

## Research Report

# Open Source Biotechnology Platforms for Global Health and Development: Two Case Studies

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### Abstract

*Using a case study approach, we examine the potential of open source biotechnology platforms for global health and development. Two initiatives relying on collaborative online platforms are analyzed: projects by the nonprofit institute Cambia and India's Open Source Drug Discovery (OSDD) project. Cambia is addressing neglected diseases by making relevant patent information available through both its Patent Lens project and its Initiative for Open Innovation. OSDD complements this initiative through a collaborative platform and open source practices to accelerate drug development for neglected diseases.*

*Cambia as well as OSDD, while sharing the goal of addressing basic needs of the developing world, have each implemented principles of the open source movement in different ways. We find that, in open source biotechnology for global health and development, at least three linked senses of "open" should be considered: open access, open licensing, and open collaborative platforms. We conclude that biotechnology for global health and development can move ahead through its own version of open source practices and collaborative online platforms.*

### Introduction

Close to 10 million children under the age of five die each year. Most of these deaths occur in lower-income countries and are preventable (WHO, 2009). Chronic noncommunicable diseases, such as heart disease and cancer, are growing in lower-income countries, and they now account for roughly 60% of all deaths worldwide (Daar, Singer, & Persad, 2007). Yet there is hope for moving forward. Millions of lives have already been saved through vaccinations, public health measures, and drugs (Levine, 2007). Many of these advances can benefit from biotechnology—the use of biological processes for industrial, health, and other purposes.

This article examines the potential of collaborative open source biotechnology platforms in global health and development. We start by summarizing the controversial role of patents in innovation, and by considering the open source approach as one response. We then describe two case studies relying on collaborative online platforms: Cambia and India's Open Source Drug Discovery (OSDD) project. These case studies are based on analyses of transcripts of semistructured interviews conducted by the authors, as well as on secondary data, including journal articles, news reports, books, and Web sites. The next section looks at related initiatives already underway and suggests issues that merit further exploration. We suggest that, in open source biotechnology for global health and

development, at least three linked senses of “open” should be considered: open access, open licensing, and open collaborative platforms.

Finally, we conclude by suggesting what might be needed to build on the modest successes to date. We argue that, supported by collaborative platforms, biotechnology for global health and development holds promise for improving health and food security in developing countries (Masum, Chakma, & Daar, 2011), and that it can move ahead through its own versions of open source practices and collaborative online platforms.

### ***The Controversial Role of Patents in Innovation***

Patents are viewed as being directly linked to innovation (Netanel, 2009). However, confounding issues surrounding intellectual property (IP), innovation, and international development have been raised. For patents, these issues include whether patents are being granted for truly novel inventions; when patent protection should be overridden for humanitarian reasons; what barriers to follow-on innovation the patent system might create in itself; and the unique needs of research and development (R&D) for international development (Commission on Intellectual Property Rights, 2002; Netanel, 2009; WHO, 2006). Furthermore, patents themselves can be expensive, time-consuming, and risky to work with.

Innovation rests on a public domain of ideas (Boyle, 2008), yet genes of important organisms like humans, rice, and maize have been patented. Discoveries related to the human genome are vital to future biomedical innovation, but it is estimated that 20% of the human genome is claimed by patents. Two-thirds of these patents are owned by private firms, and a similar fraction may be legally questionable on the grounds that they are too broad, not disclosed properly, or overlap other patent claims (Cukier, 2006). Such “patent thickets” have led to what some experts call the “tragedy of the anti-commons”—the proliferation of patents blocking fundamental tools in biotechnology research may have led to the under-use of knowledge, due to high costs and lack of cooperation by patent holders (Gold, Kaplan, Orbinski, Harland-Logan, & N-Marandi, 2010; Maurer, 2006), though the extent to which this actually takes place is debated (Joly, 2007).

