Statement of Essential Inventions to the
Commission on Intellectual Property Rights, Innovation and Public Health

April 5, 2004

1. Introduction

2. Policy Objectives for Finance Mechanisms

The Commission should focus on the mechanisms that are best to finance the advances in knowledge and innovation that improve public health. These mechanisms should be evaluated on the basis of how they address legitimate policy objectives, including those relating to:

1. *Fairness.*
2. *The advancement of scientific knowledge,*
3. *Economic efficiency (cost effectiveness, appropriate investment levels, efficient management, etc),*
4. *Public health priorities, and*
5. *Scientific, professional and political integrity,*

3. The current system of financing R&D can be criticized for being morally repugnant, economically inefficient, and corrupt.

a) It is morally repugnant to rational access to treatments.

It is morally repugnant to accept a system of financing R&D that prices medicines far higher than the competitive costs of manufacturing and distributing medicines. The majority of the world's population lacks access to important medicines. Even in

higher income countries, high prices lead to rationing for the best new medicines. As a consequence, useful therapies are routinely and predictably not available to patients who need them. This is morally repugnant precisely because it is possible to embrace other methods of financing new medicines that do not depend upon high prices and rationing of access.

b) The current system is not economically efficient

i) Expensive and not cost effective

The current system of financing new medicines relies on a mixture of public and private sector finance. The WHO TRIPS agreement is an R&D treaty, but one that focuses exclusively upon patents and rights in data to finance R&D. IMS estimated the global pharmaceutical market to be $491.8 billion in 2003, or more than 1.5 percent of world GDP. The global expenditures on pharmaceuticals rose by 9 percent in 2003, far outpacing the growth in incomes.

Experience suggests that competitive and efficient distribution can routinely bring drug prices down by 95 to 99 percent. This suggesting the cost of goods with efficient procurement and efficient manufacturing might be as low as $5 to $25 billion. Even if the efficient cost of medicines is much higher, say a fifth of the current price tag, the cost of the monopoly would still be nearly $400 billion per year, or about $63 for each person on earth. If global private sector R&D investments are $60 to $75 billion (depending upon which data are used), we are getting back only around $10 to $12 per person in R&D. And most of this is for products that are not significantly better than existing medicines. Indeed, based upon US FDA data, an estimated 80 percent of R&D investment is spent on products that are no better than existing products.[1] In other words, globally we pay $63 per person in higher drug prices to finance R&D, but only get back around $2 per person on private sector investment in products that have significant health care benefits. Moreover, next to nothing of this is spent on treatments for diseases that primarily afflict the global poor, such as malaria or TB. Finally, private sector investments are focused more on chronic treatments than on cures or vaccines.

There is also considerable evidence that a number of commercial considerations that have little to do with health care benefits often drive up the costs of clinical testing, including for example the increasing tendency to have marketing considerations influence the design of clinical trials, and efforts to maximize the duration and scope of marketing monopolies.[2]

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[1] James Love, "Evidence Regarding Research and Development Investments in Innovative and Non-Innovative Medicines," September 22, 2003.
http://www.cptech.org/ip/health/rnd/evidenceregardingrnd.pdf

[2] Robert Langreth, "Drug Marketing Drives Many Clinical Trials," Wall Street Journal, November 16, 1998. See more generally, "Evidence Regarding Research and Development Investments in Innovative and Non-Innovative Medicines."

ii) Overly broad and excessively strong IP rights impede follow-on innovation

IP rights are a *tool* to promote innovation, by attracting resources to R&D. But in many well-known cases strong IP rights impede innovation by blocking follow-on innovation. In medicine, software and information technologies, and in a number of other areas, innovation is a cumulative, collaborative enterprise. When intellectual property rights grant strong exclusive rights to use information or inventions, firms will limit access to information, and restrict licensing of technologies, in order to exploit market power in future R&D markets. The problems presented in this area have been addressed in a number of expert reports and academic studies, including for example the April 2003 report by the Royal Society, "Keeping science open: the effects of intellectual property policy on the conduct of science."[3] The following are some of the Royal Society conclusions:

