, the

\textsuperscript{22} See generally infra notes 23 – 24.


\textsuperscript{24} Cf. Jerome H. Reichman, \textit{Compulsory licensing of patented pharmaceutical inventions: evaluating the options}, 37(2) J. LAW MED ETHICS 247, 248 (2009) (“[E]very attempt to limit or constrain a state’s power to issue compulsory licenses has invariably resulted in a strengthening of that same power at the international level.” (citation omitted)). See generally Bayer Corp. v. Minister of Commerce and Industry, Bhavan, W.P. 1323 of 2013 H.C. Bom. (15 July 2014) (applying work standard requirements as grounds for compulsory licensing).

justifications for these pre-TRIPS compulsory licenses were similar to the modern justifications. The common arguments similarly addressed issues of public interest, supply, and work requirements. Though some more prominent countries, like the United States, resisted the option before the ratification of TRIPS, the agreement opened the door to compulsory licenses for every country that wishes to participate in the WTO.

It is well established that strong patent and intellectual property rights are integral to the innovation of pharmaceuticals. Very real concerns about efficacy and safety have increased the cost of research, development and production well

26 Id. at 668 – 674.
27 See Dawson Chem. Co. v. Rohm & Hass Co., 448 U.S. 176, 215 (1979) (“Compulsory licensing is a rarity in our patent system, and we decline to manufacture such a requirement”).
28 See e.g. Whitney v. Robertson, 124 U.S. 190, 194 (1887) (“By the Constitution a treaty is placed on the same footing, and made of like obligation legislation. Both are declared by that instrument to be the supreme law of the land.”) (emphasis added); but see Medellin v. Texas, 552 U.S. 491, 505 (2008) (“while treaties “may comprise international commitments . . . they are not domestic law unless Congress has either enacted implementing statutes or the treaty itself conveys an intention that it be ‘self-executing’” (citing Iguartua-De La Rosa v. U.S., 417 F.3d 145, 150 (CA1 2005)).
beyond the mere price of manufacture and distribution.\textsuperscript{30} Under the current system, there is little incentive to invest in new research without patent protection,\textsuperscript{31} especially with the ever present fear of a competitor appropriating any new drug or development and selling the drug at reduced prices without any consideration or concern towards the cost of development.\textsuperscript{32}

On the other hand, intellectual property protection is meant as an incentive for innovation, not as a reward.\textsuperscript{33} This holds particularly true for patent protection.

\textsuperscript{30} See id.; Cost of Development and Win Marketing Approval for a New Drug Is $2.6 Billion, TUFTS UNIVERSITY (Nov. 18, 2014), http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study (estimating the price of innovation for a new drug at a total cost of $2,558 million). \textit{But see} MEDECINS SANS FRONTIERES, R&D Cost Estimates: MSF Response to Tufts CSDD Study on Cost to Develop a New Drug (Nov. 18, 2014), http://www.doctorswithoutborders.org/article/rd-cost-estimates-msf-response-tufts-csdd-study-cost-develop-new-drug ("The cost of developing products is variable, but experience shows that new drugs can be developed for as little as $50 million, or up to $186 million if you take failure into account.")

\textsuperscript{31} \textit{But see} Steve P. Calandrillo, \textit{An Economic Analysis of Property Rights in Information: Justifications and Problems of Exclusive Rights, Incentives to Generate Information, and the Alternative of a Government-Run Reward System}, 9 FORDHAM INTELL. PROP. MEDIA & ENT. L. J. 301 (1998) (addressing concerns over exclusivity in drugs, and suggesting a model which would promote innovation not through market exclusivity, but through government rewards).

\textsuperscript{32} WIPO, \textit{supra} note 9, at 160-161 (2009).

\textsuperscript{33} U.S. CONS. art. I § 8. ("Congress shall have the power . . . to promote the progress of Science and useful Art, by securing for limited Times to Authors and Inventors the
While this may seem like a simple matter of semantics, the distinction can have some significant ramifications, especially regarding what deserves patent protection.\textsuperscript{34} For example, a reward might be \textit{per se} granted for any innovation as it is deserved upon a successful discovery or invention, but an incentive may – and should be – weighed against other considerations.\textsuperscript{35} 

exclusive Rights to their respective Writings and Discoveries”); \textit{see Mazer v. Stein}, 347 U.S. 201, 217 (1954) (arguing that the protections rewarded to intellectual property creators are of “secondary consideration” when compared to the potential advancement of public welfare); \textit{Bonito Boots v. Thunder Craft Boats}, 489 U.S. 141, 146 (1989) (arguing “The Patent Clause itself reflects a balance between the need to encourage innovation and avoidance of monopolies.”); 37 C.F.R. 1.56(a) (2001) (stating “a patent by its very nature is affected with a public interest.”). \textit{See also Bayer Corp. v. Union of India, Bhavan, I.P.A Order No. 45 of 2013 (Mar. 4, 2013) (arguing that “patent rights were created ‘not in the interest of the inventor, but in the interest of the national economy.’”) (citation omitted); Bayer Corp. v. Minister of Commerce and Industry, Bhavan, W.P. 1323 of 2013 H.C. Bom. (15 July 2014) (“[A]n inherent objective in the grant of patent is the obligation of the patent holder to utilize the invention to meet the needs of society.”). \textit{See generally Feist Publ’ns, Inc. v. Rural Tel. Serv. Co., 499, U.S. 340, 349 (1991} (stating the primary objective of the intellectual property clause “is not to reward the labor of authors but to promote the Progress of Science and Useful Art.”). 


\textsuperscript{35} \textit{See Lowell v. Lewis}, 15 F. CAS. 1018, (C.C. Mass. 1817) (“the invention should not be frivolous or injurious to the well-being, good policy, or \textit{sound morals of society}” (emphasis added)).
In the pharmaceutical space this could mean that the price of innovation should be weighed against the health of the public. Proponents of compulsory drug licensing could argue that drug monopolies are simply intolerably against public policy; that using a patent to monopolize a drug without concern to availability, cost, or use is a potential violation of the intent of the patent system as dictated by the courts and international law.  

It is with this debate in mind that TRIPS requires pharmaceutical products be patent eligible, but also allows for the compulsory licensing of patents in the interest of public health. Such licensing is only allowed during times of emergency, or through the express authorization of the government. Few would or should argue against the need for compulsory licensing in emergencies. For example, a mass epidemic, which would create a sudden need which could outstrip a company’s potential production capabilities could be a compelling reason for a compulsory license. Even the United States of America, well known as a “bastion of intellectual property,” has taken advantage of compulsory licensing, most famously in response to potential terrorist anthrax attacks.