Patent pools are consortiums that agree to cross-

license patents relating to a particular technology. They are beginning to be used to stimulate research in neglected diseases, allowing both access to select technologies and competitive business practices (Van Overwalle, 2009). However, more enabling tools and collaborative practices are required to harness innovation and the patent landscape for international development.

### ***The Open Source Approach***

The open source movement has had an enormous impact on the global software industry (St. Amant & Still, 2007), with estimates of an economic value in the tens of billions of dollars. However, this economic impact understates open source’s true importance. Richard Stallman emphasizes the value of software that is both open and *free*—in his phrase, “free as in ‘free speech,’ not free as in ‘free beer’” (Williams, 2002). Free and open software, as Stallman defines it, is software that not only is not proprietary, but that cannot be made proprietary—access to it is an inalienable right, regardless of location or income, and other software can build on it to create new solutions.

A range of incentives motivate participation in open source projects, including building reputation, providing public goods, and undercutting for-profit rivals (Weber, 2004). Open source methods are now being applied in different sectors, including biotechnology. However, the metaphor of open source needs adaptation when transferred to biotechnology, since biotechnology research efforts are not structured like the software industry. To take one difference, new biotechnology may require long and expensive laboratory development, followed by even more expensive clinical trials. New software, on the other hand, can be developed in a more incremental and, typically, less expensive fashion.

In the remainder of this article, we explore the Cambia and OSDD initiatives, and we discuss how open source approaches are being applied in biotechnology for global health and development, supported by collaborative online platforms.

### **Case 1: Cambia**

Cambia is a private, nonprofit institute based in Australia. Founded by Richard Jefferson, Cambia’s mission is “to democratize innovation: to create a more equitable and inclusive capability to solve problems using science and technology” (Cambia, 2011).

Cambia used its first grants from the Rockefeller Foundation to develop training and technology to support rice scientists in Asia, Africa, and Latin America. During the 1990s, Jefferson traveled to many labs doing biotechnology in the developing world; this experience influenced his later work.

### ***BiOS: An Open Source Licensing Solution for Biotech***

In 2006, Cambia launched the BiOS Initiative (Biological Innovation for Open Society), the aim of which was to create a “protected commons” to allow users to access, improve, and modify enabling technologies without infringing on proprietary rights. According to Gary Toenniessen, director of food security at the Rockefeller Foundation, “agriculture R&D for the developing world could be lost without a concept like BiOS and open source” (Miller, 2004).

The heart of the BiOS Initiative is the development of BiOS licenses, designed to cultivate collaboration. BiOS licenses derive from Jefferson’s belief in the enabling power of legal tools. They aim to allow access to, and improvement of, enabling technologies, which in turn are hoped to ease the development of solutions for local needs. BiOS follows a long line of previous open licenses like the GPL (software) and Creative Commons (cultural goods) that have “some rights reserved” (Boyle, 2008).

BiOS licensees must sign a detailed legal contract to preserve the right of others to use the technology—e.g., by agreeing not to assert IP rights against others who have also signed the contract. In exchange, they gain access to the technology (BiOS, 2009). Unlike some other open source licenses, BiOS licenses do not prohibit licensed technology from being used to develop downstream proprietary products.

When a developer makes technology available under a BiOS license, the developer does retain ownership of the technology, but the company may not assert IP rights over that technology or improvements against other BiOS licensees, nor may it prevent sharing of biosafety data. There is a technology support agreement with each BiOS license in which for-profit companies must pay a fee based on their location and size of operations.

Cambia’s first license was developed for plant molecular-enabling technologies, with subsequent licenses including one for health-related technolo-

gies, as well as a generic agreement for patented technologies and know-how. Cambia’s Web site sums up the potential benefits of the BiOS licenses as follows (BiOS, 2009):

- Ability to access the intelligence, creativity, goodwill, and testing facilities of a larger and wider community of researchers and innovators;
- Decreased transaction costs relative to out-licensing or obtaining technology via bilateral license agreements;
- Potential for portfolio growth through synergies obtained by combining pieces of technology that may, by themselves, be too small to make a profit or lack sufficient freedom to operate or implement;
- High leverage of costly investments in obtaining proofs of concept, developing improvements, and obtaining regulatory and utility data; and
- Ability to commercialize products without an additional royalty burden.

