2013

Private Rights for the Public Good?

J. Janewa Osei Tutu, *Florida International University*

Private Rights for the Public Good?

J. Janewa OseiTutu*

"IP delivers safe products to our homes by allowing consumers to identify respected and safe brands."[1]

---

* Assistant Professor of Law, Florida International University College of Law; LL.M., McGill University; J.D., Queen's University; B.A. (Hons.), University of Toronto. I would like to thank the participants of the Junior International Law Scholars Association at New York Law School, the participants of the Arizona State University International Aspects of Intellectual Property Law Conference, the participants of the University of Miami Legal Theory Workshop, the participants of the Southeastern Law Scholars Conference, and the participants of the Stetson Scholarship Forum for their comments on presentations of this Article at various stages. I am grateful to Thomas Fossler, Shubha Ghosh, Adil Ahmad Haque, Cynthia Ho, Charles Jalloh, Henning Ruse Khan, Melissa Luttrell, Joelle Moreno, Markus Wagner, and Peter Yu for their helpful discussions and suggestions. Special thanks to Patricia Judd, Molly Land, and Hannibal Travis for providing detailed comments on previous iterations of this Article. Stephanie Cua and Stephano Salani provided excellent research assistance. All errors and omissions are my own.

1. David Hirschmann, Op-Eds., Trans-Pacific Partnership Agreement—A Win for All Countries, **Richmond Times Dispatch** (Sept. 12, 2012), available at http://www.uschamber.com/press/opeds/trans-pacific-partnership-agreement-win-all-countries.

"Ruling ensures access: Generic Version Upheld in India, in a Blow to Big Companies".[2]

The counterfeit medicines discussion is an example of how the use of a turbid rationale for greater intellectual property protections serves sophisticated private interests while potentially harming the public interest. The risk of harm created by counterfeit medicines provides a compelling counter-narrative to the access to medicines critique of intellectual property rights. Intellectual property advocates and the pharmaceutical industry have portrayed poor global enforcement of intellectual property rights as contributing to the proliferation of dangerous counterfeit medications. Yet, the deliberate linkage in the literature between weak intellectual property rights and the harms caused by counterfeit medicines provides a justification for new international treaties, such as the recent Anti-Counterfeiting Trade Agreement, that require increased government enforcement of intellectual property rights, even where the public interest justifications are relatively weak. The counterfeit medicines narrative gives private industry a public interest rationale instead of a profit-oriented rationale for demanding government enforcement of private intellectual property rights. This Article advocates a public interest test to determine when, and to what extent, government monitoring and enforcement of intellectual property rights is warranted.

I. INTRODUCTION

2. Gardiner Harris & Katie Thomas, Low Cost Drugs in Poor Nations Get Lift in Court: Ruling Ensures Access—Generic Version Upheld in India, in a Blow to Big Companies, **N.Y. Times**, Apr. 2, 2013, at A1.

VIII. CONCLUSION

I. INTRODUCTION

Intellectual property rights, and patent rights in particular, are blamed for creating barriers to access to medicines.[3] Nonetheless, transnational corporations convinced governments of the need for increased enforcement of intellectual property rights.[4] Moreover, it seems that corporations have convinced governments to take on the role of enforcer on their behalf. According to the U.S. Government, enforcing our intellectual property rights is not only important for the U.S. economy, it is "of paramount importance to protect the public health."[5]

How is it that ordinary citizens, including those who cannot afford their medicines, will potentially shoulder the cost of enforcing these private intangible rights? Further, what is the rationale for moving a traditionally privately enforced right further into the realm of government responsibility? This Article explores whether the risk posed by counterfeit medicines can adequately justify public enforcement of private intangible rights. The suggestion that increased enforcement of intellectual property rights benefits the public has been particularly compelling in the context of counterfeit medicines due to the intimation that there is some health and safety

3. Id.

4. **Exec. Office of the President**, **Counterfeit Pharmaceutical Inter-Agency Working Group Report to the Vice President of the United States and to Congress**, 1 (2011), available at http://www.whitehouse.gov/sites/default/files/omb/IPEC/Pharma_Report_Final.pdf.

5. Id. at 1.

benefit to the public.[6] Naturally, we would all like to take our medications knowing that they will help to heal us, not make us sicker or kill us. To this end, the U.S. Government established a Counterfeit Pharmaceutical Inter-Agency Working Group, which studied the issue and prepared a report containing a number of legislative recommendations for submission to the Vice President and to Congress.[7]

As this Article argues, even if enforcing intellectual property rights can help curb the trade in counterfeit medicines, the role of intellectual property is limited.[8] Moreover the safety argument is unjustifiably extended to intellectual property protected goods in general.[9] This Article concludes that potential health risks from counterfeit medicines provide a powerful counter-narrative to the "access to medicines" critique of intellectual property. The dangers created by

---

6. Id. at 1.

7. Id. The working group was comprised of the Intellectual Property Enforcement Coordinator, the Food and Drug Administration, the U.S. Customs and Border Patrol, the U.S. Immigration and Customs Enforcement, and the Departments of Justice, State, and Commerce. Id.

8. **World Health Organization**, **International Medical Products Anti-Counterfeiting Taskforce**, **Counterfeit Drugs Kill!** (2008), available at http://www.who-int/impact/FinalBrochureWHA2008a.pdf.

9. James M. Cooper, Conference Report, Piracy 101, 36 **Cal. W. Int'l L.J.** 89, 100–03 (2005).

counterfeit medicines[10] thereby artificially bolster the case for public enforcement of private intellectual property rights.

There are multiple layers to the global trend towards maximum intellectual property protection. One part of this trend involves the increase in intellectual property rights through the creation of global standards, and the other part is the enforcement of those standards.[11] Two interrelated questions arise. First, what is the relevance of increased intellectual property rights to enhancing the public welfare? Second, what role should governments have in monitoring and enforcing such rights? This Article focuses primarily on the second question. That is, when, and to what extent, should public resources be used to monitor and enforce private rights that are typically held by large multinational corporations? Intellectual property rights are private rights that are normally enforced by the rights holders.[12] Yet, international intellectual property

---

10. Note that counterfeit medicines are not generic medicines. A generic medicine is normally a safe, legitimate off-patent version of a drug. A counterfeit medicine, on the other hand, can be described as a fake or illegitimate version of a patented drug or a fake or illegitimate version of a generic drug.

11. Hirschmann, supra note 1.

12. Intellectual property rights are private rights, which the right holder is responsible for monitoring and enforcing. These are not public or quasi-public rights. Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) pmbl., Apr. 15, 1994, 1869 U.N.T.S. 299, 33 I.L.M. 1197, 1198; see also 15 U.S.C. §§ 1114, 1125 (2012). There are some limited exceptions to this to the extent that intellectual property offences have been criminalized or

agreements, like the recent Anti-Counterfeiting Trade Agreement[13] (ACTA), increasingly contemplate government monitoring and enforcement of these rights,[14] and industry associations requested similar measures in the highly secretive Trans-Pacific Partnership[15] (TPP) negotiations. Drawing on the power of the state has the practical effect of strengthening

---

enforced at the border. Cynthia M. Ho, Global Access to Medicine: The Influence of Competing Patent Perspectives, 35 **Fordham Int'l L.J.** 1, 59–62 (2011); Irina D. Manta, The Puzzle of Criminal Sanctions for Intellectual Property Infringement, 24 **Harv. J.L. Tech.** 469, 469 (2011).

13. See Anti-Counterfeiting Trade Agreement (ACTA), Dec. 3, 2010, 50 I.L.M. 243.

14. Id. pmbl. ("Noting further that the proliferation of counterfeit and pirated goods, as well as of services that distribute infringing material, undermines legitimate trade and sustainable development of the world economy, causes significant financial losses for right holders and for legitimate businesses, and, in some cases, provides a source of revenue for organized crime and otherwise poses risks to the public; Desiring to combat such proliferation through enhanced international cooperation and more effective international enforcement; Intending to provide effective and appropriate means, complementing the TRIPS Agreement, for the enforcement of intellectual property rights, taking into account differences in their respective legal systems and practices.").

15. Trans-Pacific Partnership (TPP): 19th Round of Negotiations Set for Bandar Seri Begawan, Brunei—August 23–30, 2013, **Office U.S. Trade Rep.**, http://www.ustr.gov/tpp (last visited Oct. 1, 2013).

protection for intellectual property rights.[16]

In this context, public enforcement refers to the requirement that government authorities actively monitor intellectual property infringing activities and assume responsibility for prosecuting apparent violations of intellectual property law.[17] This means that the burden and cost of monitoring and enforcing intellectual property rights shift from private rights holders to the public purse, and monitoring and enforcing intellectual property rights is expensive.[18] But does this shift from private enforcement to increased public enforcement of intellectual property

16. Cooper, supra note 9, at 101–03.

17. **United States Customs & Border Protection**, **What Every Member of the Trade Community Should Know About: CBP Enforcement of Intellectual Property Rights–An Informed Compliance Publication** (2012), available at http://www.cbp.gov/linkhandler/cgov/trade/legal/informed-_compliance_pubs/entone_ipr.ctt/enforce_ipr.pdf.

18. See Rochelle Cooper Dreyfuss & Andreas F. Lowenfeld, Symposium, Two Achievements of the Uruguay Round: Putting TRIPS and Dispute Settlement Together, 37 **Va. J. Int'l L**. 275, 302 (1997) ("[T]he cost to member states of enforcing intellectual property rights is formidable. Monitoring is expensive, the obligation to destroy infringing materials entails high social costs, and countries with weak civil justice systems must spend the money to create them. All of this is in addition to the cost of setting up copyright, trademark, and patent offices and staffing them with trained personnel. Even after these costs are borne, the TRIPS Agreement may present a significant problem to developing countries.").

rights benefit the public? This Article proposes the use of a public interest[19] test to assist in answering this question.

Given the appeal of the counterfeit medicines narrative, pharmaceutical companies and other intellectual property-reliant industries, such as the music and film industries, promulgate the self-serving view that increased public enforcement of intellectual property rights has a salutary effect, not only for private companies, but for all of us.[20] The potential harm caused by counterfeit drugs enables proponents of strong intellectual property rights to effectively make their case.[21] Clearly, counterfeit medicines may pose some public health risks, but does this harm

---

19. The "public interest" can be defined as "[s]omething in which the public, the community at large, has some pecuniary interest, or some interest by which their legal rights or liabilities are affected." **Black's Law Dictionary (**6th ed. 1990). There may be a variety of "public interests" that are affected by a particular provision in an agreement. The salient interest would need to be identified and used as the gauge for ascertaining the public benefit.

20. Amy M. Bunker, Deadly Dose: Counterfeit Pharmaceuticals, Intellectual Property and Human Health, 89 **J. Pat. & Trademark Off. Soc'y** 493, 512–13 (2007); Letter on Trans-Pac. P'ship Negotiations for Various Indus. Ass'ns to the President of the U.S. (May 8, 2012).

21. Hirschmann, supra note 1 ("Strong IP protection is about not only our economic progress but also enhancing global public safety. It is not uncommon for enterprises based overseas to capitalize on the popularity of a product or brand and repackage their untested products as legitimate. Consumers can easily be duped by these counterfeit goods and, depending on the product, can also suffer from identity theft or physical harm. IP delivers safe products to our

require an intellectual property solution?[22] Furthermore, should we encourage government enforcement of private intellectual property rights in order to protect the public? In particular, should this requirement be enshrined in international obligations, thereby reducing the ability of nations to independently make this determination in accordance with their national goals and values?

Unfortunately, the theory that government enforcement of intellectual property rights is beneficial to the individual consumer is a result of the conflation of distinct issues.[23] Wealthy corporations are successfully making the case for increased state enforcement of intellectual property rights by effectively framing the issue of intellectual property enforcement as a health and safety issue in order to advance their commercial interests.[24] However, the values that inform the positions taken by the intellectual property industries have been obfuscated.[25] This is because

---

homes by allowing consumers to identify respected and safe brands.").

22. As there is no ex officio border enforcement of patent rights, this would be limited to trademarks and copyrights. Ho, supra note 18, at 59–62; Manta, supra note 12, at 469.

23. See Letter on Trans-Pac. P'ship Negotiations from Various Indus. Ass'ns to the President of the U.S., supra note 20.

24. Even if this is a common business strategy, it doesn't mean it is one that we must accept.

25. See J. Janewa OseiTutu, Value Divergence in Global Intellectual Property Law, 87 **Ind. L.J.** 1639 (2012); see also R.A. Duff & Stuart P. Green, Introduction: Searching for Foundations, in **Philosophical Foundations of Criminal Law** 1 (R.A. Duff & Stuart P. Green eds., 2011) (pointing out that when deciding what should be criminalized, what makes normative

increasing protection for trademarks, copyrights, and patents is about enhancing the ability of intellectual property owners to generate revenue.[26] Indeed, the demands for state enforcement of private intellectual property rights are not limited to industries where there is some clear health and safety issue, but extend to a variety of intellectual property goods, ranging from designer bags to films.[27] This can result in poor policy development and provisions in international agreements that are neither well-justified nor appropriate, and which may be simultaneously under-inclusive and over-inclusive.[28]

When health and safety interests are used to justify the need for the government to take an active role in monitoring and enforcing intellectual property rights, such enforcement should be limited to instances where there are demonstrable health and safety concerns that intersect with intellectual property interests. On the other hand, if state enforcement of intellectual property rights is for reasons other than health and safety, these reasons should be evaluated in light of the relevant public interest. In other words, if government enforcement of intellectual property rights is about assisting the entertainment industry or the fashion industry, rather than diabetic patients,

---

sense partly depends on underlying values).

26. See Benjamin N. Roin, Unpatentable Drugs and the Standards of Patentability, 87 **Tex. L. Rev.** 503, 507–10 (2009).

27. See Letter on Trans-Pac. P'Ship Negotiations from various Indus. Ass'ns to the President of the U.S., supra note 20.

28. See Madhavi Sunder, From Goods to a Good Life: Intellectual Property and Global Justice 198, 198–99 (2012).

this should also be clear. This will enable us to make better policy decisions as we evaluate the utility of relying on public resources to protect the intellectual property interests at stake. Furthermore, when the public is aware and able to participate in a transparent dialogue, any laws created will have more legitimacy because they are more likely to reflect national values.

With a barometer against which to assess government intervention, it will be more readily apparent that not all counterfeiting should be painted with a broad brush and that not all intellectual property counterfeiting warrants government intervention.[29] Instead, as this Article argues, international agreements mandating government enforcement of intellectual property rights should be limited to instances where there is a public interest in such enforcement. A test that limits government intervention in monitoring and enforcing intellectual property rights to instances where such intervention is justified by the public interest will help to ensure that governments do not police intellectual property rights primarily to assist private actors under the guise of promoting the general welfare of society.[30]

The shift towards greater public enforcement of private intellectual property rights raises the broader issue of transparency[31] in law making. This Article utilizes the counterfeit medicines

---

29. See id.

30. **Lawrence O. Gostin**, **Public Health Law: Power, Duty, Restraint** 92 (2d ed. 2008) ("The police power represents the state's authority to further the goal of government: to promote the general welfare of society.").

31. Webster's Dictionary defines "transparent" as "easily detected: obvious" or "readily understandable." **Webster's Dictionary** (11th ed. 1984). Transparency is used here in the

discussion as an example of how employing a turbid rationale for greater intellectual property protections serves sophisticated and resourceful private interests while potentially harming the public interest. In particular, the ability of individual nations to craft suitable domestic approaches to intellectual property enforcement is quietly being eroded. Transparency in law making leads to better laws.[32] However, there is a lack of transparency with respect to the negotiating process and the justifications for provisions in international agreements that require the government to police intellectual property violations.[33]

Drawing on the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and a public interest framework, this Article explores whether, and to what extent, we should accept the need to protect the public health as a justification for public enforcement of private intellectual property rights.[34] The justification and rationale for government enforcement of

---

ordinary sense of the word.

32. See Diane Dilanni, The Legal Framework of Transparency and Accountability within the Context of Privatization, **League Women Voters** (2011), available at http://www.wv.org/content/legal-framework-transparency-and-accountability-within-context-privatization.

33. Proposed I.P. Trade Agreement Sparks Alarm Due to Lack of Transparency, **Ctr. for Democracy & Tech.** (2008), http://www.cdt.org/policy/proposed-ip-trade-agreement-sparks-alarm-due-lack-transparency.

34. The exceptions to the private enforcement norm are limited to the criminalization of intellectual property infringement and enforcement of intellectual property rights as goods enter

intellectual property rights is relevant for a number of reasons. First, intellectual property enforcement affects the intellectual property standards that exist in practice because administrative enforcement by governments can result in standards that are effectively higher than the law requires.[35] Second, trends at the international level have an impact on what happens domestically, and vice versa.[36] Obligations that nations take on through international agreements become part of domestic law, and domestic laws and policies can serve as the impetus behind certain provisions in international agreements.[37] Third, the way the dialogue is framed impacts the outcome.[38] The narrative affects the language that is adopted in international agreements and domestic legislation, as well as the judicial and public understanding of—and reaction to—the ensuing legislative changes.[39]

Part II provides a brief background to the problem.[40] Part III elaborates on the access to

---

the country. See Ho, supra note 12, at 59–62; Manta, supra note 12, at 469–70. In both those instances, the burden of enforcement shifts to the government. See Manta, supra note 12, at 494.

