The CAMBIA BiOS Initiative

Biological Innovation for Open Society

Open Source Open Science Open Society

Implementation Phase
2006 - 2008

A path forward for comprehensive innovation system reform in the Life Sciences, including Food & Agriculture, Global Health and Nutrition, and Natural Resource Management

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Background to the Initiative

Few of the serious problems experienced by the disadvantaged of either the developing or developed world are being adequately addressed by modern biological technologies.

These problems include the lack of sustainable food production, fragile rural economies, insufficient nutrition, environmental degradation, loss of biological diversity, poor public health practices, and insufficient attention to medical conditions of poor people or marginalized communities.

While the potential of biological technology to impact these problems is undeniable, its discouraging failure to do so not a failure of technology, but rather a structural failing.

It is not the products of biotechnology that the poor need, *per se*, and given the state of science, economics, business and society, provision of these products in some subsidized or facilitated manner to the poor can never be sustainable or realistic.

What is needed is the opportunity for the creative disenfranchised to engage in collectively creating solutions to their own challenges, using tools that meet their operating constraints, and which may be uniquely suited to these tasks and constraints. Some of these tools are technology tools, and others are adaptations of simple local solutions, or a mixture of the two.

Sustainable and equitable development can only happen through committed and creative participation of those experiencing problems, in the generation of robust local solutions.

If science is to be relevant as a component of such development, it must be part of an integrated process of democratic innovation, sensitive to the constraints of problem solvers, and building on their commitment and local knowledge.

Much of modern science –particularly biological technologies and other “high tech” – has evolved in a world of high-capital, high-margin applications irrelevant to the poor or excluded communities that make up more than four billion of the world’s population.

Mirrored in the evolution of intellectual property regimes to protect and promote these high capital, high margin applications and business models to capture, develop and deliver them, this driving direction in technology reinforces the differential and furthers the disenfranchisement of the poor.

The explosion of patenting rather than delivery as a metric for investment in biological sciences, while hinting at great opportunities in the accelerating pace of discovery, has created a thicket of rights, self-reinforcing barriers, and added cost impediments to innovation. These barriers not only continue the marginalization of those most at need, but also effect constraints on the pace and direction of innovation even in the highly capitalized industries of the industrialized world.

This cycle of exclusion is neither irreversible nor inevitable.

The Information and Communications Technology (ICT) industries are evolving new innovation models that suggest a productive way forward. Concepts of collaborative invention of core technology and its provision in a protected commons are now galvanising the software industry to new levels of creativity and democratisation in business and society, without compromising profitability.

The core elements of this Open Source revolution are not new. They are a rebuilding of the original pillars of civilizations and economies -- all agriculture, medicine and indeed society were made possible through the sharing and incremental improvements of innovations by inventive farmers and citizens. All progress in agriculture, until the advent of hybrids in the early/mid 1900s, was conducted within norms that almost precisely presage open source.

Sustainability of innovation system paradigms

To be sustainable, any enablement effort should meet two critical challenges.

First, there must be mechanisms by which modest-scale local investment of both financial and social capital can be fostered, encouraged, leveraged, risk-mitigated and rewarded. Development assistance, whether through government programs or private philanthropy, is necessarily linear in scope and limited in magnitude and duration. The single greatest point of intervention will be increasing confidence of investors and innovators.

Second, the ‘representational technocracy’ must be harnessed, not bypassed. Representational mechanisms have been developed in political systems to mitigate a tendency of pure referenda to marginalize smaller or less influential constituencies, and to apportion governance responsibilities and options. Similarly, the application of science and technology to problem solving often benefits from local representation, if this can be done without imposing obfuscatory layers of scientific and informational ‘clergy’. Patents nearly require such a clergy for interpretation of the complex coverage and rights they convey. Transparency is needed to support the harnessing of science and technology information as opposed to increasing reliance on the clergy to bypass it.

One of the key tenets of open innovation – captured in its very name – is the transparency that allows technical contributions to be evaluated on their merits of and responsiveness to their constituencies. This transparency must be coupled with and responsive to a feedback system, to allow improvement of response quality and delivery.

We propose that in the strategic design of new innovation systems, local-scale agricultural and technical universities and state-funded public health and extension activities must be coopted, empowered and strengthened in a manner that furthers their relevance and transparency. Furthermore, the encouragement of small-to-medium enterprise affords a critically important, self-regulating system of 'representation' that should be galvanised and strengthened.

The BiOS initiative is designed to forge a new commons in enabling technology for biological innovations, and new paradigms and mechanisms to address market failures and weak market signals with productive, transparent and sustainable problem-solving.

BiOS will increase fairness in access to the tools of innovation as a fundamental human right. Our desire is to invent, acquire, commission and distribute inventions under new, public-good binding licenses and contracts to ensure the insulation of the new body of technology from appropriation.

BiOS will:

- explore, adapt, implement, promote and support new inclusive mechanisms for sharing IP and Intellectual Capital (IC);
- create new tools, legal and normative instruments and methods for generating and sharing biological innovations;
- make transparent, understandable and navigable the opaque world of patent rights;
- integrate this new transparency of intellectual property systems with opportunities for cooperative and collective action – technical, legal and political – to remedy its excesses;
- articulate and promulgate public-good norms in development and use of biological technologies;
- develop, commission, guide and promote new transformative technologies;

- forge synergies between diverse sectors, including life sciences, nanotechnology, and software engineering.

BiOS – What is it and what is it not?

The name, ***Biological Innovation for Open Society,*** was chosen carefully to indicate what BiOS is not, as much as what it is.

BiOS is not simply a 'biotechnology' initiative, although biological innovation is one of the first points of intervention because the opportunities are so great, and the impediments to wise use are so pronounced.

All forms of '***Biological Innovation***' ranging from plant and animal breeding, crop husbandry and protection, agronomy, genetic and natural resource conservation, management and use, medical and public health interventions and environmental remedies are becoming similarly constrained in the technology options available to disenfranchised user groups, and these constraints can be addressed by similar measures.

'***Open Society***' is a goal that is reflected in the BiOS institutional philosophy and in a desire for a self-correcting community of problem solvers, whether in the public or private sector. Unlike the usage of “free” mandated by groups such as the Free Software Foundation, ‘Open Society’ is less likely to be misunderstood as prescriptive of the mode by which social advancement is achieved, and lends itself to the diverse cultural, social, economic and environmental imperatives under which innovation systems must act.

There seems to have been a growth industry in the last few years associated with the general malaise around intellectual property use and abuse. Unfortunately, in this explosion of interest an important point is often missed: the dramatic increase in the use of intellectual property protection by both public and private sector, the concomitant low standard but broad scope of such IP grants, and the trend towards exclusive licensing and exclusionary use of IP portfolios are symptoms, not causes.

In focusing on the symptoms rather than the causes, many “IP initiatives” may fail to provide truly useful tools or alternatives, merely ‘patches’ to a defective and inadequate system.

It is helpful to distinguish between the *tools* of innovation, and the *products* of innovation The implications for the impacts of exclusionary IP regimes in tools and their use (analogous to operating systems, programming languages, middleware and standards of interoperability) or in their applications (analogous to product lines or service relationships in software companies) are very different.

Enabling technologies, the "source code" for adding value to biological information in order to make products, may be considered pre-competitive for high-margin applications, but are crucially lacking for low-margin applications. Broad access to such tools is critical for their continued evolution to be able to address the challenges of low margins and the market failures associated with the needs of poor people. Enabling technology tools are the new battleground for public good and democratic involvement in problem solving in the life sciences, whether by public agencies or by private enterprise.

