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Regulation of Medicine Patents by the Anti-Counterfeiting Trade Agreement to Broaden Access to Medicine

By Daniel Lee[1]

One of the most concerning areas of recent patent enforcement is a life or death matter for thousands of people around the world. Restricted access to vital medicines in developing countries is one of the most controversial international intellectual property issues today. There is a new international treaty called the Anti-Counterfeiting Trade Agreement (ACTA) being negotiated among developed countries, and it is expected to bring a huge impact on access to medicine in developing countries.[2]

This article proposes what ACTA should include in order to protect access to medicine in developing countries. It discusses the need to allow broader compulsory licensing of pharmaceutical patents to encourage increased production of generic drugs and bring down the overall prices of essential medicine in developing countries. It also examines the need to regulate counterfeit drugs in order to promote research and development from pharmaceutical companies, while correctly distinguishing generic drugs from counterfeit drugs. Lastly, this article concludes by suggesting the need for a provision in ACTA that recognizes the importance of access to medicine provisions in multinational treaties over the regional and bilateral agreements.

The most recent major agreement on international intellectual property rights enforcement is the World Trade Organization Agreement on Trade Related Aspects of Intellectual Property (TRIPS) Agreement.[3] The TRIPS Agreement is an international agreement that sets the basic norms of international intellectual property standards along with other international agreements such as the World Intellectual Property Organization (WIPO) agreements.[4] The TRIPS Agreement extends patent terms in all fields of technology to twenty years, and requires that all WTO states provide patent protection for all inventions.[5] This requirement also applies to pharmaceutical patents, resulting in a significant restriction on vital medicines in developing countries.[6]

While every party involved agrees that large populations of developing countries lack meaningful access to health-related technologies, approaches to this problem differ significantly between developed countries and developing countries.[7] The International Bill of Human Rights acknowledges that access to medicine is a fundamental right of every person.[8] On the other hand, pharmaceutical companies must also protect their patent rights in order to secure their profit to keep producing medicines and seeking out innovations.[9]

There are some provisions in the TRIPS Agreement and the subsequent Doha Declaration that provide some flexibility to the restricted access to medicines resulting from TRIPS. Article 6 of TRIPS allows for "Parallel Importation", which happens when a patented good sold by the patentee is imported without his consent[10]; Article 2 of TRIPS recognizes continued application of the Paris Convention, which forces patent

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2. Margot Kaminski, *The Origins and Potential Impact of the Anti-Counterfeiting Trade Agreement*, 34 Yale J. Int'l L. 247, 247 (2009).

3. *See* Maxwell R. Morgan, *Medicines for the Developing World: Promoting Access and Innovation in the Post-TRIPS Environment*, 64 U. Toronto Fac. L. Rev. 45, 48 (2006) (explaining that the access to medicine issue transcends the recent heated debate on the implementation of TRIPS Agreement and its impact on medicine prices).

4. Susy Frankel, *Challenging TRIPS-plus Agreements: The Potential Utility of Non-Violation Disputes*, 12 J. Int'l Econ. L. 1023, 1039 (2009).

5. Morgan, *supra* note 2, at 48.

6. *Id.*

7. *See* Tina S. Bhatt, *Amending TRIPS: A New Hope for Increased Access to Essential Medicines*, 33 Brook. J. Int'l L. 579, 598-599 (2008) (discussing the lack of meaningful access to AIDS/HIV medicine in African countries due to high price while addressing the need of profit from patent by pharmaceutical companies to promote research and development).

8. Siddartha Rao, *Closing the Global Gap: A Pragmatic Approach to the Access to Medicines Problem*, 3 J. Legal Tech. Risk Mgnt.1, 3 (2008) (citing to Universal Declaration of Human Rights, Art. 25 (1)).

9. *See* Bhatt, *supra* note 5, at 601 (arguing that "patent protection is necessary for the continued availability of drugs").

