

Patently Limited: The Conflict Between Public Health and Patent Rights

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IT'S POVERTY—NOT PATENTS.¹ It's the lack of resources. It's their ability to manufacture. These are just a few arguments plaguing the developing world's human right to medicine instead of acknowledging the alternative conflict—that patent rights potentially serve as a barrier to this access. Sure, all of these arguments logically contribute, but one non-obvious argument is ripe for discussion. This conflict arises from the idea that patent rights and public health rights cannot co-exist successfully without one set of rights becoming inferior. Specifically, this coexistence identifies the “juxtaposition in human rights instruments of individual rights over intellectual creations against the rights of everyone to ‘share in scientific advancement and its benefits.’”²

On one side of the spectrum, there is the property rights' regime, that values the protection of patents and its association with innovation—investment in research and development—broadening the availability of medicines in the long term.³ This side creates positive effects on patient welfare and the hope of the improvement of public health.

However, one should consider the effect of strong patent protection on the poor's ability to fight diseases threatening its public health. This side turns on the use of patent holders' power to aggres-

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1. Jamie Crook, *Balancing Intellectual Property Protection with the Human Right to Health*, 23 BERKELEY J. INT'L L. 524, 529 (2005).

2. Aurora Plomer, *The Human Rights Paradox: Intellectual Property Rights and Rights of Access to Science*, 35 HUM. RTS. Q. 143, 144 (2013).

3. Valentina Vadi, *New Forms of Dialectic Between Intellectual Property and Public Health: Pharmaceutical Patent-Related Investment Disputes*, 49 INT'L LAW. 149, 151 (2015).

sively enforce intellectual property rights, while simultaneously chilling public health rights by promoting stricter protection of their inventions. This conflict implies an access problem, particularly in developing countries, where intellectual property rights serve as a barrier to increased access to affordable medicines in the poorest of countries.

Approximately two billion people in the world “have no access to essential medicines, effectively shutting them off from the benefits of advances in modern science and medicine.”⁴ “Infectious diseases kill over ten million people, more than 90% of whom are in the developing world.”⁵ “The leading causes of illness and death in Africa, Asia, and South America—regions that account for four-fifths of the world’s population—are HIV/AIDS, respiratory infections, malaria, and tuberculosis.”⁶

Since the beginning of the HIV/AIDS epidemic over seventy million people have been infected with HIV⁷ and approximately thirty-five million have died of HIV.⁸ At the end of 2017 almost thirty-seven million people were living with HIV.⁹ The magnitude of the AIDS crisis has drawn attention to the fact that millions of people in the developing world do not have access to the medicines that are needed to treat disease, or *at the very least*, alleviate suffering.¹⁰ Because of this property regime, developing nations do not have the same access to modern medicine compared to more developed nations.

Established in 1994, the Trade-Related Aspects of Intellectual Property Rights Agreement¹¹ (“the TRIPS Agreement” or “TRIPS”) set forth the minimum regulations of intellectual property protection and attempted to address this conflict.¹² Proponents of the TRIPS Agreement viewed intellectual property as a form of investment, argu-

4. *Access to Medicines: Making Market Forces Serve the Poor*, WORLD HEALTH ORG., <https://www.who.int/publications/10-year-review/medicines/en/> [https://perma.cc/L364-KVKQ].

5. Ellen ‘t Hoen, *TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle to DOHA*, 3 CHI. J. INT’L L. 27, 27 (2002).

6. *Id.* at 40.

7. *Global Health Observatory (GHO) data*, WORLD HEALTH ORG., <http://www.who.int/gho/hiv/en/> [https://perma.cc/66BG-LXGR].

8. *Id.*

9. *Id.*

10. ‘t Hoen, *supra* note 5, at 27.

11. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement].

12. *See generally Overview: The TRIPS Agreement*, WORLD HEALTH ORG., https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm#patents [https://perma.cc/8HTX-9BPH].

ing the necessity of increased patent protection in furthering innovation and improving industrial development.¹³ Critics, however, suggest that alternative techniques exist in avoidance of regime collisions between intellectual property and public health law.¹⁴ Opponents further noted that pushing strong patent protection worldwide would have a negative effect on the cost of medicines, particularly since patented drugs are priced at a premium.¹⁵ This would inherently compromise the developing world's little access to necessary medication. The TRIPS Agreement has proved to be ineffective in addressing this balance of intellectual property rights and public health.

Therefore, so long as the current patent property regime continues, patents will remain as one of the barriers in the developing world's access to essential medicines. By defining strong terms for patent rights, we unconsciously limit the obligations patent holders should provide to their targeted consumers in providing affordable life-saving medicines.¹⁶

This comment explores the idea that public health is patently limited by strong intellectual property protection and tests this assertion in the developing world. It proceeds in three parts. Part I explores the correlation between sustainable access and the current intellectual property regime and attempts to understand the problem from both perspectives: patent owners' rights and need for continued innovation, and the effect of such rights on the developing world's access to these developments. This section also discusses the rather ambiguous intellectual property standard, which subjects patent owners to minimum requirements in commitment to boost public health. Part II discusses the competing interests between patent holders and the targeted beneficiaries of these patented works. Finally, part III evaluates the significance of these competing interests evident in the access problem and concludes with a discussion of finding balance between the two competing interests.

13. Cynthia M. Ho, *Patent Breaking or Balancing?: Separating Strands of Fact from Fiction Under TRIPS*, 34 N.C. J. INT'L & COM. REG. 371, 385–86 (2009).

14. *Id.* at 385.

15. *Id.* at 386.

16. *Access to Medicines*, 19 WHO DRUG INFORMATION 199, 236 (2005).

I. The Crossroads of Poverty and Property

A. The Connection Between Intellectual Property and Public Health Access

Today, the world faces a fundamental dilemma in balancing the interests of patent owners, the public's right to health, and the beneficiaries in the most need—the poor.¹⁷ Scientific and technological changes have accelerated and changed the way society approaches public health. Society cites the millennial idea that rapid changes are self-healing and assumes that such advancements immediately provide an “enhanced ability to overcome problems related to poverty and poor health.”¹⁸ The globe has expanded its technological and economic potential, hoping to strike a balance between the rise of technology and finding a solution to the current health issues. The apparent upside of recent innovations are the associated new medicines and treatments that bear life-saving potential. The downside, of course, is the high price tag of such innovations.

The reasons for lack of access to essential medicines are numerous and diverse. Available literature suggests that this issue is largely due to inadequate public expenditures, insufficient health coverage, deficient supply of essential medicines, and inflated drug prices.¹⁹ Other reasons include storage problems, substandard drug quality, inappropriate selection of drugs, inefficient use of drugs, and inadequate protection of the public's health.²⁰ Though, one argument not often discussed is the effect international patent protection may have on access to affordable medicines.²¹

Intellectual property rights and ownership have also expanded drastically in the last few decades.²² The nature of the trend is clear: exclusive rights over information have become broader in protection, deeper in granting robust rights, and more severe in enforcing liabil-

17. *Public Health, Innovation and Intellectual Property Rights: Report of the Commission on Intellectual Property Rights, Innovation and Public Health*, WORLD HEALTH ORG. 1 (2006), <https://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf> [<https://perma.cc/FX3U-NHAS>].