However, this battleground is largely unsurveyed. Many of the proposed "solutions" to intellectual property use and abuse are about "freeing" or creating cheaper or wider availability for particular *products* rather than liberating and providing *tools*.

This distinction is not only useful to define the best rules of engagement, but also to forge common purpose with the proprietary thinking that drives, often, both the academic and business sectors involved in biological technology. The same distinction is at the heart of the acceptance and promotion of Linux and other Open Source software by many powerful and influential corporations in IT.

New Development Vector: The 'Free Software' Lesson

The fundamental tenet driving the BiOS Initiative has resonance with the Free Software movement, which has morphed into the Open Source movement. This ethos is a recognition that 'Freedom to Innovate' is a core human right, and that infringements on the capacity of persons to improve their condition through innovation must be viewed very cautiously.

The statement widely credited to Richard Stallman, the iconoclastic founder of the Free Software movement, and further expanded on the GNU.org web site, serves as a helpful framework for the elaboration of the BIOS initiative:

> *"'Free software' is a matter of liberty, not price. To understand the concept, you should think of "free" as in "free speech", not as in "free beer".*
>
> *Free software is a matter of the users' freedom to run, copy, distribute, study, change and improve the software. More precisely, it refers to four kinds of freedom, for the users of the software:*
>
> - *The freedom to run the program, for any purpose (freedom 0).*
> - *The freedom to study how the program works, and adapt it to your needs (freedom 1). Access to the source code is a*

precondition for this.

- *The freedom to redistribute copies so you can help your neighbor (freedom 2).*

- *The freedom to improve the program, and release your improvements to the public, so that the whole community benefits (freedom 3). Access to the source code is a precondition for this. "*

(www.gnu.org , May 2005)

Similar to the ethos of the Free Software movement, the BIOS Initiative is not about cheap or free stuff, either pharmaceuticals or food. It's about creating the freedom to innovate based on what has come before, and the freedom to deliver the fruits of such innovation with few constraints. "Free Stuff' is one of the upsides of this 'freedom', but is a consequence rather than a cause of the liberty and capacity to innovate and share.

The Open Source movement is a more recent, distinct and pragmatic evolution of the Free Software movement. In Open Source, products can be created and delivered for a profit, but the source code must remain available for use and improvement.

Without pushing the metaphor too far, it can be said that the degree of accommodation of private enterprise and capital recruitment mechanisms by Open Source has more resonance with the challenges of innovation in the life sciences, where time frames and capital thresholds are of much larger magnitude than in software engineering.

Granularity of Technology: One spoke broken will stop the wheel from turning

Increasingly, biological technologies are not self-contained, but are rather interdependent technologies that require multiple key methods and components to function. By analogy, the most powerful technologies can be considered as 'wheels', requiring a number of 'spokes' to function. For instance, the ability to transfer a gene to a crop plant may require dozens of individually protected, discrete technologies. Denial of access to any one of these "spokes" can and does deny the use of the entire technology by potential users. Worse, it prevents the iterative and cooperative shaping and improvement of the technology to meet diverse users' needs.

Unfortunately, even placing one or more key methods or components into the public domain allows no leverage to bring other components into a collective whole with broad access. Virtually all practices of academic scientists promote

the belief that 'good science' can, almost by magic, transform itself into public or private goods. It can't.

In fact, in the failure to deliver such goods with broad access, the public sector science community is complicit by neglect, because the true stranglehold is where much less public sector effort is expended: the conversion process.

Reaching the delivery stage using most biological technologies requires the use of many key components. When access to a highly fragmented set of critical technologies is necessary to create a potentially viable product, when access to even one of the components is denied and no substitute exists, the project cannot move forward. This uncertainty destroys investment incentive and confidence by public or private sector.

The multinational private sector has addressed this problem by acquiring large IP portfolios and negotiating cross-licensing arrangements among themselves to obtain full platforms of enabling technologies, though these companies still usually find themselves still limited in freedom to operate. The public-good sector, and small-to-medium enterprise, in contrast, having only fractured portfolios often comprising publicly-developed technology and modest non-fixed capital pools that it believes can be expanded by eagerness to license out, is at a grave disadvantage.

Laudable work by high profile individuals and dedicated agencies to ensure genome sequences, genetic resources or indeed scientific results are placed in the public domain is insufficient, and worse, can be a diversion, because the ease and affordability of sharing data via the internet have rendered information, *per se*, no longer the critical point of control. These data, the genetic materials and the published science are routinely hijacked - enclosed - by entities, usually large multinational corporations, which have access to the means of converting that information into economic value. For an example of how this happens, see the Policy Forum in October 2005 *Science*, on the extensive patenting activity related to the Human Genome project. Similar examples have occurred with plant genomes such as rice, despite or perhaps even assisted by the public funding that has gone into making the sequences available.

The enclosure, the hijacking of the information outside the public domain rarely ensures a sustainable competitive advantage. More often it is an inadvertent and very unfortunate side effect of a strategy for industry survival. If the expense, and the perceived requirement for competitiveness and investment, of sequestering added value outside the public domain in iterative patents could be rendered unnecessary, many economically rational companies would not undertake it. Even the most ardent advocates of free market capital forces are finding that, with new business models, money can be made without controlling or restricting access to the tools of innovation.

Where is the proof? Recently, the social and technological achievements of the community of programmers who created a public-spirited and public-good-binding world of open source software have also fomented a great change in the IT business world.

IBM Corporation made a bold and unprecedented move to create the first universally accessible 'protected commons' of patents in a pool available for any open source development. While IBM, as the largest patent holder in the world (USPTO and WIPO data) could be viewed as a 'rights maximalist', over 500 of its key software patents have been made available to all – including competitors – who choose to use these patented technologies under open source rules. Within days, Sun Microsystems followed suit with another 1600 patents, and a myriad of other companies such as HP and Nokia are doing the same. The snowball effect continues.

By providing templates for new licensing and sharing regimes, approaches to greatly decrease transaction costs, new tools for technology forecasting and management and enhancing the pro-active analytical capabilities of offices of technology transfer, BiOS will similarly play a catalytic role in making parallel public-good oriented activities and IP focused initiatives in the life sciences more likely, and more successful.

Initially, it is anticipated that streamlined commissioning and management of core technology improvements will best be done in a format such as BiOS that is technologically and legally sophisticated, with a commitment to advanced informatics and communications. However, the intent is to develop fully 'portable' paradigms and procedures by which the concept can be promulgated in diverse institutional and cultural settings.

The Proposal

Summary

BiOS is focused on the empowerment of the more than four billion people at the bottom of the economic pyramid, and their creative capacity for innovation as a sustainable intervention in human development.

Innovation by and for the poor and excluded is currently constrained by policy, scientific, legal, regulatory and economic paradigms. These paradigms both reflect and shape the technologies available for problem solving.

Open innovation is becoming a strikingly successful model in Open Source Software and is currently being applied to a wide range of industries from publishing to space research. BiOS will explore, apply and extend this democratisation of innovation to problems of biology affecting the disenfranchised of the world.

BiOS will operate in life sciences fields ranging from human nutrition, food security and agriculture, to environmental management and improvement, conservation and use of biodiversity, human and veterinary medicine and public health.

Through intellectual property and investment practices. existing innovation systems in life sciences encourage attention to relatively high-margin markets, and the private appropriation of enabling technologies. Examples of barriers that are strengthened and enhanced by these innovation systems are many. There is the increasing domination of agriculture by large multinationals and the public disquiet with genetic modification of crop plants. There is the focus by medical research and development on high-margin pharmaceutical applications for the inconveniences of the rich world rather than low-margin public health interventions that could greatly enhance the quality of life for the world's poor and encourage robust local economies.