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36 See supra note 33.

37 See TRIPS supra note 18 Art. 8(1) (“Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition”).


39 See Ciprofloxacin: the Dispute Over Compulsory Licenses, CPTECH, http://www.cptech.org/ip/health/cl/cipro/ (viewed Oct. 14, 2015); see also e.g. James
TRIPS requires a country to have attempted a voluntary license before issuing a compulsory license. This requirement exists regardless of whether the compulsory license to be issued is through some unstated public health authorization of the government or because of some emergency.\textsuperscript{40} However, any other requirements which may apply are mostly left to the flexibility of the individual nations.\textsuperscript{41} India’s intellectual property act, for example, allows for the application of a compulsory license if, after three years from the date of the patent’s issue, “reasonable requirements of the public with regard to the patented invention is [sic] not being satisfied, that the patented invention is not available to the public at the reasonably affordable price, or that the patented invention is not worked in the territory.”\textsuperscript{42} Essentially, India requires that a patented technology


\textsuperscript{40} See TRIPS supra note 18 Art. 31(b) (“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 . . . [only] 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.”).

\textsuperscript{41} DOHA WTO Ministerial 2001 5(b) (Nov. 20, 2001) (“Each member has the right to grant compulsory licences [sic] and the freedom to determine the grounds upon which such licences [sic] are granted.”)

be available in India at a reasonably affordable price.\textsuperscript{43}

India’s requirements are potentially the most favorable towards compulsory licensing, bordering on – if not out-right requiring – an obligation to use.\textsuperscript{44} Though this conflicts with the United States’ laws\textsuperscript{45}, there is currently no obligation under the language of TRIPS or in WTO proceedings which would prevent such an interpretation of the agreement’s requirements. The United States, worried about its native pharmaceutical industry, has attempted to pressure some nations to adopt a higher standard, which would raise the bar for compulsory licensing.\textsuperscript{46} However, until the unlikely day this “TRIPS-plus” standard is internationally implemented under the WTO or universally ratified through treaties, India is well within its rights to interpret its own patent protection as it has.\textsuperscript{47} Whether other countries will also adopt such lenient legislation as India is

\textsuperscript{43} Id.

\textsuperscript{44} The Patents Act, § 146, \textsc{India Code} (1970); Patents Rules, § 131(2), \textsc{India Code} (2003).

\textsuperscript{45} 35 U.S.C. §154(a)(1) (2015) (granting the patent assignee the “right to exclude others from making, using, offering for sale, or selling the invention throughout the United States” (emphasis added), but not the right to use).

\textsuperscript{46} \textsc{Medicins Sans Frontieres: Access Campaign}, \textit{TRIPS, TRIPS Plus and Doha} (July 2011), \url{http://www.msfaccess.org/content/trips-trips-plus-and-doha}.

\textsuperscript{47} Ramnath Subbu, \textit{U.S. Pharma Companies Benefit From Large Indian Generic Market}, \textsc{The Hindu} (India) (Mar. 8, 2014), \url{http://www.thehindu.com/business/Industry/us-pharma-companies-benefit-from-large-indian-generic-market/article5764662ece} (quoting Mr. Diliip Shah, Secretary-General of the Indian Pharmaceutical Alliance) (“No member country of the WTO, including the
unclear, but likely. The immediate temporary benefits of affordable, potentially life-saving drugs far out-weigh the future risks especially for those governments who rely on the short-term interests and immediate concerns of their electorate.48

It is a curious fact that few TRIPS dispute claims are brought before the WTO.49 Fewer still rely on a theory of TRIPS violation.50 This is likely because the WTO does not often rely on a theory of precedent when deciding its cases.51 This makes it difficult to predict the outcome of any WTO case. Such uncertainty, coupled with the WTO’s willingness to support native intellectual property flexibility and the availability of drugs,52 and the risk of a negative decision with which all WTO member states can rely upon in deciding the scope of their obligations,53 increases the potential risk for pharmaceutical companies well

U.S. has even disputed it before the WTO. It must therefore be presumed that India’s patent law is TRIPS-compliant.”).


50 Id. at 393, 396 – 97.

51 But see Michael Lennard, Navigating by the Stars: Interpreting the WTO Agreement, 5 J. INT’L ECON. L. 17., 33 (2002) (“in practical terms, prior decisions are not lightly departed from”).

52 See TRIPS, supra note 18; cf. Pauwelyn supra note 49, at 403.

53 See Pauwelyn, supra note 49, at 399.
beyond expectable risks.

Until companies are willing to risk the potential consequences of a WTO court decision, they are limited to fighting back in local courts where they are bound by the nation’s interpretation of TRIPS and must assume that the nation’s policies are TRIPS compliant. Indeed, fighting back is not a good strategy. In fact, the many attempts to limit the flexibility of TRIPS licensing seems only to strengthen the “offending” country’s claims.

As for disputes not litigated before the WTO, it is likely, ignoring the possibility of extreme cases, a domestic court will not rule against increasing the flexibility of compulsory licenses within its borders. Trying to argue against a country’s compulsory licensing of a drug in that country’s courts does not seem a

54 Ramnath Subbu, U.S. Pharma Companies Benefit from Large Indian Generic Market, THE HINDU (INDIA) (Mar. 14, 2015), http://www.thehindu.com/business/industry/us-pharma-companies-benefit-from-large-indian-generic-market/article5764662.ece (quoting Mr. Diliip Shah, Secretary-General of the Indian Pharmaceutical Alliance) (“No member country of the WTO, including the U.S. has even disputed it before the WTO. It must therefore be presumed that India’s patent law is TRIPS-compliant.”).

55 Cf. Jerome H. Reichman, Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options, 37 J. L. MED. & ETHICS 247, 248 (2009) (“[E]very attempt to limit or constrain a state’s power to issue compulsory licenses has invariably resulted in a strengthening of that same power at the international level. Mr. Diliip Shah, Secretary-General of the Indian Pharmaceutical Alliance”).
winning strategy. A new strategy is required.

In fact, companies have employed a number of strategies. The most popular, perhaps, is the wait-and-see; the most aggressive is to retaliate. Both are flawed, especially when compared to the voluntary licensing method.

B. Voluntary Licensing: Illustrations Using Gilead’s Model

Voluntary licensing is, as the name describes, the practice of extending a licensing agreement by the patent holder to third-party generic participants for the expressed purpose of the third-party’s use to create a generic version of the patented product. Voluntary licensing has been explored as a strategy against compulsory licensing in the past, but usually as a response to direct threats of compulsory licensing. However, it is more beneficial for companies, who are worried about the compulsory licensing of valuable patents, to voluntary license the drug before the expressed threat of compulsion.