10. Morgan, *supra* note 2, at 61.

holders to file foreign patent applications within a year from their domestic filing date in order to acquire an international patent;[11] Paragraph 7 of the Doha Declaration extends the TRIPS implementation for pharmaceutical products in the least developed countries until January 1, 2016;[12] and most importantly, Article 31 of the TRIPS Agreement allows for the compulsory licensing of pharmaceutical patents and for exportation of medicines produced under compulsory licenses to eligible importing member nations.[13]

Recently, there have been rounds of new bilateral trade agreements that impose additional enforcement of patent rights between developing nations and developed nations.[14] These bilateral and regional trade agreements are called "TRIPS-plus," and include additional intellectual property provisions in the Free Trade Agreements (FTA) among developed and developing countries.[15] The TRIPS-plus agreements deter developing nations from taking full advantage of the flexibility provisions in the TRIPS, by forcing them to adopt stricter intellectual property provisions.[16]

ACTA is still a work in progress, and thirteen countries, including the United States, have joined in the negotiations. Although the negotiation process has been kept confidential, some released material indicates that the new agreement will contain even stricter enforcement measures, including increased criminal sanctions for infringement and stronger border measures.[17] Considering ACTA's purpose and nature, it can be predicted that the agreement will further decrease access to medicines in developing countries.[18]

I. Broader Compulsory Licensing and More Generic Drugs: Profit Maximizing Pricing of Medicine by Pharmaceutical Companies Creates Deadweight Loss

Pharmaceutical companies holding drug patents have almost monopolistic control over the price of their medicine.[19] When pharmaceutical companies set a price for their medicine in a market, they usually pursue a profit-maximizing strategy, rather than considering what would allow for greater access to the medicine.[20] This strategy works because the demand for essential medicine is likely inelastic in theory, in that the demand by the consumers for the medicine will tend not to decrease as the price of the medicine increases.[21] This profit-maximizing pricing strategy consequently creates a large dead weight loss in developing countries.[22] Since the majority of the population in the least developed countries earns an income below the poverty line, a small increase of a medicine price can make medicines inaccessible for an enormous amount of people in need.[23] However, it is often more profitable and more efficient for the pharmaceutical companies in developing countries to impose a high price on their medicine and target the top percentage of a rich population, rather than selling the maximum possible quantity in a market.[24] Sometimes these medicine prices in developing nations are even higher than comparable drug prices in developed countries.[25]

An example is illustrated by Professor Sean Flynn of American University in Washington, D.C. According to 2006 UNAIDS data, there are 5.5 million HIV/AIDS patients in South Africa.[26] Assuming that HIV prevalence is uniform in the population, with each decile containing 550,000 people in need of antiretroviral treatment, if the price of an anti-retroviral is set at $1,481 per patient per year, only 550,000 people (10% of total HIV patients) can afford it.[27] The total revenue earned at this price point is $814.6

11. *Id.*
12. *Id.* at 63.
13. *See id.* at 60 (quoting F.M. Scherer & J. Watal, "Post-TRIPS Options for Access to Patented Medicines in Developing Countries" in Commission on Macroeconomics and Health Working Paper Series (Geneva: World Health Organization, 2001) Paper No. WG4:1 at 13).
14. *See* Bhatt, *supra* note 5, at 617-618 (arguing that new FTA Agreements made by the United States "contain provisions that far exceed the protections offered by TRIPS").
15. *Id.* at 618.
16. *See id.* (explaining that American bilateral and multilateral FTAs include provisions that limit exclusions of patentability, require broader definition of patents, prevent parallel importation, limit scope of compulsory license, and permit prosecution of non-violation claims).
17. Kaminski, *supra* note 1, at 247.
18. *See id.* (arguing that ACTA will likely be the strictest enforcement measures among many countries).
19. *See* Morgan, *supra* note 2, at 56 (arguing that in return for granting medicine patent holders monopolistic control over their patents, society gains full disclosure of the invention).
20. Sean Flynn, Aidan Hollis & Mike Palmedo, *An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries* 8 (U. of Calgary Dep't of Econ. Working Paper No. 2009-01).
21. *Id.* at 10.
22. *Id.* at 8.
23. *Id.* at 10.
24. *Id.* at 12.
25. *Id.* at 18.
26. Flynn, *supra* note 18, at 17.
27. *Id.*

million.[28] However, if the price of an antiretroviral is set at $396, about half of the total HIV patients can afford the anti-retroviral with total revenue of $435.6 million.[29] Further calculation by Professor Flynn shows that revenues keep falling as pharmaceutical companies reduce prices and increase production.[30] Thus, in South Africa, pharmaceutical companies will profit the most if they price their antiretroviral at $1,481, so that only the top ten percent of the population can afford it.[31] This is higher than the profit-maximizing price of $1,468 in Norway, where 80% of the population can afford the same medication at this price level due to their relatively uniform high income.[32]