BiOS will act by catalysing a community of innovators to produce high quality and relevant biological technologies for the empowerment of diverse problem-solvers, and secure these technologies in a new, protected, universally-accessible commons.

BIOS's structure and activity provides a new method for innovation and the ability to secure the resulting technologies in a commons, accessible to all. While it has its current business and social validation in the Open Source movement in information and communications technology, BIOS traces its roots back to practices of farmer-breeders in the first few thousand years of agricultural development, and finds elements of its motivations in the powerful

drive to share the results of scientific endeavour that has characterized the best of science over the last four hundred years.

Interestingly, the core limitations being addressed by BIOS are being increasingly felt by biological industries of the developed world, and the solutions proposed by BIOS are fully compatible with the aims of sound business practice in innovation worldwide. Thus, the synergy of purpose between 'advanced' innovation and market system practices and those promoted by BIOS will afford unprecedented leverage of resources – intellectual, capital, financial and political – and goodwill.

By promoting new thinking, new institutional mechanisms, new technologies and a new business model, BIOS will catalyse the empowerment of both 1st world and 3rd-world innovators to address local, small-margin, small market innovations in food, agriculture, public health, industry and environment.

Extension of the BiOS Initiative to Health

The success to date by CAMBIA's BiOS initiative has hinged on our credibility and competence in agricultural biotechnology, and its related patent craft. This professional recognition has certainly made our job easier. It has also allowed us to more rapidly identify the common elements in life science-related innovation failings, and to better see new ways of creating cooperative problem-solving mechanisms that can function within the current legal, commercial, technological and social landscape.

A great deal of international funding and attention is going, quite rightly, to diseases such as malaria, TB and HIV/AIDS, which are substantially diseases of poverty. 'Tropical diseases' such as leishmaniasis, infantile diarrhea, trypanosomiasis, etc., are also finally receiving some attention from funding agencies, both governmental and private philanthropic.

There is no doubt that the recent public attention has helped to re-energize funding activities. – The 'Live8' concerts raised popular awareness around issues of poverty and debt-relief, while highlighting the work of high-profile sponsors, such as the Gates Foundation's *Grand Challenges in Global Health*.

Ironically, valuable as these contributions are, they can have the adverse effect of placating a public to think that "we're working on it – so it's ok". Implicit in this is the subtext: "it's ok to leave in place the social, legal, economic and technological paradigm that perpetuates this inequity".

Often discussions of global health equity seem to segue into discussions of the medicine of infectious disease and specifically, the treatments or prevention of tropical disease. Ultimately, such discourse becomes a review of the available pharmaceutical interventions. This trajectory of thought leads us

unproductively along a vector of disengagement. This vector turns potentially active participants in an innovative public health exercise into pliant consumers of services and products. Additionally, it fosters a paternalistic paradigm amongst R&D providers and the policy community that is associated with it.

Donors recognize that the funding mechanisms underpinning the initiatives mentioned above are not sustainable. The enduring solution to these problems is to engage a massively parallel problem-solving community as described in the BiOS Initiative as it is already beginning in agricultural biotechnology. Those experiencing the problems will be vested with tools for solving them and generating the innovations necessary to anticipate and forestall future challenges.

In crafting, or at least contributing to, a robust solution for these problems we must seek common pressure points and opportunities. The BiOS Initiative has already begun cementing key partnerships with inventive contributors from a broad spectrum of research and policy, and because of the role of nutrition in public health, these are often the same people for health and for agriculture, especially within the poorer countries.

The BiOS initiative assembles and develops mechanisms to follow through on the common pressure points. As will be described below, it is uniquely possible now because of unprecedented opportunities for:

- Communication and collaboration through the Internet
- Transformative biological platform technologies
- Informatics enhanced provision of enabling knowledge

BIOS Activities

Three interdependent groups of activities make up CAMBIA's BIOS Initiative. In each, we have already made working prototypes available to all comers, and integrated lessons learned from hands-on use of these prototypes into the fundamental elements of this three-year proposal.

a) The Patent Lens: Intellectual Property Informatics and Analysis

The purpose of the Patent Lens is shown by its name: to rendertransparent the complex and opaque worldwide patent system. More than a database, the Patent Lens seeks to provide understanding the IP landscape and develop a toolkit to navigate IP thickets, acquire freedom to operate and forecast trends and new technology developments. Critical to its further development is creation of cooperative, community-annotated mechanisms for analysis of key technology platforms and their patterns of control.

b) The BioForge: Cooperative Open Access Technology Development

The BioForge is a platform to support the development of new interactive R&D paradigms, mechanisms and initiatives to collectively create new technologies and empower diverse solutions by harnessing the communications power of the internet. The BioForge will use the Patent Lens 'living landscapes' to craft and target community-accessible innovations, invent-arounds and 'invent-beyonds'. It will also exploring and use creative incentive systems to break bottlenecks and allow efficient and effective public-good-focussed innovations.

c) The BiOS Foundation: Innovation System Structural Reform

The BiOS Initiative has formed a foundation similar to the Apache Foundation that we envision will have a certifying and model-making role to promulgate newly developed mechanisms in licensing, relationships, contracts and in national and international innovation policy to encourage democratized problem solving, It will use the Patent Lens to scope, and describe for open public and policy debate, the failures and successes in patent systems, and articulate productive means to reform these systems. Importantly, it will consider the range of options throughout the innovation system 'chain', beyond intellectual property *per se*, to expose opportunities to integrate reform with such diverse elements as regulatory and investment frameworks and incentives.

The Patent Lens: Intellectual Property Informatics and Analysis

Dispelling FUD

Sustainability of development requires local-scale investment confidence and business engagement in problem solving. Business at all scales of activity, from the smallest farm-scale enterprise in agriculture to the largest multinational pharmaceutical company, depends on clear and reasonable strategies to limit financial risk and legal exposure.

Risk mitigation is crucial to earn the confidence of investors – public or private - and to allow the long term and sustainable pursuit of innovation. Any factor that imposes a high degree of uncertainty and potential risk for an entrepreneurial activity can be ruinous of progress. This has often been done by intimations of business unreliability, technology ineffectiveness or durability of a delivery channel. For and science-based industries, social benefit can be completely destroyed by any factor sowing Fear, Uncertainty and Doubt (**FUD**) on the deliverability of innovations and the choice of partners and technology options.

Currently, in all industries worldwide that depend intensively on science & technology, there is such a FUD factor. This factor is the opacity, complexity, and misuse of the patent system.

FUD has been used as a powerful and aggressive means by which a competitor can cause an investor, client, customer and/or the public to lose trust in a technology-driven enterprise. Patent FUD has become even more effective in undermining confidence because it no longer requires competitor involvement. Innovation-based industries – including agriculture and health care - are poisoning themselves and the reputation of the sectors they purport to serve by allowing an internally-generated FUD to escalate the cost, restrain the pace and restrict the social relevance of innovation.

In technology-intensive and technology interdependent industries such as biotechnology, the complexity, the extraordinary scope of grant, the volume and the rapid increase in patent filings, and their expansion in new jurisdictions, has created an intense specialist-ridden, high-capital, high-risk innovation landscape that looms over these industries, both private and public sector. Lack of strategies to address freedom-to-operate concerns or to temper Patent FUD can only propagate and entrench this landscape, which alienates and paralyses the efforts of civil society to used the innovations well.

The public good sector, comprising both government and privately funded activities, should be a counterbalance to industry's drive to deal exclusively with high margins and large markets. The public good sector is uniquely charged to deal with market failures and weak market signals and critical neglected priorities. Unfortunately, Patent FUD has paralysed this crucial countervailing force, too.

