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# Open Source Approaches in Biotechnology: Utopia Revisited

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# OPEN SOURCE APPROACHES IN BIOTECHNOLOGY: UTOPIA REVISITED

Yann Joly

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# OPEN SOURCE APPROACHES IN BIOTECHNOLOGY: UTOPIA REVISITED

Yann Joly\*

# I. INTRODUCTION

Tracing its origin to Greek antiquity,<sup>1</sup> intellectual property has become an institution in modern legal systems worldwide.<sup>2</sup> This growing importance of intellectual property was confirmed with the 1994 adoption of the *Trade-Related Aspects of Intellectual Property Rights Agreement* by the World Trade Organization (WTO), which harmonized the rules of intellectual property amongst the various members of the international community on the model of developed countries.<sup>3</sup>

However enshrined in the legal tradition, intellectual property law has also had its share of detractors and has recently come under severe criticism.<sup>4</sup> The exercise of intellectual property rights in such diverse fields of creation as music, information technology, and biotechnology has met with intense opposition from a growing number of detractors.<sup>5</sup> In the field of biotechnology, the critique has become important enough to arouse the attention of a number of legislative bodies and propel the creation of an important corpus of normative documents (recommendations, position statements, declarations, etc.).<sup>6</sup> Surprisingly, this legislative outburst, aimed at correcting certain deficiencies of the patent system, was driven by a number of theoretical hypotheses that were unconfirmed by the available evidence.<sup>7</sup> Various solutions have been proposed in these normative documents to palliate certain presumed failings of the patent system: compulsory licenses, adoption of moratoria on gene patents, parallel

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<sup>1.</sup> See Pamela O. Long, Invention, Authorship, "Intellectual Property," and the Origin of Patents: Notes Toward a Conceptual History, 32 TECH. & CULTURE 846, 846 (1991).

<sup>2.</sup> Ann Hironaka, Changing Meanings, Changing Institutions: An Institutional Analysis of Patent Legislation, 72 Soc. INQUIRY 108, 113-14 (2002).

<sup>3.</sup> World Trade Organization, Agreement on Trade-Related Aspects of Intellectual Property Rights, 1994, WTO.

<sup>4.</sup> Yann Joly, Winds of Change: In re Fisher and the Evolution of the American Biotechnology Patent Law, 25 LAW IN CONTEXT 67, 71-73 (2007).

<sup>5.</sup> See, e.g., KEITH E. MASKUS, INTELLECTUAL PROPERTY RIGHTS IN THE GLOBAL ECONOMY (Institute for International Economics ed., 2000).

<sup>6.</sup> E.g., Canadian Bioethics Advisory Committee (CBAC), United States Patent Office (PTO), Office of Technology Assessment, United Nations Educational, Scientific and Cultural Organization (UNESCO).

<sup>7.</sup> Timothy Caulfield et al., Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies, 24 NAT. BIOTECH. 1091, 1091-92 (2006); see also infra Part II.

imports, and more restrictive evaluation of patent applications. Alongside these policy solutions, the use of cooperative strategies to facilitate the use of patented inventions has become a particularly popular alternative in academia.

It has been suggested that cooperative strategies—such as open source, patent pools, and defensive publication-could correct the inadequacies generated by the application of the patent system to biotechnological inventions without requiring a major change in current intellectual property laws. Thus, the main justification invoked in favor of the introduction of open source approaches in biotechnology is that it would remedy the various failings of the patent system. The numerous articles discussing these approaches all follow a similar structure.<sup>8</sup> The author usually begins by discussing the idyllic culture of open science that is said to have prevailed in the pre-1980 academic biomedical research field, and expresses his or her regret at the recent commercialization of academia and its adverse effect on fundamental research. He or she then advances his or her central argument in favor of open source as a solution to the possible existence of an "anticommons effect" in biomedical research that could slow down or possibly immobilize the progress of science. After reassuring readers that the introduction of open source approaches would likely prevent such a catastrophic scenario, the article ends on a positive note by evasively mentioning some of the more intrinsic benefits of these approaches.

It is not necessarily prudent for proponents of cooperative strategies to use, as a central part of their argumentation, a negative discourse that focuses largely on hypothetical risks unsubstantiated by the available empirical evidence. A better strategy would be to identify and promote the wealth of intrinsic benefits associated with these strategies in order to keep them attractive, independent from any evaluation of the patent system.

This Article will begin with a discussion of the patent system and of the cooperative approaches to licensing. It will then investigate the claim that the patent system has created an anticommons effect in the field of biotechnology by evaluating the available empirical data in order to determine whether open source approaches are needed to improve this situation. This Article will then present the various intrinsic benefits of the open source approaches reported in current academic literature. Ultimately, the Article will conclude that the collaborative approaches' intrinsic advantages not only justify the use of such methods in the biomedical research sector, but could also allow the sector to become more dynamic and functional.

#### II. OPEN SOURCE AS AN ALTERNATIVE TO INTELLECTUAL PROPERTY?

#### A. Intellectual Property: A Contemporary Perspective

A patent is a property right limited in time. It is granted by a patent office upon the filing of a patent application to an inventor, giving him the exclusive right to work his invention in the country (or countries) where the patent was granted. Although patents constitute a form of intellectual property, they do not confer property rights on

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<sup>8.</sup> E.g., Arti K. Rai, "Open and Collaborative" Research: A New Model for Biomedicine, in INTELLECTUAL PROPERTY RIGHTS IN FRONTIER INDUSTRIES, 131-58 (Robert W. Hahn ed., 2005); Matthew Herder, Presentation at Dalhousie Law School: Open Sourcing Stem Cells in Canada (March 10, 2006).

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the physical manifestation of the intangible invention.<sup>9</sup> The patent owner will need to conform to the regulatory framework applicable in the country where the invention will be used. A valid patent must also meet certain legal patentability criteria: utility, novelty, and non-obviousness.<sup>10</sup> An acceptable patent application will need to describe the invention precisely and completely, and must contain a description of the best mode known to the inventor for carrying out the invention.<sup>11</sup> Fees will need to be paid to the patent office in order to obtain and maintain the patent right on the invention.<sup>12</sup>

Patents are also expensive; the minimum cost to obtain and maintain a relatively simple patent in the United States for twenty years is around \$10,000. However, extending this patent to nine other countries could cost between \$160,000 and \$330,000, according to a research from the United States General Accounting Office.<sup>13</sup> It is also costly to enforce patents: legal defenses typically cost \$1.6 million per contested patent.<sup>14</sup> The high price of patents makes them tools that are better suited for large companies than for independent inventors. Mechanisms used to enforce or challenge patent rights are perceived by some as unpractical, time consuming, and expensive.<sup>15</sup> These limitations explain, in part, the large number of bad patents in existence.<sup>16</sup>

The patent system is usually justified on utilitarian grounds as a tool to stimulate the innovation and development of inventions for the greater good of society.<sup>17</sup> The inventor benefits from an exclusive right, limited in time, on his invention in exchange for publicly divulging it. Thus, according to its proponents, the system promotes both the interests of the inventor—who is given a means to recuperate the financial investments made for his invention—and the interests of the public—which is allowed to access information that would otherwise be held as a trade secret.<sup>18</sup> However, this argument also demonstrates the existence of a fundamental contradiction within the patent system. The system aims to stimulate innovation by granting an exclusive right to the inventor, who will then have the means to restrict the use and the perfecting of his invention by others.<sup>19</sup> Aware of this apparent contradiction, economist Joan Robinson commented, "Since it is rooted in a contradiction, there can be no such thing as an ideally beneficial patent system, and it is bound to produce negative results in

<sup>9.</sup> Yann Joly, *Biotechnologies et brevets: le cas de la pharmacogénomique*, 10 LEX ELECTRONICA 1, 9, Été 2005, *available at* http://www.lex-electronica.org/articles/v10-2/joly.pdf.

