1. BIOTECHNOLOGY AND AGRICULTURE

The polarized debate

Millions of farmers worldwide try to grow food and maintain adequate livelihoods under poor and risky growing conditions while suffering from poverty, hunger and poor health. Around the world, more than 800 million people go to bed hungry. Some 5 million die every year from nutrition-related illnesses. More than 70% of the world’s population live in rural areas in developing countries and depend on agriculture to provide income and food security. For most people in developing countries, a better standard of living depends on increasing productivity in agriculture. Agricultural biotechnology has the potential to help farmers in developing countries produce more by developing new crop varieties that are drought-tolerant, resistant to insects and weeds and able to capture nitrogen from the air. In addition, biotechnology has the potential to make the foods farmers produce more nutritious.

Nevertheless the role of modern biotechnology in agriculture and food security is the subject of increasing debate and controversy. The real heat in the debate stems back to the late 1980s when rapid scientific and technological advances added new dimensions to the discussions. Industry consolidation, the increasing commercialization of genetically modified foods, the expansion of proprietary research and products, the growth in activities and influence of environmental activists and the increasing food security in the world, particularly in Africa, has made for a difficult environment for assessment of the potential role of biotechnology in addressing food security. The ability to discuss the potential of biotechnology, how, and under what circumstances it might address problems facing millions of poor farmers, becomes hamstrung between two extreme poles. At one end, are those who tout biotechnology as a panacea, a box that if checked off will solve the problems of world hunger without other efforts and without real risk. At the other end, are those who associate all biotechnology with genetically modified organisms (GMOs), link biotechnology with nothing but danger and risk and see no potential benefits whatsoever. They believe that the development, commercialization, and application of the technology should be stopped.

The confusion created by the resulting polarized debate makes it difficult for developing countries to derive benefits from the technology while minimizing the associated risks. While not a panacea, biotechnology as it could apply to agriculture and human nutrition has the potential to help address problems that affect billions of lives.

The Generation Challenge Program and IP mechanisms

The CGIAR’s Generation Challenge Programme (GCP) reflects the belief that biotechnology research, together with appropriate policies, better infrastructure and traditional research methods, can bring benefits to millions of poor farmers and consumers. The GCP was created to use advances in molecular biology to harness the rich global heritage of plant genetic resources and create a new generation of crops that meet the needs of resource-poor people.

The majority of biotechnology research is done by a few private corporations that focus on the agricultural sectors of industrial countries, where they expect the highest rate of return on their investment. Driven by the private sector, the trend in industrialized countries has been toward the expansion of the scope and/or applications of patents and plant breeders’ rights to biomaterials and these trends are replicated (through bilateral and multilateral pressures) in the legal systems of...
developing countries. If ensuring GCP’s products make it from the lab to resource-poor farmers is integral to its work, the GCP will have to grapple with the mechanisms by which it – and it partners -- will relate to and/or manage intellectual property rights.

Fortunately, the GCP is not alone in its concerns or need to find new ways of “doing business.” Traditionally, secrecy and protection were considered two of the main pillars of the biotechnology industry and were seen as essential to generate innovation and economic yield. But today, researchers from both the private and public sectors are concerned that instead of promoting innovation, IP systems have manacled scientific knowledge production and generated transaction costs. The explosion of patenting has created a thicket of rights that is contrary to the dissemination and fluid exchange of research tools that typically characterized agricultural research. Scientists face restricted access to some crucial enabling technologies and general uncertainty as to whether they will find themselves on the wrong side of infringement litigation. If industry innovation is hampered by how the current system functions, the stifling effect of proprietary ownership of basic research tools on the development and use of biotechnology to improve human well-being on a global scale should come as no surprise.

One of the most interesting approaches for researchers and institutions eager to exploit the promise of biotechnology are based on the open source paradigm of the software movement. This paper will begin by briefly reviewing the philosophy and practice associated with open source software and in particular its copyleft licenses. Next the paper will explore the similarities and differences presented by biotechnology, in particular how copyright law (the most relevant area of IP to software) and patent law (the most relevant area of IP for biotechnology) may present different issues. Finally, the paper concludes with a summary of the main features of some of the current efforts in this field of particular relevance to the GCP.