This is as true in IT as it is in industries that have not yet embraced open source concepts. The Open Source software community, and the industries that service, support and prosper from its activities has recently experienced serious concerns over deliverability of innovations in software due to the potential lack of freedom to operate due to patent constraints. Similarly, emerging strategies in the IT industries to address these concerns may serve as an example for productive new options relevant to other industries, including the life sciences.

We have already made mention above of IBM's bold move to release a large number of patents into a pool with broad access based on covenants to maintain open source, and the fact that other companies such as Sun Microsystems rapidly followed suit with selected patents. IBM clearly perceived that Patent FUD had gone too far, and that extreme steps had to be taken to restore confidence in the innovative capacity of information and communications technology and software engineering.

While pooling patents in pre-competitive 'commons' can be a very effective means of enabling rapid and distributed improvement, its effectiveness depends completely on a knowledge of the relevance and scope of each of these patents, and on the scope of rights outside the pool. Only when empowered by transparency and definitive knowledge of the true technology patent landscapes can cooperative innovation by beneficiaries of the pool be an effective tool to forge a robust commons.

The greatest strength of the open source patent commons is the low transaction cost associated with a cost-free, rules-based access regime which characterizes the open source licensing practice. Open innovation systems flourish by harnessing the goodwill and creativity of diversely motivated and incented contributors, most of whom would balk at high transaction costs and liabilities.

The greatest weakness is the complete absence of clarity of the value of what is in and what is out, and the potential for one critical piece of the puzzle to be denied, thus rendering the pool vulnerable.

Clearly, Patent FUD can effectively slow or arrest delivery of open source innovation, and in so doing, can undermine the extraordinary value of distributive and cooperative innovation by corrupting the 'protected' commons, and the incentives and motivations that undergird the most creative inventors and innovators.

But Patent FUD has an Achilles Heel.

It is dependent on opacity, complexity and misinformation; it is vulnerable to informed collective action.

Much of the FUD that is associated with patents is caused by the perception – in some cases ill founded – that there is no way to move forward and that all technologies are locked in thickets, or that unpalatable deals must be contemplated to progress. Many such deals have been made in the guise of Public-Private-Partnerships to address challenges that may be illusory, and to solve problems that are better solved otherwise. These deals, too often made in substantial ignorance of the true state of patent coverage and patent validity, leave an unproductive and gelded public sector, apologetically mewling and cowering in the shadow of FUD.

The Patent Lens: FUDBuster

The BiOS Initiative already includes and is improving and promoting a public patent transparency resource by which Patent FUD can be substantially dispelled, new scientific, technical and business opportunities illuminated and public and industry confidence regained.

The BiOS Patent Lens (www.patentlens.net) is part of a public-good oriented effort to harmonize, parse and present worldwide patent and technology data in a full-text searchable and highly integrated manner. This will serve the aim of the BiOS Initiative to engage the R&D community in use of the patent system itself to expand and protect a technology commons, and to collectively target breakthrough inventions, work-arounds and work-beyonds.

The intent is to promote informatics-intensive and user-informed dynamic analyses of the landscape of patent specifications and claims that surrounding particular technology or technology area.

Presenting clear and timely landscape data to all involved with the innovation chain, in a form that adapts to their needs, will create new standards and will inform new, coherent innovation policies and business strategies.

The BiOS Patent Lens currently comprises three increasingly interlinked components:

- Patent database and searching
- 'Technology IP Landscapes'
- Patents, Policy & Practices (including Tutorials).

Below we list the long-term goals for each of these interlinked spheres of activity in patent transparency, progress in the initiating year, and new steps comprised in the three-year plan to reach these goals:

The Patent Database

The Lens has at its core what is probably the world's most comprehensive, fastest, full-text searchable cost-free public-access database of patents in the life sciences, with a five-year history and continuous improvement backing it up. The database, incorporating the full text of life sciences subsets of applications and granted patents from the USPTO, PCT, European and Australian jurisdictions, has a fast and user-friendly searchable interface and presents common and harmonized data structures so that these jurisdictions can be searched all at once.

This is becoming a more important resource as the consolidation of fee-requiring "value-added" patent data providers continues. The Thomson Corporation, a Canadian electronic publishing conglomerate, has consolidated its position as a key provider of patent information through the acquisition of its major competitors Derwent, Dialog, Delphion and Micropatent. There have also been numerous smaller acquisitions along the way. As well as consolidating its intellectual property business, Thomson has continued to expansion into the sciences, health and legal publishing and online databases. Although there are other commercial providers of patent information, such as

Questel-Orbit and PatentCafe, it is estimated that that Thomson controls the bulk of the market – some estimates put it as high as 80% - a dangerous concentration of power.

Furthermore, no national office views it within their mandate to harmonize collections over many jurisdictions. What is more, although national and regional patent offices providing free patent searching are seen as threat by commercial providers such as Thomson, a number of these offices are dependent on Thomson for their in-house searching. Smaller commercial providers may find it hard to compete against Thomson with its suite of information services on the one hand and the slightly improving quality of the free patent searches provided by national offices on the other. Commercial providers have been calling for a reduction in the role of national patent offices as "value added" providers. The need for a "public good" provider has never been greater.

Our goal is a worldwide, full text, all patent /application /status dataset, harmonized as free text and meta-data rich SQL databases, with API access as appropriate; and a dynamic focus for natural language and IT innovators to collectively create software for claims analysis and technology landscape visualization and navigation.

- In 2005 with continuing Rockefeller support we were able to extend the fast software engine developed for full-text patent searching to bring in INPADOC information on status of related applications in over 60 countries. This has been of considerable interest to government patent offices and inter-governmental organisations such as WIPO, which has publicly supported our activities. This will accelerate the process of bringing innovative developing country jurisdictions such as India, Brazil and the Republic of South Africa into the Patent Lens by 2008.

- Accordingly, in 2005 we began serious investigation of the informatics challenges related to incorporation of the Chinese patent database as an example in which character-based text search algorithms will require extensive adaptation. Such adaptation will require greatly increased programmer resources and we hope that it can begin in 2006. By 2008 we hope to have overcome the challenges by working together with patent professionals and programmers skilled in these languages, to include the patent databases of China, Japan and Korea.

- A critical expansion also begun in 2005 and continuing now is to broaden the scope of our collections to include patents in all classifications, not just those that the jurisdiction has called "life sciences". Synergies of purpose, process and technology with the software community and other innovative communities will lead to enormous gains in the utility of the

BiOS Patent Lens. Our eventual intent is to provide public APIs to facilitate patent claims parsing and landscape presentation.

- As a necessary adjunct to bringing many more patents and applications into the searches, as well as a useful tool for innovators, a fast relevance ranking tool for the results of patent database searches is being launched in January 2006. We would further like to implement specialised state-of-the-art thesaurus and dictionary assistance as a built-in facility, with options to associate professional phrase and word synonyms, ranked for their closeness. Thus, searches for "vaccines" may include relevant terms such as "immunology". We have also begun development of new tools for structured queries, for example relating patent content to status in specific developing countries.

A focus on user-adaptability, integration, annotation capability and availability to the world community under cost-free access terms are the key features that render the Patent Lens not only unique but invaluable in the battle to restore public good and transparency as the *raison d'etre* of intellectual property systems.

Technology IP Landscapes

Technology IP Landscapes are analyses of key platform technologies, and the IP positions associated with their development and use. They build on and use the patent database to turn the information on some of the technology areas into knowledge.

Each landscape is a searching and analysis effort involving many skilled person-months. Typically, patent "professionals" accumulate billable hours by providing the same information over and over for different customers, and charging full fees again to periodically update them. Increasingly we wish to do something no fee-requiring patent data provider will ever do: turn the landscapes into living repositories of constantly updated information, so that they will never have to be re-done.