18. *Id.*

19. Panos Kanavos et al., *Options for financing and optimizing medicines in resource-poor countries*, WORLD HEALTH ORG. 39 (2010), <http://apps.who.int/medicinedocs/documents/s18810en/s18810en.pdf> [<https://perma.cc/6RPC-G9NE>].

20. 't Hoen, *supra* note 5, at 28.

21. Crook, *supra* note 1, at 526.

22. Amy Kapczynski, *The Access to Knowledge Mobilization and The New Politics of Intellectual Property*, 117 YALE L.J. 804, 821 (2008).

ity against infringers.²³ Thus, what effect does strong intellectual property protection have on its beneficiaries, particularly those in least developed countries?

At first blush, there is no discernable overlap between intellectual property and poverty. There is, however, an immediate need to recognize the correlation between the two vastly different areas and the tension created by this relationship. This necessitates a dialogue involving patent-related barriers to access. Therefore, this comment asserts that public health access is patently limited by intellectual property protection. Specifically, patent protection in the pharmaceutical sector acts as a barrier to the developing world's access to essential medicines.

1. The Public Health Perspective: Praying for Palliatives

There is inequality in the access to medicine, specifically in resource-poor countries. Globally, developing countries account for a small fraction of the pharmaceutical market,²⁴ whereas high-income countries make up for 80.3% of global pharmaceutical expenditures.²⁵ An example of this specific divide is the AIDS²⁶ crisis. The AIDS pandemic, just shy of its fortieth anniversary, remains prevalent since the Centers for Disease Control and Prevention's ("CDC") announcement of this "mysterious new disease" back in 1981.²⁷

A patient who tests positive for HIV has the potential to contract the AIDS disease.²⁸ As the HIV virus grows in an infected person, it weakens the immune system and the patient becomes susceptible to other infections.²⁹ When a patient loses a significant number of immune cells, the human body cannot fight off infections and diseases, and opportunistic infectious agents take advantage of the patient's

23. *Id.*

24. 't Hoen, *supra* note 5, at 41.

25. WARREN KAPLAN & COLIN MATHERS, *THE WORLD MEDICINES SITUATION 2011, GLOBAL HEALTH TRENDS: GLOBAL BURDEN OF DISEASE AND PHARMACEUTICAL NEEDS* 87 (3d ed. 2011), <http://apps.who.int/medicinedocs/documents/s20054en/s20054en.pdf?ua=1> [<https://perma.cc/Z6QQ-HAQT>].

26. *What Are HIV and AIDS?*, HIV.GOV, <https://www.hiv.gov/hiv-basics/overview/about-hiv-and-aids/what-are-hiv-and-aids> [<https://perma.cc/5WT7-HNDT>] ("AIDS" is a coined acronym for acquired immunodeficiency syndrome).

27. Peggy B. Sherman & Ellwood F. Oakley, III, *Pandemics and Panaceas: The World Trade Organization's Efforts to Balance Pharmaceutical Patents and Access to AIDS Drugs*, 41 *AM. BUS. L.J.* 353, 353 (2004).

28. *See Basis Facts About HIV/AIDS*, AMFAR, http://www.amfar.org/About-HIV-and-AIDS/Basic-Facts-About-HIV/#What_is_AIDS? [<https://perma.cc/4RDL-6A62>] (The coined acronym, "HIV[,] stands for human immunodeficiency virus.").

29. *Id.*

weak immune system, and he becomes vulnerable to AIDS.³⁰ The mystery behind this disease lies in the appearance of the body visibly looking and feeling healthy, but in fact, is infected and weakened by the disease.³¹

The most reliable way to know one's status is to be tested for HIV.³² An estimated 15% of the people infected with HIV in the United States are unaware of their status.³³ About 36.7 million people live with HIV/AIDS worldwide, and the majority do not know they are part of this statistic.³⁴ Unawareness raises concerning issues: anyone infected with HIV can infect other people (absent any symptoms) through certain body fluids such as "blood, semen, vaginal secretions, and breast milk."³⁵ If the HIV-infected fluids enter the bloodstream of another person, then that person joins in on the statistic.³⁶

The HIV virus does not discriminate in the type of person it infects, although it is more commonplace in the developing world.³⁷ Fortunately, in developed countries, such as the United States, an HIV-positive status is no longer viewed as a death sentence.³⁸ Developed countries have had access to a combination of antiretrovirals to help alleviate suffering since 1995.³⁹ This combination aided death prevention from this once fatal disease. This treatment, known as the "AIDS Cocktail," can drastically improve the health and life expectancy of a patient.⁴⁰ The "daily cocktail of anti-retroviral medication transformed HIV/AIDS into a 'treatable and chronic' condition for individuals *who can afford* the treatment."⁴¹ Conversely, the least developed countries have not been quite as fortunate in obtaining such access, emphasis on the 'who can afford' the treatment. As a result,

30. *Id.*; see also *What Are HIV and AIDS?*, *supra* note 26.

31. *Basis Facts About HIV/AIDS*, *supra* note 28.

32. *Id.*

33. *Id.*

34. *World AIDS Day 2018*, CTR. FOR DISEASE CONTROL AND PREVENTION, <https://www.cdc.gov/features/worldaidsday/index.html> [<https://perma.cc/3D3E-7CYN>].

35. *Basis Facts About HIV/AIDS*, *supra* note 28.

36. *Id.*

37. See Crook, *supra* note 1, at 525.

38. *Basis Facts About HIV/AIDS*, *supra* note 28.

39. Stefano Vella, et al., *The History of Antiretroviral Therapy and of its Implementation in Resource-Limited Areas of the World*, 26 AIDS 1231, 1234 (2012), https://journals.lww.com/aidsonline/Fulltext/2012/06190/The_history_of_antiretroviral_therapy_and_of_its.12.aspx [<https://perma.cc/KJ5A-P5V7>].

40. Julie Verville, *Understanding the 'AIDS Cocktail'*, HEALTHLINE (Mar. 29, 2018), <https://www.healthline.com/health/hiv-aids/understanding-the-aids-cocktail> [<https://perma.cc/AKX6-U7E2>]; see also Sherman & Oakley, *supra* note 27, at 354.

41. Crook, *supra* note 1, at 526.

people in developing countries do not receive access to the expensive AIDS treatments,⁴² and this early death sentence is evident in present day. Thus, adequate access to such drug treatment in developing countries can transform AIDS into a treatable disease rather than add to the decimating toll.⁴³

Furthermore, access to drug treatment is particularly important because the cure to HIV/AIDS has yet to be found.⁴⁴ Until a safe, effective, and affordable AIDS vaccine is discovered, health professionals can only continue to promote utilizing prevention methods in avoiding HIV/AIDS and various treatments in alleviating suffering that is associated with this disease.

While scientific advancements work toward a cure, the crux of health-related human rights relies on the access to effective drug treatment.⁴⁵ However, pharmaceutical companies and other proponents of patent law have cited “poverty” as an excuse for lack of sustainable access.⁴⁶ Again, the illogic “poverty, not patents” argument distracts lawmakers from any intellectual property-based barrier argument.⁴⁷

Public health principles are supported by a range of national and international legal and policy instruments.⁴⁸ Public health supports the idea that each person has a right to a standard of living adequate for maintaining the health and well-being of his person and family.⁴⁹ “The right to the highest attainable standard of health” requires a set of social criteria that is conducive to the health of all people.⁵⁰ How can poor people utilize this inherent right if access to medicines is not a viable option to them?