2. OPEN SOURCE APPROACHES

Open source software

The term open source stems from the technical characteristics of most software and from a resistance to the commercial practices arising from these characteristics. Software is created using programming language—the source code -- that humans can understand. To be executed by the computer, source code must be translated by the machine into a machine-readable format called the object code. Unlike source code, object code is difficult for humans to understand. Commercial software is distributed primarily only in machine-readable or object code format. In the initial stages of software development, computer programmers freely exchanged code amongst themselves. In the 1970s, however, private companies began to exploit the difference between source and object codes and to use intellectual property rights to protect software developments that formerly would have been freely exchanged. Distributing software without the source code makes it difficult for competitors to reverse engineer or learn from software distributed and withholding it is used by commercial software firms to maintain proprietary control over their products.

The open source movement believes that source code should be freely accessible and available. In open source projects, source code is distributed with the object code so that it can be studied, improved and modified by other programmers. A description of the variations among projects and philosophies in the movement is beyond the scope of this paper2, but the primary consideration underpinning most of the projects is that software should be available without restraints upon modification, examination or re-distribution. Norms of sharing combine with the utilitarian justification that open source is a better means of producing software when compared with the products of the traditional hierarchical firm model. The open and collaborative nature of the projects lead to higher quality products developed in a shorter time and at less cost.3

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3 See, for example, Raymond, Eric, The Cathedral and the Bazaar. O’Reilly, 1999.
Studies of innovation show that the most successful researcher-developed technologies are those that the key stakeholders – the people who built, bought or used the technology – modified the most.\textsuperscript{4} The evolution of optimal solutions to challenges is best-served by a process coined “learning selection” whereby the key stakeholders – software engineers, computer hackers or farmers as the case may be – are motivated to interact with each other and share knowledge. Through a decentralized and democratic process where key stakeholders interact in improving a technology, and making those improvements available, knowledge is embedded in the technology. While some argue that the open source software movement is a model for decentralized, democratic decision-making and ownership this characterization ignores some important details. Examination of the most prominent open source software projects shows that they are actually tightly controlled by a small number of project leaders who direct the development of the project. In fact the role of reputation and normative constraints in open source software development is very similar to the traditional culture of science where work was traditionally published and accessible with quality ensured through peer-review.

The open source software movement is also not necessarily anti-business as the success of businesses like Red-Hat\textsuperscript{5} and the support of big businesses such as IBM in open source software development demonstrate. Services associated with software have proven to have commercial value without undermining the primary tenets of the open source movement. In addition, proprietary products are not prohibited long as the primary software remains available without restraints upon modification, examination or re-distribution.

The open source software projects have developed a set of novel legal mechanisms aimed to ensure that communally produced code remains freely available and is not captured into closed, proprietary forms. The concerns are addressed through licenses that accompany the distributed source code. A variety of licenses have developed which display a range of terms and conditions intended to address different concerns over capture\textsuperscript{6} but they all require that the recipient of the software must be provided with the source code.

The most prominent versions of such licenses are those that require further licensees who improve or modify the software to make such modifications available on the same terms as the initial software as licensed. The license also precludes the addition of any legal terms besides those initially found in the license.\textsuperscript{7} The licenses are commonly referred to as “copyleft” to demonstrate their differences between the objective of this approach – continued accessibility of creative works – and what many felt was the growing trend in copyright law in terms of accessibility.

It is important to understand that copyleft is not “anti-intellectual property, but is in fact a use of intellectual property, in this case copyright. Copyleft licenses use the property rights arising from copyright to ensure adherence to the terms of the license. Essentially, the activity of the licensee in copying, distributing or modifying the source code is a facial violation of the copyright holder’s exclusive rights, but the copyright holder agrees not to assert those rights as long as the licensee’s activity is conducted under the conditions set out in the license. In the case of open source, the conditions include redistributing the code under the same conditions by which it was obtained. Hence, the underlying copyright provides the property right basis for the license, but it is enforced only if additional property rights accrue.

**Biotechnology: parallels to open source software**

Because of many analogous factors, including the need for innovation to be affordable and more decentralized in order to be meaningful, the open source movement in software development presents an interesting model in distributive technological development for agricultural innovation. Thus far,


\textsuperscript{5} See, www.redhat.com

\textsuperscript{6} For example, some OS licenses impose restrictions on the modifications of the licensed software, others do not. Some forbid commercialization of the licensed software while others permit or require fees for use of the code.

