A SUMMARY OF THE ARGUMENTS SUPPORTING AND OPPOSING THE DECLARATION OF INDIA AS A PRIORITY FOREIGN COUNTRY

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ABSTRACT

In 2005, India enacted patent reform legislation that has sparked controversy in the pharmaceutical industry worldwide.[1] Among other things, India's patent reform requires patent holders to make measurable changes with regard to the efficacy of pharmaceuticals before they can obtain a secondary patent on a previously patented product and establishes standards for compulsory licensing in cases where patented products are not being worked on in India. These provisions have been decried by the multinational pharmaceutical industry as destructive to innovation and unreasonably burdensome. In response to these and other concerns, the United States International Trade Commission (USITC) is investigating India's alleged protectionism.[2] This article aims to analyze the industry's Special 301 submissions and nearly identical submissions to the USITC on the issue of whether or not India should be listed as a Priority Foreign Country due to its intellectual property policies. The following article is structured as a complete argument for and a complete argument against India's designation as a Priority Foreign Country. As similar debates will continue in the future, this article hopes to provide a holistic view of the arguments for and against pharmaceutical patent reform, and to accurately represent the views of each side in a neutral fashion.

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1 India Amended Patents Act, 2005, available at http://ipindia.nic.in/ipr/patent/patent_2005.pdf.

2 News Release, India's Trade, Investment and Industrial Policies will be focus of new USITC Investigation (Aug. 29, 2013), available at http://www.usitc.gov/press_room/news_release/2013/er0829ll1.htm.

1. INTRODUCTION

In 2005, India enacted patent reform legislation that has sparked controversy in the pharmaceutical industry worldwide.[3] Among other things, India's patent reform requires patent holders to make measurable changes with regard to the efficacy of pharmaceuticals before they can obtain a secondary patent on a previously patented product and establishes standards for compulsory licensing in cases where patented products are not being worked on in India. These provisions have been decried by the multinational pharmaceutical industry as destructive to innovation and unreasonably burdensome. In response to these and other concerns, the United States International Trade Commission (USITC) is investigating India's alleged protectionism.[4] In addition during its annual Special 301 Trade List review process, the Office of the United States Trade Representative (USTR) received multiple submissions from pharmaceutical companies and other interested parties on the subject of whether or not India should be listed as a Priority Foreign Country on due to its intellectual property policies.

On April 30, 2014, the USTR determined that India would not be designated a priority foreign country, but would remain on the Priority Watch List.[5] The USTR issued a report which simultaneously acknowledges the positive steps that India has taken in intellectual property reform and improving its legal and administrative framework but cautioned that the United States is wary of the challenges that rights holders face under India's weak IP regime. The Special 301 Report specifically cites India's plans to hire 500 new patent examiners over the next five years as a positive step to be congratulated, while expressing concerns about India's strict standards of patentability, including its enhanced efficacy requirement; its issuance of compulsory licenses, based in part on failure to work the patent locally; and need for greater administrative transparency. Overall, the USTR expressed concern about India patent and data protection policies, but did not appear to be convinced by the arguments of major pharmaceutical companies. As such, India remains a Priority Watch List country but was not elevated to Priority Foreign Country status.

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[3] The Patents (Amendment) Act, 2005.

[4] News Release, *India's Trade, Investment and Industrial Policies will be focus of new USITC Investigation* (29/08/2013), available at http://www.usitc.gov/press_room/news_release/2013/er0829ll1.htm.

[5] 2014 Special 301 Report 37-43, available at http://www.ustr.gov/sites/default/files/USTR%202014%20Special%20301%20Report%20to%20Congress%20FINAL.pdf.

Especially, because India remains on this list, these arguments continue to be relevant to patent law and international intellectual property policy. It is important to recognize that the pharmaceutical industry will continue to argue against patent reform, whether originating in India or any other country that might adopt similar (or more progressive) standards in the future. This memorandum aims to analyze industry's Special 301 submissions and nearly identical submissions to the USITC on the issue of whether or not India should be listed as a Priority Foreign Country due to its intellectual property policies. The following article is structured as a complete argument for and a complete argument against India's designation as a Priority Foreign Country. As similar debateswill continue in the future, this article hopes to provide a holistic view of the arguments for and against pharmaceutical patent reform, and to accurately represent the views of each side in a neutral fashion.

2. SUPPORTING ARGUMENTS

2.1. Whether Section 3 (d) of the Indian Patents Act violated the TRIPS Agreement?

Section 3(d) of the India Patents Act[6] violates the TRIPS Agreement Article 27.1 by discriminating against a particular field of technology and by creating an impermissible fourth criterion for patent protection. TRIPS Agreement Article 27.1 clearly states:

> "Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. (5) Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced [emphases added]."[7]

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[6] Supra 1, at S. 3(d).

[7] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27.1, at 1 (15/04/1994), Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299.

