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Intellectual Property and Licensing and their Impact on Global Public Goods for Health:
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Building a "Cottage Industry" for Health (and Wealth):
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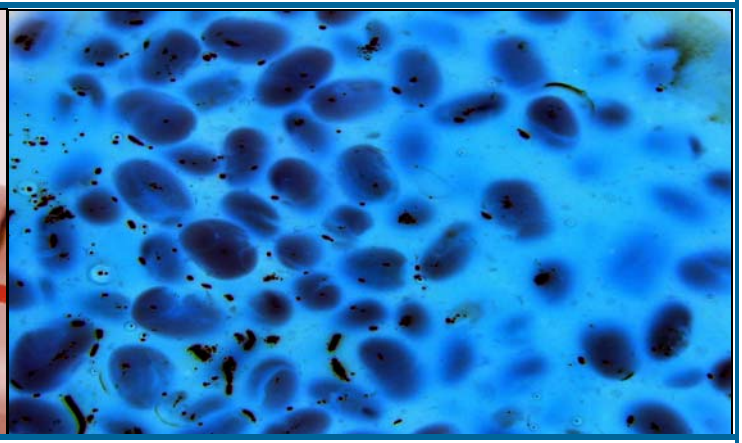

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Intellectual Property and Licensing and their Impact on Global Public Goods for Health:

Options for Public Sector and Academic Leadership [1]

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[1] Keusch, GT. 2004. Intellectual Property and Licensing and their Impact on Global Public Goods for Health: Options for Public Sector and Academic Leadership. *IP Strategy Today* No. 10-2004. pp. 1-22. www.bioDevelopments.org/ip

Executive Summary

In the past fifty years, the intensity of research and the pace of discovery in the biomedical and health fields have accelerated quite dramatically within both the public and private sectors. The result is an unprecedented increase in the number of safe and effective drugs, vaccines, and medical devices for a broad range of illnesses and conditions. But there is some risk that current laws and practices have narrowed the way in which the benefits of publicly funded research are measured to more closely resemble a private sector yardstick. Furthermore, in a more globalized world—where risk of disease and benefits from research can come from any corner of the globe—it is important to insure that the society that benefits from the public sector health investment is the global one. This paper is concerned with the public good aspect of U.S. federal research investments viewed in a global context, and it considers how to enhance the benefit of such investments on behalf of the poor in societies outside of the United States. There is no limit to improving current practice except people's creativity.

Out of an estimated $74 billion in health R&D expenditures globally, 50% is estimated to come from public sources. In the United States, most public funding of biomedical and behavioral research is through the National Institutes of Health (NIH), whose spending on research, both extramural and intramural, was approximately $25 billion in 2003. The public funding extends to scientists conducting biomedical and behavioral research in universities and academic hospitals across the country (the "extramural" scientific community receives about 90% of NIH research funds), as well as to scientists working in government laboratories at the NIH and to a lesser extent at certain other U.S. government agencies (the "intramural" scientific community).

Several arguments have been put forth to justify the government's role in funding research. First, funding basic research illustrates a classic role of government to provide public goods. Second, public funding of research ensures the availability of data at the earliest possible time to the scientific community at large. Third, publicly supported research can fill knowledge gaps not addressed by private industry, although public sector inventions are usually brought to market by private sector product development. The choice of whether to develop new ideas into products is largely left up to the private sector. The implication of this is that technology development from public research by and large gets rationed according to the priorities of the private sector.

This synergistic relationship between the public and private sectors is generally highly efficient and productive; however, the potential of this arrangement to create public goods from the investment of the public sector is uncertain. In principle, the case can be made that beyond support for the research itself, public agencies have a role in ensuring that the benefits of basic research get delivered to the public. How it can best carry out this role is not obvious. Under current arrangements, the public sector has limited capacity and experience in the downstream steps of developing and delivering products to consumer markets. These steps are costly and are not aligned with the public sector's comparative advantage.

The set of economic, legal, and policy arrangements currently in use for transferring technology from research to consumers presents significant access barriers to the poor. The main economic barrier is the high cost of developing a product from a basic discovery. The main legal barrier is the complex ownership system, which protects the interest of those who invest in research and development and maintains incentives to continue such investment. The policy barrier is the need to clearly choose or balance the elements among competing interests—scientific community, consumers, and industrial development—that vie for advantage in the increasingly lucrative world of health care products.

There are several ways that public institutions can increase the resources and tools devoted to the public health needs of the developing world. At the "upstream" end they can direct funds toward research in developing countries and their diseases; they can also partner with private and non-profit entities wishing to do the same. At the "downstream" end they can directly provide products to users in poor countries, reduce barriers to the transfer of technology that benefits developing countries, or partner with industry and academia to expedite the development of products from research. It is worth emphasizing that approximately 90% of NIH research funds go to support extramural research in universities and that control of technology from that research was transferred to universities by the Bayh-Dole Act. By

far the greatest impact of any of the innovations in intellectual property (IP) will come from decisions made by university presidents and their technology transfer officials. They determine the use of IP derived from publicly supported research, which is the major sector for public investment. Most of the public benefit or licensure arrangements discussed above could be adopted by universities for their own technologies.

For instance, universities could include public benefit clauses in their licenses to the private sector, invest part of their royalty stream in a foundation, establish an "ethical" investment fund,[2] license technologies to non-profits or others who would develop and manufacture for poor countries, and bundle technologies to encourage development of medicines aimed at diseases of the poor. Individual researchers are already establishing product development companies in large numbers, but universities may engage in such efforts specifically for products that provide global public benefits. Any or all of these options could be done unilaterally by research universities or NIH, but a multilateral approach would have far greater public awareness and public health impacts.

The evolution of technology transfer practices since Bayh-Dole places NIH and research universities in a difficult position. The delicate balancing of their scientific interests, responsibilities to the public, and need to maintain a competitive position vis-à-vis the private sector for retention of expertise has been jarred repeatedly in the past few years. It is essential to understand that any consideration to change current operating principles will require the engagement and involvement of all the stakeholders—change will not be accomplished by fiat.

This paper will assess these issues in detail as they are playing out in the United States from the author's perspective as a past and present academic, and until recently Director of the Fogarty International Center, the international research arm of the National Institutes of Health, a public biomedical research funding agency. It first discusses the role of the public sector in delivering public goods by investing in biomedical research in Section II. In Section III, the key U.S. laws governing technology transfer from federally funded research are briefly described, along with a synopsis of the legislative and media contexts of their passage. The impact of those laws and new issues that have arisen since their implementation 20 years ago are also discussed. Section IV lists some options for the public sector and universities to work within existing law to extend the benefits of biomedical research to poor countries or global beneficiaries. The paper concludes in Section V with a brief review of the major legal, economic, and policy barriers that continue to inhibit delivery of global public goods for health.

1. Introduction

In the past fifty years, the intensity of research and the pace of discovery in the biomedical and health fields have accelerated quite dramatically within both the public and private sectors. The result is an unprecedented increase in the number of proven safe and effective drugs, vaccines, and medical devices for a broad range of illnesses and conditions. Most of these new drugs, diagnostics, and devices target diseases and health conditions that are prominent in the wealthier nations where the research is conducted and where the resulting products are commercialized. This paper is concerned with the public good aspect of U.S. federal research investments viewed in a global context, and considers how it may be possible to enhance the benefit of such investments on behalf of the poor in societies beyond the borders of the United States.

Historically, biomedical R&D as a national public good in the U.S. has had clear objectives and has been backed by a large public constituency.[3] In contrast, until very recently, R&D investment for global public goods has received far less attention. Sparked by media attention to the AIDS epidemic sweeping Africa

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[2] Ethical investment funds or other financial tools are recommended among the "Top 10 Biotechnology" approaches for improving global health by a commission of the Joint Center for Bioethics at the University of Toronto (see Daar *et al* 2002).

[3] See Research! America's U.S. public polling data at www.researchamerica.org

and escalating in Asia, Latin America, and the Caribbean, as well as the appearance of "exotic" new contagious diseases within the U.S. and neighboring countries,[4] the American public is showing greater concern and awareness for the public health problems of the developing world. In recognition of the sheer magnitude of these problems and with greater expectations of their roles, universities and pharmaceutical and biotech companies are seeking ways to demonstrate their concern.

It is only in the past decade that global attention has focused on the health needs of poor and marginalized populations in developing countries and transitional economies.[5] This new attention has opened to public view the system of protections for IP and trade embodied in national rules and in the global Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement. Recent debates over access to drugs for low-income populations in developing countries have also highlighted the controversies embodied in the often arcane details of the patent system and IP laws.[6] The debates have often been portrayed in the media as a struggle between rich and poor countries, big drug companies and sick people, or insensitive bureaucracies and caring relief organizations. Such portrayals may be effective in gaining public and policy-makers' attention, but they are at best simplistic and at worst obscure the true nature of the problems and create barriers to reaching solutions.

Like the proverbial elephant being examined by the blind, the "problem" will be described by various beholders in different ways, viewed from their own vantage point and biases. For some, it is the high prices of life-saving or life-prolonging drugs that prevent the poor from gaining access to them. For others, it is the failure of developing countries to implement and enforce laws protecting IP. For still others, it is the uncertain, risky, and costly nature of the drug development process itself. Regardless of how it is described, the current attention to the issue from so many stakeholders and the often strident debate suggests that here is a problem in great need of solving.

2. Public Sector Investment in Health Research

It is generally acknowledged that publicly supported basic research makes an invaluable contribution to the development of new medical technologies. Public research agencies, such as the U.S. National Institutes of Health (NIH), have a clear commitment to provide global benefits from its research. Creating such benefits is part of the NIH's mission, and Congress and the NIH leadership realize the direct connection between global health improvement and the health and well being of U.S. citizens. NIH has exercised this commitment both through allocations of its own budget resources toward research and research-training related to specific developing country health needs (e.g., HIV/AIDS, tuberculosis, malaria, tobacco-related illness, cognitive development and others) and through technology transfer negotiations with private companies stemming from discovery in NIH laboratories, which is the portion of the IP generated by public investment in research that the government controls post Bayh-Dole.

Out of an estimated $74 billion in health R&D expenditures globally, 50% is estimated to come from public sources (Global Forum for Health Research, 2001). In the United States, most public funding of biomedical and behavioral research is from the NIH, which spent approximately $25 billion on research, both extramural and intramural, in 2003.[7] Two-thirds to three-fourths of extramural research support is

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4 *The New York Times* "SARS Declared Contained with No Cases in the Past 20 Days" July 6, 2003.

5 Prompted significantly by the World Bank when it published the "Investing in Health," the World Development Report of 1993.

6 See extensive media coverage in 2001 of the South Africa AIDS drug controversy, Brazil's decision to issue compulsory licenses for AIDS drugs, and the stalemate subsequent to the November 2001 WTO meeting in DOHA over drug access in public health emergencies.

7 The public funding extends to scientists conducting biomedical and behavioral research in universities and academic hospitals across the country (the "extramural" scientific community receives about 90% of NIH

for investigator-initiated research, while the remainder is targeted by the NIH for research in need of, and ripe for, new funding. Thus, the full spectrum of NIH's research involves a combination of investigator-initiated projects and directed basic and applied research, all of which has been deemed to be of scientific significance through the rigorous peer review system of research pioneered by NIH and now emulated by science agencies around the world.

2.1 Rationale for Public Sector Investment in Biomedical Research

Several arguments have been put forth to justify the government's role in funding research. First, funding basic research illustrates a classic role of government to provide public goods. Because the market typically under-invests in knowledge creation and utilization, government support of basic biomedical and health research is an efficient use of society's resources. It is expected that the fruits of publicly funded research—whether in genomics, developmental biology, aging, emerging infectious diseases, molecular virology, cancer, or other fields of science –will benefit the public in many ways. These benefits are delivered in the form of new medical technologies, as well as in unspecified and unforeseen ways. An example of the latter is the NIH's investment in basic retrovirology that paved the way for an early understanding of HIV when the epidemic began over two decades ago.

Second, public funding of research ensures the availability of data to the scientific community at large at the earliest possible time. Academic research careers depend on research productivity, often expressed as the "publish or perish" dictum. Thus publicly funded research discovery is often placed immediately in the public domain through presentations, publication, and professional networks. Privately funded researchers are under no obligation to make their findings available to other researchers or to the public.[8] This difference in philosophy was illustrated in the approaches of the publicly funded human genome project and the private sector funded sequencing research. The former placed the data in the public realm in real time via the Internet, whereas the private sector efforts did not but could still benefit from the publicly funded program's findings.

Third, publicly supported research can fill knowledge gaps not addressed by private industry. Because the public sector operates with a different set of incentives from the ultimate profit motive of the private sector, the government research enterprise can set priorities based on society's needs, scientific promise, and other factors that are not of paramount concern in the private sector because no market for a product exists. One consequence of this is the ability of publicly funded research to address fundamental questions without undo concern for the immediacy of the applications of the research. When patents are derived from federally supported science they are generally for early stage technology—often processes and materials to be used by other researchers.[9] Rarely does a discovery occur in federal labs that does not require years of additional funding to be advanced into the market.

Hence the mutual dependence of public and private investment in biomedical research: public sector invention is usually brought to market by private sector product development. The choice of whether to develop new ideas into products is largely left up to the private sector. The implication of this is that technology development from public research gets rationed according to the priorities of the private sector and is subject to those factors considered important by the private sector.

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research funds) as well as to scientists working in government laboratories at the NIH and to a lesser extent at certain other U.S. government agencies (the "intramural" scientific community).

[8] Thursby and Thursby (2003) report that 27% of university research licensed by industry allows for prepublication deletion of information from research papers, and 44% allows for publication delays of about 4 months on average.

[9] 75% of licensed inventions from universities are "proof of concept," (Jensen and Thursby 1998). This means that most university inventions are at an early stage of development at time of license and require further involvement from the inventor to reach the commercial stage.

2.2 Balancing Public and Private Research Investment for Society's Benefit

This synergistic relationship between the public and private sectors is generally highly efficient and productive; however, the potential of this arrangement to create public goods from the investment of the public sector is by no means certain. In principle, the case can be made that beyond the support for the research itself, public agencies have a role to insure that the benefits of basic research get delivered to the public. How it can best carry out this role is not obvious. Under current arrangements, the public sector has limited capacity and experience in the downstream steps of developing and delivering products to consumer markets. These steps are costly and are not aligned with the public sector's comparative advantage.

Priorities for public funding are identified by a public process involving interested groups of scientists within government and the academic community: scientific professional organizations, consumers, patient advocacy groups, and to some extent lawmakers and budget managers. Setting priorities often raises conflicts over disease burden and scientific opportunity as well as the proper balance between these and other elements in decision-making. The process is arduous and complex. It requires, in principle, that a case be made that research undertaken with public funds will complement what is being done by private industry, rather than compete with it.

Complementing private sector investment in health is easier said than done. It requires investment from the public sector in two different directions: one enhances private sector investment by supporting basic research that will eventually lead to private sector product development; the other augments the private sector by investing in those areas that are unattractive for private sector investment. Both avenues are essential for the public sector to pursue, and shifting public health needs require frequent rebalancing of priorities.

There is some risk that current laws and practices have narrowed how the benefits of publicly funded research are measured to more closely resemble a private sector yardstick. Furthermore, in a more globalized world—where risk of disease and benefits from research can come from any corner of the planet—it is important to insure that the society that benefits from the public sector health investment is the global one.

The conundrum for public research agencies is that however large their public funding may appear, their resources are still limited relative to scientific opportunity. The result is that they must prioritize research investments and are often unable to carry a technology far enough to determine how much public benefit might be derived from the full and vigorous exploration of the real potential. The cost of fully developing a new technology is great, and the attrition rate—explorations that end without a product or a profit—is very high.[10] There remains the concern, however, that some explorations end prematurely because the estimated market at the end of the road is insufficient to justify the needed investment up front. This may be particularly true of research for products that target the diseases of the poor or developing nations (e.g., tropical and parasitic diseases).

The NIH has created guidelines for sharing research tools (Nass and Stillman 2003) and is also tracking inventions produced from NIH investments that result in therapeutic drugs or vaccines. Eventually this system will document the public health outcomes from any commercial technology developed with NIH support. FDA approved therapeutic drugs and vaccines developed with technologies from the intramural research programs at NIH are reported on the NIH website.[11] However, while this system will produce valuable information about the benefits of research investment, it still remains an *a posteriori* exercise.

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[10] One rule of thumb is that one of 5,000 drug candidates discovered in labs will be commercialized, *Business Week*, July 9, 2001, p. 96.

[11] ott.od.nih.gov/NewPages/therapeutics.pdf

3. Intellectual Property Laws Governing Public Research Investment

A successful research endeavor creates IP, but what is being closely scrutinized is whether this ownership enhances the public good. The status and ownership of IP derived from government-funded research in the United States is framed by a series of public laws that establish the current principles and procedures used by the U.S. government and its private partners. For purposes of this discussion, the most important laws governing the use of knowledge obtained through publicly-supported R&D were put in place two decades ago and have been amended and enhanced in minor ways in the intervening years. These are the Stevenson-Wydler Technology Innovation Act (P.L. 96-480) pertaining to intramural research, and the Bayh-Dole Act (officially Amendments to the Patent and Trademark Act, P.L. 96-517), pertaining to extramural research.[12] Both Acts were passed in 1980 to stimulate greater use of technologies developed through government support. The legislative history is instructive in putting into context the public benefit the laws were designed to create.

3.1 Legislative History of Bayh-Dole and Stevenson-Wydler Acts

In the mid-1970s Congress became concerned about the failure to use federally owned patents to encourage product development stemming from federally funded R&D. At the time, only 5% of the 28,000 patents retained by the U.S. government were actually in use, whereas 25-30% of patents licensed to industry were being applied (US General Accounting Office 1998). These circumstances prompted Congressional inquiries into the ways in which federal research was transformed into usable technology. The conclusion was that the barriers were too great and the incentives too small for academia or the private sector to develop technology from the patents produced with government research support. No discussion occurred at the time regarding public sector involvement in downstream activities.

The main barrier to the use of federally patented technology was believed to rest with the unwillingness of the responsible agencies to grant exclusive licenses for companies to use the patented technology and invest in product development. An exclusive license would allow one company to have a monopoly in the invention produced with government funds as an incentive to develop and test the product. Companies also complained that even the attempt to obtain non-exclusive licensing was an excruciatingly slow process. Federal agencies imposed many paperwork requirements and other burdens on its licensees in an apparent effort to protect the public's interest in the invention. It became clear to Congress that private companies would not accept the risk and expense of developing technology for the marketplace without some exclusive rights and without a more streamlined way to obtain patent rights across agencies (US General Accounting Office. 1998).