35. For instance, limitations and exceptions are likely to only be taken into account after an intellectual property protected good as been detained at the border.

36. See Effects of Domestic Law on International Law, **Int'l Judicial Monitor** (2006), http://www.judicialmonitor.org/arhive0706/generalprinciples.html.

37. See id.

38. Ho, supra note 12, at 3–6.

39. Id.

40. See infra Part II.

medicines debate and explains how the counterfeit medicines narrative enables intellectual property owners to respond to the access to medicines critique.[41] Part IV describes the harms caused by counterfeit medicines, and explains the confusion relating to the use of the term "counterfeit."[42] Part V outlines the role of intellectual property law as it relates to counterfeiting.[43] Part VI proposes a public interest framework—specifically, the use of a health and safety test in the context of counterfeit medicines—as a litmus test for government enforcement of private intellectual property rights.[44] The purpose of such a test is to assist in reframing the discussions of counterfeit medicines and to help clarify when there is a public interest served by requiring national governments to enforce private intellectual property rights.[45] Finally, this Article employs the proposed test to evaluate some of the current trade-related intellectual property agreements.

II. BACKGROUND AND CONTEXT

The World Trade Organization (WTO) was established in 1994.[46] WTO members had to

41. See infra Part III.

42. See infra Part IV.

43. See infra Part V.

44. See infra Part VI.

45. Note that the relevant intellectual property rights may be held by foreign corporations. In fact, it could be against the national interest, depending on whom the intellectual property owner is, for the government to take on the role of enforcer.

46. Marrakesh Agreement Establishing the World Trade Organization (WTO Agreement),

commit to several agreements in order to be part of the organization.[47] One of these was an agreement that created minimum standards for intellectual property rights.[48] This intellectual property agreement, TRIPS,[49] harmonized the global intellectual property standards in a trade-based regime for the first time.[50] TRIPS covers seven categories of intellectual property, including patents, copyrights, trademarks, and geographical indications.[51]

Better enforcement of intellectual property rights was an important goal of TRIPS.[52] This is because the pre-existing international agreements, such as the Berne Convention[53] and the Paris Convention,[54] were considered inadequate by intellectual property producers, like the United States and the European Union, because they did not establish substantive norms or have any

---

Apr. 15, 1984, 1867 U.N.T.S. 154, 33 I.L.M. 1144.

47. Id. art. II.2.

48. Id. Annex 1C.

49. TRIPS, supra note 12, art. 4.

50. Id. arts. 1.2, 2, 9, 15, 22, 27.

51. Id.

52. Id. pmbl.

53. **Berne Convention for the Protection of Literary and Artistic Works** (**Berne Convention**), S. Treaty Doc. No. 99-27 (2d Sess. 1986).

54. **Paris Convention for the Protection of Industrial Property** (**Paris Convention**), Mar. 20, 1883, 21 U.S.T. 1583, 828 U.N.T.S. 305 (as revised at convention done at Stockholm, July 14, 1967).

effective enforcement mechanisms.[55] The WTO mechanism made enforcement possible through dispute resolution between countries.[56] Under this system, private entities continue to rely on domestic courts to resolve individual disputes.[57] The WTO dispute resolution process is only available to governments when a WTO member state is not respecting its WTO obligations.[58] Hence, enforcement through the WTO is distinct from government enforcement of intellectual property rights at the national level.[59]

Since the establishment of the WTO and the adoption of TRIPS, global intellectual property law has been criticized as reflecting a "top-down" approach to intellectual property regulation that is designed to meet the objectives of wealthy states.[60] Numerous scholars have commented

---

55. Marshall A. Leaffer, Protecting United States Intellectual Property Abroad: Toward a New Multilateralism, 76 **Iowa L. Rev.** 273, 293–94 (1991).

56. Understanding on Rules and Procedures Governing the Settlement of Disputes art. 1, Apr. 15, 1994, 1869 U.N.T.S. 299, 33 I.L.M. 1125.

57. Alberto Alemanno, Private Parties and WTO Dispute Settlement System (Cornell Law School LL.M. Paper No. 1, 2004), available at http://scholarship.law.cornell.edu/cgi/view content.cgi?article=1000&context=lps_clacp.

58. Understanding on Rules and Procedures Governing the Settlement of Disputes art. 1, supra note 56.

59. Id.

60. Margaret Chon, Intellectual Property "From Below": Copyright and Capability for Education, 40 **U.C. Davis L. Rev.** 803, 805 (2007) ("Global intellectual property regimes reflect

on the current imbalance between protection and access in the global intellectual property regime.[61] Some have noted the detrimental impact on developing countries, most of whom do not

---

a top-down approach to global intellectual property regulation, following from the interests and needs of intellectual property-rich states.").

61. Keith E. Maskus & Jerome H. Reichman, The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods, 7 **J. Int'l Econ. L.** 279, 286 (2004) ("[S]erious questions arise as to the sustainability of the attempt in TRIPS to resolve the international externality aspects of protecting new knowledge goods. An additional criticism leveled at the emerging IPR system is that the agenda for increasing protection has been articulated and pushed by rich-country governments effectively representing the commercial interests of a limited set of industries that distribute knowledge goods."); Sisule F. Musungu & Graham Dutfield, Multilateral Agreements and a TRIPS-Plus World: The World Intellectual Property Organisation (WIPO) (TRIPS Issues Papers No. 3, 2003), available at http://www.geneva.quno.info/pdf/WIPO(A4) final0304.pdf (noting that the appropriateness of the standards contained in the TRIPS Agreement for developing countries has been seriously questioned, and that the TRIPS standards may be too high for these countries); Joseph Straus, The Impact of the New World Order on Economic Development: The Role of Intellectual Property Rights System, 6 **J. Marshall Rev. Intell. Prop. L.** 1 (2006) ("[I]n 1994, TRIPs was at the center of multifaceted criticism, for both developing and developed countries."); see James Boyle, A Manifesto on WIPO and the Future of Intellectual Property, 2004 **Duke L. & Tech. Rev**. 9 (2004) (critiquing TRIPS).

have strong intellectual property industries.[62] Others have critiqued the effect of excessive intellectual property protections on access to intellectual property protected goods for consumers

62. Carlos M. Correa, Public Health and Patent Legislation in Developing Countries, 3 **Tul. J. Tech. & Intell. Prop.** 1, 2 (2001); Rochelle Cooper Dreyfuss & Andreas F. Lowenfeld, supra note 18 ("Now that there is time to be more reflective, we should recognize that as far as developing countries are concerned, the TRIPS Agreement could have a substantially different impact from the remainder of the WTO agreements. One effect is obvious: the cost to member states of enforcing intellectual property rights is formidable. Monitoring is expensive, the obligation to destroy infringing materials entails high social costs, and countries with weak civil justice systems must spend the money to create them."); Ruth L. Okediji, The Regulation of Creativity Under the WIPO Internet Treaties, 77 **Fordham L. Rev.** 2379, 2405–06 (2009); Jerome H. Reichman & Rochelle Cooper Dreyfuss, Harmonization Without Consensus: Critical Reflections on Drafting a Substantive Patent Law Treaty, 57 **Duke L.J.** 85, 92 (2007) ("[T]he dynamics of TRIPS and the post-TRIPS trade agreements teach that even a development-sensitive negotiation process is likely to produce an instrument that furthers interests of developed countries at the expense of poorer, less powerful participants."); J.H. Reichman, Comment, Enforcing the Enforcement Procedures of the TRIPS Agreement, 37 **Va. J. Int'l L.** 335, 349 (1997) ("[D]eveloping countries face real difficulties in overcoming technological lag at socially acceptable costs, and most of the benefits they may derive from implementing the substantive standards will take time to accrue.").

everywhere.[63] Thus, some scholars suggest models that take into account the need for accessible

63. **James Boyle, The Public Domain: Enclosing the Commons of the Mind** 8–9 (2008) (explaining that intellectual property law does not necessarily work as it should, but sometimes does the exact opposite, becoming "a kind of perpetual corporate welfare—restraining the next generation of creators instead of encouraging them"); **Lawrence Lessig**, **The Future of Ideas: The Fate of The Commons in a Connected World** (2001); James Boyle, The Second Enclosure Movement and the Construction of the Public Domain, 66–SPG **Law & Contemp. Probs.** 33, 37–41 (2003) (describing the expansion of intellectual property rights); Margaret Chon, Postmodern "Progress": Reconsidering the Copyright and Patent Power, 43 **DePaul L. Rev.** 97, 133 (1993) ("For example, many lesser developed, and even moderately industrialized, countries refused to allow pharmaceuticals to be patented. The primary reason for this is that pharmaceutical prices would then rise, impeding consumer access to the benefits of this technology. Western drug companies view this simply as a denial of fair market access."); Carlos Correa, Internationalization of the Patent System and New Technologies, 20 **Wis. Int'l L.J.** 523, 529–30 (2002) ("Patents on genes restrict the use of what are essentially research tools. Access to these tools, and hence the progress of science, may be slowed down, particularly in developing countries and in public research institutions, by the need to obtain multiple licenses and the escalation of research costs from license fees."); Reichman & Dreyfuss, supra note 62, at 91–92 ("As the endless controversies surrounding pharmaceutical patents demonstrate, higher standards of global protection—whatever their incentive effects—also generate severe and unintended distributional consequences for the developing world.").

and affordable knowledge goods as a way to respond to the imbalance in the global regime.[64] In particular, the access to medicines critique, which will be discussed in more detail in the next Part of this Article,[65] has been effective in raising public awareness about the possible deleterious effects of excessive intellectual property protection.[66]

Despite criticisms that the system is tilted too far in favor of the rights holders, there are still calls for higher intellectual property standards and increased intellectual property enforcement.[67] For instance, there has been a proliferation of agreements described as "TRIPS-Plus," which are aimed at further increasing intellectual property protection. While some commentators have attempted to treat TRIPS standards as a ceiling,[68] many more have described TRIPS standards as

---

64. Chon, supra note 60, at 805, 813.

65. See infra Part III.

66. Peter K. Yu, Intellectual Property and Human Rights in the Nonmultilateral Era, 64 **Fla. L. Rev.** 1045, 1077–78 (2012).

67. Shanker A. Singham, Symposium, Competition Policy and the Stimulation of Innovation: TRIPS and the Interface Between Competition and Patent Protection in the Pharmaceutical Industry, 26 **Brook. J. Int'l L.** 363, 363–64 ("Only a strong intellectual property system can best serve the needs of people around the world. Such a system would promote greater competition because it would allow market forces to set prices and, as part of a larger competition policy, would create a better functioning system with significant social economic gains.").

68. Henning Ruse-Khan & Annette Kur, Enough is Enough—The Notion of Binding Ceilings in International Intellectual Property Protection, (Max Planck Inst. for Intell. Prop., Comp. &

"minimum" standards for intellectual property upon which to build.[69] Indeed, some WTO members consider TRIPS enforcement provisions inadequate.[70] Hence, there is a trend described as a "ratcheting up" of intellectual property standards through various trade mechanisms.[71] These range from bilateral investment treaties[72] to bilateral trade agreements[73] and multilateral

---

Tax Law Research Paper ser. No. 09-01, 2008) available at http://ssrn.com/abstract=1326429.

69. J.H. Reichman & David Lange, Symposium, Bargaining Around the TRIPS Agreement: The Case for Ongoing Public-Private Initiatives to Facilitate Worldwide Intellectual Property Transactions, 9 **Duke J. Comp. & Int'l L.** 11, 34 (1998) ("Later commentators have, however, begun a more realistic assessment of these enforcement procedures, which on closer inspection appear to constitute a set of truly minimum standards of due process on which future legislation will have to build.").

70. Peter K. Yu, Shaping Chinese Criminal Enforcement Norms Through the TRIPS Agreement, in **Criminal Enforcement of Intellectual Property: A Handbook of Contemporary Research** 286, 286–87 (Christophe Geiger ed., 2012).

71. See id.; Deborah Gleeson & Ruth Lopert, Symposium, The High Price of "Free" Trade: U.S. Trade Agreements and Access to Medicines, 41 **J.L. Med. & Ethics** 199, 199 (2013).

72. Bilateral Investment Treaties, **Office U.S. Trade Rep.**, http://www.ustr.gov/trade-agreements/bilateral-investment-treaties (last visited Oct. 1, 2013).

73. Peter Drahos, BITs and BIPs: Bilateralism in Intellectual Property, 4 **J. World Intell. Prop.** 791, 798 (2001).

agreements such as the Anti-Counterfeiting Trade Agreement[74] and the ongoing Trans-Pacific Partnership Agreement negotiations.[75]

Arguments in support of increased global intellectual property protection often refer to the harms caused by counterfeit goods,[76] and counterfeit medicines in particular.[77] For intellectual property owners, having governments take on some of the burden of enforcement not only reduces their costs, but also makes it easier for them to pressure their own governments to

---

74. See ACTA, supra note 13

75. See TPP, supra note 15.

76. Beverly Earle et al., Combating the New Drug Trade of Counterfeit Goods: A Proposal for New Legal Remedies, 20 **Transnat'l L. & Contemp. Probs.** 676, 678–79 (2012) ("Furthermore, the problem is not only a question of lost dollars. While fashion knockoffs threaten substantial financial losses to the companies that make the originals, there are greater threats to unknowing consumers than simply a broken zipper. Many counterfeits are dangerous, such as automobile, airplane, and computer parts, as well as drugs.").

77. Daniel R. Cahoy, Addressing the North-South Divide in Pharmaceutical Counterfeiting, 8 **Wake Forest Intell. Prop. L.J.** 407, 426 (2008) ("All nations realize that widespread availability of dangerous fakes puts their own citizens at risk, at least indirectly. And it is certain that pharmaceutical companies have a strong interest in preventing the disruption to the safety and security of the market. Therefore, it is not surprising that a number of anti-counterfeiting initiatives have emerged with government-industry partnerships."); see also Bunker, supra note 20, at 497–99.

require compliance from foreign governments.[78] Thus, there is a trend toward increased intellectual property protection and enforcement, while at the same time, a strong critique of the detrimental impact of intellectual property rights on access to goods, and access to medicines in particular.[79] As the next Part argues, framing of the issues is an important part of the dialogue about adequate levels of intellectual property protections.[80]

III. FRAMING THE DEBATE

A. Intellectual Property and Access to Medicines

Those who promote increased intellectual property protections suggest that it will be in the long-term interest of countries such as India, China, and Nigeria to protect intellectual property.[81] This not only stimulates their economies, but also protects the health and safety of their citizens.[82] However, intellectual property industries faced a tremendous backlash over the past several years.[83] A number of scholars argue that the minimum intellectual property standards

---

78. Peter K. Yu, TRIPS and its Achilles' Heel, 18 **J. Intell. Prop. L.** 479, 487–88 (2011).

79. Canoy, supra note 77, at 426–28.

80. See infra Part III.

81. Earle et al., supra note 76, at 732. ("IP will be an engine of growth for both China and India. It will be in their long-term interest to protect intellectual property. Counterfeit goods may also affect their citizens' health and safety.").

82. Id.

83. Boyle, supra note 61, at 12 (noting the imbalance created by the expansionist intellectual property agenda).

imposed by TRIPS are detrimental to economically disadvantaged individuals and to the developing world.[84] Another observation is that the current regime lacks balance because it is skewed in favor of the right holders.[85] In particular, the global increase of intellectual property leads to serious concerns about the impact of intellectual property rights on access to life-saving medicines because of the changes that arose with the implementation of TRIPS.[86] For instance, although India did not provide patent protection for pharmaceutical drugs prior to TRIPS, it had

---

84. Sunder, supra note 22, at 198–99 ("A one-size-fits-all patent system for drugs in the developing world is unjust on additional grounds, beyond incentives. Patents that impede access to the poor thwart both local democracy and human development. Nations must have the freedom to democratically construct patent policies to meet their humanitarian needs.").

85. Boyle, supra note 61, at 11 (encouraging a return to the "rational roots of intellectual property rather than an embrace of its recent excesses").

86. Yu, supra note 66, at 1075–76 ("The most widely cited debate concerns the much-needed access to essential medicines in less developed countries, which was impeded by the strong protection of patents and clinical trial data . . . This debate has caught the attention of the WTO, WIPO, WHO, and other international intergovernmental bodies."); see Peter Drahos, Four Lessons for Developing Countries from the Trade Negotiations Over Access to Essential Medicines, 28 **Liverpool L. Rev.** 11, 16–17 (2007); Ellen 't Hoen, TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha, 3 **Chi. J. Int'l L.** 27, 27 (2002).

a thriving generic drug industry.[87] After the establishment of the WTO and TRIPS, India was required to provide patent protection for medicines.[88] Indeed, India was one of the first countries to appear before the WTO for allegedly failing to protect intellectual property rights as required under TRIPS.[89]

Scholars have also noted the potentially detrimental impact of intellectual property rights on the ability of individuals who lack financial resources to access the medications they need.[90] In response to the argument that life-saving medications would not be available without adequate

---

87. Frederick M. Abbott, The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health, 99 **Am. J. Int'l L.** 317, 320–321 (2005).

