24 In the Matter of Rambus, Inc., Docket No. 9302, Opinion of the Commission, August 2, 2006.

25 See http://www.gnu.org/licenses/licenses.html#LicenseList (discussing GNU General Public License and other "copyleft" licenses).

26 www.bios.org

27 Burk, D & Boettiger, S (2004) *JIBL* 1, 221 (2004); Feldman, R (2004) Minnesota Journal of Law, Science, and Technology 5: 117 (2004).

28 Commission of the European Communities, DG Internal Market and Services Working Paper, 12 December 2005.

29 Treaty on Access to Knowledge, Article 5-6, draft of 9 May 2005.

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Open Source Biotechnology – Refocusing the Debate

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In the field of biotechnology, the patent system has had its share of detractors and has come under increasing criticism of late. It has been suggested that cooperative open models of collaboration inspired from the information technology field open source project, could correct several issues generated by application of the patent system. However, the critics of the system presume its inefficiency on the basis of theoretical arguments that have not been confirmed to date by the available evidence. Ultimately, the use of open source approaches should be founded on the individual merits of these strategies rather than on the basis of highly hypothetical inefficiencies imputed to the patent system. Consequently, our text will focus on the numerous potential benefits of open source reported in the literature. Because of these benefits, the strategic use of collaborative approaches could constitute an inexpensive way of facilitating the development of a dynamic and functional biomedical research sector in academia, one that continues to work in the spirit of open science.

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I. Introduction

Tracing its origin to Greek antiquity,[1] intellectual property has become an institution in modern legal systems worldwide.[2] 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.[3]

However enshrined in the legal tradition, intellectual property law has also had its share of detractors and has recently come under severe criticism.[4] 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.[5] 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.).[6] Surprisingly, this legislative outburst that was aimed at correcting certain deficiencies of the patent system was driven by a number of theoretical hypotheses that were unconfirmed by the available evidence.[7] Various solutions have been proposed in these normative documents in order to palliate certain presumed failings of the patent system: compulsory licenses, adoption of moratoria on gene patents, parallel 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.[8] The author usually begins by discussing the idyllic culture of open science that is

expresses his regret at the recent commercialization of academia and its adverse effect on fundamental research. He then advances his 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. It may well be a better strategy to identify and promote the wealth of intrinsic benefits associated with these strategies in order to keep them attractive, independently from any evaluation made of the patent system. The intrinsic benefits of cooperative approaches deserve to be more carefully investigated because they might be where the approaches' true strengths lie.

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 the use of open source approaches is needed to improve this situation. Subsequently, this article will present the various intrinsic benefits of the open source approaches reported in the literature. Ultimately, the Article will conclude that collaborative approaches' intrinsic advantages not only justify the use of such methods in the biomedical research sector but could also allow the sector to develop into a very dynamic and functional one.

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

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.[10] 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.[11] Fees will need to be paid to the patent office in order to obtain and maintain the patent right on the invention.[12]

Patents are also expensive; the minimum cost to obtain and maintain a relatively simple patent in the United States for 20 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.[13] It is also costly to enforce patents: legal defences typically cost 1.6 million American dollars per contested patent.[14] The high price of patents makes them tools that are better suited for large companies than for independent inventors. Mechanisms permitting the enforcement or the contestation of patent rights are perceived by some as unpractical, time consuming, and expensive.[15] These limitations explain in part the existence of a large number of bad patents in existence.[16]

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.[17] 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.[18] 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.[19] Well 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 particular instances, impeding progress unnecessarily, even if its general effect is

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, that 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.[21] Moreover, vastly publicized debacles involving patents and access to HIV medicine – such as the Pretoria trial[22] and the United States-Brazil dispute[23] – have made the patent system highly unpopular.[24] 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.[25]

The extension of the patent system to the field of biotechnology has also raised significant criticism. Critics were 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 were criticized on moral grounds, as being dehumanizing,[26] an affront to human dignity,[27] and incompatible with religious beliefs.[28] Merges and Nelson have 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.[29] 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.[30] Shapiro theorized that in some "key industries, including . . . biotechnology, the patent system is creating a *patent thicket*: an overlapping set of patent rights requiring . . . those seeking to commercialize new technology [to] obtain licenses from multiple patentees."[31] Blumenthal concluded that commercial incentives were responsible for significant delays in the publication of research findings and stifled collaboration, especially in the field of biomedicine.[32] Merz and Cho claimed that patents on genetic tests not only triggered ethical concerns but also posed significant risks to patients, public health, and to the practice of medicine.[33]

patenting gene sequences was making it impossible for researchers to invent around them, essentially creating a *de facto* "double" monopoly.[34] Advocates of the patent system answered these critiques with varying degrees of success.[35]