The Bayh-Dole and Stevenson-Wydler Acts were intended to rectify this situation. They did this by creating a uniform licensing system for all federal agencies, reducing steps needed to grant licenses, and providing incentives for industry to invest risk capital in product commercialization from federal patents. Most importantly, Bayh-Dole allowed universities and small business government contractors to receive title to inventions derived from government support, rather than the prior arrangement in which government was the sole holder of the patent. It also allowed the grantees and contractors to license the technology developed under these patents for use by small business and private industry.[13] The Steven-

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[12] Stevenson-Wydler established technology transfer as a federal agency mission, creating rules by which federal agencies could license discoveries for commercial use and receive royalties and fees. Bayh-Dole extended these powers to other organizations performing federally-sponsored research, including universities. See Congressional Research Service (various) and US GAO, 1998, for further details about federal patent law.

[13] A 1983 presidential directive extended licensing rights to large businesses.

son-Wydler Act effectively allowed federal labs conducting intramural research to exercise the same privileges.

The effect of these new statutes was to transfer the ownership of IP and benefits derived from it by allowing companies to license and develop products based on discoveries of federally funded university and federal scientists with full legal protection from competition. According to the Congressional Research Service, "Proponents of this approach contend that these benefits are more important than the initial cost of the technology to the government or any potential unfair advantage one company may have over another in their dealings with the federal departments and agencies" (CRS, 2000a).

It is interesting that the Bayh-Dole legislation initially proposed a formula for repayment to the taxpayers of the government investment when a patent yielded commercialized technology. This provision was dropped in the final stages of passage because of disagreements over technical aspects of the repayment mechanisms (NIH 2001). While the legislative history demonstrates that there was widespread acceptance of the principle of a rightful return to the public from private-sector use of publicly funded technology, it was the details of implementation that ultimately defeated its inclusion in the bill.[14]

Nonetheless, the legislation was passed with several clauses intended to ensure that the monopoly powers granted to patent-holders and licensees would not be abused. These clauses have been the subject of much debate among intellectual property specialists and a cause of anxiety for the private sector, which is concerned about when and with what justification they would be invoked by the government. The legislation expressed Congress' view that the use of discoveries from federal research to improve health was clearly in the public interest, even if it must be carried out by government action.

The Bayh-Dole law states the intention "to ensure that the Government obtains sufficient rights in federally-supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions…."[15] The means to achieve that goal were codified in the following provisions that reserve certain rights for the Government:

- The right to a non-exclusive, nontransferable, irrevocable, paid-up license to practice for or on behalf of the U.S. throughout the world;[16]
- "March-in" rights that enable the government to require the licensee or patent holder to grant use rights to another user with due compensation under special circumstances. The special circumstances envisioned in this clause refer to lack of use within an agreed-upon time frame or special health or safety needs that are not being met by the licensee or patent holder;[17]

The first clause, allowing government use of the technology, has been narrowly interpreted to refer only to a true government purpose. This interpretation has not been fully litigated and therefore it is likely that private pharmaceutical companies remain concerned that changes in the interpretation could expand in such a way as to threaten their economic interests. This provision could theoretically allow the government to practice the technology—or contract with a third party to have the technology practiced—for authorized government purposes. Because the mission of the NIH is "to secure, develop and maintain, distribute and support the development and maintenance of resources *needed for research*,"

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[14] Prompted by persistent Congressional concerns regarding the return to taxpayers from federal research, NIH later attempted to impose a policy of "reasonable pricing" on the technology developed from certain types of federal research. The private sector refused to comply with this arrangement and it was eventually dropped. Reference is made to NIH Cooperative Research and Development Agreements (CRADAs); see NIH (2001) for discussion.

[15] 35 U.S.C. ss.202

[16] 35 U.S.C. ss.202c.(4). Exclusivity grants the licensee the sole right to use the intellectual property, which serves essentially as a monopoly. Non-exclusive rights allow the grantee to use the intellectual property, but do not provide the right to be the only user.

[17] 35 U.S.C. ss. 203(1)

some have suggested that there appears to be a limited scope for NIH action in this regard (McGarey and Levey 1999). However, the Department of Health and Human Services might, due to its public health mission, have a clearer justification to invoke the "government use" clause in pursuit of its mission.[18]

The second clause, the so-called "march-in" right of government, has attracted greater attention and has been more extensively explored. It has been formally tested just once in a case in which the NIH declined to initiate march-in proceedings, thereby disallowing the petitioner use of the technology.[19] This test case provided the opportunity for both the government and affected parties who were primarily third-party recipients of government research funds or prospective licensees to indicate their views on how restrictive the "march-in" rights should be.[20] The debate centered on questions of what constituted timely delivery and how critical the public health or safety need had to be to in order to warrant government action. The voluminous record produced for this petition demonstrated that universities and industry were extremely concerned that "march-in" would undermine licensing rights under Bayh-Dole. It also demonstrated that petitions for "march-in" would prompt a full-blown legal procedure, imposing both time and financial costs on any potential petitioner.

3.2 Public Debate Surrounding Bayh-Dole and Stevenson-Wydler Passage

As much as the Congressional debate itself, the media coverage amplifies the arguments and the context that motivated the passage of the Stevenson-Wydler and Bayh-Dole Acts. The issues of utmost concern to the public and to Congress at the time were notably different from those of today. In 1980, both the public and Congress feared that America was losing its innovative edge that underlay technological superiority and economic success in international markets. At the time, R&D expenditures as a percentage of economic output were dropping in the United States and rising elsewhere. Books and many news articles expressed concern that other industrialized nations such as West Germany and Japan, which were putting increasing amounts of money into R&D, might threaten America's command of new technology development.

The media placed the blame for "losing the innovative edge" squarely on the government's inability to transfer technology, its unwillingness to grant exclusivity to the private sector, and conflicting policies. The inevitable conclusion was that not only was America's economic standing damaged by these policies, but taxpayers were being deprived of useful products that could have been manufactured and sold as a result of the research their taxes supported. Business people, university researchers, and patent attorneys supported the Bayh-Dole proposal, hoping that a move to grant exclusive licensing would foster the development of products beneficial to the public.[21]

Despite this critical acclaim, the legislation was not without opponents. Consumer advocates argued that what the government pays for belongs to the people and that no one producer should be granted a

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[18] This provision is not the same under which the U.S. government might have compelled the owner of the antibiotic ciprofloxacin to allow manufacture by another company in order to meet public health needs in response to the November, 2001 anthrax threat in the U.S. Such action would have followed the guidance of the WTO TRIPS agreement which is further discussed below.

[19] CellPro Petition to DHHS, March 3, 1997, cited and discussed in McGarey and Levey (1999). CellPro petitioned for a license to practice a stem-cell separation technique developed by a researcher at Johns Hopkins University. CellPro had not been able to negotiate a license agreement with Johns Hopkins or the existing licensee but had used the technology. It was found guilty of willful infringement on the Johns Hopkins patent. CellPro argued in its petition for government march-in that Johns Hopkins and the licensee had failed to commercialize the technology in a timely fashion and that public health and safety needs were not being met. The NIH rejected both grounds of the petition.

[20] Both the timeliness clause and the public health and safety clause were tested in the CellPro case.

[21] "Patent Bill Seeks Shift to Bolster Innovation" *Washington Post*, April 8, 1979.

monopoly. Even Members of Congress decried the emphasis on the commercialization of government-funded research for profit.[22] Further concerns were expressed that the act might impede the development and dissemination of technology, promote greater concentration of economic power in the hands of large corporations, and make it possible for industry to reap unfair profits at the public expense.

3.3 25 Years After Passage of Bayh-Dole and Stevenson-Wydler

Since the 1970s, the driving force behind Congressional attention to IP arising from the federal R&D effort has been the belief that economic prosperity increases with improved technology transfer to the private sector. This belief is completely consistent with the role of government in subsidizing biomedical R&D to create and disseminate knowledge as a public good. Insufficient government support would yield a sub-optimal quantity of research as a public good, reduce innovation and technological improvement, and lower societal output of goods and services.

The laws that govern the disposition and use of technology derived from U.S. government investment in health R&D must be judged first and foremost on their ability to meet their original legislative intent. Assessments of the impacts of the Bayh-Dole Act and related legislation have suggested that the laws performed as Congress intended (NAS 2001). Most independent analyses have concluded that the Acts greatly increased technology transfer from researchers to private industry, improved the governmental patenting and licensing process, and made available to the public products that improve their health and well-being (CRS 2000b). Royalties received by universities engaged in technology transfer have grown by 20-30% annually, implying that sales of medical products and processes generated by the patents are in the tens of billions of dollars.[23] Thus, the goal of greater private sector utilization of the research output by federally funded scientists seems to have been achieved (Thursby and Thursby 2003).

It still remains difficult to determine whether or not the social returns to public investment in research have likewise increased as much as the private returns. Longevity has increased marginally in the United States in 20 years, during which time expenditures on health care as a proportion of GDP have soared, while disease incidence has risen in some cases and not in others. Outside the United States, health conditions among the poor in developing countries are in a more precarious state, owing in part to disintegrating health care systems challenged by HIV/AIDS, and in part to a lack of new therapeutics to address the problems they face.

Much has changed in the 20 years since the Bayh-Dole and Stevenson-Wydler Acts were passed. Not the least of which is an increasing concern for global health, a concern brought about through the realization of connections between the health of poor country populations and the U.S. population and between the health of poor country populations and their economic and social prospects. For example, the devastating impact of HIV/AIDS and the limited use in impoverished developing countries of technological advances for diagnosis and management of this infection and its complications is very much in the news today. This has forced many countries into a quandary over how to deliver health technology to poor and technologically marginalized populations. In the process, questions are being raised about the balance of interests between the use of new technology to reduce threats to health and the ownership rights to that technology.

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[22] Congressman Jack Brooks, Minority Report, Committee on the Judiciary, Report to accompany H.R. 6933, 1980.

[23] Despite these benefits, most university technology transfer offices have licensed few or no commercialized products and often operate at a loss (NIH, 2001).

3.4 Current Debates

New developments have given rise to debates never envisioned in the 1970s. While it is rare to find a reference to the Bayh-Dole Act in the press today, the provisions of that Act, together with other laws governing the use and availability of IP, are lurking just below the surface of the media's gaze. Hardly a day passes without mention in the major media of some aspect of medical research or health care issues in the United States or globally.

The rights of and obligations to a larger, more global public emerge as critical questions demanding resolution—just who is the public and what return on the investment is due the public? Debate continues on how to insure the availability of effective treatments to all in need while ensuring that research partnerships with industry remain viable and productive. Public research and research funding agencies such as NIH, the academic community, and industry will be challenged to consider how to interpret and apply the IP laws and regulations in the context of how a patent or a license granted or denied will affect the public good. Not only are economic, legal, and policy issues involved, but also complex ethical and social considerations created by decisions on the application of IP laws.

The controversial nature of IP for biomedical research is illustrated in public debate and in proposals in recent sessions of Congress (CRS 2000b):

- Disputes over competing claims to IP developed under government-industry ventures;
- Delays in negotiating Cooperative Research and Development [CRADA] agreements because of issues related to dispensation of IP;
- Controversies over the rights of drug companies to set prices on drugs developed in part with federal funding;[24]
- Problems obtaining technologies for research developed in the private sector for use in federal laboratories because of competitive concerns from industry;

Additional issues have recently drawn the attention of Executive branch agencies to IP and technology transfer issues in the biomedical field:

- Considerations by the U.S. government to follow the initial decision by Canada in October, 2001 to provide a compulsory license to generic manufacturers to produce the antibiotic Ciprofloxacin to address the anthrax threat (Canada's decision was later modified in negotiations with the patent-holding manufacturers).
- Demands for the government to claim a rightful return for its investment in biomedical research;[25]
- Negotiations with the legislative branch and the public over whether drug imports will be allowed into the United States from countries with lower drug prices;[26]
- An impasse at the WTO over TRIPS handling of generic drug sales from one developing country to another.[27]

This list of issues is not exhaustive and raises more questions than answers. Moreover, each could be—and indeed most have been—the subject of a rousing debate and a flurry of letters, testimony, articles, op-ed pieces, and books. One place to start searching for ways to increase the return to the public—both global and U.S.—of the public investment in research is to review the arrangements currently or

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[24] Abbott backed on AIDS drug price (see Malakoff 2003).

[25] A question raised in legislation proposed by Senator Ron Wyden in the 107th Congress.

[26] Passed the House during FY2004 appropriations debate on the Labor-HHS bill, July 2003.

[27] Agreed by member governments in August 2003 after a yearlong stalemate between the United States and other countries tied up progress in the WTO.

potentially in use to deliver these benefits. These include directing the new research enterprise and expanding access to the existing fruits of federally funded health research.

4. Options for the Public Sector to Promote Research for Global Health

There are several ways that public institutions can increase the resources and tools devoted to the public health needs of the developing world. At the "upstream" end they can direct funds toward research in developing countries and their diseases; they can also partner with private and non-profit entities wishing to do the same. At the "downstream" end they can directly provide products to users in poor countries, reduce barriers to the transfer of technology that benefits developing countries, or partner with industry and academia to expedite the development of products from research. This section describes some of the standard objections and recent innovations in addressing these two general needs and then outlines specific actions that could be taken by the NIH and its academic and private sector partners. There is room within existing legislation for creativity in applying the current IP rules.

4.1 Focus on Upstream Actions

Strengthen capacity for research in developing world

An obvious, but oft-ignored principle is that investments in human research capacity and physical and administrative infrastructure should precede major investments in medical R&D in developing nations. Because the traditional role of universities is to educate the next generation and generate new knowledge, the universities are also the most likely institutions to take the lead and commit themselves to capacity building for developing nation scientists and their scientific enterprise. Supported by the Fogarty International Center's training and capacity building programs, many U.S. universities are already doing this and are even investing university funds to educate and train developing country students.

Research conducted on diseases of the developing world, including research by developing-world scientists, is a fraction of what is devoted to developed world health concerns. However, due to different incentives, public sector funded research is more likely than private sector funded research to address the health problems of the poor. Clear evidence of this comes from the agricultural sector (Evenson and Gollin 2003), where the science underlying the green revolution derived from the publicly supported CGIAR system and created major global public goods. Increasing the support for research in developing countries is, if sustainable, one of the most direct ways to create a global benefit and ultimately increase access of the world's poor to the results of scientific research. Such funding can also lead to collaborations between developed and developing country scientists, creating more sustainable research environments and opportunity for human capacity building and research infrastructure development.

One avenue for increasing research on developing country diseases would be to invest a portion of patent royalties earned by federally funded U.S. researchers in intramural and extramural laboratories to support collaborative research with, or training of, developing country scientists in these highly successful laboratories. Already, a portion of the royalties from the NIH intramural program is returned to the lab that discovers and invents new technology, and this also applies within universities producing patentable inventions. Some of these funds could be voluntarily and specifically directed to train developing country scientists.

Academic-industry partnerships

If research partnerships are to help promote research that leads to global benefit, it seems axiomatic that there should be agreement about and commitment to that goal at the outset. This will necessitate

creative financing and IP sharing arrangements. It will also require that scientists put a priority on delivering global benefits and that university officials fully embrace the larger role of universities in society and in the global community. One example is the recent step by MIT to place its curriculum in the public domain via the Internet with the financial support of private foundations.[28] "Our hope," said Paul Brest, president of the Hewlett Foundation, "is that this project will inspire similar efforts at other institutions and will reinforce the concept that ideas are best viewed as the common property of all of us, not as proprietary products intended to generate profits."

The relative importance of private sector funding has also increased, both within and apart from the university research environment. Private companies are now estimated to spend three times as much on biomedical research as NIH does, most of it within their own research laboratories.[29] However, industry-funded university research is also growing. From 1992-1999, five U.S. universities saw their earnings from industry R&D more than double. The top ten universities in amount of research support from industry (a large proportion of it being biomedical) received $460 million in 1997.[30] It is not clear what the extent of industry involvement is in academic biomedical research at present, although one source indicates that a small portion of private R&D (about 12 percent) is conducted within U.S. academic institutions (Blumenthal, and David 1995). Whatever the overall magnitude, it is large enough to possibly blur the distinction between the objectives of universities and private industry and has caused some to question university motives for carrying out research (see e.g., Bok 2002 and Krimsky 2003).

Many universities prominent in health research are also seeking to establish the right balance among their financial objectives, achieving scientific discovery, and disseminating benefit to the public through use of the discovery.[31] PIIPA (Public Interest Intellectual Property Advisors) is an example of how U.S. universities can use their stock-in-trade to serve the global public need by offering expertise and training. PIIPA is a newly formed consortium of universities and companies intended to provide pro bono legal and professional assistance regarding IP issues to entities in developing countries, including governments and universities

4.2 Delivery of Benefits through Technology Transfer

Direct Government Delivery

It is generally agreed that IP protection plays a substantial role in R&D and is, in fact, critical to the scientific enterprise. The question for public funding agencies is how to facilitate delivery of the benefits of publicly funded research in the current setting of ownership rights conferred by IP laws. These rights translate into economic value through the mechanisms of patents, licenses, and material transfer agreements (MTAs). Along with direct placement of knowledge into the public domain, these mechanisms of technology transfer constitute a continuum of ways to move research output into the public arena. There are, however, problems in relying on technology transfer to achieve the goal of delivering global public benefits.

Some consumer interest groups have proposed that the U.S. Department of Health and Human Services license technology owned by NIH to public organizations such as the World Health Organization (WHO) or UNICEF.[32] In the case of newly developed technologies, this implies granting only non-exclusive li-

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[28] Mellon, Hewlitt Foundations grant $11 million to launch free MIT course materials on web, June 18, 2001, mit.edu/newsoffice/nr/2001/ocwfund.html

[29] Goldberg 2001. This includes product development expenditures.

[30] "Last of the Big-Time Spenders," January 17, 2003, *Science* 299:330-333.

[31] For information about PIIPA, see Gollin 2003.

[32] Nader, Love, Weissman, March 2001, letter to DHHS Secretary Thompson.

censes to private companies wishing to develop products so that the public agency can also be licensed. For existing technologies already licensed to private developers, these groups suggest that the march-in provision of the Bayh-Dole Act should be invoked to grant use rights for public health and safety reasons.