The World Health Organization enshrines, “the highest attainable standard of health as a fundamental right of every human being.”⁵¹ Yet, globally, an estimated 100 million people are pushed

42. *See id.* at 525.

43. *Id.* at 526 (In the past, a HIV-positive infection led to an early death from AIDS. But the availability of treatments ended this and transformed this disease to a “treatable chronic condition.”).

44. *What Are HIV and AIDS?*, *supra* note 26.

45. *See* Kristen Osenga, *Get the Balance Right!: Squaring Access with Patent Protection*, 25 PAC. MCGEORGE GLOBAL BUS. & DEV. L.J. 309, 309–10 (2012).

46. Crook, *supra* note 1, at 528–29.

47. *See id.*

48. *Access to Medicines*, *supra* note 16, at 236.

49. G.A. Res. 217 (III) A, Universal Declaration of Human Rights (Dec. 10, 1948); International Covenant on Economic, Social and Cultural Rights, Dec. 16, 1966, S. Treaty Doc. No. 95-19, 6 I.L.M. 360 (1967), 993 U.N.T.S. 3.

50. *Health and Human Rights*, WORLD HEALTH ORG., <http://www.who.int/mediacentre/factsheets/fs323/en/> [<https://perma.cc/YU4E-2G2U>].

51. *Id.*

below the poverty line as a result of health care expenditure.⁵² This figure is representative of how vulnerable and marginalized groups tend to suffer disproportionately from health problems.⁵³

Thus, as the situation stands today, the developing world is unlikely to relish this universal right to health. To reiterate, three of the world's most fatal communicable diseases—HIV/AIDS, tuberculosis, and malaria—disproportionally affect the world's poorest populations.⁵⁴ From a human rights perspective, focusing our attention on vulnerable populations—specifically the poor, who are often neglected—forces authorities to ask the necessary questions “about whose needs are not being met and whose voices are not being heard,”⁵⁵ and potentially, take action to ease their struggle to access life-saving medicines.

2. The Patent Owner's Perspective: The Right to Receive Just Compensation While Seeding Innovation

In the simplest definition, a patent is a property right.⁵⁶ It is “an official document granted by a nation that conveys certain legal rights.”⁵⁷ Patents are a subsidiary of a much larger regime called intellectual property law, a field that protects the “creations of the mind.”⁵⁸ A granted patent provides its owner with exclusive rights including the ability to prevent others from making, using, selling, or offering the invention for sale in, or importing it into, the country that granted the patent.⁵⁹

A patent is a limited right and it does not bestow upon the owner absolute rights.⁶⁰ Such rights can be restricted and subjected to other regulation.⁶¹ For instance, before a pharmaceutical patent can be sold, a government agency must determine whether the patented

52. *500+ Organizations Launch Global Coalition to Accelerate Access to Universal Health Coverage*, WORLD HEALTH ORG., https://www.who.int/workforcealliance/media/news/2014/500_Orgs/en/ [https://perma.cc/X3C8-MVLH].

53. *Id.*

54. 't Hoen, *supra* note 5, at 40.

55. Mary Robinson, *The value of a human rights perspective in health and foreign policy*, WORLD HEALTH ORG., <http://www.who.int/bulletin/volumes/85/3/07-040287/en/> [https://perma.cc/64MG-TA56].

56. Osenga, *supra* note 45, at 311.

57. Ho, *supra* note 13, at 381.

58. *What is Intellectual Property?*, WORLD INTELL. PROP. ORG. <http://www.wipo.int/about-ip/en/> [https://perma.cc/CMR5-8PY6].

59. TRIPS Agreement, *supra* note 11, at part II, § 5, art. 28(1).

60. Osenga, *supra* note 45, at 312.

61. *Id.*

drug is safe for the public and effective for its use.⁶² In the United States, the U.S. Food & Drug Administration, better known as the FDA, is the gatekeeper in allowing a patent holder to make or sell drugs.⁶³ Further, a patent holder possesses a right of exclusivity in which he or she may prevent other manufacturers from making and selling a product covered by the patent's term.⁶⁴ This right of exclusivity is consequential to the poor's ability to reap the benefits of such products.

To empathize with the patent holder, we must understand the burdensome process the inventor had to endure in attaining the rights. Patent rights should not be immediately construed as negative to the public at large without first understanding the justifications. The patent application process in the United States is a model for the difficulties posed to potential patent owners. The U.S. government retains the exclusive authority to grant patent rights in the United States; Congressional power in granting patents derives from Article I, Section 8 of the United States Constitution.⁶⁵ Congress then established the agency governing such rights: the United States Patent and Trademark Office ("USPTO").⁶⁶ Thus, any inventor who desires patent rights must submit an application to the USPTO, and complete all the requirements for the proposed patent application. If the application satisfies the statutory requirements necessary for patentability, the USPTO will subsequently issue the patent and its respective rights to the applicant. A U.S. patent grants protection against infringement occurring in the United States and its territories;⁶⁷ if an inventor decides to pursue protections in other countries they must file in that country's designated patent office.⁶⁸

A patent entitles the owner of a new, useful, and non-obvious invention to exclusive rights.⁶⁹ Ownership of the patent determines who

62. See 21 U.S.C.A. § 355 (West 2017).

63. See *What We Do*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/AboutFDA/WhatWeDo/default.htm> [<https://perma.cc/7UX3-U93J>]; see also 21 U.S.C.A. § 355 (West 2017) (The FDA prohibits the introduction of new drugs without its approval.).

64. See, e.g., 35 U.S.C.A. § 154 (West 2015).

65. U.S. CONST. art. I, § 8, cl. 8 (This is often referred to as the "Intellectual Property Clause.").

66. See 35 U.S.C. § 1(a) (2000).

67. See 35 U.S.C. § 271(a) (1994).

68. *General information concerning patents*, UNITED STATES PATENT AND TRADEMARK OFFICE (Oct. 2015), <https://www.uspto.gov/patents-getting-started/general-information-concerning-patents#heading-4> [<https://perma.cc/M566-JSVJ>].

69. See 35 U.S.C. § 154 (1964) (This section states that "[e]very patent shall contain . . . a grant to the patentee . . . of the right to exclude others from making, using, offering

can enforce the associated rights to exclude and collect damages for infringement upon those rights. The initial patent statute was enacted in 1790, underwent revision in the Patent Act of 1952,⁷⁰ and enacted in 2011, the Leahy-Smith America Invents Act (“AIA”)⁷¹ fundamentally changed important aspects of U.S. patent law.⁷² To obtain a patent, an applicant must submit an application to the USPTO that meets the five requirements of patentability, the patent must be: (1) within patentable subject matter,⁷³ (2) useful,⁷⁴ (3) novel,⁷⁵ (4) non-obvious,⁷⁶ and (5) the application must be in compliance with the formal requirements.⁷⁷

As for the first requirement, the U.S. government issues three types of patents: utility patents, design patents, and plant patents.⁷⁸ The most common of the three is the utility patent (most relevant here), which covers all new and useful processes, machines, manufactures, and compositions of matter, or alternatively, any new and useful improvements.⁷⁹ Design patents cover designs for articles of manufacture⁸⁰ and plant patents cover asexually reproduced plants.⁸¹

Second, a patent must be directed to a useful invention, it must serve a positive benefit to society.⁸² The patent must satisfy the general utility standard, or specific utility, and its intended use is not illegal, immoral, or contrary to public policy.