Cambia suggests that BiOS licenses may be of interest to several groups: first, anyone interested in materials and technology from Cambia itself, such as GUSPlus or TransBacter, which are available only under BiOS-compatible agreements; second, research organizations that want access to helpful information; third, smaller enterprises that want protection from the “patent thickets” described earlier that impede their progress; and fourth, large companies that see how sharing information in particular domains may help them leverage investment by selling services and building on the improvements of others (as has happened with some large companies in the software industry, like IBM).

Some conclusions can be drawn from Cambia’s experience with BiOS. Various firms did express enthusiasm toward the BiOS licensing structure during the first years of the initiative. However, the licenses still need to be worked on to have the effect that Cambia desires. Certainly, BiOS has not resulted in a flowering of open projects in the way that the GNU Public License and its offspring produced in software.

The primary reason for this may be that software is intrinsically cheap to produce. One programmer working in her basement may create a new product,

requiring none of the sophisticated laboratory equipment on which biotechnology depends. Software does not require large investments to meet regulatory and clinical testing requirements. Once created, software is easy to reproduce.

While large or mid-sized organizations will have the resources to pursue Cambia's licensing scheme, small organizations may not. Another problem is that in order to create a pool of components large enough to create new solutions, many distinct methods may need to be licensed.

An analysis of BIOS suggests that IP managers committed to open access might still benefit from the strategic use of patents in certain cases, such as to meet humanitarian goals (Boettiger & Wright, 2006). For example, by facilitating sales in developed country markets, funding might more easily be found to increase product availability in developing countries. Effective use of licenses like BIOS may depend on a clear understanding of goals, power structures, and the IP landscape.

### ***BioForge: The First Open Biotech Web Portal***

Launched by Cambia in 2005, BioForge was a Web portal designed to create an active development community that would collaborate on projects and technologies, develop protocols, discuss experiences, and access tools in a public but secure environment. BioForge was patterned on successful software development portals such as SourceForge.

To kick-start BioForge in 2005, Jefferson seeded it with patented Cambia technologies, including GUSPlus. Within two months of its launch, BioForge had 2,000 registered users. What was expected from BioForge was a cooperative development of concepts and solutions.

However, within the first year of BioForge's launch, it became clear that collaborating online was not happening within the target life sciences community. BioForge did not continue to grow.

Several factors may have contributed. Scientists may not be motivated to collaborate online unless it helps to solve immediate challenges. Similarly, Janet Hope has suggested that collaboration between biotech workers may be harder than in software, because of a lack of standardization (Hope, 2008). She gives the example of experimental protocols, which may differ from lab to lab. It is not clear that a portal like BioForge could facilitate the sharing of

lab culture. Finally, as Jefferson has said, "Now can we do [BioForge] differently? Absolutely. . . . [When] a sensible accreditation and value is ascribed to a contribution, then it'll have merit. It really will" (Personal communication, 2009).

The BioForge project did not thrive, and it was discontinued. A follow-up platform that learns from BioForge's difficulties may yet prove valuable.

### ***Patent Lens: An Open Patent Research System***

Large costs in navigating "patent thickets" risk hampering follow-on innovation, and some argue that patents have been granted for innovations of dubious novelty (Heller, 2008). Patent Lens, a free patent informatics resource, is Cambia's response to this complexity. As of 2009, the database contained more than nine million patents, and over 68 million DNA and protein sequences disclosed in patents.