88. See TRIPS, supra note 12, arts. 27, 66.1.

89. **World Trade Org.**, **WT/DS50/AB/R, India—Parent Protection for Pharmaceutical and Agricultural Chemical Products** (1997), available at http://www.wto.org/english/tratop_e/dispu_e/tripab.pdf.

90. Amy Kapczynski, The Cost of Price: Why and How to Get Beyond Intellectual Property Internalism, 59 **UCLA L. Rev.** 970, 996 (2012) ("According to the World Health Organization, these gains are largely attributable to '[t]he application of knowledge from health research' to improve, for example, sanitation and access to vaccines. These gains are, of course, unevenly distributed, and up to ten million lives per year could be saved simply by providing better access to existing informational goods such as medicines and vaccines. More research aimed at developing new vaccines and medicines for diseases that particularly affect the poor in developing countries could save many more lives still."); Sunder, supra note 28, at 173–78.

patent protection, Professor Sunder points out that patents are "but one among many alternatives for stimulating and rewarding innovation, including prizes and subsidies."[91] She goes on to observe that while patented drugs save lives, they save "only the lives of those who are willing and able to pay."[92] Thus, according to this critique of the current model, poor people may not benefit from the kind of innovation that the current patent system promotes.[93]

Although patent protection is not necessarily the primary barrier for access to medicines, patent protection is relevant to access to the extent that it affects the costs of the medicines.[94] Hence, pharmaceutical companies find themselves highly scrutinized for creating obstacles to the health of those who cannot afford the medicines.[95] From this perspective, intellectual property

---

91. Sunder, supra note 28, at 175.

92. Id. ("Second, patents do save lives, but primarily only the lives of those who are willing and able to pay.").

93. Id. at 174 ("Indeed, the evidence is mounting that in crucial ways patents fail to promote the health of people in the developing world, and in some cases in the developed world as well."); id. at 178 ("Patents fail to incentivize research that addresses poor people's diseases; patents offer little incentive for R&D in poor countries, which lack basic technological capacity; the patented drugs produced by multinationals are priced out of reach of the poor; and finally, Big Pharma will not allow generic drug production in the developing world.").

94. Abbott, supra note 87, at 322–23.

95. Kevin Outterson, Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets, 5 **Yale J. Health Pol'y**, **L. & Ethics** 193, 201–02

rights are viewed as impediments to access and harmful to the interests and lives of those who are affected.[96] While most of the drugs that are considered "essential" by the World Health Organization are no longer protected by patents, many new and more effective medications, including medications used to treat non-communicable disease like asthma and diabetes, may be

---

(2005) ("The social costs of making pharmaceutical knowledge appropriable are generally three-fold. First, the cumulative effect of these laws allows the innovator to charge a higher price under monopolistic conditions . . . Second, these higher prices hinder medical access, directly impacting the health of many low income people globally."); James T. Gathii, Approaches to Accessing Essential Medicines and the TRIPS Agreement, in **Intellectual Property and Information Wealth** 393 (Peter K. Yu ed., 2006).

96. But see Benjamin N. Roin**,** Unpatentable Drugs and the Standards of Patentability, 87 **Tex. L. Rev.** 503, 508 (2009) ("In the pharmaceutical industry, firms must invest hundreds of millions of dollars in clinical trials on their drugs before they can be sold to the public, while their generic rivals are exempted from those requirements and can enter the market at low cost. Without some way to delay generic competition, therefore, pharmaceutical companies would usually find it impossible to recoup their R&D investments and would likely invest their money elsewhere. With strong patent protection, however, firms can expect to enjoy a lengthy monopoly over their drugs, providing them an opportunity to profit from their investment in R&D. Although the public suffers from high prices for drugs while they are covered by a patent, most of those drugs probably would not have been developed without that protection. As a result, it is widely thought that the benefits of drug patents far outweigh their costs.").

patented.[97] Thus, TRIPS was significant in terms on its impact on the global pharmaceutical market.[98]

Concerns about the effect of increased intellectual property rights on the public health led to a statement from WTO members about the relationship between the two.[99] In the Doha Declaration

---

97. Abbott, supra note 87, at 322–23; see also, e.g., Azadeh Momenghalibaf, Indian Court Limits Frivolous Drug Patenting, Clearing Path to Affordable Medicines, **Open Soc'y Found.**, Jan. 3, 2013, available at http://www.opensocietyfoundations.org/voices/indian-court-limits-frivolous-drug-patenting-clearing-path-affordable-medicines?utm_source=health_A&utm_medium=email&utm_content=text_lInk1&utm_campaign=Health_A_011613 (asking "[s]hould pharmaceutical patents—which result in monopolistic pricing of medicines—apply to any new drug, regardless of how it was made and whether it offers anything new?" and applauding the Indian Patent Appeal Board for revoking a patent held by Roche on the basis that it was not novel).

98. Abbott, supra note 87, at 323 ("In considering this issue, the broad scope of the change that took place on January 1, 2005, must not be overlooked. The mandatory requirement of patent protection for pharmaceutical products is not directed to a narrow range or class of medicines. It will affect the world pharmaceuticals market generally and reshape the economy of supply.").

99. See **World Trade Org.**, **WT/MIN(01)/DEC/2**, **Declaration on the TRIPS Agreement and Public Health** (**Doha Declaration**), 41 1.L.M. 755, para. 4 (2002) ("We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect

on TRIPS and Public Health, WTO members agreed that intellectual property rights should not interfere with public health.[100] They recognized the need for intellectual property protection to promote new medicines, but also acknowledged the effect of intellectual property rights on the prices of medicines.[101] The existence of the Doha Declaration on TRIPS and Public Health is indicative of the significance of public health concerns about TRIPS and intellectual property rights.

The need to balance intellectual property protection with other societal interests is consistent with the constitutional directive of promoting the "Progress of Science and useful Arts,"[102] But

---

public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.").

100. Id.

101. Id. ¶¶ 1–3 ("1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics. 2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems. 3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.").

102. Congress has the power "[t]o promote the Progress of Science and useful Arts, by securing

this does not mean that intellectual property protection should not be beneficial to society.[103] The challenge, both domestically and internationally, is to balance intellectual property rights and other valid, and sometimes competing, interests.[104] For instance, although the United States is one of a handful of countries that is not a party,[105] the International Covenant on Economic, Social and Cultural Rights[106] recognizes both the right to health and the protection of intellectual property rights.[107]

---

for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." **U.S. Const.** art. I, § 8.

103. See Cooper, supra note 9, at 101.

104. See Abbott, supra note 87, at 357–58.

105. International Covenant on Economic, Social and Cultural Rights, STATUS AS AT: 02-09-2013, **U.N. Treaty Collection**, http://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IV-3&chapter=4&lang=en. The United States signed the ICESCR on 1977, but has not ratified or acceded to the agreement. Although a handful of other countries are not parties (i.e., South Africa, Cuba, Belize and a few others), most nations have acceded to the ICESCR. Id.

106. International Covenant on Economic, Social and Cultural Rights, Dec. 16, 1966, 993 U.N.T.S. 3, available at http://www.unhcr.org/refworld/docid/3ae6b36c0.html.

107. Article 12(1) of the ICESCR provides: "The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health," and Article 15 (1) recognizes the right of everyone "(b) To enjoy the benefits

In contrast to the access to medicines scholarship, the counterfeit medicines dialogue bolsters the argument that better enforcement of TRIPS and other intellectual property obligations will help control the circulation of counterfeit medicines.[108] Ultimately, the role of intellectual property in combating the counterfeit medicines trade is limited at best.[109] Yet, the dangers of counterfeit medicines create a palatable counter-narrative to the access to medicines critique of intellectual property rights.[110]

B. Using the Counterfeit Medicines Narrative as a Justification for Intellectual Property Enforcement Provisions in Trade Agreements

There are strong incentives for companies to identify counterfeit medicines to demonstrate the potential harm caused by intellectual property infringement.[111] Since America's competitive

---

of scientific progress and its applications; (c) To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author."

108. Cooper, supra note 9, at 102–03 (identifying the use of the Trade Act, 1974 and increased enforcement of TRIPS obligations as an important part of the solution to the counterfeit medicines issue.).

109. Bunker, supra note 20.

110. Id.

111. Hirschmann, supra note 1 ("In Virginia alone, IP-intensive industries are responsible for more than 1.3 million jobs (42 percent all private-sector jobs) and fuel 72 percent of total exports in the state. As demonstrated by these numbers, the long-term vitality of our innovative and

edge is in producing intellectual property-protected goods,[112] intellectual property industries have an interest in increasing intellectual property standards and ensuring the enforceability of those standards.[113] This trend started with TRIPS.[114] Arguably, TRIPS can be cited as an

---

creative industries relies on a robust system of IP protection. Strong IP protection is about not only our economic progress but also enhancing global public safety. It is not uncommon for enterprises based overseas to capitalize on the popularity of a product or brand and repackage their untested products as legitimate. Consumers can easily be duped by these counterfeit goods and, depending on the product, can also suffer from identity theft or physical harm. IP delivers safe products to our homes by allowing consumers to identify respected and safe brands.").

112. Cooper, supra note 9, at 101–02 ("With the transition to a knowledge-based economy, the financial future of the United States, and California in particular, very much depends on the protection of IP abroad, be it royalties for telecom technology, software from the Silicon Valley, music from Los Angeles, movies from Hollywood, or biotechnology in San Diego."). Professor Cooper goes on to describe the anti-piracy efforts as "a good public relations campaign," but encourages more effective action. Id.

113. Hirschmann, supra note 1 ("In the global economy, IP is one of our most valuable assets and a key to our competitiveness. Our innovative and creative industries contribute over 74 percent of our merchandise exports. Without proper IP enforcement, individuals are less likely to pour their time and resources into pushing the limits of human ingenuity and developing beneficial new products. This could mean a life-saving medicine going undiscovered, a great novel going unpublished or a technological advance remaining unrealized.").

example of regulatory capture.[115] However, for the proponents of increased intellectual property standards, TRIPS did not go far enough, particularly with respect to enforcement provisions.[116]

While the harm caused by counterfeit medicines provides a compelling case for state enforcement of intellectual property rights, the pharmaceutical industry is not the only industry to benefit from increased enforcement.[117] A group of more than thirty industry associations wrote to President Obama to request high standards for intellectual property protection and enforcement in the Trans-Pacific Partnership (TPP) negotiations.[118] The interests represented included the pharmaceutical industry, the publishing industry, the film industry, the biotechnology industry, the recording industry, the grocery manufacturers, the software industry, the clothing industry, and footwear distributors, among others.[119]

In a separate letter, the Pharmaceutical Researchers and Manufacturers of America (PHRMA) requested that the U.S. Government negotiate an agreement for strong intellectual property

---

114. See **Susan K. Sell**, **Private Power**, **Public Law: The Globalization of Intellectual Property Rights** 121–22 (2003).

115. Michael E. Levine & Jennifer L. Florence, Regulatory Capture, Public Interest, and the Public Agenda: Toward a Synthesis, 6 **J.L. Econ. & Org.** 167 (1990).

116. Peter K. Yu, The TRIPS Enforcement Dispute, 89 **Neb. L. Rev.** 1046, 1047 (2011).

117. See Letter on Trans-Pac. P'ship Negotiations from Various Indus. Assn's to the President of the U.S., supra note 20, at 1.

118. Id. at 2–4.

119. Id.

standards, starting with the North American Free Trade Agreement (NAFTA) and TRIPS standards as a minimum.[120] In addition to financial losses suffered by the pharmaceutical industry, PHRMA discussed the role its members play in developing life-saving medicines to fight diseases globally, as well as the need to combat counterfeit medicines.[121] In stark contrast to the position taken by PHRMA, thirty-nine civil society groups wrote to TPP negotiators to express their views on the detrimental impact of the intellectual property rights on access to medicines.[122] In their letter, the civil society groups expressed concern that "intellectual property

120. Letter from Pharm. Research & Mfrs. of Am. to Gloria Blue, Exec. Sec'y of the Trade Policy Staff Comm., Exec. Office of the President of U.S.—Trans-Pac. P'ship Agreement, USTR-2009-0041 (Jan. 25, 2010) [hereinafter Letter from Pharm. Research], available at http://www.wcl.american.edu/pijip/go/tpp.

121. Id. at 5.

122. Letter from Australian Fair Trade & Inv. Network et al. to Dep't of Foreign Affairs & Trade of Australia et al. on Safeguarding Access to Medicines in the Trans-Pac. P'ship Agreement, 1–2 (Feb. 15, 2011) [hereinafter Letter from Australian Fair Trade], available at http://www.citizen.org/documents/TPP-access-to-medicines-sign-on-letter.pdf ("Nearly two billion people still lack regular access to medicines in developing countries. Although several important factors contribute to this, one critical problem is the high price of monopolized medicines. Intellectual property provisions that go beyond the standard required by the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property (WTO's TRIPS)–so-called "TRIPS-plus" measures–restrict generic competition, leading to medicine

measures that may be included in an eventual agreement could undermine patients' access to vital medicines."[123] They further recommended that TRIPS standards be maintained as the maximum standard, and pressed for the implementation of TRIPS flexibilities.[124]

Thus, the civil society groups present the access to medicines concerns, arguing against increased intellectual property protections.[125] In contrast, advocating for higher intellectual property standards and better enforcement, the pharmaceutical industry recognizes the need to combat counterfeit medicines to discredit the idea that increased intellectual property standards are harmful to the public health.[126] Notably, that the civil society organizations that focus on public health issues have not supported higher intellectual property standards, despite industry arguments that intellectual property contribute to a safer medicine supply.[127]

In its statements regarding the TPP negotiations, the U.S. government adopted a stance that corresponds to the industry positions.[128] The United States Trade Representative (USTR)

---

prices that are unaffordable for most people, and healthcare costs that can restrict health programs' abilities to provide treatment or other services, in both developing and wealthier countries.").

123. Id. at 1.

124. Id. at 2.

125. Id. at 1.

126. Letter from Pharm. Research, supra note 5, at 5.

127. Letter from Australian Fair Trade, supra note 122, at 2.

128. **United States Trade Representative**, **White Paper on Trans-Pacific Partnership**

suggests that intellectual property is not a barrier to access to medicines but, rather, that it enhances access to medicines.[129] The USTR frames the discussion by positing that limited access to medicines is not a result of intellectual property rights.[130] It further asserts that there are many other kinds of barriers to access, including distribution networks, lack of basic infrastructure, and the circulation of counterfeit medicines.[131] In addition, the USTR stresses that the U.S. Government is finding ways to help improve access to medicines through development programs and foreign policy initiatives.[132]

Hence, in line with industry, the government narrative is that intellectual property rights are not the problem but, rather, that intellectual property is critical to the development and marketing of new medicines.[133] One of the stated aims of the TPP is to utilize border measures and criminal enforcement as tools to "prevent medicines bearing counterfeit trademarks from entering TPP markets," thereby protecting the public health.[134] This narrative, which suggests that intellectual

---

Trade Goals to Enhance Access to Medicines (TEAM) 1 (2011), available at http://www.ustr.gov/webfm_send/3059.

129. Id.

130. Id.

131. Id. at 3.

132. Id. at 2, 4.

133. Id. at 3 (stating that it is important to have an "effective, transparent and predictable intellectual property system . . . for both manufacturers of innovative and generic medicines.").

134. Id. at 2.

property is beneficial to the public, serves the interest of all intellectual property industries broadly, not just the pharmaceutical industry.[135] Once the case for increased intellectual property enforcement is successfully made based on the dangers posed by counterfeit medicines, the argument is extended—often without merit—to other consumer and industrial products.[136] Indeed, some commentators have connected counterfeit medicines not only to petty criminals, but also to terrorist organizations, thus portraying intellectual property enforcement as a national security issue.[137]

However, there are problems with extending the counterfeit medicines analysis to other goods.[138] The strongest case for state enforcement of intellectual property protected goods is with respect to medicines.[139] This is not necessarily true when it comes to other goods.[140] The film,

---

135. Id.

136. Cooper, supra note 9, at 100 ("But pirated goods pose an equal danger to the public through fake consumer and industrial products. Piracy is everywhere and affects everything we do."). Among the examples provided are engine parts, shampoo, baby formula, and wiring. Id.

137. Id. at 97; Earle et al., supra note 76, at 687 ("However, purses and dresses are only the tip of the iceberg. Terrorist and other criminals are taking advantage of the lower risks for counterfeiting not only designer goods, but also pharmaceuticals and parts for computers, cars and airplanes.").