> 6.4 The enormous investment in biotechnology and software puts great pressure on patent offices to grant patent applications, but the new technologies are, as ever, testing the boundaries between discoveries (which are not patentable) and inventions (which are). The distinction is not always clear, particularly in developing areas such as biotechnology; yet scientific progress can be stifled if what are actually discoveries are judged to be patentable. Patents with a broad scope can also stifle follow-on research and development by others. Our key recommendations here reflect the need for patent examiners to take all necessary steps to be up-to-date in order to aid their judgement of novelty and inventiveness, and to be rigorous in applying the criteria for the granting of a patent application.
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> 6.5 Access to information is also increasingly constrained and needs to be improved. Investments by publishers are, for example, protected by copyright law; this worked well when most information was stored on paper. Digital storage and transmission of scientific journals and books can permit cheap world-wide dissemination as desired by scientists and needed by science. Equally, publishers can see technology reducing their ability to get payment for their contribution. Recent copyright legislation has more closely met the needs of the entertainment industry than those of science, and difficulties now face the scientific community which has relied heavily on the 'fair dealing' provisions of the copyright legislation to access information. We believe that learned societies should take a more proactive role in promoting more efficient channels for publication on a not-forprofit basis. Several of our recommendations are designed to improve access to scientific information.
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> 6.8 We feel strongly that those funding, organising and carrying out publicly funded research should ensure that resulting data are made readily available for use by all. It makes no sense to spend millions of pounds on research, the value of which is substantially diminished because some tens of thousands of pounds are not earmarked to support public databases that ensure full, easy and cheap or nocost access to allow science to progress rapidly. Private databases can be valuable, but they almost inevitably make access more

[3] Available on the web here: http://www.royalsoc.ac.uk/files/statfiles/document-221.pdf

difficult and they can lead to undesirable monopolies. Several of our key recommendations point the way to more effective rules and procedures to improve the value to society of both privately and publicly funded databases.

6.9 Monopolies can develop where scientific information is protected by copyright, but are even more likely where a dominant position has been achieved using patents or database rights. Competition law is an overriding remedy, but it is best if restraints are such that it need not be applied.

4. Ritonavir

One timely example of the restrictions on follow-on inventions concerns ritonavir, a drug used to treat AIDS. Ritonavir was first developed by Abbott on a US NIH grant as protease inhibitor, and was initially used as one of three drugs in HAART therapy for AIDS. Later, ritonavir was seen as having beneficial use as a "booster" of other protease inhibitors. Abbott holds the patent rights on ritonavir, and markets ritonavir as a standalone treatment under the brand name Norvir, and as a fixed dose combination of ritonavir and lopinavir, under the trade name Kaletra. In the economically important US market, Abbott recently announced a 400 percent price increase that only applies when patients buy ritonavir as the standalone product, typically to "boost" non-Abbott protease inhibitors. Abbott has also reportedly refused to license the ritonavir patents to other firms that wanted to offer co-formatted fixed dose combinations of ritonavir and other protease inhibitors.

The discriminatory price increase was clearly an effort to protect or expand the market share of Abbott's Kaletra. It will also have a very negative impact on the R&D pipeline for new protease inhibitors, that would be used in combination with ritionavir. For example, tipranavir, a Boehringer-Ingelheim protease inhibitor still in development, needs to be boosted with 400 milligrams of Norvir/ritonavir. After Abbott's recent price hike, the USA price of the ritonavir boost is more than $16 thousand dollars per year. This will destroy Boehringer's market share for first line regimes, and discourage Boehringer and other firms from developing products that may be very important for "salvage" patients, who have already developed resistance to existing protease inhibitors.

Ritonavir is also expected to have utility as a booster for drugs used to treat other diseases, such as cancer, or possibly hepatitis, and efforts by Abbott to use its patent rights in an anticompetitive manner may harm public health for these diseases also.

Here it is important to note the huge public investment in the development of ritonavir. Not only has the US financed many studies that were instrumental in advancing the science for AIDS treatments, including the grants made directly to Abbott that led to the invention of ritonavir, but also in the continued development of ritonavir as a treatment. The US NIH CRISP database lists 574 federal grants to study ritonavir. ClinicalTrials.Gov recently identified 26 clinical trials planned or currently recruiting patients that involved ritonavir. Of these, 21 were sponsored by US government agencies, and Abbott was the sponsor of only one. Four were sponsored by other drug companies (including two small firms).

5. Compulsory licensing

In the case of ritonavir, the US government holds rights in several essential patents, and as a consequence, the US government may be able to exercise its "March-In" rights under the federal Bayh-Dole Act and issue compulsory licenses to the patents on the grounds that Abbott has failed to make the patents "available to the public on reasonable terms" 35 U.S.C. § 201(f).