Section 3(d) requires a showing of "enhanced efficiency," a condition, which has been applied thus far only to pharmaceuticals, thus discriminating against a particular field of technology.[8] TRIPS Article 27 requires that patents be available to "any inventions...in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application" and further requires that patent rights be "enjoyable without discrimination as to … the field of technology … ." Thus, by excluding patentability of pharmaceutical substances without an additional showing of enhanced efficacy, Section 3(d) creates an additional, discriminatory element with respect to a particular field of technology in violation if Article 27.[9] This extra step India created is undeniably destructive, and has resulted in the denial of patents for an anticancer therapy, Glivec, that have already been approved in 40 other countries.[10]

Not only is Section 3(d) discriminatory with respect to the pharmaceutical field of technology, it also impermissibly introduces a fourth element of patentability beyond the globally harmonized patentability criteria establish by Article 27.1, novelty, inventive step, and industrial applicability. Section 3(d) is contained in Chapter 2 of the Indian Patents Act, which addresses inventions that are not patentable. Section 3 contains exemptions from patentability authorized by TRIPS Article 27.2 and 27.3, but it adds other exclusions, including subsection (d) that is not authorized by TRIPS. Although there are some apparent flexibility in TRIPS to exclude subject matter not include in Article 27, e.g., abstract ideas, business methods, and computer software, there is not a *carte blanche* to adopt exclusions that undercut the patentability criteria of Article 27.1.

This "extra step" has also made it difficult to bring innovation into India's market. Pharmaceutical companies do not want to bring new investments into countries that abuse patent protection in violation of

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[8] US International Trade Commission, Statement of Rod Hunter, PhRMA, Special 301 Submission (2014), available at http://www.regulations.gov/!docketBrowser;rpp=25;po=0;dct=N%252BFR%252BPR%252BPS;D=USTR-2013-0040.

[9] BIO Special 301 Submission (2014), available at http://www.regulations.gov/#!docketBrowser;rpp=25;po=0;dct=N%252BFR%252BPR%252BPS;D=USTR-2013-0040.

[10] National Association of Manufactures, Linda M. Dempsey (07/02/2014), Special 301 Submission (2014), available at http://www.regulations.gov/#!docketBrowser;rpp=25;po=0;dct=N%252BFR%252BPR%252BPS;D=USTR-2013-0040.

their obligations under TRIPS.[11] The resulting lack of confidence has directly impacted India's foreign direct investment.[12] India's direct foreign investment went from $35.1 billion in 2011-2012 to $22.4 billion in 2013 once the challenged uses of Section 3(d) were applied.[13] Weakening intellectual property rights will cause innovators, especially individual inventors, and small to medium sized companies, to be unwilling to invest.[14] Larger players will make capital allocation decisions that favor countries with stable intellectual property environments.[15] India's failure to apply fair and equitable market access as well as its discriminatory measures will continue to weaken foreign investment in India.

If innovators will have less incentive to invest, there will be a decline in producing new life saving drugs. Article 27 of TRIPS requires patents to be made available for any non-excludable invention and yet Section 3(d) creates extra hurdles that are detrimental to U.S. businesses and the U.S. economy.

2.2. Whether India's Local Working requirement as well as its Compulsory Licensing requirement violates the TRIPS Agreement?

India's local working requirement is a clear violation of TRIPS Article 27.1, which requires "patent rights to be enjoyable without

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[11] Memorandum from the Biotechnology Industry Organization, Vice Pres. Joseph Damond, Special 301 Submission (2014), available at http://www.regulations.gov/#!docketBrowser;rpp=25;po=0;dct=N%252BFR%252BPR%252BPS;D=USTR-2013-0040, last seen on 26/07/2015.

[12] SeeMemorandum U.S. Chamber's Global Intellectual Property Center, Special 301 Submission (2014), available at http://www.regulations.gov/#!docketBrowser;rpp=25;po=0;dct=N%252BFR%252BPR%252BPS;D=USTR-2013-0040, *citing* a recent study by the Organization of Economic Co-operation and Development (OECD) concludes that a 1 percent change in the strength of the national IP environment, based on a statistical index, is associated with a 2.8 percent increase in foreign direct investment flow.

[13] Ben Wolfgang, *U.S. drug industry upset with Indian policies on patents*," Washington Times (26/09/2013), available at http://www.washingtontimes.com/news/2013/sep/26/us-drug-industry-upset-with-intian-policies-on-pat/, last seen on 26/07/2015.

[14] Notice of Intent to Testify and Hearing Statement of the IPO, Intellectual Property Owners Ass.Herbert C. Wamsley, Intellectual Property Owners Assoc. 1 (24/02/2014), Special 301 Submission (2014), available at http://www.regulations.gov/#!docketBrowser;rpp=25;po=0;dct=N%252BFR%252BPR%252BPS;D=USTR-2013-0040, last seen on 26/07/2015.