These proposals seem to overlook the reality that most of the technology developed and owned by government labs and university research enterprises is in the early stages of development and not suited for direct transfer to a user.[33] Responding to these appeals in 1999, the NIH stated, "It is well documented that technologies with potential as therapeutics are rarely developed into products without some form of exclusivity, given the large development costs associated with bringing the product to market." [34]

Further, any consideration of "march-in" on government-owned patents must contend with the government role as a minor piece of any technology. Most ready-to-use medical technology today is produced after years of product development and testing. There is often a tangle of patents and licenses that apply to the processes, materials, and components that form a final product ready for consumer distribution. Any effort to use a final technology—even with a non-exclusive license from the federal government—could infringe upon multiple patents and would likely be the catalyst to initiate time consuming and costly legal actions. In the pharmaceutical sector, efforts to invent around existing patents were estimated to add 40% to the cost of developing a new product 20 years ago—they are surely higher now (Mansfield et al., 1981). Without prior agreements from all parties, multiple stacking patents are a large barrier to any government attempt to provide non-exclusive licensing to third parties or international agencies wishing to distribute therapeutics in developing countries.

Public-Private Partnerships

The nature of science and its conduct has changed since Bayh-Dole was instituted. Few academic or public research organizations have the particular combination of scientific know-how, application tools, and commercialization potential that it takes to turn ideas into real deliverable products. For legal, economic, and scientific reasons, public-private partnerships are increasingly looked to as the mode of operation for future biomedical research that can lead to the rapid development of products. Nowadays, the complementary human capital and financial resources of the public sector, academia, and industry are all needed to bring scientific inquiry to fruition.

The situation becomes more complex when resource poor markets are involved. Absent even the potential prospect of blockbuster products, the private, for-profit sector has shown little interest in developing products that serve a small or insecure market. While this is consistent with the fiduciary responsibility of private industry, even government has been reluctant to undertake the role of product development since that has properly been allocated to the private sector with its knowledge of both process and market needs. This leaves a large and vulnerable population whose needs will most probably not be addressed unless a broader set of players that includes government, foundations, and civil society organizations decides to act.

A new public-private partnership (PPP) was established in 2002 precisely to address public sector needs in IP management. It will enable more health technologies to reach the poor in developing countries. MIHR (Centre for the Management of Intellectual Property in Health R & D) was created by a consortium of public and private organizations led by the Rockefeller Foundation. It provides a forum for multiple public and private entities to improve the management of health IP for the benefit of developing coun-

[33] According to Maskus (2000), the costs of research are estimated to be only 25% of the total cost of turning invention into technologies for use (a higher figure pertains to pharmaceutical or medical technology.)

[34] Harold Varmus, director of NIH, 1999.

tries through information exchange, training, defining best practices in licensing, and help in developing norms for IP management.[35] MIHR also could serve as an example for other consortia that could bridge the gaps between what the public and private sectors can provide in addressing global health needs.

Direct University Provision of Intellectual Property for the Public Sector

In the two and a half decades since passage of the Bayh-Dole Act, the major research universities have developed highly proficient offices of technology transfer, staffed by professionals who deal with patents and licensing. Through this infrastructure, they have come to expect financial rewards from their research effort in the form of royalties and fees from patents and licenses. In the eyes of some university officials, this income flow is justified as partial compensation for the costs incurred during the conduct of federally supported research—an enterprise most universities believe costs them more than the infrastructure support provided with federal grants.

It has also made university administrations the target of challenges to deliver biomedical products to the needy public. Under protest by its students, Yale University reassessed the exclusive licenses it granted to Bristol-Myers-Squibb to manufacture d4T, a frequent component of antiretroviral drug cocktails for the treatment of AIDS. The Wall St. Journal reports that the Yale students "succeeded in gaining 600 signatures from faculty, researchers and students 'demanding' that the university pressure Bristol-Myers Squibb Company to give up patent rights for an AIDS drug in South Africa. Six days later, Bristol-Meyers Squibb became the first drug manufacturer to relinquish patent rights for an AIDS drug in South Africa, although a company spokesperson denied that the Yale students 'played [any] role' in the company's actions."[36]

It is understandable that university presidents and scientists would tenaciously guard the prerogatives granted by Bayh-Dole to retain ownership of innovations emerging from their science labs for the benefit of the university. Millions of dollars a year in unrestricted extra income to a university can pay for many projects, additional faculty, and new program developments (not necessarily related to biomedical research) that are otherwise hard to get off the ground.

University officials generally state that money is not the motivator behind good research. Simultaneously, they correctly note that money is necessary to turn research into usable products and that licensing to industry is the only way to serve the goal of product development. One prominent university technology transfer official has listed the following reasons for universities to hold IP rights: income generation, regional economic development, and research fund raising, in that order.[37] Another has said that a university faculty's primary job is to create knowledge, and their secondary job is to earn licensing income.[38]

Yet there is no guarantee of financial returns from research, and most universities have long operated without this extra income. They still do. The intent of Bayh-Dole was not to produce supplemental revenue streams to universities. Rather it was to engender innovation and increase the use of technology for economic development. Universities do accept their responsibilities to contribute to public goods, but these have generally focused first on university, state, and national health issues, in that order. Most universities have either not addressed or achieved a balance between entrepreneurship and the generation, use, and dissemination of knowledge for the public good.

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[35] Mission statement and partners in MIHR can be viewed at www.mihr.org

[36] *The Wall Street Journal*, April 12, 2001. P. B1.

[37] David Mowery, University of California, Berkeley. www7.nationalacademies.org/step/STEP_Projects_IPR_Academic_IP_Speaker_Presentations.html

[38] Michael Crow, Columbia University. *The New York Times,* August 2, 2002. P. B1.

Recent analysis concludes that, although more university technology transfer operations have become profitable over time, many universities do not earn profits from licensing the results of research (Thursby and Thursby 2003). The occasional blockbuster technology has produced large royalties for a few universities holding patent rights, and some others generate a few million dollars annually. Most universities, however, are still barely in the technology development business. Table 1 shows royalties and licensing fees received by the ten highest earning academic institutions in 2001.[39]

These amounts are just a fraction of the funding needed for a real global effort, estimated by the economist Jeffrey Sachs to be $10-12 billion per year for AIDS alone. If the ultimate need is the delivery of medical technology to those unable to pay the costs, then royalty and licensing fees are not the means to achieve it.

Table 1: Royalty Earnings from Patents and Licenses, 2001

Institution	Gross Income (Million $)
1) Columbia University	**130**
2) M.I.T.	**74**
3) University of California System	**67**
4) Florida State University	**62**
5) Stanford University	**39**
6) Michigan State University	**30**
7) University of Rochester	**29**
8) University of Florida	**29**
9) University of Washington/ Wash. Res. Foundation	**18**
10) W.A.R.F. / University of Wisconsin—Madison	**16**

Source: AUTM 2001.

4.3 Specific Options to Extend Benefits of Research to Global Health

The evolution of technology transfer practices since Bayh-Dole places NIH and research universities in a difficult position. The delicate balancing of their scientific interests, responsibilities to the public, and need to maintain a competitive position vis-à-vis the private sector for retention of expertise has been jarred repeatedly in the past few years. As one of the major world providers of health research as a global public good, the NIH also has the responsibility to attend to global public health.

The following list presents some possible ways that NIH and universities can more effectively use technology transfer to create global public goods for health, whether or not they seem practical or feasible to implement at this moment. While some of these may appear highly impractical, especially at first blush, the global public health environment is in a very dynamic state (witness anthrax and SARS events) and this calls for revisiting prior assumptions. The list of options primarily makes the important point that all possibilities to address global health needs should be open to discussion among committed and interested parties. It is essential to understand that any consideration to change current operating principles will require the engagement and involvement of all the stakeholders. Change will not be accomplished by fiat.

1. A straightforward way to deliver social dividends from research is to write provisions into licensing agreements. On an ad hoc basis, NIH has incorporated voluntary provisions for public benefits into license agreements with private industry. As a result, many licenses granted by NIH include a public

[39] AUTM 2001. Note that figures include royalties and fees from all patents and licenses. In comparison, NIH royalties from intramural licensing were $52 million in fiscal year 2000.

benefit of some sort.[40] The types of public benefits called for in these purely voluntary arrangements include educational websites, product donations, or drug delivery to needy communities. The initiative has been palatable because no specific level of benefit or outcomes is requested in the license provisions. It appears, however, that the public benefit delivered through this approach has been, at best, modest.

Public benefit provisions in licensing agreements could state a specific aim to benefit poor countries and publicly funded research agencies as well as university technology transfer offices could increase their use. Such provisions would ensure the delivery of drugs or technologies to poor countries by whatever direct mechanism the commercial partner would prefer (i.e., drug donations or reduced prices) or indirectly through a non-profit organization that would deliver the benefits where they are most needed. For instance, a reasonable proportion (however difficult it is to determine the meaning of "reasonable") of the royalties to a university from the license would be placed within a foundation established to support global public goods in health. In general, a given dollar value of benefits provided by a licensee will go farther if spent in a developing country environment.

2. Many available technologies do not interest the private sector because of their perceived lack of profitability. One method open to NIH and academic institutions is to bundle technologies developed in their laboratories. This would require companies to license another, less profitable technology for development in order to obtain a license for more lucrative technologies. This is consistent with the paramount aim of NIH licensing and the Bayh-Dole Act to get the technologies used.

   There have so far been few takers for this type of arrangement and its impact will likely be small. The approach will no doubt be seen as "coercive" and will be counterproductive to the aim of delivering global public goods to developing countries. While bundling may help license less attractive technologies, it won't make them more profitable for companies to develop. Success depends on finding ways to improve the profitability of licensing for the delivery of medical technology to developing countries. For example, the market size and profit outlook might change if the patent holder helped broker an arrangement between a guaranteed buyer (such as WHO, UNICEF, a large foundation such as the Gates Foundation, or another agency or organization whose mission is to deliver public goods) and a private company wishing to receive a license for an NIH or university technology. With a large buyer to take the initial output, a profitability threshold might be reached if the price from the bulk purchaser met minimum average cost of production at the appropriate scale, and a private company could anticipate potential profits by establishing itself in developing countries.[41] Merck reached such a level when it chose to produce recombinant hepatitis B antigens in China for that market. It even built a state of the art plant to produce vaccine. This led to widespread use of the vaccine in China and a foothold for the company in the country—a win-win situation.

   Developing country markets can also be segmented so that the technology could be provided at low or no cost to the poorest countries through a subsidy mechanism (market "pull"), a fair price in middle-income developing countries, and a higher price as the market develops. Such an arrangement would be consistent with economic theory in which price discrimination can increase efficiency and equity in a market.[42] This approach bears some resemblance to the pricing methods currently

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[40] Ted Roumel, former Deputy Director, OTT/NIH, personal communication, June 2001.

[41] It is important to note that many existing purchase arrangements through WHO and non-profits are on off-patent medicine and technology. Thus, the recent bulk purchase through a competitive bidding process by WHO for TB drugs allowed a 30 percent lower unit price through the purchase of generic drugs from manufacturers based in The Netherlands and India (*The New York Times*, June 22, 2001).

[42] Efficiency is maximized with an arrangement of perfect price discrimination (in which each buyer pays his maximum price), but can also be improved by using block pricing according to the willingness-to-pay of different market segments. This pricing scheme is referred to as Ramsey pricing.

used by pharmaceutical companies in developed country markets and could make some undesirable technologies suddenly more financially attractive. It requires measures to insure that there is no parallel importation or smuggling from the low price to the higher price nations—a difficult goal to accomplish but one that may be expedited by agreements through the TRIPS to allow trade in generics among developing countries.

A variant of this approach would be for technology transfer offices to increase efforts to work with non-profit organizations to deliver technology, rather than seeking commercial avenues for technology adoption. NIH currently uses CRADAS to work with WHO and NGOs (e.g. PATH) to move malaria drugs and other less profitable technologies into use. An overriding concern in the development of a CRADA is to determine that there is capacity within these organizations to carry out the necessary R&D to develop a product. It is estimated that the current fully capitalized cost (including post-approval R&D costs) to the private sector to develop one drug is nearly $900 million. And with over 8 years required for just the clinical and approval phases of development, non-profit organizations just do not have the capacity to sustain such an investment.[43] However, as already noted, it is extremely difficult to make such estimates because the necessary information is not in the public domain; it is possible that the goals are achievable at lower cost. *Medecins sans Frontieres* (MSF) is exploring the viability of implementing such a mechanism, a public not-for-profit virtual pharmaceutical company, to develop medical technologies for neglected tropical infectious diseases of the poor.[44]

3. NIH has recently increased efforts to license vaccine technology in selected developing countries by requiring companies seeking to license NIH technology to produce a plan to market the technology in developing countries within 2 years of regulatory agency approval. They can either opt to deliver the product themselves or initiate a joint venture with another company that would do so. The goal is to use the potential profits from sales in developed countries to encourage companies to manufacture for the developing world at or near cost. Another way to achieve the desired access and affordability for the poor is through manufacture in developing countries at lower cost than in the United States.[45] However, this sort of a tie-in is difficult to accomplish. There are concerns about regulatory compliance, product quality and liability, and, depending on the product, leakage via re-importation into the developed world. Further, uncertainties about how much production would cost inhibits prior commitments.

4. The opportunity for NIH and universities to deliver technologies for developing country use through multiple-use licensing is in limited use. This approach identifies and licenses basic technology for specific fields of use (e.g., a cancer vaccine) and requires the same (or another) company to do parallel development of the same technology for another field of use (for instance, an HIV vaccine). Expansion of this approach would require the renegotiation of existing licensing agreements and would certainly be strongly resisted by licensees. In addition, it is likely that relevant multiple-use technologies are fairly limited in number.

5. A radical approach open to the U.S. Government but not to universities is to exert march-in rights on already-licensed NIH-derived technology to meet special health or safety needs that are not being met. The pressure to exercise such an option may soon disappear as developing countries use new-found means, such as wider use of generic drugs, compulsory licensing, or public health emer-

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[43] Tufts Center for the Study of Drug Development, Outlook 2004 (csdd.tufts.edu/InfoServices).

[44] The MSF Drugs for Neglected Diseases campaign issued a call for interest in developing drugs to treat African trypanosomiasis, chagas disease, and leishmaniasis on February 21, 2003. See www.accessmed-msf.org

[45] The domestic manufacturing requirement in the law can be waived and applies only to U.S. sales.

gencies, to expand manufacturing and distribution of needed pharmaceuticals.[46] U.S. government opposition to such moves was dropped during the recent WTO Doha Round negotiations on TRIPS, and WTO is liberalizing its interpretation of the application of special and safety needs for low-income nations. Concern remains, however, about the effects on innovation and investment.[47]

6. Finally, activities from early stage development to manufacture and distribution could theoretically be performed by a government agency, a university itself, or a contractor. For instance, NIH or academic institutions could move their own involvement further down the development pipeline to include whatever steps would be needed to get the product ready for uptake by a private or non-profit entity. Although this is clearly not the priority for a research agency such as NIH, in a few instances programs already exist to develop medications at NIH rather than wait for the private sector to show an interest in producing them.

   This option seems appealing since it is estimated that less than 5% of promising technologies coming from the work of NIH researchers are picked up and developed. However, substantial resources would be required, and the necessary capacity and expertise would need to be assembled. The significant costs associated with such a step would represent a diversion from the usual research priorities of the agency. This option has been far more popular among university faculty who have established entrepreneurial spin-offs from their university research in order to pursue profitable product development based on their lab discoveries.

It is worth emphasizing that approximately 90% of NIH research funds go to support extramural research in universities and that control of technology emanating from that research was transferred to universities by the Bayh-Dole Act. By far the greatest impact of any of the innovations in IP will come from decisions made by university presidents and their technology transfer officials, who control the use of IP derived from publicly-supported research. Most of the public benefit or licensure arrangements discussed above could be adopted by universities for their own technologies.

For instance, universities could include public benefit clauses in their licenses, invest part of their royalty stream in a foundation, establish an "ethical" investment fund,[48] license technologies to non-profits or others who would develop and manufacture for poor countries, and bundle technologies so as to encourage development of those aimed at diseases of the poor. Individual researchers are already establishing product development companies in substantial numbers, but universities could promote efforts specifically for products that provide global public benefits. Any or all of these options could be done unilaterally by research universities or even the NIH, but a multilateral approach would have far greater public awareness and public health impacts.

The adoption of any of these options by universities should, in our view, come from a consultative process among all interested parties, including public research agencies, developing country representatives, potential funding partners, and industry. Universities and their faculties would have to embrace the moral and social imperative of enhanced delivery mechanisms and become full partners in the means selected to achieve them. Because most of the relevant technology is developed by a small subset of research-intensive universities, it is not necessary to bring all universities on board; instead, a focus on the leaders would establish standards that others could follow.

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[46] The pros and cons of compulsory licensing as a means to deliver needed drugs are discussed in the Commission on Intellectual Property Rights, 2002. www.iprcommission.org.

[47] Jeff Miller in Mass High Tech, May 19, 2004.

[48] Ethical investment funds or other financial tools are recommended among the "Top 10 Biotechnology" approaches for improving global health by a commission of the Joint Center for Bioethics at the University of Toronto. See Daar et al 2002.

5. Conclusions

5.1 Challenges and Barriers

The set of economic, legal, and policy arrangements currently in use for transferring technology from research to consumers significantly bars the poor from access. The main economic barrier is the high cost of developing a product from a basic discovery. The main legal barrier is the complex ownership system designed to protect the interests of those who invest in research and development and to maintain incentives to continue such investment. The policy barrier is the need to clearly choose or balance the elements among the competing interests—the scientific community, consumers, and industrial development—that vie for advantage in this increasingly lucrative world of health products. These barriers are briefly explored below to suggest how institutions acting for the public good can overcome them.

Economic Challenges: Pharmaceutical companies have pointed both to the large investment they make in bringing products to market and to the need to retain incentives to do so in a risky scientific and economic environment. The argument is legitimate and not new—it is codified in Article I of the U.S. Constitution. However, perhaps there are ways to maintain incentives for research and development while reducing the eventual product price. There are several components to the costs of developing a new health care product, and it is useful to briefly examine specific ones to evaluate the potential to reduce overall costs.

5.2 Costs of working with government

One reason that technologies developed in government laboratories are not readily licensed, *ceteris paribus*, is that companies are wary of bureaucratic slowdowns, restrictions, and requirements of openness. There can be great reluctance on the part of private industry to get entangled with the federal government for patent rights. There is quiet but palpable concern among companies about government exercising march-in rights—although it has never happened.[49] They fear limits on their ability to make business decisions after investing hundreds of millions of dollars in product development and marketing. Thus, one part of the economic challenge is how to lower the costs to industry of working with government. This can be achieved in part through greater flexibility in development plans, a flexibility achieved not by relinquishing any public interest goals but by creating steps to review the rationality of those goals. This might allay private sector concerns and bring more of them to the table.

