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The Viability of Open Source Biotechnology

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- Represents emerging growth companies including several venture-backed software vendors in connection with the preparation and negotiation of complicated and multi-tiered software license agreements with their customers including many Fortune 100 companies such as UBS and Manulife Financial.
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- Represents multi-national gaming company in connection with the preparation and negotiation of trademark and brand licensing agreements as well as product development agreements.
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- Represented multinational life sciences company in a misappropriation of trade secrets case under the "inevitable disclosure" doctrine in connection with the unauthorized disclosure of trade secret information obtained during licensing negotiations.
- Advised developer of neonatal and prenatal screening software on dispute with former employee concerning ownership of intellectual property including source code.
- Represented major manufacturer of spectroscopy detection equipment in a patent infringement action seeking $130 million in damages in the U.S. District Court for the Eastern District of Tennessee. Successfully negotiated $10 million dollar settlement.
- Represented well-known cookie manufacturer with respect to licensing trade dress rights to co-packers.
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- Massachusetts, 1995
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- "Is Open Source a Trap for Commercial Software Vendors?," *Mass High Tech* (April 5, 2004)
- "Enforcing Licensing of Downloaded Software Creates Challenges for Companies," *Mass High Tech* (October 9, 2001)
- ".biz Address Absorbs Lawyers, Not Marketers," *Boston Business Journal* (August 17-23, 2001)
- "Critical Audit," The Deal.com (July 12, 2001)
- "Acquisition of IP Assets Requires Due Diligence Process," *Mass High Tech* (July 9, 2001)

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- "Parody" Massachusetts Continuing Legal Education Intellectual Property Conference, Boston, Massachusetts (June 2002)
- "Bankruptcy and the Intellectual Property License: A Licensee's Perspective," Massachusetts Continuing Legal Education Intellectual Property Conference, Boston, Massachusetts (June 2001)
- "Life after ICANN and the Anticybersquatting Act: Defining 'Bad Faith' in Cyberspace," Massachusetts Continuing Legal Education Intellectual Property Conference, Boston, Massachusetts (June 2000)

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The Viability of Open Source Biotechnology

Kimberly B. Herman and David W. Hesford

ABSTRACT

Open-source biotechnology is a relatively new concept inspired by the open-source software movement. The idea behind open source biotechnology is to promote an "intellectual commons" in which biotechnology would be made freely available under license agreements that would promote further development and free use. This article explores how the open source business model, in which economic gain is derived from an increased value of a technology through user improvements, could apply to the biotechnology industry. This article also addresses current efforts in the open source biotechnology movement, obstacles that could hinder its growth, and ways that the open source model could overcome these obstacles.

INTRODUCTION

Open source has changed the face of the software business by allowing a community of computer programmers from around the world to tweak and enhance software continually with the aim of developing better products for public exploitation. Software provided under an open source licensing methodology promotes the free use, development, and exploitation of source code by others. This approach has recently started to take root in biotechnology in the form of bioinformatics software with such applications as BioPerl and BioJava, both widely used by biotechnology researchers.[1] While the open source model has thus far proven viable in the bioinformatics field, what is less certain is whether the open source approach can be applied to biotechnology research and development. That is, can biotechnological research tools be used, developed, and exploited for private economic benefit under the open source model? This article addresses the nature of the open source model, why open source may be a desirable alternative to a proprietary licensing scheme in biotechnology, and how implementation of the open source model in biotechnology could lead to economic benefits for companies.

WHAT IS THE OPEN SOURCE BUSINESS MODEL?

The open source business model promotes the free use, modification and distribution of a technology in order to increase the value of the technology for its users, enabling a company to convert this enhanced use value into economic benefit.[2] Enhanced use value can translate into profit because an increase in the value of a research tool can lead to cost savings or efficiency gains.[3] The use value of a research tool is enhanced through the open source methodology because users who understand the technology improve it in ways previous users did not.[4] This, in turn, can lead to a higher quality product if improved by a large group of users who communicate, all in an effort to enhance the accuracy and reliability of a given technology.[5] Greater accessibility of a product also increases use value by making it more widely available and affordable to customers, which the open source model achieves quite well by making the technology available to all free of cost.[6]

WHY OPEN SOURCE?

