



The CAMBIA BIOS Initiative

Biological Innovation for Open Society

CAMBIA's BIOS Initiative will merge Intellectual Property Analysis, Innovation Policy Reform and Cooperative Technology Development Activities to foster democratic innovation in applications of biological technologies to sustainable development.

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Background and introduction to the initiative

Very 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, poor nutrition, environmental degradation, poor public health practices, insufficient attention to diseases and medical conditions of poor people or marginalized communities.

While the potential to impact all of these problems with biological technology of various kinds is undeniable, the discouraging lack of progress has at its core a structural failing associated with the use of science as an instrument of economic and social development.

Sustainable and equitable development can only happen through the 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 this process, it must be part of an integrated process of democratic innovation that is sensitive to the operating constraints of problem solvers.

However, much of modern science – and in particular biological technologies – has evolved in a world of high-capital, high-margin applications that are often irrelevant to the poor or excluded communities that make up more than four billion of the world's population.

This evolution of technologies – mirrored in the evolution of intellectual property regimes to protect and promote them and business models to develop and deliver their applications – reinforces the differential and furthers the disenfranchisement of the poor.

This cycle of exclusion is neither irreversible nor inevitable.

The Information and Communications Technology industries have evolved new innovation models that point to a productive way forward. The concepts of collaborative invention of core technology and its provision in a protected commons have now galvanised the software industry to new levels of creativity and democratisation in business and society, without compromising its profitability.

The explosion of patenting and the pace of discoveries and investment in biological sciences, while hinting at great opportunities, have created a thicket of rights and self-reinforcing barriers to innovation that continually marginalize those most at need.

It is not the products of biotechnology that the poor need, *per se*. This could never be sustainable or realistic, given the state of science, economics, business and society.

Rather what is needed is the opportunity 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.

The BIOS initiative is designed to forge a new commons in enabling technology for biological innovations.

BIOS will:

- explore and adapt new inclusive IP sharing mechanisms,
- articulate and promulgate public-good norms in biological technologies, commission new democratising technologies and
- promote new standards of utility in enabling technology.

BIOS will intervene with salient policy initiatives to increase fairness in access to the tools of innovation as a fundamental human right, it will 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.

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 that is one of the first points of intervention, because the opportunities are so great, and the impediments to wise use so pronounced.

Rather, 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 similarly constrained by the technology options available to often disenfranchised user groups.

'*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 public or private sector.

There must be an essential distinction between the tools of innovation, and the products of innovation.

This critical distinction will be a moving target, will be difficult and contentious, but it must be engaged. The implications for the impacts of exclusionary IP regimes in tools and their use (analogous to operating systems, programming languages and standards of interoperability) or in their applications (analogous to product lines or service relationships in software companies) are very different. This distinction is critical to forge an acceptable compromise and common purpose with proprietary thinking as reflected by much of the business community involved in biological technology use. This very distinction is also at the heart of the acceptance and indeed promotion of Linux and other Open Source software by many powerful and influential corporations in IT.

One spoke broken will stop the wheel from turning: granularity

Increasingly, biological technologies are not self-contained, but are rather interdependent technologies which require several key components to function. Powerful technologies by analogy 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 can and does 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 public sector science community is complicit by neglect, as virtually all practices of academic scientists promote the belief that 'good science' can, almost by magic, transform itself into public or private goods. In fact, the conversion process is the stranglehold. The internet, and the ease and affordability of sharing data have made information, *per se*, no longer the critical point of control.

Thus, the 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. This data, the genetic materials and the published science is routinely captured and hijacked - enclosed - by those entities, usually large multinational corporations that have access to the means of converting that information into economic value through goods or services. This enclosure rarely ensures a sustainable competitive advantage, and is sometimes an inadvertent and very unfortunate side effect of a strategy for industry survival.

These enabling technologies are the new, largely unseen battleground for public good and democratic involvement in problem solving, whether by public agencies or by private enterprise.

The clearly visible manifestation is 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.