- We have taken the first steps in 2005 by creating six prototype "commentable" landscapes, each connecting to a discussion forum in which users can pose questions and offer clarifications, suggestions, information on license availability, and usefulness of the technology. Significant improvements to the interface are being launched in the first quarter of 2006, which will enable more rapid and searchable user contributions to the landscapes.

- Later in 2006, we envision mechanisms to be implemented for dynamic updating of status information to be provided in the technology landscapes as the patent database is updated. By 2007, we hope to

have crafted ways that the landscapes and annotations made by users will be dynamically linked to the relevant specifications in the patent database, so that others interested in particular patents can more readily become aware of the community input.

- By 2007 we hope to have taken steps to further stimulate user annotation and commentary, with dynamic links to E-mail inquiries on license information and results of experimental use, and links to cited publications and business data on the assignees, wherever possible.

- Starting with a major effort in 2006, the comment interfaces will be also equipped with sophisticated community review and ranking of commentary, ideally with social voting mechanisms to provide a credibility index for contributors. We envision a collaboration through 2008 with open access journals to provide the same credibility index mechanisms for online publications, and have already built links with the Public Library of Science to begin to accomplish this.

- Landscapes to be developed in the 2006-2008 period, with sufficient resources to support skilled IP analysts, may include core technologies associated with:
    - RNA-mediated gene inactivation (silencing)
    - Homologous recombination and site-directed mutagenesis
    - Genotyping technologies
    - Vaccine technology
    - The rice genome
    - The Arabidopsis
    - Assays for drug activity and effectiveness
    - Transcriptional activators
    - Fluorescent and chromogenic reporter systems
    - Cancer therapeutics & diagnostics
    - Apomixis and hybrid technology
    - Gene transfer technologies
    - Bioremediation

- By 2008 we would like to be developing intuitive, real-time and user-driven analytical software tools to guide decision-making in technology choice, development or partnering options relevant to biological innovations in trade, public health, environment, genetic resources, agriculture and food security.

The goal is to create a facility for generating, linking and dynamically annotating patent landscape analyses through web interfaces by distributed and diverse users. This will be increasingly interlinked with the BioForge (see below).

Patents, Policies & Practices

Patents, Policy & Practices includes tutorials providing guidance in reading and interpreting patents, with the aim of increasing overall sophistication of novices in the nuanced realities of intellectual property, particularly patents. It also includes Policy & Practices papers that describe and advocate informed and productive changes in international, regional and national fora and laws.

The goal is a learning resource by which participants in innovation systems at all levels, scientists & engineers, business & legal professionals, citizens & policymakers, can become informed of critical and timely issues relevant to improving public good and social and economic value through patent system engagement.

- Supplemental material will explain and clarify linkages between trade policy and innovation systems, particularly as these continue to evolve rapidly with TRIPS implementation, TRIPS-Plus agreements, and country-specific enforcement mechanisms.

- New papers are being added in early 2006 as the result of 2005 research to explain functionalities that are available and needful for different types of searches, focusing on prior art searches for patent examination, and on freedom to operate searches that may elucidate key chinks in patent coverage.

- Recognising that a great deal of Patent FUD is engendered by intimidatingly broad patent applications, scenarios will be developed to walk users through the determination of what is a valid claim, elucidating the differences between filed claims and issued claims.

- Documentation will be provided about access points for certain patenting jurisdictions and key differences in innovation policy between important jurisdictions.

Standards of patents are widely viewed as being execrable and many patents, though presumed valid by law, are at best frivolous and often egregious. We'd like to provide the public with tools to recognise and overturn such patents where they undermine progress or are being used by unprincipled or ignorant entities without a long-term and well-articulated stake in industry or society.

The BioForge

The Patent Lens provides a resource for those who understand that it's important and useful to look at patents. For those that don't enter this gateway, we are interested in expanding the dynamic capabilities of

www.bioforge.org, which will provide a more context-rich interface, in the language of innovators. However, it's not just a portal. Our idea with the BioForge is to create an evolving and evolvable mechanism by which interested individuals and agencies can collaborate with optimum effectiveness to solve problems and create technologies under an open-access regime.

We began in 2005 by trying to craft a cyberspace meeting place, www.bioforge.org, with a look and feel different from the Patent Lens, attractive to scientists. Development of the interface that will be needed to retain their attention over the lengthy cycle times in biological innovation continues behind the scenes and will require participation and specification by experts to come to fruition in 2006-2008. Eventually we expect the BioForge to combine vigorous but positive debate, peer co-development concepts, curated and stewarded contributions, novel project management and incentive tools, extraordinary communications facilities and public-good binding norms. This can be used to forge unique collaborations and distributive problem-solving relevant to those unserved by current innovation practice. The 'Forge' will be a dynamic exercise, changing and morphing as it gains experience.

The first implementation of the BioForge, which went 'live' in 2005, was built on the backbone of a hosted software product designed by Brian Behlendorf, a key open source innovator largely responsible for the Apache Web Server, to facilitate distributive software engineering using versioning, suites of permissions, repositories etc. The desire to build synergies with the IT community and the apparent success of some its implementations (notably that by Sun Microsystems, www.java.net) convinced us to proceed with grafting the nascent BioForge capabilities onto this offered backbone.

However, as we and others used this BioForge prototype throughout 2005, we could see that the largest challenge we would face would not be permissions and versions, but the accommodation of the culture of the contributors themselves. Software coders have a unique culture, with timeframe, feedback and incentive structures that have little or nothing in common with biological innovators. They are largely context-independent: a software product developed in Java in Bangalore on a Linux box will function identically in Berkeley or Botswana on a similar platform. The developments will take hours, days or months, providing rapid feedback for success, and can be shared at no cost and with no regard for regional or national barriers.

The factors just mentioned are inapplicable for most biological innovation. Local relevance, local testing, and commitment over the full development cycle from design to deployment is essential. Time frames of development are long – often a decade or more - and specializations within the innovation chain are remarkably distinct and prone to their own cultures and hierarchies. Languages are not restricted to the formal language of programming, but flexuous and complex natural languages and dialects. Transference of 'ideas'

can sometimes be independent of locale, but transference of relevance information and the necessary feedback loops for successful innovation can be very context-dependent. Materials themselves can be difficult or expensive to transfer or develop in parallel. These are a taste of the challenges that will be met with careful social and practical 'specification' of the BioForge.

Therefore, starting in 2006 we are crafting the architecture of the BioForge beyond our experiences with the prototype, further specifying our needs using metrics beyond those of the software community. We anticipate that core activities emphasizing communications and community-building will soon take precedence over the formalities of data structure, archiving capabilities or permission hierarchies, although these latter will be relatively easy to maintain as integrated components where they facilitate participation.

Community building for the BioForge will proceed hand-in-hand with advocacy work to make the community attractive, even prestigious, and will be crafted with an eye to the 'enlightened self-interest' of participants. BioForge cannot succeed if it is perceived only as 'do-gooding' or charity. It must be fun, joyous for creative people, engaging of their imagination and time.

BioForge participation must deal with the personal and professional constraints facing scientists and other creative people. For the latter aspect, we need to form a highly credible 'peer-credit' system for contributions to the BioForge, so that career advancement is accommodated. For instance, small contributions of technical expertise, acumen or time and materials, if delayed and aggregated in conventional academic or commercial settings, could ultimately coalesce into a publication, a patent application or an otherwise recognized bolus of self-promotion. To instead encourage such contributions to be publicised rapidly on the BioForge will require compensation mechanisms.

In some cases, peer prestige will satisfy this compensation need. We've already mentioned the building of a social voting system for comments on the patents and landscapes in the Patent Lens. By building the BioForge into a high-profile prestigious activity, accredited contributions to projects will be considered signs of professional substance. In other cases, financial compensation through Innocentive-styled awards may be necessary.