Abbott has sought to limit the US government's rights by obtaining new patents on ritonavir. In the US FDA Orange Book, Abbott lists five US patents for the popular 100-milligram gel tab of ritonavir. The US government has rights in the first four. But US patent number 6,232,333 does not list US government march-in rights. This patent was granted more than five years after the FDA approved ritonavir for sale. The broadest claim for this patent is the unremarkable "invention" that ritonavir can be combined with a solvent for use in hard gelatin capsules or soft elastic capsules. It is probable that this patent can be broken, because it is not novel, or because there may be prior art. But Abbott may seek to exploit the opportunities that litigation presents to "buy time" to block generic versions of ritonavir from entering the market. Today this scenario is quite common, and firms routinely obtain trivial or poor quality patents in order to expand and extend market power, and prevent or delay competition, including innovation in the same product space.

The US Federal Trade Commission has concluded a number of studies and investigations into the anti-competitive abuses of US regulatory and patent laws.[4] In cases like the ritonavir example, the US government would benefit from the broader compulsory licensing authority that is typical in Europe and most in other countries, so that the US would not have to establish Bayh-Dole march-in rights in every patent in a product before it could act to protect the public interest.

Some countries have such laws in particular sectors of the economy. For example, the US has special compulsory licensing authority for nuclear energy technologies and for implementing the US Clean Air Act, and the European Commission's Biotechnology Directive provides for mandatory compulsory licensing of follow-on innovations involving genetically modified seeds. But more general compulsory licensing laws are also common.

Article 31 of the TRIPS sets out a number of rules governments must follow if they authorize the use of patents without the permission of patent owners. These rules generally depend upon the grounds used to justify the authorization. In cases of public non-commercial use, the rules are quite liberal, with the exception of restrictions on exports (limited to non-predominate shares of output). The only real obligation is to provide "adequate" compensation to patent owners. Public non-commercial use includes situations where private firms provide services or goods to governments. The WTO rules for public non-commercial use can also be extended to purely private sector uses "in cases of national emergency or other circumstances of extreme urgency." According to the November 2001, *Doha Declaration on TRIPS*

[4] See, for example: *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*. A Report by the Federal Trade Commission, October 2003

and Public Health, each WTO member may decide for themselves "what constitutes a national emergency or other circumstances of extreme urgency."[5]

When the licenses are issued on general public interest grounds, for use in the private sector, under non-emergency situations, there is a general requirement for prior negotiation with right owners on "reasonable commercial terms and conditions."[6] Countries have broad discretion in determining what are reasonable commercial terms, since for every provision in the TRIPS, WTO Members are "free to determine the appropriate method of implementing the [TRIPS] provisions. . . within their own legal system and practice."[7]

Special and quite flexible rules apply when compulsory licenses are issued as a remedy to anti-competitive practices (which can be determined by judicial *or* administrative process). Not only is the requirement for prior negotiation on reasonable commercial terms waived, but so too are the restrictions on exports.[8] This is a very important provision in the TRIPS, and in fact is fairly widely used, particularly in the United States, in the area of information technologies, and also in manufacturing or agriculture.

Related to the control of anticompetitive practices is Article 40 of the TRIPS, which states in part:

> SECTION 8: CONTROL OF ANTI-COMPETITIVE PRACTICES IN CONTRACTUAL LICENCES
>
> *Article 40*
>
> 1. Members agree that some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology.
>
> 2. Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market.

Finally, there are particular provisions in the TRIPS for compulsory licensing in cases involving dependent patents.[9] These are actually more restrictive than the general public interest grounds for issuing a compulsory license. In particular, Article 31(l)

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[5] Paragraph 5(c). "Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency."

[6] Article 31(b).

[7] Article 1(1).

[8] Article 31(k). "Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive."

[9] Article 31(1) of the TRIPS, which refers to cases:

> Where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"),

requires that "the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent,"[10] and provides that "the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent."[11] The European Biotechnology Directive generally follows the framework of Article 31(l) for the mandatory compulsory licenses on genetically modified seeds.

The compulsory licensing provisions in the TRIPS assure that countries can override the exclusive rights of patents in a wide range of cases, in order to protect consumers, overcome anticompetitive practices, guarantee that follow-on innovators have access to inventions, to promote technology transfer, or for other purposes.

6. R&D Mandates

Whenever governments consider compulsory licensing, there are concerns that weakening of strong exclusive rights will lead to reduced R&D investments. This is also the case for price controls, lessening of restrictions on parallel trade, reform of the commonly abused patent extension or marketing exclusivity mechanisms, or more generally for nearly any provisions designed to promote efficiency or to protect taxpayers or consumers. The public is often presented with a sobering and unpleasant choice between innovation and access.