5.3 Costs of delivering a product to market

The high cost of pharmaceutical R&D has made the pharmaceutical industry reluctant to pursue ventures that do not possess high earning potential. To the extent that new regulatory or scientific procedures can reduce the time required or the failure rate of new drug development, the willingness of industry to take on non-blockbuster ventures may increase.[50] Human clinical trials are the most costly phase of product development, and this is the stage where most experimental technologies fail. Increasing public investment in carrying out human clinical trials can therefore complement the activities

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[49] The 2001 anthrax scare may have altered the perceived threat of march-in, as Canada decided (and then modified its request) to issue a compulsory license for generic production of Cipro, owned by Bayer A.G. The U.S. government was under serious pressure to follow suit (*The New York Times*, October 21, 2001). It is interesting to note that several deaths and fears of possible exposure in North America constituted sufficient reason to consider compulsory licensing. This can be compared to the extreme conditions of mortality and morbidity that have prevailed for years in some developing countries but are not deemed a sufficient health and safety threat for compulsory licensing to take place.

[50] The rapidity with which new compounds can be tested is increasing dramatically with biotechnology and the genomic revolution. Experts believe that the costs of identifying successful products will increase dramatically in the short-run, but likely fall in the longer-term (Lehman Brothers, cited in *Boston Globe*, June 20, 2001).

of industry, and may provide leverage in the creation of global public goods when the product is proven and ready for clinical introduction.

Legal Challenges: The legal barriers to delivering products to the poor are the IP protections deemed necessary to protect industry's interests in their R&D investment (i.e., the monopoly rights to manufacture and sell products through patents and licenses). Products sold in developed countries are often not registered in developing countries because the underdeveloped IP systems in these countries are unlikely to provide adequate protection against the manufacture of counterfeit products. There appears to be an emergence of global understanding regarding the need for stronger IP protections in developing countries. MIHR and PIIPA (see earlier) are prime examples of how legal barriers to such protections are diminishing through public sector or pro bono initiatives.

Policy Challenges: The public's interests in biomedical research are many and decisions about how to balance those interests are fraught with challenges. Since October 15, 2001 the world's health focus has turned to protection from biological threats used in warfare and terrorism: the day-to-day disease scourges of the developing world are to some extent fading from the headlines. More than ever, however, economic development, drugs for the poor, breakthrough technologies for the world's most common diseases, and investing in scientific advances for tropical diseases are legitimate social goals for all nations. Indeed, all have a role to play in improving the political stability, social welfare, and economic growth that are needed to combat terrorism and civil strife. Each of these social objectives is addressed in part by government investment in the public good of R&D, although experience has shown that the inputs into research do not always translate into the outputs desired by the public.

The policy challenge is to work toward an agreement among relevant parties about the proper social return to public investment in health research and how best to achieve it. It may well be that the major barrier is not any aversion to such social goals but a lack of focus or awareness that the fundamental purpose of the research investments is to create knowledge, technology, and products for the benefit of the public. For economic, legal, and policy reasons, the creation and delivery of global public goods are enormously more difficult than the creation and delivery of national public goods. Yet this must be done. To change the current reality will require a coalition of university officials, government, industry, and NGOs to identify priorities and opportunities and then to carry them out collectively.

Whereas IP has clearly spurred development of new health technologies that promote the public good of the wealthier nations, the impact of IP in promoting global public goods for health is, at best, mixed. The fundamental premises of IP protection as a spur to innovation and a reward for risk-taking in pharmaceuticals are not different from any other industry. There are characteristics of the health care industry, however, that set it apart from other fields where IP is important. Quite simply, in health care, the outcomes of technology development and its availability are matters of life and death.

Reflecting on such issues the London *Economist* observed, "Rich countries should accept that considerations of how IP rights affect poor countries are not just a concern of overseas aid agencies but play a part in broader trade and economic relations too." (*The Economist* 2002). If Bayh-Dole were being debated today, the economic development objectives at the core of the legislation might take on a broader meaning than in 1980.

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Building a "Cottage Industry" for Health (and Wealth):

The New Framework for IP Management in India [1]

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Executive Summary

It is plausible that by 2010,
the center of gravity of innovation in drugs and vaccines
will have moved noticeably towards developing countries.

Richard Feachem (2001). Editorial, *WHO Bulletin* 79:8.

By the standards of any developing country, India's government has invested heavily in health research. About two thirds of the country's total health research infrastructure remains in the public sector, responding to national health priorities such as HIV/AIDS, malaria, tuberculosis, leprosy and cholera. Indian institutions are quite capable of contributing solutions to these global problems. To do so effectively, however, they must first bridge a gaping chasm between India's public and private sectors, a cultural divide that limits the potential of any public investment. The government has moved forward with policy changes to begin to address this problem, but much more effort is required.[3]

In North America, most health innovations arise from small- and medium-sized biotechnology companies. These companies tend to cluster tightly around academic research centers to harness the critical mass of brainpower they find there. Technologies licensed from U.S. universities have stimulated the creation of thousands of new companies, tens of thousands of new jobs, and billions of dollars in new wealth, as well as countless new products to improve human health.[4]

Thus, a significant portion of U.S. economic growth derives from innovations that arise out of a "cottage industry" of university spin-offs and small biotech companies linked to university laboratories. Because of the modest scale on which most university-industry partnerships take place, this model could be applied to at least a handful of developing countries that, like India, have significant research and manufacturing infrastructure of their own.

Significant cost advantages have already allowed India to become a major provider of low-cost drugs and vaccines for the world's least developed countries. India can also become an important engine of innovation when its universities and national laboratories become adept at establishing sound public-private R&D partnerships.[5] We believe this could help address a critical global health need for better tools: e.g., vaccines against HIV, malaria and TB; shorter TB drug treatment; microbicides against HIV and STDs; new antibiotics and antimalarials to overcome drug resistance.

Bridging the deep divide between public and private sectors in "Innovating Developing Countries" (IDCs) like India could lead not only to new health technologies that help address national health priorities but also to greater export income and economic growth as other technologies are commercialized for more lucrative markets. This opportunity exists right now. Capacity building of this kind is inexpensive. It is sustainable as it helps to maximize the multi-billion dollar annual investment that developing

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[3] After ruling for five years, a BJP-led coalition fell on May 13 2004. Most observers believe the new ruling coalition, led by the Congress Party, will continue the economic reform policies of its predecessor. However, the new coalition may include several far-left leaning parties. It is difficult to predict what impact this may have on science, technology and innovation policies affecting public-private partnerships and IP.

[4] We do not mean to argue that this model is an unqualified success in the North. Many question the high cost of products arising from tax-payer funded research, and technology managers in Northern research institutions are only now beginning to consider the impact of their licensing practices on developing countries.

[5] Public-private partnerships (PPPs) in this context refers to project-based partnerships within IDCs. These should be seen as complementary to the dozen-or-so non-profit global PPP catalysts, such as the International AIDS Vaccine Initiative (IAVI) and Global Alliance for TB Drug Development (TB Alliance), who's own portfolios of candidate products are actually collections of local PPPs based in both North and South.

countries themselves already make in health research. For the field of international development, this would appear to be a true win-win situation.

There is at least one more important reason for the developed world to consider this approach. Technical and development agencies from the North now support a variety of world-class research centers in IDCs as well as in some of the least developed countries. We believe such funders have a moral responsibility to ensure that their partners in developing countries can negotiate intellectual property rights on a level playing field. Moreover, when new inventions have applications in global health, both partners should strive to manage the IP to achieve the widest possible access.

Technology managers at public research institutions are the key players in this model. There is now a small but growing cadre of such professionals in India and a few in other IDCs, but they often work in isolation and have limited training. Like their colleagues in the North, they need critical skills, networking to share experiences, and sound, supportive institutional and national policies to be effective and promote the public good.

The process of technology management involves: 1) working with academic or government researchers to identify inventions "at the bench"; 2) development of a patent strategy around each unique invention, identifying company partners and negotiating fair licensing agreements, and 3) follow-up to ensure due diligence on the part of the licensee. Technology managers may also negotiate industry sponsored research agreements with public institutions. All these activities need to take place under clear institutional policies on IP and equally clear national policies on IP and public-private partnerships.

Ideally, IDCs could benefit from the past quarter-century of experience in the North. Technology managers in industrialized countries are adepts in a largely apprenticeship-based learn-by-doing "craft industry." As their profession has matured, some have begun to realize that the ultimate goal of their licensing practices is not to make money for their institution, but rather to maximize the public investment in a way that is consistent with their academic mission (e.g., to educate the next generation, expand and share knowledge, and even to make the world a better place).

In 2003, a new group called Technology Managers for Global Health (TMGH) formed within the North American professional society for technology managers (AUTM). Two new global organizations (MIHR, see page 48, and PIPRA) are developing "tool kits" of best practices for technology managers to address technology needs in developing countries. These efforts show that it is possible to adopt technology management practices that are consistent with global needs and the public interest without sacrificing institutional or national priorities. Technology managers, their institutional directors, and policy makers in developing countries can all learn from this experience, and perhaps avoid some common mistakes.

Building capacity and raising the stature of technology managers in IDCs could help build bridges, engage the gears and give traction to billions of dollars per year in local health research investment. The simplicity, strategic impact and cost-effectiveness of this approach is not yet widely appreciated. To be sure, it may be a necessary but still insufficient means to deliver affordable essential goods to the poor. Nevertheless, it represents an opportunity to simultaneously stimulate the development of affordable and locally relevant technologies as well as to create jobs and stimulate economic growth.

The Government of India has moved quickly to grasp this opportunity. Over the past ten years, it has developed a variety of programs, policies, and incentives to stimulate public-private research partnerships. Much more remains to be done, but India's drive and momentum could illuminate the path for other IDCs. It could also be an example for industrialized countries that are currently working to improve health and economic outcomes in the developing world by more traditional means.

1. Introduction

Despite its reputation as a "poor country," India has invested heavily over the past half Century to develop national laboratories and academic research centers. The chief architect of this effort was India's first Prime Minister, Jawaharlal Nehru. He believed that new scientific and industrial research institutions "laid a solid foundation of science on which to build a splendid edifice of New India," and he charged these "modern temples of science" to address his country's most pressing health, agricultural and industrial challenges.

Today, most of India's research infrastructure remains in the public sector (Figure 1). The Government supports at least two thirds of all health and biotechnology research in the country, and nearly 75 percent of research and development on agriculture, energy, engineering and defense[6]. This substantial public sector investment sustains many world-class government and academic research centers throughout the nation, institutions that are capable of making significant contributions to global science and innovation as well as to India's own economic development.

Of particular relevance for global health and increasing health equity, Indian health research institutions are capable of developing new drugs, diagnostics and vaccines to address "neglected" diseases such as tuberculosis, malaria, and cholera that disproportionately afflict the poor. They could develop the next generation of anti-retrovirals to combat drug resistant HIV (Chaturvedi 2002) as multinational companies may be reluctant to work on such drugs because of international controversy and pressure on pricing[7]. They are also capable of modifying indigenous crops to enhance nutrition and increase resistance to abiotic stress (Chaturvedi 2002). The trick will be to translate such technologies out of the ivory towers of academia and into products for public good.

Indian companies are just beginning to invest in original research. Member companies in the Organization of Pharmaceutical Producers of India (OPPI) invest only 2 percent of sales in R&D compared to 18% for multinationals[8]. As India moves to fulfill its obligations under the international agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) to provide product patent protection for pharmaceuticals and agricultural chemicals after 2005, the survival of its vibrant drug and biotechnology industries will depend on their ability to bring new and original products to market by forging strong research partnerships with the public sector.

Recognizing this inter-dependency, and its relevance to India's survival in the face of global competition, the Government has developed innovative grant and soft loan programs to stimulate public-private partnerships. From the mid-1990s, India's technical agencies began to establish "Patent Cells" to protect and commercialize their inventions. A few universities have also moved in this direction.

In 2000, Indian research institutions were given rights of ownership over some of their inventions, and the Government began to co-sponsor exchanges and workshops focused on intellectual property (IP) management in collaboration with the US Department of Health and Human Services. Both the Indian Government and industry now support IP awareness programs for Indian scientists.

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[6] The estimate for health research based on an analysis of budget lines for relevant technical agencies from the Government of India annual budget report, and personal communication with the Organization of Pharmaceutical Producers of India (OPPI); the overall R&D estimate is from the UNESCO Institute of Statistics (est. 83% of all R&D is funded by the public sector); and "Science & Technology Data Book," Government of India, September 2000, p.1, (est. 74.3% of all R&D&S&T is public sector).

[7] Carl Dieffenbach, Associate Director, Division of AIDS, US National Institutes of Health, personal communication.

[8] Data from the Organization of Pharmaceutical Producers of India (OPPI), and Pharmaceutical Research and Manufacturers' Association (PhRMA).

In January, 2003, the Government announced new plans to establish "autonomous technology transfer organizations at universities and national laboratories to facilitate the transfer of know-how generated to industry," and to develop a "comprehensive and well-orchestrated program for training in technology management."[9] On April 26, 2003, the Council of Scientific and Industrial Research announced formation of an "Intellectual Property Managers' Association of India" (IPMAI)[10].

These bold new efforts to leverage greater public benefit from public funds are built upon a solid foundation of practical experience gained by India's agencies and institutions over the past 10 years.

2. Global Policy Perspective

The restructuring now underway represents dramatic change—change that has gone largely unnoticed outside India, or indeed outside of a small circle of policy makers who understand such arcane issues, and an equally small collection of the very professionals who cement the process: technology managers.[11] India is just beginning to build its capacity to form effective public-private R&D partnerships. It still has a long way to go, yet other countries with comparable R&D and manufacturing capability may have even less experience in this arena.

Beyond India, several other innovating developing countries (IDCs) have substantial or increasing public sector investments in health research (e.g., Brazil, South Africa and China) collectively totaling well over a billion US dollars per year.[12] Private sector research support is also likely to increase as domestic industries grow, and as multinational pharmaceutical companies and the larger biotechnology companies seek to reduce costs. Comparable R&D may be conducted in India at less than half the cost of the same work in the US or Europe; the manufacturing cost advantage is nearly as significant, and labor costs are less than one tenth the Northern levels. Contract research and contract manufacturing in developing countries are both likely to grow over the next five years.

In response to the vast health disparities that exist between wealthy and poor countries, some foundations and government development agencies have recently created and begun to support a group of non-profit "companies," often referred to as Public-Private Partnerships (PPPs), to accelerate the development of drugs, vaccines and diagnostics for diseases that afflict the poor in developing countries. These organizations include the International AIDS Vaccine Initiative (IAVI), Medicines for Malaria Venture (MMV), Global Alliance for TB Drug Development (GATB), and International Partnership for Microbicides (IPM).

Such PPPs support R&D wherever the science is best. Capacity building in developing countries would be a happy byproduct, but is not their primary focus. However, many of these international PPPs do support research in developing countries, as well as preparations for and active clinical trials. Many will also be drawn toward manufacture in developing countries to ensure that their products are affordable.

Northern technical agencies are also key players in support for health research in less wealthy countries. The largest, the US National Institutes of Health (NIH), now supports over 830 research projects in low- and middle-income countries, and this number has more than doubled in just the past five

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[9] www.tifac.org.in/news/policy.htm and dst.gov.in/doc/STP2003.doc. All web links were last accessed on 19 August 2004.

[10] R.A. Mashelkar, Director-General, Council of Scientific and Industrial Research, personal communication, see also *Innovation*Matters 1(2):3.

[11] Specifically, technology managers who work in India's publicly funded research institutions.

[12] Global Forum for Health Research; OECD

years.[13] NIH awards involving scientists in India rose from 17 in 1998 to more than 60 in 2003. Most of these are "domestic awards with a foreign component," usually grants to US universities for collaboration with a foreign partner. Some of these projects will lead to new inventions. Yet such collaborations, funded by the NIHs, MRCs and EUs of the world, necessarily match one institution that has an experienced technology management office with another in the developing world where knowledge of IP and technology management are limited.

The Rockefeller Foundation recently launched an independent international organization called "MIHR"[14] (see also "Box: MIHR" on page 48) to build the capacity of publicly funded health research institutions in developing countries to manage their own IP, and to enter into sound, viable and accountable public-private partnerships of their own. Based on the authors' recent positive experience with a similar but smaller program in India,[15] we applaud this exciting new approach to promote both economic development and the production of locally relevant new technologies to improve health equity through indigenous public-private partnerships.[16]

"Technology management" is a key process in any public-private partnership. As seen from the perspective of a publicly funded research institution, it entails at least five steps:

1. development of an institution's IP policy and establishment of a technology management office;
2. education and outreach to researchers, and identification of bench-level inventions;
3. deciding where, what, when, why and how to file for patent protection, and knowing what not to protect, i.e., research tools;
4. identifying appropriate companies and negotiating license arrangements that are consistent with the institution's mission and the public interest; and finally
5. follow-up to ensure that licensees invest and develop the technology so it will reach the people who need it most.

We believe that capacity building in this area is a fundamental lever of change for public good for the simple reason that publicly funded R&D in developing countries tends to focus on relevant local needs.[17] Here is a golden opportunity for India and some other developing countries to amplify the outcome of their own investments in R&D, to make their own decisions about their own technologies. And here is a golden opportunity for donors to help harness the creative energies of a few key developing countries, requiring only modest investment in the very keystone of modern R&D: technology management.

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[13] NIH Fogarty International Center, Division of International Relations, personal communication. Note that NIH international awards represent roughly 2% of that agency's total budget, and most of that international investment goes to institutions in developed countries, especially Canada and Europe. NIH's mission is to support the best science, wherever that is, to advance knowledge of health.

[14] MIHR: Center for **M**anagement of **I**ntellectual Property in **H**ealth **R**esearch and Development (www.mihr.org). See Box on page 48. The Rockefeller Foundation has also launched the Public Intellectual Property Resource for Agriculture (PIPRA; www.pipra.org) to make agricultural technologies more easily available for development and distribution of subsistence crops for humanitarian purposes in the developing world. Where appropriate, MIHR and PIPRA will collaborate on joint capacity building efforts in developing countries.

[15] The Indo-US Technology Management Program.

[16] Note: As an Officer of The Rockefeller Foundation, one of the authors, CA Gardner, has a direct concern for the success and sustainability of MIHR.

[17] Whereas the 2% of sales that Indian companies invest in R&D tends to focus on developing products for the wealthy markets in Europe and the United States.