II. Broader Compulsory Licenses Can Bring in More Generic Competition and Reduce the Price of Medicine and the Deadweight Loss

One of the most effective ways to bring down the cost of high priced essential medicine is to bring in more generic competition through more aggressive compulsory licensing.[33] Compulsory licensing means that a patent holder is compelled to grant a license to third parties to use the patent. It is often used in antitrust law and patent law.[34] As mentioned earlier, Article 31 of the TRIPS Agreement contains procedural requirements to obtain compulsory licenses. The unauthorized user must make a reasonable effort to obtain a license from the patent holder and provide adequate remuneration based on the economic value of the use.[35] However, TRIPS also waives these procedural requirements in case of a national emergency or other extreme urgency.[36]

The problem with the compulsory licensing flexibility is that only some developing countries have the infrastructure to take advantage of the provision and produce generic drugs under the compulsory license.[37] Most developing countries rely on the export and import of generic drugs produced by the few capable developing nations.[38] The August 30th Agreement, adopted by the TRIPS council in 2003 in addition to the TRIPS Agreement, outlines this import and export system procedure, but its "ad hoc, case-by-case, country-by-country procedural system" creates segmented markets.[39] This results in a substantial inefficiency to the compulsory licensing system and high transaction costs.[40] Entry of generic drugs into the market then becomes burdened, because demand for a generic drug by one particular segmented market often shows insufficient incentives for an overall generic entry.[41]

In addition, there is a growing concern regarding the seizure of generic drugs being transported from a developing country to other developing countries. European countries tend to impose local intellectual property laws on pass-though cargos, which pause briefly in these countries to refuel or change their mode of transportation on the way to their final destination.[42] These "transit countries" take the view that pass-through generic drugs are in violation of their local intellectual property laws and can be seized, regardless of their destination.[43] For example, in December 2008, Dutch customs authorities seized several cargos of the generic drug Losartan Potassium in transit from India to Brazil.[44] The Dutch customs authorities released the cargos after 36 days, but they released the cargos back to India instead of allowing the cargos to ship to Brazil.[45]

In order to encourage more efficient exportation and importation of generic drugs produced under compulsory license among developing countries, ACTA should simplify burdensome procedural requirements as much as possible. It should allow the generic drug market in developing countries to be viewed as a whole, in order to create enough demand for generic entry. Furthermore, ACTA should prohibit the transit countries from applying their local intellectual property laws to generic drugs in transit to developing countries,

28. *Id*. at 18.
29. *Id.*
30. *Id.*
31. *Id.*
32. Flynn, *supra* note 18, at 20.
33. Rao, *supra* note 6, at 15.
34. *Id.* at 8.
35. Morgan, *supra* note 2, at 60.
36. *Id.* at 61.
37. *Id.* at 64.
38. *See* i*d.* (explaining that the Article 31(f) of TRIPS allows a WTO member nation that has shown insufficient or no manufacturing capacities to import medicines produced under compulsory license).
39. *Id.* at 84.
40. *Id.*
41. Morgan, *supra* note 2, at 84.
42. ConsumerInternational.com, European Countries Imposing Local Intellectual Property Laws on Cargo Passing Through, http://www.consumersinternational.org (follow "member information" hyperlink; then follow "member news" hyperlink; then follow "generic drugs seized in transit: IP laws threatening access to affordable medicine" hyperlink) (last visited Nov. 1, 2009).
43. *Id.*
44. *Id.*
45. *Id.*

to ensure the fast and efficient supply of essential medicines to developing countries.