[15] Ibid, at 2.

discrimination as to the place of invention, the field of technology and whether products are imported or locally produced [emphasis added]."[16] India's Patents Act §84(1)(c) allows The Controller General of Patents, Designs and Trade Marks, to grant a compulsory license on the ground that the patented invention is not worked in the territory of India.[17] An example of this blatant injustice came when the Indian generic pharmaceutical company NatcoPharma was granted a compulsory license on Bayer's Sorafenib, a treatment for liver and kidney cancer. The Controller General found that the license was justified on three grounds; reasonable requirements of the public are not met, the invention is not available to the public, and the invention was not "worked" in India.[18] While all three grounds are legally questionable, the pharmaceutical companies object especially to the domestic production requirement, which is a violation of Article 3 and Article 27 of the TRIPS Agreement. Article 3, confirming national treatment, states, "Each Member shall accord to the nationals of other Members treatment no less favorable than that it accords to its own nationals with regard to the protection." Therefore, imposing a local working requirement on patent holders is treating the foreign patent holders less favorably than domestic patent holders because foreign patent holders are less likely to site their production facilities in India rather than their home country. This indirect favoring of domestic or foreign patent holders is in direct violation of Article 3. Similarly, as previously stated, Article 27, by its express terms prohibits discrimination against imported patented products in favor of domestically produced patented products.
This local production requirement not only violates TRIPS, but its implementation is also infeasible and fraught with procedural and substantive challenges. India's new National Manufacturing Policy requires patent holders to complete a "Form 27," an explanation of how each patent is being worked on in India. This form is complicated and burdensome, and there is a concern that the information provided can be used to justify compulsory licenses.[19] Furthermore, there is confusion with Form 27 as most of the questions are not answerable except in a one-patent-one-product context.[20] Most companies have many patents comprising a single product. Since one or more patents comprising a product may be worked in India without every single patent being

[16] Supra 9.
[17] Supra 1, at S. 84(1).
[18] Ibid, at S. 84(1)(c).
[19] Supra 10.
[20] Ibid.

worked there, patent holders may meet India's policy goals without complying with the law with respect to each and every component. The Form 27, however, is impractical and allows India to take advantage of companies who comply with domestic production policy for components to create compulsory licenses for final products where no real policy justification exists.

India's overbroad compulsory licensing, provided for in India Patents Act § 84, poses a clear risk not only to the U.S. pharmaceutical industry but also to advanced manufacturing, industrial and other innovative U.S. businesses as well.[21] For example, in its National Manufacturing Policy, India encourages compulsory licensing of green technology that is "not available at reasonable rates". [22] This policy promotes India's own domestic industries at the expense of patent holders in the United States and elsewhere and is a clear violation of TRIPS Article 3.

2.3. Whether Strict Patent Protection is Beneficial to Developing Countries?

India's lack of consistent adherence to patent rules as well as its unnecessarily burdensome patent applications has exacerbated a bad situation by disproportionally punishing U.S. and other foreign companies' patents.[23] In May 2013, Indian President Pranab Mukherjee pointed out that the U.S and China receive 12 times more patent applications than India.[24]This is not surprising when India time and time again refuses to adhere to standard intellectual property practice.

If India had stronger intellectual property protection, it would improve the country's long-term economic growth. IP-intensive industries contribute to a more sustainable economy. In fact, in the United States the IP-intensive industries contributed nearly 35 percent of U.S. GDP in 2010, or over $1.5 trillion in economic output.[25] As much as 40 percent

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[21] Ibid, 60.

[22] Supra 8, at 3.

[23] Supra 7, 8.

[24] Speech by the President of India, Shri Pranab Mukherjee on the Occasion of the National Technology Day (01/05/2013), available at http://presidentofindia.gov.in /sp110513.html, last seen on 30/01/2014.

[25] Intellectual Property and the U.S. Economy: Industries in Focus, U.S. Department of Commerce (01/03/2012), available at http://www.esa.doc.gov/sites/default/files /reports/documents/ipandtheuseconomyindustriesinfocus.pdf, last seen on 30/01/ 2014.

of U.S. growth in the twentieth century was a result of IP-related innovation.[26] Pharmaceutical companies are important for the growth of any developing country. They provide high-paying, productive jobs. In the United States, pharmaceutical industry employment in 2011 totaled 3.4 million jobs, including direct employment of over 810,000 Americans.[27]The U.S. innovative biopharmaceutical industry exported over $50 billion in biopharmaceuticals in 2012.[28] Patents and other IP protections are critical in securing investment and helping India's economy grow. India should model the U.S. industry in order to improve its economy.[29]

Moreover, as the Biotechnology Industry Organization points out in its brief, some of the most damaging policies India has adopted are that of issuing marketing approvals for generic companies while patents are being challenged and during appeal processes:

> "India's drug regulatory agency approves generic company applications to market generic drugs if a patent is being challenged. Accordingly, a generic company needs only challenge a patent to apply for marketing approval. This loophole creates an unfair advantage for Indian generic companies and undermines U.S. IPR."[30]

Once the generic companies begin producing the drugs, innovators find it difficult to stop the Indian generic companies from exporting into countries with proper patent protection.[31] India allows companies who have these kinds of licenses to produce and export outside of India without the patent holder's permission. This policy further underscores India's disregard for standard intellectual property practices. It should adopt a pathway consistent with U.S. law necessary for Indian

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[26] See E.F. Denison, *The Sources of Economic Growth in the United Sates and the Alternatives before us,* Committee for Economic Develops, Supplementary 13 (1962); R.M. Solow, *Technological Change and the Aggregate Production Function*, Review of Economics and Statistics 39(3)312-23 (1957); R.M. Solow,*A Contribution to the Theory of Economic Growth*, Quarterly Journal of Economics 70:65-94 (1956).

[27] Hearing of Statement of Pharmaceutical Research and Manufacturers of America (PhRMA) (24/02/2014), available at http://www.regulations.gov/#!docketBrowser;rpp=25;po=0;dct=N%252BFR%252BPR%252BPS;D=USTR-2013-0040.

[28] Ibid.

[29] Supra 7, at 11.

[30] Ibid, at 12.

[31] Ibid.

manufacturers providing a linkage between patent rights and registration/ marketing approval.

2.4. Reasons for Opposing India's Patent Law and its Impact

India is spearheading an anti-IP or IP-weakening regime on the international stage. The country is violating the spirit of TRIPS by denying patent protection to some innovators whose applications have been accepted in other countries. Any weakening of intellectual property rights is inherently against the spirit of TRIPS and it is the United States' duty to ensure that no other nation weakens IP rights, as it will be detrimental to the international economy and to the innovation of life-saving medicine.

"India's weak IPR policies will serve as a model for other emerging economies. Some countries have already started to follow India's lead by proposing changes to their own national laws."[32] This shows that India is undermining patent law all over the world by leading others to embrace its own detrimental policy choices. Since 2012, India has infringed, overridden, or revoked nearly a dozen pharmaceutical patents held by foreign firms.[33] India is denying patent protection for inventions that have met internationally accepted criteria.[34]

As stated previously, India's failure to develop and adhere to conventional international practices in intellectual property law has especially hindered its economic development this past year. A growing lack of confidence by foreign investors has impacted investment in India.[35] This will directly impact innovation. No investor will invest in India with the added risk posed by India's reckless new IP regime. Furthermore, India is influencing other countries, such as South Africa, Brazil, and even China, to adopt its weak intellectual property model. Having an "enhanced efficiency" standard coupled with the broad compulsory licensing scheme under Section 84 poses a clear threat not only to the U.S. pharmaceutical industry but to advanced manufacturing, industrial and other innovative U.S. and foreign businesses [36] Any decrease in IP holder rights will disincentive innovation, perhaps to the

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[32] Supra 8.
[33] Supra 10, at 60.
[34] Supra 8.
[35] Supra 10, at 54.
[36] Ibid, at 60; SeeNational Association of Manufactures; Supra 8.

point of halting it altogether; the mere discussion in international fora of weakening IP rights serves to scare off investors and stifle innovation.

Innovators are further frustrated by the fact that India's patent office is not properly run. Companies have reported delays in post-grant opposition proceedings, and one company reported waiting almost a year for a decision.[37] "The existence of both pre- and post-grant opposition proceeding creates problems as U.S. company will survive a pre-grant opposition proceeding and have the patent granted only to face post-grant proceeding from the same opponent."[38] The Indian generic industry uses this process to purposefully delay the grant of foreign patents in order to justify the production of generic copies.[39]

The patent application process itself hampers efficient filing, especially for non-Indian entities that have joint inventions with Indian residents and institutions. India should consider accepting a first-filing regime in the country where the research or product development is conducted for joint inventions or in the country where the patent applicant is located.[40] India's Patents Act makes it more difficult for foreign companies to file and have their patents granted, which violates the spirit of the TRIPS Agreement.[41]

Although India claims that its policies improve access to medicine, its policies are not really about access to medicine. In many cases, patent holders were giving their drugs to Indian consumers either free of charge or at greatly reduced prices. In fact, Novartis provided the controversial Glivec to 95 percent of the 16,000 Indian patients for free and to the remaining five percent at a heavily subsidized rate.[42] The new generic rates are higher than the subsidized rate, and surely no price can be more accessible than free. Thus, it is more expensive for Indian patients to access these medicines after the compulsory license, contrary to the policy India is claiming to enforce.

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[37] Supra 7, at 9.
[38] Ibid.
[39] Ibid.
[40] Ibid.
[41] See TRIPS, Supra 5, at art. 27.1.
[42] Supra 10, at 58.