Governments need to embrace approaches that permit governments to make finance mechanisms more efficient and more fair at the same time. R&D mandates are one such approach that shows promise.

R&D mandates can be used in a variety of settings to preserve or increase R&D funding in cases where consumers benefit from lower prices. For example, if the US licensed parallel trade in medicines between the US, Europe and Canada, but required the parallel traders to contribute 10 or 15 percent of the price difference into an R&D fund, the US could obtain lower domestic prices, but still ensure that R&D funding was not reduced. R&D mandates could be implemented more aggressively, including for example, to restore R&D to appropriate levels when compulsory licensing is used to address abuses such as excessive pricing of medicines. An important advantage of the R&D mandate approach is that it is potentially a much cheaper mechanism to finance R&D than the system that allows monopoly prices on essential drugs. Left to its own devices, the global pharma industry now only reinvests a small fraction of sales into R&D on new products. Governments can mandate that firms invest as much into R&D as policy makers specify.

Below are a few examples of R&D mandates.

a) cisplatin

In 1983, an R&D mandate proposal was made in connection with cisplatin, a cancer drug invented at Michigan State University. When generic producers wanted to sell

[10] Article 31(l)(i).
[11] Article 31(l)(ii).

cisplatin, Bristol-Myers (before Squibb merger) claimed competition and lower prices would reduce R&D. One generic producer's response to this claim was a proposal for an R&D mandate on generic producers. The generic producer said that the government could require any amount of R&D investment, and specify also who the recipient of the funds would be.

A watered down version of the R&D mandate was eventually implemented, not in connection with the entry by generic producers, but in connection with a negotiation which gave Bristol-Myers a 5 year extension on its monopoly, in return for a 30 percent price decrease in prices, and a $35+ million obligation to fund third party cancer R&D (supervised by the NIH). Later BMS would return to this idea in 1997, and propose a 5-year extension of its Taxol monopoly in return for a 6 percent R&D mandate on Taxol sales (with half going to the NIH and half invested by BMS).

b) HR 4270, 104th Congress

Also notable was the US proposal by Representative Sanders in the 104th Congress (HR 4270) to require more transparency of R&D, and to impose minimum R&D requirements on companies that sell drugs in the United States. The contribution levels would depend on patent protection, orphan drug status, and the magnitude of sales. The 1996 Sanders' proposal demonstrated how one could make the overall level of private R&D investment a matter of public policy, and also that policy makers could do all sorts of things to protect consumer interests, and not worry about overall R&D levels, since there would be another mechanism (other than high prices) to increase private R&D investments.

On particular approach is set out in the Sanders proposal.

HR 4270 , 104th CONGRESS, 2d Session

To require reporting on research and development expenditures for drugs approved for marketing, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES
September 27, 1996

[snip]

SEC. 7. PROMOTION OF RESEARCH AND DEVELOPMENT.

(a) ACCOUNT- Any person engaged in the manufacture of drugs for introduction into interstate commerce shall, in accordance with subsection (b), establish for each drug an account for funds to be reinvested in research and development for health care technologies.

(b) REINVESTMENT IN RESEARCH AND DEVELOPMENT- To insure that adequate funds are being made available for research and development of new health care technologies, the Secretary of Health and Human Services shall establish for persons engaged in the manufacture of drugs for introduction into interstate commerce the minimum amount such person should make available for research and development of its new health care technologies based upon a percentage of sales revenue for that drug. The Secretary may require different percentages for minimum reinvestment for different classes of drugs based upon patient protection, orphan drug status, or magnitude of sales.

(c) ADDITIONAL RULES- The Secretary shall adopt regulations concerning qualifying research and development expenditures and the reporting requirements for persons who are subject to subsections

(a) and (b).

SEC. 8. REPORTS ON SALES.

Any person engaged in the manufacture and sale of drugs approved under section 505, 507, or 512 of the Federal Food, Drug, and Cosmetic Act shall report to the Health Care Financing Administration the total number of each drug it has sold and the total revenue it has received from such sales, including sales made outside the United States.

SEC. 9. GOVERNMENT EXPENDITURE ON PRESCRIPTION DRUGS.