If the culture of innovation is successfully engaged in the larger BIOS Initiative, and its advocacy campaigns, we can also hope that doing something 'because it's the right thing to do' will be a standard incentive, as it is for many of the contributors to the Open Source software movement.

However, painting a broad canvas of options for incentives will be one of the most important points of progress over the next years.

Our initial experiences with the BioForge prototype in 2005 were gratifying, educational and sobering. The merging of scientific capability, social and legal vision and cultural context knowledge with software architecture and engineering is exciting, with few precedents from which to build. We expect if development of the BioForge software itself is an open source activity, we can leverage external expertise and contributions remarkably.

Some of the goals and processes that we hope to develop given suitable funding for the BioForge are:

- Develop internet-based, collaborative protected commons initiatives through BioForge, to create diverse, decentralized nodes of research and development on projects of public or suitable private interest. Some current BioForge projects are described below under Cooperative Open Access Technology Development, followed by a section on some future BioForge portfolios we are beginning to develop

- Craft, and graft from other sources, technology management capability and methodology to evaluate, monitor, commission, value, receive, acquire and curate technology contributions in this unique forum.

Cooperative Open Access Technology Development

The first Open Access Technology activities of the BiOS initiative provided and improved within the BioForge focus key portfolios of technology that present bottlenecks to innovation by and for the developing world. These technologies are also critical for the structural reform of enterprise in the OECD countries, especially in agriculture, but ultimately in public health and environment.

Subsequent to this, and dependent on acquiring suitable funding, 'flagship' programs will be developed targeting critical future technology opportunities that can have catalytic effects on democratic innovation. This must include technologies affecting health and medical interventions.

All of CAMBIA's current intellectual property was converted to open-access BiOS licensing in 2005. Licenses have been designed for different portfolios.

Crop Molecular Enabling Technologies:

CAMBIA's reputation was initially established on the provision of critical tools for plant transformation, including GUS, under terms broadly similar to those envisioned for BiOS. Since that time, other technologies have been developed to bypass critical restrictions in plant genetics such as gene transfer by *Agrobacterium*, or screening for transgene behaviour. These technologies form the founding core for the Crop Molecular Enabling technologies for BIOS. In 2005, the most prominent of these, TransBacter, which affords a 'work-around'

to the Agrobacterium gene transfer patent thicket, was described in *Nature*, and used to prime the official launch of the BioForge.

Genetic Resource Analysis:

With the importance of genetic resource conservation, identification and use, the Genetic Resource Analysis portfolio is available for plant and animal breeders and to provide technical capacity that will be needed for substantive progress on access and benefit sharing. The 'pump-priming' technology for this portfolio has been CAMBIA's Diversity Array Technology, DArT ™, which was developed and has been patented by CAMBIA. This technology is already being used commercially by licensees to enhance molecular plant breeding activities in wheat, barley, apple, forages, rice, cattle and sheep.

New Portfolios and Directions:

CAMBIA's BioForge efforts will, upon securing suitable funding, also stimulate and commission work in the BioForge on core enabling technologies critical for the next generation of innovation, such as

- Homologous recombination (HARTs)
- Apomixis
- Medical and agricultural diagnostic systems

Because there has been high-profile publicity of the beginning work we are undertaking on the first two (see *Nature Biotechnology* editorial, August 2005) below we expand on the last listed.

Agricultural "Diagnostics"

The first commissioned project on the BioForge, to be supported over a three-year life with $600,000 from the Lemelson Foundation, is an agricultural diagnostic portfolio we are calling BiOSentinels. A bio-sentinel is a species that can sense an important constraint such as limiting nutrition or threatening pests, and relay that information in a useful way to facilitate rapid local decisions.

A traditional example is rosebush establishment in vineyards, to show symptoms to fungus that can affect grapes, providing an early signal to arrange for fungal control appropriate to the local soil, weather and consumer preference. A modern example is a bioindicator being commercialized by a Danish company, Aresa, for detection of land mines on soil being prepared for planting, a genetically engineered *Arabidopsis* in which the leaves turns red upon detection of TNT residues by the roots.

The aim of the project which will "go live" on the BioForge in 2006 is to facilitate creation of appropriate living instruments to inform a variety of local

choices in local cropping situations. Components measuring nutrient levels, heavy metals and other soil characteristics have been identified in the literature. We propose that there is no "one size fits all" BiOSentinel; useful BiOSentinels need to incorporate sensor components appropriate to particular local challenges and signaling components appropriate to farmer detection into species that can be grown alongside particular crops in particular regions. Accordingly the purpose of the BioForge project is that various labs can develop and disseminate modules that can be used by others to make whichever BiOSentinel is wanted to address a particular challenge.

The modules will be described to innovators worldwide in real time as they are developed via the BioForge. Via BiOS agreements, with covenants to share improvements and maintain them accessible to all others, these modules and any knowhow derived in their use will be made available in real time to anyone who wants to implement them anywhere for any crop. CAMBIA's technology, including plant transformation, visual markers, and promoter trans-activation, can help recombine potential sensor components into modular vector segments, and mobilise the vector segments into particular crops.

By this transformational use of plant biotechnology, farmers themselves can be empowered to make informed choices about inputs and timing for the crops they choose to grow, rather than feeling pressure to take up crops and management choices such as pest control and nutrient inputs from elsewhere.

Diagnostics and Therapeutics for Poor People

A notable option in the near future is a high-profile public health initiative to stimulate the creation of cancer diagnostics and therapeutics for resource poor people, primed with a patent estate derived from work at CAMBIA on the human telomerase. This patent estate has been secured for BiOS licensing starting in 2006.

In the intense focus on 'neglected diseases' of poorer (and often tropical) parts of the world, such as malaria and tuberculosis, there is an unfortunate tendency to forget the many health challenges such as cancer which have dramatically different markets in both first and third world, but which effect terrible carnage and misery in both worlds. Leaving the development of diagnostics and treatments of such diseases and conditions to market forces, especially when intellectual property can be used to control entry of new players, will continue to render these debilitating but familiar illnesses a sad litany of social inequities.

More of the world dies of cancer than almost any other single disease. According to the WHO, cancer kills almost seven million people a year. By comparison, AIDS-related conditions kill three million people a year.

In the industrialized world, the availability of diagnostics and therapeutics, while often outrageously expensive, can lead to very favorable outcomes. In the poorer parts of the world, diagnostic technology, when available, is inadequate to the task, and few therapeutics are affordable. There are literally millions of people who die of cancer each year in the poorer parts of the world, who could have had longer and more productive lives if the diagnostic and therapeutic options available to their rich neighbors were available to them.

With cancer, it is not the disease that is neglected, but the diseased. This is a critical issue that will galvanize the communal interest necessary to mobilize the required human resources and accelerate essential normative changes.

When cloned in late 1997 by two Nobel laureate labs in fierce competition with an inventor located at CAMBIA and collaborating with an Australia-based cancer institute, human telomerase was viewed as the platform from which a key 'silver bullet' for cancer, for diagnostics, for gerontology, even for stem cells, could evolve. CAMBIA's work was featured in 1997 on the cover of Human Molecular Genetics. In 2005 two US patents were issued covering key aspects of the use of splice variants of the human telomerase gene associated with dozens of different tumor and cell types for diagnostics and therapeutics, and proteins based on this gene.