2.5. Remarks

Over the past several years India has not only failed to address growing concerns regarding its new intellectual property system but continues to willfully violate TRIPS and take advantage of U.S. and foreign businesses and patents. India's actions are not about access to medicine, but are designed to serve its own economy through its unauthorized fourth patentability standard – enhanced efficacy – and through its impermissible local working provision. India's patent regime is a threat to the innovators who strengthen the U.S. economy. India has already pledged to take a leadership role amongst the BRICS IP Offices to spread the influence of their IP-destructive policy.[43] The simple reality is that, over the past months, India's actions are egregious and belligerent. At this point in time, simply placing India on a Priority Watch List is not a sufficient deterrent. India should be elevated to a Priority Foreign Country to send a strong message that the United States and other TRIPS-compliant nations will not stand idly by as India continues on its path of destroying intellectual property rights.

3. COUNTER ARGUMENTS

3.1. Whether India's Patent Act is in Compliance with the TRIPS Agreement with Particular Reference to Innovations?

Opponents of patent reform in the pharmaceutical industry have targeted § 3(d) of the India Patents Act, arguing that it violates international law under the TRIPS Agreement (Article 27.1 and generally) by discriminating against certain types of inventions and by imposing an impermissible fourth criteria for patent protection, and that it will discourage bio-pharmaceutical innovation. These claims are false. Section 3(d) is fully compliant with TRIPS, and history has proven that the types of restrictions imposed under § 3(d) of the Patents Act—and, indeed, even more stringent restrictions—have not stifled innovation.

In addressing anti-reformers' complaints about § 3(d), it is instructive to examine the text of the statute. Section 3 excepts certain types of innovations from qualifying as "inventions" within the context of the

[43] Supra 25, at 3.

Patents Act. Subsection (d) is but one of sixteen bullet points under that heading, and provides that:

> "[T]he mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant."[44]

In essence, this requires innovators to create truly new substances in order to qualify for patent protection. The purpose of this is to disincentivize the practice of filing new patents for extant inventions that have only been altered slightly in order to maintain market exclusivity (colloquially referred to as "evergreening"). Patent terms are limited for good reason, and allowing one manufacturer to corner the market on lifesaving drugs prevents those who need them from obtaining treatment at the favorable prices offered by generic products, as well as preventing other innovators from offering versions of the product enhanced by their own research. Section 3(d) gets around these problems by preventing patent holders from obtaining unreasonable periods of patent protection for inventions upon which they have not made sufficient improvements to justify the burden to the public and the market of such extended periods of protection.

Pharmaceutical lobbyists contend that this section violates Article 27.1 of TRIPS by discriminating against a particular field of technology (pharmaceuticals) in providing patent protection. This is simply not the case. Article 27.1 states, in relevant portion, that patents shall be available for any kind of invention within any field of technology as long as they "are new, involve an inventive step, and are capable of industrial application."[45]Section 3(d) does not impact the availability of patents under these criteria – in fact, it holds these criteria to a strict standard by imposing a high standard for "inventive step." It has long been settled that TRIPS member nations have the authority under the Agreement to tailor IP policies to national need, including defining what constitutes an invention, what is not patentable subject matter, as well as what is novel, inventive, and industrially applicable. With this interpretative authority, the policy rationale espoused under § 3(d) constitutes an allowable demarcation of patentable subject matter and exclusions, and is also an

[44] Supra 1, S. 3(d).
[45] Supra 5, art.27.1, at 1.

allowable interpretation of inventive step.[46] Creating more stringent patent requirements and including an exception requiring enhanced therapeutic efficacy for secondary patents is a TRIPS-compliant means of addressing evergreening in a manner suitable for India's national needs, and also falls well within the ambit of what has been allowed in the United States.[47]

Opponents of patent reform further contend that § 3(d) imposes an impermissible "fourth step" or requirement to patent protection. This is categorically untrue, as § 3(d) refers to patents on variations and new uses of known substancesand processes without a new component, not truly novel and inventive ones. Therefore, § 3(d) simply limits the scope of secondary patents, and does not impose an additional requirement on obtaining primary patents. With regard to the argument that § 3(d) is unduly burdensome for innovators who will have to contend with an additional "step" to obtain these secondary patents, TRIPS allows for a wide variety of patent regimes with different levels of stringency among member nations.[48] For example, Japan only allows 14% of the patents allowed by the US.[49] India is well within its TRIPS obligations in making this specific narrowing of its definition of "invention," and has in fact issued thousands of pharmaceutical patents under § 3(d). It should also be noted that the industry does not seem to object to any of the other fifteen subsections under § 3 as imposing unlawful requirements, probably because many of them parallel exclusions from patentable subject matter enforced in the US, Europe, and many other countries.