The Secretary of Health and Human Services shall report to the Congress annually on the estimate of the amount of money the Federal government expends, directly or through reimbursement, for the purchase of prescription drugs, including an estimate of the amount of money expended each year on drugs which were developed with significant Federal support.

c) The Ritonavir R&D mandate proposal

Essential Inventions, Inc. has asked Secretary Thompson of the US Department of Health and Human Services (DHHS) to exercise the US government "march-in" rights, and issue compulsory licenses on patents on ritonavir. However, because this would likely have some negative impact on Abbott's investment in R&D for AIDS, the petition proposed a compensatory R&D obligation on generic producers. The R&D mandate proposal not only proposed significant R&D contributions (about $300 per year per patient), but also including the possibility of more transparency for R&D, better priority setting, and a social reach-through clause to ensure that R&D funded from the mandate would not be subject to abuses of patent rights.

7.2. Special obligation to finance R&D for new treatments for AIDS.

We anticipate and share concerns that efforts to reduce prices for this government-funded invention will reduce profits to Abbott and consequently may reduce somewhat private sector incentives to invest in research and development. We also recognize that large research and development investments in advanced industrialized countries, and in the United States in particular, are needed to ensure access to new and better medicines for the entire world.

Therefore, in addition to a royalty payment to the patent holder, there should also be a requirement that producers of ritonavir under the open license contribute to research and development for new treatments for HIV/AIDS.

7.3. Cisplatin case as a model for funding AIDS R&D

The proposal that the open license contain a provision that requires every manufacturer of generic ritonavir to make an investment to a special fund for research for HIV/AIDS is modeled after an earlier case involving cisplantin, a cancer drug invented at Michigan State University and marketed by Bristol-Myers. After Bristol-Myers enjoyed five years of exclusive rights to market cisplatin, the federal government was asked to permit competition. Bristol-Myers said that competition would result in lower profits and less R&D. One generic manufacturer proposed that every generic manufacturer contribute to an R&D fund, either managed by NIH or a private non-profit party. While the ultimate resolution of the cisplatin case was a negotiated reduction in the price of cisplatin and an agreement that Bristol-Myers transparently fund approximately $35 million in third party R&D on cancer, the proposal is revisited, as a logical mechanism to permit competition and lower prices while ensuring that R&D objectives are met.

The Secretary can decide if such an R&D requirement is appropriate, and if so, how large the R&D contributions would be, who would manage the fund, and how the intellectual property rights would be allocated. Here we offer suggestions for alternatives the Secretary may consider, which of course are subject to discussion and further negotiation.

7.4. Mission of the fund

The mission of the fund should be to support drug discovery based on novel scientific

ideas that may not receive adequate investment but for the presence of the fund.

7.5. Required contribution to fund

We recommend that each manufacturer of ritonavir under the open license should contribute to the fund a minimum amount as follows:

1. For the US and other countries designated by the World Bank as High Income, $.004 per milligram.

2. For countries designed by the World Bank as Low Income, the minimum contribution is zero.

3. For countries designed by the World Bank as middle income, the minimum contribution should be $.004, multiplied by the ratio of the country per capita income divided by the average per capita income of the countries designed by the World Bank as high income.

7.6. Management of the Fund

There are a variety of approaches that could be used to manage the Fund, including but not limited the following options:

1. The NIH could manage the R&D Fund

2. A private non-profit foundation could be identified or created to manage the R&D Fund.

3. A for-profit investment Fund could be created, with shares allocated on the basis of contributions to the fund.

7.7. Advisory board

Essential Inventions, Inc. recommends the Secretary create an Advisory Board that would review how the R&D funds were invested. This board should include representatives from the AIDS affected community and experts in medical research.

7.8. Ownership of intellectual property rights

The Secretary could choose different approaches to the allocation of intellectual property rights. Essential Inventions, Inc. recommends that commercial discoveries be treated in one of the following manners.

1. The inventions could be owned by the Federal Government. This approach might be particularly appropriate if the Fund is managed by the NIH.
2. The inventions could be owned by the investors in the fund.
3. The inventions could be owned by the original patent owners.
4. The commercial rights in the inventions could be split evenly between the original patent owners and the investors in the Fund.

Essential Inventions preferred approach is (4).

7.9. Reach Through March-In Clause

Essential Inventions, Inc. recommends that if options (2), (3) or (4) or used, there also be a reach-through clause that attaches the same rights the government now has under the Bayh-Dole Act for March-In rights.

7.10. Transparency of R&D

Essential Inventions, Inc. strongly recommends that all contributions to the fund and all distributions from the fund should be made transparent to the public through appropriate means.