<sup>10.</sup> Patent Act, 35 U.S.C. §§ 100-103 (2000).

<sup>11.</sup> Joly, supra note 9, at 10.

<sup>12.</sup> See Patent Act, 35 U.S.C. § 41 (2000).

<sup>13.</sup> United States General Accounting Offices, Report to Congressional Requesters 10 (GAO-02-789) (2002).

<sup>14.</sup> David Malakoff, Will a Smaller Genome Complicate the Patent Chase?, 291 SCIENCE 1194, 1194 (2001).

<sup>15.</sup> Id. at 1194; Pamela Samuelson, Legally Speaking: Why Reform the U.S. Patent System?, 47 COMM. ACM 19, 19 (2004); Brian Kahin, The Expansion of the Patent System: Politics and Political Economy, 6 FIRST MONDAY, Jan. 8, 2001, available at http://www.firstmonday.org/issues/issue6 1/kahin/.

<sup>16.</sup> Mark Lemley et al., What to Do About Bad Patents, 28 REGULATION 10, Winter 2005-06, at 10. 17. William Fisher, Theories of Intellectual Property, in NEW ESSAYS ON LEGAL AND POLITICAL THEORY OF PROPERTY 168, 169 (Stephen R. Munzer ed., 2001).

Edwin C. Hettinger, Justifying Intellectual Property, 18 PHIL. & PUB. AFF. 31, 48 (1989).
Id.

particular instances, impeding progress unnecessarily, even if its general effect is favourable on balance."<sup>20</sup>

Some of the limitations of the patent system have also become apparent in the recent harmonization process initiated at the international level by the WTO, which has seen developed countries of the northern hemisphere export their own highly protectionist regimes to the rest of the world. It was claimed that the harmonization would improve international technology transfer for the benefit of developing countries; emerging evidence, however, has yet to demonstrate such positive results.<sup>21</sup> Moreover, vastly publicized debacles involving patents and access to HIV medicine—such as the Pretoria trial<sup>22</sup> and the United States-Brazil dispute<sup>23</sup>—have made the patent system highly unpopular.<sup>24</sup> According to several authors, alternative solutions are needed because the prospect of success in importing strong patent regimes from developed countries to foster innovation and technology transfer in developing countries seems unlikely at best.<sup>25</sup>

The extension of the patent system to the field of biotechnology has also raised significant criticism. Critics have been quick to point out the risks of the liberal gene patenting policies in force in the United States and often imitated in other countries. Genetic patents have been criticized on moral grounds as being dehumanizing,<sup>26</sup> an affront to human dignity,<sup>27</sup> and incompatible with religious beliefs.<sup>28</sup> Merges and Nelson argued that broad patents on foundational discoveries could limit the use of these discoveries in subsequent research and consequently reduce the pace and direction of new innovations.<sup>29</sup> Heller and Eisenberg suggested that genetic research tool patents could create a "tragedy of the anticommons," which they define as the underutilization of a scarce resource caused by multiple owners blocking each other through the proliferation of fragmented and overlapping intellectual property rights.<sup>30</sup> Shapiro theorized that in some "key industries, including... biotechnology, the patent system is creating a *patent thicket*: an overlapping set of patent rights requiring ...

<sup>20.</sup> JOAN ROBINSON, THE ACCUMULATION OF CAPITAL 87 (3d ed., 1956).

<sup>21.</sup> Keith E. Maskus & Jerome H. Reichman, *The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods, in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY: UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME 3, 23 (Keith E. Maskus & Jerome H. Reichman eds., 2005).

<sup>22.</sup> Pharm. Mfrs. Ass'n v. President of the Republic of South Africa, Case No. 4183/98 (High Ct. of S. Afr., Transvaal Provincial Division, Feb. 18, 1998).

<sup>23.</sup> Request for the Establishment of a Panel by the United States, *Brazil—Measures Affecting Patent Protection*, WT/DS199/3 (Jan. 9, 2001).

<sup>24.</sup> GRAHAM DUTFIELD, INTELLECTUAL PROPERTY RIGHTS IN THE LIFE SCIENCE INDUSTRIES 224-25 (Ashgate Publishing Company 2002).

<sup>25.</sup> Maskus & Reichman, supra note 21, at 18.

<sup>26.</sup> See Leon R. Kass, Organs for Sale? Propriety, Property, and the Price of Progress, 107 PUB. INT. 65, 76-82 (1992).

<sup>27.</sup> See id.

<sup>28.</sup> Joint Appeal against Human and Animal Patenting (May 17, 1995) (on file with the National Press Club).

<sup>29.</sup> See Robert P. Merges & Richard R. Nelson, On the Complex Economics of Patent Scope, 90 COLUM. L. REV. 839, 845-49, 908-09 (1990).

<sup>30.</sup> Michael A. Heller & Rebecca S. Eisenberg, Can Patents Deter Innovation? The Anticommons in Biomedical Research, 280 SCIENCE 698, 699-700 (1998).

those seeking to commercialize new technology [to] obtain licenses from multiple patentees."<sup>31</sup> Blumenthal concluded that commercial incentives are responsible for significant delays in the publication of research findings and stifled collaboration, especially in the field of biomedicine.<sup>32</sup> Merz and Cho claimed that patents on genetic tests not only trigger ethical concerns but also pose significant risks to patients, public health, and to the practice of medicine.<sup>33</sup> Finally, Matthijs proposed that the unique informational content locked away by patenting gene sequences makes it impossible for researchers to invent around them, essentially creating a *de facto* "double" monopoly.<sup>34</sup> Advocates of the patent system answered these critiques with varying degrees of success.<sup>35</sup>

These claimed shortcomings of the system have not shaken the faith of industry and governments of industrialized countries in intellectual property as an institution. It is still perceived as being responsible for high levels of innovation, investment, and concomitant prosperity. Intellectual property laws may not have been wholly responsible for this success, but observers believe they played a significant part.<sup>36</sup> Further empirical evidence would be needed in order for critiques to convince commercial and governmental actors that the patent system might not always be the most efficient tool to foster research and development, and that the system could benefit from substantial reforms.<sup>37</sup> Moreover, it has been suggested that the adoption of improved licensing practices in the public and private sectors would significantly reduce the prevalence of the claimed adverse effects of the patent system.<sup>38</sup>

<sup>31.</sup> Carl Shapiro, Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting, in 1 INNOVATION POLICY AND THE ECONOMY 119, 119 (Adam Jaffe et al. eds., 2000).

<sup>32.</sup> See David Blumenthal et al., Data Withholding in Genetics and the Other Life Sciences: Prevalences and Predictors, 81 ACAD. MED. 137, 145 (2006); see also David Blumenthal et al., Withholding Research Results in Academic Life Science: Evidence from a National Survey of Faculty, 277 J. AM. MED. ASS'N 1224, 1224 (1997).

<sup>33.</sup> Mildred K. Cho et al., *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5 J. MOLECULAR DIAGNOSTICS 3, 3 (2003); Jon F. Merz et al., *Diagnostic Testing Fails the Test*, 415 NATURE 577, 577 (2002).

<sup>34.</sup> Gert Matthijs, *Gene Patenting and Licensing on and Beyond the BRCA Case*, 10 EUR. SOC'Y HUM. GENETICS 13, 14 (2004).