138. Cooper, supra note 9, at 94.

139. Id. at 90.

140. Id. at 94.

clothing, and software industries, for instance, may have business reasons for advancing strong intellectual property rights in international agreements.[141] Nonetheless, it is unlikely that they can legitimately claim any significant connection between their intellectual property rights and the public health or safety, or the public welfare in general, beyond the general value of the signaling function of trademarks.[142] Thus, various intellectual property industries benefit from treaty provisions requiring increased government enforcement, even though there may be little to no public interest justification for the government role.[143]

Even if there is some additional, demonstrable public benefit, one must query whether it requires a shift from the norm of requiring a trademark owner to enforce her rights. It is not clear whether there is a public interest that warrants countries taking on obligations, through international agreements, to intervene to prosecute crimes related to the misuse of trademarks on clothing labels or the sale of pirated films.[144] In some instances, consumers will be aware, due to

141. For instance, support for local industries may be a legitimate business reason. However in the global context, it is not a persuasive reason for other nations. Support for small businesses that lack resources to pursue litigation in multiple arena may be another reason a government would seek to enforce private rights.

142. Sandra L. Rierson, Symposium, Pharmaceutical Counterfeiting and the Puzzle of Remedies, 8 **Wake Forest Intell. Prop. L.J.** 433, 434–35 (2008).

143. Id.

144. Earle et al., supra note 76, at 733.

the comparatively low price of a counterfeit "designer" item, that the goods are counterfeit.[145] Additionally, the definition of "counterfeit" medicines is not uniform,[146] and the implications may not be transferable to the use of the term "counterfeit" in reference to handbags or jeans.[147] A mark may be misapplied, or the good may be sold without authorization from the right holder, but there may be no danger to the consumer.[148] Moreover, products that promote the public

---

145. Thus while one could argue that misuse of a mark is fraudulent, the consumer may not be deceived. Cooper, supra note 9, at 95.

146. General Information on Counterfeit Medicines, **World Health Org.**, http://www.who.int/medicines/services/counterfeit/overview/en/ (last visited Oct. 1, 2013) ("The absence of a universally accepted definition not only makes information exchange between countries very difficult but it also limits the ability to understand the true extent of the problem at global level. In order to address this problem the following definition has been developed by the World Health Organization.").

147. Earle et al., supra note 76, at 682.

148. Id. ("Some authors argue that most counterfeit goods are not a serious problem and that focus should be on dangerous counterfeit goods like drugs. The argument is that selling fake luxury goods is a victimless crime. A fake Gucci purse has yet to kill anyone."); Rierson, supra note 142, at 434 ("In its least virulent form, counterfeiting does not harm the consumer and, arguably, imposes a relatively minor cost on the trademark holder (particularly when compared to the remedies available for the harm). If a defendant sells a cheap copy of a luxury good to the consumer—under circumstances such that the consumer knows exactly what she is buying—the

health, like safe generic drugs, may inadvertently be caught in the net that is cast for the purpose of capturing intellectual property infringement.[149]

Interestingly, patents are the intellectual property form that is often identified as impeding access to medicines.[150] However, the state enforcement provisions in TRIPS and ACTA, for

---

consumer has suffered no injury.").

149. Dispute Settlement: DS409: European Union and a Member State—Seizure of Generic Drugs in Transit, **World Trade Org.**, http://www.wto.org/english/trato-_e/dispu_e/cases_e/ds409_e.htm (last updated June 22, 2010).

150. Fredrick M. Abbott, Report, TRIPS in Seattle: The Not-So-Surprising Failure and the Future of the TRIPS Agenda, 18 **Berkeley J. Int'l L.** 165, 171 (2000) ("Some developing Members of the WTO, as well as multilateral institutions like the World Health Organization . . ., have expressed increasing concern that the wider granting and enforcement of patents in pharmaceutical products and processes is leading to substantially higher drug prices, with adverse effects on health care services. Some WTO Members have suggested that drugs on the WHO's list of essential pharmaceuticals be subject to exclusion from patent protection or should be entitled to some lesser form of protection than that presently mandated by the TRIPS Agreement."); Correa, supra note 62, at 6–7 ("The protection of public health is one of the most pressing issues in developing countries. A large part of the world population still lacks access to essential drugs . . . . To deal with this dramatic situation, an integrated approach to the interrelated issues of national health policy, pharmaceutical policy, and patent policy is required."); Reichman, supra note 62, at 91–92 ("As the endless controversies surrounding

instance, address trademarks and copyright, but not patents.[151] Indeed, the copyright and trademark-dependent industries may have more to gain from these agreements than patent-reliant industries.[152]

C. A Public Interest Rationale

As has been discussed, the counterfeit medicines story is one that provides intellectual property industries a public-interest rationale, rather than a profit-oriented rationale, to justify demands for the state to take a greater role in intellectual property enforcement. Notably, demands for state enforcement of intellectual property rights are not limited to counterfeit medicines or instances where there is a clear public interest at stake.[153]

In light of the nature of intellectual property rights, it is important to have a solid policy rationale for expanding such rights and for shifting enforcement to governments. As intangible goods, intellectual creations are "nonexclusive and nonrivalrous."[154] In other words, the use of an

---

pharmaceutical patents demonstrate, higher standards of global protection—whatever their incentive effects—also generate severe and unintended distributional consequences for the developing world.").

151. ACTA, supra note 13, at n.2 (With respect civil enforcement, "[a] Party may exclude patents and protection of undisclosed information from the scope of this Section.").

152. Id. arts. 7 & 8.

153. Earle et al., supra note 76, at 733.

154. **Christopher May**, **A Global Political Economy of Intellectual Property Rights: The New Enclosures** 3–4 (2d ed. 2010); Michael A. Carrier, Cabining Intellectual Property Through

intangible good by one person does not deprive another from also using the good. Since it is not diminished by additional uses, intellectual property is considered a "public good."[155] Further, unlike physical property, the boundaries of abstract objects are exclusively determined by the law.[156] Hence, various intellectual property laws enable the right holder to exclude others, where such exclusion would otherwise not be possible.[157] The right holder is given this time-limited exclusivity in exchange for her creative contribution to society.[158] Thus, intellectual property rights are part of a social contract—an exchange between the inventor or creator and the public.[159] Some commentators have even suggested that we should recognize intellectual property privileges, rather than intellectual property rights,[160] and limit the scope of these

---

a Property Paradigm, 54 **Duke L.J.** 1, 32 (2004).

155. **William M. Landes & Richard A. Posner**, **The Economic Structure of Intellectual Property Law** 14 (2003).

156. Id. at 93.

157. Joseph E. Stiglitz, Editorial, Scrooge and Intellectual Property Rights, 333 **Brit. Med. J.** 1279, 1279 (2006), available at http://www.bmj.com/content/333/7582/1295.

158. **Janice Mueller**, **Patent Law** 29 (Vicki Been et al. eds., 3d ed. 2009).

159. See, e.g., id. at 30–31. Though this explanation is often used to explain patent law, it is applicable to other forms of intellectual property as well. Staking Out the Middle Ground on Intellectual Property: IP Justice Policy Paper, **IP Justice.org**, http://ipjustice.org/WIPO/IIM3/IPJ_Middle_Ground.pdf (last visited Oct. 1, 2013).

160. **Peter Drahos**, **A Philosophy of Intellectual Property** 5 (1996) (characterizing

privileges.[161]

A public interest test would increase transparency with respect to any public interest justifications for intellectual property enforcement provisions in international agreements.[162] Such a test would also be consistent with a human-oriented approach to intellectual property, which considers the social costs of intellectual property protection.[163] The "balancing provisions" found in Articles 7 and 8 of TRIPS also recognize that intellectual property rights contemplate

---

intellectual property rights as "liberty-intruding privileges of a special kind"); Lea Shaver, The Right to Science and Culture, 2010 **Wis. L. Rev.** 121, 134 (2009).

161. Drahos, supra note 160, at 200.

162. Margaret Chon, Intellectual Property and the Development Divide, 27 **Cardozo L. Rev.** 2821, 2865 (2006).

163. Id. at 213–14, 223. Professor Drahos has argues that if intellectual property is viewed as a means to an end intellectual property laws should be developed with a view to achieving objectives that are based on some moral value. Id.; Chon, supra note 162, at 2823 ("This Article attempts to map the challenges raised by these encounters between intellectual property and development. It proposes a normative principle of global intellectual property—one that is responsive to development paradigms that have moved far beyond simple utilitarian measures of social welfare. Recent insights from the field of development economics suggest strongly that intellectual property should include a substantive equality principle, measuring its welfare-generating outcomes not only by economic growth but also by distributional effects.").

the broader public interest and the interests of the right holder.[164] The objectives of TRIPS, as set out in Article 7, establish that intellectual property rights should promote technological innovation "in a manner conducive to social and economic welfare, and to a balance of rights and obligations."[165] Further, the principles set out in Article 8 of TRIPS provide that members may adopt measures "to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development."[166]

Consistent with Articles 7 and 8 of TRIPS, this Article advocates a public interest standard for intellectual property obligations in international agreements.[167] The first step is to identify the particular public interest at issue.[168] Once that interest has been identified, one can assess the intellectual property obligation in light of the pertinent public interest.[169] This Article does not

---

164. The same is true of the various exceptions to intellectual property rights found in TRIPS. See TRIPS, supra note 12, arts. 13, 17, 30, & 31.

165. Id. art. 7.

166. Id. art. 8.

167. Id. arts. 7–8.

168. Id. art. 8.

169. If stakeholders, including the consuming public, in the nation adhering to an international intellectual property agreement see their views reflected in the development of the government position, they are more likely to view the resulting changes to domestic law favorably. Cooper, supra note 9, at 102–03. In the case of counterfeit medicines, the public interest at issue is the public health and the safety of the medicine supply. Id. at 90.

advocate a health and safety test or a public benefit test for the acquisition and maintenance of intellectual property rights. However, if government enforcement of intellectual property rights is justified, or at least presented as publicly palatable due to some health or safety benefit to the public,[170] then this is the standard against which we should assess whether agreements such as the TPP and ACTA should oblige governments to take on a greater role in enforcing intellectual property rights.[171]

D. The Limited Role of Intellectual Property

It is true that intellectual property rights can help protect the public.[172] Trademarks, copyrights, and patents may be infringed when counterfeit medicines are sold using the packaging, marks, or drug formulations that belong to legitimate companies.[173] Counterfeit medicines may contain some of the active ingredients used in the authentic medication, but they may be used in incorrect proportions or manufactured under poor conditions.[174]

---

170. See **Exec. Office of the President**, **Administration's White Paper on Intellectual Property Enforcement Legislative Recommendations** 1 (2011), available at http://www.whitehouse.gov/sites/default/files/ip_white_paper.pdf.

171. See TEAM, supra note 128.

172. Brian A. Liang, Fade to Black: Importation and Counterfeit Drugs, 32 **Am. J. L. & Med.** 279, 312–13 (2006).

173. Id. at 288.

174. Andrew Jack, Bitter Pills, 335 **Brit. Med. J.** 1120, 1120 (2007) ("It is said that around 10% of the global market was fake, rising to 30% in some parts of the developing world.").

Yet, the role of intellectual property enforcement in preventing counterfeit medicines is limited.[175] For instance, one commentator has observed that it is often impossible to differentiate a counterfeit medicine from the authentic medicine without subjecting the medicine to chemical analysis.[176] Furthermore, anti-counterfeiting technologies have been criticized as tracking "cardboard, not product."[177] In other words, the packaging may be genuine, even though the product is not.[178] Nonetheless, intellectual property industries refer to the danger of counterfeit

---

175. See Liang, supra note 172, at 290.

176. Id. (quoting a spokesperson on counterfeiting who "noted that: 'Counterfeit medicines often appear so like the genuine product that no one, not the best specialist can tell the genuine packaging from the counterfeit. And no one, not the best specialist can tell the genuine product from the counterfeit unless the product is subjected to chemical analysis. The result is that everyone, poor, ignorant, rich and smart, all are at risk from counterfeit or sub-standard products . . . .' This situation truly makes counterfeit drug production and sale the perfect crime.").

177. Id. at 305 (quoting testimony to the House Subcommittee on Commerce, Trade, and Consumer Protection).

178. Id. (quoting testimony to the House Subcommittee on Commerce, Trade, and Consumer Protection that "It is not unusual to find genuine product in counterfeit packaging and counterfeit product in genuine packaging. In the United States and the European Union, the two largest pharmaceutical markets in the world, repackaging is legal; thus . . . state of the art secure devices can end up in the trash or worse, in the hands of a counterfeiter, while genuine product is legally distributed in packaging with no security features.").

goods to justify increased policing and enforcement of intellectual property rights.[179]

Characterizing intellectual property as a tool in the fight against counterfeit medicines bolsters the trend towards increased intellectual property protections and enforcement in international agreements.[180] This potentially positive role for intellectual property is essential for the intellectual property industries, as they contend with the criticisms about the detrimental effect of intellectual property rights on access to medicines and knowledge.[181] However, it is not obvious that improved global enforcement of intellectual property rights is an appropriate or effective solution to the counterfeit medicines problem.[182] Governments may take on intellectual property enforcement obligations under the guise of health and safety without actually improving health or safety.[183] Counterfeiters may use authentic packaging for fake drugs, or legal generic drugs may be incorrectly identified as violating intellectual property rights.[184] Safe generic drugs may not reach the public because they allegedly infringe intellectual property rights.[185] In addition, state enforcement may capture intellectual property infringement related to the misuse of

179. Cooper, supra note 9, at 90–91.

180. See TEAM, supra note 128, at 2.

181. Chon, supra note 162, at 2826–27.

182. See id. at 2822–23.

183. Amir Attaran et al., Why and How to Make an International Crime of Medicine Counterfeiting, 9 **J. Int'l Crim. Just.** 325, 338 (2011).

184. General Information on Counterfeit Medicines, supra note 146.

185. See infra Parts IV.B & V (discussing the seizure of drugs in transit).

designer labels on wristwatches, for example, when there is no pressing public health or safety interest and no clear reason for the government to take on enforcement of the rights.[186]

There should be transparent guidelines for determining whether an intellectual property interest coincides with a broader public interest, like protecting the rights of the trademark owner.[187] The particular public interest at stake may change, depending on the nature of the goods.[188] In the case of counterfeit medicines, the question is whether better intellectual property enforcement can be justified on the basis of improving the public health.[189] Thus, it makes sense to begin by assessing such claims against a health and safety standard.[190] The next Part elaborates on why all counterfeit goods should not be painted with a broad brush.[191]

IV. COUNTERFEIT MEDICINES

A. Threats to Health and Safety

For many people, downloading films from the Internet without paying for them may seem innocent.[192] This is likely because no one is physically harmed by the downloads, although the

186. Rierson, supra note 142.

187. Chon, supra note 162, at 2865.

188. Rierson, supra note 142, at 434–35.

189. Id.

190. See id. at 435.

191. See infra Part IV.

192. Rierson, supra note 142, at 434.

movie industry and the actors may suffer financial losses.[193] Counterfeit medicines, on the other hand, provide a powerful case for government enforcement of intellectual property rights.[194] Criminals who traffic in cocaine or other substances may also engage in the counterfeit medicine trade.[195] And, like cocaine, counterfeit medicines can kill.[196] Intellectual property advocates and members of the pharmaceutical industry credit poor global enforcement of intellectual property rights as part of the problem.[197]

---

193. This Article does not endorse illegal downloading of films, but simply stresses that harms differ depending on the nature of the goods in question.

194. Jack, supra note 174, at 1120.

195. Earle et al., supra note 76, at 681 ("Why sell heroin if you can sell fake brakes? The profits are higher and the risks are lower.").

196. Attaran et al., supra note 183, at 332 ("Ultimately, we do not know precisely how much damage is done by this criminal arsenal of tricks. The regulatory systems to detect counterfeit are weak and the available estimates are imperfect, such as one much-cited estimate that counterfeits kill 700,000 people annually.").

197. See, e.g., Cooper, supra note 9, at 90 ("Across the globe, people are poisoned by counterfeit medicines, billions of dollars are diverted from economies, and criminal gangs and terrorists are enriched due to lackluster criminal enforcement of intellectual property (IP) rights."); Maria Nelson et al., Counterfeit Pharmaceuticals: A Worldwide Problem, 96 **Trademark Rep.** 1068, 1071–72 (2006) (linking weak intellectual property enforcement to counterfeit medicines and arguing that counterfeit medicines harm not only pharmaceutical

The sale and trafficking of counterfeit medicines is dangerous, and the effects can be devastating.[198] For instance, the thirty-six year-old owner of Pacific Orient International was convicted for selling counterfeit medicines.[199] Pacific Orient International sold drugs that

---

companies but also society as a whole).