Finally, pharmaceutical lobbyists argue that § 3(d) will stifle invention within the pharmaceutical field. This is untrue for obvious reasons: humans are unlikely to no longer require pharmaceutical innovation, particularly as the antibodies for old pathogens disappear from new generations and medicines cause current diseases to mutate and become stronger. Consequently, there will always be financial and humanitarian incentive for pharmaceutical innovation. However, this "stifled innovation" claim has also been proven false by history. Before

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[46] Ragavan, Flynn & Baker, *Special 301 Submission* (2014), available at http://www.regulations.gov/#!docketBrowser;rpp=25;po=0;dct=N%252BFR%252BPR%252BPS;D=USTR-2013-0040; Health GAP, *2014 Special 301 Watch List Submission*, available at http://infojustice.org/wp-content/uploads/2014/03/Health-GAP-2014-Special-301-Watch-List-Submission-Health-GAP-final.pdf.

[47] Supra 44, at 4.

[48] Supra 44, at 7.

[49] Supra 44, at 6.

becoming TRIPS compliant, India operated under a process patent-only administration for food and drugs.[50] This regime did not stifle innovation, but instead incentivized innovation in the manufacturing process.[51] In fact, the Indian pharmaceutical industry thrived under the process patent system.[52] This proves that less expansive IP protection does not cause stagnation, but instead incentivizes different styles of innovation. Similarly, then, § 3(d) restrictions will not stifle innovation, but will incentivize targeted innovation in pharmaceutical efficacy and reward focus on truly innovative pharmaceutical compounds. Moreover, as non-governmental third parties, the industry's views about what does and does not incentivize innovation are irrelevant with respect to the lawfulness of India's IP policies. Finally, there is ample evidence challenging anti-reformers' contention that weaker standards of patentability incentivize useful and significant innovation. Excessive patenting and patent thickets can block follow-on innovations and the search for low-hanging incremental changes and me-too medicines rewarded by easy-to-get 20-year patents can deform research away from break-through innovation. For all of these reasons, § 3(d) is fully compliant with international law. The United States should not seek to impose its own will upon the lawful policies of other nations.

3.2. Whether the Local Working and Compulsory Licensing Provisions are Legal and Whether These Provisions are within the Ambit and Scope of the Policy concerned?

The pharmaceutical industry claims that India's local working provision under § 84 of the Patents Ace violates TRIPS Articles 27.1 and 3 as discriminatory against international innovators, and further complain that Form 27 (used to monitor compliance with the local working provision) is unduly burdensome. They also argue that India's compulsory licensing practices under the same section violate TRIPS

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[50] Supra 44, at 3; Adam Mannan and Alan Story, *The Power of Pills: Social, Ethical and Legal Issues in Drug Development, Marketing and Pricing* 184-85 (27th vol., 2006).

[51] Supra 44, at 3; Supra 48, at 184.

[52] "In 1971, there were only two Indian companies in the top ten by pharmaceutical sales in India. By 1996 there were six… Today, India has about 20,000 pharmaceutical firms and employees over two and a half million people directly or in related work. It produces high-quality drugs with prices amongst the lowest in the world. India has become the prime source of generic medicines and supplies over 27 developing nations with desperately needed pharmaceuticals, including generic anti-retroviral drugs at prices that have lowered immensely the price bar for their nationals"; Ibid.

Article 31(h) by failing to ensure that the rights holder of drugs produced under a compulsory license be compensated in accordance with the "economic value of the authorization." Finally, pharmaceutical companies take issue with the policy of registering or granting marketing approvals to patents with pending appeals.

These are weak arguments founded on broad provisions within TRIPS, and premised upon faulty assumptions about the India Patents Act and the discretionary power afforded to TRIPS member nations. The pharmaceutical industry mischaracterizes the local working provision as categorical discrimination in the granting of patents to non-Indian rights holders by alleging that the local working provision violates the TRIPS Articles 27.1 and 3 requirement that patents be available to all innovators regardless of the location of origin or production of the patentable subject matter. This is incorrect. India is fully granting the patents of foreign applicants whether they produce locally or abroad. However, in some, but not all circumstances, where a patent holder does not manufacture locally, although able to do so, the patent holder must explain its decisions. Where the patent holder cannot do so or the market is not being adequately serviced, the absence of local manufacturing can legitimately be grounds for issuing a compulsory license. [53] This is in full accord with international customary law regarding the issue of compulsory licenses, dating back to the earliest patent law practices sanctioned in Article 5 of the Paris Convention.[54] Furthermore, rights holders maintain ownership of their patents and can continue to work them through import or local production despite the issuance of a non-exclusive compulsory license.