The original intention had been to license this technology both to Geron, a major biotech company that has been continuously cornering the market on telomerase-based strategies with massive patent acquisitions and filings, and also to a competitor of Geron to encourage market competition. Releasing the patents into the public domain was also considered, but with medical research, diagnostics and drug development now in the private sector, a death knell for social equity, we decided that doing so would have little effect on established practice. Recognizing the ethical challenges, and the opportunities to use these patents to foment a serious public scrutiny of patent-based pharma-strategy, in 2006 CAMBIA has decided instead to exercise an option to acquire all the patent rights for open source licensing.

We envision that in 2006-2008 these open sourced patents could provide a publicly visible means of drawing attention to the extraordinary opportunities of collective action on shared research priorities. Telomerase splice variants are not a "silver bullet", but they are the only weapon that will be explicitly directed at cancer among the disadvantaged. When sharing research on a diagnostic method for the poor begins to draw intellectual and moral strength, we envision two significant outcomes:

1. By developing a major BioForge project on telomerase-based diagnostics and therapeutics, we immediately galvanise - if not destabilize - a community that is wealthy and concerned with exorbitant prices and skewed priorities.

2. The lessons and methods learnt will enable the extension of the paradigm into 'neglected diseases'. It is essential to break the vector of “us and them”. We must weld together our seemingly different worlds into one, loosely coordinated but intrinsically inventive, global community.

A pioneering experiment in open source medical devices

Another pump-priming initiative planned is in the field of medical devices and diagnostics, to begin in 2006 with acquisition of all rights to a comprehensive patent estate associated with glucuronide metabolism. This technology portfolio will also allow exploration of ‘open-source’ modelled companies to deliver interventions in public health with market segregation.

Glucuronide conjugation and metabolism is a critical step in the excretion and detoxification of pharmaceuticals, hormones and other xenobiotics, and is directly related to metabolic robustness. This metabolic process is intimately involved with the principal detoxification process in mammals. Almost all drugs (including anti-retrovirals), hormones and xenobiotics are excreted into the bile and urine (and sometimes sweat) as conjugates with a sugar, glucuronic acid. This conjugate is typically processed by associated microbes which metabolize the sugar and allow the original compound - drug, hormone, etc.- to be re-absorbed in a process called entero-hepatic circulation. The lifetime, doses and side effects of most drugs, hormones, and even vitamins, are hugely influenced by this process. The formation of these conjugates is also indicative of liver function. From this stems a key position of glucuronide metabolism as the single point of attack for measuring key body functions and monitoring and manipulation of pharmaceuticals.

Almost all body fluids analysis is conducted by cleaving the glucuronic acid off in a lab before analysing the resulting compounds. Creating tools using glucuronidases will be a good way to drop the costs associated with diagnostics for poorer people and create new business models.

The patent portfolio also covers genes that make proteins that bind these compounds specifically, which can be used to produce a measurable signal, and genes that encode transporter proteins that specifically pump these compounds into living cells or indeed across synthetic membranes.

This patent estate will prime a good opportunity to explore OS medical diagnostics and pharmaceutical interventions. The intention at the outset of the funding period is to seek advice and counsel from those with public-good-focused business acumen, such as David Green of Project Impact, Victoria Hale of the One World Health Foundation, and other Schwab Entrepreneurs who have experience in developing businesses based on social justice principles. It is not our present intention to develop such businesses ourselves, but if our BioForge projects are to facilitate the formation and success of sustainable

enterprise that can deal with health challenges in the developing world, we must *ab initio* consider IP and incentive mechanisms.

BiOS Foundation: Innovation System Structural Reform

Our approach to harnessing the opportunities presented by the uniquely timed constellation of these open access technologies, the internet's communications technologies, and innovation system reform challenges must accommodate the unique cultural and economic realities of the individuals and industries involved, and the incentives that drive them.

In 2005, we developed and launched the first truly open source license for patented technologies. This required crafting a new legal instrument that incorporated the norms of open source software licenses, but covered much more complex legal considerations than those applied to copyright-protected IP in such licenses. We also saw the first adoption of this license (for crop molecular enabling technologies) by universities, public good institutions, and even a multinational, but we also saw occasional rejection and more often delays from some entities in which this concept was completely new to the patent licensing organs.

We believe that adoption of this license, similar to licenses such as the GPL, will be initially gradual and will mushroom as a critical mass is reached and the advantages enjoyed by collaborators become more well known. Documentation of our transactional experiences and these advantages will assist entities in other fields, such as international vaccine and neglected diseases initiatives, that are already expressing intense interest in the open source licensing model.

IP and Business Law and Practice, Policy and Advocacy

A significant activity of the BiOS Initiative in 2006-2008 is development of norms supported by standards and certification of open source agreements to disseminate and use patented technologies.

- Wider implementation of the crop molecular enabling technologies open access license, enabling cost-free access to portfolio technologies predicated on the sharing of improvements and regulatory information and on collective defence of the protected commons.

- Consultative development of a suite of open access license templates for different types of technologies including health technologies

- Discovery, evaluation and promulgation of practical business models that incorporate open source concepts and open innovation as a pre-competitive strategy.

- Identification of points of intervention and engage in debate in national and international law, *e.g.* domestic patent policies, the International Treaty on Genetic Resources for Food and Agriculture, WTO/TRIPs, Convention on Human Rights, WIPO, Convention on Biological Diversity, etc.; and networking pro-actively in law and policy, targeting the strongest intervention points to critically promote open source innovation concepts to the private sector, governments, non-profits and investment communities.

Our aim is to provide leadership in promoting BiOS as a pre-competitive paradigm suitable for participation by both large and small private enterprise, funders and public sector bodies.

Is the BiOS license just patent pooling?

While the BiOS license will function to create a pool of technology that is available to all who agree to the license covenants, it is not only a patent pooling mechanism. There are several major differences.

Patent pools tend to be formed as a defensive measure, an anticompetitive tool by players in competitive industries. They are usually open only to a select group of players who already own enough technology to trade it against others for privileged access, not open to any player or industry entrant that does not already have some leverage. For this reason, patent pools are sometimes the target of antitrust scrutiny as exclusionary mechanisms. The BiOS patent portfolio, by contrast, is available for license by any entity that will agree to maintain the technology as Open Access. It is unlikely that it would be viewed as an exclusionary mechanism, when its very intent is to keep the portfolio inclusionary.

While the BiOS portfolios are seeded with all of CAMBIA's technology, they do not comprise fixed pools. Instead, the commons protected from appropriation by BiOS license covenants will increase in size, not only through the dedication of improvements to the commons, but also by attracting and being open to additional technology owners who see the benefits of having a large researcher pool working on improvements in a distributive manner.

What is more, the technology portfolio that is protected by enclosure through the BiOS license include non-patented technologies, materials, knowhow and how-not-to. Such information and materials are normally not a part of patent pools because what maintains the pool is the "stick" that any non-participant in the pool does not have access to the technology, rather than the "carrots" and the non-punitive behavioural norms supported by the BIOS license, of sharing improvements and having access to what others share.

Once a traditional pool is formed by each participant dropping in patents as the price of entry, the patents can still be valueless or become valueless if their claims become irrelevant due to new trends in the technology or dominating claims that issue outside the pool. Through the technology landscape user participation work and the BioForge, the BiOS Initiative will be actively building a user community with the orientation to share improvements and insights into how the technology is developing. This openness will serve to greatly undermine the possibility that a patent thicket will form around improvements of this technology by others. If dominating claims do issue outside the BIOS protected commons, making it vulnerable, these many licensees are strongly incented to find work-arounds and work-beyonds.

Even the threat that dominating claims already exist, which is the main incentive for many ill-founded pooling mechanisms in Public-Private Partnerships, is vulnerable to the BiOS community, empowered via the Patent Lens and BioForge providing transparency and definitive knowledge of the true technology patent landscapes. Unshackled from Patent FUD, the BiOS licensee community is able to address challenges head-on by recruiting invent-around means, or finding prior art or other means to invalidate onerous patents.