Increasingly, large multinational corporations acquire large numbers of patents to increase competitiveness. Bayer, DuPont, Monsanto, Dow, and Syngenta currently own more than 70 percent of the patents in agricultural biotechnology, for example.[7] The conglomeration of rights can create what is referred to as a "patent thicket." In a patent thicket, patents may be so broad in scope as to block future innovation by others, or too numerous to make downstream innovation by others economically feasible. A patent thicket, for instance, became a problem for researchers seeking to develop a pro-vitamin-A-enhanced rice to aid developing countries in their fight against malnutrition and blindness. Dubbed Golden Rice, the rice's development required the use of more than 70 patented technologies. Had Syngenta, an agrichemical company, and others not provided royalty-

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free licenses, researchers would likely not have been able to develop Golden Rice at all as the license fees would have been cost prohibitive. Syngenta's generosity has proven to be the exception rather than the rule, as most companies are unwilling to give up the profits gained from licensing their patents.

However, several efforts are currently underway to develop biotechnological research tools using the open source model. The Australian research institute Cambia is active in a pursuit to make more and more patented biotechnological research tools widely available through its Patent Lens database and its BiOS license.[8] In fact, Cambia researchers recently developed a tool to modify three types of bacteria in order to transfer desirable genes into plants.[9] Cambia licenses this gene-splicing technology under the BiOS license, and while users must place technological improvements into a common pool, companies and other institutions are allowed to patent any products they make using the technology.[10] As a result, the end-product is patentable while the research tools, such as the method to modify bacteria through the gene-splicing technology, remain freely accessible.

The International HapMap Project is another example. Researchers there are pooling resources to develop a product for the pharmaceutical industry. The HapMap is a catalog of common genetic variants that occur in human beings.[11] The project, a collaboration among scientists from various countries, is "designed to provide information that other researchers can use to link genetic variants to the risk for specific illnesses, which will lead to new methods of preventing, diagnosing, and treating disease."[12] Another project underway is the Public Intellectual Property Resource for Agriculture, or PIPRA, which seeks to provide researchers, developers and farmers in underdeveloped countries with the resources to work with, as well as routes around the patent thicket and other intellectual property rights obstacles that impede growth in their communities.[13] As part of its efforts, PIPRA has developed a database of 6,600 agricultural patents from 45 different countries.[14] PIPRA aims to create an intellectual commons among various institutions to make it easier to use current and future inventions for the development and commercialization of improved staple and specialty crops.[15]

IMPLEMENTING OPEN SOURCE

Despite these efforts now underway, several roadblocks still stand in the way of applying the open source model more widely to biotechnology research and development. The length of development, capital costs and expense of obtaining patent rights and regulatory approval are greater than in the software industry.[16] This has led critics to argue that open source business opportunities are not present in biotechnology, and even if they are, will never be lucrative enough to offset investors' concerns.[17] Moreover, technological information is not as heavily codified as in software, which makes the transfer of information among researchers more difficult and effective contribution less likely.[18] Add to that the competitive culture among biotechnology researchers and open source collaboration seems even less feasible. More so than in the software industry, researchers tend to keep their findings close to the vest in the hopes of gaining economic reward.[19] Furthermore, gaining recognition through publications and awards plays a larger role in the research community than in the programming community, where peer recognition often comes more informally.[20]

Can an open source business strategy overcome these obstacles? Paradoxically, it is the greater expense associated with product development in biotechnology that has the potential to make open source even more valuable in biotechnology than it is in software. At a minimum, an open source business strategy could be used for fundamental enabling technologies that are not a source of competitive advantage for companies involved.[21] This, in turn, would likely defray some cost concerns, and with experience, companies would likely become more willing to invest in open source projects from which they can gain an economic reward. In the software context, IBM has integrated the open-source-licensed Apache HTTP server into its hardware products.[22] IBM has found that the use of open source technology has led to substantial cost savings in its product development.[23] A pharmaceutical company could employ the same strategy, using an enabling technology such as genome sequencing data compiled by the International HapMap Project to enhance a drug already established on the market. That company may then be interested in investing in the project to ensure that the economic benefit received will endure. Another potential source of funding could come from a company wishing to become more competitive where a competitor dominates the market using a particular patented technology.[24] If an open source project develops a tool that competes directly with that competitor's technology, a company may be willing to fund a project because open source would perhaps level the playing field.[25]

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As an alternative business strategy, a company could decide to make a product available under an open source regime where a product failed to produce enough revenue under a closed-source model in order to position itself better in the marketplace. If nothing else, the company would enhance its brand and reputation as a contributor to the common good.[26] More to the point, a company might then be in a position to generate revenues—fees from licensing

brand names and trademarks related to its open source product, for example.[27] Indeed, a company could augment the fees obtained through such licensing with revenues from providing services to complement the new open source technology.[28] This would be especially useful in the biotechnology context where a technology may require the inventor's know-how to use it effectively.

