Annals of Health Law

Volume 18
Issue 2 *Summer 2009*

Article 7

2009

Diseases Endemic in Developing Countries: How to Incentive Innovation

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I. INTRODUCTION

The current approach to drug discovery is costly and time consuming. Estimates indicate that bringing a new drug to market costs anywhere from $115 million to over $800 million and takes approximately twelve years.[1] To recoup these high costs, drug developers depend upon the willingness and ability of consumers to purchase the resulting drugs. The patent system provides drug developers limited exclusivity for their products.[2] Without these exclusive patent protections, many drug developers would not invest the needed funds to develop new drugs.[3] Although these patent protections are important for profitable drugs, the patent system offers less incentive for research and development (R&D) of new drugs likely to have low profit margins. Pharmaceutical companies and other drug developers thus have little incentive to develop treatments for diseases endemic in developing countries because the treatments are too expensive for the people who need them, and the developers will be unable to recoup their significant R&D expenditures.[4]

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* This comment was a finalist in Epstein, Becker & Green's 11th Annual Health Law Writing Competition.

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1. David Henry & Joel Lexchin, *The Pharmaceutical Industry as a Medicines Provider*, 360 LANCET 1590, 1592-93 (2002); Joseph A. DiMasi, Ronald W. Hansen & Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 180 (2003). All dollar amounts in this comment refer to U.S. dollars.

2. *See* Henry & Lexchin, *supra* note 1, at 1593.

3. *See id.*

4. Stephen M. Maurer, Arti Rai & Andrej Sali, *Finding Cures for Tropical Diseases: Is Open Source an Answer?*, 6 MINN. J.L. SCI. & TECH. 169, 169 (2004) (This article is based on Stephen M. Maurer, Arti Rai & Andrej Sali, *Finding Cures for Tropical Diseases: Is Open Source an Answer?*, 1 PLOS MED 3 (2004)), *available at* http://mjlst.umn.edu/pdfs/

On May 24, 2008, the World Health Assembly (WHA), the decision-making body for the World Health Organization (WHO), released a document entitled *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property* (*Global Strategy*).[5] In *Global Strategy*, WHO Member States suggest implementation strategies to promote R&D for diseases endemic in developing countries.[6] An Intergovernmental Working Group (IGWG) consisting of representatives from over twenty countries developed these strategies.[7] One stated aim of the action plan is to explore a variety of incentive mechanisms "addressing the de-linkage of the costs of research and development and the price of health products and methods for tailoring the optimal mix of incentives to a particular condition or product with the objective of addressing diseases that disproportionately affect developing countries."[8] Some of the proposed strategies include open source research, patent pools, and prizes.[9]

On January 21, 2009, the WHO released another document entitled "Proposed Time Frames and Estimated Funding Needs" to implement the WHO IGWG plan of action.[10] The total cost estimate to implement the WHO IGWG plan of action is $2.064 billion dollars, with a proposed time frame from 2009 to 2015.[11] Annually, approximately $160 billion is spent globally on health R&D; however, only three percent of that money is "directed at diseases that disproportionately affect developing countries."[12] Under the proposed global strategy and action plan, twelve percent of global health spending will be directed at R&D for these diseases.[13] The plan represents global support for a variety of strategies to incentivize research in this much-needed area of health care.

This comment reviews three proposals identified in the *Global Strategy*: open source initiatives, patent pools, and prizes. In addition, this comment discusses an additional strategy, wild card patent extensions. Although the

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mauer_a3.pdf [hereinafter Maurer et al., MINN. J.L. SCI. & TECH.].

5. Sixty-First World Health Assembly, *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property*, WHA61.21, at 1 (May 24, 2008), *available at* http://www.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf.

6. *Id.* at 1, 6.

7. *See* World Health Organization [WHO], Pub. Health, Innovation and Intellectual Prop., *Expert Working Group on R&D Financing*, http://www.who.int/phi/R_Dfinancing/en/index.html (last visited Jan. 24, 2009) [hereinafter *Expert Working Group*].

8. Sixty-First World Health Assembly, *supra* note 5, at 5.

9. *Id.* at 10, 14, 16-17.

10. WHO, Executive Bd. 124th Session, *Public Health, Innovation and Intellectual Property: Global Strategy and Plan of Action: Proposed Time Frames and Estimated Funding Needs* 1, EB124/16 Add.2 (Jan. 21, 2009), *available at* http://www.who.int/gb/ebwha/pdf_files/EB124/B124_16Add2-en.pdf [hereinafter WHO Executive Bd.].

11. *Id.* at 1-2.

12. *Id.* at 3.

13. *Id.*

Global Strategy did not endorse wild card patent extensions, this alternative represents a contrasting model that leverages the patent system to incentivize research. Part II of this comment addresses the inadequacy of research and development for diseases that disproportionately affect people in developing countries. Part III analyzes how the patent system can inhibit innovation of new drugs for these neglected diseases. Part IV discusses possible strategies to spur drug and vaccine development including open source, patent pools, prizes, and wild card patent extensions. Part V concludes by suggesting that a combination of proposals identified in the WHO *Global Strategy* can synergistically work together to help solve the problem.

II. LACK OF R&D FOR DISEASES ENDEMIC IN DEVELOPING COUNTRIES

Tropical diseases affect more than half a billion people, most of whom live in developing countries.[14] Malaria, one of the most deadly and widespread tropical diseases, afflicts between 300 to 500 million people and causes an estimated 1.0 to 2.7 million deaths per year.[15] Additionally, over fourteen million people die from infectious diseases each year, ninety percent of whom reside in developing countries.[16] Likewise, ninety percent of the forty million people infected with human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) live in the developing world.[17] Moreover, tuberculosis (TB) annually kills approximately two million people, ninety-nine percent of whom are in developing countries.

The WHO has estimated that 1.7 billion people lack access to essential medicines.[18] Additionally, one study found that approximately ten million children in developing countries die every year from preventable and treatable illnesses because of inadequate access to basic treatment.[19]

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14. Maurer et al., MINN. J.L. SCI. & TECH., *supra* note 4, at 169.

15. *See* PATH MALARIA VACCINE INITIATIVE, FACT SHEET: PLASMODIUM FALCIPARUM MALARIA 1 (2004), *available at* http://www.malariavaccine.org/files/FS_Pfalciparum-Sept-2004_FINAL.pdf.

16. Bryan Mercurio, *Resolving the Public Health Crisis in the Developing World: Problems and Barriers of Access to Essential Medicines*, 5 NW. U. J. INT'L HUM. RTS. 1, 1 (2006); MÉDECINS SANS FRONTIÈRES [MSF] [DOCTORS WITHOUT BORDERS], MILLIONS HAVE A DRUG PROBLEM. THEY CAN'T GET ANY. 3 (2004), *available at* http://www.msf.org.hk/fs/download/?file%5fid=17937 [hereinafter MSF].

17. Mercurio, *supra* note 16, at 1; MSF, *supra* note 16, at 7.

18. WHO, THE WORLD MEDICINES SITUATION, at 61 (2004), *available at* http://www.searo.who.int/LinkFiles/Reports_World_Medicines_Situation.pdf.

19. *See* Robert E. Black et al., *Where and Why are 10 Million Children Dying Every Year?*, 361 LANCET 2226, 2226 (2003); *see also* Teresa Cerojano, *Charity: 10 Million Children Die Without Basic Health Care*, J. INQUIRER (Manchester, Conn.), May 6, 2008, at

The WHO's Commission on Intellectual Property, Innovation and Public Health (CIPIH) classifies diseases into three categories: Type I diseases, Type II diseases, and Type III diseases.[20] Type I diseases occur in both developed and undeveloped countries and include communicable diseases (i.e., hepatitis B and *Haemophilus influenzae* type b) and non-communicable diseases (i.e., diabetes, cardiovascular diseases, and tobacco-related diseases).[21] Type II diseases occur in both wealthy and poor countries, but they are proportionally higher in poor countries.[22] Type II diseases, which the WHO has classified as "neglected diseases," include communicable diseases such as HIV/AIDS and TB.[23] Type III diseases, which encompass infectious diseases, such as malaria, trypanosomiasis (African sleeping sickness), and onchocerciasis (African river blindness), overwhelmingly or exclusively occur in developing countries.[24] The WHO considers Type III diseases "very neglected diseases."[25] Public health scholars James Love and Tim Hubbard have emphasized that "under a system of incentives that targets prices (and incomes of patients), there is considerable under-investment in Type II and III diseases relative to need when measured on medical and social grounds."[26]

Around the world, research resources applied to health problems in developing countries contrast sharply with the preventable disease burden represented in those countries. Some scholars have termed this the "research and development gap" (R&D gap).[27] The Commission on Health Research for Development first identified this research gap in 1990.[28] The Commission later termed this the "10/90 gap," finding that less than ten percent of global health R&D is spent on health problems in poor countries, which account for over ninety percent of the global disease burden.[29] The severe imbalance between the magnitude of Type II and Type III diseases

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Nat'l.

20. WHO, PUBLIC HEALTH INNOVATION AND INTELLECTUAL PROPERTY RIGHTS: REPORT OF THE COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INNOVATION AND PUBLIC HEALTH 12-13 (2006), *available at* http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf [hereinafter REPORT OF THE CIPIH].

21. *Id.* at 13.

22. *Id.*

23. *Id.*

24. *Id.*

25. *Id.*

26. James Love & Tim Hubbard, *The Big Idea: Prizes to Stimulate R&D for New Medicines*, 82 CHI.-KENT L. REV. 1519, 1527 (2007); *see also* REPORT OF THE CIPIH, *supra* note 20, at 16-17.

27. Amy Kapczynski et al., *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, 20 BERKELEY TECH. L.J. 1031, 1037 (2005).

28. GLOBAL FORUM FOR HEALTH RESEARCH, THE 10/90 REPORT ON HEALTH RESEARCH 2003-2004 35 (2004).

29. *Id.*

and the amount spent on R&D persists today.[30]

III. PATENT SYSTEM INHIBITING R&D

The pharmaceutical and biotechnology industries both rely on the patent system for protection of their developed products.[31] Most drugs easily can be reverse engineered.[32] Therefore, without the guarantee of limited exclusivity offered by drug patents, most pharmaceutical companies would have little incentive to invest the amount of money needed to bring a new drug to market.[33] The same patent protections that incentivize research for profit-making drugs can foreclose R&D for necessary, albeit unprofitable, drugs, vaccines, and products. Love and Hubbard note, "[w]hen marketing exclusivity is the reward, investors rationally target research investments to address the problems of patients who have the highest incomes and can pay the highest prices."[34]

Additionally, the profusion of patents can create problems for downstream research in the form of "anticommons" and "patent thickets."[35] When the number of patent rights interferes with the development and marketing of new products, this is referred to as an "anticommons problem."[36] A "pure" anticommons problem exists when "multiple, non-overlapping rights must be obtained in order to develop an additional non-overlapping right."[37] A patent thicket, by contrast, exists when there are many overlapping patent claims on different aspects of biotechnology products.[38] Patents often state broader claims than the actual developed product; consequently, many patents may cover the same area.[39] Accordingly, multiple patentees can lay claim to the same area of biotechnology.[40] When this occurs, researchers must obtain rights from each patent holder within the patent thicket prior to proceeding

30. Patrice Trouiller et al., *Drug Development for Neglected Diseases: A Deficient Market and a Public-Health Policy Failure*, 359 LANCET 2188-94 (2002) (finding that of the 1,393 new drugs approved between 1975 and 1999, only 16 were indicated for tropical diseases and tuberculosis, diseases which predominantly affect the developing world).

31. Katherine M. Nolan-Stevaux, *Open Source Biology: A Means to Address the Access & Research Gaps?*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 271, 276 (2007).

32. *Id.*

33. *Id.*

34. Love & Hubbard, *supra* note 26, at 1527.

35. Nolan-Stevaux, *supra* note 31, at 276.

36. *Id.* at 277; *see also* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698, 699 (1998).

37. Nolan-Stevaux, *supra* note 31, at 277.

38. *See* Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1614 (2003).

39. *See id.*

40. *See id.*

independently with their research.[41]

Many researchers investigating diseases endemic in developing countries do not have the resources to assume the high transaction costs associated with anticommons and patent thickets.[42] Thus, some researchers forgo investigating areas where the necessary patent rights are "held by multiple parties who are difficult to locate and may be reluctant to bargain with a downstream inventor."[43] Moreover, to protect their interests and to prevent competition, patent owners may not want to license their patented products even if they do not anticipate conducting further research on those products.[44] One scholar has contended that highly fragmented patent rights, coupled with restrictive legislative and university policies in the life sciences, create a "perfect storm of innovation destroying transaction costs."[45]

Therefore, the problem of patents foreclosing research on diseases disproportionately affecting developing countries is twofold: (1) patents inhibit R&D because the market drives drug development and the limited exclusivity on the resulting drugs does not incentivize research for drugs with low profit margins; and (2) navigating the anticommons and patent thicket problems can be prohibitively costly and time-consuming. This comment will outline several strategies to combat these problems.

IV. PROPOSED SOLUTIONS TO THE LACK OF ACCESS AND INNOVATION

A. Open Source

"Open source" refers to collaborative, community-based initiatives where the components of the project are made available to all and can be modified by all, such that individual members re-contribute to the larger project.[46] Open source has been lauded as a successful approach to software development.[47] The Linux operating system (Linux) is perhaps the best-known and most impressive example.[48] Linux was produced by a group of volunteers collaborating through the Internet.[49] The "source code" was made freely available for anyone to view, modify, or improve with the

41. *See id.*

42. *See* Nolan-Stevaux, *supra* note 31, at 278.

43. *See id.*

44. *See* Burk & Lemley, *supra* note 38, at 1614.

45. Lee Petherbridge, *Road Map to Revolution? Patent-Based Open Science*, 59 ME. L. REV. 339, 355 (2007).

46. Thomas B. Kepler et al., *Open Source Research—The Power of Us*, 59 AUSTL. J. CHEMISTRY 291, 291 (2006).

47. *An Open-Source Shot in the Arm?*, ECONOMIST, June 12, 2004, at 17.

48. *Id.*

49. *Id.*

provision that the volunteers agreed to share their modifications openly.[50]

The participants in open source initiatives are mostly unpaid volunteers who "donate their time and expertise for the satisfaction of contributing to the solution of a large, complex problem and peer-recognition for having done so."[51] Open source's primary benefit is "to cross-fertilize minds and tap creativity quickly, cheaply and on a scale that is beyond the reach of scientists working in the 'ivory towers' of academia or behind the 'corporate moats' of industry."[52]

There are several significant obstacles to applying an open source model to R&D for pharmaceuticals due to the fundamental differences between software and drug development.[53] First, the costs between developing software and drugs differ to an extraordinary extent.[54] Open source software simply requires a laptop computer and an Internet connection, whereas the laboratory expenses and clinical trials involved in developing a new drug can cost over $800 million.[55]

Second, software development does not include a discovery phase that compares to pharmaceutical research.[56] Programmers immediately begin developing source code and make steady progress; in contrast, the discovery of target compounds to develop a new drug can take years or decades, without knowledge at the outset of whether the target compound will generate rewarding results.[57] Third, software development spans few disciplines, whereas drug development requires coordination among multiple specialties.[58] Fourth, unlike software, the U.S. federal government highly regulates drug development and requires Food and Drug Administration (FDA) approval.[59] Finally, different intellectual property laws regulate the software and pharmaceutical industries.[60] Copyrights that "arise automatically as code is written" protect software, whereas patents, which may have a costly application process and are subject to more stringent legal standards, protect drug research.[61]

Despite these differences, precedent exists for using open source ideas in

50. *Id.*
51. Kepler et al., *supra* note 46, at 291.
52. Bernard Munos, *Can Open-Source R&D Reinvigorate Drug Research?*, 5 NATURE REVS. DRUG DISCOVERY 723, 723 (2006), *available at* http://www.nature.com/nrd/journal/v5/n9/pdf/nrd2131.pdf.
53. *Id.* at 724.
54. *See id.*
55. *Id.*; Henry & Lexchin, *supra* note 1, at 1593.
56. Munos, *supra* note 52, at 724.
57. *Id.*
58. *Id.*
59. *Id.*
60. *Id.*
61. *Id.*

biomedical research.[62] In this context, open source refers to the "open origin of contributors."[63] The international effort to sequence the human genome, known as the Human Genome Project, resembled an open source initiative by placing all of the resulting data in the public domain rather than allowing any individual researcher to patent the results.[64] The primary distinction is that the Human Genome Project involved extensive government "top-down" involvement, whereas an open source software project involves "bottom-up" organization among volunteers and researchers.[65] Open source approaches also have been used in the field of bioinformatics, where supercomputers are used to conduct biological research.[66] The public shares the software code and databases.[67]

Although the open source approach appears to work well in pre-competitive platform technologies such as biological research tools, the question remains as to whether it will also work "further downstream, closer to the patient, where the development costs are greater and the potential benefits more direct."[68]

While drug developers may be unwilling to participate in open source initiatives for the development of potentially highly profitable or blockbuster drugs, open source may not meet resistance and may be effective in two areas.[69] One is in the development of non-patentable compounds or drugs whose patents have expired.[70] Since discovery involving these drugs and compounds cannot be protected, nor can they garner large profits, developers generally are less interested in pursuing research in these areas.[71] The second is in the area of neglected diseases because there is not a large enough market of paying customers to justify the expense involved in developing a new drug.[72] Given that pharmaceutical companies and other drug developers would not lose money by participating in open source projects in these areas, they may be amenable to this system.

The WHO called for support of open source initiatives in its May 2008 *Global Strategy* proposal with the following provision:

62. Munos, *supra* note 52, at 724.
63. *Id.* at 723.
64. *See An Open-Source Shot in the Arm?*, *supra* note 47, at 17, 19.
65. *Id.* at 18.
66. *Id.* at 17.
67. *Id.*
68. *Id.*
69. *See id.*
70. *An Open-Source Shot in the Arm?*, *supra* note 47, at 17.
71. *Id.*
72. *Id.*

(2.2) promoting upstream research and product development in developing countries

(a) support discovery science, including where feasible and appropriate, voluntary open-source methods, in order to develop a sustainable portfolio of new products

(b) promote and improve accessibility to compound libraries through voluntary means, provide technical support to developing countries and promote access to drug leads identified through the screening of compound libraries

. . . .[73]

Due to the international diversity of the WHO representatives who developed this document, this proposal represents global support for open source initiatives in the realm of treatment for neglected diseases.

1. The Tropical Disease Initiative

Stephen Mauer, Arti Rai, and Andrej Sali argue for an open source approach for developing drugs to fight tropical diseases such as malaria.[74] An example of a promising open source approach is the Tropical Disease Initiative (TDI), a decentralized, internet-based, community-wide effort.[75] Through TDI, scientists from laboratories, universities, institutes, and corporations can collaborate to mine data from multiple sources to obtain promising leads on drug compounds for specific diseases.[76] The authors describe an open source drug discovery in the following manner:

> As with current software collaborations, we propose a Web site where volunteers use a variety of computer programs, databases, and computing hardware []. Individual pages would host tasks like searching for new protein targets, finding chemicals to attack known targets, and posting data from related chemistry and biology experiments. Volunteers could use chat rooms and bulletin boards to announce discoveries and debate future research directions. Over time, the most dedicated and proficient volunteers would become leaders.[77]

The authors further explain that new lead compounds can be identified

73. Sixty-First World Health Assembly, *supra* note 5, at 10.

74. Stephen M. Maurer, Arti Rai & Andrej Sali, *Finding Cures for Tropical Diseases: Is Open Source an Answer?*, 1 PLoS MED., 183, 183 (2004) [hereinafter Maurer et al., PLoS MED.].

75. *Id.*

76. *See id.*

77. *Id.* at 184.

using computation alone - an impossibility just ten years ago.[78] Therefore, there will be incentives for graduate students and young professionals to volunteer and gain experience, or to enhance their professional reputations. This is one of many approaches that uses elements of the open source software-development model in drug research.[79] Professor Yochai Benkler, of Yale Law School, contends that this model can exploit the "'excess capacity' of graduate students and university labs, much as students and academics also contribute to open-source software development."[80]

Under the TDI model, "Virtual Pharmas" could competitively bid for the lead components.[81] In the Virtual Pharmas approach, teams funded by governments and philanthropies search for promising private and academic research on new drug compounds.[82] Virtual Pharmas do not perform the actual R&D (from a promising compound to a marketable drug), instead they award the bid for promising drug candidates to a laboratory based on a competitive bidding process.[83] TDI would help Virtual Pharmas contain the costs of discovering, developing, and manufacturing drugs by finding promising target compounds.[84] Moreover, the open source drugs would not be patented; rather, the drug itself would enter the public domain for generic manufacturers to produce.[85] This helps achieve the goal of bringing new medicines to people who need them, at the lowest possible price.[86]

Finding promising lead compounds is especially important because it takes up to approximately twelve years to develop a new drug.[87] Moreover, many pharmaceutical companies and research laboratories can spend years developing a potential drug that proves unsuccessful. Using open source, a team of scientists collaborate and explore all the existing literature to find the most promising leads, which could prevent years of research on less promising compounds, allowing Virtual Pharmas to help contain costs in discovering, developing, and manufacturing drugs.[88]

2. The Synaptic Leap

Recently, an open source collaboration investigating tropical diseases

78. *Id.*
79. *An Open-Source Shot in the Arm?*, *supra* note 47, at 18.
80. *Id.*
81. *See* Maurer et al., PLOS MED., *supra* note 74, at 184.
82. *Id.* at 183.
83. *Id.* at 183-84.
84. *Id.* at 184.
85. *Id.*
86. *See id.*
87. Henry & Lexchin, *supra* note 1, at 1592.
88. Maurer et al., PLOS MED., *supra* note 74, at 184.

was described in the *Australian Journal of Chemistry*.[89] The Synaptic Leap (TSL) is an open source biomedical research community that aims to investigate diseases where "profit-driven research is failing."[90] TSL is collaborating with TDI to research malaria and schistosomiasis, one of the most serious tropical diseases.[91] This joint, open source initiative employs both "armchair and wet-laboratory modes" and contributors may post comments on the internet to suggest possible routes to the drugs studied, to propose suitable reactions, or to share their experiences on suggested chemical steps.[92] Those with laboratory access can "attempt reactions of interest and post results, either as part of spare-time activities or as more formal student projects."[93] The authors note, "[o]pen source communities thus expand the borders of what is already commonplace within chemistry schools."[94]

3. Open Source Drug Discovery

In addition, an open source initiative called Open Source Drug Discovery (OSDD) is currently under way in India through the Council of Scientific and Industrial Research (CSIR).[95] Samir Brahmachari, director general of the CSIR, states that the goal of OSDD is "to establish a novel web-enabled open source platform—both computational and experimental—to make drug discovery cost effective and affordable by utilising the creative potential of college and university students along with senior scientists, a collective approach to drug development."[96] The project will receive one-third of its funding from the government, one-third from international sources, and one-third from philanthropic organizations.[97] The Indian government already has committed the equivalent of $38 million to OSDD.[98]

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89. Kepler et al., *supra* note 46, at 293.
90. *Id.*
91. *Id.*
92. *Id.*
93. *Id.*
94. *Id.*
95. Seema Singh, *India Takes an Open Source Approach to Drug Discovery*, 133 CELL, 201, 201 (2008).
96. The Rediff Interview with Samir K. Brahmachari, Director, CSIR, Open Source Drug Discovery Will Lower Costs, Rediff.com, Feb. 15, 2008, http://www.rediff.com/money/2008/feb/15inter.htm.
97. Soma Banerjee & Gireesh Chandra Prasad, *Govt to Rope in Young Minds to Invent Cheaper Drugs*, ECON. TIMES, Dec. 20, 2007, *available at* http://economictimes.indiatimes.com/Pharmaceuticals/Govt_to_rope_in_young_minds_to_invent_cheaper_drugs/articleshow/2635842.cms.
98. Open Source Drug Discovery, http://www.osdd.net/what_is_osdd.htm (last visited Apr. 2, 2009).

OSDD has created a database of requirements for infectious disease drug development, whereby individual researchers can contribute to solutions for specific aspects of drug discovery.[99] "The chemical entities thus developed will instantly become generics as the knowledge will be in public domain. This is diametrically opposite to the concept of intellectual property protection, which involves legal expenses to bar others from applying their minds on the invention," Mr. Brahmachari said in an interview with *The Economic Times*.[100]

While an open source initiative is a strategy largely outside of the patent system, this comment will next address a strategy within the patent system, namely, the collective management of intellectual property rights through patent pools.

B. Patent Pools

The WHO, UNITAID, and pharmaceutical companies like GlaxoSmithKline (GSK) have recommended patent pools as a potentially effective means to promote innovation and access to medicines to target diseases endemic in developing countries.[101] A patent pool is defined as:

> An agreement between two or more patent owners to aggregate (pool) their patents and to license them to one another or to third parties. Pools usually offer standard licensing terms to licensees and allocate a portion of the licensing fees (royalties) to patent owners according to a pre-set formula or procedure.[102]

Agreements between the members of the patent pool and third parties can be established directly through patentees and licensees or indirectly

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99. Banerjee & Prasad, *supra* note 97.

100. *Id.*

101. *See* WHO, Regional Office for South-East Asia, Briefing Note: Medical Innovation, *Innovation for Diseases That Mainly Affect Developing Countries: Issues and Ideas*, at 3 (Oct. 2007), *available at* http://www.searo.who.int/LinkFiles/AIDS_Innovation_Oct07.pdf [hereinafter WHO, *Innovation for Diseases*]; Press Release, Universities Allied for Essential Medicines (UAEM), UAEM Urges Universities to Support UNITAID Patent Pool (Aug. 5, 2008), http://www.essentialmedicine.org/uaem-urges-universities-to-support-unitaid-patent-pool/; Press Release, Médecins Sans Frontières, MSF Statement on UNITAID Medicines Patent Pool Decision (July 9, 2008), http://www.doctorswithoutborders.org/news/article.cfm?id=2843 [hereinafter MSF Press Release]; Sarah Boseley, *Drug Giants Urged to Create Patent Pools*, GUARDIAN, Mar. 24, 2009, at 5, *available at* http://www.guardian.co.uk/society/2009/mar/24/pharamcuticals-patent-pools-hiv-drugs.

102. KNOWLEDGE ECOLOGY INT'L, IGWG BRIEFING PAPER ON PATENT POOLS: COLLECTIVE MANAGEMENT OF INTELLECTUAL PROPERTY – THE USE OF PATENT POOLS TO EXPAND ACCESS ESSENTIAL MEDICAL TECHNOLOGIES 1 (2007), *available at* http://www.keionline.org/content/view/65/ [hereinafter KEI].

through an entity specifically created to administer the pool.[103] This type of collective management strategy can be voluntary or governmentally-imposed.[104] Patent pools can accelerate innovation by removing problems associated with "blocking" patents, reducing transaction costs, and streamlining and centralizing licensing procedures, thereby making it quicker and simpler to obtain licenses.[105] According to James Love, "[i]ncreased use of patent pools and collective management of IP [intellectual property] rights can foster access to patented medicines and improve the traditional patent system. This collective management will streamline patent procedures globally and lower costs."[106]

Precedents for patent pools in the United States began as early as the mid-nineteenth century.[107] In 1856, the Sewing Machine Combination patent pool was formed, which was comprised of sewing machine patents.[108] In 1917, an aircraft patent pool was formed, Manufacturer's Aircraft Association (MAA), which included almost every aircraft manufacturer in the U.S.[109] The U.S. government considered development of the MAA crucial because two aircraft patent holders, the Wright Company and the Curtiss Company, blocked the building of new airplanes just as the United States was entering World War I.[110] Indeed, the MAA was created when the government threatened to compulsorily license the needed patented technology.[111] Patent pools also have been used in the electronics and telecommunications industries for development of technology such as radio, DVD-video, DVD-Rom, and MPEG_2 compression technology.[112]

However, critics of patent pools caution that patent pools could have anti-competitive effects.[113] These critics argue that patent pools cover competitive alternatives to certain technologies that can expand monopoly pricing.[114] In 1912, in *Standard Sanitary Manufacturing Co. v. United*

103. Birgit Verbeure et al., *Patent Pools and Diagnostic Testing*, 24 TRENDS BIOTECHNOLOGY 115, 115 (2006).

104. WHO, *Innovation for Diseases*, *supra* note 101, at 2.

105. *Id.* at 2-3.

106. James Love, *Measures to Enhance Access to Medical Technologies, and New Methods of Stimulating Medical R & D*, 40 U.C. DAVIS L. REV. 679, 694 (2007).

107. JEANNE CLARK ET AL., U.S. PATENT & TRADEMARK OFFICE, PATENT POOLS: A SOLUTION TO THE PROBLEM OF ACCESS IN BIOTECHNOLOGY PATENTS? 4 (2000), *available at* http://www.uspto.gov/web/offices/pac/dapp/opla/patentpool.pdf.

108. *Id.*

109. *Id.*

110. *Id.*

111. KEI, *supra* note 102, at 2.

112. *Id.*

113. Clark, *supra* note 108, at 10.

114. *Id.*

States, the U.S. Supreme Court dissolved a patent pool because of antitrust violations, including fixing prices and blocking unlicensed manufacturers.[115] In 1945, in *Hartford-Empire Co. v. United States*, the U.S. Supreme Court dissolved a glass manufacturer patent pool because it comprised ninety-four percent of all glass made in the U.S. and was thus able to set and maintain unreasonably high glass prices.[116] In an attempt to deal with potential anticompetitive effects of patent pools, the U.S. Department of Justice and the Federal Trade Commission issued *Antitrust Guidelines for the Licensing of Intellectual Property* in 1995.[117] Although these guidelines specify how patent pools can be deemed anticompetitive, they also indicate that patent pools "may provide procompetitive benefits by integrating complementary technologies, reducing transaction costs, clearing blocking positions, and avoiding costly infringement litigation."[118] The European Commission and Japanese Fair Trade Commission also have issued guidelines outlining procedures to manage any potential anticompetitive effects of patent pools.[119]

While there are significant precedents for patent pools in the electronics and telecommunications industries, patent pools largely have been untested in biotechnology, and some analysts question whether patent pools can be applied effectively to the medical biotechnology industry.[120] The Organisation for Economic Co-operation and Development (OECD) called for further study into the use of patent pools in the field of biotechnology.[121] The OECD was concerned that "the fact that biotechnology companies rely heavily on their intellectual property (IP) and foster what has been called a 'bunker mentality' might cause difficulties in the process of creating a pool."[122] The WHO also called for research into the feasibility of patent pools in its *Global Strategy* proposal in the following provision:

> (4.3) developing possible new mechanisms to promote transfer of and access to key health-related technologies
>
> (a) examine the feasibility of voluntary patent pools of upstream and

115. *Id.* at 5.

116. *Id.*

117. *See* U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY 1 (1995), *available at* http:/www.usdoj.gov/atr/public/guidelines/0558.pdf.

118. *Id.* at 28.

119. Verbeure et al., *supra* note 103, at 115-16.

120. *Id.* at 117; Patrick Gaulé, *Towards Patent Pools in Biotechnology?*, 2 INNOVATION STRATEGY TODAY 123, 123 (2006), *available at* http://www.biodevelopments.org/innovation/ist5.pdf; Geertrui Van Overwalle et al., *Models for Facilitating Access to Patents on Genetic Inventions*, 7 NATURE REVS. GENETICS 143, 145 (2006).

121. Overwalle et al., *supra* note 120.

122. *Id.*

> downstream technologies to promote innovation of and access to health products and medical devices. . . .[123]

One precedent for patent pools exists in the field of agricultural biotechnology—the Golden Rice case.[124] In this case, private and public corporations worked together to create a non-profit, humanitarian patent pool.[125] The private company, Potrykus, wanted to transfer its genetically-enriched rice grains, Golden Rice, to developing countries for breeding; however, thirty-two different companies and universities had seventy patents in Golden Rice, precluding the transfer.[126] Potrykus approached six key patent holders, who agreed to give Potrykus permission to grant free licenses to developing countries with a right to sub-license.[127] A voluntary humanitarian board, HumBo, was established to aid in the governance of the patent pool.[128] This case received much attention as an example of private-public collaboration in negotiating through patent thickets to reach a humanitarian end.[129] The following examples demonstrate how the collaborative approach of patent pools that was exhibited in the Golden Rice case can be applied to R&D for drugs and vaccines that combat specific diseases.

1. Severe Acute Respiratory Syndrome Patent Pool Proposal

In 2005, the *Bulletin of the World Health Organization* put forth a proposal to create a patent pool to facilitate the development of a vaccine for Severe Acute Respiratory Syndrome (SARS).[130] The proposal contended that since the outbreak of SARS in late 2002, numerous organizations have filed patent applications that incorporate the genomic sequence of the SARS coronavirus, which likely would result in a fragmentation of intellectual property rights and thus hinder the development of a vaccine.[131] A patent pool was recommended to help set a precedent for the use of patent pools in health care.[132] This proposal has yet to be adopted.

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123. Sixty-First World Health Assembly, *supra* note 5, at 14.
124. Verbeure et al., *supra* note 103, at 117.
125. *Id.*
126. *Id.*
127. *Id.*
128. *Id.*
129. Overwalle et al., *supra* note 120, at 145.
130. James H.M. Simon et al., *Managing Severe Acute Respiratory Syndrome (SARS) Intellectual Property Rights: The Possible Role of Patent Pooling*, 83 BULL. WORLD HEALTH ORG. 707, 707 (2005), *available at* http://www.who.int/bulletin/volumes/83/9/707.pdf.
131. *Id.*
132. *Id.* at 708.

2. Malaria Vaccine Patent Pool Proposal

The promises and challenges of a patent pool approach for the development of a malaria vaccine was analyzed in a study published in 2007 in the *Intellectual Property Handbook for Best Practices*.[133] The authors of the study note that no safe malaria vaccine currently exists, and the vaccine is an increasing priority as malaria parasites are becoming resistant to known drug treatments.[134] A malaria vaccine could have the following benefits in comparison with the existing treatments: (1) cost-effectiveness; (2) minimization of negative effects on the environment by reducing the need for pesticides to control mosquito populations; (3) assistance in solving the problem of drug-resistant parasites; and (4) the potential to save lives, which is of the utmost importance.[135]

Developing and commercializing a malaria vaccine, however, presents significant economic, technical, and intellectual property challenges. Although there is a profound need for a malaria vaccine, a profitable market that would incentivize a sustained source of funding does not exist.[136] However, a number of philanthropic, public, and private initiatives fund R&D for a malaria vaccine.[137] The largest contributor by far is the Bill & Melinda Gates Foundation, which has spent $1.2 billion to further its stated goal of eradicating malaria.[138]

Technically, the development an effective vaccine poses a number of challenges. Malaria results from different parasite species in different countries, and there are numerous variants within each parasite species.[139] The malaria parasite produces many different antigens during each stage of its life cycle.[140] Antigens are "substances that can evoke an immune response in humans" and can be useful in developing a vaccine.[141] Although several thousand potential target antigens could lead to potential vaccines, researches have only studied "a few dozen" of these antigens for

133. Sandra L. Shotwell, *Patent Consolidation and Equitable Access: PATH's Malaria Vaccines*, *in* INTELLECTUAL PROPERTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATION: A HANDBOOK OF BEST PRACTICES 1789, 1789 (Anatole Krattiger et al. eds., 2007), *available at* http://www.iphandbook.org/handbook/resources_and_tools/Publications/links/ipHandbook%20Volume%202.pdf.

134. *Id.*

135. *Id.*

136. *Id.*

137. *Id.* at 1789-90.

138. *See* Donald G. McNeil, Jr., *Eradicate Malaria? Doubters Fuel Debate*, N.Y. TIMES, Mar. 4, 2008, at F1, *available at* http://www.nytimes.com/2008/03/04/health/04mala.html?ref=health.

139. Shotwell, *supra* note 133, at 1790.

140. *Id.*

141. *Id.*

use in potential vaccines.[142] In 2006, sixteen vaccine candidates were being investigated in clinical trials globally.[143] Recently, the first malaria vaccine has been effective in Phase 2 clinical trials in Africa.[144] Although several malaria vaccines are undergoing analysis in human clinical trials in Africa, Asia, Europe, and the United States, it could be ten years before an effective vaccine achieves regulatory approval and is licensed and produced.[145]

Additionally, there are a number of significant intellectual property challenges to developing a malaria vaccine. Many antigens needed for vaccine development are covered by multiple patents, some of which have overlapping claims, creating a patent thicket.[146] Such a patent thicket can prove a forbidding obstacle, given that more than one antigen is usually needed to develop an effective vaccine.[147] For instance, a recent study found one malaria antigen that could be targeted for a vaccine is subject to thirty-four patents.[148] Gaining access to patents one at a time through traditional licensing and partnering utilizes much needed time and resources that could otherwise be used to develop and deliver the vaccines.[149] Further, the negotiations needed to acquire access to needed patents could cause additional delays.[150] Access to key patents could be thwarted if the patent owner is unwilling to license to others, thus blocking access to the antigen.[151]

A patent pool could help solve many of these problems, allowing access to multiple antigens, simplifying licensing transactions, and lowering the transaction costs associated with navigating through a patent thicket. However, the 2007 study published in the *Intellectual Property Handbook* concluded that a patent pool for *existing* malaria-antigens would be ill advised, due to the high costs of starting a pool, the difficulty engaging the current patent holders to contribute to the pool, and the likelihood that only a few entities would be interested in accessing any particular malaria-antigen patent.[152] The main obstacle is that almost all of the malaria-antigen patents currently are assigned or exclusively licensed to private

142. *Id.*

143. PATH Malaria Vaccine Initiative, http://www.malariavaccine.org/malvac-state-of-vaccine-dev.php (last visited Apr. 7, 2009).

144. Shotwell, *supra* note 133 at 1790.

145. PATH MALARIA VACCINE INITIATIVE, FACT SHEET: *PLASMODIUM FALCIPARUM* MALARIA, http://www.malariavaccine.org/files/FS_Pfalciparum-Sept-2004_FINAL.pdf (last visited Apr. 7, 2009).

146. Shotwell, *supra* note 133, at 1790.

147. *Id.*

148. Nolan-Stevaux, *supra* note 31, at 272.

149. Shotwell, *supra* note 133, at 1790.

150. *Id.* at 1790-91.

151. *Id.* at 1791.

152. *Id.* at 1794-95.

companies and are not available for licensing from the original publicly funded institution.[153] However, the study suggests "the concept of a technology trust or patent pool may still be useful for patents to be filed in the future."[154]

3. GSK Patent Pool for Neglected Tropical Diseases

Indeed, encouraging patent holders, particularly private companies, to contribute voluntarily to the pool is a large barrier with regard to the feasibility of biotechnology patent pools.[155] However, the tides may be turning in terms of garnering private company interest in voluntary patent pools for drug and vaccine development. *Nature* recently reported that "pharmaceutical giant" GSK has agreed to participate in a voluntary patent pool to allow access to intellectual property relevant to neglected tropical diseases, including malaria and tuberculosis.[156] Under the proposal, "[r]esearchers and companies, including manufacturers of generic drugs, would be able to license participants' patents from the pool for free to develop new treatments for neglected diseases in the world's [fifty] least-developed countries (LCDs)."[157] GSK has agreed to place 500 patents and 300 pending applications into the pool.[158]

4. UNITAID Patent Pool Proposal for Pediatric AIDS Drugs

Moreover, UNITAID, an international agency created in 2006 by Brazil, Britain, Chile, France, Norway, and other countries to buy medicines to combat AIDS, tuberculosis, and malaria, recently announced a proposal to establish a patent pool for medicines.[159] Three private companies, Gilead, Johnson & Johnson, and Merck, have agreed to negotiate with UNITAID.[160] The UNITAID patent pool initially will focus on pediatric AIDS drugs and drugs developed for adults who are resistant to first-line AIDS drugs.[161] Unlike first-line AIDS drugs, whose patents have expired and are available inexpensively from generic manufacturers, pediatric and second-line AIDS

153. *Id.* at 1794.

154. *Id.* at 1795.

155. *See* Shotwell, *supra* note 133, at 1791; MSF Press Release, *supra* note 101.

156. *GSK Backs Patent Pool for Neglected Diseases*, 457 NATURE 949, 949 (2009).

157. *Drug Patent Plan Gets Mixed Reviews*, 457 NATURE 1064, 1064 (2009).

158. *Drug Patent Pools Start to Take Shape*, 458 NATURE 562, 562 (2009).

159. Donald G. McNeil, Jr., *Effort for Lower Drug Prices Would Focus on Gaining Patents*, N.Y. TIMES, July 8, 2008, at F6.

160. Posting of James Love to Knowledge Ecology Notes: The KEI Staff Blog, KEI Reaction to GSK Announcement on Patent Pool for Neglected Diseases, http://www.keionline.org/blogs/2009/02/19/gsk-patent-pool/ (Feb. 19, 2009) [hereinafter Love, Knowledge Ecology Notes].

161. McNeil, Jr., *supra* note 159.

drugs largely are still covered by existing patents.[162]

The UNITAID and GSK proposals could set a precedent for the use of patent pools in the biomedical field, specifically for drug and vaccine development. Médecins Sans Frontières (Doctors Without Borders) strongly endorsed the UNITAID patent pool proposal as a visionary first step in providing increased access to lower-priced medicines.[163] The Director of Policy at Médecins Sans Frontières' Access Campaign, Ellen 't Hoen, stated, "[w]hether this works or not now depends on the willingness of patent holders to share, in exchange for royalties, the relevant patent rights in the pool."[164]

Prizes are another strategy for incentivizing research in unprofitable (but socially valuable) fields and can be used in tandem with strategies such as open source initiatives and patent pools.

C. Prizes

As a recent article in *Slate* suggested, prizes are not a new concept: "[o]ver the past few centuries, prizes have been designated for a longitude-measuring device (announced 1714, for up to 20,000 British pounds), a nonstop flight from New York to Paris (announced 1919, for $25,000; eventually awarded to Charles Lindbergh), and private space travel (announced 1996, the $10 million X-Prize)."[165] In the past year, politicians, scholars, and socially-conscious entrepreneurs, such as U.S. Senator Bernard Sanders, Senator John Edwards, Senator Lindsey Graham, Secretary of State Hillary Clinton, former speaker of the house Newt Gingrich, and Nobel laureate Joseph Stiglitz have suggested prizes for medical and environmental inventions.[166]

Love and Hubbard recommend prize systems that reward based on the impact of the inventions on healthcare.[167] They suggest:

> The reward system could be more rational than the existing system, allocating greater rewards for innovative products and less for 'me too' products that do not work better than existing products. Premiums could be given for therapies that address treatment gaps or for inventions that pave the way to new classes of drugs.[168]

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162. *Id.*

163. MSF Press Release, *supra* note 101.

164. *Id.*

165. Catherine Rampell, *Invent a Drug, Win $1 Million: Should the Government Start Handing Out Prizes for Science Breakthroughs?*, SLATE, Jan. 23, 2008, http://www.slate.com/id/2182663/.

166. *Id.*

167. Love & Hubbard, *supra* note 26, at 1529.

168. Tim Hubbard & James Love, *A New Trade Framework for Global Healthcare*

The prize system is a unique alternative to the patent market monopoly system as an incentive for private investment.[169] Love and Hubbard assert, "[t]he elimination of marketing monopolies, the de-coupling of R&D incentives from prices, and the creation of an evidence-based reward system linked to changes in health outcomes will lead to significant reductions in expenditures to market products, the area of the largest waste in the current system."[170]

1. Medical Innovation Prize Fund Act of 2005 and 2007

In 2005, U.S. Representative (now Senator) Bernard Sanders proposed the Medical Innovation Prize Fund Act of 2005, which was based upon the principles espoused by Love and Hubbard.[171] According to Love and Hubbard:

> [The Medical Innovation Prize Fund of 2005] does not do away with the patent system. Innovators can still get patents[] and use patents to protect inventions, up until the point when a product is registered for sale. At that point, however, rewards for the invention from the prize fund replace the exclusive rights of patent as the incentive mechanism. In effect, it changes the way the patent system works and provides a new system of intellectual property incentives.[172]

Two years later, Senator Sanders reintroduced the bill as the Medical Innovation Prize Fund Act of 2007 to offer "prize payments for medical innovation relating to a drug, a biological product, or a new manufacturing process for a drug or biological product."[173] The proposed management structure consists of a thirteen member board of trustees; including the Administrator of the Centers for Medicare & Medicaid Services; the Commissioner of Food and Drugs; the Director of the National Institutes of Health; the Director of the Centers for Disease Control and Prevention; and nine individuals appointed by the President representing the business sector, the private medical research and development sector, and consumer and patient interests.[174] The Board administers the prizes, with the amounts based upon the following criteria: (1) the number of patients who benefit from the innovation; (2) the incremental therapeutic benefit of the innovation; (3) the degree to which the innovation addresses priority health

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R&D, 2 PLOS BIOLOGY 147, 149 (2004), *available at* http://biology.plosjournals.org/archive/1545-7885/2/2/pdf/10.1371_1545-7885_2_2_complete.pdf.

169. Love & Hubbard, *supra* note 26, at 1553.

170. *Id.* at 1554.

171. *Id.* at 1532; Medical Innovation Prize Act of 2005, H.R. 417, 109th Cong. (2005).

172. Love & Hubbard, *supra* note 26, at 1532.

173. Medical Innovation Prize Act of 2007, S. 2210, 110th Cong. § 9(a) (2007).

174. *Id.* § 7(b).

care needs, including emerging global infectious diseases, orphan diseases, and neglected diseases that predominantly afflict developing countries; and (4) efficiency improvements in manufacturing processes for drugs or biological processes.[175] The proposed budget for the prize fund each year is 0.6% of the U.S. gross domestic product for the preceding fiscal year.[176] The legislation was not adopted, but it represents the most comprehensive, evidence-based prize legislation linked to changes in health outcomes and priority healthcare needs proposed in the United States.

2. Privately-Sponsored Medical Innovation Prizes

Numerous private, philanthropic organizations have sponsored medical innovation prizes such as the Gotham Prize for Cancer Research (created by two hedge fund managers and two professors), the X-Prize Foundation (started by a physician), Prize4 Life (founded by a group of Harvard Business School students), and InnoCentive (created by pharmaceutical company, Eli Lilly).[177] For instance, Prize4Life initially posted challenges to anyone who could find a biomarker to track the progression of amyotrophic lateral sclerosis (ALS) in 2006.[178] In May 2007, Prize4Life awarded $15,000 for each of the five best theoretical proposals submitted.[179] Further, in April 2009, Prize4Life gave $100,000 in prize money to two InnoCentive "Solvers" for their contributions to biomarkers for measuring disease progression in ALS.[180]

3. Prizes and Patent Pools

A novel idea for incentivizing private companies to participate in patent pools has been a combined prize fund/patent pool model, whereby entities that license patents to a patent pool are rewarded with a prize fund.[181] The WHO endorsed the use of prizes as an incentive for R&D for diseases that

175. *Id.* § 9(c).

176. *Id.* § 15(a)(2).

177. Elizabeth Bernstein, *Gotham Prize Honors New Cancer Research*, WALL ST. J., Apr. 1, 2008, D3; Steve LeVine, *The X Factor: Can Big Money Contests Save Innovation?*, BUS. WK., Dec. 1, 2008, at 54; Press Release, Prize4Life, Prize4Life Awards Prizes for ALS Biomarker Challenge to InnoCentive Solvers (Apr. 29, 2009), *available at* http://www.prize4life.org/uploaded_files/prize4life_press_release_v13_ccaNrc.pdf [hereinafter Prize4Life Press Release]; InnoCentive FAQ, http://www.innocentive.com/crowd-sourcing-news/faq/#What%20is%20InnoCentive.

178. Prize4Life, http://www.prize4life.org/page/prizes/biomarker_prize (last visited Apr. 4, 2009).

179. *Id.*

180. Prize4Life Press Release, *supra* note 177. InnoCentive "Solvers" are individuals or organizations who register with InnoCentive to solve InnoCentive Challenges. InnoCentive FAQ, *supra* note 177.

181. Love, Knowledge Ecology Notes, *supra* note 160.

disproportionately affect developing countries in the following provision of its *Global Strategy* proposal:

> (5.3) exploring and, where appropriate, promoting possible incentive schemes for research and development on Type II and Type III diseases and on developing countries' specific research and development needs in relation to Type I diseases
>
> > (a) explore and, where appropriate, promote a range of incentive schemes for research and development including addressing, where appropriate, the de-linkage of the costs of research and development and the price of health products, for example through the award of prizes, with the objective of addressing diseases which disproportionately affect developing countries
> >
> > . . . .[182]

Furthering this endorsement of prizes, the governments of Barbados and Bolivia suggested a linked prize fund/patent pool proposal as one alternative when they presented to the WHO Expert Group on R&D Financing in April 2008.[183] While the governments submitted six alternatives overall, Proposal 5, "Licensed Products Prize Fund for Donors," represents a linked patent pool/prize fund.[184] In this proposal, developers who voluntarily license innovations to a patent pool for HIV-AIDS, TB, and malaria will be rewarded with cash prizes.[185] The amount of the prize awarded is based on the relative impact of the products on health outcomes.[186] Moreover, the private companies Gilead and Johnson & Johnson also have expressed a willingness to support such a combined proposal.[187]

4. Prizes and Open Source Initiatives

Likewise, prizes can incentivize participation in open source initiatives. An example is the model proposed by OSDD: any scientist who contributes a novel idea, such as posting a new algorithm or information on a new target drug, will receive microcredits, and when a certain number of microcredits have been accrued, the scientist will receive a monetary

182. Sixty-First World Health Assembly, *supra* note 5, at 16-17.

183. *Id.*; *see* Barbados & Bolivia Submissions to WHO IGWG, Working Document - Barbados and Bolivia: Proposal 5: A Licensed Products Prize Fund (LD/pf) for Donors (Apr. 2008), http://keionline.org/misc-docs/b_b_igwg/prop5_donor_drugs_prizes.pdf [hereinafter Proposal 5].

184. Proposal 5, *supra* note 183, at 1.

185. *Id.* at 2.

186. *Id.*

187. Love, Knowledge Ecology Notes, *supra* note 160.

reward.[188] Further, according to Love, revisions to the Medical Innovation Prize Fund Act of 2007 are being contemplated which would stipulate that one percent of the total prize fund be allocated to "the researchers whose open-source publications and databases contributed the most to the products that actually worked."[189]

Other examples are the Barbados and Bolivia prize fund proposals that offer "incentives for collaboration and access to knowledge" by allocating prizes based upon open source contributions.[190] For example, the allocation of the Barbados and Bolivia Proposal 3, "Priority Medicines and Vaccines Prize Fund," would be structured as follows:

> The winning entrant would get 90 percent of the prize money. The remaining 10 percent of the prize money would be given to unaffiliated and uncompensated (by the winning entrant) scientists and engineers that openly published and shared research, data materials and technology, in the basis of who provided the most useful external contributions to achieving the end result. This would include research, data, materials and technology that were either placed in the public domain, or subject to open, non-remunerated licenses.[191]

Similar provisions were proposed for the Barbados and Bolivia Proposal 1, "Prize Fund for Development of Low-Cost Rapid Diagnostic Test for Tuberculosis."[192]

In April 2009, the governments of Barbados, Bolivia, Suriname and Bangladesh submitted a proposal, "A Prize Fund to Support Innovation and Access for Donor Supported Markets," based on the proposals offered by the governments of Barbados and Bolivia in the April 2008 WHO IGWG meeting.[193] This proposal combined the use of prizes to reward

188. Singh, *supra* note 95, at 201.

189. JAMES LOVE, THE ROLE OF PRIZES IN DEVELOPING LOW-COST, POINT-OF-CARE RAPID DIAGNOSTIC TESTS AND BETTER DRUGS FOR TUBERCULOSIS (2008), *available at* http://www.keionlieorgmisc-docs/Przes/prize_tb_msf_expert_meeting.pdf.

190. *See* Barbados & Bolivia Submissions to WHO IGWG, Working Document - Barbados and Bolivia: Proposal 3: Priority Medicines and Vaccines Prize Fund (PMV/pf) (Apr. 2008), http://keionline.org/misc-docs/b_b_igwg/prop3_pmv_pf.pdf [hereinafter Proposal 3]; Barbados & Bolivia Submissions to WHO IGWG, Working Document - Barbados and Bolivia: Proposal 1: Prize Fund for Development of Low-Cost Rapid Diagnostic Test for Tuberculosis (Apr. 2008), http://keionline.org/misc-docs/b_b_igwg/prop1_tb_prize.pdf [hereinafter Proposal 1].

191. Proposal 3, *supra* note 190.

192. Proposal 1, *supra* note 190.

193. Proposal by Barbados, Bolivia, Suriname, and Bangladesh, A Prize Fund to Support Innovation and Access for Donor Supported Markets, Linking Rewards for Innovation to the Competitive Supply of Products for HIV-AIDS, TB, Malaria and Other Diseases for Humanitarian Uses 1, 1 (Apr. 15, 2009), http://www.who.int/phi/Bangladesh_Barbados_Bolivia_Suriname_DonorPrize.pdf.

participation in a qualified, voluntary patent pool[194] and prizes to reward openly sharing critical information.[195] The governments called the latter prize "The Openness Dividend," and stipulated that five percent of the prize fund be set aside "to reward parties that openly share the knowledge, materials and technology that was critical to the success of the development of the products that qualify for the prize money."[196]

Unlike open source initiatives, patent pools, and prizes, the final strategy this comment addresses, transferable intellectual property rights or wild card patent extensions, was not endorsed in the WHO's *Global Strategy*. Rather, this proposal has been suggested by such groups as the Infectious Diseases Society of America (IDSA) and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) and is presented as a contrasting model that leverages the patent system to incentivize research.

D. Wild Card Patent Extensions

Wild card patent extensions work by allowing a company developing a new agent targeting a disease or drug-resistant pathogen that would otherwise not have a high-profit margin to extend the patent term on a high-profit-making drug already within their active portfolio.[197] The term "wild card" is used because the drug company can choose the particular drug to which the patent extension is applied.[198] Wild card patent extensions could be applied to a number of research activities to motivate private companies to conduct important research in areas where they would otherwise be unable to recoup the R&D costs.

Groups such as the IDSA have proposed wild card patent extensions as incentives to stimulate critically needed antibiotic development by private entities such as pharmaceutical companies.[199] Infectious disease experts have discussed the sky-rocketing incidence of life-threatening infections caused by multi-drug resistant organisms, coupled with a dearth of development of novel antibiotics by pharmaceutical companies.[200]

194. *Id.* at 3.

195. *Id.* at 4.

196. *Id.*

197. *See* Jorn Sonderholm, *Wild-Card Patent Extensions as a Means to Incentivize Research and Development of Antibiotics*, 37 J.L. MED. & ETHICS 240, 241 (2009); Henry I. Miller, *Bad Bugs, Few Drugs*, WASH. TIMES, May 3, 2006, at A16.

198. Dee Ann Divis, *BioWar: Bioshield Wild-Card Patent Curbed*, UNITED PRESS INT'L, April 27, 2005, http:www.upi.com/Science_News/2005/04/27/Biowar_Bioshield_wild-card_patent_curbed/UPI-54431114656656/.

199. INFECTIOUS DISEASE SOC'Y OF AM. (IDSA), BAD BUGS, NO DRUGS: AS ANTIBIOTIC R&D STAGNATES, A PUBLIC HEALTH CRISIS BREWS 1, 3 (2004), *available at* http://www.idsociety.org/WorkArea/showcontent.aspx?id=5554.

200. *See* Brad Spellberg, *Antibiotic Resistance and Antibiotic Development*, 8 LANCET

According to the IDSA, "[t]he potential crisis at hand is the result of a marked decrease in industry R&D, government inaction, and the increasing prevalence of resistant bacteria."[201] To combat this public health crisis, the IDSA proposed legislative solutions that include wild card patent extensions.[202] In a recent study published in *Infection*, Spellberg and colleagues estimated the societal costs of wild-card patent extensions compared to the savings gained from the availability of new antibiotics.[203] The researchers found that a wild card patent extension implemented with regard to one new antibiotic to treat multi-drug-resistant *Pseudomonas aeruginosa* would be cost-neutral in the first ten years of approval of the new antibiotic; however, the extension would result in $4.6 billion in savings within twenty years of approval.[204] The study thus concluded that wild card patent extensions would be a cost-effective strategy to incentivize development of needed anti-infective agents.[205]

Critics argue that wild card patent extensions would not only inefficiently cross-subsidize antimicrobial research and development but also would act as a more than $40 billion annual tax on common diseases such as heart disease, hypertension, chronic obstructive pulmonary disease, asthma and depression.[206] Spellberg responded to such criticism by pointing out that these cost calculations do not consider the possibility of shorter-term patent extensions of six months as opposed to two years and "do not account for the money priority antibiotics can save society by reducing the enormous costs of multidrug-resistant infections." [207]

IFPMA, whose members include twenty-six leading international companies and forty-four national and regional industry associations,[208] also has proposed a "transferable market exclusivity" model.[209] Under this

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INFECTIOUS DISEASES 211, 211 (2008); George H. Talbot et al., *Bad Bugs Need Drugs: An Update on the Development Pipeline from the Antimicrobial Availability Task Force of the Infectious Diseases Society of America*, 42 CLINICAL INFECTIOUS DISEASES, 657, 657 (2006); Richard P. Wenzel, *The Antibiotic Pipeline—Challenges, Costs, and Values*, 351 N. ENGL. J. MED. 523, 523 (2004).

201. IDSA, *supra* note 199, at 3.

202. *Id.* at 4.

203. Brad Spellberg et al., *Societal Costs Versus Savings from Wild-Card Patent Extension Legislation to Spur Critically Needed Antibiotic Development*, 35 INFECTION 167, 167 (2007).

204. *Id.* at 167, 170.

205. *Id.* at 167, 172.

206. Kevin Outterson, Julie Balch Samora & Karen Keller-Cuda, *Will Longer Antimicrobial Patents Improve Global Public Health?*, 7 LANCET INFECTIOUS DISEASES 559, 559, 561-62 (2007).

207. Spellberg, *supra* note 200, at 211.

208. International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), http://www.ifpma.org/aboutus/ (last visited Apr. 4, 2009).

209. Tove Iren S. Gerhardsen, *Meeting the Need for Treatment: The Initiatives: How Do*

model, a company would be granted patent extensions for products marketed in developed countries, in exchange for conducting R&D on neglected diseases to improve the supply of medicines.[210] Additionally, GSK has suggested the use of wild card patent extensions internationally as a means to stimulate research on diseases that affect the developing world.[211]

In the United States, wild card patent extension legislation has been highly controversial.[212] Congress proposed this type of legislation in the Project Bioshield II Act of 2005.[213] The bill proposed modifications to Project Bioshield I, which authorized "$5.6 billion over 10 years to encourage pharmaceutical and biotechnology companies to work with the NIH [National Institutes of Health] to develop antidotes, vaccines and other products to treat and protect against a number of potential biological weapons."[214] The wild card patent extension provision within Bioshield II would allow a company receiving FDA approval for a new agent targeting a drug-resistant pathogen to extend the patent on a high-profit-making drug already within their active portfolio.[215] The term of the extension could range from a minimum of six months to a maximum of two years.[216] The Secretary of Health and Human Services would be granted discretion to set the period of term extension based upon various factors, such as the nature of the threat to public health, the difficulty and expense associated with the development of the drug, and the impact of patent extension upon consumers and healthcare providers.[217]

The bill spurred much controversy, and ultimately Congress rejected it. The bill's sponsors, including Senators Orrin Hatch, Joseph Lieberman, and Sam Brownback, argued that pharmaceutical companies would not invest in

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You Stimulate Research and Development (R&D) for New Drugs, Vaccines and Diagnoses for Which There Will Never Be a Lucrative Market?, 84 BULL. WORLD HEALTH ORG. 346, 347 (2006), *available at* http://www.who.int/bulletin/volumes/84/5/news30506/en/index.html.

210. *Id.*

211. Sarah Lueck, *'Bioshield' Drug-Patent Plan Draws Fire; Generics Makers Fight Extending Exclusivity Protection to Areas Outside Biodefense*, WALL ST. J., April 1, 2005, at A4.

212. *See* Miller, *supra* note 197; Lueck, *supra* note 211; Spellberg et al., *supra* note 203, at 171.

213. Project BioShield II Act of 2005, S. 975, 109th Cong. § 1(a) (2005); Joe Pappalardo, *Congress Poised to Act on Weak Bio-Preparedness*, NAT'L DEF., Aug. 2005, at 40, 41.

214. Stephen Albainy-Jenei, *Bioshield Bill Would Provide Drug Patent Term Extension*, PATENT BARISTAS, Apr. 29, 2005, http://www.patentbaristas.com/archives/2005/04/29/bioshield-bill-would-provide-drug-patent-term-extension/; *see also* Pappalardo, *supra* note 213.

215. *See* Lueck, *supra* note 211.

216. *See* S. 975 § 301(b)(4)(A)(iv).

217. *See* S. 975 § 301(b)(4)(A)(ii).

financially risky bioterrorism research without incentives such as wild card patent extensions.[218] Insurance companies and generic drug makers opposed extending patent terms for drugs unrelated to bioterrorism.[219] Kathleen Jaeger, president of the Generic Pharmaceutical Association, stated, "[t]he wildcard would destroy the generic industry. We would never know which products might be protected by the branded maker, and so we would lose the predictability we need to do our own research and development into drugs coming off patent."[220] U.S. Congressman Henry Waxman, one-half of the legislative team who created the historic Hatch-Waxman Act of 1984, spoke out against the wild card patent extension provision in Bioshield II at the Generic Pharmaceutical Association in 2005:[221]

> Under this provision, a company that developed a countermeasure would have been entitled to a patent extension of up to 2 years on any drug or other product the company markets, regardless of whether that product is related to bioterrorism. In other words, if Pfizer developed and obtained approval of a countermeasure, it could obtain a two-year patent extension on Lipitor. With U.S. sales of $7.7 billion last year, a two-year patent extension on Lipitor would be worth over $10 billion to Pfizer. . . . There simply is no reasonable argument that a drug company needs a windfall of this magnitude to develop a countermeasure.[222]

The Pharmaceutical Research and Manufacturers of America (PhRMA) also was not overtly supportive of Bioshield II, skeptical of assurances that R&D on bioterrorist countermeasures would pay off.[223] Rather, PhRMA

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218. Marc Kaufman, *Bioterrorism Response Hampered by Problem of Profit*, WASH. POST, Aug. 7, 2005, at A5, *available at* http://www.washingtonpost.com/wp-dyn/content/article/2005/08/06/AR2005080601164.html.

219. *Senators Propose Patent Extensions to Spur Biodefense R&D*, AAAS, Apr. 6, 2005, http://sippi.aaas.org/ipissues/updates/?res_id=540.

220. Kaufman, *supra* note 218.

221. *Waxman Cries Foul over Proposed Legislation Favoring Big Pharma*, DRUG STORE NEWS, Mar. 21, 2005, at 20, *available at* http://findarticles.com/p/articles/mi_m3374/is_4_27/ai_n13490559/print. The Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act, allows generic drugs to receive FDA marketing approval by submitting bioequivalence studies as opposed to clinical trials which are more costly and time consuming. Additionally, the Act grants additional market exclusivity of up to five years to compensate for the time needed to develop the generic drug. *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 15 U.S.C. §§ 68b-68c, 70b (1994); 21 U.S.C. §§ 301 note, 355, 360cc (1994); 28 U.S.C. § 2201 (1994); 35 U.S.C. §§ 156, 271, 282 (1994)).

222. Congressman Henry A. Waxman, Remarks at the Center for Business Intelligence, 5th Annual Forum on Generic Drugs 9 (Nov. 17, 2005), *available at* http://waxman.house.gov/UploadedFiles/speech_cbi_11.17.05.pdf.

223. *See* Dee Ann Divis, *BioWar: 'Wild Card' Patent in Bioshield 2?*, UNITED PRESS INT'L, Sept. 1, 2004, http://www.upi.com/Science_News/2004/09/01/BioWar-Wild-card-

supported other incentives instead of wild card patent extensions, such as liability protection or advance purchase commitments.[224]

Proponents of wild card patent extensions argue that patent-based incentives on profitable products, such as "blockbuster" drugs, are needed to encourage firms to develop potentially less profitable products.[225] Critics question the fairness of funding the development of unprofitable drugs through increasing the cost of current medications needed by the ill by delaying the entry of cheaper copies to the market.[226] In fact, a recent report indicates that IDSA is no longer aggressively pursuing adoption of wild card patent extensions due to "the extreme controversy that has been associated with this idea."[227] While wild card patent extensions are unlikely to receive global support from the WHO, since they are seen as "solving one problem by creating another,"[228] this proposition nonetheless offers an alternative model that could be utilized with the current patent system.

V. CONCLUSION

There is no panacea for closing the 10/90 research gap and incentivizing private and public entities to perform critically needed R&D in the absence of clear financial incentives. The patent system that rewards R&D on profit-making drugs by offering significant protections for the drug developers may actually foreclose research for less profitable drugs developed to treat diseases endemic in developing countries. Open source initiatives, patent pools, and prizes represent innovative responses to the current reality that the market fails economically disadvantaged people suffering from neglected diseases in developing countries; these responses are supported by the recent WHO May 2008 *Global Strategy* proposal. Born out of an increased awareness of the limitations of intellectual property rights to incentivize R&D for diseases endemic in developing countries,[229] the *Global Strategy* represents an endorsement of WHO member-nations to try novel approaches to promote innovation for

patent-in-Bioshield-2/UPI-28861094089655/.

224. *Senators Propose Patent Extensions to Spur Biodefense R&D*, *supra* note, 219; Lueck, *supra* note 211.

225. Lueck, *supra* note 211.

226. *Id.*; *see also* Otto Cars et al., *Innovating for Antibacterial Resistance*, ESCMID NEWS, 2-2007 at 22-23.

227. Brad Spellberg et al., *The Epidemic of Antibiotic-Resistant Infections: A Call to Action for the Medical Community from the Infectious Diseases Society of America*, 46 CLINICAL INFECTIOUS DISEASES, 155, 161 (2008).

228. WHO, *Innovation for Diseases*, *supra* note 101, at 4.

229. Nicoletta Dentico, *Implementing the WHO Global Strategy on Public Health, Innovation & IP: An Opportunity that Should Not Be Squandered by Poor Implementation*, IQSENSATO IN FOCUS, Mar. 12, 2009, at 8, *available at* http://www.iqsensato.org/wp-content/uploads/2007/10/in-focus-vol-3-no1.pdf.

neglected diseases both inside and outside of the patent system. By contrast, the WHO has not endorsed the final strategy addressed in this paper, wild card patent extensions.[230] It is presented as a contrasting model that leverages the patent system to incentivize private companies in researching new drugs for diseases where the likelihood of profit is low.

Although none of the strategies proposed in the WHO *Global Strategy* in and of themselves likely will solve the problem, a combination of these solutions might spur critically needed R&D and help close the 10/90 gap. For instance, prizes can work synergistically with either open source or patent pool models to incentivize innovation. Since the current market-based model of drug development offers great challenges in developing drugs for essential medicines that are available to everyone at affordable prices, the strategies proposed by the WHO represent a step in the right direction.

230. WHO, *Innovation for Diseases*, *supra* note 101, at 4.