3. The Indian Context

3.1 Introduction

Ever since India gained its independence in 1947, science and technology have received considerable attention and occupied a notable position in the management structure at the highest levels of the new government. A government policy resolution on science, piloted by Pandit Nehru and adopted by Parliament in 1958, was one of the first such official statements in the world. From a humble start, with just 20 universities, 60 national laboratories and negligible industry-based research, India has built over 200 universities, 400 national laboratories, and 1,300 industry-based R&D units.[18]

Total national spending on science and technology is just $2.5 billion per year. Yet firm commitment and a strong R&D cost advantage have allowed the country to develop world-class facilities and expertise in a few vital areas and select institutions. The development of hepatitis B vaccine through indigenous R&D independently by two small private biotechnology companies in India has demonstrated that it is possible to translate the newfound scientific strength into low-cost products for the public health system. Both products were developed through public-private partnerships involving companies, Indian research universities and national laboratories, and venture capital from the Technology Development Board of the Government of India.

Significant changes now underway in India affecting public-private partnerships and IP management are all the more extraordinary given the country's past adherence to Nehruvian Socialism, general distrust of the profit motive, prohibition (until recently) of foreign direct investment, and staunch support for and bias toward "cottage industries" and "indigenous" manufacture.

The Government of the Indian State of Kerala defines cottages industries as "Artisans or small industrial activities (viz., manufacturing, processing, preservation and servicing), involving utilisation of locally available natural resources and/or human skills"[19] In this context, research partnerships involving industry and government laboratories or academic institutions represent on the one hand a revolutionary new approach, while on the other hand they remain consistent with a deep rooted national bias toward small scale industry.

3.2 Economic Blueprint: Health and Wealth from a "Cottage Industry"?

In developed countries, the benefits of technology management are weighted heavily toward the life sciences, especially health. According to the Association of University Technology Managers (AUTM), life science inventions account for 70 percent of US university licenses and 87 percent of university royalties (AUTM 1997 and T Young, pers. com.). Over 4,300 companies have been formed since 1980 as a direct result of licensing inventions from American universities (AUTM 2002). The vast majority are small- and medium-sized biotech companies, all clustering tightly around the academic research institutions that provide their intellectual nourishment (Zucker, Brewer and Darby 1998).

Nearly three-quarters of those companies focus on human health applications,[20] and they collectively encompass most of the innovation in that field. Two thirds of all new chemical entities are currently under development by small- and medium sized biotechnology companies; the remainder are in big

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[18] Science and Technology System in India, Vigyan Prasar www.vigyanprasar.com/stindia/about.htm.

[19] www.keralaindustry.org/schemes/Schemes_Refinance.htm

[20] *A Survey of the Use of Biotechnology in U.S. Industry*, U.S. Department of Commerce, Technology Administration, October 2003, found that "Almost three-quarters of firms (72%) indicated that human health applications are their primary area of biotechnology-related activity."

pharma and the top 25 biotechnology comapnies (analysis by the Boston Consulting Group, prepared for The Rockefeller Foundation). Increasingly, university research, small companies and the venture capital that supports them, have come to insulate the pharmaceutical industry from the risks of new product development.Many hope to partner with (or be bought up by) large pharmaceutical companies once they prove their technology. Recent examples[21] of products arising from North American public research institutions and developed through public-private partnerships include:

- a "photodynamic" anti-cancer treatment developed at Queen's University in Ontario, Canada, and licensed to DUSA Pharmaceuticals, now approved by the FDA and in use;
- an oral rinse to prevent tooth decay, and a broad-spectrum new antibiotic, developed at the University of Florida and licensed to a Florida-based biotechnology company called Oragenics Inc.;
- an FDA-approved implant that stimulates regeneration after injury of the shoulder joint, developed at Purdue University and licensed to a small company that was later purchased by Johnson & Johnson;
- a breakthrough in 3-D x-ray that increases comfort and accuracy of mammography, developed at Wake Forest University and licensed to a company in Helsinki, Finland;
- a diagnostic to determine the correct dosage of chemotherapeutic agents (thiopurines) used to treat childhood acute lymphoblastic leukemia (ALL) to help reach a five-year event free survival rate of 80 percent, developed at St. Jude Children's Research Hospital and licensed to PPGx Inc., which was acquired by DNA Sciences Laboratories, which sublicensed the technology to Prometheus Laboratories;
- a novel anti-sense chemotherapy developed at McGill University in Montreal, Canada, and licensed to a small Montreal-based biotechnology company called MethylGene Inc.;
- a acoustically customizable hearing aid developed at Brigham Young University and licensed to Sonic Innovations which has since sold over 200,000 units;
- an inexpensive method to synthesize the anti-cancer drug Taxol® from renewable starting materials, developed at Florida State University and licensed to Bristol-Myers Squibb where the drug reached worldwide sales of over $1 billion dollars in 1998; and
- an FDA-approved topical treatment for AIDS-related Kaposi's sarcoma, developed at the Salk Institute which spun-out a new biotechnology company called Ligand Therapeutics to produce the product.

Technology transfer from academia to industry, that is, project-level local public-private partnerships, can occur on a scale that is appropriate for India as well as other developing countries that have a comparable R&D and industrial base (IDCs). Nearly 60 percent of US biotechnology companies have fewer than 50 employees (AUTM 2002). University spin-off companies may be even smaller; many have less than 10 employees. Yet this is where the innovation lies. According to the Biotechnology Industry Organization (BIO), this "cottage industry" in the United States generates over 400,000 jobs, nearly $50 billion in sales, and $10 billion in annual tax revenues (Earnst & Young 2000).

Predictably (and unfortunately for global health), in the United States and Europe the growth and success of the health biotech industry is weighted heavily toward high-cost solutions to the chronic diseases and lifestyle concerns of people in the United States and Europe. Of the 1,393 new chemical enti-

[21] www.autm.net/pubs/survey/storylist.html

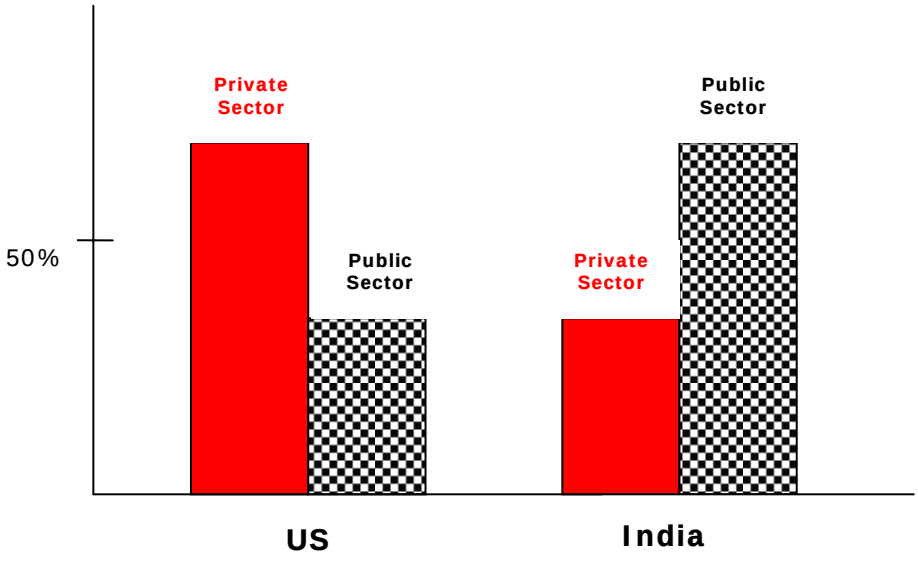
ties marketed around the world between 1975 and 1999, only 16 were developed to combat tropical diseases and tuberculosis (Trouiller and Olliaro 1999 and Trouiller *et al*. 2002).

So far, most of the benefits of biotechnology have accrued to the developed world. But if it can be applied in developing countries as well—many of which enjoy significant research and manufacturing cost advantages—it could lead not only to new jobs and export income but also to greater health equity. This seemingly improbable outcome follows from the fact that public sector research investments in any country tend to focus on local health priorities. Therefore, products arising out of publicly funded laboratories, developed through public-private partnerships in developing countries, will be weighted heavily toward lower cost interventions against the greatest local burdens of disease.

India's public-sector investment is not insubstantial. The budget of the Indian Council of Medical Research ($40 million/year) is spent almost entirely on R&D relating to India's national health priorities.[22] Other public sector funding agencies also support health research, as well as non-health initiatives, including India's Department of Biotechnology ($52 million/year, about half of which goes to health), the Council of Scientific and Industrial Research ($104 million/year, about a third of which goes to health), Department of Science and Technology ($160 million/year), University Grants Commission ($326 million/year) and Department of Atomic Energy ($821 million/year).[23] Overall, India's R&D spending in health is approximately one third by the private sector and two-thirds by the public sector (Figure 1); a ratio that is just in reverse in the US.

In contrast, of course, India's private sector must respond to the same bottom-line pressures that its US or European counterparts face. Indian companies will therefore tend to focus in-house R&D efforts on the development of products that would find a ready market. Such a goal may overlap poorly—if at all—with a country's national health research priorities.

Figure 1: Health R&D Profile of the US and India
(percent of total, 2000)



[22] This budget is supplied directly by the Indian Council of Medical Research.

[23] Union Budget of India, 2003-2004: indiabudget.nic.in/ub2003-04/eb/vol2.htm

In India's case, the official national health research priorities include: "communicable diseases, fertility control, maternal and child health, nutritional disorders, strategies for health care delivery, environ mental and occupational health problems, cancer, cardiovascular diseases, blindness, diabetes and other metabolic and haematological disorders, mental health and drug research (including traditional remedies)."[24]

These factors highlight an opportunity to forge stronger links between the public and private sectors to ensure that innovations arising from India's relatively strong public sector health R&D investment are translated into products that reach the public through sound public-private partnerships. This opportunity is not unique to India. Over the coming decade, India and a handful of other innovating developing countries (IDCs) could become powerful engines of innovation, generating new products to combat diseases that have caused the greatest suffering to their own people (see "Box: Innovating Developing Countries" below).

3.3 Wealth from Public-Private Partnerships in India? Wealth from IP?

3.3.1 Case Study I: Technology Licensing from a Public Laboratory to Industry

Central Drug Research Institute (CDRI), under the Council for Scientific and Industrial Research (CSIR), has developed a drug to treat cerebral malaria, now licensed to Indian company which "sells it under

Box: Innovating Developing Countries

Many of these considerations were anticipated in a 2002 report of U.K. Commission on Intellectual Property Rights (www.iprcommission.org), which recommended "a network of public-private partnerships in developing countries, taking advantage of the concentration of research resources in public sector institutions but also the opportunity to build research capacity in the private sector" (p. 34). The report cautioned that "the arrangements for intellectual property arising from such research need to be such that access by the poor to the products of research is ensured as much as possible" (ibid.). The UK Commission report also considered the impact of technology management practices in the United States, and their relevance for developing countries (pp. 123-125). It emphasized that there is continuing debate over the economic impact of university-industry technology transfer in the United States, yet made the following recommendations with which we wholeheartedly agree (p. 125):

Based on the above, we believe that there is a role for IP in public research institutions in developing countries to promote the transfer and application of technologies. But it is important that:

- generating alternative sources of funding is not seen as the principal goal, which is rather to promote technology transfer.
- care be taken to ensure that research priorities, particularly as regards the technology requirements of the poor, be it in agriculture or health, are not distorted by the search for a larger licensing income.
- patenting and licensing should only be undertaken where it is judged necessary to encourage private sector development and the application of technologies.
- careful consideration be given to the need to take out "defensive" patents on important inventions, particularly for use as a bargaining tool where complementary technologies are owned by private sector entities and cross-licensing may be required to access those technologies.
- expertise in IP is developed in public sector institutions which traditionally have had none, but without losing sight of the objectives of public policy for research.

[24] ICMR Public Document: icmr.nic.in/abouticmr.htm

the brand name E-mal to 48 countries at affordable prices" (R.A. Mashelkar, Director-General of the CSIR, pers. com.). The following is from the CDRI's website (www.cdriindia.org/Arteether.htm):

"Arteether is a semi synthetic derivative of artemisinine, the active constituent of the plant, *Artemisia annua*. CDRI conducted extensive preclinical, toxicological and other regulatory studies in which the drug was not only found to be very safe but also proved to be a fast acting, blood schizontocidal agent which attacks at the erythrocytic stage of malaria in blood. Extensive clinical trials were conducted at 7 centres in malaria prone areas of India. Over 500 patients showed excellent response and the recrudescent rate was very low. Arteether has been developed by CDRI and is being prescribed to the patients as second line of treatment for chloroquine-resistant *P. falciparim* malaria including cerebral malaria.

Though choloroquine has been and still remain one of the most extensively used first line drug for malaria, resistance against this drug is quite frequent. Search for a drug which could be more effective than chloroquine and which could minimize the chance of resistance development has been going on the world over. CDRI has always been quite in the forefront in searching for natural or synthetic drug that could be used as a weapon to fight malaria since it is causing so much of devastation in tropical countries, especially India. Many plants used by traditional systems of medicine have been tried and many of the leads are being pursued.

CDRI got a major success when it developed Arteether from the plant Artemisia annua while working in collaboration with, Central Institute of Medicinal and Aromatic plants (CIMAP), the other CSIR laboratory based at Lucknow. The Drugs Controller General (India) has allowed the drug exclusively for use in hospitals and nursing homes.

Being a new drug, it is indicated for use only in severe *P. falciparum* malaria including cerebral malaria as a second line treatment for chloroquine resistant cases. It is not recommended to be used as a first line treatment for malaria to avoid its overuse which may lead to the emergence of resistance against this drug once again.

CDRI has licensed the drug to Themis Chemicals Ltd., Mumbai which is marketing it under the trade name E-Mal as an injectable formulation.

Post marketing surveillance data on 400 patients received from clinicians from 6 states has validated the efficacy and safety of Arteether in uncomplicated/complicated cases of *P.falciparum* malaria. No drug related side effects have been observed so far."

3.3.2 Case Study II: A Public-Private Partnership within India[25]

The Central Salt and Marine Chemicals Research Institute (CSMCRI) developed a new process to manufacture Zeolite A (used as an intermediate for making eco-friendly detergents). The CSMCRI is, a laboratory of the Council of Scientific and Industrial Research (CSIR), and the Government of India. The process was patented in India and then licensed to Nalco, the National Aluminum Company.

There were four partners in the deal:

1. CSMCRI, a public sector laboratory that generated the know-how
2. the National Research Development Corporation (NRDC), a public sector technology transfer organization, evaluated the technology, filed for protection and then negotiated the license,
3. Engineers India Ltd., fine tuned of pilot plant trials to generated data for design of a commercial size plant, provided detail design and engineering advice, and
4. a company, Nalco, that invested in manufacturing capacity to scale up to 10,000 tons per year.

[25] Source: NRDC, 2003.

Terms of the license included the following points: commercial use of the technology would be owned jointly by all four partners; all royalty or other revenues would be shared equally; each party was free to charge reasonable fees for their respective services; and all expenses relating to the management of the IP would be shared equally by the NRDC and the CSMCRI.

3.3.3 Case Study III: Rice Husk Particle Board[26]

Indian Plywood Research Institute developed the technology. The Indian patent rights were assigned to the NRDC. NRDC assigned the rights and transferred the know-how to M/s. Padmavati Panel Boards (PPBL), a relatively new company. The company developed some specific products (laminated boards) based on the know-how. The up scaling outlay was jointly funded by PPBL and NRDC. (data on revenue generated not available).

NRDC licensed the technology to a Malaysian client (MHES) with an up front payment of $50,000 and a royalty of 2.5% on sales for 10 years. Technology has also been licensed to an Indonesian client with an up front payment of $90,000.

3.3.4 Case Study IV: Other Private Initiatives in India

Shantha Biotechnics, a small but rapidly growing biotech company in Hyderabad, got its start at Osmania University in that city, incubated further at the Center for Cellular and Molecular Biology (CCMB), and then scaled up to manufacture hepatitis B vaccine in its own new facility. This was the first recombinant vaccine in India. Slightly later, another Hyderabad company, Bharat Biotech, leased 10,000 square feet of laboratory space at the Indian Institute of Science (IISc) in Bangalore to develop its own hepatitis B vaccine before scaling up in its own facilities. Bharat maintains the lease agreement with IISc to access brainpower and equipment and continue a research program.

Clinical trials to demonstrate product safety for both companies have been conducted in collaboration with local public sector medical colleges. Shantha sponsored preclinical testing at the National Institute of Nutrition in Hyderabad, which is part of the Indian Council of Medical Research (and has a large primate facility).

Scientists from the Indian Institute of Science (IISc) recently spun out a company called Metahelix Life Sciences to do contract research in genomics, molecular markers and bioinformatics. They have raised $1.5 million in venture capital, employ more than 30 professionals and support staff, and are working to build a sustainable contract research business (Chaturvedi 2002).

3.3.5 Case Study V: Examples of IP Protection Leading to Wealth Creation

The National Chemical Laboratory in Pune (NCL) is a national laboratory under the CSIR. CSIR's Director-General, Dr. R.A. Mashelkar, is a polymer chemist, and prior to assuming the Director-Generalship of CSIR he directed the NCL in Pune. While there, his laboratory developed a polymer that now coats one third of all the compact discs in the world (RA Mashelkar, pers. com.). The polymer was patented worldwide by CSIR. Significant royalties have flowed back to CSIR and the Government of India.

India's pharma industry also has examples of wealth generation from IP protection. Several years ago, Ranbaxy licensed an oral antibiotic formulation that was developed in its own laboratories to the Bayer Corporation in Germany for $50-60 million. Dr. Reddy's Laboratory has licensed numerous compounds with anti-diabetic properties to Novartis.

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[26] Source: NRDC.

4. From Ivory Tower to Engagement: the Birth of IP Management in India

4.1 A Brief History of IP Laws in India

The past decade has seen significant changes in policies and laws relating to public-private partnerships and IP management in India, but these are just the latest steps in a long journey. India passed its first patent laws in 1856, one year before its first war of independence. Under British rule, these laws were modified over time, culminating in stable patent and design laws by 1911. These laws were similar to those followed in England, and therefore comparable to most advanced countries of that time.

After independence in 1947, some Indian leaders felt that the patent laws should be revisited. Changes were proposed to reflect the social and economic needs of a country with a large population of poor people who did not have easy access to medicines and other advancements of science. At the same time, there was a strong emphasis on self-reliance in many areas of technology. This emphasis led to serious efforts to nurture "indigenous" science and technology (so called self-reliance) following economic policies that have sometimes been called "Nehruvian socialism."

After lengthy debate, the patent laws were finally revised through the Patent Act of 1970. The new law did not recognize patenting of substances that result from chemical reactions, and it did not allow product patent protection for drugs. Only process patents were allowed for pharmaceuticals and agricultural chemicals. During the 1970s and 1980s, India's pharmaceutical industry grew rapidly as it focused on the manufacture of generic drugs and "reverse engineering" of products that had been developed in the West.