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.[36] 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.[37] Moreover, it has been suggested that the adoption of good licensing practices in the public and private sectors would significantly reduce the prevalence of the claimed adverse effect of the patent system.[38]

B. From Open Science to Open Source

According to some authors,[39] 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. In the beginning of the 20th century, the practice of patenting was perceived as unethical by a large portion of the biomedical academic community.[40] 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.'"[41] 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.[42] Therefore, in light of this value of communality, claiming property rights in inventions or keeping discoveries secret was discouraged prior to 1980.[43]

Open science is said to have prevailed both in the fields of biotechnology[44] and information technology in the pre 1980 era.[45] In 1980, the American

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.[46]

The most important of these laws is the Bayh-Dole Act,[47] adopted to facilitate public access to the research financed by the American federal government. This law had the objective of encouraging small enterprises, universities an other not-for-profit contractors of the federal government to obtain patents on their inventions.[48] Thus, the 1980s started what many have now come to see as a commercialization era,[49] in which governments of other developed countries imitate United States pro-patent policies with varying amounts of success.[50]

However, this popular binary picture of an ideal "open science" period opposed to a grim commercialization period 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.[51] Although the biomedical academic community demonstrated some resistance to patenting in the early part of the 20th century,[52] it remains uncertain that there existed any specific prohibitive norm against seeking intellectual property before the 1980s or after.[53] Moreover, "[a]s sociologists of science have more recently demonstrated, scientists are not specially unbiased, altruistic or cooperative [, and] their dealings with one another" can at times 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 programmer community that started to emerge after the Second World War and that would eventually become known as "hackers," undeniably tended towards the "Mertonian" ideal.[55] It is thus no surprise that the first "open source" project was born in the field of information technology in 1984.[56] The Free Software Foundation created by Richard Stallman was based

on a software toolbox (GNU) an general public licence (GPL) that would eventually become the backbone of the free programming community. The GPL licence, also called "copyleft," allowed everyone to run the program, copy the program, modify the program, as well as distribute modified versions, but it did not authorize users to add restrictions of their own.[57]

In 1997, Bruce Perens would inspire himself from the GPL to draft the Open Source Definition. This major document aimed to provide a clearer alternative terminology to that of the GNU/GPL that would be acceptable to those who did not share Richard Stallman's view of proprietary software licensing as being morally wrong. 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 licences. A certification from the OSI would indicate compliance with the official Open Source Definition.[58]

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 access to information problems that poorer communities were experiencing, reduce the extent of overlapping patents, share the financial risk of highly exploratory research, and make biotech innovation tools widely available.[59] 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 P3G Observatory.[60]

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[61] that aim to facilitate the dissemination of biotechnology research results and foster 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.[62] However, the SARS IP Working Group is really a patent pool, whereas the SNP Consortium is an example of a "defensive publication" strategy.

"[Biotechnology] innovations are far more diverse in . . . composition than software, which is essentially non-physical and instantly reproducible."[63] Open source biotechnology initiatives have been proposed in the areas of bioinformatics software, genomic databases, and "wet lab" biology.[64] Bioinformatics could be the most naturally suited of these three areas for the open source approaches because of its great similarities with computing.[65] 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 regards to more downstream innovation. 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.[66] "Wet lab" system biology projects are less likely prospects for open source.[67] However, even in the "wet lab," open source projects could be justified when intractable problems would otherwise impede the development of breakthrough drugs.[68]

II. The Anticommons Dilemma in Biotechnology

Of the numerous critiques of the application of the patent system 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.[69] These articles were able to persuade a large audience of academics and policymakers both at the international and national level that an "anticommons effect" was putting biomedical research in jeopardy.[70] Variants of the "anticommons theory" were used as a central argument by a majority of authors supportive of open source in order to justify its necessity.[71] 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 empirical evidence relating to the effect of patents on biomedical research is necessary to assess the strength of this