\textsuperscript{7} These licenses are sometimes said to have a “viral” quality because the terms of the initial license attach to any subsequent products incorporating the original code.
biotechnology is being developed largely with a view towards simple and immediately profitable so-called solutions to complex ecological problems. Some authors argue that what has happened in the seed industry is directly comparable to computer software in the 1970s and hence some version of open source may also have direct relevance to agricultural research and development. These authors note that like computer programmers who traditionally shared code freely among themselves, for millennia farmers exchanged seed and allowed others to grow and reproduce it. Then, in both software and agriculture, private companies sought to appropriate for themselves which previously would have been shared. They sought to replace a public property regime with a private one. As noted above, in software, an innovative legal mechanism called copyleft was developed to ensure that no one could take someone else’s copyleft protected program, change it and then prevent others from copying and changing it too. An open source initiative in agriculture would be based on the inclusive, relatively decentralized and democratic model of open source inviting all innovators to participate if they abide by the rules of making their innovations available for further research and improvement. The idea is based also on the logic that farmers are both users and innovators of technology. The model could be applied for the development of plant varieties, for agro-machinery, for biotechnologies and for the sharing of information and knowledge.

**Biotechnology: divergences from open source software**

An open source initiative in agriculture will not just happen. It will need to be catalyzed and to have champions. The relevance and more importantly the limits of the analogy will need to be pushed and understood not so the effort is abandoned but so the differences can be addressed. The capital barrier to entry for a computer hacker, for example, is much lower than that for an innovator in agricultural research and development. Issues of regulatory costs and needs, liabilities, profit margins all need to be explored and analyzed. Getting the incentives right will also be important as well as establishing the appropriate legal enforcement mechanisms. It will also be important to see where we are chronologically in the technology development in agriculture compared to where software was when the open source initiative was launched in that field. The concerns of the private sector agricultural interests with regard to the effects of patents and other intellectual property rights compared to those of the software giants may also give insight into the means of launching an open source initiative in agriculture.

One critical legal difference is that software largely deals with copyright and in biotechnology the intellectual property of most relevance is patent law. An essential function of patent law is disclosure and, at least in theory, it is meant to keep the characteristics of the invention publicly accessible. A patent application must provide sufficient information to allow one of ordinary skill in the art to make and use the invention or it should not be granted. But as noted above, the underpinnings of open source software are about access, improvement and production and source code disclosure largely achieves these aims. One of the essential functions of patent law, the intellectual property law of most relevance to biotechnology, is disclosure yet this is not sufficient to achieve the aims of access, improvement and production in this field. Indeed, with the trends of industry consolidation and the expansion of intellectual property in the biosciences, the patents themselves may block public use. To reflect the ideals of the software open source movement, the focus of “open source” biotechnology must therefore be on the accessibility of biological discoveries and the ability to innovate rather than on disclosure.

As noted above, norms of the open source software movement to keep information and discoveries communal and accessible is similar to the traditional practice of science. Nevertheless, publication or dedication to the public domain – the traditional approach of scientific researchers and research institutions -- does not necessarily make an invention publicly available. This is because biological

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8 See, Douthwaite, supra; and Ravi The Case for Biolinuxes (the South Centre).
10 In the cathedral versus the bazaar sense explored by Eric Raymond.
11 Rebecca Eisenberg notes that prompt disclosure in the public domain can be potentially treacherous if one’s ultimate goal is to keep information freely available. Eisenberg uses the following hypothetical to illustrate: Two rivals, Public University and Private Company each sequence a different portion of the same gene. The patent system in their jurisdiction offers more generous protection for full-length genes than for gene fragments. If Public University freely discloses the portion in a public
technologies are increasingly not self-contained, but are rather interdependent technologies which require several key components to function. Technologies can be seen as ‘wheels’ requiring a number of ‘spokes’ to function. The ability to transfer a gene to a crop plant, for example, may require dozens of individually protected, discrete technologies. Denial of access to any one of these can deny the use of the technology by potential users, and worse, prevents the iterative and cooperative shaping and improvement of the technology to meet diverse users’ needs. Unfortunately, the placing of one or more key components into the public domain allows no leverage to bring other components into a collective whole with broad access. The potential and limits of licensing in an open source patent context — as opposed to publication or dedication to the public domain — is therefore of interest to encouraging innovation in the field of biological technologies.