Other IP laws have been enacted or modified in the post-independence period. The Indian Copyearight Act, first passed in 1957 and amended in 1983, 1984, 1992, 1994 and 1998, is comparable to laws in developed countries. A Geographical Indication of Goods (Registration and Protection) Act and a new Trademark Act were passed in 1999, and a new Design Act in 2000. A new act for the protection of integrated circuit layout design, "The Semiconductor Integrated Circuit Layout Design Act 2000," has been promulgated. A new act for protection of new plant varieties and farmers' rights is also in place. Both the Contract Act of 1872 (modified in 1932), which protect trade secrets, and the Design Act of 1911, have been left unchanged. These changes were intended to bring Indian law in line with international standards in a way that was consistent with Indian priorities.

As a developing country that had not previously followed an open market model, India was allowed a transition time of 10 years to bring her laws into agreement with TRIPS. Following its signing of the WTO Agreement in 1995, India took many steps to develop new laws regarding various forms of IP rights. The immediate post WTO-entry period also saw a large number of policy and program initiatives undertaken by government, industry and R&D institutions to prepare for new challenges emerging from the multi-lateral trade regime. India is now a member of Paris Convention, the Patent Cooperation Treaty and Budapest Treaty.

India is the largest democracy of the world. As with any democracy, it must evolve a political and social consensus before bringing in major new legal changes. The process of negotiating passage of bills through both houses of Parliament has been time consuming, and there have been some set-backs. India's patent laws were amended in 1999, and then again in 2002, to make them TRIPS compliant. However, some authorities believe the new laws are not yet fully compliant.

There has been stiff opposition in India to the General Agreement on Tariffs and Trade (GATT), and a growing feeling among some authorities that trade negotiations are being used to coerce developing countries to amend their domestic laws in a non-transparent way. Patent law amendments imposed by the World Trade Organization (WTO) have been opposed by public in both developed and developing

countries with increasingly noisy demonstrations from Seattle to Davos. Not surprisingly, it is taking time to build consensus within India to change patent laws to make them TRIPS-complaint.

4.2 Legacy of Government Economic Controls

While science has received continued strong support from the Government since Independence, the stress was on building basic research infrastructure and the generation of new knowledge with the implicit assumption that innovations would automatically lead to applications. Industrial policy emphasized self-reliance and "indigenization" of materials and products to reduce imports. The result was a dramatic increase in the number of trained scientists and published papers, but a failure to bridge the gap between bench-research and the translation of new knowledge into usable products for local use and export.

The domestic industry was protected, and foreign investment was actively discouraged. Many Indian companies acquired dated technology for the local market, and precious time was lost—technological progress remained near-dormant while the heavily protected domestic industry had no incentive and therefore failed to invest in original R&D.

India's first hesitant steps towards liberalizing the economy began under Prime Minister Narasimha Rao and Finance Minister Manmohan Singh in the early 1990s. These changes triggered a debate on globalization, awareness of and the need to generate and protect IP. Technology generation, the "knowledge society" and global competitiveness all entered the vocabulary of policy makers. Various steps were taken to begin to educate scientists and science managers about the generation and management of new technology,[27] sometimes with support from experienced technology mangers from abroad.

Despite recent progress, the legacy of earlier government policies remains and may take serious effort to overcome. During a series of workshops on technology management in the spring of 2001, held in New Delhi, Pune and Hyderabad, Indian participants highlighted the following challenges to the nascent local biotechnology industry: conflicting and confusing regulations by different Government ministries; longer product development time and higher capital requirements compared to information and communication technology (ICT); lack of understanding among Indian venture capitalists; naiveté and lack of business acumen among Indian Government and university scientists; and a strong undercurrent of distrust between industry on the one hand, and Government and academia on the other.

The Director of one major research center noted that "most Indian research institutions are still IPR illiterate." A faculty member from a research university expressed his frustration because of a lack of administrative support on IP rights at his institution. He had an invention and a potential partner in the private sector, but no idea how to negotiate a fair deal. These anecdotal stories are telling. Despite the fact that IP laws have been in place for nearly 150 years, until very recently leaders in industry, government, and the scientific community were not aware of, nor conversant with, the fundamentals of IP rights and IP management. This is beginning to change.

4.3 India's Private Sector

If the Indian government supports 75 percent of all R&D in the country now, it is safe to say industry's share was even lower during the first decades after independence. The bulk of the government's investment went to energy, defense and space industries under focused programs intended for just one consumer: the Government. Though many of India's "modern temples of science" had been specifically established to conduct research to support the industrial sector, the country's emphasis on self reliance

[27] E.g., training courses sponsored by the Patent Facilitation Center, TIFAC/DST, under the directorship of one of the authors (R. Saha).

had often led to research that did not reflect local or international market needs. R&D in these institutions rarely led to marketable products or processes.[28]

Some elements of Indian industry have been a bit more patent-savvy, especially those with links to foreign companies, including Indian subsidiaries of multinational companies (e.g, Hoechst and Hindustan Lever). Since the 1950s, such companies have developed strong IP divisions to manage their own inventions. In contrast, most wholly-owned Indian companies remained unfamiliar with the protection of IP, especially patents. Faced with government price controls on thousands of products and an almost impenetrable thicket of licensing requirements for newly developed products, industry was reluctant to support R&D on its own. This reluctance was all the stronger because of the ease with which any real innovation might be copied by competitors who could then benefit from sales without having had to make the original investment in R&D.

In the 1990s, the tide began to turn, driven by economic reform from the Central Government as well as real success stories in the private sector. Some Indian companies began to reap immense benefits from their own and foreign R&D investments in information technology. Pharmaceutical companies and the new biotech industry also began to invest in research. While pharmaceutical R&D in 2000 remained relatively low by international standards, at just 2 percent of sales, this still represents a doubling from 1990, and the top five companies invest far more, putting an average of 7 percent of sales into R&D (A Dangi, pers. com. OPPI Director-General). Over the past few years, a few Indian companies have negotiated multi-million dollar licensing arrangements with European companies for product formulations that were developed in their own laboratories.

The Director-General of the Organization of Pharmaceutical Producers of India (OPPI) estimates that as many as 35 Indian companies have (or could develop) a capacity for original research. The number of patent applications from Indian industry, while still small, is growing (*Business India* 2004; see also Figure 2).

But critical realities within the country still make it difficult for Indian companies to invest heavily in R&D for health technologies. Government is, of course, the largest buyer of drugs for public sector distribution. It has imposed longstanding (though recently relaxed) price controls. This, along with the inherent price sensitivity of the local market, guarantees comparatively low profit margins. Companies have little surplus to invest in research.

Despite these impediments, India's pharmaceutical industry is growing at a healthy pace, expanding at about 10 percent each year, largely due to the export potential of bulk drugs at very competitive prices (A Dangi, pers. com.). While annual sales are just $4.4 billion (out of a current global market of about $400 billion), India's pharmaceutical industry is the fifth largest in the world by volume, and the sector has become a powerhouse for the generation of jobs and export income. Over 30 Indian manufacturing plants have been approved by the US Food and Drug Administration for export to the United States (A Dangi, pers. com.).

While most of those plants manufacture generics, the future may look very different. Some observers put India's R&D and manufacturing cost advantage at more than 1-to-10 over the West. Certainly, labor cost differentials are in that range. With a rapid growth in sales, a large cost advantage over the North, and TRIPS looming on the horizon, India's pharmaceutical and biotechnology industries are likely to increase their R&D investments over the coming years.

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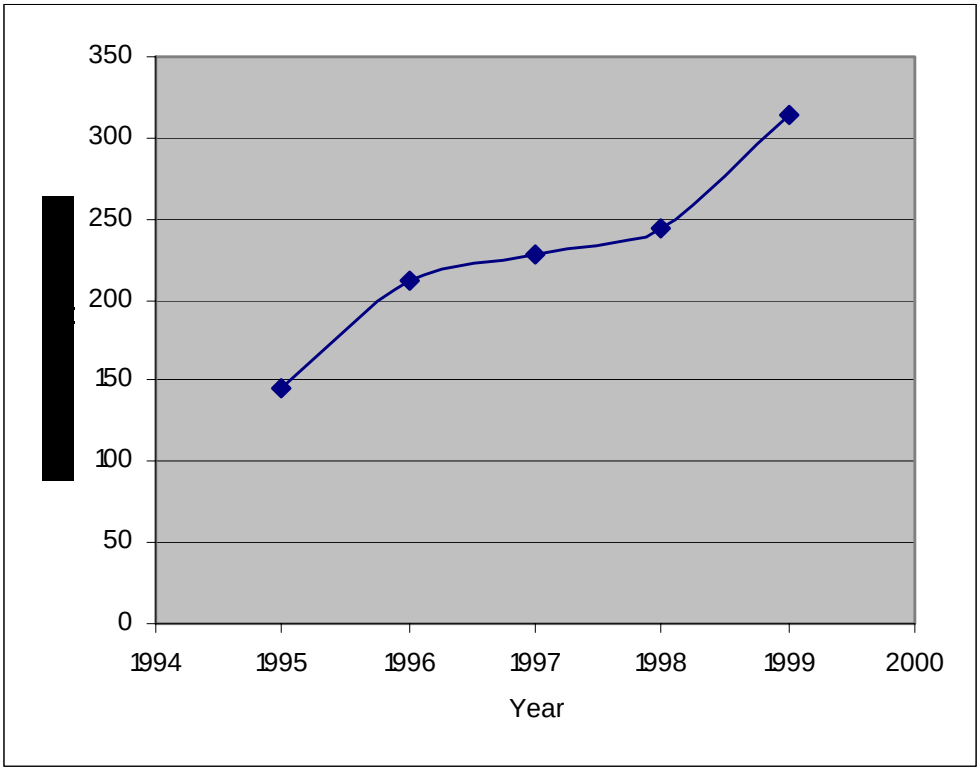
[28] This is beginning to change, as we describe below. The largest public sector R&D agencies—Space, Defense and Atomic Energy—have all initiated steps to translate the technologies they generated into products for the civilian sector. Interestingly, Defense now has very strong public-private partnerships and has established substantial in-house R&D management skills. The Space, Atomic Energy and Defense Departments have all set up IP Units to commercialize their products.

Figure 2: Patent applications filed by Recognized R&D units and Public Sector Undertakings



Unfortunately, HIV/AIDS, TB, nutrition, water borne diseases, and malaria are not high on their agenda. India's private sector alone cannot be expected to solve India's most pressing public health problems. Like their counterparts elsewhere in the world, Indian companies are in business to maximize a return to their shareholders, and this will drive their choice of targets for product development. During a symposium on "Managing Intellectual Property in Public-Private Partnerships" held in New Delhi, in 2002, one executive stated clearly—if resignedly—that his company was pursuing the same strategy as its multinational counterparts, developing high-profit-margin treatments for chronic diseases such as cancer, Alzheimer's and other neurological disorders for wealthy markets around the world.

Whatever road Indian industry follows, most of the country's research infrastructure still lies in the public sector, in academic and national laboratories scattered throughout the subcontinent. Some companies have already taken advantage of this. Shantha Biotechnics Pvt. Ltd. got its start at Osmania University, scaled up at a national laboratory, the Center for Cellular and Molecular Biology (CCMB), and then shifted to its own laboratories and manufacturing facilities to produce India's first recombinant product: hepatitis-B vaccine. Bharat Biotech International Ltd. leased over 10,000 square feet of laboratory space from the Indian Institute of Science in Bangalore to develop its own version of the hepatitis-B vaccine. Such arrangements are common in the United States and Europe, but relatively new to India.

According to press reports in December of 2000, several of India's larger pharmaceutical companies, including Dabur, Ranbaxy, Zydus, and Cadila, planned to establish a "Technology Transfer Deck" involving publicly-funded scientists and institutions in biotechnology and bioinformatics. The "Deck" would be coordinated by the Confederation of Indian Industries (CII), and monitored by the Department of Biotechnology. Its goal is to promote innovation and commercialization of IP rights for drugs and vaccines. Larger pharmaceutical companies such as Ranbaxy, Dr Reddy's Laboratory, Cadila, Sun Pharma and Wockhardt have very active patent divisions.

CII, the Federation of Indian Chambers of Commerce and Industries (FICCI), the Associated Chambers of Commerce and Industry of India (ASSOCHAM), and other industry associations have been active in creating IP awareness among their members through workshops, seminars and training programs with the help of Indian and foreign experts. FICCI has established an IPR institute,[29] and an Indian law firm, Lall, Lahiri and Salhotra, has established an Institute of Intellectual Property Practices and Research.

Thus, despite financial constraints, some Indian pharmaceutical and biotechnology companies are beginning to support original research. They are actively seeking to protect IP that arises from that research, and are increasingly eager to partner with experts and facilities in India's public sector to carry out original research.

Is the public sector ready to work with these companies? Historically (with some exceptions), the gulf between India's technical agencies, national laboratories and universities on the one hand, and the private sector on the other, has been large. Again, this appears to be changing.

4.4 India's Technical Agencies

While most of India's universities have been slow to adapt, the country's technical departments and agencies have been moving toward indigenous public-private partnerships for some time. Since 1995, almost all have established offices to manage and protect IP arising from their own laboratories. These offices are often staffed with tremendous enthusiasm, though with varying levels of expertise. As yet they are linked only informally with each other, and rarely to their international counterparts.[30]

The following pages contain a selective survey of IP Management Offices among India's technical departments and agencies. Websites of are included when possible. The discussion resumes on page 44 with a summary of recent policy changes initiated by the Government of India affecting technology management.

4.4.1 NRDC (www.nrdcindia.com/index.html)

The National Research and Development Corporation was established by the Indian Government in 1953 as a central technology transfer office to commercialize technologies developed by government funded agencies. It acts "as a link between scientific laboratories and industrial establishments for transferring technologies," and is "wholly dedicated to transfer of technologies from R&D laboratories to industry [covering] the entire spectrum of industrial technologies ranging from chemical to metallurgy, mechanical engineering, electrical engineering, electronics, biotechnology, etc."

The NRDC used to provide patenting services as well, but many government agencies have now begun to handle IP on their own. The NRDC still provides financial assistance to individuals and institutions for patent filing in India, but does not provide funds for patent maintenance. It will assist with foreign filing as well, but only if the patent is assigned to the NRDC and if 50 percent of the filing costs are borne by the inventor/institution. The NRDC will assist inventors and institutions in the search for potential licensees, and will facilitate legal and other tasks associated with negotiating licensing agreements and technology transfer (see "Box: Brief History of NRDC" on next page for additional information on NRDC).

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[29] www.iprindia.net/newiprindia/index.htm

[30] In contrast, from a small founding group of 51 in 1975, the U.S.-based professional society AUTM has grown to nearly 3,000 members, publishes its own journal, has regular meetings, and is reaching out to its counterparts in other countries through the establishment of a Global Network of Technology Transfer Societies.

Box: Brief History of NRDC

The National Research Development Corporation (NRDC) was established as early as in 1953 under the Department of Science and Technology, Ministry of Science and Technology, under Section 25 of the Companies Act (as non-dividend paying company), on the pattern of NRDC of UK to promote, develop and commercialise indigenously developed technologies primarily of the Council of Scientific and Industrial Research (CSIR) with the prime objective of smooth, effective and efficient flow of technology from R&D centers and individual inventors to the industry and to bring the fruits of science and technology to the people. Pt. Jawaharlal Nehru, the great visionary and Dr. S.S. Bhatnagar, the celebrated scientist became the founding scribers of the Corporation and signed as being the President of Council of Scientific & Industrial Research and on behalf of the President of India respectively. Since then many eminent Indians had been the chair-persons of the Corporation - Shri R. Venkataraman (ex-President) of India and noted scientists like Dr S.H. Zaheer and Dr. G.S. Sidhu are from amongst them.

The Corporation commercialised CSIR technologies exclusively till 1986. After that CSIR laboratories were given the freedom to license the know-how developed by them directly to industry and since then the CSIR technologies were commercialised by both NRDC and CSIR laboratories. Over the last five decades of its existence, the Corporation has tied up with over 300 R&D Institutes/Universities/IITs[spell out]/Industries for assignment of technologies, and over 2500 technologies were assigned. The Corporation executed more than 4,500 licence agreements for commercialization of wide variety of technologies.

The Corporation has been carrying out several promotional programs under which the Corporation undertakes the following major activities:

- Awarding meritorious inventions ["providing award for meritorious inventions?"]
- Publication of Invention Intelligence (English) and Awishkar (Hindi)
- Providing technical, legal and financial support to the inventors for filing patents in India and abroad
- Promotion and development of Rural & Household technologies
- Providing Techno Commercial [can you use a non-jargon phrase?] support to its licencees

The Corporation has diversified its activities from transfer of technology to provide knowledge-based information. The Corporation has initiated the project for setting up technology e-channel on the Internet for providing information on technologies. The Corporation has also developed Interactive Multimedia Training Package on Intellectual Property Rights (IPRs) for disseminating information and giving training on IPR related issues.

Source: Courtesy of S.K.Sakhuja, NRDC Company Secretary.

4.4.2 CSIR (www.csir.res.in)

The Council for Scientific and Industrial Research – with 42 laboratories scattered around the country conducting research ranging from aeronautics to ceramics to molecular biology – has always had a strong orientation toward private and State owned industry. Most CSIR laboratories were specifically created during Nehru's time to assist industry. The CSIR itself was established in 1947. However, up to the 1980s they focused more on basic research and filed few patent applications. In the early 1980s, negative criticism grew as journalists and policy makers pointed out how few CSIR technologies were ever taken up by the Indian industry. In response, the CSIR began to increase its thrust and focus on the 'industrial' component of its work. CSIR laboratories that had focused primarily on generating new knowledge were now required to create new policies and facilities for converting that knowledge into products.

They began to establish and strengthening in-house facilities for industrial liaison and technology transfer of bench level inventions to the pilot plant level of manufacture. Today, the CSIR model is unique among Indian technical agencies. Each of the 42 CSIR laboratories has its own IP coordinator (other technical agencies have numerous national and regional laboratories throughout the country but still manage IP centrally, in New Delhi). The CSIR also has a strong IP division in its headquarters, which

coordinates the work of individual CSIR laboratories. The CSIR shares revenues from technology transfer with its scientists.

In 1995, the CSIR filed 58 patent applications, and in 1999 it filed 112 (many in India alone). In 2003, the CSIR filed a record 100 US patents. As noted earlier, one recent CSIR success from the laboratory of the current Director-General, Dr. R.A. Mashelkar, is a polymer that now coats one-out-of-three compact discs in the world, and is bringing significant royalties back to CSIR. This and other success stories have raised eyebrows on Rajpath (the Government corridors of power), highlighting how IP can work in India's favor.