198. See, e.g., Peter Aldhous, News Feature, Murder by Medicine, **Nature**, Mar. 9, 2005, at 133, available at http://www.nature.com/nature/journal/v434/n7030/full/434132a.html (describing deaths from fake anti-malarial drugs); Amir Attaran et al., supra note 183, at 329 ("For example, a recent forensic study documented the movement of counterfeit medicines from China to nearby Cambodia, Laos, Myanmar (Burma), Thailand and Vietnam. The products in this study were all fakes of artesunate—a highly effective cure for life-threatening falciparum malaria."); Brian A. Liang, Symposium, A Dose of Reality: Promoting Access to Pharmaceuticals, 8 **Wake Forest Intell. Prop. L.J.** 301, 305–06 (2008) ("For example, patients who are prescribed drugs such as growth hormone for HIV treatment and other diseases have received dangerous substitutes including insulin and steroids, expertly labeled to be indistinguishable from the true drug. . . . Counterfeiters have used bacteria-laced water, but in addition they have employed brick dust, rat poison, boric acid, colored dye, floor wax, powdered cement and toxic yellow road paint. . . . Another outrageous case involves counterfeit cystic fibrosis inhalers for pediatric patients that were filled with bacterially contaminated materials. This substance, masquerading as an authentic medication, was then sprayed directly in the children's vulnerable lungs.").

199. News Release, U.S. Attorney's Office, Internet Distributor Convicted of Trafficking in

appeared to be legitimate medications produced by established and reliable pharmaceutical companies like Pfizer and Eli Lily.[200] However, these counterfeit drugs did not have the required level of effective ingredients.[201] In this case, the drugs in question were for the treatment of serious illnesses like schizophrenia and cancer.[202] The individuals relying on these medications had no reason to believe that there was anything wrong with their medications, particularly since they looked authentic.[203] Unfortunately, this kind of crime occurs more commonly than one might expect.[204] Hence, there is an apparent need for tighter controls on the drug supply, both in

---

Fake Cancer Drugs (July 7, 2008), available at http://www.justice.gov/criminal/cybercrime/press-releases/2008/xuConvict.pdf; see United States v. Xu, 599 F.3d 452 (5th Cir. 2010), amended by No. 4:07-CR-00362-001 (S.D. Tex. Apr. 23, 2010).

200. News Release, supra note 199.

201. Id.

202. Id.

203. Id.

204. See Ashworth v. Albers Med., Inc., 395 F. Supp. 2d 395, 398–99 (S.D.W. Va. 2005) (mem. op.) (Patient asserted claim against manufacturer, pharmacy, and others for injuries sustained after consuming counterfeit Lipitor tablets.); Fagan v. AmerisourceBergen Corp., 356 F. Supp. 2d 198, 204 (E.D.N.Y. 2004) (Patient sought to recover damages for injuries after "suffer[ing] from continued anemia and excruciating side effects" from taking counterfeit Epogen injections.).

the United States and elsewhere.[205]

Professor Liang outlines three ways in which counterfeit medicines can be harmful.[206] First, a counterfeit drug might contain incorrect or ineffective medicine, or drug may have expired.[207] Second, a counterfeit drug's incorrect concentration might be the result of dilution.[208] Third, a counterfeit drug may have either no active ingredients or harmful ingredients such as powdered cement, boric acid, or toxic road paint.[209] Frequently, counterfeit drugs with some active ingredient are mixed with some authentic materials, in an effort to evade detection when samples

---

205. Attaran et al., supra note 183, at 331 ("Even the United States, which has probably the world's best-regulated pharmaceutical market, experienced an 800% increase in reported instances of counterfeit drugs between 2000 and 2006. Essentially, no part of the world is exempt."); Stephanie Feldman Aleonga, Green Medicine: Using Lessons from Tort Law and Environmental Law to Hold Pharmaceutical Manufacturers and Authorized Distributors Liable for Injuries Caused by Counterfeit Drugs, 69 **U. Pitt. L. Rev.** 245, 247 (2007) ("The drug distribution system in the United States is porous and vulnerable."); Liang, supra note 198, at 310 ("Counterfeit drugs in the U.S. are not new. Although the domestic drug supply has been relatively closed to counterfeits, the system has been infiltrated in the past by numerous breaks in the supply chain.").

206. Liang, supra note 172, at 283–85.

207. Id. at 283–84.

208. Id. at 284.

209. Id.

are selected for testing.[210]

Although medicines in the United States are generally quite safe, counterfeit medicines that enter the country compromise the safety of the medical supply, and create health risks for the public.[211] The U.S. Government has also identified piracy and counterfeiting in the online environment as a threat to health and safety.[212] Further, counterfeit drugs and other counterfeit goods may be circulating in significant numbers in developing countries.[213] This risk to developing nations is noteworthy, particularly because developing country advocates have critiqued the impact of TRIPS and other intellectual property agreements on their social and economic development,[214] including the ability of their nationals to access the life-saving medicines they need.[215] This raises the question of whether developing countries will benefit or suffer from increased intellectual property rights and enforcement.[216] On one hand, stricter intellectual property enforcement could help, although to a limited extent, ensure that the

---

210. Id. at 285. This is referred to as "salting." Id.

211. Jack, supra note 174, at 1120 ("It is said that around 10% of the global market was fake, rising to 30% in some parts of the developing world.").

212. **Exec. Office of the President**, supra note 170.

213. Jack, supra note 174, at 1120.

214. Chon, supra note 162, at 2823 ("Intellectual property, while purporting to heed the issues of development, often runs rough-shod over the central concerns of development.").

215. Id.

216. Id. at 2866.

medicine supply is safer for everyone.[217] On the other hand, increased intellectual property rights and enforcement of those rights may limit access to medicines needed to maintain health and access to relevant knowledge and information, as was the case when generic drugs were seized while transiting through Holland.[218] The perception of the harm caused by weak intellectual property rights makes the counterfeit medicines narrative such a powerful one for the intellectual property industries.[219]

Ultimately, the challenge of effectively controlling the counterfeit medicines trade may most appropriately lie with national health regulatory bodies and criminal authorities, perhaps working in concert with their global counterparts.[220] Due to the complexity of trafficking in counterfeit medicines, the solution is complex and must be tackled from multiple angles.[221] Clearly, fake or

---

217. Cahoy, supra note 77, at 421 ("When a counterfeit mimics the identity of a legitimate company, there is obviously a strong incentive to take legal action to stop the confusion. Certainly this can take the form of a trademark infringement action if source confusion is at issue. . . . The specter of litigation may cause some counterfeiters to refrain from operating with a particular drug.").

218. See infra Part V.

219. Manta, supra note 12, at 484.

220. See, e.g., Attaran et al., supra note 183, at 333 (arguing in favor of an international crime for medicine counterfeiting).

221. See id. at 328–29.

counterfeit medicines can be harmful.[222] But what role should intellectual property laws play in regulating the safety of the medicine supply? Some commentators, such as Professor Liang, suggest that intellectual property rights make counterfeiting profitable.[223] Whether intellectual property is part of the problem or the solution, the challenge of combatting the trade in counterfeit medicines is exacerbated by the lack of clarity regarding the meaning of the term "counterfeit medicine."[224]

B. What is a Counterfeit Medicine?

It is difficult to argue with the need to maintain a safe medicine supply. However, the word "counterfeit" is often used in ways that can cause confusion about products that are harmful versus those that are not harmful.[225] The discussion also lends itself to the slippery slope of treating all "counterfeit" goods as harmful, due to the fact that some counterfeit goods are extremely dangerous.[226] Often, it is not clear what precisely is meant by "counterfeit medicine," which contributes to the confusion in discussions about counterfeit goods.[227]

---

222. See id. at 326.

223. Liang, supra note 172, at 322 ("However, the potential importation of, and manufacture and sale of fake drugs exists because of high prices; and high prices exist in part due to high development costs and lack of price controls.").

224. General Information on Counterfeit Medicines, supra note 146.

225. Rierson, supra note 142, at 434.

226. See id.

227. General Information on Counterfeit Medicines, supra note 146.

For instance, generic versions of patented products have been mischaracterized as counterfeit drugs.[228] A generic drug and a counterfeit drug are not the same thing, although they have been confused for one another.[229] Dutch officials seized generic drugs that were in transit from India on the basis that they infringed intellectual property rights.[230] This seizure led to a request for consultations under the WTO dispute settlement mechanism.[231] India manufactured the generic medicines, which were not patented in India, and shipped them to a third country where there was also no patent, via Holland.[232] Although the medicines only had to transit through Holland, and were not intended for the Dutch market, the Dutch authorities seized the goods in question.[233] These goods were not made illegally, nor were these fake or poor quality medicines.[234] Rather, these were authentic generic medicines, made consistent with Indian law and India's obligations under the WTO agreements, including TRIPS.[235] However, these legally

228. See **World Trade Org.**, **WT/DS408/1, G/L/921**, **IP/D/28**, **European Union and a Member State-Seizure of General Drugs in Transit: Request for Consultations by India** (2010), available at http://trade.ec.europa.eu/doclib/docs/2011/january/tradoc_147464.pdf.

229. Id.

230. Id.

231. Id.

232. Id.

233. Id.

234. Id.

235. Id.

made goods were treated as intellectual property-infringing goods under Dutch law.[236] This is just one example of the confusion surrounding the meaning of the term "counterfeit" and the potential impact of state enforcement of intellectual property rights.[237]

It is, therefore, important to clarify what is meant by the term "counterfeit medicine." A counterfeit medicine can be defined in a variety of ways. An item can be described as a "counterfeit" if it is an illegal copy that one intends to pass off as the original.[238] According to the World Health Organization (WHO):

> A counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.[239]

In other words, a "counterfeit medicine," as defined by WHO, is one that leads the consumer

---

236. **Frederick M. Abbott et al.**, **International Intellectual Property in an Integrated World Economy** 270 (2d ed. 2011).

237. General Information on Counterfeit Medicines, supra note 146.

238. Counterfeit is defined as ". . . to copy or imitate without authority or right, and with a view to deceive or defraud, by passing the copy or thing forged for that which is original or genuine." **Black's Law Dictionary** (6th ed. 1990).

239. General Information on Counterfeit Medicines, supra note 146.

to believe it is from a legitimate source.[240] It may also be a product that is not medicinal or effective, even though the consumer thinks he or she is purchasing medicine.[241]

Importantly, the WHO definition is distinct from the definition of counterfeit found in TRIPS, which limits counterfeiting to the misuse of a trademark, and defines "counterfeit" as:

> [A]ny goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation.[242]

For the purpose of criminal trademark prosecution in the United States, a "counterfeit drug" is defined as:

> [a] drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or

240. Id.

241. Id.

242. TRIPS, supra note 12, art. 51 n.14.

distributor.[243]

Thus, in the intellectual property context, counterfeiting is primarily about the misuse of trademarks.[244] Copyright infringement, for example, is commonly referred to as "piracy."[245] The term "counterfeit medicine," as used in the health context, is broader than the way "counterfeit" is normally understood when referring to intellectual property.[246] A "counterfeit medicine," according to the WHO definition, is primarily about the substantive product, although it can also encompass misuse of the trademark associated with the product.[247] An intellectual property focus on the misuse of a trademark is distinct from a focus on the substantive product, and could lead to very different treatment of the goods in question.[248] The substantive goods are important, from a health perspective, because they could be dangerous.[249] From an intellectual property perspective, the concern is on the use of the mark without authorization, which does not necessarily mean that the goods are dangerous.[250] Instead, this means that the trademark was used without permission of the right holder or, perhaps, that the packaging used was confusingly

243. 21 U.S.C. § 321(g)(2) (2006).

244. TRIPS, supra note 12, art. 51 n.14.

245. Id.

246. General Information on Counterfeit Medicines, supra note 146.

247. Id.

248. Carrier, supra note 154, at 19.

249. Liang, supra note 172, at 288.

250. Id.

similar to that used by another producer.[251] Of course, because trademarks perform a signaling function, there may be instances where the consumer relies on the trademark as an indicator of quality and safety.[252] Thus, intellectual property interests and health concerns may intersect. However, this is not always the case.

Some commentators suggest that the public health meaning of counterfeit and the intellectual property meaning of counterfeit should be more clearly distinguished.[253] Professor Attaran and his co-authors propose adopting a definition "solely to capture threats to public health and safety."[254] They suggest taking the WHO definition as a "starting point" for differentiating the public health concerns from the intellectual property interests.[255] A definition focused on public health and safety will help clarify the discussion and avoid confusing intellectual property interests with health and safety concerns.[256]

The same can be said for using health and safety as a barometer against which to measure the propriety of government enforcement of intellectual property rights, at least with respect to

---

251. Id.

252. Carrier, supra note 154, at 18.

253. Attaran et al., supra note 183, at 339 ("[T]here should be more assiduous separation between the public health meaning of 'counterfeit' (i.e. non-therapeutic) and the intellectual property meaning of 'counterfeit' (i.e. infringing).").

254. Id.

255. Id.

256. See id.

counterfeit goods.[257] When there is potentially a serious impact on the public health or safety, the government may be justified in taking on the enforcement of intellectual property rights.[258] In contrast, when there is no overriding health or safety concern, some other rationale for government enforcement must be found. Certainly, public health and safety is not the only basis upon which to justify state enforcement of intellectual property rights.[259] However, it is the most pertinent to the use of intellectual property laws to curtail the distribution of counterfeit medicines.[260]

For the purposes of this Article, the broader WHO definition will be employed when referring to counterfeit medicines, because that is how the term "counterfeit" is commonly used in the health context. Taking counterfeit medicines as fake drugs and/or medicines that misuse trademarks, copyrights, or patents, the next inquiry concerns the appropriate role for intellectual property law. This requires a brief consideration of the extant intellectual property rules.

V. ENFORCEMENT

Intellectual property rights are private rights, as is explicitly recognized in TRIPS.[261]

---

257. Id.

258. For instance, if consumers trust that a particular trademark is an indicator of quality and safety, the intellectual property interests would coincide with the health and safety concerns.

259. See Rierson, supra note 142.

260. See id.

261. The TRIPS Preamble recognizes "that intellectual property rights are private rights." TRIPS, supra note 12.

Generally speaking, intellectual property owners are responsible for monitoring and enforcing rights.[262] When the owner of a trademark or a copyright suspects infringement, the right holder has judicial recourse.[263] In other words, the right holder must commence litigation to enforce the right against infringement.[264] However, trade agreements like ACTA require states to alter domestic laws such that the responsibility is increasingly shifted to the government and to the public purse.[265]

When the infringement amounts to a crime, or when there are border measures in place, the right holder can rely on the state to take action on its behalf.[266] Although copyright infringement and trademark infringement have been criminalized, the same is not true for patent infringement in the United States.[267] Thus, the discussion of state enforcement here is limited to copyright and trademark.[268] With respect to counterfeiting, trademark is the primary form of intellectual

---

262. Lanham Act, Pub. L. No. 79-489, § 32, 60 Stat. 427, 437–38 (1946) (codified as amended at 15 U.S.C. § 1114 (2012)).

263. See id. (providing for a civil action for the misuse of a trademark); see also Lanham Act § 43 (codified as amended at 15 U.S.C. § 1125 (2012)).

264. Lanham Act § 32.

265. ACTA, supra note 13.

266. Manta, supra note 12.

267. Id.

268. See id. at 469, 472.

property right that tends to be implicated.[269]

A. Intellectual Property Border Measures

The Department of Homeland Security and its agencies report governmental seizures of allegedly infringing goods at the border, which led to 691 arrests and 334 prosecutions in 2012.[270] Goods bearing a trademark similar to any trademark that is recorded with the U.S. Customs and Border Patrol (Customs) and that is likely to cause confusion can be detained at the border.[271] Trademark and copyright owners can register their rights with Customs, and can then report alleged infringements activity through an online service or by calling a 1-800 number.[272]

---

269. See id.

270. **U.S. Customs & Border Prot.**, **Office of Int'l Trade, Intellectual Property Rights: Fiscal Year 2012 Seizure Statistics**, available at http://www.cbp.gov/linkhandle/cgov/newsroom/publications/trade/fy_2012_final_stats.ctt/fy_2012_final_stats.pdf.

271. 19 C.F.R. § 133.22(b) (2013) ("Any articles of foreign or domestic manufacture imported into the United States bearing a mark or name copying or simulating a recorded mark or name shall be denied entry and subject to detention.").

272. e-Allegations Submission, **U.S. Customs & Border Protection**, http://apps/cbp.gov/eallegations/ (last visited Oct. 1, 2013); U.S. Government Agencies: U.S. Customs and Border Protection (CBP), **STOPfakes.gov**, http://www.stopfakes.gov/us-gov-agencies/cbp (last visited Oct. 1, 2013) ("Holders of registered trademarks and copyrights concerned about imports or exports of infringing goods [can] record their trademarks and

Customs will then seize the goods[273] and notify the intellectual property owner.[274] If Customs seizes goods that infringe a copyright, the goods must be destroyed.[275] If the goods bear a counterfeit trademark, the goods will be destroyed unless it is determined that the goods do not pose a health risk and the trademark owner gives his consent to the goods being released after the infringing mark is removed.[276]

---

copyrights with U.S. Customs and Border Protection (CBP). Patents may not be recorded with CBP for border enforcement protection; however, patent owners may be entitled to exclusion of infringing imports into the United States under section 337 of the Tariff Act of 1930.").