The obvious benefit is the inherent leverage voluntary licensing grants the pharmaceutical company while negotiating the contract. Pre-emptive voluntary licensing creates a better position in negotiating contracts that would not exist if

56 See id.


58 See discussion infra section II.C. Benefitting from Cooperation.

59 See discussion infra section II.B – D.
the offer is only made after the threat of compulsion. However, the patent owner also gains other advantages, especially when compared to the other strategies that have been explored.

Gilead, for example, has contracts with eleven companies to produce a generic version of its hepatitis C drugs. The companies are only permitted to manufacture and ship the generic version of their drug to ninety-one expressly defined countries. Gilead’s contract also sets the royalties to be 7% of the profits; places requirements on how third-party sellers can be chosen; includes protections of Gilead’s intellectual property rights and the drug’s reputation; and shields Gilead from liability. Gilead, thus, created a price differential plan based, not on government influence or dictates, but on what works best for

60 See discussion infra section II.C Benefitting from Cooperation.


63 Id. at § 4.1.

64 Id. at § 2.3(d)-(f).

65 Id. at §§ 7-10.2, 7.5, 7.6.

66 See id. at § 6.

67 License Agreement § 8.2 (“Licensee shall be solely responsible in respect of any product liability or any other statutory liability under any regulation”).
Gilead, the generics, and potential customers that cannot afford Gilead’s brand name drug.

The most common alternative strategies include the retaliation and wait-and-see strategies. These strategies have been explored by other companies in Thailand and Brazil respectively. Though these strategies may have potential benefits when compared to simply fighting against compulsory licensing, the two strategies fail on significant aspects.

Perhaps the only real weakness in Gilead’s licensing agreement is the section on “Anti-Diversion.”68 This section of the contract requires that “the parties shall discuss in good faith programs that [the] Licensee may implement to minimize diversion of Product.”69 Though such open terms are typically enforceable,70 this particular clause may not be helpful for Gilead. Of course, a contract cannot force a participant into future contracts,71 but can only require “good faith” negotiations in the future, and does not require agreement on what may be appropriate to prevent diversion, especially in regards to yet unforeseen circumstances. However, diversion is not something the pharmaceutical industry should worry too much about.72

68 License Agreement § 6.1(a).

69 Id.

70 See SIGA Techs., Inc. v Pharmathene, Inc., 67 A.3d 330, 343-44 (Del. 2013) (reaffirming a previous holding that a contract obligation to negotiate in good faith is enforceable).

71 See Ford, infra note 4, at 945.

72 See discussion infra section I.C.
C. Addressing Diversion

Pharmaceutical companies have publically decried the use of compulsory licensing, citing their fear of generic divergence. However, this worry is typically out-weighed by the benefits of licensing, and is potentially over-stated. After all, pharmaceutical products are traditionally protected from divergence by two steady pillars of law: (1) the lack of international exhaustion on generics versions of patented products, and (2) drug administrations’ specific interests in

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73 See Cassedy infra note 7. See also TRIPS supra note 184, Art. 31(f) (“Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder . . . any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing use.”).

74 TRIPS itself generally prevented the exportation of compulsorily licensed drugs, but the standards for protection are ambiguous enough to warrant more discussion than is appropriate for this paper. See Jerome H. Reichman, Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and Overview of the Practice in Canada and the USA, in Issue Paper No. 5, UNCTAD-ICTSD Project on Intell. Prop. RTS. & SUSTAINABLE DEV. 3 (June 2003) (addressing the limitations under TRIPS on exportation of licensed goods); Charitini Stavropoulou & Tommaso Valletti, Compulsory Licensing and Access to Drugs, 16 EUR. J. HEALTH ECON. 83, 85 (2015) (“Products made under compulsory licensing should be manufactured mainly for domestic use. However, this was weakened in a landmark decision made by the WTO in 2003: the so called ‘Paragraph 6 problem’ allowed the generic copy made under compulsory licenses to be exported to developing countries that lack production capacity.”).

75 Infra notes 78 – 93 and associated text.
preventing the import of unapproved drugs on issues of safety. Rather, the more prominent concern is the potential use of compulsory licensing, not as a tool to promote access, but as a hammer to beat down prices.

i. Exhaustion

Exhaustion, despite sounding rather ominous, is a simple enough concept to

76 See Letter from Randall W. Lutter, Deputy Comm’r for Policy, Office of Pub. Health Serv., FDA, to Governor Linda Lingle of Hawaii (Aug. 14, 2008), http://www.fda.gov/Drugs/DrugSafety/ucm179204.htm (addressing the threat of diversion into the United States by stating “Virtually all prescription drugs imported for personal use into the U.S. from Canada or other foreign countries violate the Act because they are unapproved new drugs (21 U.S.C. § 355), labeled incorrectly (21 U.S.C. §§ 352, 353), or dispensed without a valid prescription (21 U.S.C. § 353(b)(1)). Importing or causing the importation of a drug into the United States that is unapproved and/or does not comply with the labeling requirements and dispensing requirements in the Act is a prohibited act under 21 U.S.C. §§ 331(a), and/or (d), and may be enjoined or prosecuted.”); see also 21 U.S.C. §332(a), 333(a).1; see also Abigail Alliance v. von Eschenbach, 495 F.3d 695, 712-13 (D.C. Cir. 2007), cert. denied Abigail Alliance v. von Eschenbach, 552 U.S. 1159 (2008) (“we cannot say that the government’s interest does not bear a rational relation to a legitimate state interest . . . Although terminally ill patients desperately need curative treatments . . . their deaths can certainly be hastened by the use of a potentially toxic drug.”).

77 Christopher J. Clugston, International Exhaustion, Parallel Imports, and the Conflict Between the Patent and Copyright Laws of the United States, 4 BEIJING L. REV. 95, 95 (defining “exhaustion” as the termination of certain patent rights, like the right to exclude in commerce, after “an authorized sale of a product” by either the patent holder or a legitimate licensee).
understand. Essentially, government wishing to balance the monopolistic powers of intellectual property with antitrust principles have applied a “first-sale” doctrine to most intellectual property.\textsuperscript{78} The idea was that intellectual property owners, after having already benefitted from the sale of their intellectual property, have “exhausted” some of their rights. The most pertinent of these exhausted rights is the right to prevent the re-sell of the invention.\textsuperscript{79} Most countries apply exhaustion to those products sold domestically, but whether sales made on foreign soil should affect those exhaustible rights in all countries is still at debate. Here, the worry is simple: pharmaceutical companies are concerned about the potential of competitors infiltrating low-cost markets, to purchase and resell the drug for profit without fear of litigation because the patent owner has exhausted their rights.