<sup>35.</sup> E.g., F. Scott Kieff, Perusing Property Rights in DNA, in PERSPECTIVE ON PROPERTIES OF THE HUMAN GENOME PROJECT 125, 125-51 (F. Scott Kieffed., 2003); David B. Resnik, The Morality of Human Gene Patents, 7 KENNEDY INST. ETHICS J. 43, 51-57 (1997); John P. Walsh et al., View from the Bench: Patents and Material Transfers, 309 SCIENCE 2002 (2005) [hereinafter Walsh et al., View].

<sup>36.</sup> Sigrid Sterckx, Can Drug Patents be Morally Justified?, 11 SCI. & ENGINEERING ETHICS 81, 82 (2005).

<sup>37.</sup> E. Richard Gold et al., Needed: Model of Biotechnology Intellectual Property, 20 TRENDS BIOTECH. 327, 327 (2002).

<sup>38.</sup> See Organization for Economic Co-operation and Development (OECD) Guidelines for the Licensing of Genetic Inventions, *available at* http://www.oecd.org/document/26/0,2340,fr\_2649\_34537\_34317658\_1\_1\_1\_0.0.html; see generally Canadian Biotechnology Advisory Committee (CBAC), Human Genetic Materials, Intellectual Property and the Health Sector (2006), *available at* http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/vwapj/CBAC Report e.pdf/\$FILE/CBAC Report e.pdf.

#### B. From Open Science to Open Source

According to some authors, the concept of "scientific progress," which originated in the 16th and 17th centuries, has always been associated with the ideal of free and open dissemination of scientific knowledge.<sup>39</sup> In the beginning of the 20th century, the practice of patenting was perceived as unethical by a large portion of the biomedical academic community.<sup>40</sup> Early sociologists of science theorized that the research community was motivated by a number of social norms. These norms "operated as 'prescriptions, proscriptions, preferences and permissions . . . legitimated in terms of institutional values . . . transmitted by precept and example and reinforced by sanctions."<sup>41</sup> Regarding the property of research findings, a norm of "communism" or "communalism," dictated that these were a product of social collaboration, a common heritage that "should be dedicated to the scientific community."<sup>42</sup> In light of these communalist values, claiming property rights in inventions or keeping discoveries secret was discouraged prior to 1980.<sup>43</sup>

Open science is said to have prevailed both in the fields of biotechnology<sup>44</sup> and information technology in the pre-1980 era.<sup>45</sup> In 1980, Congress—following pressures from economic and legal circles—decided that traditional research norms, even though they allowed for the deposit of research results in the public domain, did not sufficiently encourage the development of commercializable products. Consequently, it adopted several laws favorable to patents and technology transfer to redress the situation.<sup>46</sup> The most important of these laws is the Bayh-Dole Act,<sup>47</sup> adopted to facilitate public access to the research financed by the federal government. This law had the objective of encouraging small enterprises, universities, and other not-for-profit contractors of the federal government to obtain patents on their inventions.<sup>48</sup> Thus, the 1980s started what many have now come to see as an era of commercialization,<sup>49</sup> in

44. Id.

46. Rai, *supra* note 43, at 88.

<sup>39.</sup> See, e.g., Charles Weiner, Patenting and Academic Research: Historical Case Studies, 12 SCI., TECH. & HUMAN VALUES 50, 50-51 (1987).

<sup>40.</sup> *Id*.

<sup>41.</sup> Janet E. Hope, *Open Source Biotechnology* (Dec. 23, 2004) (unpublished Ph.D. dissertation, The Australian National University) at 11 (quoting Merton, Certified Knowledge 40-41, 552-53 (1957)), available at http://opensource.mit.edu/papers/hope.pdf.

<sup>42.</sup> Rebecca S. Eisenberg, Proprietary Rights and the Norms of Science in Biotechnology Research 97 YALE L.J. 177, 183 (1987).

<sup>43.</sup> Arti Kaur Rai, Regulating Scientific Research: Intellectual Property Rights and the Norms of Science, 94 Nw. U. L. REV. 77, 88 (1999).

<sup>45.</sup> John Willinsky, The Unacknowledged Convergence of Open Source, Open Access, and Open Science, FIRST MONDAY, Aug. 1, 2005, available at http://www.firstmonday.org/issues/issue10\_8/ willinsky/.

<sup>47.</sup> Universities and Small Business Patent Procedures Act, Pub. L. No. 96-517, 94 Stat. 3015 (1980) (codified at 35 U.S.C. §§ 200-212 (2000)).

<sup>48.</sup> Arti K. Rai & Rebecca S. Eisenberg, Bayh-Dole Reform and the Progress of Biomedicine, 66 LAW AND CONTEMP. PROBS. 289, 290 (2003).

<sup>49.</sup> See Don Chalmers & Dianne Nicol, Commercialisation of Biotechnology: Public Trust and Research, 6 INT'L J. BIOTECH. 116 (2004); Benjamin Coriat & Fabienne Orsi, Establishing a New Intellectual Property Rights Regime in the United States; Origins, Content and Problems, 31 RES. POL'Y 1491 (2002).

which governments of other developed countries imitated United States's pro-patent policies with varying degrees of success.<sup>50</sup>

However, this popular binary picture of an ideal "open science" period as opposed to a grim era of commercialization is in some respects naïve and should be contextualized. The "norms of science" theory was not intended to demonstrate how science actually is (or was at the time); on the contrary, Merton argued that these norms were ideals towards which scientists were rather ambivalent.<sup>51</sup> Although the biomedical academic community demonstrated some resistance to patenting in the early part of the 20th century,<sup>52</sup> "no . . . specific prescriptive norm against seeking intellectual property existed in the basic biological science community before 1980, or thereafter."<sup>53</sup> Moreover, "fals sociologists of science have more recently demonstrated, scientists are not specially unbiased, altruistic or cooperative"; their interactions occasionally result in "fierce controversy, ruthless competition, personal animosity, greed and dishonesty."54 Thus, although early 20th century researchers were, to a certain extent, more inclined to share scientific findings rather than shroud them in secrecy, the applicability of the "norms of science" theory in the field of biology is now refuted by scholars from a variety of fields encompassing sociology. law, and biological science.

In contrast, the programming community that started to emerge after World War II—and that would eventually become known as "hackers"—undeniably tended towards the Mertonian ideal.<sup>55</sup> It is thus no surprise that the first open source project was born in the field of information technology in 1984.<sup>56</sup> The Free Software Foundation, created by Richard Stallman, was based on a software toolbox (GNU) and a general public license (GPL) that would eventually become the backbone of the free programming community. The GPL license, also called "copyleft," allowed everyone to run, copy, modify, and distribute modified versions of the program, but it did not authorize users to add restrictions of their own.<sup>57</sup>

<sup>50.</sup> Aldo Geuna & Lionel Nesta, University Patenting and its Effects on Academic Research: The Emerging European Evidence, 35 RES. POL'Y 772, 794-97 (2006).

<sup>51.</sup> Stephen Cole, Merton's Contribution to the Sociology of Science, 34 Soc. STUD. SCI. 829, 839 (2004).

<sup>52.</sup> Weiner, supra note 39, at 50.

<sup>53.</sup> Scott F. Kieff, Facilitating Scientific Research: Intellectual Property Rights and The Norms of Science—A Response to Rai and Eisenberg, 95 Nw. U. L. REV. 691, 692 (2001).

<sup>54.</sup> Janet E. Hope, Open Source Biotechnology, (unpublished Ph.D. thesis, The Australian National University) (December 2004), *available at* http://rsss.anu.edu.au/~janeth/OpenSourceBiotechnology27 July2005.pdf.