Third, the novelty requirement is quite complex. Inventors can generally obtain patent protection in the United States only if the invention is “new.”⁸³ The AIA implemented certain changes to the 1952 Act in terms of priority and novelty. The AIA made several changes: (1) the critical date is the date the patent application is first filed, (2) prior art to a patent claim consists of all references available under the

for sale, or selling the invention throughout the United States or importing the invention the United States.”).

70. See U.S. Patent Act of 1952, 35 U.S.C. § 101 (1952) [hereinafter 1952 Act].

71. See Leahy-Smith America Invents Act, 28 U.S.C. § 1454 (2011) [hereinafter AIA].

72. Practical Law Intellectual Property & Technology, Patent: Overview, Practical Law Practice Note Overview 8-509-4160, Westlaw (2019).

73. See 35 U.S.C. § 101 (1964).

74. *Id.*

75. See 35 U.S.C. § 102 (1964).

76. 35 U.S.C. § 103 (1964).

77. 35 U.S.C. § 112 (1964).

78. *General information concerning patents, supra* note 68.

79. See 35 U.S.C. § 101 (1964).

80. 35 U.S.C. § 171 (1964).

81. 35 U.S.C. § 161 (1964).

82. See 35 U.S.C. § 101 (1964).

83. *General information concerning patents, supra* note 68.

statute prior to the filing date, and (3) priority is now based on when each applicant filed their patent application.⁸⁴ The previous 1952 Act promoted the “first-to-invent” system, whereas the AIA introduced a more precise definition, where the “first-proven-inventor-to-file” can show proof through an earlier filing date or public disclosure.⁸⁵ The AIA addressed the two distinct concepts of novelty and statutory bars by: (1) prior art appearing before the critical date deprives the inventor of entitlement to a patent; (2) defining all categories or types of references that qualify as prior art under the AIA; (3) defining the critical date as the inventor’s filing date; and (4) there is a grace period as exception to general rule of prior art appearing earlier than an inventor’s filing date.⁸⁶

Fourth, a patent will not be granted if it is “obvious.”⁸⁷ The AIA states that an invention may not be patented “if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date.”⁸⁸

Fifth, the last requirement of the formal application has four basic elements: (1) the specification in the patent application must describe the invention in a manner that would enable someone skilled in the art to make and use such an invention (the “enablement” requirement); (2) the written description of the specification must fully describe the claimed invention (“the written description requirement”); (3) the language must be clear and concise (“definite”); and (4) the specification must include the most effective mode of the invention.⁸⁹

The patent owner’s right to exclude lasts only for a limited duration known as the patent term.⁹⁰ An issued patent contains three components: the specification, the drawings, and the claims.⁹¹ These components describe the applied-for patent in great detail, in which such information can be utilized in using the invention and built

84. Robert P. Merges, *Priority and Novelty Under the AIA*, 27 *BERKELEY TECH. L.J.* 1023, 1023–24 (2012).

85. *Id.* at 1027–28.

86. *Id.* at 1025; *see also* 35 U.S.C. § 102 (1964).

87. *General information concerning patents, supra* note 68.

88. *Id.*; *see also* 35 U.S.C. § 103 (1964).

89. 35 U.S.C. § 112 (1964).

90. *See* 35 U.S.C.A. § 154(a)(2) (West 2015).

91. *See* 35 U.S.C. §§ 111–12 (1964).

upon for further inventions. If all of these requirements are met, then the USPTO may grant the owner patent rights.⁹²

Thus, it is naïve to assert patent rights as the sole reason in preventing people from accessing essential medicines before understanding the counter perspective. “While the human rights side is quick to point to the ability of the patent holder to set monopolistic prices or otherwise thwart ready availability, the positive aspects of patenting often go unnoticed.”⁹³ There are three policy justifications for awarding patent rights after such an arduous process.⁹⁴

The first justification for protecting patent rights is that patents incentivize invention.⁹⁵ “The purpose of a patent is to encourage inventors to produce socially valuable goods that would not otherwise be produced.”⁹⁶ In the general sense, inventors do not have unlimited funds and resources, thus choosing where to expend time and effort originates from the expectation that the inventor will profit and be rewarded for his work.⁹⁷ Following this logic, inventors tend to invent based on a problem immediate to the inventor.⁹⁸ However, when the invention is not for a personal gain, the inventor will want to spend resources if he is likely to benefit financially.⁹⁹ The period of exclusivity gives the patent owner monopoly rights, where he has the opportunity to recoup costs expended on the invention process and potentially to profit before his “competitors can exploit the fruits of his invention” without enduring the development costs themselves.¹⁰⁰

Secondly, patents encourage companies to invest in innovation. These activities include “developing and testing a commercial embodiment of the new technology, marketing and selling the new technology, and making improvements on the new technology.”¹⁰¹ The exclusive rights associated with a patent allows the patent holder an opportunity to recoup all expenditures on the project. The limited monopoly period also allows the patent holder to utilize resources in

92. *General information concerning patents*, *supra* note 68.

93. Osenga, *supra* note 45, at 312.

94. *Id.*

95. *Id.*

96. David S. Olson, *Taking the Utilitarian Basis for Patent Law Seriously: The Case for Restricting Patentable Subject Matter*, 82 TEMP. L. REV. 181, 192 (2009).

97. Osenga, *supra* note 45, at 312; Olson, *supra* note 96, at 195–96.

98. Osenga, *supra* note 45, at 312.

99. *Id.*

100. *Id.*

101. *Id.* at 313.

expanding the space and creating further innovation such as making further improvements on the invention itself.¹⁰²

Thirdly, granted patents encourage disclosure of new technologies. The development of new technologies is not enough for the continued advancement of science.¹⁰³ In order to advance, the knowledge associated with the new technologies must be available for subsequent researchers to learn and build upon its foundation.¹⁰⁴ Referring back to the patent process, the patent holder must disclose sufficient and specific details of the technology to qualify for patent protection.¹⁰⁵ This embodies a “quid pro quo” exchange that builds the foundation of public knowledge and the offering of invention to the public once the term of exclusivity expires.¹⁰⁶ Conversely, an inventor may choose to keep his creation a trade secret without receiving any compensation associated with a patent. In doing so, an inventor may waste the efforts of other inventors in trying to discover the same technology. Overall, inventions kept as trade secrets delay the progress of technology and may prove to be costlier. Granted patents reduces duplicate research and allows for more productive investment in other projects.¹⁰⁷

Therefore, the disclosure of patented information encourages innovation, reduces wasted research on already discovered information, and heightens efficient investment in innovation.¹⁰⁸ In the context of the AIDS crisis, the disease itself is still without a vaccine; medications and treatments are constantly being developed in hopes of finding a solution.¹⁰⁹ Therefore, patents are highly relevant in this ongoing public health crisis, as recent scientific advances have sparked a sense of optimism in the race to cure HIV/AIDS.¹¹⁰

B. Global Expansion of Intellectual Property Rights

The World Trade Organization (“WTO”) is an international organization of 164 member countries, composed of developed and

102. *Id.*

103. *Id.*

104. Osenga, *supra* note 45, at 313.

105. *Id.*

106. Maureen A. O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177, 1186 (2000).

107. John M. Olin, *The Disclosure Function of the Patent System (or Lack Thereof)*, 118 HARV. L. REV. 2007, 2009 (2005).

108. *Id.*

109. See Alison Hill, *Why There's No HIV Cure Yet*, PBS (Aug. 27, 2014), <https://www.pbs.org/wgbh/nova/article/missing-hiv-cure/> [<https://perma.cc/DU3X-GYFG>].

110. *Id.*

least developed countries, that deal and discuss rules of trade.¹¹¹ A country that becomes a Member State of the WTO must adhere to specific agreements, including the TRIPS Agreement, which came into effect on January 1, 1995.¹¹² At the release of the TRIPS Agreement, the rest of the world did not recognize the repercussions it would have in the pharmaceutical sector and overall effect on least developed countries.

1. Understanding the Global Intellectual Property Standard: The TRIPS Agreement

The TRIPS Agreement establishes minimum standards for intellectual property rights in Member States.¹¹³ The TRIPS Agreement was negotiated among developed countries with strong intellectual property laws and least developed countries with weak to nonexistent intellectual property laws.¹¹⁴ It recognizes intellectual property rights as private rights, while simultaneously “recognizing the underlying public policy objectives of national systems for the protection of intellectual property.”¹¹⁵ This attempted to address the special needs of the developing countries in respect of maximizing flexibility in the domestic implementation of laws and regulations.¹¹⁶ It further strived to establish a mutually supportive relationship between WTO and the World Intellectual Property Organization (“WIPO”).¹¹⁷

The TRIPS Agreement is considered to be pro-patent.¹¹⁸ Under TRIPS, all Member States are obliged to provide the minimum levels of patent protection.¹¹⁹ Because Member States adopted varying approaches in implementing regulations towards drug patents,¹²⁰ the TRIPS Agreement was subject to interpretations and appeared open-ended.

111. *History of the multilateral trading system*, WORLD TRADE ORG., https://www.wto.org/english/thewto_e/history_e/history_e.htm [<https://perma.cc/NX2E-XPR6>].

112. TRIPS Agreement, *supra* note 11 at 84.

113. Germán Velásquez & Pascale Boulet, GLOBALIZATION AND ACCESS TO DRUGS: IMPLICATIONS OF THE WTO/TRIPS AGREEMENT 3 (2d ed. 1999), <http://www.who.int/medicines/areas/policy/who-dap-98-9rev.pdf?ua=1> [<https://perma.cc/XX48-VN2M>].

114. Clark A.D. Wilson, *The TRIPS Agreement: Is It Beneficial to the Developing World, or Simply a Tool Used to Protect Pharmaceutical Profits for Developed World Manufacturers*, 10 J. TECH. L. & POL'Y 243, 245 (2005).

115. TRIPS Agreement, *supra* note 11 at 84.

116. *Id.*

117. See WORLD INTELL. PROP. ORG., *supra* note 58.

118. Osenga, *supra* note 45, at 315.

119. Ho, *supra* note 13, at 384.

120. Velásquez & Boulet, *supra* note 113, at 3; see also Osenga, *supra* note 45, at 315.

Arguably, the most pertinent parts of the TRIPS Agreement are found in Articles 27–34. Some of the Member States granted patents for pharmaceutical products and processes, while others allowed patent protection for only processes.¹²¹ Thus, the latter did not prevent local companies from developing different manufacturing processes for drugs that were not patent protected as a product.¹²² Other Member States chose not to grant any form of protection for pharmaceutical inventions.¹²³ Facially, the TRIPS Agreement allows some flexibility in the pharmaceutical sector.¹²⁴ Therefore, patent protection enforcement varies greatly between Member States.

There are key features tucked away in the provisions. The TRIPS Agreement undercuts this flexibility directed to the least developed states, while simultaneously requiring that the provisions adhere with the patent-protection measures of the TRIPS Agreement.¹²⁵ It called upon Member States to grant patents for a minimum of twenty years for any inventions of a pharmaceutical product or process that fulfills the established standards.¹²⁶ Accordingly, when the TRIPS Agreement is in effect in a Member State, the patent holder has the rights to defend against unwarranted copies of patented drugs. As such, if a country fails to introduce legislation that conforms with TRIPS, it is subject to the WTO dispute settlement system.¹²⁷ If an adverse ruling is found for the non-compliant country, and if it continues to falter in compliance, the country may be subject to trade sanctions as authorized by the WTO.¹²⁸ These applications for patented products are stored until modified national patent laws are adopted for the respective Member State.¹²⁹ If accepted, a patent will be granted for the next twenty years counted from the date of filing.¹³⁰ In a situation where market authorization is given before the introduction of new patent regulations, and if another Member State has allowed such protection for the same invention, the owner of the invention may be granted exclusive marketing rights “for up to five years until the decision to grant or reject the patent application is made.”¹³¹ Patent owners’ right

121. TRIPS Agreement, *supra* note 11, at part II, § 5, art. 27.

122. *Id.*

123. *Id.*

124. Crook, *supra* note 1, at 531.

125. *Id.*

126. Velásquez & Boulet, *supra* note 113, at 3.

127. *Id.* at 4.

128. *Id.*

129. *Id.*

130. *Id.*

131. Velásquez & Boulet, *supra* note 113, at 4.

to exclusivity deepens the access problem, for example, by limiting access during the patent term by set prices.¹³²

There are fundamental principles with respect to the scope of intellectual property in the TRIPS Agreement. Such underlying themes promoted by TRIPS include: minimum intellectual property protection through domestic laws, effective enforcement of those laws, and dispute settlement if necessary.¹³³ The most notable include Article 7 and Article 8. The first, Article 7, notes that protection and enforcement of intellectual property should contribute to technological innovation, while simultaneously promoting social and economic welfare for all.¹³⁴ Article 8 explicitly allows for Member States to tailor their intellectual property regimes in accordance with the needs and interest of the public.¹³⁵ The ambiguities within the TRIPS Agreement reveal the inherent tension between economic interests of patent holders and public interests in promoting health and development.

The TRIPS Agreement attempts to strike a balance between the short-term objective of providing access to essential medicines and the long-term objective of encouraging and providing incentives to the pharmaceutical industry for its work in development.¹³⁶ However, the TRIPS Agreement appears to be problematic to least developed countries.

The first problem is that increased patent protection leads to premium drug prices which widens the access gap between developed and still developing nations.¹³⁷ Secondly, enforcement of the TRIPS Agreement may have a detrimental effect on the local manufacturing capacity.¹³⁸ This may affect the developing world's access to generic medicines, which is one of the limited sources developing countries depend on.¹³⁹ Thirdly, the TRIPS Agreement is unlikely to promote research and development in least developed countries because there is no substantial profit.¹⁴⁰ Lastly, developing countries may falter under pressure from the pharmaceutical industry to implement patent legislation that is aligned with their ideals. Thus, the TRIPS Agree-

132. Ho, *supra* note 13, at 1057.

133. Wilson, *supra* note 114, at 245.

134. TRIPS Agreement, *supra* note 11, at part I, art. 7.

135. *Id.* at part I, art. 8.

136. Bryan C. Mercurio, *Trips, Patents, and Access to Life-Saving Drugs in the Developing World*, 8 MARQ. INTELL. PROP. L. REV. 211, 218 (2004).

137. 't Hoen, *supra* note 5, at 29.

138. *Id.*

139. *Id.*

140. *Id.*

ment contains far too many textual and operational flaws¹⁴¹ that makes it unsuccessful in its intended efforts. On the surface, the TRIPS Agreement is scarce in aid directed toward the developing world.

2. The TRIPS Agreement's Limitation on Patent Rights

The TRIPS Agreement provides a framework for patent standards, but also includes highly controversial exceptions.¹⁴² These exceptions include those relating to patentability: the possibility to make limited exceptions to exclusive rights, compulsory licensing, parallel importation, and the recognition that member countries may adopt necessary measures to protect public health.¹⁴³

Compulsory licensing allows for a third party to “make, use, or sell a patented invention without first obtaining the patent holders’ consent.”¹⁴⁴ Compulsory licensing, as defined in Article 31, allows use that is “non-commercial, non-exclusive, non-assignable, and limited to the domestic market” so long as the patent holder receives fair compensation.¹⁴⁵ These new provisions are superficial at best. Patent holders often minimize discussion of whether such licenses are even legal, and tensions rise when developing countries ignore patents’ promotion of innovation to emphasize the literal language of the TRIPS Agreement.¹⁴⁶ This raises issues with the patent owners as they argue that compulsory licenses will kill associated profits to fund further research and develop costs.¹⁴⁷ With no funds, innovation remains at a standstill. In the context of the AIDS crisis, this concept offers a way to achieve lowered drug prices and increase access to essential medicines.¹⁴⁸ Compulsory licensing is authorized under the TRIPS Agreement through necessity of public health emergencies.¹⁴⁹ Article 31(b) does not clearly define what constitutes a “national emer-

141. Mercurio, *supra* note 136, at 218.

142. Ho, *supra* note 13, at 385.

143. Lisa Anderson, Comment, *The Conflict Between Intellectual Property Rights of Pharmaceutical Companies and the Right to Health of AIDS Victims in South Africa*, 10–11, GLOBAL POL. NETWORK (2002).

144. Colleen Chien, *Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?*, 18 BERKELEY TECH. L.J. 853, 855–56 (2003).

145. Crook, *supra* note 1, at 531; TRIPS Agreement, *supra* note 11, at part II, § 5, art. 31.

146. Ho, *supra* note 13, at 1049.

147. *Id.* at 1048–49.

148. Chien, *supra* note 144, at 855.

149. *Id.* at 855–56.

gency.”¹⁵⁰ The issuance of compulsory licenses is subject to review by a higher authority, and as such, an individual Member State does not have the right to declare an emergency on its own.¹⁵¹

Additionally, the TRIPS Agreement allows parallel importation, which is vital in increasing access to medicines in the developing world. Parallel importation allows for the use of a patented product without the consent of the patent-holder in another country either by the patent holder or with the patent holder’s consent.¹⁵² Parallel importation is built as a further alternative to compulsory licensing by avoiding liability to the patent owner through “exhaustion of rights.”¹⁵³ The TRIPS Agreement declared that exhaustion of rights cannot be raised in a dispute, unless fundamental discrimination principles are at issue.¹⁵⁴

Member States may adopt necessary measures to protect public health through generic substitution of drug treatments. Arguably, this is the most beneficial provision for developing countries. In the AIDS crisis, low-cost generic antiretroviral therapy can be used as a strategy for treating patents.¹⁵⁵ The use of generic equivalents aids the fight for affordable essential medicines. Since the prevalence of the HIV/AIDS pandemic, there is an urgency to make treatment available for millions of people. For example, when patent-protected antiretroviral treatments were first introduced to the market, the cost was over \$10,000 per patient in a given year.¹⁵⁶ Most of the developing world could not afford this treatment as most live on two dollars per day,¹⁵⁷ and such treatment seemed to be a far-reaching dream.

An announcement by a pharmaceutical manufacturer, however, brought a sense of hope by supplying a generic treatment for HIV/AIDS priced at \$350 per year.¹⁵⁸ Consequently, for pharmaceutical companies, market competition resulted in reductions in prices of antiretroviral therapy.¹⁵⁹ “The pharmaceutical industry underscores the importance of effective patent protection as an incentive for continued investment in discovery of new medicines and treatments.”¹⁶⁰ In

150. Crook, *supra* note 1, at 531.

151. *Id.* at 531 n.54.

152. *Access to Medicines, supra* note 16, at 240.

153. Wilson, *supra* note 114, at 247.

154. *Id.*

155. *Access to Medicines, supra* note 16, at 237.

156. *Id.*

157. *Id.*

158. *Id.*

159. *Id.*

160. *Id.*

the example here, the market exclusivity conferred by patents leads to company profits that often outstrip the associated research, development, and production costs altogether. Therefore, the current patent system does not provide sufficient incentive for development of medicines needed to approach the needs of public health. Thus, concern grew as the question of how adoption of intellectual property regimes can be balanced with efforts in promoting public health programs.¹⁶¹ The provisions in the TRIPS Agreement falter in aiding the developing world,¹⁶² and the prohibitive prices make access to treatment an even more challenging goal.

3. The Impact of the TRIPS Agreement

The TRIPS Agreement was the first treaty to set the minimum standard of intellectual property protection internationally.¹⁶³ In the pre-TRIPS era, countries were only obligated to honor patents reciprocally and had the option to exempt certain inventions from patent protections altogether.¹⁶⁴ Considered a pro-patent agreement, the ambiguity found in TRIPS makes the impact on human rights less-well defined,¹⁶⁵ and the correlation between patent rights and access to medicines less clear. “Facially, TRIPS allows some flexibility in pharmaceutical manufacturing.”¹⁶⁶

In reality, it does not. Article 7 of the TRIPS Agreement encourages the “transfer of the fruits of intellectual property to developing countries”¹⁶⁷ in the promotion of innovation.¹⁶⁸ The TRIPS Agreement also strives to prevent abuse within the intellectual property regime, allowing members to grant protection while avoiding practices that unreasonably restrain trade and dissemination of information.¹⁶⁹ Therefore, TRIPS undercuts its initial promise of flexibility afforded to least-developed countries. Instead, each state varies in its adoption and what might be consistent for developed countries may not be in developing countries.

161. *Access to Medicines*, *supra* note 16, at 237.

162. *Id.* at 236.

163. Crook, *supra* note 1, at 530.

164. *Id.*

165. Osenga, *supra* note 45, at 315.

166. Crook, *supra* note 1, at 531.

167. *Id.*

168. TRIPS Agreement, *supra* note 11, at part I, art. 7.

169. *Id.* at part I, art. 8(2).

II. Leveling the Scale Between Intellectual Property Protection and the Human Right to Health

There is no disputing the existence of competing interests between the patent holders and the people that patents intend to benefit. The main question presented is whether access can only be attained at the expense of patents. Scholars suggest that human rights and intellectual property law are fundamentally conflicting.¹⁷⁰ First, the discussion is shifted to those assuming the benefit of the patents are people in the developing world. Their interests lie in survival and the necessity for access to medication and treatments. As mentioned above, the mortality statistics in the developing world are alarming. The principles behind compulsory licenses offer a way to alleviate the high price point of drugs by allowing more access to medicine through generic substitutions.¹⁷¹ Adequate access gives hope of survival, but only to those who can afford treatment.¹⁷² For example, HIV/AIDS rates in developed countries have largely plateaued.¹⁷³ This proven success arises from anti-retroviral treatments in prolonging life expectancy.¹⁷⁴ If not halted, the AIDS crisis will continue to affect “political, social, and economic structures.”¹⁷⁵ This public health crisis will continue to undermine any form of societal stability as a substantial portion of the developing world is lost to AIDS.¹⁷⁶

Conversely, proponents of strong intellectual property practices place the blame on poverty, not patent protections, as the barrier to access to essential medicines,¹⁷⁷ commonly known as the “poverty, not patents” argument.¹⁷⁸ Pharmaceutical companies, in particular, assert that a return on profits is essential for continued efforts of research and development.¹⁷⁹ Without this market exclusivity guaranteed by patents, companies would falter and new products would not be introduced.¹⁸⁰ Further, arguments suggest that the patent system exists to promote public goods and creates a monopoly for inventors, which

170. Peter K. Yu, *Reconceptualizing Intellectual Property Interests in a Human Rights Framework*, 40 U.C. DAVIS L. REV. 1039, 1075–76 (2007).

171. Chien, *supra* note 144, at 855.

172. Crook, *supra* note 1, at 526.

173. *Id.* at 539.

174. *Id.* at 538.

175. *Id.*

176. *Id.* at 550.

177. *Id.* at 528–29.

178. Crook, *supra* note 1, at 529.

179. *Id.*

180. Wilson, *supra* note 114, at 250.

circles back to the argument of inventors furthering innovation.¹⁸¹ Human rights advocates argue that this justification masks the high profit return with the intention of development aimed toward poor people.¹⁸² Moreover, the conflict follows that continued patent protection ensures further research and production, and through the discovery of new treatments, there is an increased access.¹⁸³ However, this logic is not sound. Various treatments can still enjoy strong patent protection but may continue to be out of range for the developing world.¹⁸⁴ The AIDS crisis in the developing world continues for those who cannot afford existing medicines and treatments.¹⁸⁵

Furthermore, advocates of the “poverty, not patents” theory remain skeptical of increased generics as a solution to AIDS-struck countries. They argue that “no infrastructure exists for proper disbursement and monitoring,” meaning that patients will face challenges in adhering to the treatments.¹⁸⁶ Thus, even if access were available, failure to comply with the treatment cycle renders the drugs ineffective. Proponents of strong intellectual property rights reiterate the reasoning poverty remains the true barrier to access by assuming poverty is synonymous with the inability to afford medication while belittling the unaffordability of the drugs’ argument. Many pharmaceutical companies have over-emphasized the “poverty, not patents” argument in the restriction to access to essential medicines.¹⁸⁷

A. The Effect of the TRIPS Agreement

Ambiguity lies in the enforcement of the TRIPS Agreement. The following cases are examples of how U.S. policy is geared toward the protection of intellectual property priority rights. A number of factors have shaped the debate on TRIPS and access to medicines.¹⁸⁸

In a dispute in South Africa, better known as *Big Pharma v. Nelson Mandela*,¹⁸⁹ pharmaceutical companies banded together and brought suit against the government of South Africa, alleging that the Medicines and Related Substances Control Amendment Act No. 90 of

181. Olson, *supra* note 96, at 183.

182. Osenga, *supra* note 45, at 312.

183. Crook, *supra* note 1, at 529.

184. *Id.*

185. *Id.*

186. *Id.*

187. *Id.* at 530.

188. ‘t Hoen, *supra* note 5, at 43.

189. 1998: *Big Pharma versus Nelson Mandela*, ACCESS CAMPAIGN (Feb. 20, 1998), <https://msfaccess.org/1998-big-pharma-versus-nelson-mandela> [<https://perma.cc/6685-VSZN>].

1997 (the “Amendment Act”) violated the TRIPS Agreement and the South African constitution.¹⁹⁰ The Amendment Act introduced a proposal in increasing affordable medicines in South Africa; the provisions include generic substitution of off-patent medicines, transparent pricing, and the parallel importation of patented medicines.¹⁹¹ At the start of the litigation, the companies relied on the support of their home countries to get such agenda moving forward.

The United States, however, put pressure on the South African government to repeal the Amendment Act by “withholding trade benefits and threatening further trade sanctions.”¹⁹² At the start of trial, the respective home countries could no longer support the pharmaceutical companies and faced immense public pressure.¹⁹³ Eventually, the public’s outrage over the drug companies’ legal challenge of alleviating the access problem forced them to drop the case altogether.¹⁹⁴

This widely publicized suit brought two issues to light: “the interpretation of the flexibilities of TRIPS and their use of public health purposes needed clarification to ensure that developing countries could use its provisions without the threat of legal or political challenge.” Additionally, “it became clear that industrialized countries that exercised trade pressure to defend the interest of their multinational industries could no longer exert pressure without repercussions at home.”¹⁹⁵

Similarly, public outcry was effective when a U.S. trade action threatened the AIDS program in Brazil,¹⁹⁶ in which the United States challenged Brazil’s patent law for allegedly discriminating against U.S. patent holders in Brazil.¹⁹⁷ History shows that Brazil has successfully maintained comprehensive AIDS care which included universal access to antiretroviral treatment.¹⁹⁸ The success of this program stems from its ability to produce medicines locally, and the law provides for compulsory licensing.¹⁹⁹ Public pressure and the potential negative effect

190. *Id.*

191. ‘t Hoen, *supra* note 5, at 43.

192. *Id.* at 43–44.

193. *Id.* at 44.

194. *Id.*

195. *Id.*

196. See Tina Rosenberg, *Look at Brazil*, N.Y. TIMES MAG. (Jan. 28, 2001), <http://www.nytimes.com/2001/01/28/magazine/look-at-brazil.html> [https://perma.cc/U5U4-LJEL].

197. See *id.*

198. ‘t Hoen, *supra* note 5, at 44.

199. *Id.*

on Brazil's successful program ended this litigation with the United States announcing its withdrawal.²⁰⁰

B. Acknowledging the Access Problem: Doha Declaration

In 2001, Member States adopted a special declaration at the WTO Ministerial Conference in Doha, Qatar to clarify ambiguities created by the TRIPS Agreement.²⁰¹ Widely known as the "Doha Declaration," it was enacted to address concerns over how patent protection might restrict access to affordable medicines against developing countries' efforts to control diseases.²⁰² The Doha Declaration acknowledged the role of patent protection developing new medicines and how the Declaration will affect patented premiums.²⁰³ The Doha Declaration sought to refine these facially conflicting obligations found in the TRIPS Agreement²⁰⁴ and shed some light on the tension between patent rights and public health.²⁰⁵

The Doha Declaration appeared pro-public health access and found that promoting access to medicines justifies Member States to enact exceptions to patent protection.²⁰⁶ Thus, the generic drug industry embraced the Doha Declaration because of such liberty with compulsory licensing.²⁰⁷ However, compulsory licenses are rarely granted and ultimately "antithetical to patent rights."²⁰⁸ Because Article 31 restricted compulsory licensing to domestic use, this limit minimized the utility of licensing flexibilities from the poorest countries because of their law of manufacturing capability in the pharmaceutical sector.²⁰⁹ Developing countries attempted to add a provision that allowed foreign suppliers to provide medicines in the domestic market and subsequently supply foreign markets.²¹⁰ Developing countries

200. Barbara Crossette, *U.S. Drops Case Over AIDS Drugs in Brazil*, N.Y. TIMES (Jun. 26, 2001), <http://www.nytimes.com/2001/06/26/world/us-drops-case-over-aids-drugs-in-brazil.html> [<https://perma.cc/WZY7-DPVS>].

201. *The Doha Declaration on the TRIPS Agreement and Public Health*, WORLD HEALTH ORG., http://www.who.int/medicines/areas/policy/doha_declaration/en/ [<https://perma.cc/D9C4-JKRB>].

202. *Id.*

203. *Id.*

204. See World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 ILM 746 (2002) [hereinafter Doha Declaration].

205. Ho, *supra* note 13, at 390.

206. Mercurio, *supra* note 136, at 226.

207. *Id.* at 235.

208. Cynthia M. Ho, *Unveiling Competing Patent Perspectives*, 46 HOUS. L. REV. 1047, 1071 (2009) [hereinafter *Unveiling Competing Patent Perspectives*].

209. Mercurio, *supra* note 136, at 229; see also Crook, *supra* note 1, at 532.

210. Mercurio, *supra* note 136, at 229.

failed to persuade developed countries to add such a provision,²¹¹ and global rules required that such licenses be issued only as last resort and in extraordinary circumstances.²¹²

The Doha Declaration reaffirmed its commitment to TRIPS and how it should be utilized in a manner that supports and protects public health.²¹³ Those present at the conference further reiterated that TRIPS should be interpreted and implemented in favor of Member States' right to protect public health, particularly, in promoting access to medicines for all.²¹⁴ However, this reaffirmation fell short in fully addressing the access problem, and simply recognized the developing world's ineffective use of the amended provisions. Therefore, the Doha Declaration's spirit failed to provide a solution to the access problem.

III. A Patently Promising Future

A. Amendment to the TRIPS Agreement: A Modified Hope

On January 23, 2017, WTO members amended the TRIPS Agreement.²¹⁵ This amendment became the first multilateral treaty amendment agreed upon by WTO members since the introduction of the TRIPS Agreement.²¹⁶ The TRIPS Agreement as amended January 23, 2017, provided the "legal basis for WTO members to grant special compulsory licenses exclusively for production and export of affordable generic medicines to other members that cannot domestically produce the needed medicines in sufficient quantities for their patients."²¹⁷ Simply put, this amendment permanently allows additional flexibilities in the export of essential medicines. Facially, this amendment would help the developing world's efforts to facilitate access to medicines.

However, there may be some drawbacks to the amendment, though they are uncertain. Though the Doha Declaration on the TRIPS Agreement recognized the importance of compulsory licens-

211. *Id.*

212. *Unveiling Competing Patent Perspectives*, *supra* note 208, at 1071.

213. Doha Declaration, *supra* note 204, at 24.

214. *Id.*

215. *Agreement on Trade-Related Aspects of Intellectual Property Rights (as amended on 23 January 2017)*, WORLD TRADE ORG. (Jan. 23, 2017), https://www.wto.org/english/docs_e/legal_e/31bis_trips_01_e.htm [<https://perma.cc/7CVF-5M7P>].

216. *How to Accept the Protocol Amending the TRIPS Agreement*, WORLD TRADE ORG., https://www.wto.org/english/tratop_e/trips_e/accept_e.htm [<https://perma.cc/Z6EB-WSM7>].

217. *Agreement on Trade-Related Aspects of Intellectual Property Rights (as amended on 23 January 2017)*, *supra* note 215.

ing, WTO members noted the significant obstacles encountered by nations without the manufacturing capability for effective use of compulsory licenses in supplying medicines.²¹⁸ Article 31(f) of the TRIPS Agreement restricted this concept to supply of the domestic market.²¹⁹ This meant producing medicines in the developing world was virtually impossible to do, thus those who relied on this addition would have only been successful with the capacity for production.²²⁰ The TRIPS Agreement as amended on January 23, 2017 addressed this issue by creating a permanent waiver to Article 31(f), allowing Member States to issue compulsory licenses *specifically* for export.²²¹ Hopefully, this is a solution for developing nations whom were unsuccessful in sharing in the generic medicines' production, and that with this permanent waiver, the practice will change, and developing nations will soon join in the success.

B. Conclusion: A Balancing Act

In a utopian world, there would be an even balance of patent rights and public health needs. Patent holders would be able to create and both reap the benefits of their invention and provide innovation that improves public health. Simultaneously, developing nations would have unlimited access to the products of the patent holders at lower-priced premium or have access to generic medicines. Unfortunately, that is not an option here, as there is an unsolvable tension between patent rights and public health access. While there is an idealistic concept behind such an idea, a proponent of both sides can dare dream.

Moving forward, the regulatory authorities must approach this issue with a well-balanced thought process, granting what is fair for patent holders, while simultaneously encouraging innovation and providing affordable medicines to the poor. As mentioned, there is an underscored importance of effective patent protection in its continued investment in discovery of new medicines, but there is little movement in finding a viable solution for the developing world to catch up to such development.

218. Mercurio, *supra* note 136, at 229.

219. TRIPS Agreement, *supra* note 11, at part II, § 5, art. 31(f).

220. Ellen 't Hoen, *Access to Medicines Amendment of the WTO TRIPS Agreement – Hype or Hope?*, GLGH BLOG (Apr. 3, 2017), <https://ghlgblog.wordpress.com/2017/04/03/access-to-medicines-amendment-of-the-wto-trips-agreement-hype-or-hope/> [<https://perma.cc/M764-BXJQ>].

221. *Agreement on Trade-Related Aspects of Intellectual Property Rights (as amended on 23 January 2017)*, *supra* note 215.

There remains a renewed hope for developing nations in the 2017 amendment to the TRIPS Agreement. One of the key focuses moving forward may fall on the developing nations to work collectively in participating in the updated system. As mentioned, Member States must take subsequent steps in implementing the new system in their own legislation. Should the new amendment be considered a success story for poor people? One may view this as a result of the lobbied efforts for poor people. After all, the updates on the TRIPS Agreement are once again directed at alleviating the access problem.

On the other hand, how do we address the intellectual property rights of patent owners? Without discovery and continued research, not only does the developing world suffer, but each person is deprived of the potential products patent holders may produce. The idea behind patents is to promote creativity and innovation, and without all the benefits associated with agreeing to disclosed inventions, it must be asked whether patent holders are reciprocally being deprived. A minority argument may conclude that intellectual property should be treated with the same importance as those suffering in the developing world. Does society prioritize innovation or the current state of the public? If society were to prioritize public health, is the future of medicines bleak?

One may belittle the rights of patent holders because the poor are more in need. Inversely, patent holders and pharmaceutical companies need to halt the “poverty, not patents” argument, as it continually shifts the blame to one side; developing countries do not have access because they are impoverished. Both sides of this issue need to be acknowledged. This is truly a balancing act, and leveling the scale proves to be challenging. Is it even possible to achieve balanced efforts of patent property rights, while lessening the statistic in the developing world? For now, there is some truth in that the patent property regime patently limits poor people’s access to essential medicines.