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Tripping Over TRIPS: Devloping Countries' Access to Lifesaving Medications

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I. Introduction

After years of pressure, the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) has become a prerequisite for any country if it wishes to join the World Trade Organization (WTO).[1] TRIPS is an international treaty which globalizes and regulates intellectual property. Article 31 in the TRIPS Agreement deals with authorized use of patents without the authorization of the patent holder.[2] In this article we specifically examine some problems and potential solutions of authorized use for emergencies provided for in Article 31. Many countries sign onto the TRIPS Agreement in order to benefit from joining the WTO. However, most developing

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[1] Kato Gogo Kingston, *The Implications of TRIPS Agreement 1994 of the World Trade Organisation for the Developing Countries*, 1 Afr. J. Soc. Sci. 37, 41-42 (2011); *See* Emir Aly Crowne, *Fishing TRIPS: A Look at the History of the Agreement on Trade-Related Aspects of Intellectual Property,* 2 Creighton Int'l & Comp. L.J. 77, 80 (2011).

[2] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 31, ¶ 2, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement].

countries are not equipped to meet the demands of the TRIPS Agreement, though they are allowed four years to comply with its requirements.[3] These third-world countries often need lifesaving drugs they cannot afford to produce themselves and cannot acquire without special provisions. Consequently, it is necessary to allow special provisions in the TRIPS Agreement to meet the pharmaceutical and health care needs of these developing countries. New provisions and clarifications are required to remove this barrier to pharmaceutical access. The dilemma lies in how to successfully implement such provisions. .

II. How TRIPS Has Limited Access to Lifesaving Medicines in Developing Nations

Without flexibility to tailor a country's patent laws to its economic climate and specific health care needs, implementation of strict patent protection can substantially limit drug availability to developing countries.[4] In addition, a lack of infrastructure supporting the research and patent process may make it impossible for *a nation* to deliver drugs to patients.[5] In an attempt to address this issue, a provision was added that least-developed countries will not be obligated, with respect to pharmaceutical products, to implement or apply Section 5 in Part II of the TRIPS Agreement[6] or to enforce rights provided for under these sections until January 1, 2016.[7] In addition, these countries

[3] *Id.* at art. 65; *See* Crowne, *supra* note 1, at 78-79, 93.
[4] Molly Land, *Rebalancing TRIPS*, 33 MICH. J. INT'L L. 433, 436 (2012).
[5] Stephen Barnes, *Pharmaceutical Patents and TRIPS: A Comparison of India and South Africa*, 91 KY. L.J. 911, 932 (2003).
[6] Section 5 defines patentable subject matter and the rights of an international patent holder.
[7] World Trade Organization, Ministerial Declaration on the TRIPS Agreement and Public Health of 14 November 2001, WT/MIN(01)/DEC/2, 45 I.L.M. 755 (2002).

can simultaneously benefit from Articles 30-32, which allow a waiver of authorization from a right holder during times of emergency.[8]

The TRIPS Agreement also contains a provision allowing a country during a state of emergency to use patentable subject matter without the authorization of the patent holder.[9] Paragraph 6 of TRIPS explains that an export license[10] can be limited to address a "grave" or "urgent" public health emergency such as HIV/AIDS or malaria.[11] Currently, the "emergency clause" under Article 31(a) states that such emergencies shall be authorized on "its individual merits."[12] Furthermore, under Article 31(b), if it is deemed a case of national emergency, the right holder must be notified that the government will be using its valid patent.[13] Past such a requirement, the treaty does not expand what the protocol is if the country cannot produce a generic equivalent of the patentable subject matter.[14]

Many developing countries tried to have "pharmaceutical products" defined within TRIPS to expand the provision in Article 31 to include vaccines, microbicides, blood tests and active ingredients that were separately patented.[15] The United States and European Union attempted to push back and create limitations for the emergency clause until the United States, in the wake of the anthrax scare post-September 11, 2001, found itself in need of the emergency clause provisions. Spurred by several deaths from anthrax-laden letters delivered to government offices, officials in

[8] TRIPS Agreement, *supra* note 2, at art. 31(b).
[9] *Id.*
[10] An export license permits a country to regulate what goods are exported out of the country.
[11] Brook K. Baker, *Arthritic Flexibilities for Accessing Medicines: Analysis of WTO Action Regarding Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, 14 IND. INT'L & COMP. L. REV. 613, 630 (2004).
[12] TRIPS Agreement, *supra* note 2, at art. 31(a).
[13] TRIPS Agreement, supra note 2, at art. 31(b).
[14] *See id.*
[15] Baker, *supra* note 11, at 635.

both the United States and Canada threatened Bayer, the patent owner of ciprofloxacin, a preferred anthrax treatment, with compulsory licenses if Bayer could not supply needed quantities of ciprofloxacin at low cost and in high volumes.[16] Suddenly, the United States' policy on the emergency clause changed when the urgency of public health concerns became a reality.[17]