Currently, no international agreement on the question of international exhaustion of patent rights exists; so there is no international forum in which to pursue this issue.\textsuperscript{80} In fact, the effects of an international exhaustion regime, as it would apply to the global market, is not yet well understood.\textsuperscript{81} The German


\textsuperscript{79} \textit{Id.} at 488.

\textsuperscript{80} See TRIPS supra note 18, Art. 6 (“For the purposes of dispute settlement under this Agreement, subject to the provisions of Article 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.”).

\textsuperscript{81} See Sarah R. Wasserman Rajec, \textit{Free Trade In Patented Goods: International
courts, for example, have applied international exhaustion only to those patents sold by legal licensees, whereas the United States, at the time of this writing, does not allow international exhaustion to touch patents. In fact, the United States has attempted significant steps to influence foreign governments to prevent international exhaustion from touching patents in other countries.

Some might say that the rights of international patent owners have come under attack in recent years, as more courts throughout the world have started to apply


82 This protection can be further strengthened by terms set in a voluntary licensing agreement, but would only allow legal action against the licensee as the reseller lacks privity to the original licensing agreement, but may allow the licensor to attach additional liability upon the licensee. See generally Thomas Musmann, *No Mercy: Exhaustion of patent rights and burden of proof*, Kluwer Patent Blog, (Mar. 14, 2014) http://kluwerpatentblog.com/2014/03/14/no-mercy-exhaustion-of-patent-rights-and-burden-of-proof/; see also Lexmark Int’l, Inc. v. Impression Prod., Inc., 816 F.3d 721 (Fed. Cir. 2016).


84 See Rajec, *supra* note 81 at 320 (“[T]he United States Trade Representative is currently negotiating a trade agreement – the Trans-Pacific Partnership-requiring that member countries not recognize international exhaustion in intellectual property rights.” (citation omitted).
the international exhaustion standards to patents.\textsuperscript{85} This would obviously be problematic for those patent owners which cannot afford to register their patents in every country where one may infringe,\textsuperscript{86} and potentially for those patent owners with public health patents.\textsuperscript{87}

There is some question as to whether exhaustion should even apply to compelled or compulsory licensed drugs, or even if any exhaustion would apply to generic versions of a patented product.\textsuperscript{88} Despite good arguments on either


\textsuperscript{86} See Oral Argument at 27:30, Lexmark Int’l, Inc. v. Impression Prod., Inc., 816 F.3d 721 (Fed. Cir. 2016) (No. 14-1617), http://oralarguments.capecourts.gov/default.aspx?fl=2014-1617_1022015.mp3 (presiding over the question of applying international exhaustion via common law cases while expressing explicit concerns over the expense inherent in pursuing patent rights in all international jurisdictions)


\textsuperscript{88} This topic is subject to enough supposition and interest as to warrant further discussion than is appropriate in this paper. However, it is sufficient to know that generics are unlikely to affect the condition of patent pharmaceuticals’ exhaustion principles. See Cynthia Ho, Access to Medicine in the Global Economy: International
side, it is unlikely any government would apply such broad conditions to exhaustion principles. For now, pharmaceutical companies are protected from exhaustion in regards to compulsory licensed drugs.

ii. Administrative Protection

However, should this first pillar fail, pharmaceuticals are still generally protected under a second pillar: administrative law. Various laws and interests protect against the divergence of generic drugs into most markets. For example, the United States Food and Drug Association (“FDA”) requires generic companies to register generic drugs. The FDA, however, cannot grant registration for generics which infringe upon existing and valid U.S. patents, and generic companies cannot market their drugs without registration. While certain exceptions do exist regarding drugs not available in the United States, none of


89 To market a generic drug in the United States, the FDA requires a company to submit an Abbreviated New Drug Application (ANDA) which must include “a certification . . . with respect to each patent which claims the listed drug . . . for which the applicant is seeking approval (I) that such patent information has not been filed, (II) that such patent has expired, (III) of the date on which such patent will expire, or (IV) that such patent is invalid.” 21 U.S.C. § 355(b)(2)(A).

90 Supra note 76; Warning Letter from David J. Horowitz, Dir., CDER Office of Compliance to Harry Lee Jones, Store Manager, Rx Depot, Inc. (Mar. 21, 2003).
these exceptions would apply to drugs under the threat of divergence.91

Thus, the biggest potential threat of divergence comes from personal use, which the FDA is reluctant, or unable, to stop.92 However, this is unlikely to greatly affect pharmaceutical companies, as this policy is very limited, and should not touch drugs susceptible to compulsory licensing. The cost to wages and travel, coupled with the uncertainty inherent in generics and general inability to travel, will probably outweigh the potential benefits from the purchase of foreign generics for most consumers.93

II. THE STRATEGY: A COMPARISON

A. The Potential Threat of Compulsory Licenses

The less stated but greater concern for pharmaceutical companies is the impending threat of compulsory licenses. Historically, compulsory licenses have not been abused. Rather, many activists encourage countries to exercise the

91 Supra note 89.


93 Cf. Erol Kohli & Allison Buller, Patterns of Generic Versus Brand Name Over-the-Counter Drugs, 106 S. MED. J. 155 (2013) (postulating that though price is the “most influential factor” in determining which OTC to purchase, other factors like advertisements, safety, and preferred company names will “persuade others to pay more for brand name drugs”).
compulsory licensing right more often.94 With the growing cost of health care, more and more countries may feel compelled to issue compulsory licenses. It would start with low income countries licensing high demand drugs.95 With each subsequent successful license, countries will become emboldened,96 licensing seemingly insignificant drugs.97 Then, middle-income countries could start issuing licenses on expensive drugs, which could seriously hurt profitability. Though a single country compulsory licensing a single drug is not so troubling, dozens of countries compulsory licensing on hundred drugs could seriously hurt


95 Kristina M. Lybecker, Elisabeth Fowler, Compulsory licensing in Canada and Thailand: comparing regimens to ensure legitimate use of the WTO rules, 37 J. LAW MED. ETHICS 222 (2009).

96 Patralekha Chatterjee, India’s First Compulsory License Upheld, But Legal Fights Likely to Continue, INTELLECTUAL PROPERTY WATCH (May 4, 2013), http://www.ip-watch.org/2013/03/04/indias-first-compulsory-licence-upheld-but-legal-fights-likely-to-continue/ (quoting Leena Menghaney, India campaign manager, Médecins Sans Frontières, “the decision means that the way has been paved for compulsory licences to be issued on other drugs”).