Patent Lens allows diverse players to investigate and analyze key IP issues, facilitating community involvement in guiding the patent system. Cambia plans to integrate business information into the database to make visible IP power chains aimed to reveal who owns what, and dependencies between technologies. According to Jefferson:

Patents are not about science—they're about the conversion of science into perceived economic value, and that specialized language and capability has emerged as the ecclesiastical elite. What we wish to do is democratize that process. (Personal communication, 2009)

Patent Lens was first developed with funding from the Rockefeller Foundation, which saw that industrialized countries were seeking patents on the rice genome. These patents could inhibit the improvement of rice in the developing world. Early on, Cambia's team used the Patent Lens technology to map out the patent landscape of *Agrobacterium*—a widely-used tool for making transgenic plants, tied up in many patents mainly owned by a few large life sciences companies. Cambia was then able to develop TransBacter, a way to implant genes into a plant using a different family of bacteria than that used by *Agrobacterium*.

Patent Lens has been praised by the World Intellectual Property Organization (WIPO) and commentators. The next step Jefferson sees is to develop informatics for analyzing patents, as discussed later in the Initiative for Open Innovation section.

With an understanding of Cambia's history and projects, we turn now to the second case study in collaborative open source biotechnology platforms.

## Case 2: OSDD (Open Source Drug Discovery)

India's OSDD consortium was launched in 2007 by the country's Council of Scientific and Industrial Research (CSIR). OSDD has been strongly supported by CSIR's director, Samir Brahmachari.

The OSDD initiative attempts to encompass the drug discovery process: identification of nontoxic drug targets, *in vitro* and *in vivo* validation, *in silico* screening of small molecules, lead optimization, pre-clinical toxicity, and clinical trials. OSDD aims to achieve affordable health care through a platform where talented minds can collectively discover novel therapies, as well as to bring openness and collaboration to the drug discovery process, and keep drug costs low.

Brahmachari has suggested the necessity of retaining patent protection alongside open source development, rather than in opposition to it:

We will not put a wall around drugs that are required by the masses and which we want to sell cheaply (such as Hepatitis or TB drugs), but will put a wall around drugs that have high market affordability, where the diseases that these drugs treat are not yet prevalent among lower income groups. In addition, by patenting, we can also challenge monopolies. (Kochupillai, 2008)

For Brahmachari and OSDD, openness represents an instrument—one that, like patent law itself, is to be used appropriately to achieve specific goals and social results.

### How OSDD Works

Developments in bioinformatics have enabled researchers to do some drug discovery *in silico*, while sitting in front of their computers. CSIR has set up a collaborative online platform, SysBorgTb, focused on tuberculosis. The Web portal provides bioinformatics tools, biological information, data on the pathogens, projects for participation in drug discovery, and discussion forums. As of October 2009, there were more than 1,700 registered participants for OSDD (SysBorgTb, 2009).

OSDD aims to break down drug discovery into smaller activities with clear deliverables, which are

posted on its Web portal. Participants can contribute ideas, software, articles, IP, or anything else that helps to solve these problems.

Users of the portal must comply with OSDD's terms and conditions, which aim to prevent third parties from acquiring proprietary rights based on information available on the portal without contributing improvements made back to OSDD. Like the BIOS license, OSDD allows users to commercially or noncommercially use improvements, additions, or modifications. Users, though, must grant back an unencumbered worldwide non-exclusive right to OSDD for use of any IP rights acquired for their improvements or modifications.

Participants have clear incentives—an element that Jefferson identified as missing from BioForge. All contributions are planned to be peer-reviewed; contributors will receive rights within the system based on credits accrued. A more subtle incentive may come from OSDD's momentum: clear goals and high-profile backers.

The OSDD project has investigated the genetics of *Mycobacterium tuberculosis*, with a view to finding new treatments. In October 2009, OSDD announced a collaborative project to re-annotate the entire *Mycobacterium tuberculosis* genome in order to make all information available on each gene easily accessible and searchable. While the success of this project remains to be assessed, it follows the earlier successful completion by OSDD of "TBrowse," an analysis tool for the tuberculosis genome (Bhardwaj, Bhartiya, Kumar, et al., 2009). The complexity of developing better tuberculosis treatments highlights the need for the best minds to collaborate and share expertise in an open environment.