While financial obstacles may be surmountable, concerns over the competitive environment in biotechnological research are perhaps more difficult to overcome. Open source would presumably negate competition among researchers because researchers may not gain financially by competing. On the other hand, the lack of financial rewards for open source contributors may subvert the incentive to contribute, since the patent-heavy biotechnology industry relies on financial incentives to spur innovation. The whole premise behind the patent system is, after all, to provide incentive to innovate through the grant of a short-term monopoly on one's invention. Nevertheless, aside from the possibility that researchers would be willing to cooperate merely for the intangible reward of contributing to the common good, open source is also liberating because it can accelerate development of protectable ideas.

For instance, many researchers view patent protection on fundamental enabling technologies as possibly hindering vital discoveries that may cure a disease or solve an environmental problem.[29] If researchers view their contributions in an open source project as a means to overcome this problem and potentially improve the lives of others, then the intangible benefit derived from contribution might offset the lack of financial reward. The real power of open source, however, is that by advancing the capabilities of technologies that enable new discoveries, but are not necessarily imbedded within such discoveries, the financial incentive to discover remains strong. Thus, the open source model could lead to greater contribution among researchers who are genuinely concerned with the betterment of society, such as those at Cambia, the International HapMap Project, and PIPRA.

Open source project leaders could also enhance contribution among researchers by establishing clear guidelines as to how project development is to occur.[30] For instance, the International HapMap Project explains its guidelines for contributors on its website, allowing researchers to clearly understand how they can add value to the project and what rights they are dedicating to the public good.[31] A website encourages collaboration and should be easy to navigate in order to accommodate new users.[32] Finally, as often times occurs in open source software development, projects should publicly acknowledge researchers' contributions on a website, for example, as both a reward for that researcher and an incentive for future contributions.[33] This, too, may alleviate some of the concerns that the culture of prestige in biotechnology is a roadblock to further collaboration.

THE PROPER LICENSING APPROACH

A further challenge is to convert open source software licensing practices based in large part in copyright law into a licensing scheme that will cater to the patent-heavy biotechnology industry. One attempt is the BiOS license. This license as currently drafted, however, actually fails to conform with the Open Source Initiative's open source definition, which "requires licenses to allow modifications and derived works to be distributed under the same terms as the license of the original software."[34] The license also requires users to contribute any improvements back to the original inventor, a grant-back provision that could exceed the scope of the subject patent and perhaps encourage patent misuse challenges.[35] A better approach might be to employ a license model that allows users to license the product freely to others under any terms they choose.[36] While such an approach has already been employed in bioinformatics, it has yet to be tested in the area of biotechnology research and development.[37] Greater licensing freedom could lead to a greater use value for the subject biotechnological research tool developed under an open source model, which in turn could lead to increased economic benefits for the company using the open source approach. Further, a business-friendly licensing system will likely maximize the growth potential of open source biotechnology by encouraging businesses to get involved in open source development.

The legal enforceability of a patent licensed under the open source model is unclear beyond the theoretical patent misuse issues. Indeed, a U.S. court has only recently squarely addressed the enforceability of an open source software license, more than 20 years after Richard Stallman began the open source software movement with the Free Software Foundation and the well-known General Public License.[38] Perhaps a U.S. court will not take as long to reach a decision on an open source biotechnology license, but whether a court even will have the opportunity to address the enforceability of such a license is contingent on the growth of the movement.

SUMMARY

The early stages of the open source software movement were fraught with uncertainty as to the feasibility and wide-scale acceptance of the concept. More than 20 years later, the open source movement is becoming more mainstream, recognized and utilized in the software industry. While many legal uncertainties concerning open source licenses have yet to be addressed by the courts, the movement has nevertheless grown. A similar potential exists for the open source movement in biotechnology. So much has yet to be done in this area that it might take 20 more years of trial-and-error to find a solution that works within the patent-heavy biotechnology industry. Still, the underpinnings are there. The next step is overcoming the obstacles that stand in the way of progress.

ENDNOTES

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20. *Id.*
21. Hope, *supra* note 1, at 211.
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26. *Id.* at 210.
27. *Id.*
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