97 See Shibu Thomas, High Court’s Nexavar Ruling Strikes a Blow For Patient’s Rights in India, THE TIMES OF INDIA (July 17, 2014), (addressing the compulsory licensing of the “orphan drug” Nexavar, a treatment drug for liver and kidney cancer).
the pharmaceutical industry.98

Voluntary licensing protects pharmaceutical companies from this potential proliferation of the compulsory licensing system. Voluntarily licensing grants the patent owner additional control over which countries the licensee can export to or even to which markets the licensee can enter.99 This allows the licensor to steer the exports away from potentially profitable markets and provides additional potential awards in litigation through a theory of contracts.100 However, voluntary licenses which should include some exportation clause also attacks the most

98 See Cassedy supra note 7 (“If this generic Indian company is now going to sell this product, then South Africa [can], and then New Zealand . . . that puts the whole industry and patent rights of an industry at risk.”).


100 Compulsory licensed pharmaceuticals may have an additional protection from international exhaustion when compared to voluntary licensing. Most international exhaustion regimes require a sale by a party with a legitimate claim to the patent. While a generic company may have a right to production through a compulsory license, they should lack the voluntary component required to be considered a “legitimate” licensee. However, there is no known litigation addressing this issue at the moment. Such a distinction may slightly weaken the protection of voluntarily licensed pharmaceuticals. See generally Rajec, supra note 81 at 326 n. 39 (2014) (“[A]n international exhaustion regime would mean that an authorized sale abroad exhausts domestic patent rights so that importation does not constitute infringement, even if the authorization was limited to sales in a particular foreign market.”).
common incentive for compulsory licenses: affordability.

B. The Lost Cause: Bayer Suing Under TRIPS in India

The main problem with compulsory licensing is its inherent confrontation with patent protection. For example, under India’s law, compulsory licensing allows the government to revoke the intellectual property right in favor of better prices.\(^\text{101}\) This seems contrary to TRIPS requirement that pharmaceuticals be offered patent protection.\(^\text{102}\) However, suing under TRIPS is potentially the worst strategy for companies. Though a country’s continued use of compulsory licensing may strain trade relations between nation states and companies,\(^\text{103}\) countries are not likely to abandon compulsory licensing and companies are just

\(^{101}\) See Cassedy, supra note 7 (“In our case, the Indian government said ‘No no, your patent is valid . . . we just think you charge too much’”).


\(^{103}\) See Bernie Becker, India’s policies boxing out US companies, The Hill (Dec. 22, 2014), http://thehill.com/policy/finance/227930-indias-policies-boxing-out-us-companies (“India’s unfair policies increasingly are harming U.S. exports of a wide array of products” (quoting Chris Moore of the National Association of Manufacturers)); Andrew Ward & Amy Kazmin, Bayer loses bid to block cheap version of cancer drug in India, FINANCIAL TIMES (Dec. 12, 2014), http://www.ft.com/cms/s/0/36a2d942-8202-11e4-a9bb-00144feabdc0.html#axzz3vrZ4459Q (“There is a huge amount of pressure from multinational companies discouraging their Indian partners from filing those applications”) (quoting Leena Menghacy of Médecins Sans Frontières).
as unlikely to win a TRIPS related suit.\textsuperscript{104} Rather, with each success, India and countries with similar interests are likely to further push the boundaries of the reasonable interpretation of TRIPS.\textsuperscript{105} While this may help those concerned with access to medicine in the short-term, it could lead to the slow degradation of the innovative pharmaceutical industry.

Though the WTO has a system in which TRIPS related decisions can be appealed, there is a lack of incentives to bring such an appeal for fear of a solid, global model for which other countries could emulate.\textsuperscript{106} Thus, companies are generally limited to fighting back in local courts, hoping to inspire some judicial sympathy or to limit precedent to the borders of the presiding nation. This strategy

\textsuperscript{104} See discussion \textit{infra} section II.B.

\textsuperscript{105} Ed Silverman, \textit{Will India Issue a Compulsory License for an AstraZeneca Diabetes Pill?}, \textit{The Wall St. J.} (July 9, 2015), http://blogs.wsj.com/pharmalot/2015/07/09/will-india-issue-a-compulsory-license-for-an-astrazeneca-diabetes-pill/ (“Lee Pharma filed an application for a license to manufacture a version of Onglyza, an AstraZeneca diabetes pill, on the grounds that the drug is not sold at an affordable price in India and that supplies are inadequate). \textit{But see} EJ Lane, \textit{India’s Lee Pharma turned down on CL challenge to AZ’s Onglyza}, \textit{FiercePharmaAsia} (Aug. 18, 2015), http://www.fiercepharmaasia.com/story/indias-lee-pharma-turned-down-cl-challenge-azs-onglyza/2015-08-18 (“India’s Controller of Patents has turned down a, compulsory license application by Lee Pharma to make a version of AstraZeneca’s Onglyza, citing competing substitutes already in the market and patent terms”).

\textsuperscript{106} See discussion \textit{supra} section II.A (addressing the possible threat of countries more commonly issuing compulsory licenses).
is likely to fail almost every time. For what fair judicial court is so divorced from the purpose of government as to rule against the interests of its people over foreign interests.

In the likely failure of this “fight back” strategy, the company is now irrevocably tied to the terms of the licensing agreement. The company has to fulfill terms for which it had no say over; no negotiable control; and no right to argue price, participating parties, or production. It is thrust into a market which may not be profitable to enter, and is subject to the very real control of the ruling government. This cannot be considered a desirable outcome, and should probably be avoided at any reasonable cost. It also encourages additional compulsory licenses with each failed claim.

For example, in Bayer’s lawsuit against Natco Pharmaceuticals Limited, an Indian generics company, the court established the prevailing interpretation of the law. According to the Indian court, the law requires the patent holder to make

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107 *See supra* note 18, at § 5: Patents Art. 31(b) (“use without authorization of the right holder . . . 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”) (emphasis added).

reasonable steps to “work” the patent within India or risk compulsory licensing.\textsuperscript{109} This requirement includes an expectation of availability. The Bayer’s case sets a precedential interpretation of the law, providing India with another weapon with which to attack American pharmaceutical companies’ prices. Though it is likely another company would have fared as poorly, such precedent is only possible if a company is willing to submit to the judgment of a court.

Bayer had the patent. Bayer had the opportunity to market, price, and provide the licensed drug in India. It had no economic reason to do so, and thus chose not to.\textsuperscript{110} Bayer had no reason to fight back. It could have offered to negotiate a license, delaying the court’s precedent until another unwitting company chose to pursue judicial activism. Bayer did not, and Bayer lost.