With regard to complaints that Form 27 is unduly burdensome due to its basis on a one-patent/one-product model, administrative difficulties with the structure of a form are an insufficient basis to classify India as a Priority Foreign Country, and complicated or ill-suited government forms are hardly uncommon, let alone unlawful. The information sought in the form is perfectly legal given India's legitimate concerns for technology transfer and need to collect information on the degree of

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[53] Doha Declaration (14/11/2001), available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm, at S. 5(2); Supra 44, at 4; Supra 44, at 7-8.

[54] Paris Convention for the Protection of Industrial Property (March 20, 1993; effective July 7, 1884, and amended June 2, 1934 and July 14, 1967), Article 5; Supra 44, at 7.

local manufacture. The fact that the form is not traditional in international practice does not render it unlawful.

If necessary, the form could be amended to address the needs of patent holders with multiple patents on a single medicine: simply adding an invention designation that would allow patents to be indexed with reference to product could suffice. Because India's purpose in gathering the information is lawful under international norms of compulsory licensing, Form 27 hardly warrants the attention of policymakers, and concerns regarding its structure would be better forwarded on to India's Controller General.

The assertion that India has not met the TRIPS Article 31(h) requirement of reasonable remuneration for patent holders in compulsory licensing cases is plainly false, as § 95 of the Patents Act provides that such rights holders will be given reasonable royalties and other remuneration, satisfying the 31(h) requirement.[55] Moreover, in the single license granted to date, the Indian Intellectual Property Appeals Board raised the royalty to 7%, a figure which is fully reasonable in medicines licensing agreements and higher than the rate granted on compulsory licenses in other countries.[56] In addition, many countries have royalty guidelines that would be satisfied by the granted 7% royalty.[57]

The complaint regarding the issuance of compulsory licenses during periods of pending appeal similarly mischaracterize a generous policy as destructive. A pending patent (the only kind of patent subject to appeal) is not a granted patent, so India would be within its rights to allow generic versions of these unpatented products to be sold without any of the guarantees or restitutions available to rights holders under compulsory licensing. By allowing generic versions of such products under a compulsory license regime, then, India is in fact granting the

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[55] Supra 1, at S. 95(1)(i) ("In settling the terms and conditions of a license granted under S. 84, the Controller shall endeavor to secure…that the royalty and other remuneration, if any, reserved to the patentee or other person beneficially entitled to the patent, is reasonable, having regard to the nature of the invention, the expenditure incurred by the patentee in making the invention or in developing it and obtaining a patent and keeping it in force and other relevant factors.").

[56] Compulsory licenses granted in Thailand had royalties ranging from .5% to 5%.

[57] James Love, *Remuneration Guidelines for Non-Voluntary Use of a Patent* (WHO & UNDP 2001), available at http://keionline.org/sites/default/files/who_undp_2005_royalty_guidelines.pdf.

patent applicant even greater rights than those to which they are entitled. The pharmaceutical industry's efforts to characterize India's compulsory licensing policy as reckless and underhanded have no leg to stand on.

3.3. Whether strict Patent regime and protection of Patents is considered to be a viable solution?

Opponents of patent reform point to India's 2013 GDP and claim that it has been negatively affected by weakening patent protection, pointing to the United States economy as an example of how strong patent protections drive economic growth and claiming that strong patent protections foster growth in developing nations. Contrary to this assertion, ample evidence exists to show that heightened intellectual property protections are actually bad for many low- and middle-income countries.[58] Stringent IP protections kick away the ladder of imitation that most developed countries use to develop their own technological capacity.[59] Economic and other evidence indicates that IP produces high prices for essential global goods, including medicines, educational resources, climate control and mitigation technologies, and agricultural products, and that access to such global goods is adversely affected in low- and middle-income countries.

Furthermore, holding India to a rigorous standard of IP protection actually undermines United States policy initiatives, such as the U.S. President's Emergency Plan for AIDS Relief and U.S. global AIDS programs, which are dependent for success on continued, robust Indian generic production of AIDS drugs through continued Indian use of WTO-compliant legal flexibilities.[60] Listing India on the 301 Watch List would undermine President Obama's declared priority of creating an "AIDS Free Generation," waste U.S. taxpayer funds, and imperil the PEPFAR program.

3.4. Whether arguments advances by Industrial Players are founded in Law?

Reviewing the briefs submitted by pharmaceutical players, the arguments listed in Sections I through III of this paper are the only ones

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[58] Brook Baker, *Debunking IP-For-Development: Africa Needs IP Space, Not IP Shackles*, African Law and Economic Development: International Perspectives 1 (in publication 2014).

[59] Ibid, at 2.

[60] Supra 44.

founded on legitimate legal or policy issues. The remainder (and majority) of the industry's arguments revolve around "boogey man" tactics designed to paint India as an unscrupulous pirate spear-heading an international coup against patent rights. The industry accuses India of claiming a dedication to access to medicine as a facade to mask its "true goals" of weakening IP rights worldwide and propping up its own economy by forcing rights holders to work their patents in India. They complain that India has violated "the spirit" of TRIPS by denying patent protection to innovators whose applications have been accepted in other countries, and claim that being so selective disincentives innovation, possibly leading to an end to all new invention. They claim also that any weakening of IP rights on the international stage, or discussion thereof in international fora, frightens innovators and investors and that the United States must vigorously oppose attempts at such weakening under "the spirit" of TRIPS.