Even now, with the support of the United States regarding broader availability of the emergency clause implementation, problems still exist with the emergency clause in the TRIPS Agreement. With the marriage of trade and intellectual property rights in the TRIPS Agreement, the threat of ill will and trade sanctions on non-compliant states has resulted in overcompliance[18] with what otherwise would be flexible provisions.[19] This overcompliance is due in large part to an overly strict interpretation of the articles that relax patent protection—including the provisions of Article 30 and 31.[20] For instance, Article 30 states:

> Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.[21]

Article 30 does not define the terms "unreasonably," "normal," or "legitimate."[22] Additionally, Article 31(b), which contains the emergency clause, fails to define "boundaries"

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[16] *Id. See also* Naomi A. Bass, *Implications of the Trips Agreement for Developing Countries: Pharmaceutical Patent Laws in Brazil and South Africa in the 21st Century*, 34 GEO. WASH. INT'L L. REV. 191, 217 (2002-2003) (explaining how the TRIPS agreement has negatively impacted developing countries--especially Brazil and South Africa.)
[17] Baker, *supra* note 11, at 625.
[18] Compliance beyond what is required by a strict interpretation of a treaty.
[19] Land, *supra* note 4, at 434. *See also,* Amy Kapczynski, *Harmonization and Its Discontents: A Case Study of Trips Implementation in India's Pharmaceutical Sector*, 97 CAL. L. REV. 1571, 1573 (2009).
[20] Land, *supra* note 4, at 442. *See also* Kapczynski, *supra* note 19, at 1573-74 ("Many developing countries, particularly the poorest ones, have adopted IP laws that are more restrictive than TRIPS requires.").
[21] TRIPS Agreement, *supra* note 2, at art. 30.
[22] Land, *supra* note 4, at 441.

and "standards."[23] Despite the Articles' room for positive need-based allowances for patented medicines, their enforcing entities have strictly interpreted and applied them.[24] As a result, in order to avoid sanctions, developing countries have erred on the side of caution and implemented more stringent intellectual property laws than are likely required for TRIPS compliance.[25]

A major factor in the over compliance in developing countries is a result of the "TRIPS plus" provisions found in regional trade agreements.[26] Developing countries have been pressured and coerced to accept commitments beyond those in TRIPS in a something of a quid pro quos arrangement often due to a variety of different kinds of political pressure and threats of unilateral sanctions.[27] These developing countries, without resources and bargaining power, are unable to assert their needs and interests against developed nations because they cannot bear the burden of trade sanctions or manufacture their own goods.[28] These developing countries cannot afford to test

[23] TRIPS Agreement, *supra* note 2, at art. 31(b) ("[S]uch use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable . . . .").

[24] Land, *supra* note 4, at 442.

[25] *Id.* at 441. *See also* Kapczynski, *supra* note 19, at 1573-74.

[26] *See* Charles T. Collins-Chase, *The Case Against Trips-Plus Protection in Developing Countries Facing AIDS Epidemics*, 29 U. PA. J. INT'L L. 763, 765 (2008) (These agreements are termed "TRIPS-plus" because they augment the intellectual property protection available to developed countries existing under TRIPS. This is not to say that TRIPS provides weak protection for developed countries. In fact, some scholars have argued that the TRIPS agreement not only provides protection that is too strong, but further that it is a coercive treaty of adhesion to which developing countries only acceded based on explicit or implied threats of trade sanctions.). *See also* Donald P. Harris, *Carrying A Good Joke Too Far: Trips and Treaties of Adhesion*, 27 U. PA. J. INT'L ECON. L. 681, 732 (2006) (The economic coercion applied by developed countries solidified the treaty as one of adhesion).

[27] *See* Matthew Turk, *Bargaining and Intellectual Property Treaties: The Case for A Pro-Development Interpretation of Trips but Not Trips Plus*, 42 N.Y.U. J. INT'L L. & POL. 981, 1006 (2010) (The economic consequences of TRIPS and the Uruguay Round substantially favored the United States at a cost to developing countries, while the results of TRIPS Plus FTAs are less one-sided.); Kapczynski, *supra* note 19, at 1573.

[28] Land, *supra* note 4, at 448.

the emergency clause boundaries provided in the TRIPS Agreement.[29] Thus, vague drafting and the threat of sanctions and litigation has led to overcompliance of Article 30 and 31 of the TRIPS Agreement across the board.

III. How the Need for Access to Medicines in Developing Countries May be Balanced with the Need to Maintain Incentives to Develop New Drugs

It would be difficult to create a "catch-all" treaty that satisfies the needs of every country. One of the difficulties with the TRIPS Agreement is that it does not allow a country to create reservations, unless all member parties consent. Signatory countries must otherwise abide by all articles of TRIPS.[30] However, what works for some countries regarding intellectual property protection may not work for all.

One potential solution proposed by Professor Alan Skyes is that "[g]overnments might commit themselves to eschew compulsory licensing or parallel imports, for example, in exchange for discounted sales of medicines to be administered to its poorest citizens and not to be resold to citizens who can afford the medicines at the usual price."[31] This proposed solution might help to remove some of the existing fear of loss of profits bothering the pharmaceutical patent holders, although it might be very difficult to keep track of and to enforce.