Bayer’s CEO, Marjin Dekkers, claims the decision will not significantly change Bayer’s marketing strategy. Mr. Dekkers claims that “investors . . . don’t care about these issues all that much.”\textsuperscript{111} Indeed, this may be true, as Bayer’s stock has shown a net growth since \textit{Natco v. Bayer} was decided.\textsuperscript{112} However, his statement is misleading. The main concerns regarding compulsory licensing do not directly concern the worries of investors, but rather the attack on potential


\textsuperscript{109} \textit{Id.}

\textsuperscript{110} See Cassedy, \textit{supra} note 7 (“So now, is this going to have a big effect on our business model? No, because we did not develop this product for the Indian market”).

\textsuperscript{111} \textit{Id.}

profitability. A single drug being compulsory licensed in a single country which could not have afforded the drug is unlikely to injury a large international company. However, continuous compulsory licenses on blockbuster drugs, issued in any number of countries could have an extremely detrimental effect. Additionally, the more compulsory generics exist the harder it will be for a company to control the threat of divergence. While investors may not be concerned about “these issues,” it is obvious that companies should be.

Indeed, the only benefit for companies, under this “fight-back” strategy, is a potentially stronger protection from international exhaustion of their patents. This reason alone should not be sufficient to hold this strategy as a viable one.

The fight-back strategy fails on cooperation, sets unwanted precedence, lacks leverage in negotiations, fails to increase revenue, and further creates animosity between patent owners and countries. Rather, all other strategies rely on the sheer undesirableness of a compulsory license and the unlikely success of this strategy.

C. Benefitting from Cooperation: Learning from Roche in Brazil

It has been stated that “reciprocity . . . is the key to every relationship.” While a superficial understanding of economic theory might indicate a need for selfishness and opportunism, a more modern analysis of game theory requires

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113 See Cassedy, supra note 111 and associated text.

114 See supra notes 85 – 88.

reciprocity and trust, especially in those relationships which will continue beyond a known number of encounters. Indeed, corporations and countries, much like people, are likely to learn from each new encounter, adapting their strategies on considerations of effectiveness and reputation.\footnote{Id. at 268 – 269.} After extensive research and modeling, the strategy considered most effective has been labeled “TIT FOR TAT”\footnote{ROBERT M. AXELROD, *The Complexity of Cooperation: Agent-based Models of Competition and Collaboration* 14 (1997).} by Professor Axelrod of the University of Michigan.\footnote{Id. at 20.}

TIT FOR TAT uses a pattern involving five potential options: (1) “don’t rock the boat,” or be nice; (2) “be provicable,” return nice behavior with nice behavior, and retaliate when the other party provokes but be willing to apologize occasionally; (3) “accept an apology,” resume interactions after cooperation has been restored; (4) “forget,” forgive past behavior after mutual cooperation is well established; and (5) “accept a rut,” if no chance of reconciliation exists, remove one’s self from the game.\footnote{Prof. Axelrod is a professor of political science and the Walgreen Professor for the Study of Human Understanding at the University of Michigan.} As complicated as this pattern may seem, the basic principle is rather simple. First, do not be the initial aggressor. If aggression or conflict occurs, do not submit ideally, but if the opportunity for reconciliation occurs, take it. If further aggression occurs and is unfixable, defect away from the position. Or, as simply as possible, TIT FOR TAT says to try and be nice.

\footnote{See, supra note 117 at 20 (2007).}
TIT FOR TAT is not a new concept in the legal field. Perhaps its most obvious applications are in the realm of transactional law, but TIT FOR TAT has huge implication in health law policy, drug availability, and licensing doctrines. TIT FOR TAT should not be ignored.

Realistically, if a company waits for the country to make the first move, it is likely the country will move towards aggression, which should, under TIT FOR TAT, incite “provocation.” In the case of pharmaceuticals, this could mean compulsory licensing leading to litigation. The immediate incentives for countries are just too enticing. However, if the company chooses to make the first move it can weaken those incentives through native support and attrition, or by simply removing the need.

There are obvious benefits towards cooperation beyond the theoretical. The most obvious benefit from cooperation is the potential support of native, cooperative parties. Native parties, for example, are better equipped in dealing

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122 See discussion *supra* notes 21 – 48 and associated text.

with the eccentricities of their governments. Native parties have better notions of what arguments are persuasive in their courts and have more influence within their borders.

Perhaps the best known case of this is Apple Inc. and Samsung Electronics Co.’s continuous litigation over gestures used in smartphone applications in Germany, South Korea, and California. The South Korean company lost its case in the United States and was forced to pay damages while suffering an injunction on appeal, a ruling deemed rather “Apple-friendly.” Essentially the same case was decided differently in South Korea, where the court awarded damages to both parties, but netted Samsung the higher reward. The case was merely dismissed in Germany.

Pharmaceutical companies seeking the support and protection of their patent

http://www.fiercepharma.com/legal/new-gilead-patent-challenger-pops-up-as-delhi-court-forces-a-rehearing (“In sending the appeal back to the patent office, [Justice] Shakdher said the office appeared to rely too much on material supplied by the three opponents.”).


rights would certainly benefit from native support.127 Additionally, such cooperation is now required by some foreign governments,128 over disputes on “standard essential patents,”129 though this is unlikely to greatly affect the pharmaceutical industry.

Furthermore, cooperation between pharmaceutical companies and low-income countries promotes good will, mitigating the growing negativity directed towards pharmaceutical companies,130 and could promote business within the cooperating


128 See Huawei Tech. Co. Ltd v. ZTE Corp., CJEU Case C-170/13 (July 16, 2015) (requiring, through a reading of the EU’s competitions rules, that “standard essential patent” owners who have licensed their patents on “fair, reasonable and nondiscriminatory terms” take several steps to offer a license to infringers before seeking injunction).

129 See Competition Directorate-General of the European Commission, Standard-essential patents, 8 COMPETITION POL’Y BRIEF, 1-2 (June 2014) (defining a standard essential patent as a “patent that protects technology essential to” “a requirement for a specific item, material, component, system, or service.” (citation omitted)).

These benefits obviously support the interests of both the pharmaceutical companies and countries.