Open source licensing in the software context has developed around the rights granted by copyright. Copyright protects the fixed and original expression of software in the form of symbols or indications of computer code. Copyright arises automatically when the copyrighted work is fixed in a tangible medium. No formal institutional process, publication or distribution is needed to perfect the rights. Copyright confers exclusive rights only against unauthorized copying, or against other violations of the specifically enumerated rights of the copyright holder. The exclusive rights of the copyright holder extend only to those arising out of contact with the copyrighted work. Independent creation of a work is a defense to claims of copyright infringement even if the work is similar or identical to the protected work. Copyleft-type licensing takes advantage of this by creating a contractual relationship between the creator and user of the software. In copyright, whenever there has been access, there is an opportunity to condition such access on agreement to particular terms for access. In copyleft, the copyright owner agrees not to assert her exclusive rights so long as the agreed terms of the license are followed. The exclusive rights associated with patents are different from those associated with copyright and open source patent licenses will need to develop with those differences fully explored. For example, patents prohibit the making, using, selling, offering for sale or importation of the claimed invention or information provided by the patent holder even if the invention is independently created. Patents may therefore where the alleged infringer is neither aware of the patent nor the terms of by which the patent owner would authorize the activity.

Shrink-wrap licenses and material transfer agreements have been used in ways that are analogous to the label licensing approach taken under open source copyright. For example, patented seeds may be provided in a “seedwrap” license containing terms restricting the commercialization of any improvements. The point of access is the point where a license can be imposed. But in the case of patents, an independent developer of a patented invention has not been in the position to invoke a license and so remains prohibited from all uses of the invention. It is not clear under US patent law whether a patent holder can make the claimed invention available under binding, generally announced terms of use as opposed to a license between parties. Another option would be for the patent holder to not sue for infringement when the invention is used. What is not clear, however, is if a failure to enforce will ensure accessibility or have the same practical effect as a failure to patent in the first place and the risk of the invention being captured in proprietary improvements.

The major differences between the letter and practice patent and copyright law will need to be analyzed to understand the potential and limitations of open source patenting. It is clear that an open source approach is a promising approach to resolving the tension amongst the communality of science, the broad ability to innovate and the economic incentive of patent law. From open source software we have seen new business models emerge that demonstrate that money can be made without controlling or restricting access to the tools of innovation. In biological technologies, these tools — enabling technologies — may be considered pre-competitive for high-margin applications, but are crucially lacking for low-margin applications. Free access to such tools is critical for their continued evolution in all contexts but in particular to be able to address the challenges of low margins and the market failures

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13 E.g., the existence of improvement patents.
associated with the needs of those people for whom the GCP was established to serve: the resource poor.

3. CURRENT EFFORTS

A number of organizations are exploring the issue of the application of open source beyond the arena of software. In the area of biological innovation, probably the most prominent and relevant example to the GCP is the BIOS Initiative of Cambia. BIOS – Biological Innovation for an Open Society – is developing, promoting and validating a new model for the innovation and delivery of biological technologies. BIOS will first apply this democratization of innovation to problems of biology, ranging from food nutrition and agriculture through its paradigm should extend to challenges in environment, medicine and public health. BIOS will do so by catalyzing a large community of innovators to produce high quality and relevant technologies and secure them in a protected, universally-accessible commons.

The private sector has addressed the access problem by creating large IP portfolios and negotiating cross-licensing arrangements to obtain full platforms of enabling technologies. This bars entry in even the private sector to all but a few big players. The public sector, with its fractured portfolio and its eagerness to license out publicly-developed technology, is at a grave disadvantage. This was one of the impetuses to the creation of the GCP in the first place. Without a mechanism – like the protected, limited commons envisioned in the BIOS Initiative – the critical work of the GCP could be for naught. This is why the founding institutions of the GCP put the issue of product delivery and its relationship to infrastructure, policy and legal mechanisms as a high priority.