CSIR laboratories in fields with a strong industry focus such as synthetic chemistry, chemical technology and engineering generally have strong technology transfer units. However, two premier CSIR research centers, the Center for Cellular and Molecular Biology (CCMB) in Hyderabad, and the Central Drug Research Institute (CDRI) in Lucknow, still file only a few patent applications per year. In contrast, the Center for Biochemical Technology in Delhi, recently renamed the Institute of Genomics, has increased its technology transfer activities dramatically over the past few years, developing a healthy portfolio of US patents, and has entered into several public-private partnerships with significant co-funding from industry.

4.4.3 DST Patent Facilitation Center (www.tifac.org.in/do/pfc/pfc.htm)

The Department of Science and Technology (DST), the Federal nodal agency for science and technology, responded quickly to the changing IP and technology transfer scenario. A first step in this direction was to create awareness among Indian scientists, technologists, academicians and policy makers from universities, R&D institutions, industries and government departments. The DST established its Patent Facilitation Center (PFC) under the Technology Information Forecasting and Assessment Council (TIFAC) in June of 1995.

The PFC's goal is "to spread IPR knowledge and encourage and help scientists to commercialize their technologies," with objectives to introduce the culture of using patent information as an input for the development of research programs, providing technical and financial assistance to Indian scientists, especially from universities, to protect their inventive work in India and elsewhere, and to create IPR awareness among the Indian scientists, technologists, policy makers and students.

Since 1995, the PFC has assisted researchers to file over 125 patent applications (including 23 outside of India). While the numbers remain modest, the PFC is unique in one particular way. It takes all comers. Anyone in the country who thinks he or she has an invention can come to the PFC for advice and assistance. Even the quintessential backyard inventor can get help from the PFC. Other technical agencies have established offices with more circumscribed missions, to transfer technologies only from their own laboratories into the private sector. See Appendix A for a full description of the PFC.

PFC has been conducting patent awareness workshops all over the country and has conducted over 200 workshops sensitizing about 20,000 scientists, students and policy makers from about 110 universities, more than 350 industries and 200 R&D institutions. Its monthly IPR Bulletin is circulated to about 10,000 readers and has a large membership on the net. PFC has filed 205 patent applications on behalf of universities, government departments and ministries in India and elsewhere. Many foreign patents have been granted for these inventions; these results show the expertise developed by PFC in conducting patent searches and assessment of novelty and inventiveness.

In order to reach out to many scientists, PFC has set up Patent Information Centers (PIC) in the states of Andhra Pradesh, Gujarat, Kerala, Madhya Pradesh, Manipur, Punjab, Rajasthan, Sikkim, Tirpura, Uttar Pradesh, Uttranchal, and West Bengal. The PICs are performing the role of the PFC at the state level. The PFC Model has caught the attention of, and received delegations from, many other developing

countries. Over the years, the PFC has developed considerable expertise in the negotiation of IP agreements.

The Government of India, through the DST, has taken major strides at the international level by signing IP rights agreements with the European Union and Russian Federation in respect of their joint S&T programs. The first such agreement was put in place for the Indo-French Center, set up for promoting joint research among Indian and French institutions.

4.4.4 DBT Biotechnology Patent Facilitation Cell (dbtindia.nic.in/programmes/patent/patentmain.html)

The Department of Biotechnology (DBT), DST and CSIR all fall under the umbrella of the Ministry of Science and Technology. Following the PFC model, the DBT established a Biotechnology Patent Facilitation Cell (BPFC) in 1999. To date, the BPFC has filed over 72 patent applications, most in India, but a few in the United States and Europe. For the identification of companies to work with, and negotiating licenses, the DBT had established an autonomous technology transfer office, the Biotechnology Consortium of India, Ltd. (BCIL).

One top-level DBT Advisor has observed a dramatic shift in the attitude of Indian companies. He now receives visitors from the private sector almost every day—Indian companies seeking him out to explore potential partnership opportunities with the DBT. The DBT has now has well-established linkages with Indian industry (and some foreign biotechnology companies, notably in the United States) to develop vaccines against HIV and other diseases.

4.4.5 ICMR IP Rights Unit (www.icmr.nic.in/ipr.htm)

The Indian Council of Medical Research is an autonomous body funded by the Ministry of Health and Family Welfare. The ICMR created its Intellectual Property Rights Unit (IPRU) in 1999 to provide technical and legal support to its scientists. During the summer of 2002, the Indo-U.S. Technology Management Program supported training for the Director of the IPRC at Michigan State University and with the Office of Technology Transfer, National Institutes of Health (NIH). The Indo-US program also supported a consultant from NIH who spent two weeks with the IPRC and subsidiary ICMR institutes to review their IP policies. For ICMR's IP policy, see Appendix II.

4.4.6 ICAR Intellectual Property Rights Cell (www.icar.org.in)[31]

The Indian Council of Agricultural Research established its Intellectual Property Rights Cell in 1998. Its Director received training on Technology Management and IPR at Michigan State University in 1999.

4.4.7 India's Academic Institutions

Universities receive the bulk of their funding from the University Grants Commission, but are also among the largest recipients of extramural research funding from India's technical agencies. Few, if any, autonomous research centers or State Government-based universities have developed skills in IP management. Aside from faculty who have participated in PFC training programs (noted above), most students and faculty have little knowledge of basic IP principles.

Many of India's institutions of higher learning, including the well-known Indian Institutes of Technology (IITs), were established with the help of more developed countries during the first three decades after

[31] This is the agency's homepage; no website is available for the IP office.

independence. The IITs, among India's most prestigious academic institutions, were also the first Indian institutions of higher education to establish industrial liaison and technology transfer offices.

The IITs have not traditionally been involved in health or molecular biology research, despite that one of the models of the IIT system, the Massachusetts Institute of Technology, moved into the life sciences nearly 40 years ago. However, most IITs have bioengineering centers, and most have or are now developing biotechnology centers, and making a shift to consider life sciences research and development as part of their core missions.

In no particular order, these institutions include the IIT New Delhi, IIT Bombay, IIT Kharagpur, IIT Kanpur, IIT Guwahati, IIT Roorkee, and IIT Chennai. Most of the IITs have offices that handle IP and technology transfer issues. One knowledgeable observer of the technology management landscape in India has noted that these offices are not very busy or productive compared to their foreign counterparts. Nevertheless, they are developing experience and a deeper understanding of the issues involved.

4.4.8 Foundation for Innovation and Technology Transfer (www.fitt-iitd.org/fittdisplay.html)

IIT Delhi maintains a Foundation for Innovation and Technology Transfer (FITT). It was established in 1992, and its mission is "To be an effective interface with the industry to foster, promote and sustain commercialization of Science & Technology in the Institute for mutual benefits." The Foundation has held workshops on IP awareness.

4.4.9 Industrial Research and Consultancy Center (www.ircc.iitb.ac.in)

IIT Bombay now provides a course for students on intellectual property. IIT Bombay's Industrial Research and Consultancy Center (IRCC) coordinates, facilitates and manages externally funded research and development projects, including IIT-Industry interaction. The IRCC "handles not only aspects related to intellectual property protection and technology transfer but also the complete financial management and recruitment of research scientists and engineers to work on funded projects."

4.4.10 Office of Sponsored Research and Industrial Consultancy (www.iitkgp.ernet.in/sric)

IIT Kharagpur has an "IPR and Industrial Relations Cell," created recently within its office of Sponsored Research and Industrial Consultancy (SRIC). The SRIC is a "special R&D Cell established in 1982 as an interface between funding agencies and the Institute to handle sponsored research projects and industrial consultancy assignments." Since its creation, the SRIC has handled over 1,200 research projects worth over $20 million US dollars. The center currently manages over 450 sponsored projects from national and international clients worth more than $8 million dollars. Clients include both Indian companies and ministries, as well as companies from Germany and the United States.

4.4.11 Office of Sponsored Research and Industrial Consultancy (www.rurkiu.ernet.in/sric)

IIT Roorkee has an Office of Sponsored Research and Industrial Consultancy (SRIC), and "encourages its faculty, scientists, technicians and students to interact with industry in all possible ways with the spirit of deriving mutual benefit." An IP Rights Cell was established in September 2000 within the SRIC to assist faculty who are involved with the creation of intellectual property. The Cell organizes lectures, conferences, and workshops to increase awareness of patents, copyrights and other IP rights.

4.4.12 Center for Industrial Consultancy and Sponsored Research (www.iitm.ac.in/ICSR)

IIT Chennai's Center for Industrial Consultancy and Sponsored Research (IC&SR) was established in the early seventies to promote interaction between the Industry and the Institute. Today, the center for

IC&SR is an independent section of the Institute, headed by a Dean. Over the years, this center has played a vital role in bringing together the people from the Industry and the faculty of the Institute resulting in important contributions to design and development in the country.

4.4.13 Innovation and Incubation Center (www.iitk.ac.in/siic/about1.html)

IIT Kanpur: In 2001, with funding from the Small Industries Development Bank of India (SIDBI), the IIT Kanpur established an Innovation and Incubation Center to "foster successful entrepreneurs and develop industry," with a special focus on information technology and biotechnology.

4.4.14 IISc Center for Scientific Industrial Consultancy (www.csic.iisc.ernet.in)

The Indian Institute of Science (IISc) established its Center for Scientific Industrial Consultancy (CSIC) in 1975. The Center was "vested with the responsibility of further promoting the already existing institute-industry relationship for mutual benefits and advancement." It negotiates leasing of IISc facilities, consulting by IISc faculty in product and process development, as well as technology transfer from IISc laboratories to the private sector. The CSIC has succeeded in launching companies with equity participation by faculty members (a novel approach in India).

4.4.15 The Small but Growing Cadre of Indian Technology Managers

Universities with similar technology management centers include Delhi University, G B Pant Nagar University, Pant Nagar, Bidhan Chandra Krishi Vishwavidyalaya, Kalyani (West Bengal) and Jadavpur University, Kolkata. Many more such centers will soon come up depending on the need of each institution.

Yet the IITs and IISc are the exception. India has about 250 universities and close to 700 engineering and medical colleges. Only a handful have IP cells. University management often fails to appreciate the need, and often lack resources to support work in this area. Finally, there is a shortage of faculty volunteers who understand and are willing to take the responsibility for an IP management office.

Despite these impediments, organizers of the March 2002 All India Technology Managers Workshop/Retreat were able to identify individuals who focused on IP management (at least part time) from the following Indian institutions: National Center for Cell Sciences, Pune; Bidhan Chandra Krishi Viswavidyalaya, Nadia District; Department of Atomic Energy, Mumbai; Defense Research and Development Office, New Delhi; Agarkar Research Institute, Pune; International Center for Genetic Engineering and Biotechnology, New Delhi; Punjab Agricultural University, Ludhiana; GB Pant University of Agricultural and Technology, Pantnagar; IIT Bombay; IIT New Delhi; IIT Kharagpur; Indian Space Research Organization, Bangalore; MS University, Baroda; Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram; National Institute of Pharmaceutical Education and Research, Punjab; Center for Cellular and Molecular Biology, Hyderabad; Central Drug Research Institute, Lucknow; Center for DNA Finger Printing and Diagnostics, Hyderabad; Center for Biochemical Technology, Delhi; National Institute of Immunology, New Delhi; IISc, Bangalore; Bose Institute, Kolkatta.

4.5 Indian Policy Breakthroughs

As in many other countries, ownership of inventions arising from government-funded research has historically resided with the government of India, which retained the right to transfer such technologies for commercialization. However, the government had little expertise to guide it in this process. The concerned research institutions had a role in negotiating technology transfer and also in helping industry overcome problems arising during scale-up.

One of the arguments supporting this arrangement was that it would not be fair for one institution or a few individuals (inventors) to enjoy the fruits of R&D that was funded at the taxpayers' expense. The government was thought to be the only organization capable of ensuring that the benefits of research would be distributed equitably. Government financial rules did not allow for the collection of assets generated through R&D.

With the coming of the WTO, the Government of India recognized that scientific inventions would have an increasingly important role. In the knowledge society, conducive environments and circumstances should be created to increase the number of scientific inventions leading to the generation of IP. Since India signed TRIPS in 1995, with the help of WIPO and the WTO, the Ministry of Commerce and Industries (which sets the country's rules for patents, designs, trademarks and geographical indications) has conducted many workshops and seminars, both national and international. Similarly, the Ministry of Human Resource Development, the rule making body for copyrights, has taken many initiatives in spreading IPR knowledge.

Unless scientists and institutions capable of generating new knowledge are adequately motivated, no society could expect to benefit from a growing research portfolio. Against this backdrop, injecting a new paradigm is not an easy task. Many people enter this debate over the relative advantages and disadvantages of public goods and private property without realizing that a property, duly owned, can be used for public good (rather than profit) if the owner so desires.

4.6 New Government Ruling

Based on the positive experiences of individual agencies and institutions since 1995, and following the advice of top officials from the Ministry of Science and Technology, in March 2000 the Ministry of Science and Technology issued an Official Notice to "encourage institutions to file patent applications on their innovations, motivate them to transfer their technologies for commercialization, and facilitate them to reward their inventors." The ruling gives ownership of inventions to any research institutions that receive funding from the Ministry of S&T. It also requires research centers to direct 25 percent of IPR-derived income into a "Patent Facilitating Fund" to cover the cost of patent applications, protect against infringement, and to create awareness and build competency on IPR. One of the results of this policy has been a significant rise in patent applications by academic institutions (Figure 3).

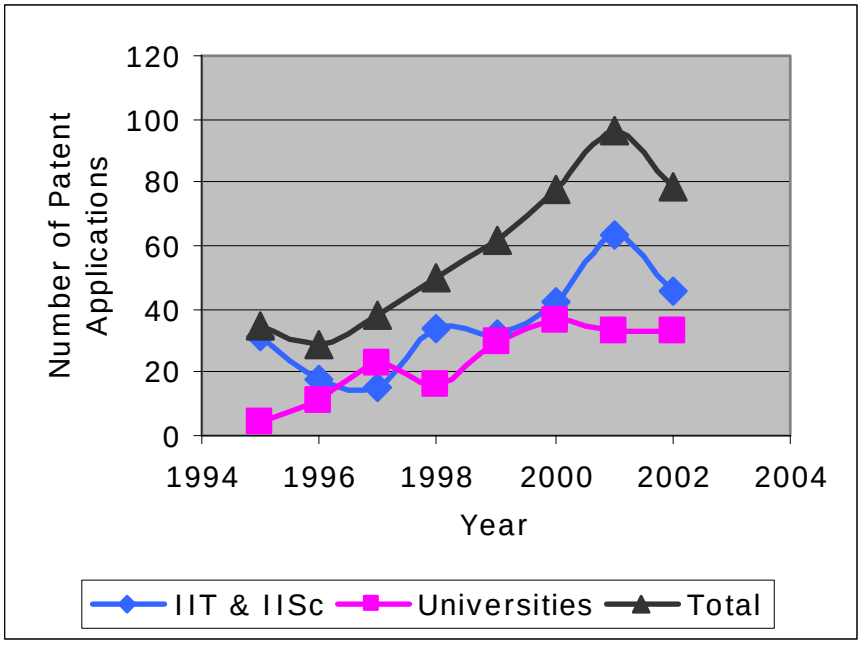
These guidelines were intended to enhance the motivation of scientists, research institutions and universities in projects funded by the Department of Science and Technology, Department of Biotechnology, Department of Scientific and Industrial Research and Department of Ocean Development. The salient features of the guidelines are:

1. Institutions shall be encouraged to seek protection of intellectual property rights in respect of the results of R&D. They may retain the ownership of such IPR. "Institutions" mean any technical, scientific or academic establishment where research is carried out through funding by the central or state government.

2. The institutions shall take necessary steps to commercially exploit patents on a exclusive or non-exclusive basis.

3. The owner institution is permitted to retain the benefits and earnings generated out of the IPR. The institution may determine the share for inventor(s) and other persons from such actual earnings. However, such share shall be limited to one third of the actual earning.

Figure 3: Patent Applications from Academic Institutions



Source: Data collected by R. Saha, Patent Facilitation Center, TIFAC/DST

4. IPR generated through joint research by institution(s) and industrial concern(s) through joint efforts can be owned jointly by them as may be mutually agreed by them through a written agreement. The institution and industrial concern may transfer the technology to a third party for commercialization on an exclusive or non-exclusive basis. The third party, exclusively licensed to market the innovation in India, must manufacture the product in India. The joint owners may share the benefits and earnings arising out of commercial exploitation of the IPR. The institution may determine the share for the inventor(s) and other persons from such actual earnings. Such share shall not exceed one third of the actual earning.

5. The owner institution shall set apart not less than 25% of the revenue generated from IPR to create a Patent Facilitating Fund which shall be utilized by the institution for updating inventions, filing new patent applications and protecting IP rights against infringement and for building competency in the area of IPR and related issues.

6. The Government shall have a royalty free license for the use of the intellectual property for the purposes of the Government of India.

This represents a major departure for one government ministry. Unfortunately, implementation has been uneven. Other departments and government agencies follow different rules. Many of India's research centers were established under a socialist banner with prohibitions against ownership of inventions etched into their founding charters. Many institutions simply have not received the message from the Ministry of Finance, or haven't noticed it, or do not have sufficient expertise to understand and implement the ruling. In order to have a more uniform policy, new legislation may be required.

The Ministry of Science and Technology ruling was a radical departure from past practice, yet it went largely unnoticed in the local press. Twenty years ago, a similar law in the United States (the Bayh-Dole Act) sparked considerable controversy with charges that American consumers would be forced to pay twice: first through taxes to support research, and second to purchase the products of research. Twenty

years later, the consensus is that Bayh-Dole has been a net positive factor helping to build the nexus of public-private interaction and venture capital that drive innovation, high-tech job creation and wealth formation in the United States. (However, Bayh-Dole has done little to address specific health needs of the poor, especially in developing countries.)

4.7 Incentives for Public-Private Partnerships and for Research

Former Prime Minister Vajpayee had announced plans to double national R&D spending (both public and private) by 2005 through a combination of increased public investment and incentives. The Government of India now encourages pharmaceutical and biotechnology research and promotes public-private partnerships through a range of tax concessions, soft loans and grants to Industry.

Research incentives include a 10-year tax holiday on income arising from R&D, a 3-year Excise Duty waiver on goods developed by Indian companies and patented in the United States, Japan, or any two or more countries of the European Union. Bulk drugs, produced in India through a manufacturing process developed from Indian R&D, are exempt from Drug Price Controls for up to 5 years, and novel drugs developed through indigenous R&D will remain outside price controls for up to 10 years from the date of commercial production.