<sup>55.</sup> See Eric S. Raymond, The Revenge of the Hackers, in OPEN SOURCES: VOICES FROM THE OPEN SOURCE REVOLUTION (Chris DiBona et al. eds, 1999), available at http://www.oreilly.com/catalog/open sources/book/raymond2.html. A more controversial and insufficiently explored source of inspiration could originate from elements of the Marxist political theory. Components of both socialism and Marxism can be found in the works of the major proponents of the Free Software movement. It remains to be verified whether these ideological ingredients subsisted within the open source approach.

<sup>56.</sup> The non-rival and non-exclusive aspect of computer data likely facilitated the development of the open source approach in the field of information technology.

<sup>57.</sup> See Bruce Perens, The Open Source Definition, in OPEN SOURCES: VOICES FROM THE OPEN SOURCE REVOLUTION, supra note 55.

In 1997, Bruce Perens drafted the Open Source Definition in order to provide an alternative to the GNU/GPL that would be acceptable to those who did not share Richard Stallman's moral objections to proprietary software licensing. In 1998, Eric Raymond, Bruce Perens, and several others established the Open Source Initiative (OSI), a non-profit advocacy organization that would act as a certification body for open source licenses. A certification from the OSI would indicate compliance with the official Open Source Definition.<sup>58</sup>

The use of open source in the field of biotechnology is a recent phenomenon. In the last decade, biotechnology researchers began borrowing and adapting the approaches and concepts developed by programmers from the information technology sector; these efforts to engage in collaborative research were designed to alleviate the problems that poorer communities were experiencing with respect to accessing information, reduce the extent of overlapping patents, share the financial risk of highly exploratory research, and make biotechnology innovation tools widely available.<sup>59</sup> Inspired by Mertonian ideals, an impressive number of open source related initiatives started to develop, such as the International HapMap Project, the International Stem Cell Forum, the CAMBIA Biological Innovation for Open Society (BIOS) Initiative, the Open Source Stem Cell Research Platform, the SNP Consortium, and the P<sup>3</sup>G Observatory.<sup>60</sup>

The open source biotechnology movement is still in its infancy and promises to be much more heterogeneous than its information technology counterpart. Biotechnology projects associated with open source do not necessarily use methods similar to that of Richard Stallman or that would meet the Open Source Definition developed by Bruce Perens. Open source is often used as a catch-all category that designates a variety of approaches<sup>61</sup> aimed at facilitating the dissemination of biotechnology research results and fostering scientific collaboration. For example, the SARS IP Working Group and the SNP Consortium are both mentioned in the literature as examples of successful open source initiatives.<sup>62</sup> However, the SARS IP Working

<sup>58.</sup> Id.

<sup>59.</sup> Robin C. Feldman, *The Open Source Biotechnology Movement: Is It Patent Misuse?*, 6 MINN. J.L. SCI. & TECH. 117, 135 (2004).

<sup>60.</sup> International HapMap Project, About the HapMap, http://www.hapmap.org/thehapmap.html.en; International Stem Cell Forum, About the ISCF, http://www.stemcellforum.org.uk/about\_the\_iscf.cfm; CAMBIA, The CAMBIA BIOS Initiative: Biological Innovation for Open Society, http://www.cambia.org.au/daisy/bios/10/version/live/part/4/data; U.S. BioDefense Inc., U.S. BioDefense Stem Cell News, http://www.usbiodefense.com/; Wellcome Trust, The SNP Consortium and International HapMap Project, http://www.wellcome.ac.uk/doc%5Fwtd003500.html; P<sup>3</sup>G Project, P<sup>3</sup>G: Public Population Project in Genomics, http://www.p3gconsortium.org/.

<sup>61.</sup> Some of these approaches include defensive publications, open source innovation clearinghouses, open source licensing (non-proprietary contractual agreements), open access databases, and open source patent licenses. Some sources also include patent pools, patent clearinghouses and research exception in their definition of open source. David Castle, *Open Source and Patent Pooling in Canadian Science and Biotechnology*, (forthcoming) (presented at the CBAC conference 2005). However, there are important technical and/or ideological differences between these collaborative approaches and open source that would need to be further investigated before such rapprochement can be made.

<sup>62.</sup> Stephen M. Maurer et al., Finding Cures for Tropical Diseases: Is Open Source an Answer?, 1 PLOS MEDICINE 183, 184 (2004), available at http://medicine.plosjournals.org/archive/1549-1676/1/3/pdf/10.1371\_journal.pmed.0010056-L.pdf.

Group is really a patent pool, whereas the SNP Consortium is an example of a "defensive publication" strategy.

As Janet Hope notes, "[Biotechnology] innovations are far more diverse in . . . composition than software, which is essentially non-physical and instantly reproducible."<sup>63</sup> Open source biotechnology initiatives have been proposed in the areas of bioinformatics software, genomic databases, and "wet lab" biology.<sup>64</sup> Bioinformatics could be the most naturally suited of these three areas for the open source approaches because of its great similarities with computing.<sup>65</sup> The increased use of collaborative databases on the "open access" model could help to ensure the availability of fundamental research data or research tools, but might be difficult to justify from a commercial standpoint with respect to its inability to protect downstream innovations. Variants of open source, such as the "defensive publication" technique, could also be used by industry in emerging fields of research (e.g., pharmacogenomics) where success or future profitability of projects remains highly uncertain.<sup>66</sup> "Wet lab" system biology projects are less likely prospects for open source.<sup>67</sup> However, even in the "wet lab," open source projects could be justified when intractable problems would otherwise impede the development of breakthrough drugs.<sup>68</sup>

#### **III. THE ANTICOMMONS DILEMMA IN BIOTECHNOLOGY**

Of the numerous critiques of the patent system's application to the field of biotechnology, the most influential and damaging to date has been the anticommons theory developed by Michael Heller, and adapted to the field of biotechnology by Heller and Rebecca Eisenberg.<sup>69</sup> These scholars persuaded a large audience of academics and policymakers—both at the international and national level—that an anticommons effect was jeopardizing biomedical research.<sup>70</sup> Many authors supportive of open source applied variants of the "anticommons theory" to justify its necessity.<sup>71</sup> Since a presumed anticommons effect is the most popular basis used to advocate the use of an open source model in the field of biotechnology, a careful review of the

<sup>63.</sup> Janet E. Hope, *A New Way to Manage Scientific Intellectual Property*, GENEWATCH MAGAZINE, Jan.-Feb. 2005, *available at* http://www.gene-watch.org/genewatch/articles/18-1Hope.html.

<sup>64.</sup> Arti K. Rai, Open and Collaborative Research: A New Model for Biomedicine, in INTELLECTUAL PROPERTY RIGHTS IN FRONTIER INDUSTRIES 131, 140-45 (Robert W. Hahn ed., 2005).

<sup>65.</sup> See id. at 145-47.

<sup>66.</sup> Rebecca S. Eisenberg, *Will Pharmacogenomics Alter the Role of Patents in Drug Development?*, 3 PHARMACOGENOMICS 571, 571-73 (2002).

<sup>67.</sup> Hope, supra note 63.

<sup>68.</sup> Rai, supra note 64, at 143.

<sup>69.</sup> See generally Heller & Eisenberg, supra note 30.

<sup>70.</sup> Id.

<sup>71.</sup> See, e.g., Sara Boettinger & Dan L. Burk, Open Source Patenting, 1 J. INT'L. BIOTECH. L. 221 (2004); Hope, supra note 41; Robert P. Merges, Colloquium: A New Dynamism in the Public Domain, 71 U. CHI. L. REV. 183 (2004); Michael S. Mireles, An Examination of Patents, Licensing, Research Tools, and the Tragedy of the Anticommons in Biotechnology Innovation, 38 U. MICH. J.L. REFORM 141 (2004); Dianne Nicol & Janet Hope, Cooperative Strategies for Facilitating Use of Patented Inventions in Biotechnology, 24 LAW IN CONTEXT 85 (2006); Iain M. Cockburn, Blurred Boundaries: Tensions Between Open Scientific Resources and Commercial Exploitation of Knowledge in Biomedical Research (Apr. 30, 2005) (unpublished article prepared for the Advancing Knowledge and Knowledge Economy Conference), available at http://people.bu.edu/cockburn/cockburn-blurred-boundaries.pdf.

empirical evidence relating to the effect of patents on biomedical research is necessary to assess the strength of this argument.

#### A. The Anticommons Theory

The anticommons theory states that important patented upstream technologies will be underused (and therefore underdeveloped) due to the concurrent patent rights on them: a potential downstream inventor could be deterred from engaging in further research because in order to develop a single downstream product, he would be required to go through a complex and potentially expensive process of negotiating licenses with multiple upstream patentees.<sup>72</sup>

This problem of "bundling" patents is especially relevant for biotechnological research because this sector advances most efficiently when knowledge is shared. In other words, although scientific cooperation fosters progress, such cooperation is prevented as a consequence of patent rights. It is therefore not surprising that this "bundling" concept appears frequently in discussions regarding the likely impact of intellectual property rights in biotechnology.<sup>73</sup>

Applying this theory to the field of biotechnology, Heller and Eisenberg argued that the tragedy of the anticommons is a possible threat to the advancement of this sector.<sup>74</sup> According to these two scholars, an anticommons is more likely to materialize in biomedical research than in any other area of intellectual property because of the high costs of bargaining, heterogeneous interests among owners, and cognitive biases of researchers (the over-valuation of one's assets, such as patents, and the undervaluation of others' assets) that can lead to bargaining failure.<sup>75</sup> They did not actually take the position that there currently exists an anticommons in biomedical research, but rather meant their article to be a warning to policy makers and scientific and academic communities.<sup>76</sup> According to Heller and Eisenberg, the preconditions for the emergence of an anticommons exists in the biomedical research sector.<sup>77</sup> Therefore, sole reliance on markets and norms to avoid an anticommons tragedy could be an inappropriate strategy.<sup>78</sup>

#### B. Analysis of the Existing Empirical Evidence

The emerging evidence does not support Heller and Eisenberg's apprehensions. Rather, it demonstrates the absence of a generalized anticommons effect in biomedical research.<sup>79</sup> Reviewing the evidence, a recent article expressed the opinion that "[t]he

<sup>72.</sup> Hope, supra note 41, at 36.

<sup>73.</sup> Id.

<sup>74.</sup> Heller & Eisenberg, supra note 30, at 699-700.

<sup>75.</sup> Id. at 701.

<sup>76.</sup> Id.

<sup>77.</sup> Id. at 700.

<sup>78.</sup> Id.

<sup>79.</sup> See, e.g., John P. Walsh et al., Effects of Research Tool Patents and Licensing on Biomedical Innovation, in PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285 (Wesley M. Cohen & Stephen A. Merrill eds., 2003) [hereinafter Walsh et al., Effects]; Walsh et al., Views, supra note 35; JOSEPH STRAUS ET AL., GENETIC INVENTIONS AND PATENT LAW: AN EMPIRICAL SURVEY OF SELECTED GERMAN R & D INSTITUTIONS (2004) (unpublished manuscript, on file at the Max Planck Institute for Intellectual Property,

empirical research suggests that the fears of widespread anticommons effects that block the use of upstream discoveries have largely not materialized."<sup>80</sup>

This growing body of empirical evidence comes from various small-to-medium scale surveys representative of both the industry and academia on the effect of patents and licensing practices on biomedical research and clinical access. An interesting example is Walsh, Arora, and Cohen's 2003 survey on research tool patenting and biomedical innovation.<sup>81</sup> The authors conducted seventy interviews with intellectual property attorneys, business managers, university researchers and technology transfer officers from six universities, patent lawyers, government and trade association personnel, as well as scientists from ten pharmaceutical firms and fifteen biotechnology firms. Although generally positive, the conclusions of their research were somewhat less idyllic than some recent commentaries have suggested.<sup>82</sup> According to Walsh, Arora, and Cohen:

Through a combination of luck and appropriate institutional response, we appear to have avoided situations where a single firm or organization using its patents has blocked research in one or more broad therapeutic areas. However, the danger remains that progress in a broad research area could be significantly impeded by a patentholder trying to reserve the area exclusively for itself.<sup>83</sup>

Focusing on the most negative findings of this study, there still does not seem to be enough evidence to support the position that there exists a substantial "anticommons effect." The study does agree with Heller and Eisenberg that the preconditions of an "anticommons effect" (characterized by the existence of a large number of patents, owned by different parties with different agendas) seem to exist.<sup>84</sup> Indeed, the patent landscape has become even more complex since Heller and Eisenberg's 1998 article. For example, concerns about licensing costs for research tools were reported by half of the respondents in Walsh, Arora, and Cohen's 2003 study.<sup>85</sup> Other disturbing facts include the widespread complaints from universities, biotechnology firms, and pharmaceutical representatives over patent holders' assertions of exclusivity over an important class of research tools that include "any cell receptor, enzyme, or other protein implicated in a disease."<sup>86</sup> Also significant is the fact that all respondents who addressed the question of negotiation delays noted that dealing with research tool patents caused significant delays and added to research costs. These respondents felt

- 82. See, e.g., Caulfield et al., supra note 7, at 1092.
- 83. Walsh, et al., Effects, supra note 79, at 335.
- 84. See Heller & Eisenberg, supra note 30 and accompanying text.

Competition and Tax Law); Stephen Hansen et al., *The Effects of Patenting in the AAAS Scientific Community* (2006), *available at* http://sippi.aaas.org/survey/AAAS\_IP\_Survey\_Report.pdf; Sadao Nagaoka, An Empirical Analysis of Patenting and Licensing Practices of Research Tools from Three Perspectives, Presentation at the OECD Conference on Research Use of Patented Inventions (May 18–19, 2006), *available at* http://www.oecd.org/dataoecd/20/54/36816178.pdf; Dianne Nicol & Jane Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (Centre for Law & Genetics, Occasional Paper No. 6, 2003), *available at* http://www.ipria.org/publications/workingpapers/ BiotechReportFinal.pdf.

<sup>80.</sup> Caulfield et al., supra note 7, at 1093.

<sup>81.</sup> Walsh, et al., Effects, supra note 79, at 335.

<sup>85.</sup> Walsh, et al., Effects, supra note 79, at 293-94.

<sup>86.</sup> Id. at 310.

that the process of sifting through a large number of potentially relevant patents and subsequent negotiations was extremely time consuming. Walsh, Arora, and Cohen also recognized an important limitation to their study design: the difficulty of measuring the extent to which projects were not started or had been redirected because of patent concerns.<sup>87</sup>

Despite these hurdles, Walsh, Arora, and Cohen's study concluded that one of the main reasons that no projects were stopped due to the issue of access to research tools is that industrial and university researchers had been able to develop "working solutions."<sup>88</sup> Examples of these solutions include inventing around, going offshore, and infringement. However, the conclusion that researchers need to either infringe patents or go offshore to proceed with their research plans should not necessarily be interpreted as a positive sign. If there is no problem accessing research tools, then why must people resort to such drastic working solutions? This being said, the study results nevertheless demonstrate that there is no systemic anticommons effect in the biomedical industry.

Other studies on the topic offer similar, if not less worrisome, findings.<sup>89</sup> According to these studies, there are some grounds for concern, but there does not seem to be a widespread anticommons effect in biomedical research. It is worth noting that several guidelines relating to licensing practices have been issued in recent years.<sup>90</sup> Once implemented by the industry and technology transfer offices, these guidlines could further reduce the risk of an anticommons effect. Consistent with the findings of Walsh, Arora, and Cohen, most contemporary studies report a difficulty in precisely assessing the number of research projects that were abandoned (or never initiated) due to problematic patents in the selected area. In 2005, a larger study from Walsh, Cho, and Cohen found that academic research "offer[ed] little empirical basis for claims that restricted access to intellectual property is currently impeding biomedical research," and indicated that, "for the time being, access to patents on knowledge inputs rarely imposes a significant burden on academic biomedical research."<sup>91</sup>

The implications of these empirical findings regarding the existence of an anticommons or of a widespread patent thicket are important for the future prospects of open source. According to the findings, although the patent system might be responsible for a number of minor impediments in biomedical research, claims of a generalized problem of access to research tools are unsubstantiated.<sup>92</sup> If the central argument to justify the introduction of open source licensing approaches is a risk that is both hypothetical and uncorroborated by the available evidence, then this argument seems both intuitively and empirically flawed. In the last part of this Article, I shift

<sup>87.</sup> Id. at 303.

<sup>88.</sup> Walsh, et al., Effects, supra note 79, at 322.

<sup>89.</sup> See Straus et al., supra note 79; Hansen et al., supra note 79; Nagaoka, supra note 79; Nicol & Nielsen, supra note 79.

<sup>90.</sup> See ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT [OECD], Guidelines for the Licensing of Genetic Inventions (2006).

<sup>91.</sup> Walsh et al., Views, supra note 35, at 2003.

<sup>92.</sup> One important exception is in the area of human gene patents that cover diagnostic genetic tests and therapies. There are several instances of researchers and firms claiming that the patent owner is asserting exclusivity or license terms that are considered inappropriate. *See* Cho et al., *supra* note 33; Merz et al., *supra* note 33.

focus from this "negative approach" to open source licensing to a more "positive approach," through which open source could be justified on intrinsic merits rather than unsubstantiated fears.

# IV. THE BENEFITS OF USING OPEN SOURCE APPROACHES

The intrinsic benefits of the various cooperative strategies for facilitating the use of patented inventions in biotechnology have been insufficiently investigated in the academic literature. They are usually only briefly mentioned with little explanation or evidence to support them.<sup>93</sup> If collaborative approaches are to be successfully promoted in biotechnology, it is imperative that these benefits take a more central position in the dialogue. Thus, the following section will concentrate on the intrinsic benefits that could be fostered by using open source approaches in this field. These potential benefits were selected because they apply in general to these types of approaches rather then to a specific commercial strategy implicating particular actors. The list is not exhaustive and should only be used as a basis for others to build upon. Also, given that the private sectors, university technology transfer offices, and not-forprofit organizations often have different objectives, the same benefit will likely weigh more in the balance for some than it will for others.

The negative, hypothetical argument on the systemic failing of the patent system in biotechnology could still be considered in the assessment, but it should not be given additional importance, a more central position, or priority over any of the intrinsic benefits inventoried below.

# A. Scientific Benefits

# 1. Peer Evaluation and Validation of Findings

The transparent nature of an open source system plays an important role in eliminating errors. The objective of open approaches is to make knowledge available to the broader public, which is a major requirement for criticism essential in the learning process. Similarly, open source licenses would likely diminish the need for secrecy around patent applications in the private sector.

Culture is not merely a social control mechanism. It can also have a role in the activation and channeling of criticism and in error correction, and therefore plays a part in the process of innovation and learning in a distributive system. Open development exposes new input to all interested eyes and thus encourages an open, critical discussion in order to foster higher quality research. In the course of such peer review, the contributor's reputation improves by creating useful solutions and contributing sound critical evaluations of the work of others. On the one hand, the quality of prior submissions becomes a currency that developers exchange for the community's attention to their next submission; on the other, the criticism received allows all parties to evaluate the quality of the work.<sup>94</sup>

<sup>93.</sup> See, e.g., Merges, supra note 71, at 196; Herder, supra note 8, at 38.

<sup>94.</sup> See Gwendolyn K. Lee & Robert E. Cole, From a Firm-Based to a Community-Based Model of Knowledge Creation: The Case of the Linux Kernel Development, 14 ORG. SCI. 633, 639 (2003).

#### **OPEN SOURCE APPROACHES**

#### 2. Increase Intellectual Curiosity and Motivation

Intellectual curiosity is one of the main incentives for joining an open source project in the field of information technology.<sup>95</sup> It could also be a contributing factor when applied to open source biotechnology initiatives. Exposure to new ideas, refining scientific skills, and being part of a community that is able to recognize personal achievements are important elements of the rewards that an individual expects when dedicating his or her time to an open source project. It has been observed that having the choice and opportunity for self-direction actually enhances enjoyment and motivation, and also affords a greater sense of autonomy, challenge, and stimulation.<sup>96</sup>

#### 3. Maximize Rational Development

As Niman and Kench have noted, open source projects could maximize the potential value of new developments and ideas:

[R]ather than achieving benefits *ex post* (after the first innovation has been created) [open source] expands diffusion *ex ante* by drawing in as many as possible in the initial development of the idea.... Each user becomes a potential source of new ideas for future directions in the product, and the workload for implementing change is shared between an expanded group of developers.<sup>97</sup>

Moreover, the increase in communication and exchange encouraged by open source will likely allow a more modular and effective coordination of research projects.<sup>98</sup>

# 4. Facilitate Sharing of Technical Information

A collaborator would typically be encouraged to learn as much as possible in order to make technical contributions instead of asking general questions. Having learned about the technical details of the project, the collaborator can contribute more actively and effectively to the ongoing technical discussion.<sup>99</sup>

# 5. Facilitate Technology Transfer and Access to Health in Developing Countries

A recent Canadian study highlighted the potential of biotechnologies for improving health in developing countries.<sup>100</sup> New solutions to developing treatments

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<sup>95.</sup> Josh Lerner & Jean Tirole, *The Economics of Technology Sharing: Open Source and Beyond*, 19 J. ECON. PERSP. 99, 105 (2005).

<sup>96.</sup> Yan Li et al., Motivating Open Source Software Developers: Influence of Transformational and Transactional Leaderships, in SIGMIS CPR '06: PROCEEDINGS OF THE 2006 ACM SIGMIS CPR CONFERENCE ON COMPUTER PERSONNEL RESEARCH: FORTY FOUR YEARS OF COMPUTER PERSONNEL RESEARCH: ACHIEVEMENTS, CHALLENGES & THE FUTURE 34, 39-40 (2006), available at http://delivery. acm.org/10.1145/1130000/1125182 /p34li.pdf?key1=1125182&key2=4938971611&coll=GUIDE&dl=GUIDE&CFID=3075455&CFTOKEN=51623844.

<sup>97.</sup> Neil B. Niman & Brian T. Kench, *Open Source in the Pharmaceutical Industry*, PROC. MIDWEST BUS. ECON. ASS'N 124, 127 (2003), *available at* https://www.usi.edu/business/mbea/2003/WordFiles/NIMAN-KENCH.doc.