A. The Anticommons Theory

The anticommons theory, developed by Michael Heller, hypothesizes 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.[72]

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 due to 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.[73]

Applying their premise to the field of biotechnology, Heller and Eisenberg have argued that the tragedy of the anticommons is a possible threat to the advancement of this sector.[74] 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 asset, such as patents, and the under valuation of others' assets) that can lead to bargaining failure.[75] 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 the scientific and academic community.[76] According to them, the preconditions for the realization of an anticommons existed in biomedical research along with some serious structural concerns.[77] Therefore, sole reliance on market and norms to avoid an anticommons tragedy could be an inappropriate strategy.[78]

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.[79] Reviewing the evidence, a recent article on the topic

expressed the opinion that "[t]he empirical research suggests that the fears of widespread anticommons effects that block the use of upstream discoveries have largely not materialized."[80]

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.[81] The authors conducted 70 interviews with intellectual property attorneys, business managers, university researchers and technology transfer officers from 6 universities, patent lawyers, government and trade association personnel, as well as scientists from 10 pharmaceutical firms and 15 biotechnology firms. Although generally positive, the conclusions of their research were somewhat less idyllic than some recent commentaries have suggested.[82] According to Walsh, Arora, and Cohen:

> Through a combination of luck and appropriate 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 patent holder trying to reserve the area exclusively for itself.[83]

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 precondition of an "anticommons effect" (characterized by the existence of a large number of patents, owned by different parties with different agendas) seems to exist. The patent landscape has become more complex, and concerns about licensing costs for research tools are reported by half of the respondents. Other disturbing facts include the widespread complaints from universities, biotech 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."[84] 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 the research costs. These respondents felt that the process of sifting through a large number of potentially relevant patents and subsequent negotiations was very 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.[85]

Despite these hurdles, the 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."[86] 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 taken as an indication that everything is well and good. 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 were able to demonstrate that there was no systemic "anticommons effect" in the biomedical industry.

Other studies on the topic offer similar, if not less worrisome, findings.[87] According to their results, 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 good licensing practices have been issued in recent years.[88] Once implemented by the industry and technology transfer offices, they could further reduce the risk of an "anticommons effect." Consistent with the findings of Walsh, Arora, and Cohen, most 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 that focused on "academic research" led to results that "offer 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."[89]

The implications of these empirical findings regarding the existence of an "anticommons" or of a widespread patent thicket are important for the future

might be responsible for a number of minor impediments in biomedical research, claims of a generalized problem of access to research tools are unsubstantiated.[90] 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 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 on unsubstantiated fears.

III. 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.[91] 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-for-profit 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-style 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 have a role in the activation and channeling of criticism and in error correction, and therefore also play 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 partially by creating useful solutions and partially by 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 hand, the criticism received allows all parties to evaluate the quality of the work.[92]

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.[93] 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 an important element of the rewards that an individual expects when dedicating his 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.[94]

3. Maximize Rational Development

Open source projects could maximize rational development because "[rather] than achieving benefits *post-hoc* (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."[95] Moreover, the increase in communication and exchange encouraged by open source will likely

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 to the ongoing technical discussion in a way that increases his recognition.[97]

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.[98] New solutions to developing treatments 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. The latter often poses barriers to new drug development for combating many neglected diseases.[99] 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. Or, a collaborative open-source drug discovery project such as the Tropical Disease Initiative proposed by Maurer, Rai, and Sali could be implemented.[100]

B. Economic Benefits

1. Reduce Duplication

The open licensing of scientific results will generate a greater overall transparency and a reduction in excess cost generated by duplication of research efforts because peers will be able to learn more quickly and easily when they are working on similar projects.[101]

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."[102] 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 situations where 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."[103] 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.[104]

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.[105]

4. Share Financial Risk in Projects

Often, in the field of biotechnological research, the only way to obtain the desired final product is to share the burden of innovation because this sector requires much more capital investment than other fields of innovation.[106] In addition, 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 for important research tools while retaining the right to patent downstream innovations developed with the help of such fundamental tools.[107]

A good illustration of this utilization of open source is the SNPs Consortium, a non-profit foundation organized for the purpose of providing public genomic data via a publicly accessible computer database that is pivotal for subsequent downstream pharmacogenomic research. Industry giants such as AstraZenecca, Aventis, Bayer, Bristol-Myers Squib, Hoffman–La Roche, Pfizer, SmithKline Beecham[108] were collaborators in this open source project together with the independent charity fund Wellcome Trust.