By promoting new thinking, new institutional mechanisms, new technologies and a new business model, BIOS will allow complete re-thinks about empowering 3rd-world (and indeed 1st world) innovators to address local, small-margin, small market innovations in food, agriculture, public health, industry and environment. BIOS’s structure provides a new method for innovation and the ability to secure the resulting technologies in a commons, accessible to all.

BIOS is an international initiative, catalyzed by CAMBIA in the early stages. Core activities involve the construction and curator ship of portfolios of biological enabling technologies and the development of a suite of open access license templates, applying aspects of the open source licensing found in software to patented technologies. Portfolios will be seeded with CAMBIA technology and will grow through contributions of existing technology (either by assignment or licensing) and the commission of future technologies. Open access licensing will prevent the technologies from being privately appropriated and enable cost-free public access, predicated on the sharing of improvements and on collective defense and sharing of regulatory information. BIOS will also play a leading role as an international coordinator and advocate for the identification of key areas in the technology and/or intellectual property landscape where targeted innovation is needed to democratize problem solving. This will involve stimulation and sponsorship of targeted innovations as well as interventions with salient policy initiatives to increase fairness in access to the tools of innovation.

While all BIOS technologies will be freely available, contributions to BIOS will be received in exchange for support services and direct access to a portfolio manager who is a leading expert in the chosen specific technology and its intellectual property landscape. Contributors will be notified of advances and improvements in the field, whether in the form of know-how or more formal intellectual property, have facilitated direct access to others in the field, have the ability to target problems for solving on a web-based incentive structure, and more.

Now in its initial phases, BIOS is focusing on developing the core structures necessary to enable the application of an open innovation, collaborative production model to biology. A suite of open access licenses are being developed, with the first one to be concluded before the end of 2004. Two publicly-accessible, technology-specific portfolios will be established with accompanying services and the IT facility to analyse IP and technology landscapes. In order to harness the creative efforts of a large community, BIOS has begun the design of an IT infrastructure to facilitate communication between

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15 See Wired Article Open Source Everywhere
16 www.bios.net and www.cambia.org
innovators and the exchange of knowledge. BIOS’s IT capabilities and its choice of skilled staff is designed to enable the identification of policy interventions relevant to biological innovations in trade, public health, environment, agriculture and food security. Collaborations are in process with existing firms (e.g. InnoCentive, Inc.) to allow for web-based technology commissioning. Relationships with participants will be established (whether contributors, licensees, innovators, or collaborating firms) through international workshops and the promotion of BIOS’s underpinning rationale, philosophy, and business plan.

A new project called the “Science Commons” will be officially launched in the winter of 2005. Started by the founders of the Creative Commons and with advice from the Center for the Public Domain at Duke Law School, the project will encourage universities to voluntarily forgo some of the protections of patent and trade secret laws in order to make scientific research more accessible to other universities, researchers and the public through an alternative licensing regime. John T. Wilbanks, who has worked on the Semantic Web in the life sciences for the World Wide Web Consortium, will head the Science Commons beginning in November. The Science Commons will cooperate with the World Wide Web Consortium on the development of the Semantic Web to allow more sophisticated searches related to the life sciences. Its proponents say the Semantic Web holds great promise for scientific research because it could help scientists easily find and use data related to their fields of study. Science Common developers also want to encourage efforts to find cures for rare diseases. It is considering setting up a patent pool where scientists studying rare diseases could deposit research that a health foundation or public agency could aggregate and eventually help commercialize through negotiations with drug companies.

4. CONCLUSION

The existing innovation system in biology encourages the private appropriation of enabling technologies. Researchers, institutions and initiatives like the GCP with an interest in exploring the promise of biological technologies for addressing the problems of the 4 billion people at the bottom of the economic pyramid have trouble accessing the tools that govern the conversion of information into processes or products because of intellectual property, capital, regulatory, trade, and other barriers. The GCP recognizes that a cornerstone of its program is that its outputs are released as “public goods,” that they are accessible and, enable scientists in developing countries to engage in an innovation process that is relevant and addresses their own problems. One promising mechanism is the application of the open source approach. The GCP should consider collaborating with ongoing initiatives in this area. The open source approach is inclusive, supports the innovation process without being anti-business and can proceed without a needed modification of current IP system. The GCP, like open source patenting in the biological sciences, is breaking new ground.