The Department of Science and Technology supports soft loans and grants to promote public-private partnerships through an Industry R&D Partnership Program and the DST's Drug Discovery Program, while the Drugs and Pharmaceuticals Research Program supports joint research projects between academic or national laboratories and industry. Both the Indian Council of Medical Research and the Department of Biotechnology have also begun to develop partnerships with Indian industry to develop vaccines and diagnostics, however current Government of India restrictions still make it difficult for them to support Indian companies directly.

4.8 International Exchanges and Experience

The Indo-US Technology Management Program (IUTMP) is a first-of-its-kind effort to raise local capacity for public-private R&D partnerships in a developing country. Its goal is "To create linkages between Indian and American technology management experts to highlight the benefits of public-private partnerships and intellectual property protection for India, and to stimulate local research and innovation to address India's own public health, agricultural and environmental needs." One lesson for Indian institutions is that patents are just a tool in the much larger process of technology management, of which the end result is new technologies, job creation and economic development.

The IUTMP was created in 2000 with funding from the US Embassy Public Affairs Office. It is managed by the Health Office of the US Department of Health and Human Services (HHS) in the Science Section of the US Embassy. In 2001, in collaboration with India's Council of Scientific and Industrial Research (CSIR), this program supported a series of multi-sectoral Symposia in New Delhi, Pune and Hyderabad, as well as training exchanges with Michigan State University. In 2002, the program collaborated with the Patent Facilitating Center of the Technology Information Forecasting and Assessment Council (TIFAC), under the Department of Science and Technology, to support a Workshop/Retreat for Indian technology managers as well as a multi-sectoral Symposium on "Managing Intellectual Property in Public-Private Partnerships."

IUTMP Events focused on case studies to highlight lessons learned from successes and failures over the past 20 years in the United States, and more recently in India. Agendas were typically divided into five areas, highlighting the perspective of public-sector research institutions:

1. developing your institution's IP policy;
2. how to identify an invention in the laboratory, and how to educate researchers about IP;
3. where, when, how and why to file a patent application;

4. how to identify company partners and negotiate fair license agreements with them;
5. follow up to ensure the company invests sufficient resources to commercialize the technology.

Recommendations from the March 2002 All India Technology Managers' Workshop/Retreat are included in Appendix C (page 55). They are consistent with, and appear to be largely incorporated into the Indian Government's 2003 S&T Policy.

Symposium participants included Government policy makers, research administrators, scientists, industry representatives and venture capitalists. These events generated significant enthusiasm from participants, were highly successful in the view of the Indian technical agencies involved, and included a recommendation from the 2002 All India Technology Managers Retreat/Workshop to establish an "Indian professional society for technology managers" which was subsequently endorsed, in the presence of the US Ambassador, by the Secretary of the Department of Science and Technology Dr. V.S. Ramamurthy, and the Principal Scientific Advisor to the Government of India, Dr. R. Chidambaram

As this new association gets started, every effort should be made to link it to its counterparts in other developing countries, as well as to the U.S.-based Association of University Technology Managers (AUTM), and to European counterparts such as the Association of European Science and Technology Transfer Professionals (ASTP) and the Public Research Organisations' Technology Offices Network (Pro-Ton-Europe). No such organizations yet exist in the developing world, though MIHR (see "Box: MIHR" below) is working to create supportive conditions for professional associations to form.

India's head start in technology management (among developing countries) also makes it an ideal partner for developed countries in many areas of research. Sharing experience in technology management only strengthens the relationship. Northern technology managers gain an understanding of the needs and capabilities of Indian institutional partners, and when an invention arises from joint research both sides can negotiate from the same frame of reference. India's private sector will also benefit as it reaches out to the public sector, and as Northern technology managers enable the transfer of technologies that are available in the United States (presentations by US technology managers through the IUTMP led serendipitously to the transfer of several health technologies from NIH to Indian companies).

4.9 The 2003 Science and Technology Policy[32]

During the annual Indian Science Congress in January of 2003, the Prime Minister announced a radical new science and technology policy (Appendix D). One of the Policy objectives is:

> To establish an IPR regime which maximizes the incentive for generation and protection of IP by all types of inventors. The regime will also provide a strong, supportive and comprehensive policy environment for speedy and effective domestic commercialization of such inventions so as to be maximal in the public interest.

Box: MIHR

In 2002, The Rockefeller Foundation launched MIHR, the Center for the Management of Intellectual Property in Health Research and Development (www.mihr.org), to help build technology management capacity in developing countries, as well as to conduct research and share best practices in the management of IP to promote global health. The organization is international in scope, based in Oxford UK, with linkages and activities throughout the world. Though young, MIHR has already developed a handbook of best practices, conducted workshops in South Africa, Egypt and India, and is now exploring partnerships with the ICMR, South Africa's Medical Research Council and other technical agencies in developing countries. One of MIHR's primary goals is to raise the stature and build capacity of technology managers and technology management offices in publicly funded health research institutions in developing countries – so they can enter into sound, viable "indigenous" public-private partnerships that are accountable to the public interest.

[32] See also dst.gov.in/doc/STP2003.doc

The Policy further states:

> Intellectual Property Rights have to be viewed, not as a self contained and distinct domain, but rather as an effective policy instrument that would be relevant to wide ranging socio-economic, technological and political concepts. The generation and fullest protection of competitive intellectual property from Indian R&D programs will be encouraged and promoted.

In order to enhance the synergy between industry, scientific organizations and universities, the new policy includes plans to develop a comprehensive program on technology management training, and to create autonomous technology transfer offices at research institutions throughout the country. This represents the culmination of ten years of experience by India's technical agencies and institutions. It also points the way toward a future in which technology management in publicly funded research institutions will play a central role in the country's economic development, and in the development of new locally relevant technologies.

It is also a significant shift away from a focus on what were once called "Patent Cells" in the technical agencies. The new policy now recognizes the full spectrum of interactions in technology management from invention disclosures to patents, licensing and follow-up, scale up and manufacturing. In this context, IPR and patents can be seen as necessary – though never sufficient – tools in a larger process to create incentives that bring private sector know-how to address public sector goals. See Appendix E for selected highlights of the new policy.

5. Conclusions

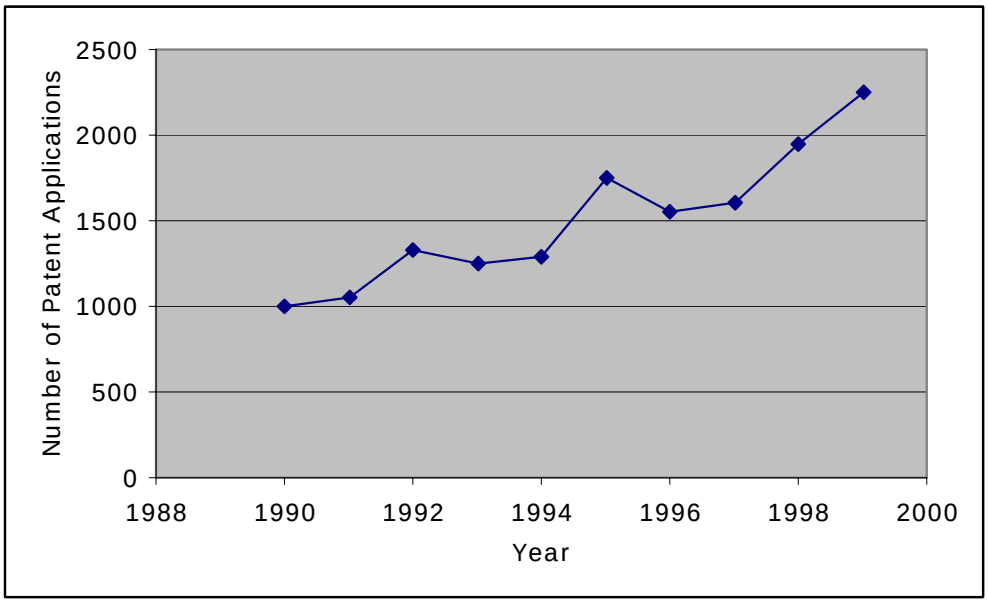
It is difficult to bridge the gap between public and private sectors in any country. In many ways, these two cultures are more distinct than any two communities in the world. Models for public-private partnerships and the management of IP in such partnerships are being tested, but are still only tentatively established in India, still less in other developing countries (they are also relatively new in the United States, Europe and Japan). Patent filings by Indian academia, national laboratories and industry are low, but growing. Government policy and the move toward stronger product patent protection are encouraging greater investment in R&D by the pharmaceutical and biotechnology industries. The trend lines all are positive, even impressive (Figure 4).

In contrast to the United States and other developed countries, the lion's share of India's health research infrastructure is in the public sector. The country's rapidly growing pharmaceutical and biotechnology industries are hungry for new technologies, yet the historical chasm between public- and private sectors has prevented effective technology transfer in the past. The engine was running, but the gears were not engaged.

Now, and at least for the next several years, there would appear to be a unique window of opportunity for India and, by analogy, other countries at a similar stage of development. Raising the capacity of publicly funded health research institutions so they can transfer their own innovations to their own private sector could give traction to a very significant public investment that is based on national health priorities rather than profit.

Technology transfer from such institutions would include a high proportion of diagnostics, drugs and vaccines against diseases of the poor. As technology management offices become more experienced, they will help move other technologies as well, from cancer drugs to advances in engineering and chemical synthesis (most research institutions don't just work on health). Capacity building in health technology management, therefore, could be a key factor in overall economic development.

Figure 4: Total Patent Applications Filed by Indians in India



Source: Patent Facilitation Centre, TIFAC/DST

The authors have had some experience and success in establishing technology management linkages and information exchanges between India and a more developed country. Still, we feel that Indian IP managers may have as much or more to learn from each other, and from their counterparts in other developing countries, than they do from Northern technology managers (similarly, U.S. technology managers have much to learn about Indian conditions and capabilities). Networks, including professional societies, are sorely needed to create these linkages among technology managers throughout the developing world. We are delighted that MIHR is working to meet this need.

There is still much to do, but India appears well on the way toward the construction of a substantial and comprehensive platform to support IP management and public-private partnerships. We believe this structure could be a model for other developing countries.

The positive impact of a small Indo-US program to share information and experience with Indian technology managers (IP managers) highlights a lever of change that has gone largely unnoticed by many development agencies. This seems strange; the role of innovation in economic growth in "wealthy" countries is generally acknowledged. Why should it be any different in less wealthy countries such as India?

Northern technical agencies should also take note, particularly health research organizations. NIH has become increasingly involved in a new approach to capacity building in developing countries, incorporating management training (e.g., project management, financial management, data management, ethical review management, and clinical trial management) into large research awards in addition to the more traditional technical training and provision of equipment that usually come under the heading of "research capacity building." So far, however, this new emphasis does not include capacity building in technology management.

The NIH Office of Technology Transfer (OTT) provided significant intellectual input into the design and execution of the Indo-US Technology Management Program. Unfortunately, no current mechanism exists for that office or its counterparts in individual institutes to become more actively involved in this

area. Yet NIH currently supports over 80 collaborative research projects in India, and nearly ten times that number in other low- and middle-income countries around the world.

We believe NIH has a moral responsibility to build capacity in technology management in developing countries where it supports research. If an invention arises from that research, the developing country institution needs to be on a level playing field in negotiating ownership and licensing arrangements consistent with its own institutional and national interests. OTT understands this, and is exploring creative ways to support such capacity building wherever possible.

Capacity building in technology management represents a tremendous opportunity for donors and local governments alike to simultaneously stimulate the development of locally relevant technologies, create jobs and wealth, and improve the lives of people throughout the developing world (as the least developed countries import low cost products made in IDCs like India). With the right support, local technology managers themselves can shoulder the hard work to build a sound cottage industry for health and wealth. India is showing us how.

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Appendices

A. Patent Facilitation Center

Technology Information Forecasting and Assessment Council

Intellectual property protection plays a key role in gaining an advantageous position in the competitive technological game for achieving economic growth. India enjoys a large asset of R&D personnel and infrastructure. Scientists would need information, orientation and facilities for protecting the products of their intellectual prowess. As a first step in this direction a Patent Facilitating Cell now called Center (PFC) was set up by the Department of Science and Technology under the Technology Information Forecasting and Assessment Council (TIFAC) in 1995. Major Indian Scientific establishments have in-house facilities to provide patent support to their scientists. However, such facilities are not available to most of the academic sector and smaller scientific institutions whether in the Central or the State sector. PFC was created as a single window facility to service this large ALL INDIA clientele with a smile and "may we help you" approach. This helpful and human approach has helped PFC reach out to remote universities and R&D centers. Scientists thus have a direct and easy access to PFC's complete coverage.

Objectives

- Introducing patent information as a vital input in the process of promotion of R&D programs.
- Providing patenting facilities to scientists and technologists in the country for Indian and foreign patents on a sustained basis.
- Keeping a watch on development in the area of IPR and make important issues known to policy-makers, scientists, industry, etc.
- Creating awareness and under standing relating to patents and the challenges and opportunities in this area including arranging workshops, seminars, conferences etc.

Services and Conditions

- PFC provides technical, legal and financial support for obtaining patents and also for post patent actions in respect of patentable inventions emanating from research funded by government and Indian university / educational institution
- Scientists and their institutions are expected to keep track of developments in areas related to patented inventions and inform PFC about possible exploitation and also violation of their patents.
- For patentable inventions funded by a university/ educational institution, applications for patents will be filed in the name of the university/educational institution with the concerned scientist(s) as inventor (s).
- For patentable inventions funded by central / state government department/ agency, applicants for patents will be decided by the term and conditions mutually agreed between the funding agency and the research agency.
- Request for patent search are entertained from scientists, universities/educational institutions, government industry, attorneys and PSUs, with a levy of nominal change.
- Scientists concerned or their institutions, requesting PFC's help in patenting or patent search should send a list of key word, a brief technical description of the invention and names and addresses (if possible) of agencies and scientist engaged in similar R&D work. This would ensure more extensive data search and saving in time. Information so furnished by inventors will be kept confidential.
- Queries on IPRs from individuals, government, university, industry, PSUs, R&D institutions and other agencies are quickly responded to.
- Advisory services are available to all.

Facilities

- Patent search facilities
- Databases on Indian patent applications filed and applications accepted.
- These are now available on-line (www.indianpatents.org.in) and on CDs entitled Ekaswa A & Ekaswa B.
- Mechanism for obtaining full text patent documents and patent searching elsewhere.
- Panel of patent attorneys drawn from all over the country for helping PFC in patenting activities
- Panel of expert faculty for patent awareness workshops
- Free of cost bulletin on IPR

B. ICMR Intellectual Property Rights Policy[33]

Preamble

The Indian Council of Medical Research (ICMR) is the premier autonomous organization of the Government of India for the planning, promoting, co-ordinating and conducting biomedical research in India. The objectives of the ICMR are in consonance with the national health policy and aim towards improving the health of the people of India through biomedical research.

The ICMR (established in 1911) is one of the oldest medical research organizations in the world with a broad mandate to acquire new knowledge through the conduct and support of biomedical research in all areas of biomedical research that would have a bearing on improving the health of Indian people. The Council carries out its mandate through its network of 27 permanent Institutes/Centers and extramural research support system to investigators in various institutes and medical colleges in India and active international collaboration.

Over the past nine decades, scientists working within and with support from the Council have been carrying out high quality research to achieve the objectives. Any new information/data generated in the laboratory are immediately published for its widest dissemination and application for public good.

Of late, scientists of the Council are becoming increasingly conscious of the need and importance of protecting such new knowledge generated through appropriate IPR systems before publication. Such an awareness has largely been triggered by changes like liberalization and globalization of economy and the encouraging participation of industry in the increasingly technology-driven medical research, and health care.

In addition, the realization that in the present context, public-private partnership could well be an important means of achieving the goal of providing affordable health care to the needy has reinforced the thinking that such joint ventures could help health care products reach the needy public more efficiently and quickly. For such partnerships to be viable and successful, it is essential that the Council has appropriate IPR, technology transfer and licensing policies in place.

Mission

ICMR thus recognizes and supports new intellectual property development and technology transfer as integral components of its mission and asserts that the guiding principle governing the conduct of these activities shall be the prompt and efficient availability of the products developed for the service of its mission.

Policy

To meet its objectives of improving public health through research, the ICMR will pursue an active policy of ensuring the most rapid and efficient development of new medical technologies developed by its scientists through seeking IP rights in India and abroad. The Council, as an agency of the Indian government, will ensure that its basic mission will not be compromised by its efforts to commercialize new technologies. Further, where research and development is not necessary to realize the technology's primary use and future therapeutic, diagnostic or preventive uses, IP protection may not be sought and instead those technologies can be commercialized through non-patent licensing.

The Intellectual Property Rights Unit in the ICMR Headquarters Office will help scientists in their efforts to identify, protect and commercially exploit all new knowledge generated with ICMR support. The IPR Unit would provide technical, legal and other support needed for IP protection, technology transfer, licensing and commercialization issues.

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[33] See also www.icmr.nic.in/ipr.htm

Major objectives

- To make scientists aware of the need and responsibility to protect new knowledge generated through IP rights, ownership of biological and other materials and data generated using ICMR funds and facilities.
- To develop procedures at ICMR institutions to capture, assess and protect new intellectual property generated.
- To provide ICMR scientists information on demand relating to patents in their areas of interest by maintaining appropriate national and international databases.
- To provide appropriate technological, professional and legal expertise and services to assist ICMR scientists to file patents in India and abroad.
- To encourage and provide all support to universities and other institutions for protecting and commercializing new knowledge generated with ICMR support.
- To develop a licensing policy that ensures the maximal public health benefit and a fair return on investment from ICMR research.
- To develop and implement a royalty policy at ICMR institutions that encourages innovative scientists and technology generators through a system of royalty sharing, and reward system.
- To serve in an advisory capacity to the Indian government on IP related issues concerning public health.
- To forge appropriate strategic alliances with national and international S&T agencies and industry to market its new inventions and develop professional knowledge networks for ICMR's technology management professionals.

Strategy

- Some steps to achieve the objectives are as follows:
- Appropriate internal and external systems would be set up at various ICMR Institutes/Centers for the identification of new IP before publication.
- Innovation-driven research would be encouraged through a IPR-friendly climate. Scientists would be made aware of need for prompt IP protection before public disclosure, through personal contacts, regular training workshops, seminars, etc.
- To help promote a sound IPR system, some basic and essential practices like record keeping, appropriate recording of data, maintenance of laboratory handbooks etc. will be encouraged at various ICMR Institutes.
- The IPR Unit would be engaged in regular monitoring of the Indian and global patent scenario to keep track innovations of the world.
- The advice of experts would be sought for furthering the objectives.

C. Recommendations from the First All India Technology Managers' Workshop & Retreat

March 11-14, 2002, Neemrana Fort-Palace, Rajasthan

1. