EQUITABLE LICENSING AND PUBLICLY FUNDED RESEARCH: A WORKING MODEL FOR INDIA?

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The patent law and access to essential medicine debate has come a long way since the adoption of the TRIPS Agreement of 1994, and the focus is now on new and alternative models of pharmaceutical innovation, which can adequately meet the policy objectives of encouraging research & development (R&D) and equitable access. Indian generic medicines play a critical role in various treatment and access to medicines programs and the existing scenario in the Indian pharmaceutical market is bound to change after the implementation of new patent law. Indian government is also considering the introduction of new law that will encourage patents on publicly funded R&D. This article explores the existing models of licensing publicly funded R&D and argues that Indian government should adopt a cautious approach while introducing the new law. The article further argues that alternative incentives and R&D models such as open source and patent pools should be further explored in the Indian context.

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I. INTRODUCTION

The anti-retroviral drug Zerit (stavudine) was approved by the *U.S. Food and Drug Administration* (FDA) on June 24, 1994, and was the fourth drug of its kind in the existing market.[1] Despite the fact that the drug was highly effective in treating HIV/AIDS, and was much needed by patients in South Africa, it took extensive lobbying before Yale University announced its willingness to make stavudine more available and refused to enforce the drug's patent in South Africa.[2]

The development of stavudine began in 1964 when Dr. Jerome Horwitz of the Michigan Cancer Foundation, now the Barbara Ann Karmanos Cancer Institute, synthesized a group of compounds called dideoxythymidines, which include AZT, ddc, ddl and d4T.[3] Although testing with these compounds failed to successfully treat cancer, discovery laid the foundation for HIV/AIDS treatment.[4] In the late 1980s, Dr. Tai-Shun Lin and Dr. William Prusoff of Yale University used the compound d4T to develop stavudine, which was later licensed to Bristol-Myers Squibb (BMS).[5]

1. Susa Coffey, *Stavudine (Zerit)*, HIVINSITE (2006), http://www.hivinsite.org/InSite?Page=AR-01-04; The Ctr. for AIDS Info. & Advocacy, Zerit (Stavudine), http://www.centerforaids.org/pdfs/drugfacts/zerit.pdf; U.S. Dep't of Health and Human Services, Approved Medications to Treat HIV Infection, http://img.thebody.com/hivatis/hiv_treatment.pdf#8.

2. Ashley J. Stevens, *Valuation and Licensing in Global Health*, *in* 1 INTELLECTUAL PROPERTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATION: A HANDBOOK OF BEST PRACTICES 89, 95 (Anatole Krattiger et al. eds. 2007), *available at* http://www.iphandbook.org/handbook/resources/Publications/links/ipHandbook%20Volume%201.pdf.

3. STEVEN EPSTEIN, IMPURE SCIENCE AIDS, ACTIVISM AND THE POLITICS OF KNOWLEDGE 192-93 (1996); Stevens, *supra* note 2, at 94-95; Coffey, *supra* note 1.

4. EPSTEIN, *supra* note 3, at 192-93.

5. Stevens, *supra* note 2, at 94; Yale Univ. Office of Pub. Affairs, *Yale Innovators: Forging a Potent Weapon in the Battle Against HIV/AIDS*, http://innovators.yale.edu/faculty-prusoff.asp (last visited Sept. 28, 2009).

This research was jointly funded by the National Institute of Health (NIH) and BMS, and on January 12, 1988, BMS acquired an exclusive license to stavudine.[6] Yale University secured an initial patent in 1990, and gave BMS rights to determine where to file for additional patents.[7] BMS filed stavudine patents in several countries, including South Africa, Mexico and Egypt.[8] By 2000, Toby Kasper, working with Médecins Sans Frontières (MSF), compiled a list of essential medicines needed for treating HIV/AIDS patients in South Africa.[9] Given the exorbitant prices for drugs such as stavudine, MSF started campaigning for the availability of generic versions of anti-retroviral drugs. In 2001, Indian drug manufacturer, Cipla, offered to supply generic versions of several anti-retroviral drugs, including stavudine, at a considerably low price, but patent holder companies rejected Cipla's request for a voluntary manufacturing license.[10]

Yale University entered the scenario when first-year law student Amy Kapczynski started campaigning for Yale, as an inventor and initial patent holder of stavudine, to play its role in allowing generic competition in South Africa.[11] MSF also wrote Yale, asking if it "would consider the importation of generic versions of stavudine for use in providing [free] treatment . . . to people with HIV/AIDS unable to afford treatment[, permit] . . . infringement of [the schools] intellectual property rights . . . [or perhaps] issue a voluntary license to allow the importation and use of generic stavudine in South Africa."[12] Yale denied the request. In response, Amy Kapczynski and her colleagues gathered more than 600 signatures, mobilized students and faculty, and demanded decisive action from the University.[13] After much media attention and public commentary, BMS announced on March 14, 2001 that it would be more lenient regarding stavudine patent enforcement in South Africa.[14] BMS further announced it would reduce the price of stavudine in South Africa and eventually signed a non-suit agreement with Aspen Pharmaceuticals, South Africa's generic manufacturer.[15]

6. Stevens, *supra* note 2, at 95.
7. *Id.* at 94
8. *Id.*
9. *Id.*
10. *Id.* at 93.
11. Stevens, *supra* note 2, at 93-94.
12. *Id.* at 94.
13. *Id.*
14. *Id.* at 94-95.
15. *Id.* at 95.

The stavudine controversy highlighted the largely neglected problem of university patenting and related practices in the United States. Initial research and development (R&D) by universities in the pharmaceutical sector is often conducted with funding from public sector grants.[16] Research results are then typically licensed to private companies that develop them further before launching a commercial product.[17] In the life cycle of an invention, the role of public sector entities such as universities, hospitals, and research institutions is crucial. Like stavudine, several drugs were initially developed, wholly or partially, with public sector funding before commercial pharmaceutical or biotechnology companies assumed private ownership.[18] Many recent studies have examined the role of universities amidst the global crisis of medicine inaccessibility.[19]

The dispute over stavudine is not the only case where publicly funded research has been the subject of large political debate. Commentators have cited several other examples where public sector funding helped the development of crucial medicines and other health technologies, which were later acquired by private companies through exclusive licenses.[20] It is a widely recognized phenomenon that private companies use licenses to transfer technology and commercialize academic research.[21] License terms are critical in determining the scope of exclusivity and accessibility of products.[22] The licensing regime developed in the United States after the enactment of the University and Small Business Patent Procedures Act (Bayh-Dole Act) of 1980[23] has led to a range of problems. In the pharmaceutical sector, exclusive license agreements between drug companies and academic and research institutions have created access barriers in foreign countries.[24] Once drug companies obtain licenses from U.S. universities, they then often secure patents in many developing countries, specifically on medicine desperately needed in those countries.[25] Against this backdrop, the role of publicly funded academic patents and

16. *See* Amy Kapczynski et al., *Addressing Global Health Inequities: An Open Licensing Approach for University Innovation*, 20 BERKELEY TECH. L.J. 1031, 1078 (2005).

17. *See id.* at 1080-81, 1083.

18. *See id.* at 1083.

19. *Id.* at 1085.

20. *Id.* at 1083 nn. 247-48.

21. *Id.* at 1080-81, 1083.

22. *See id.* at 1081.

23. University and Small Business Patent Procedures (Bayh-Dole) Act of 1980, 35 U.S.C. §§ 200-12 (2006) [hereinafter Bayh-Dole Act]; Stevens, *supra* note 2, at 161.

24. *See, e.g.*, Stevens, *supra* note 2, at 94.

25. *Id.* at 93.

licences has been scrutinized, and has raised questions about the ramifications of university licensing policies.[26] Commentators have questioned the nature of academic research and its direction.[27] This debate involves several key themes that look beyond the limitations of the existing licensing regime. These themes include concepts of public goods, the commons, and social production, and they help shape alternative licensing ideas, best practices, and other appropriate models.[28] Effective intellectual property management through publicly minded licensing can presumably help address the problem of medicine inaccessibility.[29] Licensing tools can be innovatively reshaped with socially responsible licenses, equitable access licences, patent pools, and a wide array of open source techniques.[30] This article explores these themes, focusing on how to transform existing licensing practices to achieve the objective of equitable access.

Part II of this paper addresses academic innovations and open licensing strategies, first explaining the current licensing practices of academic institutions, followed by an exploration of alternative approaches. These alternatives focus primarily on adopting carefully crafted safeguard measures. Part II also introduces the proposed Indian law on publicly funded research patents. Part III focuses on the Open Source Drug Discovery (OSDD) model, including discussions about various theoretical perspectives and practical nuances of this model, as well as the prospects of this model for India. Part IV considers the patent pool proposal and the initiatives of UNITAID and GlaxoSmithKline, analyzing both to determine their relevance in the Indian context.

After surveying various licensing regimes, and considering the history of academic licenses in the United States, this article concludes that the problem of inaccessibility to needed medicines in developing countries can be partially alleviated through publicly-minded licensing practices. Universities and academic institutions can proactively perform their role through innovative means and existing regulatory frameworks. The article further concludes that the Indian government would fail to successfully achieve the stated objectives of accessibility and technology transfer by adopting a one-size-fits-all approach. A comparison of different models shows that India can most benefit

26. Kapczynski et al., *supra* note 16, at 1081.

27. *See id* at 1081.

28. *See id.* at 1069-78.

29. *See generally id.*

30. *See id.* at 1078.

from the open source regime instead of following a patent-based framework.

II. ACADEMIC INNOVATIONS AND OPEN LICENSING STRATEGIES

A. *The Bayh-Dole Act: The University and Small Business Patent Procedures Act of 1980 (US).*[31]

In the United States, the innovative role of universities has been shaped by a series of policy interventions and transformations in the marketplace.[32] Historically, U.S. universities were seen as institutions rooted deeply in the traditions of social values and public interest.[33] Grounded in the tradition of academic freedom, the creative and academic atmosphere in U.S. universities aimed to optimize the public benefit.[34] It was widely believed that U.S. universities should be socially responsible and that academics should be used to enhance the social well being of the masses.[35] This public mission of U.S. universities was defined in terms of promoting the common good through academic policies and practices.[36] In fact, initial scientific research was heavily influenced by the notion of "communalism" where scientific innovation was treated as a common good, and intellectual property rights were waived.[37] Thus, academic results would be freely communicated and distributed.[38]

Throughout this period, public funding played a pivotal role in determining the scope and direction of university research priorities.[39] American universities in the era before the Bayh-Dole Act were free

31. Bayh-Dole Act §§ 200-12.

32. *Id.* § 200.

33. Katherine J. Strandurg, *Curiosity-Driven Research and University Technology Transfer, in* 16 ADVANCES IN THE STUDY OF ENTREPRENEURSHIP, INNOVATION AND ECONOMIC GROWTH, UNIVERSITY ENTREPRENEURSHIP AND TECHNOLOGY TRANSFER: PROCESS, DESIGN, AND INTELLECTUAL PROPERTY 93, 103 (Gary Libecup ed., 2005).

34. REPRESENTATIVES OF THE AMERICAN ASS'N OF UNIV. PROFESSORS AND THE ASS'N OF AMERICAN COLLEGES, 1940 STATEMENT OF PRINCIPLES ON ACADEMIC FREEDOM AND TENURE (1969), *available at* http://www.aaup.org/NR/rdonlyres/EBB1B330-33D3-4A51-B534-CEE0C7A90DAB/0/1940StatementofPrinciplesonAcademicFreedomandTenure.pdf.

35. *Id.*

36. *Id.*

37. *See generally* ROBERT K. MERTON, THE SOCIOLOGY OF SCIENCE: THEORETICAL AND EMPIRICAL INVESTIGATIONS (Norman W. Storer ed., 1979); *see also* Strandurg, *supra* note 33, at 103 (detailing a critique, by Professor Arti Rai and Professor Eisenberg, that the Bayh-Dole Act has adversely affected communalism concepts in academics); *see also* Piotr Sztompka, *Trust in Science: Robert K. Merton's Inspirations,* 7 J. OF CLASSICAL SOC. 131, 211-20 (2007).

38. Sztompka *supra* note 37, at 211-20.

39. *See* Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1633, 1667-68 (1996).

from obligations to adopt a uniform and strict ownership regime in the form of a coherent patent policy, and campuses could determine the best mode of dissemination and technology transfer:[40]

> Congress did not follow the suggestion of the Attorney General to adopt a uniform policy vesting ownership of all federally sponsored research discoveries in the government, although over the years it did enact such a policy on a more limited basis in a number of statutes applicable to particular programs or agencies. Agencies not bound by such explicit statutes had considerable discretion to choose whatever patent policy best suited their missions. Not surprisingly, there was considerable variation in the policies adopted by the different agencies.[41]

However, this policy was fundamentally changed in the United States with the promulgation of two laws aimed at streamlining the intellectual property management of publicly funded innovations and technology transfer.[42] The laws include the Stevenson-Wydler Technology Innovation Act of 1980[43] and the Bayh-Dole Act.[44]

Birch Bayh, one of the founders of the Bayh-Dole Act, reflects that "[t]his legislation combined the ingenuity and innovation from our university laboratories with the entrepreneurial skills of America's small businesses."[45] He also stated that "this combination created the incentive necessary for private investment to invest in bringing new ideas to the marketplace."[46] A wealth of literature is available on the implications of the Bayh-Dole Act, covering issues from technology transfer to the Act's effect on university patent profiles and income generation.[47] Researchers have also analyzed the actual implications of this law on patenting activity and how the law

40. *Id.* at 1676, 1679.

41. *Id.* at 1676.

42. *Id.* at 1663, 1665.

43. Stevenson-Wydler Technology Innovation Act of 1980, 15 U.S.C. §§ 3701-714 (2006).

44. Bayh-Dole Act §§ 200-12.

45. Birch Bayh, U.S. Senator (Ind.), Statement of Senator Birch Bayh to the National Institutes of Health (May 25, 2004) [hereinafter Bayh, Statement], *available at* www.orpc.unh.edu/Bayhstatement.pdf.

46. *Id.*

47. BAYHDOLE25, INC., THE BAYH-DOLE ACT AT 25, 42-44 (2006), http://www.bayhdole25.org; *see* JEFFREY A. BAUMEL, THE BAYH-DOLE ACT: THE TECHNOLOGY REVOLUTION SHOWS ITS AGE (2009), http://www.sonnenschein.com/docs/docs_vc/Bayh-Dole_Act.pdf.; *see also* WILLIAM N. WOFFORD, DO I NEED TO CARE THAT THE INVENTION MY COMPANY IS LICENSING WAS FUNDED BY THE GOVERNMENT? (2007), http://www.hutchlaw.com/resources/docs/Do_I_Need_to_Care_that_the_Invention_My_Company_is_Licensing_was_Funded_by_the_Governmen.pdf.

has changed the dynamics of learning, innovation and research in U.S. universities.[48]

Nevertheless, it is important to mention that the Bayh-Dole Act changed the presumption of ownership, which previously favored the funding agency for government-funded inventions.[49] This shift in the presumption is now in favor of the funding recipient, unless a contrary intention arises.[50] Since its enactment, the Bayh-Dole Act has drastically changed the patenting practices of universities.[51] Shortly after the law's implementation, a manifold increase was reported in the number of university patents.[52] Likewise, a massive amount of patenting activity seemingly consisted of inventions funded by the NIH.[53]

On the contrary, this increase in U.S. University patenting of publicly funded inventions is not static.[54] Additionally, statistics describing a large number of university patents are often misleading, because they tend to overstate potential benefits of the Bayh-Dole Act.[55] Despite this caveat, it is undeniable that the Bayh-Dole Act significantly impacts university patents.[56] Moreover, the Bayh-Dole Act, coupled with the advent of biotechnology and several advancements in the area of chemistry, has contributed towards new modes of wealth creation and resource generation in U.S. universities.[57] The development of several new drugs, along with successful licensing to private companies, has influenced universities to adopt royalty-based licensing strategies.[58] Universities also established technology trans-

48. *See, e.g.,* Bhaven N. Sampat et al., *Changes in University Patent Quality After the Bayh-Dole Act: A Re-examination*, 21 INT'L J. OF INDUS. ORG. 1371, 1371-90 (2003), *available at* http://www.card.iastate.edu/research/stp/papers/Sampat-Mowery-Ziedonis.pdf.

49. Bayh-Dole Act § 202.

50. *Id.*

51. *See* Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289, 292 (2003) (providing different sets of data and related analysis).

52. *Id.* at 291-92.

53. Sheldon Krimsky, *The Profit of Scientific Discovery and its Normative Implications*, 75 CHI.-KENT L. REV., 15, 22 (1999); *see also*, Rai & Eisenberg, *supra* note 51, at 304.

54. Loet Leydesdorff & Martin Meyer, *The Decline of University Patenting and the End of the Bayh-Dole Effect*, SCIENTOMETRICS, Jan. 10, 2009, at 4, *available at* http://users.fmg.uva.nl/lleydesdorff/Bayh-Dole/Bayh-Dole%20Effect.pdf.

55. *See* Rai & Eisenberg, *supra* note 51, at 294.

56. Nicola Baldini, *Implementing Bayh–Dole-like Laws: Faculty Problems and Their Impact on University Patenting Activity*, 38 RESEARCH POL. 1217, 1217 (2009).

57. Rachel A. Nugent & Gerald T. Keusch, *Global Health: Lessons From Bayh-Dole*, *in* 1 INTELLECTUAL PROPERTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATION: A HANDBOOK OF BEST PRACTICES 153, 158-59 (Anatole Krattiger et al. eds., 2007).

58. *Id.*

fer offices to facilitate licensing arrangements between universities and their private commercial partners.[59]

Additionally, the Bayh-Dole Act contains a march-in provision that allows the government funding agency, either on its own initiative or at the request of a third party, to effectively ignore the exclusivity of a patent awarded under the Act and to grant additional licenses to others.[60] This right is limited and can only be exercised if the agency investigates and determines, that one of four criteria is met.[61] The two most important of these are: (1) a failure by the licensee to take "effective steps to achieve practical application of the subject invention," and (2) a failure to satisfy the "health and safety needs of consumers."[62] On its face, this appears to be a promising safeguard, but in practice it has rarely been used successfully.[63] Indeed, all attempts to invoke a march-in rights clause for public health purposes have failed thus far.[64]

So far, three petitions have asked the NIH to exercise march-in rights based on failures by licensees to achieve purposeful application of subject inventions, but the requests were denied.[65] In the first case, *In Petition of CellPro, Inc.*, the NIH denied Cellpro's petition, which asked for a license to a Johns Hopkins University stem cell patent, which Cellpro argued it needed to stay in business.[66] Cellpro also argued that the university and licensee, Baxter Healthcare, failed to take reasonable steps to commercialize certain patented stem cell technologies.[67] The NIH declared that Johns Hopkins had adequately licensed its technology, which Baxter sufficiently practiced, and that

59. *Id.* at 161, 165.

60. *Id.* at 158.

61. Bayh-Dole Act § 203.

62. *Id.*

63. *See* DAVID HALPERIN, CONSUMER PROJECT ON TECH., THE BAYH-DOLE ACT AND MARCH-IN RIGHTS 2 (2001), http://www.essentialinventions.org/legal/norvir/halperinmarchin2001.pdf (noting an example of such promising use, but pointing out the lack of the provision's use); *see also* Rai & Eisenberg, *supra* note 51, at 294.

64. *See* Halperin, *supra* note 63.

65. *See* National Institutes of Health, Determination in the Case of Petition of Cellpro Inc., Aug. 1, 1997 [hereinafter In the Case of Petition of Cellpro Inc.], *available at* http://web.archive.org/web/20070418135645/http://www.nih.gov/icd/od/foia/cellpro/pdfs/foia_cellpro39.pdf.; *see also* Determination in the Case of NORVIR® Manufactured by ABBOTT LABORATORIES, Inc., July 29, 2004 [hereinafter In the Case of NORVIR®], *available at* http://www.ott.nih.gov/policy/March-in-norvir.pdf.; National Institutes of Health, Determination in the Case of Xalatan® Manufactured by Pfizer, Inc., Sept. 17, 2004 [hereinafter In the Case of Xalatan®], *available at* http://ott.od.nih.gov/policy/March-in-xalatan.pdf.

66. *See* In the Case of Petition of Cellpro, *supra* note 65, at 1.

67. *Id.*

the exercise of march-in rights would have adverse effects on the commercialization of federally funded research.[68]

In the second case, *In the Case of Norvir*, the NIH rejected Essential Invention's petition that asked the NIH to "march-in" on patents that were partially developed with federal funds that were related to the HIV/AIDS treatment drug ritonovir.[69] Abbott Laboratories owned the patents and marketed this important anti-retroviral drug under the trade name Norvir®, at a considerably high price.[70] Members of the U.S. Congress supported Essential Inventions.[71] In dismissing the petition, the NIH observed that the drug had reached practical application because it was being utilized and made widely available for use by HIV/AIDS patients for at least eight years, and thus it reached practical application and met health and safety needs, as the Bayh-Dole Act requires.[72] The NIH referred the question of high price and consumers' inability to afford this medicine to Congress and other government agencies empowered to consider these arguments.[73]

For the third time, *In the Case of Xalatan,* the NIH received a petition asking it to exercise march-in rights, in relation to Pfizer's glaucoma drug.[74] The petitioner requested the NIH to adopt a policy of granting march-in licenses to patents when the patent owner charged significantly higher prices in the United States than they did in other high-income countries.[75] The NIH cited rulings in the two earlier cases and, once again, denied the extraordinary remedy of march-in rights, maintaining that price cannot be regulated through the extraordinary remedy of march-in.[76]

These cases demonstrate that safeguard provisions can face several practical limitations, and the mere incorporation of such provisions in the law or licensing documents is insufficient. The NIH had construed the march-in provision very narrowly by giving much consideration to the Bayh-Dole Act's commercialization objective. However, the fact that march-in rights has never been practiced in the U.S. should be construed in the right context. The U.S. pharmaceutical

68. *Id.* at 1, 7, 9.
69. *See* In the Case of NORVIR®, *supra* note 65, at 1.
70. *See id.*
71. *Id.* at 3-4.
72. *Id.* at 5.
73. *Id.* at 6.
74. *See* In the Case of Xalatan®, *supra* note 65, at 1, 5.
75. *Id.* at 1.
76. *Id.*

market is very different from markets such as India and other developing countries.[77] The U.S. may not have experienced many cases where inaccessibility to medicines was problematic enough to warrant use of march-in interventions.[78] However, a practical failure of the march-in clause should not become an argument to avoid the incorporation of this right in the statutes of other countries. A march-in right can achieve desirable policy goals with institutional support and political will.

Birch Bayh, one of the authors of the Bayh-Dole Act, has defended the NIH's refusal to exercise march-in rights, arguing:

> It would be the ultimate folly to march in and alleviate the problem addressed by the petition, availability of a drug to treat AIDS today, and in so doing dampen the ingenuity, entrepreneurial skills and incentives necessary to develop a permanent cure for AIDS, or for that matter the cure for other diseases that plague all too many American mothers, fathers, children and seniors today.[79]

However, these failed attempts to exercise march-in rights show the inherent limitations of the Bayh-Dole Act. Despite the safeguard provisions and related flexibilities, licensing practices could not be modified to protect public interest. It is troubling that one of the Bayh-Dole Act authors is so hostile to the use of march-in rights.

There have been unsuccessful attempts to address problems associated with the Bayh-Dole Act. On September 29, 2006, U.S. Senator Patrick J. Leahy introduced the Public Research in the Public Interest Act of 2006 to ensure that inventions "developed at federally-funded institutions are available in certain developing countries at the lowest possible cost."[80] Although this bill never became law, it is viewed as a symbol of dissatisfaction with the Bayh-Dole Act, the workings of the NIH, and the limitations of access to publicly funded research.[81] While introducing this bill in the Senate, Senator Leahy observed that it would greatly decrease the cost burden of generic drugs in the developing world:

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77. *See* Robert Eiss et al., *Developing Countries and TRIPS: What Next?, in* 1 INTELLECTUAL PROPERTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATION: A HANDBOOK OF BEST PRACTICES 247, 249 (Anatole Krattiger et al. eds., 2007).

78. *See* In the Case of Petition of Cellpro, *supra* note 65; *see* In the Case of NORVIR®, *supra* note 65; *see* In the Case of Xalatan®, *supra* note 65; *see* Rai & Eisenberg, *supra* note 51.

79. Bayh, Statement, *supra* note 45, at 6.

80. Public Research in the Public Interest Act of 2006, S. 4040, 109th Cong. §§ 1-2 (2006), *available at* http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_cong_bills&docid=f:s4040is.txt.pdf. (introduced by Mr. Leahy, read twice and referred to the S. Comm. on the Judiciary).

81. *See generally id.*

> [B]y requiring federally funded research institutions to permit their inventions, such as drugs, vaccines, and innovative medical devises, to be provided inexpensively by generic companies distributing medical supplies to the developing world. Federally funded labs and research institutions have a vital role to play in meeting this goal . . . It is time to ensure that public funds truly serve public purposes - in this instance, delivering essential health care needs at minimal costs to American taxpayers, universities, and pharmaceutical companies.[82]

This bill specifically required that universities adopt licensing provisions to allow generic competition in developing countries in order to reduce prices.[83] Given the lack of bipartisan support and strong industry lobbying, this bill will not be adopted in the foreseeable future and the Bayh-Dole Act will continue to govern U.S. University licensing practices.

In this context, universities and academic institutions are left with one option, which involves changing their own licensing practices. Professor Arti Rai and others have provided a list of safeguards that universities should adhere to upon entering into technology licensing agreements to better, and can serve, the public interest.[84] These commentators argue that under the Bayh-Dole Act, properly negotiated licenses can still ensure that public interests are served.[85] Universities and academic institutions could achieve this under notions of social responsibility and public interest by considering the use of humanitarian licensing options.[86]

B. Licensing University Technology

Since the enactment of the Bayh-Dole Act, universities have developed several breakthrough drugs for the treatment of emerging diseases and epidemics that were later licensed to pharmaceutical companies for commercial exploitation.[87] In addition to stavudine, discussed earlier, several key treatments were developed as a direct

82. Patrick Leahy, U.S. Senator (Vt.), Statement of Sen. Patrick Leahy, "Public Research in the Public Interest Act Of 2006," (Sept. 29, 2006) [hereinafter Leahy, Statement], *available at* http://leahy.senate.gov/press/200609/092906c.html.

83. *See* Public Research Act of 2006 § 2.

84. Anthony D. So et al., *Is Bayh-Dole Good for Developing Countries? Lessons from the US Experience*, 6 PLOS BIOL 2078, 2081 (2008), *available at* http://www.plosbiology.org/article/info:doi/10.1371/journal.pbio.0060262.

85. *Id.*

86. *Id.*

87. *See* Rai & Eisenberg, *supra* note 51 at 290-92; *see also* Evelyn Cottle Raedler, *Chemical Cures*, UNIV. OF MINN. ALUMNI ASS'N, Nov. 13, 2003, *available at* http://www.alumni.umn.edu/Chemical_Cures.html.

outcome of public funding, which universities licensed exclusively to private companies.[88] For example, the University of Minnesota licensed its patented drug, carbovir, to GlaxoSmithKline, which the company used to develop its anti-retroviral drug, Ziagen.[89] This drug was developed with NIH funding and the university expected Ziagan to generate annual sales from U.S. $300 to $700 million.[90] The University of Minnesota received five to ten percent royalty payments on all the drug's sales.[91] Other examples include Duke University's patent on enfuvirtide and Emory University's patent on lamivudine.[92]

A recent study, surveying 1988 to 2005, shows that academic institutions in the United States still have a substantial share of total granted drug patents.[93] A sample of new drug applications included 1,947 related patents, of which 96 were academic patents.[94] Although the academic patents accounted for a small number of the patents related to new drug applications, they belong to an upstream category that is crucial for further R&D.[95] The study further shows that of the 72 drugs with academic patents, 12 were HIV/AIDS drugs – an unusually high portion for only one disease.[96] The study states that:

> The overall share of drugs approved between 1988 and 2005 on which universities own patents was relatively low-7.7% - and the share for new molecules was only slightly higher-10.3%. However, universities' own patents on nearly 1 in 5 (19.2%) of the drugs that are arguably the most innovative — new molecular entities that received "priority" approval by the FDA; this share has been basically stable since the late 1980s. In addition, universities own key patents on over one quarter of the HIV/AIDS drugs approved since 1988, which is particularly important given the potentially catastrophic impact of this disease in the developing world.[97]

These findings are critical for two reasons. First, this study presents the most updated picture of academic patents and confirms

88. Raedler, *supra* note 87.

89. *Id.*

90. Consumer Project on Tech., Additional Notes on Government Role in the Development of HIV/AIDS Drugs, http://www.cptech.org/ip/health/aids/gov-role.html (last visited October 14, 2009).

91. *Id.*

92. Amy Kapczynski et al., *Global Health and University Patents*, 301 SCI. MAG. 5640, Sept. 19, 2003, at 1629, *available at* http://www.sciencemag.org/cgi/content/short/301/5640/1629.

93. *See* Bhaven N. Sampat, *Academic Patents and Access to Medicines in Developing Countries*, 99 AM. J. OF PUB. HEALTH 1, 9, 15.

94. *Id.* at 11.

95. *Id.* at 15.

96. *See id.* at 12.

97. *Id.* at 15.

the relevance of these patents in the access to medicines debate.[98] Second, the study clearly establishes that academic patents can be leveraged to ensure accessibility of drugs in developing countries.[99] Despite some research gaps concerning the extent that university intervention can really improve access to patented drugs in developing countries, there is no doubt these institutions can play a crucial role in improving such access.[100]

Exclusive licensing and restricted access clauses are common features of universities' license agreements.[101] University ownership of these crucial patents has further aggravated the dismal state of access to essential medicines in developing countries.[102] These technologies are often licensed to pharmaceutical companies, giving them full rights to determine the countries where they intend to file subsequent patents.[103] The companies generally file strategic patents in many developing countries to minimize the risk of competition from generic drugs.[104]

Over the years, strong resentment and frustration have emerged as a result of the licensing and patent policies of universities. Commentators have started questioning the role universities actually play through their licensees, who restrict access to essential products in the developing world.[105] The Yale controversy over the stavudine patent triggered a thorough debate among academics and students, and strong voices emerged, calling on universities to revisit their licensing polices and practices.[106] The case of stavudine seemed to be a point of culmination, yielding some positive outcome in some American universities.[107]

The concept of socially responsible licensing first emerged in 2002 when University of California, Berkely, Associate Professor Eva Har-

98. Sampat, *supra* note 93, at 16.

99. *Id.* at 15.

100. *Id.* at 16.

101. *See* So et. al., *supra* note 84, at 2078.

102. Richard R. Nelson, *Linkages Between the Market Economy and the Scientific Common*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME 121, 130 (Keith E. Maskus & Jerome H. Reichmen eds., 2005).

103. *See* Stevens, *supra* note 2, at 95.

104. *See id.* at 94.

105. *See id.* at 95.

106. *See id.* at 94-95.

107. *See* MELEEHA MOHUIDDIN & OMAR IMTIAZUDDIN, ACUMEN FUND CONCEPTS, SOCIALLY RESPONSIBLE LICENSING: MODEL PARTNERSHIPS FOR UNDERSERVED MARKETS 1, 2 (2007), *available at* http://www.acumenfund.org/uploads/assets/documents/Acumen%20Fund%20%20Socially%20Responsible%20Licensing%20July%202008_kYAIb8kF.pdf.

ris, at the School of Public Health, negotiated a license relating to technology for dengue fever diagnosis.[108] This technology, known as ImmunoSensor, was widely believed to help detect and treat dengue fever, which is a leading cause of death in many developing countries.[109] Acumen Fund, a non-profit global venture fund, agreed to invest in the development of this technology, and proposed that the university license ImmunoSensor to a non-profit company, Sustainable Services Institute, which would develop and distribute the technology in developing countries either at cost or for free.[110] According to the arrangement, the university could still earn future royalties from this technology by marketing it in developed countries.[111] This example of socially responsible licensing served as a starting point that led to many similar agreements between UC Berkeley and its partners, opening the door for more access to patients in developing countries.[112]

The concept of socially responsible licensing has worked in certain cases, but no evidence exists that academic institutions have adopted the practice as a norm and standard licensing practice.[113] In 2007, top U.S. universities and the Association of American Medical Colleges issued guidelines for more responsible licensing policies.[114] These public interest guidelines, entitled "Nine Points to Consider in

108. *Id.*

109. *Id.* at 3.

110. *Id.*

111. MOHIUDDIN & IMTIAZUDDIN, *supra* note 107, at 3.

112. Josefina Coloma & Eva Harris, *Open-Access Science: A Necessity for Global Public Health*, 1 PLOS PATHOG., Oct. 28, 2005, 99, 100-01 (2005), *available at* http://www.plospathogens.org/article/info:doi/10.1371/journal.ppat.0010021.

113. While some universities have taken serious initiatives towards adopting policies and guidelines on socially responsible licensing, most of the universities have yet to respond. *See generally* OFFICE OF INTELLECTUAL PROP. AND INDUS. RESEARCH ALLIANCES, UNIV. OF CAL. BERKELEY, SOCIALLY RESPONSIBLE LICENSING AT U.C. BERKELEY: AN INTELLECTUAL PROPERTY MANAGEMENT STRATEGY TO STIMULATE RESEARCH SUPPORT AND MAXIMIZE SOCIETAL IMPACT (2007) (discussing suggestions for changing licensing policies at the University of California, Berkeley), *available at* http://ipira.berkeley.edu/page.php?nav=79 (to access a pdf copy of this file click on the word "Update" at this bullet point on the webpage: "Update of UC Berkeley's Socially Responsible Licensing Program").

114. Participating institutions include: California Institute of Technology, Cornell University, Harvard University, Massachusetts Institute of Technology, Stanford University, University of California, University of Illinois, Chicago, University of Illinois-Urbana-Champaign, University of Washington, Wisconsin Alumni Research Foundation, Yale University and the Association of American Medical Colleges (AAMC). Press Release, Stanford Univ. & Representatives of the Ass'n of Am. Med. Colleg. & U.S. Univ., In the Pub. Interest: Nine Points to Consider in Licensing Univ. Tech. 1, 1 (March 6, 2007), *available at* http://news-service.stanford.edu/news/2007/march7/gifs/whitepaper.pdf for the full text and details.

Licensing University Technology,"[115] consider various aspects of technology licensing and its social impacts. The points direct universities to: retain the right and power to practice licensed technology; structure exclusive licenses with a more appropriate scope of exclusive licensing; attempt to minimize the risk of licensing future improvements; avoid conflicts of interest; ensure access to research tools; and carefully consider enforcement actions and unmet needs of patients in developing countries.[116] It is pertinent to note that these guidelines do not specifically address how universities should use academic patents in developing countries. The focus of these guidelines is limited to licensing practices, and they fail to address how universities can use patents to create markets to meet the unmet medical demands in other countries.[117] The last point acknowledges some of the access barriers in the developing world but does not categorically place social responsibility on academic institutions to ensure that their license agreements prevent licensees from exclusively controlling several markets in developing countries as the only provider of needed medicines.[118]

Amidst the Yale-stavudine controversy in 2001, the Universities Allied For Essential Medicines (UAEM) began as a private, nonprofit organization, and now has more than 46 campus chapters in leading universities in the United States, Canada and United Kingdom.[119] UAEM aims to promote access to medicines for people in developing countries by changing the norms and practices around university patenting and licensing.[120] It further aims to ensure that university medical research meets the needs of the majority of the world's population and empowers students to respond to the access and innovation crisis.[121] UAEM has also adopted the "Philadelphia Consensus Statement on Universities Policies for Health Related Innovations."[122] The document highlights the problem of access to essential medicines

115. *Id.*

116. *See id.* at 2-8.

117. *See generally id.*

118. *See id.* at 8.

119. *See* Universities Allied for Essential Medicines, http://www.essentialmedicine.org/?page_id=40 (last visited Oct. 9, 2009).

120. Univ. Allied for Essential Med., About Us, http://www.essentialmedicine.org/about-us/ (last visited Oct. 9, 2009).

121. *Id.*

122. UNIV. ALLIED FOR ESSENTIAL MED., PHILADELPHIA CONSENSUS STATEMENT ON UNIVERSITIES POLICIES FOR HEALTH RELATED INNOVATIONS (2006) [hereinafter Philadelphia Consensus Statement], *available at* http://www.essentialmedicine.org/cs/wp-content/uploads/2006/10/philidelphiaconsensusstatement.pdf.

in developing countries and builds a case for university action.[123] Universities can play their role in three distinct ways by: (1) promoting equal access to university research; (2) undertaking research for neglected diseases; and (3) measuring research success according to the impact on human welfare.[124] To reach the objectives of this statement, UAEM has developed and advocated a model for university action in addressing global health inequities and called for the adoption of an open licensing approach.[125] The group supports the Equitable Access License (EAL), further discussed in Part III, and campaigns for major universities and academic institutions to show their commitment to social responsibility by adopting this license.[126] UAEM follows a simple and straightforward approach by requesting that universities encourage generic competition in developing countries through their technology licenses.[127]

C. *The Protection and Utilisation of the Public Funded Intellectual Property Bill 2008 (India) (PUPFIP)*

The Bayh-Dole Act represents an influential model for creating opportunity for universities to profit from their innovations, and over the last decade many countries have attempted to adopt this model for their academic and research institutions.[128] A report by the Organization of Economic Cooperation and Development (OECD) claims that making government-funded research publicly available may not be sufficient to generate social and economic growth.[129] The report suggests that academic institutions and researchers need opportunities to commercialize their inventions by creating spin-off companies and joint ventures with the commercial sector.[130] Although the report does not specify a particular model that countries can adopt to achieve the goal of intellectual property commercialization, it categorically refers to some of the benefits that U.S. institutions have reaped after the

123. *Id.*

124. *Id.*

125. Univ. Allied for Essential Med., Our Proposals, http://www.essentialmedicine.org/our-proposals/ [hereinafter UAEM, Our Proposals] (last visited Oct. 9, 2009).

126. Philadelphia Consensus Statement, *supra* note 122.

127. UAEM, Our Proposals, *supra* note 125.

128. *See* BAYHDOLE25, INC., *supra* note 47.

129. ORG. OF ECON. COOPERATION AND DEV., TURNING SCIENCE INTO BUSINESS: PATENTING AND LICENSING AT PUBLIC RESEARCH ORGANIZATIONS 9, 9 (2003), http://epip.eu/papers/20031124/200411_conference/papers/Cervantes.pdf.

130. *Id.*

enactment of the Bayh-Dole Act.[131] With regard to practices of OECD countries, the report states:

> Across OECD countries, laws and policies governing the ownership of IP generated with public research funds are being re-examined with a view to encourage ownership of inventions by the institution performing the research . . . Austria, Denmark, Germany and Norway have recently introduced new legislation to grant universities title to IP resulting from publicly funded research . . . In Japan and Korea, recent reforms in funding regulations have given universities more control over the IP generated by their researchers. These policy trends echo the landmark US *Bayh-Dole Act* of 1980.[132]

This trend is not only confined to economically developed countries, as, recently, many developing countries have also shown interest in this direction.[133]

In 2008, the Indian government introduced the Protection and Utilisation of Public Funded Intellectual Property Bill 2008 (PUPFIP) in the parliament to provide for the protection and utilization of intellectual property originating from publicly funded research.[134] According to the statement of objects and reasons:

> To compete in a global environment, it is necessary for India to innovate and promote creativity. . . . India needs to protect and utilise the intellectual property created out of public funded research and development. Over the years, the Government has invested large funds in research and development. To provide incentives for creativity and innovation, it is necessary to develop a framework in which the protection and utilisation of intellectual property is put in place. The ultimate objective, however, is to ensure access to such innovation by all stakeholders for public good . . . Such innovations can be utilised for raising financial resources of these establishments, through royalties or income.[135]

This bill has been largely criticized in India and it was lamented as the Indian Bayh-Dole Act that would restrict access to publicly funded research.[136]

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131. *Id.*

132. *Id.* at 11.

133. *See* BAYHDOLE25, INC., *supra* note 47, at 41-42.

134. The Protection and Utilisation of Public Funded Intellectual Property Bill, Bill No. LXVI of 2008. 1, 1 [herinafter PUPFIP], *available at* http://www.prsindia.org/docs/bills/1229425658/1229425658_The_Protection_and_Utilisation_of_Public_Funded_Intellectual_Property_Bill_2008.pdf.

135. *Id.* at 8.

136. *See* Shamnad Basheer, *India Unveils National Innovation Act*, SPICY IP BLOG, Oct. 1 2008, http://spicyip.blogspot.com/2008/10/breaking-news-india-unveils-national.html.

Before turning to the substantive provisions of PUPFIP, it is pertinent to analyze some broader issues that are key to understanding the relevance of this law in the Indian context. Several basic questions can be raised about the opportunities of this proposed law for India. First, is the Indian science and technology environment fully prepared to respond to the so-called opportunities that this law will create? Second, given the level of development and technological advancement, what is the best model that India can follow to promote the culture of innovation? Specifically, to what extent will a law modelled on the Bayh-Dole Act help achieve India's policy objectives? Third, what are the main concerns regarding provisions of the proposed law, and how can India learn from best practices used elsewhere? These questions are considered separately in the following analysis.

The adoption of a law along the lines of Bayh-Dole clearly presumes the existence of innovative capacity on the part of Indian universities.[137] However, it is arguable that the current state of science and technology in Indian universities is not very promising.[138] There is no doubt that India is shining[139] and achieved tremendous growth during the last few years, but the educational institutions in India are still lagging behind.[140] The public sector investment in research and education in India is marginal, and Indian universities produce very little research.[141] Most of the existing innovative capabilities are in government agencies, particularly in the Council for Scientific and Industrial Research (CSIR),[142] the Department of Science and Technology (DST),[143] the Department of Biotechnology (DBT),[144] the Ministry of Science and Technology,[145] the Indian

137. So et al., *supra* note 84, at 2082.

138. H. S. Virk, *Does India Shine in Scientific Research?* 87 CURRENT SCI. 1, 7 (2004), *available at* http://www.ias.ac.in/currsci/jul102004/7.pdf.

139. The slogan "shining India" became popular in 2003-2004 during the information technology boom. However, commentators have challenged this notion by raising questions about malnutrition, poverty, illiteracy and poor governance. *See id.*

140. *Id.*

141. *Id.*

142. *See generally* The Council for Scientific and Industrial Research (noting that the Council for Scientific and Industrial Research is an innovative government agency), www.csir.res.in (last visited Oct. 9, 2009).

143. *See generally* Department of Science and Technology, http://dst.gov.in (last visited Oct. 9, 2009) (noting that the Department of Science and Technology, a department within the Ministry of Science and Technology, is an innovative government agency).

144. *See generally* Department of Biotechnology, http://dbtindia.nic.in/index.asp (last visited Oct. 9, 2009) (noting that the Department of Biotechnology is an innovative government agency).

145. *See generally* Ministry of Science and Technology, http://dst.gov.in (last visited Oct. 9, 2009) (noting that the Ministry of Science and Technology is an innovative government agency).

Council of Medical Research (ICMR),[146] and the National Research and Development Corporation (NRDC).[147] Although these institutions have produced great scientists and academics, the innovative capacity of the institutions has been relatively weak.[148] In terms of patent filing, India's ratio of resident to foreign is just 0.58, which is less than Russia, South Africa, China and Poland.[149] This is notwithstanding the fact India is also emerging as a key destination of global R&D and outsourcing, both in a general sense and in the pharmaceutical sector.[150]

Beyond the structural limitations of India's innovative capacity, the Bayh-Dole Act's suitability and relevance for India is another crucial question. PUPFIP shows that Indian policy makers are fully satisfied with the U.S. model, as they have simply replicated the same provisions in India's proposed law.[151] The sponsors of this bill have failed to address the fundamental question concerning the relevance of the U.S. model in India and its possible implications for India's innovation, culture, and public domain.[152] The proponents of a Bayh-Dole type model argue that U.S. universities have largely benefited from that law and secured better licensing royalties.[153]

However, data regarding the benefits of the Bayh-Dole Act is misleading and, according to Professor Eisenberg, facts do not correspond to these proponents' claims.[154] She analyzed data about the Bayh-Dole Act and found that the Act marginally impacted an in-

146. *See generally* The Indian Council of Medical Research, http://icmr.nic.in (last visited Oct. 9, 2009).

147. *See generally* The National Research and Development Corporation, http://www.nrdcindia.com (last visited Oct. 9, 2009) (noting that The National Research and Development Corporation is an innovative government agency).

148. *See* Michael E. Porter & Scott Stern, *National Innovative Capacity*, *in* THE GLOBAL COMPETITIVENESS REPORT 2001-2002, 2, 9 (Oxford Univ. Press 2002), *available at* http://www.isc.hbs.edu/Innov_9211.pdf.

149. Gregory D. Graff, *Echoes of Bayh-Dole? A Survey of IP and Technology Transfer Policies in Emerging and Developing Economies*, *in* 1 INTELLECTUAL PROPERTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATION: A HANDBOOK OF BEST PRACTICES 169, 188 (Anatole Krattiger et al. eds., 2007) (identifying India's National IP Systems), *available at* www.iphandbook.org/handbook/resources/Publications/links/ipHandbook%20Volume%201.pdf.

150. *Id.* at 177.

151. *See* Bhuvan Kala, *Govt Nod for 'Protection and Utilisation of Public Funded Intell.l Prop. Bill,'* TOPNEWS.IN, Nov. 1, 2008, http://www.topnews.in/govt-nod-protection-and-utilisation-public-funded-intellectual-property-bill-282410.

152. Kaushiki Sanyal, PRS Legislative Research, *The Protection and Utilisation of Funded Intellectual Property Bill, 2008*, LEGIS. BRIEF, May 13, 2009, at 4, *available at* http://www.prsindia.org/uploads/media/1229425658/LB_Protection%20and%20Utilisation%20of%20Public%20Funded%20Intellectual%20Property%20Bill.pdf.

153. *Id.* at 3-4

154. *See* Eisenberg, *supra* note 39, at 1701-05.

crease of financial revenues for universities.[155] In fact, the latest data shows that domestic academic patents in the U.S. have declined and that patents are losing their importance for universities as new university rankings criteria emerge.[156] Relying on data from 1990 to 2008, Loet Leydesdorff and Martin Meyer suggest that there is a decline in university patenting in the U.S. and the European Union:

> At the global level university patenting is still gaining momentum, but in the most advanced economies the effects of the *Bayh-Dole Act* of 1980 seem to have faded away since the turn of the millennium. In our opinion, the reason for this is structural. More universities are nowadays increasingly ranked in terms of their knowledge output, and patents or spin-offs are usually not part of this ranking . . . The nature of the competition among universities is changing, and the incentive to patent has thus withered. International collaborations and co-authorships, for example, have become more important in research assessment exercises than university-industry relations.[157]

This finding is quite relevant for India as university patents in India are already negligible, and new legislation may result in the same chilling effects that are now reported in other countries.[158] The idea that Bayh-Dole type laws have positive effects on innovative culture is a simplistic approach, and India should not introduce a new bill under such assumptions, but should instead learn from the results of the experiment of the Bayh-Dole Act.[159]

One of the Bayh-Dole Act's objectives was to mobilize additional revenues and financial resources for academic institutions.[160] Indeed, PUPFIP also envisages similar objectives, but shortcomings of the Bayh-Dole Act, as a revenue generator for universities, are well established.[161] Dr. Anthony D. So and others have observed that the com-

155. *See id.* at 1703-05.

156. *See* Leydesdorff & Meyer, *supra* note 54, at 4.

157. *See id.* at 8-10.

158. UNIV. GRANTS COMM'N, GUIDELINES FOR AWARENESS, PROTECTION AND MANAGEMENT OF INTELLECTUAL PROPERTY RIGHTS IN THE UNIVERSITY SYSTEM IN INDIA 4 (2005), http://www.ugc.ac.in/new_initiatives/IPRguidelines_aug05.pdf; Pranesh Prakash, *Does India Need its own Bayh-Dole?*, INDIAN EXPRESS, Apr. 24, 2009, *available at* http://www.cis-india.org/news/does-india-need-its-own-bayh-dole.

159. *See* John A. Fraser & Jennifer Washburn, Remarks at the International Patent Licensing Seminar 2007 on Twenty-Five Years of the Bayh-Dole Act: Past, Present and Future of Academia-Industry Collaboration in the US, 70-71, *available at* http://www.ryutu.inpit.go.jp/seminar_a/2007/pdf/A2_e.pdf.

160. Bayh-Dole Act §§ 200-12; COUNCIL ON GOV'T RELATIONS, THE BAYH-DOLE ACT: A GUIDE TO THE LAW AND IMPLEMENTING REGULATIONS 11 (1999), *available at* http://www.cogr.edu/docs/Bayh_Dole.pdf

161. *See* So et al., *supra* note 84, at 2079.

mercial benefits of university patenting have been overstated.[162] Lita Nelson, former president of the Association of University Technology Managers, goes one step further, stating that: "The direct economic impact of technology licensing on the universities themselves has been relatively small (a surprise to many who believed that royalties could compensate for declining federal support of research)."[163] In light of such research, the Indian government should conduct a cost-benefit analysis on how much the proposed bill will contribute towards revenue generation.

There are several additional points establishing that the Bayh-Dole Act is not an ideal model, and it has many negative implications on public science.[164] To promote innovation and technological development, the Indian government should itself adopt an innovative policy approach. So far we have seen that India's innovative capacity is still in its nascent stage; it needs more creative space instead of exclusivity-based property rights to flourish.[165] Furthermore, the Bayh-Dole Act does not represent an ideal model that India can readily adopt for its domestic purposes.[166]

> India's bill fails to address one of its stated objectives of favoring the public good because the bill lacks a mechanism to protect public interest.[167] According to former Indian science minister, Kapil Sibal, "the benefits of publicly funded research are not reaching the public,"[168] and India's PUPFIP policy response is unlikely to improve this situation. Instead, the bill introduces measures that will narrow the public domain by creating new property rights.[169] According to its proposed scheme: the bill is modelled on the 1980 US *Bayh–Dole Act*, which allowed US universities to patent discoveries derived from federally funded work. According to the Indian bill, scientists would be allowed to retain 30% of the net income earned from patents and licences. The scientist's institute would retain 40%, with the rest going into a fund maintained by the institute for

162. *Id.*

163. Lita Nelson, *The Rise of Intellectual Property Protection in The American University*, SCI. MAG., March 6, 1998, at 1460-61, *available at* http://www.sciencemag.org/cgi/content/full/279/5356/1460.

164. Thomas J. Siepmann, *The Global Exportation of the U.S. Bayh-Dole Act*, 30 U. DAYTON L. REV. 209, 235 (2004).

165. Prakash, *supra* note 158.

166. *See id.*

167. Rahul Vartak & Manish Saurastri, *The Indian Version of the Bayh-Dole Act*, INTELL. ASSET MGMT. MAG., Mar./Apr. 2009, at 62-64, 63, *available at* http://www.iam-magazine.com/issues/article.ashx?g=af438a8b-2c4e-4771-b573-32171a1c4c65.

168. T.V. Padma, *Patent Pledge to Indian Universities*, NATURE 685 (2008), *available at* http://www.nature.com/news/2008/081210/pdf/456685a.pdf.

169. *See id.*; PUPFIP, *supra* note 134.

> managing intellectual property. Researchers in publicly funded institutes or universities would also be allowed, for the first time, to set up and work in private companies without having to leave their academic jobs.[170]

PUPFIP lacks effective public use mechanisms;[171] the drafters even failed to incorporate a march-in right provision, like the one previously discussed.[172] It is ironic that the bill is drafted along the lines of the Bayh-Dole Act, but does not contain a march-in right provision.[173] PUPFIP only has one similar provision with quite restrictive language.[174] According to this provision, the government has a right to reuse title belonging to a research institution within 90 days of learning the research institutions' intentions for using a patent.[175] This brief 90-day period is a big limitation, and beyond this period, the government would not be able to exercise this right.[176] In pharmaceuticals, the decisions to retain patent rights are made at very early stages and they would be accordingly communicated to the government. It remains unclear how the government can successfully evaluate the intentions of patent filers within 90 days of initial notice when it is unknown whether the pending patents will successfully treat an epidemic, if at all. This time-bound access clause is indeed narrower than the march-in right provided in the Bayh-Dole Act.

Another problematic aspect of PUPFIP is its requirement that universities and publicly funded institutions apply for patent protection. Universities will have to follow strict timelines throughout their research processes to ensure compliance. A researcher must disclose the invention immediately after learning of the patent right.[177] Thereafter, the research institute has 60 days to notify the government about the invention, and the institution has 90 more days to show its intention of retaining patent rights over the disclosed invention.[178] As the Bayh-Dole Act merely demands such notifications within reasonable time, these pressurized timelines are unprecedented. It is inevitable that universities may excessively and prematurely give patent notifications as a strategic tactic to secure future interests when they have insufficient time to decide whether to file patents.

170. Padma, *supra* note 168.
171. PUPFIP, *supra* note 134.
172. *Id.*
173. *Id.*
174. *Id.* § 5.
175. *Id.*
176. PUPFIP, *supra* note 134, § 5.
177. *Id.* § 9.
178. *Id.* §§ 4, 5(1).

This analysis shows that the Indian attempt to adopt a licensing regime for publicly funded R&D suffers from serious deficiencies. The Indian government should withdraw the proposal and initiate a new process to formulate a coherent and consistent policy regarding public sector licensing. The Indian National Knowledge Commission declared in 2007 that intellectual property infrastructure and assets should be used in the best public interest and for the overall benefit of society.[179] PUPFIP is a complete antithesis of this approach because it restricts the public domain by encouraging private rights over public benefit.[180]

III. OPEN SOURCE DRUG DISCOVERY (OSDD)

Richard Stallman introduced the concept of free software amidst the strong wave of commercialization in the field of computer software and programs.[181] As a member of the Massachusetts Institute of Technology's Artificial Intelligence Laboratory, Stallman laid the foundation of the free software movement by advocating that software users be able to run a program for any purpose.[182] Software is free if a user can analyze and improve it for further distribution, source code is disclosed, and copyright restrictions are removed through a typical copyleft license.[183] The free software movement was later institutionalized thorough the Free Software Foundation,[184] which adopted the General Public License[185] (GPL) approach to facilitate software distribution in a non-proprietary fashion. In 1998, Bruce Perens and Eric S. Raymond established the Open Source Initiative, starting the open source software movement.[186] Perens and Raymond did not share Stallman's position on proprietary software

179. Letter from Sam Pitroda, Chairman, The Nat'l Knowledge Commiss'n, to Manmohan Singh, Prime Minister of India, (Oct. 15, 2007), *available at* www.knowledgecommission.gov.in/downloads/recommendations/IPRPM.pdf.

180. PUPFIP, *supra* note 134.

181. *See generally* SAM WILLIAMS, FREE AS IN FREEDOM: RICHARD STALLMAN'S CRUSADE FOR FREE SOFTWARE (2002) (introducing Stallman's concept of free software in chapter 10), *available at* http://oreilly.com/openbook/freedom.

182. *See id.* at 1, 14.

183. *See* DANIEL G.R. ANDERSSON, IT UNIV. OF GOTEBORG, COMPARING OPEN SOURCE AND PROPRIETARY ENTERPRISE CONTENT MANAGEMENT SYSTEMS: ALFRESCO COMPARED TO IBM LOTUS DOMINO DOCUMENT MANAGER INTEGRATED WITH IBM LOTUS WORKFLOW 10 (2008), *available at* http://gupea.ub.gu.se/dspace/bitstream/2077/10473/1/gupea_2077_10473_1.pdf.

184. *See* Free Software Foundation, http://www.fsf.org/ (last visited Oct. 15, 2009).

185. *See* GNU Operating System, http://www.gnu.org/ (last visited Oct. 15, 2009).

186. Press Release, Open Source Initiative, OSI Launch Announcement (Nov. 22, 1998), *available at* http://www.opensource.org/pressreleases/osi-launch.php.

and their initiative basically established a certification body for open source licenses.[187]

The non-proprietary software movement and open source initiative rapidly attracted considerable attention and contributed in the development of several important computer programs, which successive generations of programmers built upon.[188] Despite the peculiarity of the term "open source" with regard to computer programs, the term is now widely used in other disciplines too, denoting unrestricted and free access.[189] Open source techniques propogate little or no use of intellectual property protections, like copyright or patents, and are now suggested in certain unconventional areas such as biotechnology, ecology and medicine.[190]

OSDD is a relatively new phenomenon proposed to offset the problems typically associated with patented medicines and pharmaceuticals.[191] The existing patent system incentivizes pharmaceutical R&D of treatments for certain disease categories that generally affect wealthier groups of patients.[192] This system has failed in the area of neglected and tropical diseases.[193] The OSDD proposal is aimed at addressing such problems by finding incentives for new drug discovery using non-traditional intellectual property methods.[194]

A. Theory of Open Source Drug Discovery

Commentators have provided detailed theoretical justification for the remarkable success of the open source movement in the area of computer programs and software.[195] The nature of information technologies, the incentives associated with open programming, the

187. ANDERSSON, *supra* note 183, at 10.

188. Yochai Benkler, *Coase's Penguin, Or Linux and the Nature of the Firm*, 112 YALE L.J. 369, 371-72 (2002) [hereinafter Benkler, *Coase's Penguin*].

189. *See* YOCHAI BENKLER, THE WEALTH OF NETWORKS: HOW SOCIAL PRODUCTION TRANSFORMS MARKETS AND FREEDOM 1-2 (2006) [hereinafter BENKLER, THE WEALTH OF NETWORKS]; *see, e.g.*, Zdravko Mauko, *Open Source Pharmaceuticals – New Business Model*, FARMAVITA.NET, Jan. 12, 2007 (discussing the applicability of open source with pharmaceuticals), http://www.farmavita.net/content/view/336/84/.

190. *See generally* Mauko, *supra* note 189 (describing Linus Torvalds', an influential individual in the open source world, views of the future as moving towards everything becoming open source).

191. *Id.*

192. Bernard Pécoul et al., *Access to Essential Drugs in Poor Countries: A Lost Battle?* 281 THE J. OF THE AM. MED. ASS'N 361, 363-64 (1999), *available at* http://jama.ama-assn.org/cgi/content/abstract/281/4/361.

193. *Id.*

194. Mauko, *supra* note 189.

195. Benkler, *Coase's Penguin*, *supra* note 188, at 400.

probability of low cost production and the critical mass participation of technically skilled people are some reasons commonly attributed to the success of open source.[196] Harvard Law professor, Yochai Benkler, provides the most comprehensive account of open source, both as a theory and as a technique.[197] In his seminal article for the Yale Law Journal in 2002, Benkler used a "Coasean"[198] rationale to explain commons-based approaches to managing resources in networked environments.[199] This work was later expanded through *The Wealth of Network: How Social Production Transforms Markets and Freedom* where Benkler explains his view of networks, social production and open source methods.[200]

Several aspects of Benkler's thesis directly relate to the discussion of OSDD and its objectives.[201] The notion of social production and appropriate changes in existing intellectual property norms are key factors that can play a pivotal role in the transformation of existing production processes, currently characterized by propriety emphases.[202] Once the existing production process transforms, Benkler argues that social production will lead to social transformation by eradicating poverty and empowering masses living in developing countries.[203] Benkler discusses social production as a process that is not based on proprietary claims, motivated by market sales, or organized around property and contract claims intended to form firms or market exchanges.[204] He asserts that most of the wealth accumulated in the society is generated through non-proprietary motivations,[205] and argues that social production is often a better method of creating wealth than market-based production, which depends upon traditional incentives such as monetary payments and intellectual property rights.[206] He describes that social production systems can be more efficient than the proprietary marketplace to motivate substantial amounts of human creativity and mechanical capacity.[207]

196. *See id.* at 372.

197. *Id.* at 369 (Benkler's article thoroughly explains open source theory and technique).

198. *See id.* at 401-03 (describing the theory presented by Ronald Coase about the efficiency of firms' decisions and transaction cost).

199. *See id.* at 402-03.

200. BENKLER, THE WEALTH OF NETWORKS, *supra* note 189, at 1-2.

201. *Id.*

202. *See id.* at 2-3, 37-38.

203. *Id.* at 329.

204. *Id.* at 105.

205. *Id.* at 44-47.

206. *Id.* at 115.

207. *Id.*

Open source is a manifestation of social production and Benkler describes some promising features of open source, discussed in the next section. Social production and open source methods are not merely alternative modes of production, but core inputs into human welfare.[208] To Benkler, both are critical as an end and as a means, and he advocates that a social production model will ultimately transform the lives of the people and that "information policy has become a critical element of development policy."[209] Benkler discusses how nonexclusive production in the information economy will affect distribution and human well-being.[210] Benkler recognizes that the issue is complicated and that there is a multiplicity of factors responsible for global inequality, poverty, hunger and injustice.[211] Benkler realizes some critics are pessimistic that more cooperative production processes cannot solve big problems, but argues that information, knowledge and culture are core inputs in human welfare, and social production can provide a normative basis to resolve some of these sufferings.[212]

Social and developmental benefits of social production and open source methods are numerous, but their successful implementation depends upon careful consideration of existing policies and practices.[213] Benkler provides a detailed account of relevant elements through a survey of liberal theories of justice and network information economy and then builds a case for concrete and asserted action in the realm of human welfare and development, industrial organization, access to medicine, food security and biomedical research.[214] He observes that social production "offers a new path, alongside those of the market and formal governmental investment in public welfare, for achieving definable and significant improvements in human development throughout the world."[215]

B. A Practical Model of Open Source Drug Discovery

The application of open source for the discovery of new drugs requires considerable adaptation of conventional open source techniques. In the backdrop of Benkler's theoretical approach towards social production and commons-based peer production, it is now

208. *See id.* at 301-02.
209. *Id.* at 302.
210. *Id.* at 301.
211. *Id.* at 301-02.
212. *Id.*
213. *See id.* at 301-02.
214. *Id.* at 301-55.
215. *Id.* at 355.

widely agreed that open source methods can be effectively used for the production of resources and products, beyond traditional computer programs and software.[216] The open source movement in bioinformatics has come to an age where the bulk of the information and databases in this new field are available as nonproprietary resources.[217] The convergence of biology and computing has given rise to a phenomenal expansion of open source software such as Biojava,[218] BioPython,[219] Bio-SPICE,[220] BioRuby,[221] Simple Molecular Mechanics for Proteins,[222] and Generic Software Components for Model Organism Databases (GMOD).[223]

In addition to these computing technologies in the area of bioinformatics, some basic science projects were also launched with open source modalities.[224] For example, the SNP Consortium aimed to discover human genome data and place it in the public domain.[225] Moreover, the SNP Consortium introduced a public domain model with a user access interface aimed at comparing multiple human genomes to find disease-causing variations.[226] Although these attempts, along with many other initiatives, provide a promising state of open source projects in the fields of biology, chemistry and disease mapping, their direct and unambiguous relation with drug discovery is still a missing link.[227]

Growing realization has developed about this critical gap between open source theory and its application in pharmaceutical

216. *Id.* at 328-29.

217. *Id.* at 351-52.

218. R.C.G. Holland et al., *BioJava, an Open-Source Framework for Bioinformatics*, 24 BIOINFORMATICS OXFORD J. 2096, 2096-97 (2008) (discussing BioJava), *available at* http://bioinformatics.oxfordjournals.org/cgi/content/abstract/24/18/2096.

219. JEFF CHANG ET AL., BIOPYTHON, BIOPYTHON TUTORIAL AND COOKBOOK, http://biopython.org/DIST/docs/tutorial/Tutorial.pdf (last visited Oct. 14, 2009).

220. Bio-SPICE, Biological Simulation Program for Intra- and Inter-Cellular Evaluation, http://biospice.sourceforge.net/. (last visited Oct. 14, 2009).

221. BioRuby, Open Source Bioinformatics Library for Ruby, http://bioruby.org/ (last visited Oct. 14, 2009).

222. 222.F. EISENMENGER ET AL., SMMP USER MANUAL (2005), http://www.smmp05.net/manual.pdf.

223. Lincoln D. Stein, et al., The Generic Genome Browser: A Building Block for a Model Organism System Database (2002), http://genome.cshlp.org/content/12/10/1599.full.pdftml.

224. BENKLER, THE WEALTH OF NETWORKS, *supra* note 189, at 351-52.

225. Gudnundur A. Thorisson & Lincoln D. Stein, *The SNP Consortium Website: Past, Present and Future*, *in* 31 NUCLEIC ACIDS RES. 124, 124-27 (2003).

226. The Int'l HapMap Consortium, *A Second Generation Human Haplotype Map of Over 3.1 Million SNP's*, 449 NAT. 851, 851 (2007), *available at* http://hapmap.ncbi.nlm.nih.gov/downloads/presentations/nature_hapmap3.pdf; *see also* Thorisson & Stein, *supra* note 225, at 124-27 (describing and analyzing the SNP Consortium database).

227. BENKLER, THE WEALTH OF NETWORKS, *supra* note 189, at 346.

R&D.[228] The key challenge lies in designing an appropriate and practical model of OSDD. In light of ongoing projects and experiments, two models explain the practical nuances attached to OSDD. First, I will discuss Professor Yochai Benkler's proposal describing how open source can help in the production of medicines for some of the poorest populations of the world. Second, I will briefly discuss the proposal of Professor Arti Rai to explain the open source model of The Tropical Disease Initiative.

Why is an OSDD model important at all? As Benkler suggests, the open source model is important for drug discovery because it is a vehicle of economic political, and social empowerment.[229] Through the case of OSDD, Benkler recognizes that once medicine is produced and readily available under social production arrangements, transformation can occur and access to medicines in developing countries will be improved.[230] He states that:

> [O]ne of the lessons we learn as we look at the networked information economy is that the work of governments through international treaties is not the final word on innovation and its diffusion across boundaries of wealth. The emergence of social sharing as a substantial mode of production in the networked environment offers an alternative route for individuals and nonprofit entities to take a much more substantial role in delivering actual desired outcomes independent of the formal system. Commons-based and peer production efforts may not be a cure-all. However, as we have seen in the software world, these strategies can make a big contribution to quite fundamental aspects of human welfare and development. And this is where freedom and justice coincide.[231]

Open source drug innovation has the potential to create a transformation. One solution offers a three-pronged strategy that can be used to facilitate access to medicines through common-based biomedical research.[232] This model heavily relies upon academic institutions and universities, and strongly advocates a major shift in the attitude of these institutions towards their existing patenting and licensing practices.[233]

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228. *Id.*

229. *Id.* at 302, 355.

230. *Id.* at 355.

231. *Id.*

232. Samantha Chaifetz et al., *Closing the Access Gap for Health Innovations: An Open Licensing Proposal for Universities*, 3 GLOBALIZATION & HEALTH 3 (2007), http://www.globalizationandhealth.com/content/pdf/1744-8603-3-1.pdf.

233. *Id.* at 5.

Universities can play a key role in improving the dismal state of access to medicines in the developing world by revisiting their intellectual property policies. Empirical evidence also shows that universities in the U.S. can actually forgo some of their patent rights by entering into licensing arrangements that allow generic competition in certain jurisdictions.[234] Also, evidence suggests that the revenue patent licensing generates at top U.S. universities is only a minor portion of their gross income.[235] These universities would maintain revenues if they adopted an Equitable Access License (EAL), and likely stand to gain a significant revenue stream.[236]

An EAL aims to make health-related products available at marginal prices in low and middle-income countries.[237] The details of this license are important; it contains some critical features to ensure access through generic production.[238] By adopting an EAL, universities' technology transfer agreements will allow generic competition by providing open licenses, which will guarantee third party manufacturers the right to compete in low and middle income countries.[239] The inclusion of middle-income countries along with low-income ones is important to ensure the practical feasibility of this proposal, as generic competition can come only from middle-income countries.[240] An EAL does not deliberately adopt the fair pricing approach, where universities can stipulate appropriate pricing caps on manufacturers.[241] Such an obligation will increase the risk of litigation and involves the establishment of elaborate and detailed monitoring mechanisms, which universities may not favor.[242] Thus, a simple market-based mechanism is proposed to facilitate generic competition.[243]

The scope of an EAL is less restrictive and covers a wide range of health technologies and products.[244] It categorically rejects the notion that developing countries only need some medicines for the treatment of infectious diseases.[245] Thus, an EAL is designed to cover chronic

234. *Id.* at 6.
235. *Id.*
236. *Id.* at 3-4.
237. Chaifetz et al., *supra* note 232, at 3.
238. *Id.*
239. *Id.* at 3.
240. *Id.* at 4.
241. *Id.* at 3.
242. Chaifetz et al., *supra* note 232, at 3.
243. *Id.*
244. *Id.* at 2.
245. *Id.* at 4.

non-communicable diseases too, which comprise a major burden in the developing world.[246]

An EAL works in three steps: (1) a license exchange; (2) notification procedures; and (3) a sharing of improvements. First, a university and a licensee exchange a license of an innovative product.[247] A university grants rights that enable the licensee to use the technology in designated jurisdictions.[248] At this stage, the licensee will grant back certain rights to the university, including all the licensee's exclusive rights that could prevent a third party from using the end product.[249] This is a critical aspect of EAL because the grant back of these rights is crucial for a third party manufacturer in a low or middle-income country. However, the original licensee is not supposed to grant back its own material property rights, such as cell lines.[250]

The second stage involves the notification procedures when a new third party wants to use the innovative product. The third party must notify both the university and the original licensee of its intention to exploit licensed technology in low and middle-income countries.[251] The third-party permission for use will be almost automatic because of the original licensee's grant back.[252] The third party can be a generic manufacturer, a government body, non-governmental organization, or even researchers wanting to adapt the end product.[253] The EAL envisages a probability of multiple notifications to ensure true competition to achieve marginal cost pricing.[254] Finally, an EAL requires all third-party manufacturers' to grant any improvements on the original license back to the university for sublicensing.[255]

In addition to this public-minded licensing proposal, Benkler offers another practical approach for OSDD, the peer-production model.[256] This model truly reflects the spirit of the open source movement, but it has challenges in that it may be too complex, expensive,

246. *Id.*

247. Chaifetz et al., *supra* note 232, at 4.

248. *Id.*

249. *Id.*

250. *Id.* at 5.

251. *Id.*

252. Chaifetz et al., *supra* note 232, at 5.

253. *Id.*

254. *Id.*

255. *Id.*; *see also* UNIV. ALLIED FOR ESSENTIAL MED., CLOSING THE ACCESS GAP: THE EQUITABLE ACCESS LICENSE 65, http://www.essentialmedicine.org/EALPrimer.pdf (last visited Oct. 14, 2009).

256. BENKLER, THE WEALTH OF NETWORKS, *supra* note 189, at 351.

and time-consuming.[257] Despite these challenges, the convergence of computing and drug discovery methods has opened new and innovative means of making a peer-production model work.[258] Benkler sees how patent-driven R&D fits in the drug discovery process and how it is compatible with and relevant to open source methods.[259]

The peer production approach can begin with a critical mass of young scientists who are ready to volunteer their time and energy to computer modeling of disease patterns and candidate substances.[260] The biomedical field offers one example of how peer production might work:[261]

> As more of the process of drug discovery of potential leads can be done by modeling and computational analysis, more can be organized for peer production. The relevant model here is open bioinformatics. Bioinformatics generally is the practice of pursuing solutions to biological questions using mathematics and information technology . . . allow[ing] projects to harness volunteer computation resources . . . This stage of the process is the one that most directly can be translated into a peer-production model, and, in fact, there have been proposals, such as the Tropical Disease Initiative proposed by Maurer, Sali, and Rai.[262]

Once computer modeling is completed and candidate compounds are identified, then wet-lab experiments present a context where scientists and researchers face some of the biggest challenges to commons-based peer production.[263] This is one of the biggest challenges because much of the wet-lab experiments occur independently, under drastically different lab conditions, resulting in a waste of resources and funding.[264] While Benkler has no clear solution for this problem, he discusses several options to overcome this insurmountable barrier.[265]

Professor Arti Rai presents a slightly different model of OSDD in the form of the Tropical Disease Initiative.[266] This approach, which is

257. Stephen M. Maurer, *Open Source Drug Discovery: Finding a Niche (or Maybe Several)*, 76 UMKC L. REV., 405, 409 (2007) [hereinafter Maurer, *Open Source Drug Discovery*].

258. BENKLER, THE WEALTH OF NETWORKS, *supra* note 189, at 351.

259. Maurer, *Open Source Drug Discovery*, *supra* note 257, at 407.

260. *Id.* at 406.

261. *See* BENKLER, THE WEALTH OF NETWORKS, *supra* note 189, at 351.

262. *Id.* at 351-52.

263. *Id.* at 352.

264. *Id.* at 352-53.

265. Yochai Benkler, *Commons-Based Strategies and the Problems of Patents*, 305 SCI. 1110, 1111 (2004) [hereinafter Benkler, *Commons-Based Strategies*].

266. Stephen M. Maurer et al., *Finding Cures for Tropical Diseases: Is Open Source an Answer?*, 1 PLOS MED. 183, 183 (2004) [hereinafter Maurer et al., *Finding Cures for Tropical Dis-*

less focused on a licensing format, encourages the development of a web portal where feasible open source projects can be launched.[267] This open discovery approach might look something like:

> [A] website 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.[268]

Professor Rai and her colleagues hardly seem concerned with intellectual property constraints in OSDD and believe that big pharmaceutical companies should pay less attention to revenues generated in developing markets.[269] Thus, their proposal does not revolve around any particular kind of license to ensure unrestricted and free access to new technologies.[270] They suggest that any open source license can be adopted to facilitate the process of social production.[271] This position is understandable in the context of an initiative that is solely reserved for tropical diseases. However, a project with much broader ambitions and objectives will need a comprehensive licensing regime such as the EAL.[272]

C. *Open Source Drug Discovery (OSDD) and India*

The application of an open source model for the development of medicines offers both challenges and opportunities for India. The local Indian pharmaceutical industry is uniquely situated to benefit from OSDD initiatives, which can ultimately narrow the access gap within and outside India.[273] As a major emerging economy, India has initiated key shifts in a range of public policies, including national indus-

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eases], *available at* http://www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.0010056; *see generally* The Tropical Disease Initiative, http://tropicaldisease.org (last visited Oct. 14, 2009).

267. Maurer et al., *Finding Cures for Tropical Diseases*, *supra* note 266, at 183.

268. *Id.* at 184.

269. *Id.* at 184-85.

270. *Id.* at 183.

271. *Id.* (discussing the various license options available to the open source movement).

272. *Compare* Severine Dusollier, *Sharing Access to Intellectual Property Through Private Ordering*, 82 CHI.-KENT L. REV. 1391, 1404-05 (2007), *with* Arti K. Rai, *"Open Source" and Private Ordering: A Commentary on Dusollier*, 82 CHI.-KENT L. REV. 1439, 1439-43 (2007).

273. Samir K. Brahmachari, *Remarks by the Chair*, *in* PROCEEDINGS OF THE CHINA-INDIA-US WORKSHOP ON SCIENCE, TECHNOLOGY, AND INNOVATION POLICY 371, 374 (William A. Blanpied ed., 2008), http://www.law.gmu.edu/nctl/stpp/us_china_pubs/china_india_us_workshop/sec7_session5/sec7_item1_cover_chair_remarks.pdf.

trial and innovation framework.[274] The relevance of an open source model is less promising in India because the Indian government is introducing changes in its patent laws to give incentives to local researchers who apply for domestic and foreign patents.[275]

There are several positive signals that suggest OSDD projects could be successfully implemented in India. The most optimistic is that none of the alternative non-open source R&D models discussed in this article could actually start building their roots in India. The Indian Council for Scientific and Industrial Research is largely responsible for this and is a pioneer in leading and launching the Open Source Drug Discovery (OSDD) Foundation project.[276] The government has earmarked over U.S. $120 million in its eleventh Five Year Plan for OSDD projects.[277] Additionally, the government will increase funding once the project is implemented.[278]

This project is currently focused on tuberculosis, and will also target other neglected tropical diseases in the future.[279] The decision to focus the project on tuberculosis is understandable because of the widespread effect this disease has on India's population.[280] The rationale of this project is stated as "to provide affordable healthcare to the developing world by providing a global platform where the best minds can collaborate. . . to solve the complex problems associated with . . . neglected tropical diseases[,] . . . to collaboratively aggregate the biological and genetic information available to scientists in order to . . . hasten the discovery of drugs."[281] This project started with the creation of a huge database of tuberculosis information, known as Sys-

274. William A. Blanpied, *Preface, in* PROCEEDINGS OF THE CHINA-INDIA-US WORKSHOP ON SCIENCE, TECHNOLOGY, AND INNOVATION POLICY v (William A. Blanpied ed., 2008), http://www.law.gmu.edu/nctl/stpp/us_china_pubs/china_india_us_workshop/intro/Preface.pdf.

275. Lisa Saum-Manning & Anne Poduska, *Rapporteurs' Reports: Pharmaceuticals, in* PROCEEDINGS OF THE CHINA-INDIA-US WORKSHOP ON SCIENCE, TECHNOLOGY, AND INNOVATION POLICY 405, 406-07 (William A. Blanpied ed., 2008), http://www.law.gmu.edu/nctl/stpp/us_china_pubs/china_india_us_workshop/sec8_rapporteurs_reports/sec8_item1_cover_reports.pdf.

276. OPEN SOURCE DRUG DISCOVERY, OPEN SOURCE DRUG DISCOVERY BROCHURE JANUARY 2009 (2009), http://www.osdd.net/publications.

277. Brahmachari, *supra* note 273, at 377.

278. *See id.*

279. *See* Open Source Drug Discovery, About Us, http://www.osdd.net/about-us (last visited Oct. 14, 2009).

280. Open Source Drug Discovery, Why Tuberculosis as the First Target, http://www.osdd.net/what-is-osdd/why-tuberculosis-as-the-first-target (last visited Oct. 14, 2009).

281. Open Source Drug Discovery, What is OSDD, http://www.osdd.net/what-is-osdd (last visited Oct. 14, 2009).

BorgTB, that serves as an open source community portal to attract participants across the world.[282]

It will take some time before substantial breakthroughs can be achieved because the project is still in its infancy.[283] Organizers campaign to gather the critical institutional support needed for the different stages of the project.[284] For example, the Indian government has separately established The Centre for Genomic Application.[285] This Centre has facilities designed for testing, screening, sequencing and proteomics analysis.[286] This Centre, along with the massive infrastructure of laboratories in other public sectors and academic institutions, can provide the important information and technical input to the open source initiative.[287]

In addition to project infrastructure and funding commitments, the OSDD initiative requires expanding the current state of knowledge through individual effort and participation.[288] In the area of tropical diseases, such background knowledge is unavailable for open source buildup because it is missing or under proprietary control.[289] The Tropical Disease Initiative overcame this problem with a team of experts who developed a kernel for OSDD in tropical diseases.[290] While the practical coordination between these two projects is unknown, this new kernel could be a useful starting point for the Indian open source project.

India's OSDD project should be a hybrid model because it incorporates direct incentives in the form of credit and prizes. The project will award small prizes to those who find solutions.[291] The "InnoCentive" model is readily available for this purpose.[292] India's scientific

282. Open Source Drug Discovery, SysBorgTB, http://sysborgtb.osdd.net/bin/view/Main/WebHome (last visited Oct. 14, 2009).

283. Brahmachari, *supra* note 273, at 376.

284. *See* OPEN SOURCE DRUG DISCOVERY, *supra* note 276.

285. The Centre for Genomic Application, Profile, http://www.tcgaresearch.org/index.htm (last visited Oct. 14, 2009).

286. *Enabling Drug Discovery with Cutting-Edge Tech,* THE FIN. EXPRESS (New Delhi, India), Nov. 28, 2005, *available at* http://www.financialexpress.com/news/Enabling-drug-discovery-with-cutting-edge-tech/158251/.

287. *Id.*

288. *See* Leticia Orti et al., *A Kernel for Open Source Drug Discovery in Tropical Diseases*, 3 PLOS NEGL. TROP. DIS. 1, 2 (2009), *available at* http://www.plosntds.org/article/info:doi/10.1371/journal.pntd.0000418.

289. *See id.* at 4.

290. *Id.* at 2.

291. Brahmachari, *supra* note 273, at 374.

292. Innocentive, What is a Solver?, http://innocentive.com/solvers-contract-research.php (last visited Oct. 14, 2009).

and technological landscape will help with the successful implementation of a domestic OSDD project.[293] India's large unit of skilled scientists will be able to use the open source model as a thrilling opportunity to produce new and innovative solutions.[294] If the new model is properly implemented, Indian scientists, who do not have much exposure to lead patent R&D, will be able to expand the field and enter mainstream.[295]

Policy coherence and consistency are important factors for the successful implementation of an open source program in India.[296] However, mixed signals are emerging from India regarding these policy factors. The Indian government is seriously considering new intellectual property policies contrary to the open source movement for drugs developed from public sector funded R&D.[297] Because the Indian open source model is largely dependent upon the public sector for drug discoveries by academic and research institutions, advanced drug discovery will be impossible without the heavy involvement of the public sector.[298] Furthermore, the introduction of an intellectual property based system in the public sector for R&D institutions will change institutional dynamics.[299]

The scarcity of open source expertise is another practical obstacle. As the specific examples above demonstrate, the open source system is unique and works optimally if requisite conditions are met. In the absence of an open source culture in India, the success of OSDD is reliant on several factors, including the agreed focus by the critical mass, identification of the right projects, organization of innovative activity and its final culmination.[300] One government-sponsored project may not single-handedly lead to the wider acceptability of open source methods unless it is going to become a standard norm in public institutions.

293. *Id.* at 373.

294. Kristen Bound, *India: The Uneven Innovator*, DEMOS 1, 18 (2007), *available at* http://search.creativecommons.org/ (Search: Kristen Bound, India: The Uneven Innovator).

295. *Id.* at 18.

296. *See id.* at 26.

297. *Id.* at 34-35.

298. *See* OPEN SOURCE DRUG DISCOVERY, *supra* note 276.

299. Bound, *supra* note 294, at 35.

300. Vandana Gombar, *Outsourcing Research*, BUSINESS STANDARD, (New Delhi, India), May 9, 2006, at 10, *available at* http://www.tcgaresearch.org/press.htm (click on the Outsourcing Research PDF document).

IV. PATENT POOLS

In 2006, the World Health Organization's Commission on Intellectual Property Rights, Innovation and Public Health observed that:

> [P]atent pools . . . could be most useful for technologies particularly relevant to developing countries, because the lack of strong market incentives may enable agreements that would otherwise be more difficult to engineer. Low-margin research directed towards problems of poor people might be promoted. Patent pools have also been proposed for the development of vaccines, given the large number of products owned by different entities and, consequently, the complexity of identifying, tracking and obtaining licences for patented technologies.[301]

The World Health Organization's Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (WHO's Plan) urges member states to explore the potential role of patent pools in promoting innovation in upstream and downstream technologies.[302] Thus, WHO's Plan supports the Commission's proposition.

In 2008, UNITAID's Executive Board approved a proposal to establish a patent pool for medicine, attracting substantial attention from almost all stakeholders.[303] This initiative is now in its advanced stage.[304] The UNITAID patent pool mainly deals with HIV/AIDS medicine and is still developing a following in India.[305] Because India is a major supplier of HIV/AIDS medicine to many African countries,

301. THE COMM'N ON INTELLECTUAL PROP. RIGHTS, INNOVATION AND PUB. HEALTH, WORLD HEALTH ORG., PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY RIGHTS 53 (2006), *available at* http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf.

302. WORLD HEALTH ASSEMBLY, GLOBAL STRATEGY AND PLAN OF ACTION ON PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY 1, 14 (2008), *available at* http://apps.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf.

303. UNITAID, DRAFT RESOLUTION EB8/PATENT POOL (2008), *available at* http://www.msfaccess.org/fileadmin/user_upload/medinnov_accesspatents/Draft%20Resolution%20EB8.pdf.

304. *See* Ryan Lampe & Petra Moser, *Do Patent Pools Encourage Innovation? Evidence from the 19th – Century Sewing Machine Industry* 2-3 (Soc. Sci. Res. Network, Working Paper No. 1308997, 2009), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1308997; European Aids Treatment Group, UNITAID Statement on GSK Patent Pool for Neglected Diseases, (Feb. 16, 2009), http://www.eatg.org/eatg/UNITAID-statement-on-GSK-patent-pool-for-neglected-diseases.

305. UNITAID, PROPOSAL FOR NEW AND INNOVATIVE SOURCES OF FUNDING MEDICINES PATENT POOL 1 (2009), *available at* http://www.who.int/phi/UNITAID.pdf.

it can potentially play a key role in the implementing UNITAID's patent pool.[306]

On February 13, 2009, GlaxoSmithKline (GSK) CEO Andrew Witty set out an ambitious four-point strategy to tackle the challenges of improving global public health. While speaking at Harvard Medical School, Witty unleashed his company's four-point strategy to accomplish the huge task of lowering the burden of diseases in the developing world.[307] His speech, entitled "Big Pharma as a Catalyst for Change," set out an ambitious plan of action, and has given a strong signal of possible policy shift, which the pharmaceutical industry may elect to pursue following GSK's lead. One of the points he presented concerned GSK's willingness to participate in a patent pool for the development of neglected tropical disease medicine.[308] Thus, his speech gave a strong signal of a possible shift in policy.

A. The "Tragedy of the Anticommons"

Law and economics scholars extensively debate the relevance of the patent pool as a policy prescription.[309] Economists generally look at the merits and effectiveness of intellectual property, particularly patent law, and develop theories to state a plausible relationship between patents and allied products.[310] Also, intellectual property rights play a crucial role in the disclosure of information.[311] Economists note the importance of patents in disclosing information, which would otherwise be kept secret. However, contrary to the conventional approach, some economists assign a market to intellectual property rights, independent of the assets associated with them.[312] Thus, pat-

306. Pooja Van Dyck, *Importing Western Style, Exporting Tragedy: Changes in Indian Patent Law and Their Impact on AIDS Treatment in Africa*, 6 NW. J. TECH. & INTELL. PROP. 138, 143 (2007).

307. Andrew Witty, CEO, GlaxoSmithKline, Address at Harvard Medical School: Big Pharma as a Catalyst for Change 1 (Feb. 13, 2009), *available at* http://www.gsk.com/media/Witty-Harvard-Speech-Summary.pdf.

308. *Id.*

309. *See* Courtney C. Scala, *Making the Jump from Gene Pools to Patent Pools: How Patent Pools Can Facilitate the Development of Pharmacognenomics*, 41 CONN. L. REV. 1631, 1631-67 (2009); Nancy T. Gallini, *The Economics of Patents: Lessons from Recent U.S. Patent Reform*, 16 J. ECON. PERSP. 131, 142-44 (2002); Phillips B. Nelson, *Patent Pools: An Economic Assessment of Current Law and Policy*, 38 RUTGERS L.J. 539, 539-72 (2007), *available at* http://org.law.rutgers.edu/publications/lawjournal/38-2/07NelsonVol.38.2.pdf.

310. *See* Kenneth J. Arrow, *Economic Welfare and the Allocation of Resources for Invention*, *in* THE RATE AND DIRECTION OF INVENTIVE ACTIVITY: ECONOMIC AND SOCIAL FACTORS, 609, 609-19 (1962), *available at* http://www.nber.org/chapters/c2144.pdf.

311. Gallini, *supra* note 309, at 132.

312. Arrow, *supra* note 310, at 617.

ents play a vital role in facilitating information exchange in markets.[313]

However, this facilitating role of patents becomes somewhat problematic when several layers of property rights are created. The transaction costs then escalate to a point where the information bargain becomes a futile exercise for market players.[314] This situation typically exists in the form of patent thickets,[315] creating "a dense web of overlapping intellectual property rights" that become obstacles for companies trying to commercialize new technology.[316] Thus, academics have recently scrutinized the problem of overlapping patent rights in a wealth of scholarly publications.[317] In an influential article in 1998, Michael A. Heller and Rebecca S. Eisenberg used a "commons" property law metaphor to explain the problem of patent thickets.[318] Employing the terminology of Garrett Hardin, Heller and Eisenberg explain how excessive proprietary patents can create the "tragedy of the anticommons."[319]

In 1968, Hardin coined the term "tragedy of the commons," in an article published in *Science*.[320] The "tragedy of the commons" is excessive use and ultimate relinquishment of property rights, given the lack of private ownership.[321] On the other hand, the "tragedy of the anticommons" is under-utilization of an asset because of multiple proprietary claims over it.[322] Heller introduced "the tragedy of the anticommons" in his Harvard Law Review article: "In an anticommons . . . multiple owners are each endowed with right to exclude others from a scarce resource, and no one has an effective privilege of use. When too many owners hold such rights of exclusion, the re-

313. *See* Gallini, *supra* note 309, at 132.

314. *See id.* at 141.

315. Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, *in* 1 INNOVATION POLICY AND THE ECONOMY, 119, 119-21 (Adam B. Jaffe et al. eds., 2001), *available at* http://www.nber.org/chapters/c10778.pdf.

316. *Id.* at 119-20.

317. *See id.* at 119-50; *see* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698, 698 (1998), *available at* http://www.sciencemag.org/cgi/reprint/280/5364/698.pdf; Birgit Verbeure et al., *Patent Pools and Diagnostic Testing*, 24 TRENDS BIOTECHNOLOGY 115, 115-20 (2006), *available at* http://www.epip.eu/conferences/epip02/lectures/Verbeureetal-2006-TIB-Publication.pdf.

318. Heller & Eisenberg, *supra* note 317, at 698.

319. *Id.* at 698-99.

320. *Id.* at 698.

321. *Id.*

322. *Id.*

source is prone to underuse – a tragedy of the anticommons."[323] The whole theory is applied to biotechnology patents where Heller cites many existing and potential tradgedies.

In 1998, Heller and Eisenberg applied the concept of anticommons in biomedical research to elaborate the excessive patenting.[324] The "tragedy of the anticommons" in biomedical and pharmaceutical research is the tragedy of millions of poor patients living without secured access to life saving drugs.[325] The authors note that:

> The tragedy of the anticommons refers to the more complex obstacles that arise when a user needs access to multiple patented inputs to create a single useful product. Each upstream patent allows its owner to set up another tollbooth on the road to product development, adding to the cost and slowing the pace of downstream biomedical innovation. . . . Current examples in biomedical research demonstrate two mechanisms by which a government might inadvertently create an anticommons: either by creating too many concurrent fragments of intellectual property rights in potential future products or by permitting too many upstream patent owners to stack licenses on top of the future discoveries of downstream users.[326]

The main concern is the entry barrier that an existing or future user can face because of granted patents.[327] These patents usually have very broad claims and their upstream location gives them an advantage of seeking high rents and license royalties from downstream users.[328] Up to an optimal point, users may find the innovation worth pursuing, but, beyond that point, the innovation is typically underutilized.

In 2008, Heller provided a spectrum of economic implications of his anticommons thesis.[329] In essence, too many stakeholders can virtually kill the optimal usefulness of a property.[330] Moreover, Heller maintains that the "tragedy of the anticommons" can be found in ar-

323. Michael A. Heller, *The Tragedy of the Anticommons: Property in the Transition from Marx to Markets*, 111 HARV. L. REV. 622, 622 (1998).

324. Heller & Eisenberg, *supra* note 317, at 698-99.

325. *See* MICHAEL HELLER, THE GRIDLOCK ECONOMY: HOW TOO MUCH OWNERSHIP WRECKS MARKETS, STOPS INNOVATION, AND COSTS LIVES 6 (2008).

326. Heller & Eisenberg, *supra* note 317, at 699.

327. *See id.* at 699.

328. *See id.*; *see* Fed. Trade Comm'n, *The Role of Competition and the Patent System in Spurring Innovation*, *in* TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY: A REPORT BY THE FEDERAL TRADE COMMISSION 1, 2-3 (2003) [hereinafter TO PROMOTE INNOVATION], *available at* http://ftc.gov/os/2003/10/innovationrpt.pdf.

329. HELLER, *supra* note 325, at 2-16.

330. *Id.*

eas such as medical research.[331] One example includes a story of a treatment for Alzheimer's, Compound X, that remains undeveloped because there are too many owners of relevant patents, each demanding a substantive share in the form of royalties.[332] Heller warns that the potential threat of gridlock in biomedical research does not mainly come from litigation or uncertainty about patent claims.[333] He notes that:

> Fragmented ownership can be enough, by itself, to deter innovation. For example, consider the potential gridlock effect of patents related to brain receptors . . . Shapiro, Merck's vice president for worldwide basic research, explains that people who take "compounds for schizophrenia often develop other disorders some of which resemble Parkinson's disease, another disease involving the dopamine system. A rational approach to discovery of improved schizophrenia drugs would be to target specific dopamine receptors. But if different companies hold patents on different receptors, the first step on the path to an important and much needed therapeutic advance can be blocked."[334]

Whether the "tragedy of anticommons" has any real relevance to the pharmaceutical R&D has generated conflicting opinions.[335] Commentators generally agree with patent thickets and the associated "tragedy of anticommons," which is evidently prevailing in the area of information technology and related fields where standard setting is a key issue.[336]

However, beyond analytical comprehension and sporadic incidences, empirical studies have yet to establish the existence of this problem in the area of pharmaceutical research.[337] Nevertheless, leading commentators in this field have discussed various situations where overlapping patent rights create entry barriers for follow-up

331. *See id.* at 4.

332. *Id.* at 4-5.

333. *Id.* at 53.

334. *Id.*

335. *See* Richard A. Epstein & Bruce N. Kuhlik, *Navigating the Anticommons for Pharmaceutical Patents: Steady the Course on Hatch-Waxman* 1 (Univ. Chi. Law & Econ., Working Papers No. 209, 2004), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=536322.

336. *See* Shapiro, *supra* note 315, at 19-20. *But see* Verbeure et al., *supra* note 317, at 115-20 ("[T]he existence of an anticommons effect of patents has not been validated by comprehensive empirical data").

337. ANN MILLS & PATTI TERESKERZ, THE BIOTECHNOLOGY INDUS. ORG., PROPOSED PATENT REFORM LEGISLATION: LIMITATIONS OF EMPIRICAL DATA USED TO INFORM THE PUBLIC POLICY DEBATE (2008), *available at* http://www.fr.com/news/2008/Feb/UVA_Limitations_of_Empirical_Data.pdf. It is generally believed that low patenting standards encourage patent thickets. *See* Gallini, *supra* note 309, at 132.

R&D.[338] According to the Pharmaceutical Sector Inquiry Preliminary Report of the European Commission:

> One commonly applied strategy is filing numerous patents for the same medicine (forming so called 'patent clusters' or 'patent thickets'). . . . an important objective of this strategy is to delay or block the market entry of generic medicines. In this respect the inquiry finds that individual blockbuster medicines are protected by up to 1,300 patents and/or pending patent applications EU-wide and that, as mentioned above, certain patent filings occur very late in the life cycle of a medicine.[339]

Heller enumerates a long list of corrective actions that can offset the "tragedy of anticommons."[340] The remedial measures suggested by Heller include: market-driven solutions; property-preventing investments; patent pools and other cooperative solutions; and regulatory solutions.[341] Heller starts with a positive note on patent pools, and considers patent pools a workable solution in particular technological spheres.[342] He is specifically appreciative of the history of patent pools that worked well largely in aircraft and sewing machine cases.[343] However, Heller acknowledges the complexity of law and economics of patent pools and warns that they may not work in all cases, as "their internal dynamics are fraught with peril for bargaining failure."[344]

Heller is not alone in his prescription of patent pools as a plausible solution to the problem of anticommons.[345] Many commentators have recently considered this option and concluded that patent pools can effectively address the problems associated with patent thickets and anticommons.[346] However, certain qualifications are attached to this proposal because most of the studies conclude that patent pools work well only in certain areas of technology, and their universal ap-

338. *See* European Comm'n, Pharmaceutical Sector Inquiry Preliminary Report, 161 (Nov. 28, 2008) (unpublished manuscript, on file with DG Competition), *available at* http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf; HELLER, *supra* note 325, at 4-5; Verbeure et al., *supra* note 317, at 115-20.

339. European Comm'n, *supra* note 338, at 9.

340. HELLER, *supra* note 325, at 69-76.

341. *Id.*

342. *Id.* at 72-73.

343. *See id.;* Lampe & Moser, *supra* note 304, at 1- 27.

344. HELLER, *supra* note 325, at 73.

345. *See generally* Robert P. Merges, Institutions for Intellectual Property Transactions: The Case of Patent Pools (August, 1999) (unpublished manuscript, on file with Boalt Hall School of Law), http://www.law.berkeley.edu/institutes/bclt/pubs/merges/pools.pdf.

346. *E.g., id.*; Lampe & Moser, *supra* note 304, at 1- 27. *See generally* Josh Lerner & Jean Tirole, *Efficient Patent Pools* (Nat'l Bureau of Econ. Research, Working Paper No. W9175, 2002), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=330314.

plication and relevance is not clear.[347] This skepticism is even reflected in Heller's approach as following:

> On balance, I doubt the biotech industry is amenable to pooling, even if the antitrust environment were to become more favourable. Patent pools may be a good solution to gridlock in some circumstances—for example, in telecommunications, semiconductors, or nanotechnology, where standard setting is important—but it is doubtful they will do the same for biomedical research.[348]

The doubts about the appropriateness of patent pools for biomedical and pharmaceutical research can be fully anticipated.[349] The lack of any concrete example makes the case of patent pools quite difficult in the area of biomedical research. Nevertheless, the situation is now changing, and some recent developments and initiatives are challenging the conventional wisdom in this regard.[350]

B. UNITAID's Proposed Patent Pool: A Search for a Workable Model

The best mode of assembling the patent rights to facilitate R&D of new drugs for the treatment of neglected and tropical diseases, among the several options mentioned, appears to be patent pools. Patent pools are arrangements among patent holders to license one or more of their patents. These arrangements could substantially help in remedying the tragedy of anticommons created in biomedical and pharmaceutical R&D. The merits of patent pools are well recognized, and many studies and declarations reflect the idea of pooling patent rights for the development of new and effective drugs.[351]

On June 6, 2006, Médecins Sans Frontières (MSF) submitted its proposal to the government of France and UNITAID suggesting the creation of a patent pool, initially as a test case, for a limited number

347. HELLER, *supra* note 325, at 73.

348. *Id.* at 74.

349. In 2003, the United Sates Federal Trade Commission analyzed the scope and application of patent pools in various fields of technologies and concluded that patent pools may not help in the biotechnology industry. *See* TO PROMOTE INNOVATION, *supra* note 328, at 102-04.

350. *See id.* at 128.

351. *See generally* Anatole Krattiger & Stanley P. Kowalski, *Facilitating Assembly of and Access to Intellectual Property: Focus on Patent Pools and a Review of Other Mechanisms*, *in* 1 INTELLECTUAL PROPERTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATION: A HANDBOOK OF BEST PRACTICES 131 (Anatole Krattiger et al. eds., 2007), *available at* http://ipmall.info/hosted_resources/IP_handbook/ch02/ipHandbook-Ch%2002%2008%20Krattiger-Kowalski%20Assembly%20and%20Pooling.pdf; *see generally* Lerner & Tirole, *supra* note 346.

of diseases.[352] MSF has faced problems of high costs and inaccessibility to medicines in the many years it has worked as a humanitarian organization in many parts of the world.[353] Other non-governmental organizations also began similar lobbies, asking for the implementation of a patent pool proposal.[354] A 2006 study observed that: "[t]his commitment to back up the Doha Declaration with purchasing power should signal to global holders of HIV, tuberculosis and malaria drug patents that the time has come to open their products to competition in developing countries, for example by voluntarily creating a patent pool."[355] This call was clearly for a patent pool that could cater to essential medicine for tackling HIV, tuberculosis and malaria. However, UNITAID is inherently limited by its mandate, and it was impossible for the organization to launch an initiative covering broader areas stated in the study.

In 2008, the Board of UNITAID adopted a resolution and principally agreed on the creation of a patent pool.[356] The world applauded this as a significant move and an important, concrete step towards patent assembly for the public health purpose.[357] The UNITAID Board resolved that in following its EB6/6 resolution, the work of "further exploring patent pooling, identifying operational alternatives for the pool (taking into consideration its voluntary/non-voluntary nature, governance and geographical coverage), as well as in providing elements for a cost/benefit analysis" is also necessary.[358] In light of this mandate, UNITAID is still working on the modalities of proposed patent pools, a process that involves extensive consultation and negotiations with relevant stakeholders.[359] Although UNITAID's model

352. E. RICHARD GOLD ET AL., THE INNOVATION PARTNERSHIP FOR UNITAID, PRELIMINARY LEGAL REVIEW OF PROPOSED MEDICINES PATENT POOL 1 (2007), http://www.theinnovationpartnership.org/data/documents/00000003-1.pdf.

353. *See* JEREMIAH NORRIS & S. JEAN WEICHER, HUDSON INSTITUTE, UNITAID/IDPF: AN ANALYSIS OF THE INTERNATIONAL DRUG PURCHASE FACILITY 10 (2006), *available at* https://www.policyarchive.org/handle/10207/7658.

354. *Id.* at 5.

355. *Id.* at 4-5.

356. Press Release, Médecins Sans Frontières, MSF Welcomes UNITAID Patent Pool Endorsement, (July 9, 2008) (providing general comments and reactions to the UNITAD resolution), *available at* http://www.msfaccess.org/media-room/press-releases/msf-welcomes-unitaid-patent-pool-endorsement/.

357. *Id.*; Kaitlin Mara, *Patent Pooling is Next Step for Innovative Drug Puchasing Agency*, INTELL. PROP. WATCH, July 9, 2008, http://www.ip-watch.org/weblog/2008/07/09/patent-pooling-is-next-step-for-innovative-drug-purchasing-agency/.

358. UNITAID, *supra* note 305.

359. Press Release, Action for Global Health, UNITAID Presents Patent Pool in European Parliament, (Apr. 15, 2009), *available at* http://www.actionforglobalhealth.eu/news/unitaid_presents_patent_pool_in_european_parliament.

at this stage is still uncertain, it can be anticipated that it largely will be based upon the initial proposal of MSF in terms of its scope and coverage of disease.

The Innovation Partnership (TIP) conducted a preliminary legal review of the MSF proposal in 2007.[360] This review provides a comprehensive survey of issues that may be involved in creating a medicine patent pool.[361] It also gives a practical snapshot of how a patent pool can be initiated, and what measures are important for the successful implementation of such a pool.[362] UNITAID's patent pool will start with a limited scope, mainly aimed at producing 'fixed-dose combination medicines (FDCs) or the new formulations' of existing medicine adapted, for developing countries.[363] The focus on new, anti-retroviral combinations is obvious for two reasons. First, this problem is increasingly confronted by international humanitarian organizations, such as MSF when they outreach to far-flung areas to distribute HIV/AIDS medicine.[364] Second, the organizational mandate of UNITAID warrants that organizations can channel their resources to meet the particular needs of the developing world.[365]

Seven drugs and combinations are identified as targeted medicine, including: Efavirenz; heat-stable Ritonavir; Tenofovir; Lamivudine; Abacavir; a combinataion of Lopinavir with heat-stable Ritonavir; and a combination of Atazanavir with Ritonavir.[366] All of these drugs are critical for a treatment program in developing countries, but some of them have no generic substitute.[367] Some are more important in certain countries given the patients' profiles and resistance patterns.[368] Evidence also shows that most of these drugs are patented in major developing countries that have manufacturing capacity in this field.[369] A patent pool can simplify the licensing process and help reduce costs and overhead expenditures.[370] The benefit of a patent pool of these drugs is evident from the fact that:

> Without a patent pool, coordination of the right to manufacture and sell combinations and new formulations of anti-retroviral medicines

360. *See generally* GOLD ET AL., *supra* note 352.
361. *See id.* at 45.
362. *Id.*
363. *Id.* at iv.
364. *Id.* at 34.
365. *See* GOLD ET AL., *supra* note 352, at vi.
366. *Id.* at 63.
367. *Id.* at 24.
368. *See id.* at 1.
369. *See id.* at 66-68.
370. GOLD ET AL., *supra* note 352, at 3.

> for developing countries is costly and time consuming . . . In the example of an Atazanavir/Ritonavir combination, each of the patent-holders would need to individually license each manufacturer and distributor . . . This is not only complicated, but is time-consuming and requires a significant investment in simply negotiating and managing the various licenses. . . . The pool would also use standard licensing agreements, reducing transaction costs and harmonizing royalty rates, countries covered and general responsibilities. Further, the pool would be in a position to impose quality standards and monitor compliance with those standards through the use of appropriate licensing terms. The pool could also be easily adapted to new formulations and combinations.[371]

A patent pool can be established through both volunteer and compulsory measures, but a UNITAID pool will adopt a volunteer licensing scheme.[372] The selection of participants is a crucial aspect of a patent pool, and in addition to patent holders, the identification of licensees is highly critical.[373] Given the fact that very few developing countries have sophisticated medicine manufacturing capacity, a pool should be created with a good mix of licensees, both from developed and developing countries.[374] Indian companies are in a unique position to lead this process as will be discussed.

James Love conducted a cost-benefit analysis for UNITAID's patent pool in 2008 and presented different scenarios in which a patent pool can efficiently work.[375] This analysis presumes that a patent pool will be initially focused on fixed-dose combinations of anti-retroviral drugs, and Love provides cost analysis of first and second line treatments for AIDS.[376] The main objective is to establish an access point in which a patent pool can contribute in lowering the prices of concerned anti-retroviral drugs.[377] The role of patent pools in price reduction and in enhancing affordability is a crucial issue. The first TIP study did not conclude anything on this point, finding that:

> The capacity of the pool to address affordability is less certain. While a pool will likely lessen the costs of medicines through in-

371. *Id.*

372. *See* GOLD ET AL., *supra* note 352, at 33; *see* GlaxoSmithKline, Global Public Policy Issues: GlaxoSmithKline's Position: Voluntary Licensing of ARVs (2009), http://www.gsk.com/policies/GSK-on-voluntary-licensing-of-ARVs.pdf.

373. *See* GOLD ET AL., *supra* note 352, at 40.

374. *See id.*

375. James Love, *Annex 1: Cost Benefit Analysis for UNITAID Patent Pool, in* Biotech Patent Pool Workshop, 1, 18-21 (2008), http://www.law.berkeley.edu/institutes/bclt/patentpools/Panel%202%203.pdf.

376. *Id.* at 9.

377. *Id.* at 20.

> creased competition, it is unclear how significant those cost reductions will be and whether there are better tools to specifically target costs. These other tools could include, for example, advance purchase commitments, the establishment of a prize fund, the creation of purchasing groups among purchasing countries and other non-governmental actors, formal price controls and so on.[378]

Love estimates that a UNITAID patent pool will cost approximately U.S. $1.5 million per year.[379] This figure is based on his calculations in three different scenarios comparing and varying innovators' prices, generic savings, patients' estimated population, and other related factors.[380] Love contends that patent pooling will improve access to essential medicines, concluding that:

> [A] patent pool will be only one factor among several in determining outcomes. In the absence of such a pool, generic suppliers, treatment activists, procurement managers, and developing country governments have managed to implement generic competition to some extent for many important products. The 'impact' of the pool is an assumption regarding the degree to which open competition is expanded by the existence and activities of a UNITAID patent pool.[381]

This analysis shows that establishing and implementing a patent pool is possible if relevant factors are considered carefully.

C. *Patent Pools and India*

India is an uneven innovator, and its technological capabilities vary sharply in different fields of R&D. This issue becomes peculiar when alternative R&D models are considered in India because the implications may vary across different technological fields. As a policy measure, it is very difficult to suggest the adoption of a particular model in a limited sphere of technological innovation (i.e. pharmaceutical). However, a policy response is generally coherent and all encompassing in order to demonstrate equal attention to all fields of science and technology.

The relevance of patent pools, as an alternative R&D strategy for the discovery of new and improved drugs, raises various questions. First, the very notion of patent pools within the domestic policy framework presumes the existence of certain key patents in a particular field of technology, and will potentially restrict future R&D. A

378. GOLD ET AL., *supra* note 352, at 37.
379. Love *supra* note 375, at 20.
380. *Id.* at 19-20.
381. *Id.* at 21.

patent pool solution might be considered to overcome this barrier. In India, the strategy of patent pools is an unlikely solution, at least for the time being, because of a lack of patents recorded in the area of pharmaceuticals and biomedical research that can be shared.[382] India can rely upon a number of flexibilities incorporated in the patent law to achieve the same objectives without being a target of criticism by multinational pharmaceutical. Nevertheless, an international patent pool proposal, such as initiatives launched by UNITAID and GSK, has many promising implications both for Indian local manufacturers and poor patients.[383] The following sections entertain the issue of the extent to which patent pools can be used as an alternative model of drug development in India.

A patent pool model for India may or may not be a relevant model depending on whether the party affected by the pool is a local manufacturer or patient. UNITAID's patent pool offers many opportunities for Indian pharmaceutical manufacturers. A patent pool for HIV/AIDS medicine does not automatically mean that pooled patented innovations will be licensed to Indian manufacturers. Nor will the patent pool give them unprecedented business opportunities throughout the world. As some indications show, patent holders involved in a patent pool may decide that manufacturing will take place in a particular developing country, such as South Africa.[384] However, both market dynamics and technological superiority favor Indian manufactures. Furthermore, it can be anticipated that Indian companies will capture the opportunities arising out of a patent pool, if not exclusively, then substantially.[385]

India's track record of supplying HIV/AIDS medicines to international humanitarian organizations is one example of Indian manufacturers taking advantage of available opportunities.[386] The importance and volume of Indian pharmaceuticals for the procure-

382. *See* Colleen V. Chien, *HIV/AIDS Drugs for Sub-Saharan Africa: How Do Brand and Generic Supply Compare?* 2 PLOS ONE, Mar. 2007, at 1, *available at* http://www.plosone.org/article/info:doi/10.1371/journal.pone.0000278.

383. *See* Press Release, World Health Organization, Innovative Funding Facility, Unitaid, Meets Indian Generic Manufacturers in Delhi (June 23, 2009), *available at* http://www.unitaid.eu/en/20080709113/News/UNITAID-moves-towards-a-patent-pool-for-medicines.html.

384. Oswald A. Mascarenhas et al., *Global Marketing of Lifesaving Drugs: An Analogical Model*, 22 J. CONSUMER MKTG., 404, 409 (2005).

385. *See* Andrew Maykuth, *India's Drug Firms Aim to Compete with Giants*, PHILA. INQUIRER, May 4, 2004, at A01.

386. *See* 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*, 42 AM. BUS. L.J. 353, 381-82 (2004) (discussing India's role as a major provider of generic anti-AIDS drugs).

ment programs of international organizations, like UNITAID and WHO, is well known.[387] The proposed UNITAID patent pool will probably start with: Efavirenz; heat-stable Ritonavir; Tenofovir; Lamivudine; Abacavir; Lopinavir-Ritonavir; and Atazanavir-Ritonavir.[388] The objective of this pool is to achieve fixed-dose combinations.[389] It would be very advantageous for Indian manufacturers to become involved in this arrangement.[390] Indian manufacturers are already producing most of the first and second line anti-retroviral. Furthermore, even in the market of adult fixed-dose combinations, Indian generic manufactures are at the forefront.[391]

Table 1 shows the comparative advantage that Indian manufacturers are currently enjoying. This data reveals interesting insight into HIV/AIDS drugs and its manufacturers. It is evident that Indian generic manufactures play a vital role in producing affordable generic versions of medicine. They have also, over periods of time, developed the sophisticated technological base required to undertake this task.[392] The Indian generics industry share is almost eighty-five percent of the total Indian market and makes approximately $900 million a year from Indian sales.[393] Additionally, India is the world's largest manufacturer of generic anti-AIDS drugs.[394] Cipla, a well-known Indian generics manufacturer, offered to sell the Sub-Saharan African government fifty-three percent of its generic anti-retroviral drugs for $600 per year, compared to the $10,000 to $15,000 annual cost in the United States.[395] Thus, the Western pharmaceutical industry may have some concern about Indian pharmaceutical companies because they can supply cheaper versions of patented drugs to countries seeking low-cost imports.[396]

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387. *See id.*

388. GOLD ET AL., *supra* note 352, at 63.

389. 389.17TH EXPERT COMM. ON THE SELECTION AND USE OF ESSENTIAL MED., WORLD HEALTH ORG., 1 UNITAID AND WHO SECRETARIAT PROPOSAL: THE PRIORITY MISSING ESSENTIAL MEDICINES FOR HIV (2009), http://www.who.int/selection_medicines/committees/expert/17/Essential_Missing_ARVS.pdf.

390. *See* Sandhya Srinivasan, *India: Anti-HIV Drugs Made Here, but Most Can't Afford Them*, REDORBIT NEWS, (Nov. 22, 2005), http://www.redorbit.com/news/health/312138/india_antihiv_drugs_made_here_but_most_cant_afford_them/.

391. *See* Daniele Dionisio et al., *HIV Drug Policies and South Markets: Settling Controversies,* 5 THERAPY 707, 709 (2008).

392. Ficci-b2b.com, Sectoral Overview: Drugs & Pharmaceuticals, http://ficci-b2b.com/sector-drugs-overview.asp (last visited Oct. 15, 2009).