### Scarecrow or Wall: Using the Right Form of Protection

Samir Brahmachari's approach to open source is to add it to the toolkit next to patent protection. Brahmachari likens the difference between the two approaches to the difference in protecting a factory (by erecting an expensive wall) as opposed to protecting a rice paddy (by erecting a cheap scarecrow):

In growing a paddy, we will use an open source model. While building a factory, we will patent. If my discovery benefits millions, and I want to give it to them cheaply, I do not want to raise the costs by spending a lot of money in protecting.

But if the R&D is highly expensive, then we will patent. (Personal communication, 2009)

Brahmachari sees open source as a methodology that can be used for sidestepping certain issues, rather than meeting them head-on. For instance, by developing free diagnostics based on pharmacogenomic principles, an open source initiative can revive older, inexpensive drugs, thus sidestepping the arduous process of developing new drugs.

### Looking Ahead

#### ***The Initiative for Open Innovation***

Cambia's Patent Lens project was a significant success, and it is now an open Web resource for patent search and analysis. The BIOS licensing infrastructure was met with enthusiasm by some organizations, but it had problems in becoming truly effective in its goals. BioForge did not complement the culture of scientists, and this first attempt at a collaborative portal for biotech was not successful.

With these lessons learned, Cambia is moving ahead with the new Initiative for Open Innovation (IOI). IOI will explore and validate new collaboration and licensing tools with the aim of fostering a "commons of capability." This commons is hoped to lower costs of creating new biotechnology solutions by helping nonspecialists identify areas of opportunity.

As of 2010, IOI was being funded by the Bill and Melinda Gates Foundation and the Lemelson Foundation. The initial funding of AU\$5 million was focused on creating "patent landscapes" for malaria, tuberculosis, dengue, and other critical infectious diseases of the developing world.

IOI aims to create an evidence base for policy changes for public benefit. Jefferson describes how these tools will help to reduce barriers to innovation by reducing the need for expensive IP professionals or "clergy":

What we're trying to do with this, in terms of the low hanging fruit, is to bring in the world's patent information in a form that lends itself to much higher order mark-up and navigation tools. . . . How does it affect your life as a drug developer? Or as a citizen? There's no way to know that right now except through clergy interventions and our job is to break that down. (Personal communication, 2009)

IOI has plans to partner with the Indian government and OSDD. OSDD may benefit both from Cambia's philosophy on system-level barriers, and from its IT tools to navigate patents.

#### ***Four Issues for Future Exploration***

The case studies in this article indicate the potential and modest achievements to date of collaborative platforms and open source methods for development-oriented biotechnology. Many issues remain to be explored.

***Viable collaborative platforms:*** Cambia and OSDD both deployed collaborative platforms. While BioForge was not a success, OSDD and Patent Lens suggest the potential of open platforms.

Success factors included low cost of entry for participants and subdivision of complex challenges into simpler sub-challenges (Benkler, 2006). Institutional support, strong leading personalities, and a humanitarian mission encouraged volunteering. As Jefferson and OSDD noted, metrics that reward users' contributions may be helpful. Other factors include interface design and the platform's perceived utility for helping users solve the problems they care about.

***Three kinds of "open":*** The demonstrated value of collaborative platforms in both Cambia and OSDD illustrates a point about the "open source" nomenclature. In the software world, open source literally refers to the ability to see the source code of programs. However, "open source" also embodies a set of cultural practices, licenses, and innovative collaboration methods.

In development-oriented life sciences, therefore, at least three linked senses of open source should be considered: open access to underlying information, open licensing practices, and open collaborative methods and platforms. Open access to information by itself, while often the easiest step to take, may be of little value without the freedom and collaborators with which to apply such information to create solutions.

***The IP reform debate:*** Many calls for reform have been raised in IP and international development (Netanel, 2009; WHO, 2006). While global health issues have featured prominently in these debates, such as compulsory licenses to permit lower-cost manufacturing of essential medicines, the use of collaborative platforms and open source for global health has, thus far, received little attention.