But the reality is that the technologies themselves are reflective of the marginalization of the needs of poor people, in their irrelevance, high expense and continued dependence on the suppliers of the technology.

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 has also fomented a great change in the IT business world.

Interestingly, 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. These tools 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 to be able to address the challenges of low margins and the market failures associated with the needs of poor people.

BIOS will play an important role in making other, parallel public-good oriented activities and IP focused initiatives more successful by providing templates for new licensing and sharing regimes, new tools for technology forecasting and management and by enhancing the pro-active analytical capabilities of Offices of Technology Transfer and the policy activities within those entities represented in its membership.

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 CAMBIA BIOS Initiative: Proposal

Summary

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, in 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.

BIOS will act by catalysing a large 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.

Supporting Rationale

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.

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

Examples of these limitations are many, ranging from the increasing domination of agriculture by large multinationals and the public disquiet with genetic modification of crop plants, through to the focus by medical research and development on high-margin pharmaceutical applications for the rich world rather than low-margin public health interventions that can greatly enhance the quality of life for the world's poor, and could encourage robust local economies.

The existing innovation system in biology encourages the continued attention to relatively high-margin markets, and the private appropriation of enabling technologies through its intellectual property and investment practices.

Reaching the delivery stage using most biological technologies requires the use of many key components. Necessary access to a highly fragmented set of critical technologies in order to create a potentially viable product creates two major problems for the public-good agenda to accommodate market failures.

First, 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 creating large IP portfolios and negotiating cross-licensing arrangements to obtain full platforms of enabling technologies, albeit usually finding themselves limited in freedom to operate. The public-good sector, and small-to-medium enterprise with its fractured portfolios, modest non-fixed capital pools and its eagerness to license out publicly-developed technology is at a grave disadvantage.

The second problem concerns a mistaken belief that technology in the public domain is protected from private appropriation. When all but one of the enabling technologies necessary to develop a product have been placed in the public domain, the owner of that one remaining component has complete control over development of the product. Thus, the economic value from scientific results, including genome sequences placed in the public domain is routinely captured only by entities that have access to the means of converting that information into economically valuable goods and services.

For these reasons, enabling technologies are the new, largely unseen battleground for public good.

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.

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, these 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.

BIOS Activities

Three interdependent activities make up the BIOS Initiative. These are:

- a) Intellectual Property Informatics and Analysis,
Understanding the IP landscape and developing a toolkit to navigate IP thickets, acquire freedom to operate and forecast trends and new technology development
- b) Cooperative Open Access Technology Development
Developing 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.
- c) Innovation System Structural Reform;
Developing new mechanisms in licensing, relationships, contracts and in national and international policy to encourage democratized problem solving;

Intellectual Property Informatics and Analysis

The CAMBIA BIOS Initiative has at its core what is probably the world's most comprehensive cost-free public-access database of patents in the life sciences, developed at CAMBIA over the last five years. The database, representing the full-text of life sciences subset of both applications and granted patents from the USPTO, PCT, European and Australian jurisdictions, has a fast and user-friendly searchable interface.

(www.cambiaip.org)

- The database will be further expanded to include new jurisdictions e.g. China, Japan, India, Brasil, Russia, regional LDC offices.
- Continuing work will ensure that patents in the life sciences, impacting public health, medicine, pharmaceuticals, chemistry, environmental management and genetic resources, as well as food, nutrition, agriculture and biotechnology are fully represented.
- The database will be expanded to encompass full images as well as text-searchable records.
- Information relevant to the legal status of patents from INPADOC will also be integrated.
- DNA, RNA and protein sequence searching within specifications and claims will be added, with dynamic links to public sequence databases.
- Searching selectively within patent claims will be implemented.
- Intuitive, real-time and user-driven analytical software tools will be developed to guide decision making in technology choice or

partnering options and to provide guidance in creating new technology development strategies. This dynamic software will use professional IP law, scientific and informatics skills integrated into a multi-purpose front-end.