273. Any article "imported into the United States bearing a counterfeit trademark shall be seized and, in the absence of the written consent of the trademark owner, forfeited for violation of the customs laws." 19 C.F.R. § 133.21 (2000); **U.S. Customs & Border Prot.**, supra note 270, at 2 ("In Fiscal Year (FY) 2012, DHS and its agencies, CBP and ICE, remained vigilant in their commitment to protect American consumers from intellectual property theft as well as enforce the rights of intellectual property rights holders by expanding their efforts to seize infringing goods, leading to 691 arrests, 423 indictments and 334 prosecutions.").

274. 19 C.F.R. § 133.21(c) (requiring that the right holder be given notice).

275. 19 C.F.R. § 133.52(b) (2013) ("Articles forfeited for violation of the copyright laws shall be destroyed.").

276. 19 C.F.R. § 133.52(c) ("Merchandise forfeited for violation of the trademark laws shall be destroyed, unless it is determined that the merchandise is not unsafe or a hazard to health and the Commissioner of Customs or his designee has the written consent of the U.S. trademark owner,

B. Intellectual Property Crimes

It is not the purpose of this Article to argue that existing intellectual property crimes should be repealed or that intellectual property infringement should never be criminalized.[277] Rather, this Article focuses on international agreements mandating state enforcement of intellectual property rights, whether through creating more intellectual property crimes or border enforcement.[278] The content of these agreements is relevant to national intellectual property laws and policies because the agreements require government participants to make changes to domestic law.[279]

There are some fairly serious penalties for criminal infringement of intellectual property.[280] Under current U.S. trademark law, an individual or entity may be subject to criminal sanctions for intentionally trafficking or attempting to traffic in counterfeit goods or services, including counterfeit drugs.[281] For purposes of criminal trademark infringement, a counterfeit drug is one that is mislabeled such that it falsely purports to originate from a particular manufacturer.[282] This

---

in which case the Commissioner of Customs or his designee may dispose of the merchandise, after obliteration of the trademark, where feasible.").

277. The question as to whether or not intellectual property offenses should be criminalized at all is an interesting question, but it is beyond the scope of this Article.

278. TRIPS, supra note 12, art. 61.

279. See id.

280. See, e.g., 18 U.S.C. § 2320(b) (2006 & Supp. V 2011).

281. 18 U.S.C. § 2320(a) (2006 & Supp. V 2011).

282. Id. § 2320(f)(6). The term "counterfeit drug" means a drug, as defined by Section 201 of

captures not only reproductions of a mark, but also misuse of a genuine mark with fake drugs. The potential penalties for first-time offenders who traffick in counterfeit goods or services include a maximum prison term of ten years, or a maximum fine of two million dollars for individuals and five million dollars for entities.[283] Repeat offenders may be imprisoned for up to twenty years or fined up to five million dollars for individuals, and fifteen million dollars for entities.[284] Trafficking in counterfeit labels[285] affixed to or accompanying copyrighted works has also been criminalized.[286] Trafficking in counterfeit labels carries a maximum term of five years of imprisonment and a fine of up to two hundred and fifty thousand dollars for individuals and five hundred thousand dollars for entities.[287] For these offences, the penalty may be either imprisonment, a fine, or both.[288]

Intellectual property offenses that result in physical harm or death are punished more harshly

---

the Federal Food, Drug, and Cosmetic Act, that uses a counterfeit mark on or in connection with the drug. Id.

283. Id. § 2320(b)(1).

284. Id. § 2320(b).

285. "Counterfeit label" is defined as an "identifying label or container that appears to be genuine, but is not." Id. § 2318(b)(1).

286. Id. § 2318(a)(1)(A).

287. Id. § 2318.

288. Id.

than those that do not.[289] Even for first-time offenders, the penalties are more severe for trafficking in counterfeit goods or services that lead to serious bodily injury or death.[290] The maximum term of imprisonment for an individual increases from ten years to twenty years, when serious bodily injuries are sustained.[291] If the trafficking in counterfeit goods or services results in the death of an individual, the maximum penalty is life in prison.[292] For an entity that causes serious bodily injury or death, the maximum fine is fifteen million dollars.[293] Thus, the current law distinguishes between intellectual property crimes resulting in tangible harm to human life or health from those that do not.[294]

Unlike trademark and copyright infringement, patent infringement has not been criminalized in the United States.[295] Nonetheless, it is an offense to forge patent letters.[296] It is also an offense to counterfeit or falsely imitate a patentee's mark, or to falsely claim that an item is patented or

289. Id. § 2320.

290. Id. § 2320(b).

291. Id.

292. Id.

293. Id.

294. Id.

295. Patent infringement has, however, been criminalized elsewhere. See Manta, supra note 12, at 471.

296. 18 U.S.C. § 497 (2006).

that the patent is pending.[297] There are also criminal copyright offenses for the commercial distribution of infringing works.[298] A violation of the Copyright Act[299] can lead to a maximum term of imprisonment of ten years,[300] depending on whether it is a repeat offense and on the value of the copyrighted work involved.[301]

C. Food & Drug Offenses

The penalties for intellectual property infringement are harsher than those for violations of the

297. 35 U.S.C. § 292(a) (2006 & Supp. V 2011) ("Whoever, without the consent of the patentee, marks upon, or affixes to, or uses in advertising in connection with anything made, used, offered for sale, or sold by such person within the United States, or imported by the person into the United States, the name or any imitation of the name of the patentee, the patent number, or the words "patent," "patentee," or the like, with the intent of counterfeiting or imitating the mark of the patentee, or of deceiving the public and inducing them to believe that the thing was made, offered for sale, sold, or imported into the United States by or with the consent of the patentee . . . shall be fined not more than $500 for every such offense. Only the United States may sue for the penalty authorized by this subsection.").

298. Manta, supra note 12.

299. 17 U.S.C. § 506(a) (2012).

300. 18 U.S.C. § 2319 (2006 & Supp. V 2011).

301. 17 U.S.C. § 506(a) (2012) (The severity of the sanctions differ depending on several factors including the nature of infringing act committed under § 506(a)(1)(A), (a)(1)(B), or (a)(1)(C)).

laws regulating the food and drug supply.[302] Counterfeit drug crimes can be prosecuted under the Federal Food, Drug & Cosmetics Act (FD&C Act).[303] Counterfeit medicine cases that are prosecuted under the FD&C Act are misdemeanors, unless there was intent to defraud or mislead.[304] The maximum sentence is three years in prison.[305] Trafficking in counterfeit medicines is therefore not considered a crime carrying severe consequences.[306] Some commentators suggest that the penalties for trafficking in counterfeit goods are so inadequate that the activity even appeals to persons not normally expected to engage in criminal activity.[307] It is no surprise, therefore, that there are proposals to strengthen criminal penalties relating to counterfeit medicines in the United States.[308] In comparison to the three-year sentence for food

---

302. 18 U.S.C. § 2319.

303. 21 U.S.C. § 333 (2006).

304. Id.

305. Id.

306. Id.; see also, Liang, supra note 172, at 292 ("Allen Valentine, the mastermind of the UK counterfeit ring, who had been convicted on 14 previous occasions on charges of medication fraud, only received 5.5 years imprisonment—and the sentence was due to his copyright infringement, not his threat to public health.").

307. Earle et al, supra note 76, at 679 ("When even housewives consider selling counterfeit products a good job, one must conclude that the penalties are not a sufficient deterrent compared to the rewards.").

308. **Exec. Office of the President**, **Joint Strategic Plan on Intellectual Property**

and drug crimes, the maximum penalty for selling goods bearing counterfeit trademarks is ten years in prison.[309]

Given that the protection of health and safety is not one of the purposes of intellectual property law, perhaps the penalties related to violations of the FD&C Act should be increased to deter and punish health-related crimes.[310] However, intellectual property laws can and should be used to counter medicine-related infringement, to the extent that intellectual property is a relevant and effective tool.[311] Both private industries and the government seem to view intellectual property laws as a tool in the fight against counterfeit medicines.[312] For instance, the Obama Administration recommended increasing the sentencing guidelines for "intellectual property offenses that risk death or serious bodily injury and for those offenses involving counterfeit drugs (even when those offenses do not present that risk)."[313] As discussed throughout this Article, intellectual property appears to play a role in enhancing public health

---

Enforcement 19 (2010), available at http://www.whitehouse.gov/sites/default/files/omb/assets/intellectualproperty/intellectualproperty_strategic_plan.pdf.

309. 18 U.S.C. § 2320.

310. An increase in FD&C Act penalties has been recommended. See **Exec. Office of the President**, supra note 4.

311. Nelson et al., supra note 197, at 1078–80.

312. Id.

313. **Exec. Office of the President**, supra note 170, at 2.

and welfare. However, the importance of intellectual property laws in this context is much more limited than intellectual property industries suggest. The next Part of this Article will examine the extent to which the utility of intellectual property law in protecting the public justifies provisions in international agreements that mandate government monitoring and enforcement of intellectual property rights.

VI. PUBLIC INTEREST AS THE GUIDING PRINCIPLE

This Article posits that government enforcement of private intangible rights is justifiable when there is harm or risk of harm to the public. In this context, harm means human cost, such as the loss of life or risk to health. This is not to suggest that we should promote the misuse of intellectual property or that intellectual property rights should not be respected. Rather, the argument here is that provisions in international agreements that will require governments to enforce private intangible rights should be limited to situations where such intervention is necessary to protect the public interest. In particular, with respect to counterfeit medicines, this should be limited to instances where the government seeks to protect the public from harm by protecting the public interest in health and safety.[314] This public interest framework is consistent not only with objectives and principles of TRIPS,[315] but also with aspects of international human rights law.[316] Furthermore, in so limiting state enforcement of private intangible rights, it will

314. OseiTutu, supra note 25, at 1652–83.

315. TRIPS, supra note 12, art. 7 (requiring a balancing of interests); id. art. 8 (recognizing flexibility to protect the public health).

316. International Covenant on Economic, Social and Cultural Rights, supra note 106, art. 12.

become apparent that such instances are relatively limited.

Public health is clearly a matter that falls within the purview of the government,[317] while intellectual property rights are private rights that are generally enforced privately.[318] In

---

317. Andrew Ashworth & Lucia Zedner, Just Prevention: Preventive Rationales and the Limits of the Criminal Law in **Philosophical Foundations of Criminal Law** 279, 281 (R.A. Duff & Stuart Greens eds., 2011) ("Given the problems of identifying limits, let us focus first on what may fairly be taken to be the core. Any account of the state's obligations towards citizens ought surely to include the obligation to take all reasonable measure to protect people from death or serious physical harm. This suggests the provision of public health services regulation of activities such as driving to ensure maximum coordination as well as safety; and the prevent of physical harm through a mixture of regulation (health and safety, for example), private law (a system of tort law), and criminal law."); Lawrence O. Gostin, Health of the People: The Highest Law?, 32 **J.L. Med. & Ethics** 509, 510 (2004). ("The word public in public health has two overlapping meanings—one that refers to the entity that takes primary responsibility for the public's health, and another that indicates who has a legitimate expectation of receiving the benefits. The government has primary responsibility for the public's health. The government is the public entity that acts on behalf of the people and gains its legitimacy through a political process. A characteristic form of "public" or state action occurs when a democratically elected government exercises powers or duties to protect or promote the population's health.").

318. See generally Copyright Act of 1976 (Copyright Act), Pub. L. No. 94-553, 90 Stat. 2541 (codified as amended in 17 U.S.C.); U.S. Patent Act of 1952 (Patent Act), Pub. L. No. 82-593,

intellectual property law, as with civil litigation in general, the role of the state is primarily limited to providing a system of private enforcement that intellectual property owners can use to enforce their rights.[319] Bear in mind that health and safety considerations are not relevant when it comes to acquiring, maintaining, or enforcing intellectual property rights.[320] Copyright protection arises automatically upon the creation of the work.[321] Trademarks can be acquired and maintained as long as the mark is used in association with goods and services.[322]

Governments may protect the public through the use of private law, regulation of activities, or through the use of criminal law,[323] including the police power. Professor Gostin defines the

---

66 Stat. 781 (codified as amended in 35 U.S.C.); Lanham Act, Pub. L. No. 79-489.

319. See Copyright Act § 504; Patent Act § 271(a); Lanham Act § 43.

320. See Patent Act §§ 101-105; Lanham Act § 1051; Copyright Act § 201.

321. 17 U.S.C. § 101 (2012) ("A work is 'created' when it is fixed in a copy or phonorecord for the first time; where a work is prepared over a period of time, the portion of it that has been fixed at any particular time constitutes the work as of that time, and where the work has been prepared in different versions, each version constitutes a separate work."); **Berne Convention**, supra note 53; TRIPS, supra note 12.

322. 15 U.S.C. § 1051 (2012).

323. Ashworth, supra note 317, at 281 ("Any account of the state's obligations towards citizens ought surely to include the obligation to take all reasonable measure to protect people from death or serious physical harm. This suggests the provision of public health services regulation of activities such as driving to ensure maximum coordination as well as safety; and the prevent of

police power as:

> The inherent authority of the state (and, through delegation, local government) to enact laws and promulgate regulations to protect, preserve, and promote the health, safety, morals, and general welfare of the people. To achieve these communal benefits, the state retains the power to restrict, within federal and state constitutional limits, private interests—including . . . economic interests in freedom to contract and uses of property.[324]

Thus, state enforcement of intellectual property rights can be justified, to some extent, on the basis of protecting the public health.[325] However, where there is no public health or safety

---

physical harm through a mixture of regulation (health and safety, for example), private law (a system of tort law), and criminal law. Resort to the criminal law, rather than another possible approach, is a decision that therefore needs to be justified independently.").

324. **Gostin**, supra note 30.

325. This is not to suggest that the right to health is more important than other human rights norms, like the right to culture. For instance, Article 25 of the Universal Declaration of Human Rights refers to the right to "a standard of living adequate for the health and well-being of himself and his family . . . including medical care . . . ". Universal Declaration of Human Rights (UDHR) art. 25, Dec. 10, 1948, 19 U.S.T. 6228, 999 U.N.T.S. 302. Article 27 of the Universal Declaration of Human Rights recognizes the right of everyone to "freely participate in the cultural life of the community, to enjoy the arts, and to share in scientific advancement and its benefits." Id. at art. 27.

benefit, some other justification for an active government role must be found. For instance, state governments[326] may choose to use its police power to protect and preserve the general welfare of the people, which is very broad and can encompass many different things.[327] Unless it can be shown that some public interest would be promoted by a shift to government enforcement of private intellectual property rights, private rights holders should be left to monitor and enforce their rights.[328] This would be an appropriate limitation of the use of the power of the state to police private interests.[329]

A. Hierarchy of Rights, Goods, or Harms?

If counterfeiting involves luxury goods, such as designer handbags, rather than medicines, there is less justification for the state to be involved in monitoring and enforcing pertinent

---

326. Because the Tenth Amendment of the United States Constitution reserves for the states all powers not explicitly granted to them by the Constitution, the federal government, which is the government that enters into international agreements, does not have a general police power but must resort to other constitutional authority (such as the commerce clause) for its actions with regard to health and safety. **U.S. Const.** amend. X; see Nat'l Fed'n of Indep. Bus. v. Sebelius, 132 S. Ct. 2566, 2578 (2012).

327. **Gostin**, supra note 30.

328. Earle et al., supra note 76, at 682.

329. **Gostin**, supra note 30, at 91 ("The 'police power' is the most famous expression of the natural authority of sovereign governments to regulate private interests for the public good.").

intellectual property rights.[330] Instead, it would be appropriate for the right holder to take the primary role in enforcing the rights.[331] Is this creating a hierarchy of goods? Yes, but only with respect to government enforcement, and justifiably so. Intellectual property-protected products do not have to be treated identically.[332] Harm, insofar as there is a financial loss suffered by the individual right holder, is insufficient to warrant the use of public resources to enforce private intangible rights absent some broader public interest.[333] Recall that the right holder has the primary responsibility for monitoring and enforcing his or her rights.[334] For instance, if a trademark holder fails to police and enforce his mark, the mark may eventually lose its distinctiveness, and the right holder may lose his claim to the mark.[335]

---

330. Earle et al., supra note 76.

331. Id. at 731.

332. See Patricia L. Judd, Towards a TRIPS Truce, 32 **Mich. J. Int'l L.** 613, 617 (2011) ("[B]reathing new life into TRIPS flexibilities helps rights holders by allowing judgments of compliance to take into account not just geography, but also the market for the particular product in question. For instance, the impact of seemingly non-commercial systems facilitating peer-to-peer trading of copyrighted files over the internet may need to be assessed differently than the impact of a rogue textbook printer.").

333. This is not to suggest that the government may never have an interest in prosecuting financial harms, like securities fraud, for instance.