III. Funding for Innovation by Stronger Regulation on Counterfeit Drugs

Research and development of new drugs cost substantial amounts of money and involves high risks of unsuccessful products.[46] On the other hand, generic drugs bear little to no research and development costs and involve substantially fewer risks, since the drug is already proven to be successful.[47] This is why the introduction of generic alternatives of more expensive patented medicines in markets is often said to be the deterrent to research for innovative new drugs.[48] Pharmaceutical companies often view high profits as incentives for their patented technology, and when these incentives are low, they are reluctant to make investments to enter into the market and experiment with new drugs.[49]

In order to promote research and development of new drugs and vaccines for neglected diseases, incentives to pharmaceutical companies are needed while keeping generic competition in place.[50] There have been many mechanisms proposed to help research and development, such as public and private research funding, advance purchasing, and bulk purchasing.[51] However, these mechanisms are separate from ACTA since they involve voluntary funding and are not geared toward altering enforcement mechanisms.

One way that ACTA can help increase research and development of new drugs is by drawing a clear line between generic drugs and counterfeit drugs and imposing strict regulations to eliminate counterfeit drugs. Regulating counterfeit drugs through ACTA can have two positive effects. First, casualties caused by dangerous counterfeit drugs can be eliminated. Second, by gaining back the market share held by counterfeit drugs, pharmaceutical companies can increase their revenue and thus have more financial support for their research and development. However, it is important not to confuse generic drugs with counterfeit drugs since elimination of generic alternatives can only cause restricted access to medicine in developing countries.

A counterfeit drug is a medicine "which is deliberately and fraudulently mislabeled with respect to identity and source."[52] Unlike generic drugs, counterfeit drugs can have incorrect or inactive ingredients that can cause injuries or even death, instead of curing a disease.[53] Counterfeit drugs are extremely profitable because there is a high demand for affordable medicine from the large poor populations in developing countries.[54] Many customers in developing countries cannot distinguish between counterfeit drugs and generic drugs.[55] In Africa, counterfeit drugs encompass up to thirty percent of all medicines sold among developing African nations.[56] Inadequate knowledge and insufficient regulations continue to contribute to the expansion of counterfeit drugs.[57]

In 2006, the World Health Organization formed an international partnership called IMPACT to combat counterfeit drugs.[58] IMPACT's goal is to "eradicate counterfeit drugs by influencing legislation and increasing awareness".[59] There has not yet been an international treaty to regulate counterfeit drugs.[60] ACTA can be the first international treaty to regulate counterfeit drugs by imposing criminal and civil penalties for the production and distribution of counterfeit medicines, while keeping a wide door open to the production of generic drugs and compulsory

46. *See* Bryan Mercurio, *Resolving the Public Health Crisis in the Developing World: Problems and Barriers of Access to Essential Medicines*, 5 Nw. U. J. Int'l Hum. Rts. 1, 53 (2006) (explaining that research and development cost of drugs account up to thirty percent of total production costs: only 5 of every 250 compounds enter into clinical trials where over half of the compounds fail, and additional large numbers of fail at the regulatory stage).

47. See Morgan, *supra* note 2, at 82 (explaining that a generic drug company does not incur front-end investments cost associated with researching and developing new drugs even though there are still transaction costs and capital costs).

48. *See id.* at 56 (introducing an existing theory that monopolistic incentives from patent stimulate research and development by pharmaceutical companies).

49. Flynn, *supra* note 18, at 6.

50. *See* Morgan, *supra* note 2, at 99 (arguing that in addition to keeping medicine prices down in developing countries, new strategies to incentivize innovation are required).

51. *See id.* at 99-105 (explaining financial strategies such as pull and push mechanism, advance purchasing and orphan drug laws to promote innovation).

52. Amanda Chaves, *A Growing Headache: The Prevalence of International Counterfeit Pharmaceutical Trade in Developing African Nations*, 32 Suffolk Transnat'l Rev. 631, 633 (2009).

53. *Id.* at 637.

54. *Id.* at 635.

55. *Id.* at 637.

56. *Id.* at 636.

57. *Id.* at 637.

58. Chaves, *supra* note 45 at 644.

59. *Id.* at 645.