<sup>98.</sup> Hope, supra note 54, at 199.

<sup>99.</sup> Georg von Krogh et al., Community, Joining, and Specialization in Open Source Software Innovation: A Case Study, 32 RES. POL'Y 1217, 1229 (2003).

<sup>100.</sup> See Abdallah S. Daar et al., Top Ten Biotechnologies for Improving Health in Developing

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for rare diseases or for diseases found in poor nations may come from open source research practices in biotechnology. Such approaches can foster biomedical innovation while significantly reducing research and development expenditures, which often pose barriers to new drug development for combating many neglected diseases.<sup>101</sup> Assistance from developed countries could take the form of public databases containing information on biological data, the development of new research tools, and promising therapeutic molecules. Alternatively, a collaborative open-source drug discovery project such as the Tropical Disease Initiative proposed by Maurer, Rai, and Sali could be implemented.<sup>102</sup>

#### **B.** Economic Benefits

# 1. Reduce Duplication

The open licensing of scientific results will generate a greater overall transparency and a reduction in costs. Because peers will be able to learn more quickly and easily when they are working on open source projects, they will avoid the excess costs generated by the duplication of their research efforts.<sup>103</sup>

#### 2. Develop Market for Complementary Goods and Services

Open source licensing can potentially foster a user base for the technology, "thereby growing the market for complementary goods and services and perhaps even establishing a *de facto* industry standard."<sup>104</sup> It would be advantageous for a company to use an open source license when it expects to boost its profits from these complementary goods and services; in other words, when profit in the complementary segment can offset "profit that would have been made in the primary segment, had it not been converted to open source."<sup>105</sup> In this situation, the invention made available through open source can serve as an enticement to attract customers to the proprietary goods and services of the company.<sup>106</sup>

# 3. Enhance Reputation and Public Relations

Private biotechnology companies can enhance their reputations by using open source. By making the technology they develop freely available to the general public, these companies can boost their reputations for innovation and expertise, as well as user-friendliness and social-mindedness.<sup>107</sup>

Countries, 32 NATURE GENETICS 229 (2002).

<sup>101.</sup> Luis A. Salicrup & Lenka Fedorková, Challenges and Opportunities for Enhancing Biotechnology and Technology Transfer in Developing Countries, 24 BIOTECH. ADVANCES 69, 73 (2005).

<sup>102.</sup> See Maurer et al., supra note 62.

<sup>103.</sup> See Jean-Michel Dalle & Paul M. David, *The Allocation of Software Development Resources, in* 'OPEN SOURCE' PRODUCTION MODE 88 (The Stanford Institute for Economic Policy Research, SIEPR Discussion Paper No. 02-27, 2003), *available at* http://opensource.mit.edu/papers/dalledavid.pdf.

<sup>104.</sup> Hope, supra note 54, at 152.

<sup>105.</sup> Lerner & Tirole, supra note 95, at 106.

<sup>106.</sup> See Hope, supra note 63.

<sup>107.</sup> Id.

#### 4. Share Financial Risk in Projects

Because biotechnological research requires significantly more capital investment than other fields of innovation, it is often the case in this field that the only way to obtain the desired final product is to share the burden of innovation.<sup>108</sup> Additionally, there are limits to the foresight and control of firms over how certain biotechnology sectors will unfold and where commercial benefits will fall. By joining efforts via a "copyleft" style license or a public database, each firm minimizes the risk of paying excessive prices for future licenses on important research tools while retaining the right to patent downstream innovations developed with the help of these tools.<sup>109</sup>

The SNPs Consortium illustrates this beneficial use of open source in the biotechnology sector. A non-profit foundation organized for the purpose of providing public genomic information, the SNPs Consortium publishes data that is pivotal for subsequent downstream pharmacogenomic research via a publicly accessible computer database. In addition to industry giants such as AstraZeneca, Aventis, Bayer, Bristol-Myers Squib, Hoffman-La Roche, Pfizer, and SmithKline Beecham,<sup>110</sup> the independent charity fund Wellcome Trust collaborated in this open source project.

# 5. Attract Volunteer Labor

Open source collaborations in the field of information technology demonstrate that it is possible to extract a substantial amount of labor from unpaid, highly trained manpower.<sup>111</sup> Volunteers respond to the "supply side" incentives of idealism, learning new skills, and impressing potential employers.<sup>112</sup> The use of open source can prevent the "private appropriation of volunteer labor," thus providing "an incentive for volunteers to contribute in the first instance."<sup>113</sup> These types of incentives might work equally well in the field of biotechnology.<sup>114</sup>

# 6. Eliminate Time-Consuming Negotiations

In a project using an open source style license, potential problems with "contractual non-uniformity [would be] eliminated because each party desiring . . . access to the confidential protected commons must sign a standard licensing agreement."<sup>115</sup> Technical and legal language and clauses dealing with issues that are not central to the transaction generally make a license more difficult to read and understand, though they typically make it easier to enforce. Open source licenses—such as

<sup>108.</sup> Id.

<sup>109.</sup> Eisenberg, supra note 66, at 572.

<sup>110.</sup> Smith Kline Beecham became GlaxoSmithKline after a 2000 merger.

<sup>111.</sup> Stephen M. Maurer, New Institutions for Doing Science: From Databases to Open Source Biology 13 (Nov. 19, 2003), available at http://www.merit.unimaas.nl/epip/papers/maurer\_paper.pdf. (paper presented to the European Policy for Intellectual Property Conference on Copyright and database protection, patents and research tools, and other challenges to the intellectual property system),

<sup>112.</sup> Id.

<sup>113.</sup> Rai, supra note 64, at 137.

<sup>114.</sup> Maurer, supra note 111, at 13.

<sup>115.</sup> Joseph Eng, Jr., From Software to Life Sciences: The Spreading of the Open Source Production to New Technological Areas, 24 TEMP. J. SCI. TECH. & ENVTL. L. 419, 438 (2005).

the GPL used in the information technology sector—do not contain such technical language, making them popular with their users.<sup>116</sup> Moreover, companies can decide to give away the data by placing it in the public domain, thus avoiding not only negotiation of IP access among themselves and other companies down the line, but also the considerable costs associated with patent protection.<sup>117</sup>

# 7. Customizable

Under open source approaches, changes to the product will not only originate from a small group of scientists under the leadership of a management team that might not fully anticipate the needs of the market, but rather from those who are actually using the product in real world situations. As a result, the whole product can eventually move in a direction that is more closely aligned with the needs of its users than with those of its developers. As Niman and Kench have noted, the improvements are "driven from a bottom up approach where end-users both initiate and implement modifications based on real needs," making the invention more attractive and useful to its users.<sup>118</sup>

# 8. Produce Usable Output at a Lower Cost

If highly skilled collaborators use an open source approach to undertake the fundamental research, sponsors could avoid overpaying the research and development costs that are so difficult to estimate in the early stages. Moreover, because the intellectual property would be accessible to everyone, any company could manufacture the good, and the resulting competition would likely keep down the market price for the completed product.<sup>119</sup> In the case of drug development incentives, governments and charities could invite companies to bid against each other for the right to perform further development under contract. Competitive bidding is a powerful method for containing costs.<sup>120</sup>

# C. Social Benefits

## 1. Increase Respect of Peers

As Lerner and Tirole have illustrated, an open source environment fosters greater transparency, making it easier for peers to signal the production of a higher level of work since they can see each contribution made by individuals participating in a given project. They can also detect "whether that component 'worked,' whether the task was hard, if the problem was addressed in a clever way, and whether the [contribution] can be useful for other tasks in the future."<sup>121</sup> This peer monitoring process, in turn, will likely spur an increase in efforts by the contributor. In the field of information technology, it has been demonstrated that developers tend to allocate their efforts

<sup>116.</sup> Hope, supra note 54, at 99.