Countries that weaken patent protections also risk attacks on their distribution system. Compulsory licensing only allows the country to acquire a cheaper version of the drug, but does not assist in distribution. Though production, intellectual property rights, and distribution seem like wholly different matters, they are not unrelated. A system which lacks strong intellectual property laws only encourages counterfeiting. Theft and counterfeit drugs complicate distribution for low-income countries, potentially and paradoxically increasing the cost of compulsory licensed generics for those that most need them.132

Cooperation also potentially allows for experimentation not permitted within the patent owner’s native country.133 These experimentations could, for example,

131 See, e.g., Reichman, supra note 24 (“[A]ggressive use of compulsory licenses to address emergencies, including even medical emergencies within the Doha Ministerial Declaration on TRIPS and Public Health, may obscure other possible courses of action, such as regulatory and cooperative measures, that might persuade foreign producers to invest in local production facilities with greater long term prospects.”) (citations omitted).


include drug combination testing that may be restricted in the United States through the stricter application of patent laws and protections.\textsuperscript{134} Obviously, the opportunity to explore new innovations and discoveries should not be overlooked, but it is within the patent owner’s best interest to maintain some control over the scope and scale of the research, which may not be possible under a more traditional compulsory license.\textsuperscript{135}

Indeed, ignoring all these benefits would be a mistake. Compare, for example, Gilead’s voluntary licensing in India to Hoffman-La Roche’s (“Roche”) “voluntary” licensing in Brazil.

In 2001, Brazil announced its plan to compulsory license nelfinavir, from Roche, after initial negotiations over pricing failed.\textsuperscript{136} The U.S. Trade Representative at the time, Robert Zoellick, filed a claim with WTO, but eventually withdrew his support after receiving considerable negative publicity.\textsuperscript{137} Under the threat of a Brazil compulsory license and without any government support, Roche eventually agreed to license the drug’s patents to local generic

\begin{verbatim}
\textsuperscript{134} Id.
\textsuperscript{135} However, companies should be careful while drafting any contract to not generate induced infringement through the license terms.
\textsuperscript{136} Brazil Intends to Break Patent on Roche’s Nelfinavir to Produce Drug Locally, KAISER HEALTH NEWS (Aug. 23, 2001), http://khn.org/morning-breakout/dr00006553/.
\textsuperscript{137} Negotiating Trade: Developing Countries in the WTO and NAFTA 96 (J. Odell 2006).
\end{verbatim}
manufacturers. This “compelled” licensing agreement allowed Roche the same right to draft the agreement as a voluntary license would, but only under threat of compulsory licensing. Thus, Roche lacked the leverage necessary for fair negotiations. Should the negotiations have failed, Brazil still held the right to compulsory license the drug. This and other compelled licenses should only be described as contracts made under coercion and are as unconscionable as the compulsory license. Yet, they are just as enforceable under the letter of every law.

Roche had some power over the terms of the negotiation, but lacked any native support, had little leverage in the negotiations, lost the support of the U.S. government, lost control over their patent rights in Brazil, and invited future attacks.

Meanwhile, Gilead recently negotiated a deal with eleven Indian generic manufacturers. Though the India Patent Office initially deemed the drug “not inventive enough” to warrant patent protection, the Indian court granted Gilead another opportunity to defend its patent before the Patent Office. It would not

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138 Example of Health-Related Compulsory Licenses, CPTECH (Oct. 28, 2015), http://www.cptech.org/ip/health/cl/recent-examples.html (“[O]n August 31, they reach[ed] an agreement; Roche will sell the drug in Brazil at an additional 40% discount, and Brazil will not issue the compulsory license”).


140 See Michael Mezher, Follow the Rules, Indian Court Tells Patent Office in
be unreasonable to believe this grant was made in light of growing local interests, including those eleven companies which have exclusive licensing agreements with Gilead.

**D. The Joys of Revenue: Abbott’s Mistake in Thailand**

Perhaps the most obvious advantage, aside those already mentioned, for companies that choose to voluntary license blockbuster drugs, is the ability to protect existing revenue streams and the potential creation of additional revenue sources.

If the incentive of drug patents is the ability to control the pricing of drugs, compulsory licensing is a serious threat. If compulsory licensing of drugs forces lower drug prices, not only on the licensed generic, but on all related drug prices.

The apparent fact that directly competing generics reduce the price of a brand name drug is too often taken at face-value. Indeed, there is some conflicting evidence on what effect competing generics have on the price of brand name.

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See Charitini Stavropoulou, *Compulsory licensing and access to drugs*, 16 EUR. J. HEALTH ECON. 83 (2015).

Id.

drugs in well-established markets. There is some evidence that generics actually increase the price of said brand name drugs. However, whether generics introduced after a patent expires tend to increase or decrease the actual price of the brand name drug is irrelevant. The actual affect, whether positive or negative, is too insignificant to be important. However, this only holds true for an already well-established drug.

Professor Stavropoulou best illustrates this in her paper using mathematic models. Though her paper was intended to present compulsory licensing as a bargaining tool for development countries, it also perfectly illustrates the dangers of compulsory licensing to drug prices. The paper illustrates and

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145 *Id.*

146 *Id.* at 931 (“each generic entrant is associated with an average 1% increase in the branded price”).

147 Though the introduction of new generic drugs into a market might not affect the price of the brand-name drug, it would be incorrect to infer that brand-name drug company do not see a substantial decrease in profits after the introduction of the generic. *See* U.S. Cong. Budget Off., *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* 28 (1998).


149 *Id.* at 83-84.

150 Prof. Stavropoulou makes some assumptions in her paper. For starters, she
models three main propositions. When the cost of production is high, the threat of compulsory licensing is low.¹⁵¹ When the cost of production is intermediate, the threat a compulsory license is credible, but it can be more economic if the patent owner maintains its rights and simply supplies the drug.¹⁵² If the cost is low, it can also be more economic for the country to exercise its compulsory licensing right.¹⁵³

Once the compulsory license right is enacted, there exists a new competitor. Even when limited to specific markets, the availability of a cheaper generic unregulated by the patent owner or mitigated by an established and trusted brand name creates demand of a cheaper product in the remaining market. Exportation policies should help slow the declining drug price, but demand for the cheaper drugs will continue to increase and more licenses could be compelled. In this scenario, even without the threat of licensing or exportation, the prices of the generics would equalize towards the cheapest price, cutting heavily into potential profits. While Professor Stavropoulou’s paper may prove this mathematically, the

assumes the model’s hypothetical governments do “not regulate any aspect of drug production and consumption.” Of course, this is untrue, but is simply a way to simplify the model. She also assumes “cross-national drug price differentials” are influenced by demand and through the “interference of national governments.” This can be assumed to be true for all intents and purposes. Id. at 86.

¹⁵¹ This must be true, as there would be little incentive to compulsory license a drug if the offered price did not greatly differ from the price of production. Id. at 88.