60. *Id.* at 646.

licensing.[61]

IV. Preemptive Power of TRIPS Over Regional Treaties

As mentioned in the introduction, flexibilities in multinational treaties such as TRIPS and ACTA can be jeopardized by bilateral and regional TRIPS-plus agreements.[62] TRIPS-plus agreements include intellectual property provisions in Free Trade Agreements between developed countries and developing countries, and they usually impose stricter domestic intellectual property enforcement than the multinational treaties.[63]

The TRIPS-plus provisions are usually unfair negotiations resulting from unequal economic power between the negotiating nations.[64] Developing nations are forced to agree upon the TRIPS-plus provisions in obtaining other bigger trade benefits.[65] The U.S. and the EU are known to have non-negotiable 'template' intellectual property chapters for the FTAs.[66]

For example, TRIPS-plus provisions in the U.S. bilateral and multilateral Free Trade Agreements include "limiting the potential exclusions from patentability, requiring the grant of patents for 'new uses' of known compounds, requiring the extension of patent terms under certain conditions, preventing parallel importation, limiting the ground on which compulsory licenses can be granted, and permitting the prosecution of non-violation nullification or impairment claims."[67] Any country that agrees to a Free Trade Agreement with the U.S. is bound by this term, which clearly limits or eradicates the flexibility provisions provided in the TRIPS Agreement and the Doha Declaration.[68]

It is true that the TRIPS Agreement allows the member nations to enact stricter enforcement provisions.[69] However, international law allows nations to make an international agreement with other nations under a condition that such agreements do not conflict with other international agreements of these nations.[70] Thus, TRIPS-plus add-on intellectual property provisions, such as the intellectual property provisions in FTAs, are international agreements that must obey the minimum standard and frameworks of the TRIPS Agreement to comply with basic international law.[71] It can then be said that by enforcing stricter intellectual property standards and taking benefits of the TRIPS Agreement away from developing nations, the TRIPS-plus provisions deteriorate the TRIPS Agreement in violation of international law.[72]

By continuing to push TRIPS-plus provisions, the U.S. and EU are violating an international treaty and standards that are viewed necessary by the rest of the world.[73] One way to resolve the problems caused by the TRIPS-plus agreements can be adopting a provision in ACTA that requires all of the negotiating nations to abide by the international treaties, such as ACTA and the TRIPS Agreement, prior to regional TRIPS-plus agreements. This provision will provide preemptive power to ACTA and the TRIPS Agreement over the TRIPS-plus provisions and deem conflicting TRIPS-plus provisions unenforceable.

Concerns regarding access to medicines in developing countries keep growing each day. The upcoming Anti-Counterfeiting Trade Agreement needs to demonstrate a new way to enforce intellectual property rights while preserving adequate access to medicine for developing countries. One way of supporting access to medicine is to provide wider access to generic drugs by allowing more compulsory licensing. Introduction of generic drugs in a market brings down drug prices and can offer greater access to essential medicine.

Introduction of generics lowers drug prices but also deters research and development of new drugs by pharmaceutical companies. There needs to be global research support mechanisms in place to encourage further innovation. In addition, by eradicating counterfeit drugs while carefully distinguishing them from generic drugs, ACTA can increase total revenue for pharmaceutical companies, and thus more money can be used for more research and development of new drugs.

However, all of these flexibilities and efforts for greater access to medicine can only be successful

61. *Id.* at 647.
62. Bhatt, *supra* note 5, at 618.
63. *Id.*
64. Frankel, *supra* note 3 at 1024.
65. *Id.*
66. *Id.*
67. *See also* Bhatt, *supra* note 5, at 618.
68. *Id.*
69. Frankel, *supra* note 3 at 1040.
70. *Id.*
71. *Id.*
72. *Id.*
73. Bhatt, *supra* note 5 at 619.

if all the parties to the treaty abide by it prior to other bilateral and regional agreements. If the U.S. and other members of the WTO are dedicated to increase access to medicine and the right to health, they should agree to adopt and abide by multinational treaties such as TRIPS and ACTA over the provisions in the TRIPS-plus agreements.