- Informatics tools will be created which can also guide informed policy relevant to biological innovations in trade, public health, environment, genetic resources, agriculture and food security through analysis of patterns of IP development, protection and ownership.

Cooperative Open Access Technology Development

The cultivation of OATs and the creation of the BioForge

The first Open Access Technology activities of the BIOS initiative will focus on the key portfolios of technology that are presenting real bottlenecks to innovation by and for the developing world, and indeed 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 can be developed targeting critical future technology opportunities that can have catalytic effects on democratic innovation. This must include technologies affecting health and medical interventions.

The first two portfolios will be directed to Genetic Resource Analysis and to Crop Molecular Enabling Technologies. All of CAMBIA's current intellectual property falls into these two portfolios, and will be converted to open-access BIOS licensing.

Genetic Resource Analysis:

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

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, many new technologies have been developed which have been targeted to bypass critical restrictions in plant genetics such as gene transfer by *Agrobacterium*, or screening for

transgene behaviour. These technologies will form the founding core for the Crop Molecular Enabling technologies for BIOS.

New Portfolios and directions:

BIOS Technology efforts will, upon securing suitable funding, also stimulate and commission work on core technologies that all players, large and small, need for the next generation of innovation, such as Bioindicators (sentinel plants), homologous recombination (HARTs) and apomixis, new pharmaceutical screening or production systems, or vaccine development and delivery.

Establishment of BioForge

It will be essential to create a mechanism by which like-minded individuals and agencies can collaborate with optimum effectiveness to solve problems and create technologies under an open-access regime. As sourceforge.net has done for the open source software community, we envision a cyberspace meeting place that will combine vigorous but positive debate, peer co-development concepts, curated and stewarded contributions, and public-good binding norms to forge unique collaborations and distributive problem-solving relevant to those unserved by current innovation practice. This will be a dynamic exercise, changing and morphing as it gains experience.

- 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.
- Development of technology management capability and methodology to evaluate, monitor, commission, value, receive, acquire and curate technology contributions.
- Continuation of in-house and out-sourced molecular technology development as an Open Access Technology (OAT) under a BIOS License.
- Construction and curatorship of portfolios of critical biological enabling technologies.
- Stimulation and sponsorship of targeted innovation through commissioned, managed research, and through participation in challenge or bounty systems such as InnoCentive, Inc. (www.innocentive.com).

Innovation System Structural Reform:

IP and business law and practice, policy and advocacy

- Consultative development of a suite of open access license templates, by applying to patented biological technologies aspects of the open source licensing of software.
- Development of contractual and bailment (e.g. Materials Transfer Agreements) templates that can bind users, and user-developed improvements into open-access regimes in the absence of patent grants.
- Implementation of the 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.
- Develop, discover, evaluate and promulgate practical business models that incorporate BIOS concepts and open-innovation as a pre-competitive strategy.
- Develop pro-active law, policy, advocacy and networking activities to critically promote the BIOS concept to the private sector, governments, non-profits and investment communities.
- Identify points of intervention and engage in debate in national and international law, eg. domestic patent policies, Treaty on Genetic Resources for Food and Agriculture, WTO/TRIPs, Convention on Human Rights, WIPO, Convention on Biological Diversity, etc.
- Identification, leadership and advocacy of key areas in the technology and/or intellectual property landscape where targeted innovation is needed to democratize problem solving.
- Provide leadership in promoting BIOS as a pre-competitive paradigm suitable for participation by both large and small private enterprise.