334. Copyright Act § 504; Patent Act § 271(a); Lanham Act § 43.

335. 15 U.S.C. § 1064(3) (2006) (A mark may be cancelled if "the registered mark becomes the

Moreover, if the public, through taxes paid for law enforcement, absorbs the cost of protecting the right, there should be some relevance to the public welfare beyond the general desire to protect and promote innovation or efficient business transactions. Given the nature of intellectual property rights, as discussed in Part VI.B,[336] the innovation goal is already promoted by the existence of intellectual property protection.[337] Furthermore, despite the rhetoric about counterfeit goods and organized crime,[338] it is inadequate to justify government intervention in monitoring and enforcing private intellectual property rights based on the hypothesis that counterfeiting luxury goods is attractive to those who make counterfeit medicines or industrial goods and to terrorist organizations.[339] First, it is not the purpose of intellectual property law to

---

generic name for the goods or services, or a portion thereof, for which it is registered.").

336. See infra Part VI.B.

337. Article I, Section 8 of the Constitution of the United States authorizes Congress to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." **U.S. Const.** art. I, § 8.

338. See ACTA, supra note 13, pmbl. ("Noting further that the proliferation of counterfeit and pirated goods, as well as of services that distribute infringing material, undermines legitimate trade and sustainable development of the world economy, causes significant financial losses for right holders and for legitimate businesses, and, in some cases, provides a source of revenue for organized crime and otherwise poses risks to the public.").

339. Earle et al., supra note 76, at 687 ("Terrorists and other criminals are taking advantage of

control the activities of terrorist organizations. Second, any such terrorist-related organized crime can be addressed through legislation specifically directed toward that purpose.[340]

Creating a hierarchy of products and a hierarchy of harms is distinct from creating a hierarchy of rights as between the different forms of intellectual property.[341] This differentiation is with respect to government action, depending on the nature and scope of the harm vis-ā-vis the public.[342] If the harm does not amount to a significant risk to the public, such as risk of death or serious illness, the case for government monitoring and enforcement of intellectual property rights is not satisfied.[343] Furthermore, not all counterfeit goods are harmful to the public.[344] For instance, under the current law, when Customs detains counterfeit goods at the border, the goods may be released after the infringing mark has been removed, absent all public health risks.[345]

---

the lower risks for counterfeiting not only designer good, but also pharmaceuticals and parts for computers, cars, and airplanes.").

340. For instance, 18 U.S.C. § 2339(c) prohibits activities that finance terrorism, with penalties ranging from 10 to 20 years imprisonment. See 18 U.S.C. § 2339(c) (2006). Providing material support to terrorists or to terrorist organization can lead to a term of imprisonment ranging from 15 years to life in prison. See 18 U.S.C. § 2339 (a), (b) (2006).

341. See Earle et al., supra note 76, at 682.

342. See id.

343. See id.

344. See id.

345. 19 CFR §133.52 (2013) ("Merchandise forfeited for violation of the trademark laws shall

B. Underlying Values

Policy decisions are informed by underlying values, even if the values are not explicitly stated.[346] International agreements that aim to enforce intellectual property rights place value on these rights and on their enforcement.[347] Some intellectual property industries are seeking state enforcement of intellectual property-protected goods that do not have a health and safety impact.[348] However, such justifications should be clearly distinguished from any health and safety arguments.[349] This is important in the intellectual property context because the other public welfare justifications may be far less persuasive than assertions about protecting public health and safety.[350] For example, the loss of tax revenue or profit for a handful of intellectual property owners offers a less compelling justification for government enforcement of intellectual property rights than the potential health risk associated with counterfeit medicines.[351]

---

be destroyed, unless it is determined that the merchandise is not unsafe or a hazard to health and the Commissioner of Customs or his designee has the written consent of the U.S. trademark owner . . . .").

346. As I have argued elsewhere, underlying values inform the development of suitable national policies. See OseiTutu, supra note 25, at 1657.

347. See TRIPS pmbl. & arts. 7 & 8.

348. See infra Part III.B (discussing TPP negotiations).

349. See Earle et al., supra note 76, at 682.

350. See id.

351. See id.

Even the view that counterfeit goods are harmful to society, and that this justifies high levels of intellectual property protection and enforcement, reflects a particular perception of copying, which is open to debate.[352] For instance, it is not entirely clear that copyright piracy or trademark counterfeiting have a deleterious effect on public morals or on the general welfare of society.[353] To the contrary, some commentators argue that excessively strong intellectual property rights are more detrimental to society than weak intellectual property rights.[354] Even if one were to take the position that all copying is bad, the question remains as to whether differing counterfeit goods should be treated homogeneously. The answer to this question requires another value judgment. But, what criteria is used to answer this question? One view might be that intellectual property

---

352. See Llewellyn Joseph Gibbons, Do As I Say (Not As I Did): Putative Intellectual Property Lessons for Emerging Economies from the Not So Long Past of the Developed Nations, 64 **SMU L. Rev.** 923, 973 (2011).

353. For instance, the United States had a history of piracy in the early years of the country's development. See Peter Drahos, The Universality of Intellectual Property Rights: Origins and Development 5 (1999), available at http://www.wipo.int/edocs/mdocs/tk/en/wipo_unhchr_ip_pnl_98/wipo_unhchr_ip_pnl_98_1pdf.

354. Outterson, supra note 95, at 201–02 ("The social costs of making pharmaceutical knowledge appropriable are generally three-fold. First, the cumulative effect of these laws allows the innovator to charge a higher price under monopolistic conditions . . . Second, these higher prices hinder medical access, directly impacting the health of many low income people globally.").

infringement should never be tolerated, and that government intervention is always justifiable.[355] Another view is that some counterfeiting has more serious implications for society than other kinds of counterfeiting, and that government intervention is not always required.[356]

The criteria used to ascertain when the governments must, in accordance with their international obligations, monitor and enforce intellectual property rights should be clear.[357] As this Article suggests, when it comes to government intervention, the benefit for the public generated by reducing the risk of harm should be the primary criterion used to determine whether government enforcement of intellectual property rights is warranted.[358] This would militate in favor of some government role with respect to counterfeit medicines, but not necessarily the same role with respect to music piracy, for instance.[359]

Consistent with the idea of differential treatment depending on the harm caused, the Obama Administration's recommended legislative changes reflect a policy decision to treat crimes related to counterfeit medicines and intellectual property crimes that risk serious injury or death more harshly than those that do not.[360] In its White Paper, the Administration recommended

---

355. See OseiTutu, supra note 25, at 1657.

356. See id.

357. See id.

358. See id.

359. Rierson, supra note 142, at 450–56.

360. **Exec. Office of the President**, supra note 170, at 2 ("Increase the U.S. Sentencing Guideline range for intellectual property offences that risk death or serious bodily injury and for

increasing the penalty for economic espionage and for drug offenses under the FD&C Act, "particularly for counterfeit drug offenses."[361] There is an emphasis on harsher penalties for counterfeit drug offenses in particular.[362] This differential treatment makes sense in light of the potentially serious impact of such offenses.[363] An implicit value guides these legislative proposals, and appears to relate to the level of economic harm or the potential harm to human health or life.[364]

---

those offenses involving counterfeit drugs (even when those offenses do not present that risk) . . . .").

361. Id. at 1.

362. Id. at 2 ("Require importers and manufacturers to notify the Food and Drug Administration (FDA) and other relevant agencies when they discover counterfeit drugs or medical devices, including the known potential health risks associated with those products; Provide for civil and criminal forfeiture under the FFDCA, particularly for counterfeit drug offenses; . . . increase the statutory maxima for drug offenses under the FFDCA, particularly for counterfeit drug offenses; and 6 . . . , recommend that the U.S. Sentencing Commission increase the U.S. Sentencing Guideline range for intellectual property offenses that risk death and serious bodily injury, and for those offenses involving counterfeit drugs (even when those offenses do not present that risk).").

363. Id.

364. Although there may be no problem with the criteria that inform the government's policy decisions, and clear set of criteria has the benefit of transparency.

Thus, when the harm is less significant, insofar as there is little to no risk to human health and safety, governments should refrain from taking on the role of enforcer of intellectual property rights. But, if a Gucci bag is stolen—as opposed to a mark being misused—the crime of theft, which is prohibited by our criminal law, was committed.[365] Why should we treat intellectual property differently? Intellectual property is different because it is non-rivalrous and, though often discussed as property, it does not have the same characteristics as tangible property.[366] The effect of use of intangible goods without permission is distinct from the impact of use of tangible property.[367] If a thief steals a designer purse from its owner, the owner is deprived of its use. In addition, the unauthorized use of intangible goods lacks the element of physical violence that tends to accompany the theft of personal property.[368]

---

365. See Manta, supra note 12, at 473–80.

366. **F.H. Lawson and Bernard Rudden**, **The Law of Property** 38 (3d ed. 2002) ("[Intellectual property] confers the right to require everyone not to do something, and to make him or her pay compensation if they do. In that way, intellectual property rights are similar to the rights of a landowner against trespassers. But of course they are very dissimilar in that there need be no tangible object: they protect the products, not of nature but of the human mind . . . . [Intellectual property rights] are really monopolies, protected by the law for a limited, and in some cases, unlimited, time.").

367. Manta, supra note 12, at 471 (discussing the differences between the harms that result from property crimes versus IP infringement).

368. Id. at 475 (citing the Model Penal Code § 223 cmt. 2(a)(1980), "That history begins with a

When it comes to misuse of a designer label, the designer is deprived of revenue to which he would otherwise be entitled.[369] However, unlike the physical purse, a trademark can be used multiple times by multiple people, and several individuals can download the same piece of music.[370] This is done without depriving anyone of the ability to use the mark or enjoy the music.[371] When this is done with the permission of the right holder, there is no objection. However, when a mark is used without permission, or when music is downloaded without permission, we object.[372] The harm relates to the lack of permission from and remuneration to

---

concern for crimes of violence – in the present context, the taking of property by force from the possession of another, i.e. robbery. The criminal law then expanded, by means of the ancient quasi-criminal writ of trespass, to cover all taking of another's property from his possession without his consent, even though no force was used.").

369. See Sam Cocks, The Hoods Who Move the Goods: An Examination of the Booming International Trade in Counterfeit Goods and an Assessment of the American Efforts to Curtail its Proliferation, 17 **Fordham Intell. Prop. Media & Ent. L.J.** 501, 503–04 (2007).

370. See James Boyle, The Second Enclosure Movement and the Construction of the Public Domain, 66-SPG **Law & Contemp. Probs.** 33, 41 (2003).

371. Id.

372. Stephen E. Siwek, **The True Cost of Sound Recording Piracy to the U.S. Economy** (Inst. for Policy Innovation Ctr. for Tech. Policy Report No. 188 2007), available at http://www.ipi.org/docLib/20120515_SoundRecordingPiracy.pdf ("The true cost of sound recording piracy far exceeds its impact on U.S. producers and distributors of sound recordings.

the right holder.[373] However, use by one—whether legal or illegal—does not affect the ability of another to make use of the same intellectual property.

Ultimately, it remains the primary responsibility of the individual property owner, not the government, to monitor the use of its intellectual property, and to enforce its rights against infringing parties.[374] Arguably, there is a justifiable exception to this rule when there is some greater public interest that warrants government intervention. When discussing intellectual property enforcement in relation to counterfeit medicines, the impact on public health and safety is the relevant societal good against which to gauge the need to resort to the state's police power.[375]

Even if intellectual property laws can help curb the trade in counterfeit medicines, they are only a very limited part of the solution to a complex problem.[376] Arguably, state enforcement of intellectual property has little to do with protecting the public. Existing international intellectual property agreements contain enforcement provisions for all intellectual property rights; not just

---

Piracy harms not only the owners of intellectual property but also U.S. consumers and taxpayers.").

373. See Cocks, supra note 369.

374. IpVenture, Inc. v. ProStar Computer, Inc., 503 F.3d 1324, 1325 (Fed. Cir. 2007) ("Only the entity or entities that own or control all substantial rights in a patent can enforce rights controlled by that patent.").

375. See OseiTutu, supra note 25, at 1657.

376. **World Health Org.**, supra note 8.

for counterfeit medicine-related crimes or public safety-related offenses.[377] New agreements seek to build on what TRIPS established.[378] However, these agreements generally aim to limit the flexibility that was built into TRIPS.[379] The next Part of this Article turns to a more specific consideration of the enforcement provisions of some of the international intellectual property agreements.

VII. INTERNATIONAL ENFORCEMENT PROVISIONS & GOALS

A. TRIPS & TRIPS Plus

TRIPS requires countries to implement enforcement procedures that will prevent and deter infringement.[380] Importantly, however, the precise nature of these procedures is left to the WTO

---

377. TRIPS, supra note 12, art. 41.

378. ACTA, supra note 13.

379. Cynthia M. Ho, A New World Order for Addressing Patent Rights and Public Health, 82 **Chi-Kent L. Rev.** 1469, 1496 (2007) ("Whereas TRIPS allowed countries flexibility in defining the terms of patentability to meet their individual needs, subsequent FTAs infringe on that flexibility.").

380. TRIPS, supra note 12, art. 41.1. ("Members shall ensure that enforcement procedures as specified in this Part are available under their law so as to permit effective action against any act of infringement of intellectual property rights covered by this Agreement, including expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements. These procedures shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse.").

member states to determine.[381] In addition, WTO member states must have criminal penalties for willful trademark counterfeiting or copyright piracy on a commercial scale.[382] This includes a requirement to allow the authorities to commence investigations or legal action on their own initiative.[383] These provisions in TRIPS mean that "in appropriate cases," member states must enable government authorities to enforce trademark and copyrights—at least where it appears that there may be infringement on a commercial scale.[384]

Nonetheless, some allege that the enforcement provisions of TRIPS have no teeth.[385] In

---

381. See id. art. 1 ("Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.").

382. Id. art. 61.

383. Id.

384. **World Trade Org.**, **WT/DS362/7**, **China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights: Request for the Establishment of a Panel by the United States** (2007), available at http://www.wto.org/english/tratop_e/dispu_e/362r_d_e.pdf.

385. Peter K. Yu, The TRIPS Enforcement Dispute, 89 **Neb. L. Rev.** 1046, 1049 (2010). For a contrary view, see Laurence R. Helfer, Human Rights and Intellectual Property: Conflict or Coexistence?, 5 **Minn. Intell. Prop. Rev.** 47, 54 (2003) ("[U]nlike earlier intellectual property

particular, the meaning of infringement on a "commercial scale" is not always clear, as the WTO dispute between China and the United States illustrates.[386] In addition, under TRIPS, member states retain the discretion to determine when state enforcement of intellectual property rights is appropriate.[387]

Since TRIPS, many bilateral trade agreements include provisions that increase intellectual property protections and omit the provisions that were included in TRIPS to protect the public interest or allow nations greater national control.[388] WTO members agreed to allow each nation to determine which principle of exhaustion to apply, and when right holders may use intellectual property rights to control the circulation of goods.[389] However, some of the post-TRIPS bilateral agreements reject international exhaustion and therefore prevent parallel importation.[390] This

---

agreements, TRIPS has teeth."); J.H. Reichman & David Lange, Bargaining Around the TRIPS Agreement: The Case for Ongoing Public-Private Initiatives to Facilitate Worldwide Intellectual Property Transactions, 9 **Duke J. Comp. & Int'l L.** 11, 35 (1998) ("The enforcement provisions are crafted as broad legal standards, rather than as narrow rules, and their inherent ambiguity will make it harder for mediators or dispute-settlement panels to pin down clear-cut violations of international law.").

386. **World Trade Org.**, supra note 384.

387. TRIPS, supra note 12, art. 1.

388. Ho, supra note 379, at 1502.

389. TRIPS, supra note 12, art. 6.

390. Ho, supra note 379, at 1501 ("Some of these agreements prohibit developing countries

means that lower-priced authentic products, which are intended for a market other than the one in which they are being sold, may be considered infringing goods.[391]

B. The Anti-Counterfeiting Trade Agreement

The Anti-Counterfeiting Trade Agreement (ACTA) attempts to address some of the perceived weaknesses of TRIPS with respect to enforcement.[392] TRIPS requires members to enable a right holder to apply to have goods held by customs authorities when the right holder has reason to believe that infringing goods are about to be imported.[393] ACTA expands on TRIPS enforcement obligations in various ways.[394] For instance, under ACTA, member states must have measures for competent authorities to act upon their own initiative to investigate or commence criminal prosecutions for willful trademark counterfeiting or copyright infringement on a commercial scale.[395] In contrast to TRIPS, the ACTA obligation is not tempered by the language, "in

---

from importing patented drugs from countries that sell them at the lowest price; that is, they prohibit parallel importation and reject the principle of exhaustion. For example, the US-Singapore and US-Morocco Free Trade Agreements limit parallel importation by requiring member countries to provide patent holders with the means to block importation of patented drugs if it violates a distribution agreement.").