5. Attract Volunteer Labor

Open source collaborations in the field of information technology demonstrate [illegible] attract a substantial amount of labor from unpaid, highly

idealism, learning new skills and impressing potential employers.[110] 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."[111] These types of incentives might work equally well in the field of biotechnology.[112]

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."[113] 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 make it easier to enforce. Open source licenses, such as the GPL, used in information technology do not contain such technical language, making them popular with the users.[114] 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.[115]

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 in tune with the needs of its users than those of its developers. Thus, 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.[116]

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 research and development costs, which are difficult to estimate in 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.[117] 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.[118]

C. Social Benefits

1. Increased Respect of Peers

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 detect whether the tool or idea worked, whether the task was difficult, whether the problem was addressed in a clever way, and whether the invention can be useful for other tasks in the future.[119] 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 according to the level of recognition and reputation enhancement that the community attaches to different tasks.[120] 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.[121] 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 enounced by Merton; these norms recognize that scientific progress does not come from a void, but always depends on the body of knowledge accumulated by previous generations of researchers.[122] The importance of recognizing this reality is especially marked in the field of biotechnology, where the technological trajectory is now increasingly reliant on a broader and less concentrated knowledge base, with various [illegible] evolution.[123]

3. Improved 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.[124] Feedback from the cumulative results of individual actions will foster improved coordination and coherence among the collective of researchers.[125]

An example of this type of collaboration is the Public Population Project in Genomics (P3G) Observatory. P3G is an international consortium for the promotion of collaboration and international harmonization between researchers and population genomic databases.[126] The P3G Observatory is a knowledge transfer platform, with a mission to: provide the tools that support researchers in the development, harmonization and implementation of research projects, disseminate scientific and technical information developed and collected by P3G Cores and International Working Groups, and to make the comparison and sharing of information between studies feasible.[127] Thus, the P3G Observatory illustrates that open source can assist researchers in developing the necessary tools to facilitate the transfer of knowledge among large genomic database projects and thereby potentially improve coordination and coherence in such projects.

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 up the databases in standardized and nonproprietary ways that would increase the availability of scientific data.[128] These initiatives allow students to obtain the latest information relevant to their chosen scientific field while avoiding the high costs of standard textbook or other copyrighted material. In addition, open source biotechnology projects could permit 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.[129]

5. Increased Motivation of Employees

Employees are usually motivated by "signalling incentives," the desire of the employee to become well known through the improved accessibility of their work. 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."[130] 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.[131] It also entails ego gratification through peer recognition because attribution clauses are often included in open source licenses, allowing others to know who made what contribution.[132]

IV. Conclusion

The patent system is an institution in 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 science. However, this approach remains controversial in the field of information technology, where it was originally developed, and it is only present in its infancy stage in the field of biotechnology.[133] Given this 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 existence or danger of an "anticommons effect" in the field of biotechnology and proposes the use of open source approaches as ideal solutions to this hypothetical problem.

In this Article, I have suggested that this kind of argument is both objectively unsatisfactory and unlikely to convince the major actors of the importance of

rather focus on the often overlooked intrinsic benefits associated with these approaches. The final part of this Article consisted of an enumeration of some of the benefits that I felt best justified 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; 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 its incorporation as a viable option into the numerous emerging guidelines on good 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 highly hypothetical risks uncorroborated by currently available evidence.

About the Author

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8

Re-Engineering Biosafety Regulations in India: Towards a Critique of Policy, Law and Prescriptions

*A. Damodaran**

Bio-safety measures are taken in India to deal with the implications of biotechnology. These bio-safety rules are backed by the decision making structures at various levels that include, Recombinant DNA Advisory Committee, Review Committee on Genetic Manipulation, Institutional Bio-safety Committees, Genetic Engineering Approval Committee and the Biotech Coordination Committees at the state and district levels. Indian strategies to tackle the biotechnology is felt to be ineffective, hence a strong need for revamping the strategies are proposed by various stakeholders, such as civil society, industry, ministry of environment and forests and the biotechnology department etc. This article examines the existing regulatory framework, administrative mechanism relating to the bio-safety in India and suggests certain remedial measures for its strengthening and effective functioning.

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