Outputs

- Development and provision of BIOS Open Access licenses and contracts allowing for the extension and adaptation of the open source software licensing concept to patented technologies and to MTAs and other contracts.
- Development of Certification program to validate BIOS license structures by and for third parties.
- Open Access license templates available for download in several languages.
- Partnering with public-good oriented agencies to extend the BIOS paradigm into public health, medicine, environment, agriculture and biological industries.
- A portfolio of current technology e.g. genotyping and plant genetics tools will be developed, seeded with CAMBIA patents and IP.
- Analysis of existing technology targeted for inclusion in BIOS portfolios, including identification of contributors.
- Promoting and negotiating a détente with current institutional IP holders and potential adversaries of open-access innovation mechanisms.
- Initiation of at least one coordinated new technology program based on (e.g.) BioIndicators and Sentinels for farm and resource management, HARTs or Apomixis.
- Increase coverage of all relevant Life Sciences into the BIOS IP Database.
- Increase breadth of IP database to include new jurisdictions, e.g. China, Japan, India, Brasil, Regional offices in LDCs.
- Integration of patent-status information, e.g. INPADOC with core patent database.
- Advanced informatics-driven patent database tools developed on the CAMBIA IP Resource baseline set.
- Searchable portfolios of BIOS-certified technologies; i.e. those which are either non-proprietary or in a protected commons.
- Development and promotion of BioForge, a new international network mechanism for collaborative efforts on problems of particular relevance to the poor,

- Exploration of incentive systems, including Innocentive, for targeted technology-bottleneck breakthroughs.
- Materials for university technology transfer offices and public agencies aimed at receiving their understanding, support, and permission for faculty to participate in BIOS.
- Analysis of key points of policy intervention for democratisation of innovative capacity in international instruments.
- Productive engagement in international negotiations.
- Analysis of and intervention in national IP policy formulation with constructive alternative IP management and development paradigms.

Indicators of success:

- Increase in public and private engagement in biological interventions relevant to poor and excluded communities.
- Development of creative nodes of R&D as BIOS Collaborators within LDCs.
- Use of BIOS-certified technologies in LDC problem solving.
- Increasing equity and parity in public-private partnerships.
- Reduction in private-sector use of aggressive patenting of pre-competitive core technology.
- Reduction in public-sector exclusive licensing practices.
- Institutional partnering with BIOS, including CGIAR, National Programs in public health, environment and agriculture.
- Number of licensees, and number and stature of subscribers.
- Growth of portfolios through donation or development of IP.
- Worldwide acknowledgement of the Open Access BIOS philosophy and adoption and adaptation of BIOS in diverse settings.
- Increased sophistication and flexibility in international and national innovation policy.
- Development and growth of BioForge as a collaborative community of problem-solving.

Structure and Modes of Participation

The BIOS initiative will be developed within CAMBIA's framework but will increasingly be associated with an autonomous non-profit identity as this becomes practical. BIOS will extend to a worldwide network of participants, currently constrained, unserved or marginalized by the existing intellectual property culture, using BIOS as a mechanism for collectively inventing, and securing biological technology into a publicly accessible commons, protected from private appropriation but available to all – public and private - and as a venue for collaboration, *de novo* innovation and the free exchange of information.

Contributors will assign, provide or license their technologies or knowledge to a protected commons created by BIOS or to a BIOS-approved license or contract mechanism, which may include patent, trademark, copyright, contracts, materials transfer agreements or other binding agreements.

Licensees will acquire cost-free access to any BIOS technologies, based on the open access license which commits the licensee a) to grant back to BIOS rights to any improvements made, b) to collectively defend the protected commons of BIOS technologies and c) to share regulatory and biosafety information with all licensees.

Subscribers will be licensees who contribute a non-compulsory annual fee to BIOS, proportional to their capabilities. BIOS's technologies will be grouped in technology-specific portfolios and subscribers will specify the portfolios to which they wish to subscribe. Subscribers will receive related support services and direct access to a portfolio manager who is a leading expert in the specific technology and its intellectual property landscape. They 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 post problems for solving on a web-based incentive structures such as the InnoCentive network, and more.

Collaborators will be partner institutions providing research or services related to BIOS-focused aspects of IP systems analysis, ethics, theory, and practice. Collaborators should include many international institutions who face common constraints of tool access and use and IP policy.

Sponsors will contribute financially or in-kind to support BIOS and will collectively assert political and moral endorsement to its mission and its community of innovators. Sponsors may include philanthropic donors, national governments and agencies, and private and public benefactors.