7. First best mechanism for financing R&D

Are R&D mandates the first best solution for funding R&D? Probably not in the format presented above. A system that more clearly separates the R&D and product markets would better.[12] In general, we need to introduce a global treaty that mandates a minimum level of R&D effort for every county, but which permits each country to experiment and use the mechanisms to finance R&D that work the best.

8. Improving transparency and the evidence for policy making

It is essential that we have better evidence regarding R&D outlays, the costs of drug development, and that we know more about how R&D funds are spent, and what the outputs are.

9. Open Medicine Initiatives

The life sciences field is now experimenting with a variety of "open medicine" initiatives, most notably open databases and open academic journals, often justified on the grounds that greater openness leads to better and faster scientific progress. Linus Torvald's claim in the software field that "with enough eyeballs, all bugs are shallow" has resonated with medical researchers who pushed to have the sequencing of the Human Genome be free of patents and freely available to researchers globally, as well as a diverse group of stakeholders who have supported a plethora of other new "open medicine" databases and journals.[13] In launching the new Public Library of Science Journal *PloS Biology*, Patrick Brown, Michael Eisen and Harold Varmus explained the rationale for a new publishing model for journals. One consideration was clearly to offer researchers a new strategic model for reducing the costs of journals. But also, they were seeking to expand the usefulness of the information.[14]

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[12] Burton A Weisbrod, "Solving the drug dilemma," *Washington Post.* Aug 22, 2003: A21., Tim Hubbard and James Love, A New Trade Framework for Global Healthcare R&D, PLoS Biology, February 2004, Volume 2, Issue 2.

[13] Sulston, J., and G. Ferry. 2002. *The Common Thread: A Story of Science, Politics, Ethics and the Human Genome.* London: Bantam Press, Cukier, K. N. 2003. Community Property: Open-source proponents plant the seeds of a new patent landscape (http://www.cukier.com/writings/opensourcebiotech.html). *Acumen* 1 (3):54-60.

[14] Brown, P. O., M. B. Eisen, and H. E. Varmus. 2003. Why PLoS Became a Publisher. PLoS Biol 1 (1):E36.

> Freeing the information in the scientific literature from the fixed sequence of pages and the arbitrary boundaries drawn by journals or publishers— the electronic vestiges of paper publication—opens up myriad new possibilities for navigating, integrating, "mining," annotating, and mapping connections in the high-dimensional space of scientific knowledge. . . Consider how the open availability and freedom to use the complete archive of published DNA sequences in the GenBank, EMBL, and DDBJ databases inspired and enabled scientists to transform a collection of individual sequences into something incomparably richer. With great foresight, it was decided in the early 1980s that published DNA sequences should be deposited in a central repository, in a common format, where they could be freely accessed and used by anyone. Simply giving scientists free and unrestricted access to the raw sequences led them to develop the powerful methods, tools, and resources that have made the whole much greater than the sum of the individual sequences. Just one of the resulting software tools—BLAST—performs 500 trillion sequence comparisons annually! Imagine how impoverished biology and medicine would be today if published DNA sequences were treated like virtually every other kind of research publication—with no comprehensive database searches and no ability to freely download, reorganize, and reanalyze sequences. Now imagine the possibilities if the same creative explosion that was fueled by open access to DNA sequences were to occur for the much larger body of published scientific results.

More recently, some have suggested that the role of open medicine can be expanded to address drug development, making it also possible to address ethical concerns over access to medicine.[15]

Attachments

January 29, 2004. Essential Inventions, Inc., Petition to use authority under Bayh-Dole Act to promote access to ritonavir, supported by National Institute of Allergy and Infectious Diseases contract No. Al27220

James Love, "Evidence Regarding Research and Development Investments in Innovative and Non-Innovative Medicines," September 22, 2003.

Burton A Weisbrod, "Solving the drug dilemma," *Washington Post.* Aug 22, 2003:

Hubbard and Love, 2004. A New Trade Framework for Global Healthcare R&D. *PLoS Biology* 2 (2):147-150

[15] Tim Hubbard, 2003. Human Genome: Draft Sequence. In Nature Encyclopedia of the Human Genome, edited by D. N. Cooper. London: Nature Publishing Group. Tim Hubbard and James Love in a series of articles, including Hubbard and Love, 2003. Medicines without barriers. *New Scientist*, 29. Hubbard and Love, 2004. A New Trade Framework for Global Healthcare R&D. PLoS Biology 2 (2):147-150, Hubbard and Love, 2004. We're patently going mad. Guardian, 4th March 2004, 6. Also available from http://www.guardian.co.uk/life/opinion/story/0,12981,1161123,00.html.