These arguments are conclusory and disingenuous, and do not contain citations to law or real-world examples of the ill effects they foretell. It is important that those who allege catastrophic consequences show some foundation for their beliefs beyond "parade of horribles" assertions, particularly where history (in this case, India's IP regime before becoming TRIPS-compliant) has tended to prove otherwise. The United States pursues its IP interest according to national policy in international fora, and India has the clear right to do the same as a sovereign nation to which the United States should show comity, not enmity. Similarly, developing nations seeking to establish favorable IP policies should be free to choose a regime that suits their own national policy needs best in accordance with their sovereignty. If the United States and pharmaceutical companies' positions are losing the debate on the global stage to proponents of IP reform, India is hardly to blame. Suggesting that India has somehow coerced these developing nations into unfair or damaging policies is the patronizing, imperialist argument of a sore loser.

Similarly, it is disingenuous to argue that India's history of reducing prices for drugs by over 90% - sometimes over 99% - is not about access to medicines. Moreover, countries are allowed to issue compulsory licenses under the Paris Convention, the TRIPS Agreement, and national law, as confirmed by the Doha Declaration. They can do so in whole or in part based on the desire to achieve technology transfer and local pharmaceutical capacity. The arguments by anti-reformers that India is not sincere in its dedication to access to medicine because India

benefits economically from the effects of its efforts are duplicitous in that American industry asks the USTR and USITC to protect U.S. corporate interests with one side of its mouth, but demands that India should have not power to protect or promote its own industry (as long as that power threatens profit margins) out of the other.

The complaint that India has declined to grant patent protection in some cases where other countries have granted it is simply a function of the international patent system, and not attributable to unfairness in the India Patents Act or any other Indian IP policy. Countries have different patent standards and make different decisions with respect to the same application on a daily basis. As stated above, Japan only allows 14% of the patents allowed by the US.[61] The fact that a patent has been granted elsewhere, under different or less stringent standards, has no bearing whatsoever on whether a patent must be or should be granted in another country.

The industry makes much of the "spirit of TRIPS," but TRIPS is an international treaty, not a religious organization or a moral code, and meeting its spirit merely requires meeting its minimum harmonized standards. It doesn't mean adopting the higher standards codified in U.S. law and practice. If the United States truly believes that TRIPS standards are being violated by India, its sole and exclusive remedy is through the WTO multilateral dispute resolution procedures. In that case, the U.S. should not seek to retaliate for perceived violations by placing India on its special 301 watch list, but should deal frankly with its ally. Moreover, the United States Chamber of Commerce's Global Intellectual Property Committee (GIPC), which advanced this argument in its submission,[62] would do well to avoid the pot and kettle scenario created by the suggestion that any sort of IP weakening is illegitimate, as the United States Supreme Court has recently ruled against patents on isolated, naturally occurring genes, thus "weakening" patent rights in that regard.[63]

Although a favorite argument of proponents of strong IP rights, the assertion that strong IP protections incentivize innovation and those weak protections, conversely, disincentive or scare away innovation and investment is not necessarily supported. The evidence on whether IP

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[61] Supra 44, at 6.
[62] Supra 10, at 58.
[63] Association for Molecular Pathology v. Myriad Genetics, 569 U.S. 12-398 (2013).

incentivizes true innovation or whether it actually deforms R&D and blocks follow-on innovation is highly contested. Similarly, evidence of whether IP incentives direct foreign investment in low- and middle-income countries is highly contested.[64] India is not decreasing IP holders' rights overall, but enforcing the right they have under Indian law and using lawful flexibilities authorized by the TRIPS Agreement. As the saying goes, necessity is the mother of invention, and proposing that the mere discussion of weakening IP rights in international fora could result in a complete halt in innovation and investment therein worldwide is farcical.

4. CONCLUSION

Arguments that India should be sanctioned for its perfectly lawful activities that rely on scare tactics and conclusory allegations only serve to muddle the issue at hand, and further underscore the pharmaceutical industry's utter lack of legal support for its claims. Those legal arguments that the industry does advance are flimsy at best, relying upon "the spirit" of the law, broad provisions of TRIPS that do not directly address the industry's arguments, and mischaracterizations of India's policies. At present, India's patent reform has not been caused the downfall of pharmaceutical innovation, and as their policies are fully compliant with TRIPS and long-held international legal norms, the United States should respect India's sovereignty with regard to its own national policy at least until they can marshal a better argument supported by legal authority or credible evidence.

[64] Supra 56, at 1.