391. Id.

392. See ACTA, supra note 13.

393. See TRIPS, supra note 12, art. 51.

394. ACTA, supra note 13, pmbl.

395. See id. arts. 23 & 26. Article 23.2 provides: "Each Party shall provide for criminal

appropriate cases."[396] This modifying language provides WTO members with a significant level of flexibility in implementation.[397] By comparison, ACTA parties undertake to have their competent authorities (the government) monitor the misuse of trademarks and copyrights and prosecute the offenders.[398] In addition, ACTA mandates criminal enforcement of trademark and copyright infringement that occurs on a commercial scale.[399]

However, proponents of increased intellectual property enforcement face the need to justify directing public resources towards enforcement.[400] Both TRIPS and ACTA provide that governments are under no obligation to redirect resources to the enforcement of intellectual property rights.[401] For instance, Article 2.2 of ACTA provides that "[n]othing in [the] Agreement creates any obligation with respect to the distribution of resources as between enforcement of

---

procedures and penalties to be applied in cases of willful importation and domestic use, in the course of trade and on a commercial scale, of labels or packaging." See id. art. 23.

396. See id.

397. TRIPS, supra note 12, art. 61.

398. ACTA, supra note 13, arts. 23, 26.

399. Id. art. 23.1 ("Each Party shall provide for criminal procedures and penalties to be applied at least in cases of willful trademark counterfeiting or copyright or related rights piracy on a commercial scale.").

400. Sean M. Flynn et al., The U.S. Proposal for an Intellectual Property Chapter in the TransPacific Partnership Agreement, 28 **Am. U. Int'l L. Rev.** 105, 185 (2012).

401. See TRIPS, supra note 12, art. 41.5; ACTA supra note 13, at art. 2.2.

intellectual property rights and enforcement of law in general."[402] Article 4.15 of TRIPS contains similar language.[403]

In addition, those seeking to maximize intellectual property protections attempt to illustrate the value in promoting their objective by characterizing the benefit as belonging not only to private corporations, but to the broader public as well.[404] Indeed, trademark counterfeiting or copyright infringement on a commercial scale may be something that a government would like to prosecute.[405] Alternatively, it may be that prosecuting intellectual property infringers is not a governmental priority,[406] or that it would only become a government priority in instances where

402. ACTA, supra note 13, art. 2.2.

403. TRIPS, supra note 12, art. 41.5 ("It is understood that this Part does not create any obligation to put in place a judicial system for the enforcement of intellectual property rights distinct from that for the enforcement of law in general, nor does it affect the capacity of Members to enforce their law in general. Nothing in this Part creates any obligation with respect to the distribution of resources as between enforcement of intellectual property rights and the enforcement of law in general.").

404. Id. art. 41.5.

405. **Trans-Pacific Partnership**, Draft: Intellectual Property Rights Chapter (Feb. 10, 2011) (unpublished), available at http://keionline.org/sites/default/files/tpp-10feb2011-us-text-ipr-chapter.pdf.

406. Gibbons, supra note 352.

the public would be harmed by the infringement.[407]

Measuring the ACTA provisions against a health and safety standard, it is apparent that the provisions are overreaching.[408] Misuse of a trademark "on a commercial scale" may capture all kinds of activities that have little to no impact on the public health.[409] For instance, the misuse of trademarks on clothing labels may have little to no negative health or safety impact.[410] The same is true for copyright infringement occurring through music piracy.[411] Even utilizing a general public benefit standard, ACTA's state enforcement provisions go too far from an intellectual property perspective, and they are completely inadequate from a health perspective.[412] Counterfeit medicines that do not involve trademark or copyright infringement "on a commercial scale" will not be impacted.[413] For instance, if the scope of the operation is relatively small, it

---

407. See OseiTutu, supra note 25, at 1657.

408. See id. at 1668–69.

409. **World Trade Org.**, supra note 384.

410. Rierson, supra note 142, at 434.

411. See id.

412. Margot Kaminski, The Origins and Potential Impact of the Anti-Counterfeiting Trade Agreement, 34 **Yale J. Int'l L.** 247, 255 (2009).

413. See ACTA, supra note 13, art. 23.1 ("Each Party shall provide for criminal procedures and penalties to be applied at least in cases of willful trademark counterfeiting or copyright or related rights piracy on a commercial scale. For purposes of this Section, acts carried out on a commercial scale include at least those carried out as commercial activities for direct or indirect

may not meet the "on a commercial scale" requirement.[414] Finally, even if promoting social order is asserted as the public good arising from state-enforced intellectual property, intellectual property theft does not lead to the same kind of social chaos as the theft of real property, due to its non-rivalrous nature.[415] If there is no other public interest that is served by the adoption of these enforcement provisions, then it may be that the primary purpose is to protect certain industries.

C. The Trans-Pacific Partnership Agreement

The Trans-Pacific Partnership (TPP) provisions proposed by the United States in the leaked 2011 version, require all parties to make patents available for new uses of existing products.[416]

---

economic or commercial advantage.").

414. **World Trade Org.**, supra note 384.

415. See Manta, supra note, 12, at 480 ("IP infringement does not tend to endanger the safety of an owner like some property crimes do. The non-rivalrous nature of IP also means that an infringer cannot completely deprive the owner of a good, unless she also commits an accompanying property crime such as the theft of all copies of a manuscript.").

416. **Trans-Pacific Partnership**, supra note 405, art. 8.1 ("Each Party shall make patents available for any invention, whether a product or process, in all fields of technology, provided that the invention is new, involves an inventive step, and is capable of industrial application.15In addition, the Parties confirm that: patents shall be available for any new forms, uses, or methods of using a known product; and a new form, use, or method of using a known product may satisfy the criteria for patentability, even if such invention does not result in the enhancement of the

This proposed change is particularly relevant for the pharmaceutical industry, because it allows for the extension of the patent term on the basis of the new use.[417] The difficulty with new use patents is that they facilitate potential "evergreening" of patents, or ongoing extensions of what is supposed to be a time-limited right without requiring much inventiveness.[418] The U.S. proposal also effectively eliminates the current exception to patentability under Article 27.3 of TRIPS.[419] The United States proposed that all parties make patents available for plants and animals, and for diagnostic, therapeutic, and surgical methods for the treatment of humans or animals.[420] By contrast, TRIPS specifically provides that WTO members may exclude plants and animals and diagnostic, therapeutic, and surgical methods for the treatment of humans or animals from patentability.[421] Clearly, as requested by U.S. intellectual property industries, the TPP aims

---

known efficacy of that product.").

417. See id.

418. See Janice M. Mueller & Donald S. Chisum, Enabling Patent Law's Inherent Anticipation Doctrine, 45 **Hous. L. Rev.** 1101, 1106 (2008).

419. **Trans-Pacific Partnership**, supra note 405, art. 8.2.

420. Id. ("Each Party shall make patents available for inventions for the following: (a) plants and animals, and (b)diagnostic, therapeutic, and surgical methods for the treatment of humans or animals.").

421. TRIPS, supra note 12, art. 27.3 ("Members may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) plants and animals other than micro-organisms, and essentially biological processes for the production

to establish standards that surpass TRIPS requirements, while using TRIPS as a baseline.[422]

Due to the secrecy of the TPP negotiations, it is difficult to fully assess the potential impact of this agreement.[423] However, increased intellectual property standards and enforcement are amongst the U.S. intellectual property goals for the TPP.[424] Utilizing public interest as the standard against which to assess the intellectual property provisions in these TRIPS Plus agreements may cause the balance to shift away from increased protections and increased enforcement of existing or higher standards. For instance, government enforcement of copyright-protected films is not related to public safety.[425] Thus, government enforcement of copyrighted works should not be subsumed under the broader health and safety justification that is advanced with respect to counterfeit medicines.[426] Rather, the copyright concerns should be isolated in order to ascertain the interests at stake, including whether there is any pertinent public interest

---

of plants or animals other than non-biological and microbiological processes.")

422. Outlines of the Trans-Pacific Partnership Agreement, **Office U.S. Trade Rep.**, http://www.ustr.gov/about-us/press-office/fact-sheets/2011/november/outlines-trans-pacific-partnership-agreement.

423. David S. Levine, Bring in the Nerds: Secrecy, National Security, and the Creation of International Intellectual Property Law, 30 **Cardozo Arts & Ent. L.J.** 105, 127–31 (2012).

424. Outlines of the Trans-Pacific Partnership Agreement, supra note 422.

425. Manta, supra note 12.

426. See Rierson, supra note 142, at 434–35.

served by mandating government enforcement of copyright.[427] Due to the secrecy of the negotiations, the affected citizens are not able to participate in shaping the outcome.[428] However, a set of clear and transparent standards may help alleviate concerns about whether negotiating governments are representing the interests of their citizens or the interests of industry stakeholders to the detriment of their citizens.[429]

If agreements like the TPP, or the recently announced Trans-Atlantic Trade and Investment Partnership,[430] will provide for increased intellectual property enforcement, it is essential to foster transparency regarding the rationales for such enforcement.[431] It is easy to minimize

---

427. As indicated earlier, the relevant public interest will differ depending on the nature of the industry, and the kind of intellectual property at issue.

428. See Levine, supra note 423, at 151.

429. Id.

430. In February 2013, the European Union and the United States announced that they will commence negotiations on a trans-Atlantic partnership to liberalize trade and investment rules. No details as to possible content of this agreement as available at this time. Press Release, Office of the United States Trade Representative, U.S., EU Announce Decision to Launch Negotiations on a Transatlantic Trade and Investment Partnership (Feb. 13, 2013), available at http://www.ustr.gov/about-us/press-office/press-releases/2013/february/statement-US-EU-Presidents.

431. See David S. Levine, Transparency Soup: The ACTA Negotiating Process and "Black Box" Lawmaking, 26 **Am. U. Int'l L. Rev.** 811, 813–15 (2011).

potentially less popular justifications for government enforcement of intellectual property by emphasizing public welfare-related justifications, such as the safety of the medicine supply. Governments need to be clear about when and how an identifiable public interest is being protected.[432]

VIII. CONCLUSION

The standardized intellectual property rights created under TRIPS have been criticized on many levels.[433] In particular, the impact of these rights on access to medicines offers a persuasive argument against the ratcheting up of intellectual property rights.[434] Additionally, the potentially detrimental impact of overzealous intellectual property protection on access to knowledge is an

---

432. See id.

433. Robert M. Sherwood, Symposium, Some Things Cannot Be Legislated, 10 **Cardozo J. Int'l & Comp. L.** 37, 40 (2002) ("The TRIPS Agreement was the result of a compromise among sharply divided countries and does not reflect a robust level of protection."); Maskus & Reichman, supra note 61, at 286 ("[S]erious questions arise as to the sustainability of the attempt in TRIPS to resolve the international externality of protecting new knowledge goods."); Reichman & Dreyfuss, supra note 62, at 92 ("The dynamics of TRIPS and the post-TRIPS trade agreements teach that even a development-sensitive negotiation process is likely to produce an instrument that furthers interests of developed countries at the expense of poorer, less powerful participants.").

434. Reichman & Deyfuss, supra note 62, at 91–92, 95–96.

important part of the critique.[435] Nonetheless, the life and death nature of the medicines debate has been a more powerful tool for pressuring intellectual property industries and their advocates to respond and adjust.[436] On the other hand, the dangerous nature of counterfeit medicines provides intellectual property industries a powerful counter-narrative to the access to medicines critique of intellectual property.[437]

In light of the balancing provisions of TRIPS,[438] subsequent international agreements should retain sufficient flexibility to enable all nations to implement intellectual property laws and

---

435. See, e.g., Molly Beutz Land, Intellectual Property Rights and the Right to Participate in Cultural Life (Inst. for Info. Law & Policy Ser. 08/-09 #2, 2008), available at http://www.ssrn.com/abstract=1475430 ("Intellectual property rights can restrict the ability of individuals to participate in cultural life by limiting their access to cultural goods."); Shaver supra note 160, at 121; Lea Shaver & Caterina Sganga, The Right to Take Part in Cultural Life: On Copyright and Human Rights, 27 **Wis. Int'l L.J.** 637, 639 (2010).

436. Although there have been discussions about access to knowledge at WIPO and elsewhere, there is still no declaration or draft treaty that is comparable to the Doha Declaration on TRIPS and Public Health. See Sisule F. Musungu, The Third Access to Knowledge (A2K3) Conference, **WIPO Mag.**, December 2008, http://www.wipo.int/wipo_magazine/en/2008/06/article_0007.html; Cahoy, supra note 77, at 426.

437. Rierson, supra note 142, at 434–35.

438. See TRIPS, supra note 12, arts. 7 & 8.

policies that suit their national circumstances.[439] This proposal is consistent with the spirit of TRIPS, which was the first agreement to establish global intellectual property standards.[440] New obligations that impinge on domestic policy choices must be adequately justified.[441] Intellectual property laws could be part of a broader solution aimed at curbing the circulation of counterfeit medicines. Arguably this is consistent with a public interest approach to intellectual property law that should be encouraged and promoted. Yet the role of intellectual property law in combating counterfeit medicines has been exaggerated. Regrettably, the notion that increased government monitoring and enforcement of these private rights will help promote public health and safety is based more on rhetoric than reality. While we may all agree that counterfeit medicines crimes are serious and warrant harsh penalties, the harm caused by counterfeit drugs does not provide as compelling a case for an increased government role in intellectual property enforcement, as it may initially seem.

First, although counterfeiting can be prosecuted as an intellectual property crime, the use of intellectual property laws is not an ideal solution.[442] Yes, intellectual property laws can contribute to the efforts to curb the trade in counterfeit medicines. In particular, intellectual property interests and health concerns may overlap to the extent that consumers rely on

439. Gibbons, supra note 352, at 972–73.

440. See TRIPS, supra note 12, arts. 1, 7–8.

441. See Dreyfuss & Lowenfeld, supra note 18, at 302–03.

442. Earle et al., supra note 76, at 732.

trademarks, for example, as an indication of safety.[443] However, packaging may be legitimate while the drugs are not.[444] In such cases, tracking the packaging does nothing to control the distribution of the fake drugs.[445] Second, using health and safety to characterize all counterfeit goods as dangerous enables intellectual property producers to obtain state-enforced protection for goods protected by intellectual property, such as fake designer purses or clothing, for which there may be no health or safety concern. In such instances, there is no apparent reason why the government, rather than the right holder, should enforce the rights. In fact, this could lead to overly stringent protection of intellectual property and impede the distribution of safe products, such as legal generic drugs, which would otherwise enhance the public welfare. Thus, where there is a non-health-related public interest justification for government enforcement of intellectual property rights, the justification should be clearly articulated.[446]

Whatever the goals in a particular international agreement, transparency with respect to the process and the substantive rationale for the agreement is critical to the ability of the affected citizens to contribute to the dialogue. Information about the rationale for government action affects the capacity of citizens to participate in shaping domestic laws that are consistent with

---

443. Bunker, supra note 20, at 495–99, 506–08.

444. See Donald deKieffer, Trojan Drugs: Counterfeit and Mislabeled Pharmaceuticals in the Legitimate Market, 32 **Am. J. L. & Med.** 325, 346 (2006).

445. Id.

446. The Washington Declaration on Intellectual Property and the Public Interest, 28 **Am. U. Int'l L. Rev.** 19, 26–27 (2012).

their national values.[447] For instance, a nation may rationally choose to protect copyright-dependent industries through government enforcement of copyrights.[448] However, if a government aims to support copyright industries while purporting to make decisions based on health and safety, there is a lack of transparency and accountability.[449] In such instances, national values are rendered irrelevant.[450] For example, there might be widespread support in a particular country for government enforcement of intellectual property rules to combat counterfeit medicines, but the citizens of the same country may not support broad government enforcement provisions that also limit access to knowledge goods or cultural products.[451]

Arguably, it is not meaningful to have intellectual property standards without corresponding enforcement of those standards. A balanced intellectual property system can play a positive and important role in society by rewarding creativity and inventiveness.[452] Thus, the matter of enforcement provisions in international intellectual property agreements is not a question of whether to enforce intellectual property rights; rather, it is a question of to whom this responsibility should fall. As a general rule, the intellectual property owner is responsible for

447. See OseiTutu, supra note 25, at 1657.

448. See id.

449. See id.

450. See id.

451. See id.

452. Land, supra note 435.

monitoring and enforcing his or her rights.[453] Private enforcement is preferable for a number of reasons, including the ability of individuals to more effectively avail themselves of legitimate exceptions to intellectual property rights.[454]

Although there is a trend toward greater government enforcement of intellectual property rights through multilateral agreements, this increased enforcement is poorly justified, and often used to rationalize government enforcement for all intellectual property-protected goods, even though the public interest rationale may actually relate to a narrow subset of goods, such as medicines. Consistent with the balance reflected in Articles 7 and 8 of TRIPS,[455] this Article has argued for a public interest test as a barometer for determining when state enforcement of intellectual property rights is warranted. This public interest approach can assist in reframing the discussions about intellectual property enforcement, thereby promoting greater transparency in the development of international and domestic intellectual property law and policy. It will also help to ensure that the net that is cast to capture dangerous intellectual property infringement is not overly broad.

453. Cf. IpVenture, Inc. v. Prostar Computer, Inc., 503 F.3d 1324, 1325 (Fed. Cir. 2007).

454. When the state enforces intellectual property rights at the border, for instance, goods that are allegedly infringing would be detained ex officio, which gives the intellectual property owner the upper hand.

455. See TRIPS, supra note 12, arts. 7 & 8.