393. Sherman & Oakley, *supra* note 386, at 382.

394. *Id.*

395. *Id.*

396. *Id.*

With the implementation of UNITAID's patent pools for HIV/AIDS medicine, Indian firms will simply increase their manufacturing base by assuming a strong position as potential licensees.[397] Developing new manufacturing facilities through patent pools will not be a viable option, both for economic and technological reasons. It is also important to note that this large-scale generic activity in HIV/AIDS medicine is not due to the presence of brand name companies.[398] Nor is it the case that brand name companies are finding it hard to enforce their patent rights. Indian manufacturers are producing these drugs. Many Indian generic manufacturers entered into the HIV/AIDS medicine business only after the announcement of the United States President's Emergency Plan for HIV/AIDS Relief Initiative (PEPFAR) in 2004.[399] Moreover, they are already in licensing arrangements with brand name companies.[400] Other companies are getting the benefit of automatic licensing provisions incorporated into Indian patent law, as they started manufacturing these drugs well before the enactment of new law and were given blanket immunity from infringement prosecution.[401]

A patent pool along these lines can be highly useful for Indian patients too because of the large domestic market in India for the consumption of HIV/AIDS medicine.[402] As philanthropy starts from home, Indian companies can initially address the needs of the local segment. At the same time, they can build a strong case to become partner in the proposed patent pool. India has the second highest number of patients in the world living with HIV/AIDS,[403] and most of these patients desperately need affordable drugs.[404] UNITAID's patent pool can become a great hope for them. However, careful consid-

397. *See* UNITAID, UNITAID Moves Towards a Patent Pool for Medicines (July 9, 2008), http://www.unitaid.eu/en/20080709113/News/UNITAID-moves-towards-a-patent-pool-for-medicines.html.

398. *See* THE WORLD BANK, BATTLING HIV/AIDS: A DECISION MAKER'S GUIDE TO THE PROCUREMENT OF MEDICINES AND RELATED SUPPLIES 82 (Yolanda Tayler ed., 2004).

399. *See* Jonathan Todres et al., *International Health Law*, 41 INT'L L. 629, 632 (2007) (discussing the manufacture of a once-a-day AIDS drug used in the PEPFAR distribution chain).

400. *Id.*

401. *See* Janice M. Mueller, *Taking TRIPS to India—Novartis, Patent Law, and Access to Medicines*, 6 NEW ENG. J. MED. 541, 542 (2007).

402. Susan Finston, *India: A Cautionary Tale on the Critical Importance of Intellectual Property Protection*, 12 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 887, 892-93 (2001).

403. *India 'Second Highest in AIDS,'* BBC NEWS (London), July 3, 2002, *available at* http://www.aegis.com/news/bbc/2002/BB020707.html.

404. Press Release, Brook K. Baker, Policy Analyst Health GAP (Global Access Project), India's 2005 Patent Act: Death by Patent or Universal Access to Second- and Future-Generation ARVs? (Sept. 19, 2005) (on file with author).

eration of additional facts reveals that Indian companies will not be the absolute beneficiaries of a patent pool windfall.[405]

On the contrary, the first market-driven patent pool proposal by GSK carries less optimism for Indian generic manufacturers.[406] The GSK patent pool is aimed at facilitating the development of new drugs for the treatment of neglected tropical diseases.[407] GSK has provided a list of 16 such diseases, including: tuberculosis, malaria, blinding trachoma, buruli ulcer, cholera, dengue/dengue haemorrhagic fever, racunculiasis, fascioliasis, human African trypanosomiasis, leishmaniasis, leprosy, lymphatic filariasis, onchocerciasis, schistosomiasis, soil transmitted helminthiasis and yaws.[408]

GSK's patent pool is exclusively for the development of products for developing countries, and domestic use in India is thus automatically out of question, despite the fact that some designated diseases are prevalent in India.[409] The humanitarian benefit of this initiative is not a relevant factor for India. The remaining question considers the commercial prospects, which Indian generic manufactures may have under GSK's arrangements. Theoretically speaking, there should be a fair and equal chance for Indian manufacturers to compete for the licenses of pooled patents.[410] It is clear that GSK wants to contribute to the global response to the HIV/AIDS pandemic.[411] To achieve this objective, GSK negotiates preferential pricing arrangements with middle-income countries on a case-by-case basis.[412] They also aim to grant voluntary licenses to the most appropriate licensee to ensure a long-term supply of good quality medicine.[413] So, for domestic purposes, Indian companies will have to negotiate a royalty fee with

405. *See* GlaxoSmithKline, GSK's Contribution to the Pool, http://www.gsk.com/collaborations/contributions.htm (last visited Oct. 15 2009) [hereinafter GSK's Contribution] (discussing the types of disease GSK's patent pool will target and the types of countries the patent pool will be available to).

406. *See id.*

407. *See* GlaxoSmithKline, Creating a Pool of Intellectual Property to Fight Neglected Tropical Diseases, http://gsk.com/collaborations/patentpool.htm (last visited Oct. 15, 2009) [hereinafter Creating a Pool].

408. GSK's Contribution, *supra* note 405.

409. *See id.*

410. *See* Julia A. Martin, *Proposition 187, Tuberculosis, and the Immigration Epidemic?*, 7 STAN. L. & POL'Y REV. 89, 91-2 (1996) (discussing the prevalence of tuberculosis in India).

411. GLAXOSMITHKLINE, CORPORATE RESPONSIBILITY REPORT: A HUMAN RACE, 23 (2006).

412. *Id.*

413. *Id.*

GSK, or, in turn, need to sell their follow-up inventions back to GSK.[414]

Notably, GSK has categorically excluded HIV/AIDS patents[415] from this patent pool. Thus, given the patent data on the anti-retroviral drugs mentioned above and GSK's share in it, a large segment of the patient population will not benefit from this pool.[416] GSK's tuberculosis related patents will be available in patent pools, but again, the implications for Indian patients are slight because India is not considered one of the least developed countries.[417] Indian companies can, however, seek licenses from the proposed pool to improve their technology base in this area with very little effects on the affordability and accessibility of these drugs in India.[418]

As illustrated, a patent pool could definitely be applied in the Indian context. The relevance of a patent pool in India largely depends upon its nature and arrangement. An international patent pool initiative such as UNITAID will be extremely relevant in India, and both patients and the industry will benefit from such a scheme. Also, as indicated, a purely industry-based initiative such as GSK's patent pool may not be useful for practical reasons. The industry's strategic positioning and dynamics of ongoing competition in the pharmaceutical market will likely dictate the terms and conditions of patent pool alliances.

V. CONCLUSION

Academic institutions have great potential to transform the existing state of patent policies and practices by revisiting their role amidst the global medicine crisis. American universities are increasingly showing their interest in new forms of socially responsible licenses. Furthermore, in certain cases, equitable licensing terms are incorporated in recently concluded technology commercialization agreements. However, India's government seems reluctant to integrate an equitable licensing regime, and existing rules are likely to remain.

The options are considerably limited for introducing a cogent and publicly minded licensing regime. The most promising opportunities

414. *See* GlaxoSmithKline, License Terms, http://www.gsk.com/collaborations/licence-terms.htm (last visited Oct. 15, 2009) [hereinafter GSK's License Terms].

415. *See* GlaxoSmithKline, FAQs, http://www.gsk.com/collaborations/faqs.htm (last visited Oct. 15, 2009).

416. *See* GSK's Contribution, *supra* note 405.

417. *Id.*

418. *See* GSK's License Terms, *supra* note 414.

lie in transforming institutional principles, which allow for experimentation in intellectual property licensing. Equitable licensing options are also more likely to be relevant in the Indian context. While the Bayh-Dole Act influences existing licensing practices of publicly funded R&D, it poses serious challenges to developing economies, and India's proposed legislation fails to consider the level of its own economic and scientific development.[419]

Open source licensing offers numerous opportunities for India, with almost no associated risks. The Indian government can enhance its developmental policy goals with open source initiatives. A policy framework that encourages open source methods will strengthen India's support and push for the Development Agenda at the platform of World Intellectual Property Organization.[420] On the other hand, a patent based incentive system to stimulate publicly funded research may hamper India's position and do very little to increase public access to innovation.[421] Although an offshoot of intellectual property management through collective licensing in the form of patent pools is possible and promising for India, it cannot practically benefit from this mechanism. The Indian domestic patent base is weak and sporadic, and patent barriers have yet to play their role in Indian innovation.[422] The objectives of patent pools can be easily managed with the help of safeguard provisions under Indian patent law. Thus, India could become the largest beneficiary of an international patent pool. To conclude, OSDD is the best option for India to build a strong, scientific base with equitable access norms. A socially responsible licensing regime can create a mutual relationship between universities and funding agencies by allowing patients to benefit from India's innovative capabilities.

419. *See* Sara Boettiger & Alan Bennett, *The Bayh-Dole Act: Implications for Developing Countries*, 46 IDEA 261, 262 (2006) (discussing the potentially negative effect on the poor from the North's concentrated ownership and control of technologies necessary for health); Janice M. Mueller, *Biotechnology Patenting in India: Will Bio-generics Lead a "Sunrise Industry" to Bio-Innovation?*, 76 UMKC L. REV. 437, 448 (2007) (describing India's lack of Bayh-Dole Act-style legislation).

420. *See* MARTIN KHOR & SANGEETA SHASHIKANT, CHOIKE, SOUTH COUNTRIES ELABORATE ON THEIR WIPO DEVELOPMENT AGENDA (2009), http://www.choike.org/nuevo_eng /informes/2836.html; Shailly Gupta, Critique on Public Funded R&D Project Bill: Indian Version of U.S. Bayh Dole Act (Oct. 20, 2008), http://centad.org/focus_64.asp.

421. *See* Gupta, *supra* note 420.

422. *See* Stephen Barnes, *Pharmaceutical Patents and TRIPS: A Comparison of India and South Africa*, 91 KY. L.J. 911, 919 (2003) (discussing India's basis for adopting weak patent laws).

TABLE 1

First-line Anti-retrovirals (ARV's)			
Drug	**Originator/Patent Holder**	**Indian Generic Producers**	**Generic Producers in the Rest of the World**
Stavudine (d4T) Zerit	Bristol Myers Squibb	Cipla, Hetero, Matrix, Ranbaxy, Aurobindo, Strides Acrolabs, Emcure	Duopharma (Malaysia), Aspen Pharmacare (South Africa), Ranbaxy (Malaysia)
Zidovudine (ZDV) *Retrovir*	GlaxoSmithKline (UK)	Ranbaxy, Cipla Ltd, Hetero, Strides Acrolabs, Aurobindo, Emcure, Matrix	Aspen Pharmacare (South Africa)
Zidovundine (AZT) *Retrovir*	GlaxoSmithKline (UK)	Matrix, Strides Acrolabs, Hetero, Aurobindo, Cipla, Ranbaxy, Micro Labs	Aspen Pharmacare (South Africa), Apotex Inc (Canada)
Lamivudine (3TC) *Epivir*	GlaxoSmithKline (UK)	Cipla Ltd, Aurobindo, Micro Labs, Ranbaxy, Matrix, Strides Acrolabs, Hetero, Emcure	Aspen Pharmacare (South Africa)
Nevirapine (NVP) *Viramune*	Boehringer Ingleheim (USA)	Ranbaxy, Cipla Ltd, Aurobindo, Hetero, Strides Acrolabs, Emcure, Matrix, Micro Labs	Aspen Pharmacare (South Africa), Huahai Pharmaceutical (China), Duopharma (Malaysia)
Efavirenz (EFV) (200 mg) *Stocrin 200*	Merck	Ranbaxy, Aurobindo, Strides Acrolabs, Hetero, Micro Labs, Cipla Ltd.	
Efavirenz (EFZ) (600 mg) *Stocrin 600*	Bristol Myers Squibb (Puerto Rico), Merck Sharp and Dohme (Australia)	Cipla, Hetero, Matrix, Aurobindo, Strides Acrolabs, Ranbaxy, Emcure, Micro Labs, Emcure	
Emtricitabine (FTC) *Emtrival*	Gilead Sciences but Merck owns the rights for Canada and Australia	Aurobindo, Matrix, Cipla	
Didanosine (DDI) (200 mg) *Videx*	Bristol Myers Squibb	Aurobindo, Micro Labs, Cipla Ltd.	
Didanosine (DDI) (400 mg) *Videx EC*	Bristol Myers Squibb	Aurobindo, Ranbaxy, Micro Labs	

Second-line Anti-retrovirals			
Tenofovir disoproxil fumarate (TDF) *Viread*	Gilead Sciences	Cipla Ltd, Aurobindo, Hetero, Strides Acrolabs, Matrix, Ranbaxy	
Indinavir (IVD) *Crixivan*	Merck	Ranbaxy, Strides Acrolabs, Emcure, Micro Labs, Hetero, Cipla Ltd, Cadila Pharmaceuticals	
Lopinavir (LPV/r) *Kaletra*	Abbott	Aurobindo, Hetero, Emcure, Matrix, Ranbaxy, Cipla Ltd.	
Nelfinavir (NFV) *Viracept*	Pfizer, but Roche has the distribution rights	Cipla Ltd, Aurobindo, Hetero, Emcure	
Abacavir (ABC) *Ziagen*	GlaxoSmithKline	Ranbaxy, Cipla Ltd, Aurobindo, Hetero, Strides Acrolabs, Emcure, Matrix	
Atazanavir (ATV) *Riyataz*	Bristol Myers Squibb	Hetero, Emcure, Matrix, Aurobindo	Aspen Pharmacare (SA)
Saquinavir (SQV) *Fortovase or Invirase*	Roche		
Ritonavir *Norvir*,	Abbott	Aurobindo, Matrix, Ranbaxy, Cipla Ltd	
Adult Fixed-dose Combinations			
Abacavir + Lamivudine 600 mg + 300 mg (ABC + 3TC	GlaxoSmithKline (UK)	Aurobindo, Cipla Ltd., Hetero Drugs	
Abacavir + Lamivudine + Zidovudine 300mg + 150 mg + 300mg (ABC + 3TC + AZT)	GlaxoSmithKline (UK)	Matrix Laboratories, Ranbaxy, Aurobindo, Hetero Drugs	
Didanosine + Efavirenz + Lamivudine (ddI + EFV + 3TC) 400mg + 600mg + 300mg		Cipla Ltd.	

Efavirenz + Emtricitabine + Tenofovir 600mg + 200mg + 300mg (EFV + FTC + TDF)	Merck Sharp and Dohme (Canada; the Netherlands), Bristol Myers Squibb and Gilead Sciences Int. (Canada)	Matrix Laboratories, Cipla Ltd	
Efavirenz + Lamivudine + Stavudine 600mg + 150 mg + 30mg/ 40 mg (EFV + 3TC + d4T)		Strides Acrolabs, Emcure, Ranbaxy	
Efavirenz + Lamivudine + Zidovudine 600mg + 150mg + 300mg (EFV + 3TC + AZT)		Ranbaxy, Strides Acrolabs, Aurobindo, Cipla Ltd., Emcure	
Emtricitabine + Tenofovir 200mg + 300 mg (FTC + TDF)	Gilead Sciences	Hetero Drugs, Strides Acrolabs	
Lamivudine + Zidovudine 150mg + 300mg (3TC + AZT)	GlaxoSmithKline (UK), Pharmacare Ltd. (South Africa)	Cipla Ltd., Hetero Drugs, Cadila Pharmaceuticals, Ranbaxy, Matrix Laboratories, Aurobindo, Strides Acrolabs, Emcure	
Lamivudine + Nevirapine + Zidovudine 150 mg + 200mg + 300 mg (3TC + NVP + AZT)		Strides Acrolabs, Hetero Drugs Ltd.	Aspen Pharmacare (South Africa)
Lamivudine + Stavudine 150 mg + 30 mg/ 40 mg (3TC + d4T		Cipla Ltd., Ranbaxy, Strides Acrolabs, Aurobindo, Matrix Laboratories, Hetero Drugs, Emcure	

Source: *Padmashree Gehl Sampth*[423]

423. Padmashree Ghel Sampath, UK Dept. for Int'l Dev., India's Pharmaceutical Sector in 2008: Emerging Strategies and Global and Local Implications for Access to Medicines, 41-46 (2008), http://www.genomicsnetwork.ac.uk/esrcgenomicsnetwork/publications/reports/title,21120,en.html.