Part of the reason may be the complexity of the issues involved. It is easy to understand a situation where a Brazilian, South African, or Indian company wishes to manufacture a low-cost version of an AIDS drug. It is much harder to grasp the opportunity costs of a complex patent regime, the unrealized potential of drugs that are *not* being developed when barriers to innovation are high, or the potential inhibiting effect on innovation of relaxing IP protection. Tools like Patent Lens help to demystify such issues.

To enable a more informed debate, it may help to look at examples such as Cambia and OSDD. Better metrics and tools might also be created to analyze IP policy options.

**Incentives for innovation:** A key issue raised by private sector entities in favor of stricter IP regimes is incentives for innovation. If innovators are not rewarded, who will invest in innovation?

There is a need to better understand viable business models addressing this issue. For example, Hope (2008) has proposed that a biotech company could remain profitable while open-sourcing its core technology. Her model assumes the following to be true: increased access to a product or method will increase its adoption and customer base; wide adoption may lead to improvements in the product or technology; and the company can position itself to profit through analysis and contract research, and to act as the “expert” in the open-sourced technology. This model is analogous to one that has been successful for companies like Red Hat in the software world: Red Hat’s original business model was to give away its core Linux operating system for free, and then to charge for premium support services.

While intriguing, more analysis is needed. Biotechnology innovations may be the result of a complex chain of discoveries, each of which entails risky investments that may fail. At which of these stages are open source approaches most viable? What partial rights regimes might release humanitarian rights that promote use in low-income countries, while keeping core rights that a company needs to maintain profitability (akin to the BIOS and Creative Commons “some rights reserved” approach)? How can investments into enabling collaborative platforms be supported as pre-competitive tools that help all parties achieve more?

Both Cambia and OSDD were largely supported

through government and foundation grants. However, a variety of innovative funding mechanisms are being explored for global health that span the spectrum from for-profit to grant-based (Hecht, Wilson, & Palriwala, 2009). There is ample room for research into viable open source models that apply at each stage of the biotechnology value chain.

With research into diseases of the poor receiving increasing funding, there may be more receptiveness to the argument that open source approaches can increase the pool of knowledge capital on which downstream innovations will be based, even though they may make private capture of short-term profits more difficult in some cases. Future initiatives may need incentives to attract sufficient early adopters for the innovation or platform to become self-sustaining, and metrics to measure forms of output that add to the global knowledge commons may also be necessary.

## Conclusion

In this article, we have explored two case studies of collaborative open source biotechnology platforms, and considered implications for new solutions for international development.

Each area of endeavor that open source principles are applied to may require adaptation. Attempts at mapping collaborative platforms and the software analogy onto such areas (for instance, BioForge as an explicit copy of SourceForge) may fail. However, they may fail in an educational way, indicating which alternative way forward may succeed. For example, the Tropical Disease Initiative is trying open source methods for neglected disease research and drug discovery (Maurer, Rai, & Sali, 2004), attempting to kick-start participation with publication of a small base of seed work (Orti et al., 2009), though with limited success to date.

The fact that organizations like India’s OSDD are pursuing collaborative platforms for open source drug development is indicative of the potential in the developing world. While OSDD is at a very early stage, it has attracted thousands of contributors and received major funding from the Indian government. Initiatives like OSDD may enable North-South collaborations to tackle international development challenges.

“Open source” can entail open access to information, open licensing practices, and open collaborative platforms. A project may gain differential

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benefits from different ways of being “open.” One universal principle, suggested by Richard Jefferson and others—a *right of access to enabling technologies*—may be more important than the details of a particular license. With this principle and the observations above in mind, the need now is for further research and implementation to harness open source and collaborative approaches for solving challenges in international development. ■

### Acknowledgment

This study was funded by the Bill & Melinda Gates Foundation through the Grand Challenges in Global Health Initiative, and supported by the McLaughlin-Rotman Centre for Global Health at the University Health Network and the University of Toronto.

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