BioForge Integration with the BiOS policy efforts

Our needs to develop culture-informed policy initiatives are great in the life sciences, particularly in health. The medically related industries are vastly more lucrative than those of agriculture and food. The self-interest, self-confidence and self-perpetuation of their 'success' stories is daunting. Extravagant profits and the cultural prestige and power of ‘curative’ interventions breed a conservative culture entrenched in its resistance to structural or behavioral change.

Using the BioForge and particular projects in enabling technology as a platform build constituency and tools to create common cause, we will be able to expand the agenda beyond common problems to those which are more specific to poverty, including ‘neglected diseases’.

Patent Lens Integration with the BiOS policy efforts

Arguments being made for substantial changes in innovation policy, including patent policy, will be greatly strengthened by lucid and informed appreciation of the true nature and extent of the problem, and its effects on sustainable prosperity of technology-based industries in society.

The intent of patent systems – to provide incentives for disclosure with an aim to stimulate invention –is being lost in the flooding and indeed gaming of the system. The Patent Lens can provide tools to help innovators, business professionals, citizens and policymakers to endure its current excesses and

guide its future improvements to improving public good and social and economic value.

Thus, we look to the development of alliances with public good funding entities to use patent transparency as a mechanism for influencing the course of public good research. Our aim is a scenario in which granting agencies will not fund research until the patent landscape has not only been investigated, but the proponents have mounted a public, commentable technology landscape.

Another scenario is that patent offices in less developed jurisdictions can use the Patent Lens public facility for increasing quality of prior-art searching to improve the quality and merit of patent grants, and decrease the FUD in the innovation process. To this end we are mounting, early in 2006, a tutorial on trends in patent searching informatics. We also hope that the expanding tutorials can serve as a guide influencing the policies of national offices that may not otherwise realise their options under TRIPS.

Summary: Outputs of the BIOS Initiative (2006-2008)

The BIOS mechanism is expected to diffuse out to inventors and technology providers as a mark of relevance, quality, fair-play and accessibility. We foresee distributed nodes sited at influential technology centers certified to validate and commission BIOS licenses and technologies.

The Patent Lens: Intellectual Property Informatics and Analysis

Overarching goal: A core public facility offering patent data transparency that doesn't require mediation by expensive patent attorneys for each jurisdiction.

Year 1 activities and deliverables:
Further integration of patent status information, e.g. INPADOC and WIPO National Phase data, with core patent database.

Add relevance ranking and expand to patent classes other than life sciences, and begin expansion of databases to include additional countries.

Begin linking patent database search outputs with semi-automated license commentary and annotation capability, and with technology landscapes and other databases.

Year 2 activities and deliverables:
New technology landscapes around technologies targeted for inclusion in BiOS portfolios.

Increase breadth of IP database to include new jurisdictions, *e.g.* China, Korea, Japan, India, Brasil, regional offices in LDCs.

Year 3 activities and deliverables:
Integration of search and natural language queries, and searches in multiple languages, through APIs with other non-patent information, eg. GenBank, PubMed etc.

Searchable portfolios and more analyses of work-around BiOS-certified technologies.

Bio-Forge: Cooperative Open Access Technology Development

Year 1 activities and deliverables:
Further extension and adaptation of the open source software licensing concept to other types of patented technologies and to MTAs and other contracts.

Expansion of the portfolio of current technology seeded with BiOS-licensed patents and IP, to include additional tools beyond Crop Molecular Enabling Technologies.

Initiation of at least one coordinated new technology program based on open access innovation (*e.g.* BiOSentinels for farm and resource management)

Year 2 activities and deliverables:
Open Innovation License templates available for download in several languages.

Expansion of at least one coordinated technology program in global health.

Year 3 activities and deliverables:
Development of Certification program to validate similar license structures by and for third parties.

Integration of project management and coordination tools, including funding mechanisms and progress over-sighting into BioForge.

BiOS Foundation: Innovation System Structural Reform

Year 1 activities and deliverables ongoing into Years 2-3):
Institutional partnering with BiOS, including Harvest Plus as well as One World Health Foundation, Drugs for Neglected Diseases, or other programs in public health.

Engagement with public-good oriented agencies and universities to extend the BIOS paradigm into public health, medicine, environment, agriculture and biological industries.

Year 2 activities and deliverables:
Promoting and negotiating détente scenarios with current institutional IP holders and potential adversaries of open-access innovation mechanisms.

Publication of materials for university technology transfer offices and public agencies aimed at receiving their understanding, support, and permission for faculty to participate in BIOS.

Year 3 activities and deliverables:
Incorporation and integration of incentive systems, including Innocentive-like awards schemes, for targeted technology-bottleneck breakthroughs.

Analysis of key points of policy intervention for democratisation of innovative capacity in international instruments, and the productive engagement in international negotiations.

Analysis of and intervention in national IP policy formulation with constructive alternative IP management and development paradigms.

Long-term Indicators of Success:

Development and growth of BioForge as a collaborative community of problem-solving, including creative nodes of R&D as BiOS collaborators within LDCs.

Increase in public and private engagement in biological interventions relevant to poor and excluded communities, and increasing equity and parity in public-private partnerships.

Use of BIOS-certified technologies in research oriented to LDC problem–solving, and growth of BioForge IP portfolios through donation or development of IP.

Reduction in private-sector use of aggressive patenting of pre-competitive core technology.

Adoption and adaptation of BiOS licenses in diverse settings, ideally coupled with reduction in public-sector exclusive or barrier-setting licensing practices.

Growing numbers of licensees, and number and stature of subscribers.

Increased sophistication and flexibility in international and national innovation policy.

Acronyms, Trademarks, key and 'coined' terms

API	-	Application program Interface: a set of routines, protocols, and tools for building software applications.
BOS	-	Biological Innovation for Open Society. An initiative promoted and guided by CAMBIA. Also, Biological Open Source. 'BiOS' means 'life' in Greek.
CAMBIA	-	And international non-profit institute, based in Canberra Australia. CAMBIA was formerly an acronym for 'Center for the Application of Molecular Biology to International Agriculture'. Now comprising only the word CAMBIA, meaning 'change' in Spanish & Italian, as the legal name of the institute promoting the BIOS initiative.
DArT	-	Diversity Arrays Technology; a solid-state genotyping technology developed at CAMBIA and licensed under BiOS
FTO	-	Freedom to Operate
FUD	-	Fear, Uncertainty and Doubt. Term coined in the software industry for business 'disinformation' that compromises investment and client confidence in a product, platform, person or entity.
GUS	-	Glucuronidase gene
GUSPlus	-	A successor-technology to GUS, a reporter gene platform technology provided by CAMBIA, also under a BIOS OIL
ICT	-	Information and Communications Technology
IT	-	Information Technology
Patent Lens	-	the Patent Informatics, Database and Analysis facility of CAMBIA's BIOS Initiative
PatentLens – BioForge – BIOS Foundation	-	An incorporated non-profit entity, currently registered in the USA, but with intended to have numerous 'franchise' counterparts for certification, oversight and promotion of open innovation practices in life sciences.
Protected Technology Commons	-	a normative and legal collection of technologies and practices intended to maximize access, creative furthering and benefit sharing amongst participants. Other than adherence to the norms of the PTC, which center around the responsibility to 'preserve' the integrity of the commons, there should be no barriers to participating.
TransBacter	-	The technology developed by CAMBIA and published in Nature in February 2005, which affords the first practical, open-source alternative to the Agrobacterium plant gene transfer technology, provided on the BioForge and covered by OIL.