¹⁵² Id.

point is further supported through empirical observation

Using Gilead as a model again, the price of sovaldi, Gilead’s hepatitis C drug continues to decrease even in those protected markets. Even with the control on pricing and third-party participants that Gilead tries to maintain, the demand for cheaper drugs continues. Indeed, even Gilead cannot prevent the decline in pricing, but can only stem the tide. However, this slow pricing decline does not seem to have hurt Gilead’s business. Still, Gilead is afforded more control over the tide through its licensing deals than would be available to the victim of a compulsory license who would have no say in pricing or distribution. Rather, by removing the main incentive for a government from compulsorily licensing sovaldi, Gilead has protected its marketability in those markets which can afford the price of innovation.

The large force of pharmaceutical marketing is rarely directed towards low-income nations. The obvious truth is most countries that issue compulsory

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156 *See* Cassedy, *supra* note 7 (“So now, is this going to have a big effect on our business model? No, because we did not develop this product for the Indian market, let’s
licenses for non-emergency use cannot afford the pharmaceutical product at the brand name prices. As a result, there is little threat of lost revenue due to lower prices in these low-interest markets. However, even if a pharmaceutical company is not too concerned about the inevitable increase of generic alternatives, the company should not ignore the potential for additional revenue available through voluntary licensing.

In perhaps the best counter-example and most aggressive strategy against TRIPS compulsory licensing, Abbott withdrew two of its applications from Thailand’s Drug Office after the Royal Thai government issued a compulsory license on Kaletra, one of Abbott’s HIV treatment drugs. Eventually, and perhaps obviously, Abbott would eventually resubmit these applications. Unlike the previously explored strategies, Abbott’s strategy was purely retributory. Abbott risked potentially losing all the revenue it might have made in Thailand, and, perhaps more importantly, Abbott’s withdrawal from the Thai market opened the door for more potential compulsory licenses. After all, if a work requirement is TRIPS compliant, by making the drugs unavailable, Abbott had

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be honest. I mean, you know, we developed this product for Western patients who can afford this product.”


essentially abandoned its patent rights in Thailand.

Compare this strategy against the voluntary licensing model. At its simplest comparison, voluntary licensing creates additional sources of revenue, while retaliation can only hurt revenue. Gilead does not have to worry about the costs of production, negotiation, or shipping for the generic drugs, but more importantly, Gilead makes money from its licensing deal. Abbott’s strategy merely delayed the sale of two additional drugs.

Allowing countries to produce the drug locally and then using existing domestic shipping methods is a better way to produce and disperse the drug, thus allowing a more complete distribution within a country. If the country also participates, by stringently protecting patent rights, it would protect its citizens from the plague of counterfeit or diluted drugs. But, what should be more compelling for the company is how this licensing strategy might create additional profits. Gilead, again, illustrates the best method.

Egypt has one of the highest rates of Hepatitis C infection in the world.\textsuperscript{159} Egypt would be an ideal market for Gilead’s hepatitis drug. However, most of the population of Egypt cannot afford the drug at Gilead’s price.\textsuperscript{160} More importantly,

\begin{itemize}
\item \textsuperscript{159} Daniel Lavanchy, \textit{The Global Burden of Hepatitis C}, 29 \textit{LIVER INT’L} 74 – 76 (2009).
\item \textsuperscript{160} Compare GNI per capita, PPP, \textsc{The World Bank}, http://data.worldbank.org/indicator/NY.GNP.PCAP.PPCD (last visited Nov. 11, 2016) (citing the gross national income of Egypt at $10,260 (USD) per year) with Eric Palmer, \textit{Gilead Strikes Sovaldi Price Deal in Germany as it Picks Up Speed in EU}, FIERCEPHARMA (Feb. 13 2015).\textsc{http://www.fiercepharma.com/story/gilead-strikes-}\
\end{itemize}
those that can afford such relatively high prices are not as susceptible to Hepatitis C infection.\textsuperscript{161} Hepatitis C is typically shared through exposure to infected blood, like through the sharing of needles.\textsuperscript{162} If one can afford the price of sovaldi, one should certainly also be able to afford the simple preventative measure of a new needle.

Consequentially, those that cannot afford the drug are the ones in the direst of needs, and those that can afford the drug do not often require it. In India the estimated amount of people infected with the Hepatitis C virus is approximately 11 million.\textsuperscript{163} However, the majority of Indians are not so economically affluent that they could afford sovaldi at Gilead’s market price.\textsuperscript{164} With the growing price

sovaldi-price-deal-germany-it-picks-speed-eu/2015-02-13 (citing the price of a twelve week course of Sovladi at $85,000 (USD) in the U.S. and approximately $44,546 (USD) in Germany).


\textsuperscript{163} \textit{See Hepatitis in India: Burden, Strategies and Plans}, 3 QUARTERLY NEWSL. FROM THE NAT’L CTR. FOR DISEASE CONTROL 1, 3 (2014) (number calculated from percentage infected and population census at the time of publication).

of pharmaceuticals, such circumstances could become more prevalent, meaning fewer and fewer people and countries will be able to afford the cost of similar treatments.

Rather than risk almost no income in such low profit markets, it would be better a strategy to invite what revenue may come. After all, a percentage of something is better than the whole of nothing. Even if only half of the infected population of India can afford the generic price, Gilead still stands to make $2.5 billion (USD) in India alone. Of course, Gilead hopes for the distribution to affect an even higher percentage of the world population, with a long term goal of eradicating HCV. Though the eradication of HCV would eventually hurt sovaldi’s profitability, world-wide integration should allow for Gilead to amass a sizable profit without fear of eventual competition.

CONCLUSION

Voluntary licensing is currently the best strategy for any company worried about compulsory licensing, and should be considered even for those patents not

(providing the average Indian household income at 47,804 Rs (~ 7,300 USD), but the median income as low as 27,857 Rs (~424 USD)).

165 See generally Eric Palmer, Gilead Science prices Sovaldi in India at a Tiny Fraction of the U.S. Cost, FIERCEPHARMA (Aug. 7, 2014),

yet considered under controversy. The other strategies employed by pharmaceutical companies – at best – barely stem the oncoming tide or – at worst – compel countries to apply compulsory licenses for intellectually protected drugs. These strategies increase animosity between countries and companies and needlessly waste money, ultimately hurting both the company and the country.

Voluntary licensing pulls ahead of the well-debated issue of compulsory licensing by ignoring the losing strategy employed by the majority of pharmaceutical patent owners. The voluntary licensing strategy focuses on the potential benefits of licensing. Voluntary licensing allows the patent owner to better control the threat of divergence through contracting; benefits the cooperating parties through potential gains in research, good-will, pricing, and marketing; and partially protects the economic interests of the patent owner while creating additional sources of revenue. In short, voluntary licensing grants the most rewards for the smallest cost.
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