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[29] See *id.*

[30] TRIPS Agreement, *supra* note 2, at art. 72.

[31] Alan O. Sykes, *TRIPs, Pharmaceuticals, Developing Countries, and the Doha "Solution"* 24 (Univ. of Chic. Law School John M. Olin Law & Economics Working Paper No. 140, 2002), *available at* http://www.law.uchicago.edu/files/140.Sykes_TRIPs.pdf (emphasis in original).

One proposal is that developing countries should return to the bargaining table and undo the damage done by the emergency clause language in the treaty.[32] For instance, Professor Baker argues that "[i]nstead of relying on a highly conditioned, limited, and procedurally burdensome Article 31(f) solution, developed countries should go back to the simplified approach they championed for so long and that was subsequently endorsed by the European Parliament, the WHO, and leading NGOs around the world—a limited exception under Article 30 of the TRIPS Agreement."[33] Prof. Baker notes that a better solution may be to create a system with which all WTO members may access data on drugs so that the information may be available during a public health scare.[34] Alternatively, using Article 30 of the TRIPS Agreement to authorize export to non-producing countries would be a better solution.[35] These countries need to take a stronger stand and will be able to more effectively negotiate if they band together.

Implementing a standard of review for TRIPS cases could establish a foundation for effective implementation of the flexible provisions. To date, all attempts have failed to arrive at a mutually satisfactory standard of review.[36] Within this need for a standard of review is the need to evaluate based on a standard that recognizes human rights. One suggestion has been to draw "on the jurisprudence of the European Court of Human Rights...[and]...its lengthy experience in grappling with the question of how to exercise international supervision over a treaty that provides states with

[32] *See generally* Carlos Correa, *Integrating Public Health Concerns into Patent Legislation in Developing Countries*, Section X.2 (2000), *available at* http://apps.who.int/medicinedocs/en/d/Jh2963e/ (last visited Feb. 21, 2014) (advocating this approach).
[33] Baker, *supra* note 11, at 713.
[34] *Id.*
[35] *Id.*
[36] Land, *supra* note 4, at 462.

flexibility in meeting their obligations."[37] Additionally, human rights law could be considered, or there could be a "human rights presumption" when defining ambiguous areas or special situations needing interpretation, such as the emergency clause and other flexible provisions of TRIPS.[38] Another unique solution to the problem may be to allow reservations. A reservation is an international law concept defined as a "unilateral statement, however phrased or named, made by a State, when signing, ratifying, acceding to, accepting or approving a treaty, whereby it purports to exclude or to vary the legal effect of certain provisions of the treaty in their application to that State." [39] Conventions that preceded the TRIPS, such as the Paris Convention, had these mechanisms.[40] By allowing reservations, TRIPS would permit underdeveloped countries to have negotiating room before signing the agreement.

One encouraging development addressing the aforementioned problems is seen in India's new Patent Act of 2005.[41] The Act addresses a practice that was common among drug companies that would make a slight variation or change to a drug in order to extend the life of its patent rights.[42] The Act increased the threshold required to extend a patent right, so that slight changes or simple combinations of pre-existing drugs are no longer enough to extend the patent rights. This in turn increases the availability of generic drugs. Not surprisingly, pharmaceutical companies fought this, but lost, since the Act is constitutional under Indian law.[43] If more countries followed this scheme,

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[37] *Id*. at 471.
[38] *Id*. at 472.
[39] LOUIS HENKIN ET AL., INTERNATIONAL LAW CASES & MATERIALS 414 (2d ed. 1987).
[40] Ruth L. Gana, *Prospects For Developing Countries Under the TRIPs Agreement*, 29 VAND. J. TRANSNAT'L L. 735, 744-45 (1996).
[41] The Patents (Amendment) Act, No. 15 of 2005, India Code (1970).
[42] V.K. Unni, *Indian Patent Law and TRIPS: Redrawing the Flexibility Framework in the Context of Public Policy and Health,* 25 PAC. MCGEORGE GLOBAL BUS. & DEV. L.J. 323, 336 (2012).
[43] Novartis AG. & Natco Pharma Ltd. v. Union of India & Others, CIVIL APPEAL Nos. 2706-2716 (India 2013) (finding that (1) the court does not have jurisdiction over TRIPS; (2) section 3d was not unconstitutional or unreasonable; and (3) there was no unconstitutional delegation of a legislative function to the patent office.).

it is likely more generic drugs would become available with a lower price point making them more readily affordable for developing countries. Perhaps, even if a uniform solution within the TRIPS Agreement is not soon-coming, using India as a model, it may be possible for countries to address the problem individually.

IV. Conclusion

Action is required, and soon. Developing countries must have greater options to opt out of provisions that will not work for them. Precedent in TRIPS interpretation is being set by the inaction in defining flexibilities within the Articles, making it increasingly harder for developing countries to test the boundaries.[44] The longer the problem festers, the harder it will be to fix, with greater ensuing upheaval.

[44] Land, *supra* note 4, at 449.