<sup>117.</sup> See id. at 91.

<sup>118.</sup> Niman & Kench, supra note 97, at 127.

<sup>119.</sup> See Hope, supra note 63.

<sup>120.</sup> Maurer et al., supra note 62, at 184.

<sup>121.</sup> Lerner & Tirole, supra note 95, at 104.

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according to the level of recognition and reputation enhancement that the community attaches to different tasks.<sup>122</sup> Therefore, the greater the significance that peers in this field attach to a project and the role of the agents, the greater the extent of technical critique of his or her contribution and the greater the reward that can be anticipated.<sup>123</sup> This proposition could likely apply to the biomedical community as well.

# 2. Compatible with the Scientific Ethos of Open Science

The use of open source approaches could be the perfect way for academia to progress toward the "communalism" norm of science embraced by Merton; these norms recognize that scientific progress does not emerge from a void, but always depends on the body of knowledge accumulated by previous generations of researchers.<sup>124</sup> The importance of recognizing this reality is especially marked in the field of biotechnology, in which the technological trajectory is now increasingly reliant on a broader and less concentrated knowledge base, with various companies participating in the same technological evolution.<sup>125</sup>

# 3. Improve Coordination

Open source is an efficient way to develop research tools. It facilitates effective collaboration within the research community—both nationally and internationally—by enabling the sharing of expertise, resources, and knowledge. Open source projects can provide a forum to share and generate new knowledge that capitalizes on the efficiency and power of international collaboration and information exchange.<sup>126</sup> "[F]eedback from the cumulative results of individual actions" will foster improved coordination and coherence among the collective of researchers.<sup>127</sup>

An example of this type of collaboration is the Public Population Project in Genomics (P<sup>3</sup>G) Observatory. P<sup>3</sup>G is an international consortium for the promotion of collaboration and international harmonization between researchers and population genomic databases.<sup>128</sup> The P<sup>3</sup>G Observatory is a knowledge transfer platform, with a mission to: (1) provide the tools that support researchers in the development, harmonization and implementation of research projects; (2) disseminate scientific and technical information developed and collected by P<sup>3</sup>G Cores and International Working Groups; and (3) to make the comparison and sharing of information amongst different studies feasible.<sup>129</sup> Thus, the P<sup>3</sup>G Observatory illustrates that open source can assist researchers in developing the necessary tools to facilitate the transfer of knowledge among large genomic database projects.

<sup>122.</sup> Dalle & David, supra note 103, at 14.

<sup>123.</sup> Id.

<sup>124.</sup> Arnold Plant, The Economic Theory Concerning Patents for Inventions, 1 ECONOMICA 30 (1934).

<sup>125.</sup> See Heller & Eisenberg, supra note 30; John P. Walsh, supra note 79.

<sup>126.</sup> Public Population Project in Genomics, Draft Blueprint 4 (2005), available at http://www.p3gconsortium.org/docs/blueprint\_Draft2005.pdf.

<sup>127.</sup> Dalle & David, supra note 103, at 9.

<sup>128.</sup> See P<sup>3</sup>G Project, supra note 60.

<sup>129.</sup> See id.

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#### 4. Facilitate Access to Information for Learning and Educational Purposes

The simplest form of open source material is the publication of research. A number of initiatives exist to link the databases in standardized and non-proprietary ways that would increase the availability of scientific data.<sup>130</sup> These initiatives allow students to obtain the latest information relevant to their chosen scientific field while avoiding the high costs of a standard textbook or other copyrighted material. In addition, open source biotechnology projects could enable students to benefit from the latest research tools without them or the university having to worry about possible infringement suits or the status of the common law research exemption.

Open source could provide students with an opportunity to acquire practical experience by working on challenging projects while leveraging the cultural values of collaboration. Unlike contexts outside of academia, working together does not threaten the income of the academic institution.<sup>131</sup>

## 5. Increase Motivation of Employees

As Lerner and Tirole have noted, employees are usually motivated by "signalling incentives," which are characterized by the desire to become well-known through the improved accessibility of their work.<sup>132</sup> Open source projects permit the individual to be more visible to the relevant audience—peers, the job market, and venture capital communities—giving rise to advantages or "strategic complementarities."<sup>133</sup> This, in turn, propels contributors to work on projects involving a large number of participants because these efforts result in a higher impact on performance and are more indicative of talent.<sup>134</sup> It also entails ego gratification through peer recognition because attribution clauses are often included in open source licenses, allowing others to know who made which contribution.<sup>135</sup>

# V. CONCLUSION

The patent system is an intractable feature of contemporary law. Given the absence of strong empirical evidence, its application to the field of biotechnology is unlikely to be seriously challenged by purely moral or theoretical arguments. Open source, while not necessarily incompatible with the patent system, offers a radical alternative that will foster creativity and a climate of open scientific collaboration. However, this approach remains controversial in the field of information technology, where it was originally developed, and it is only present in its nascent stages in the

<sup>130.</sup> Kenneth Neil Cukier, Community Property Open Source Proponents Plant the Seed of New Patent Landscape, 1 ACUMEN 54, 58 (2003).

<sup>131.</sup> Chris Coppola & Ned Neelley, Open Source—Opens Learning: Why Open Source Makes Sense for Education 6 (Summer 2004), *available at* http://www.rsmart.com/assets/OpenSourceOpensLearning July2004.pdf.

<sup>132.</sup> Lerner & Tirole, supra note 95, at 103.

<sup>133.</sup> *Id*.

<sup>134.</sup> Id.

<sup>135.</sup> See Eng, supra note 115, at 426.

biotechnology sector.<sup>136</sup> Given the somewhat precarious position of open source, the arguments raised to promote its introduction in the field of biotechnology need to be carefully selected. Thus far, the main argument invoked has been a negative one, based on the existing or potential danger of a biotechnological anticommons effect. These biotechnology anticommons theorists propose the use of open source approaches as an ideal solution to a hypothetical problem.

In this Article, I suggested that this kind of argument is both objectively unsatisfactory and unlikely to convince the major actors of the importance of open source. I consequently recommended that proponents of open source should instead focus on the often overlooked intrinsic benefits associated with these approaches. The final part of this Article enumerated some of the benefits that best justify the use of open source in biotechnology.

It is unlikely that open source will completely supersede the more traditional licensing approaches in this dynamic research field. Instead, all of the involved actors will need to carefully consider the benefits and inconveniences of using such approaches in each individual circumstance. Sometimes, the use of open source will complement the patent system; at other times, it will work best as an independent alternative. A list of intrinsic benefits of open source approaches constitutes an important tool to assist those making this critical assessment. Open source licensing presents significant intrinsic benefits that warrant incorporation into the numerous emerging guidelines on licensing practices.

Due to its unique ideological foundation, open source might eventually come to confront and threaten the foundation of the patent system. For now, however, it will need to be promoted to future users on the basis of rational arguments rather than on negative feelings towards the patent system and hypothetical risks uncorroborated by currently available evidence.

<sup>136.</sup> See Thomas B. Kepler et al., Open Source Research – The Power of Us, 59 AUSTL. J. CHEMISTRY 291, 294 (2006), available at http://www.publish.csiro.au/?act=view\_file&file\_id=CH06095.pdf.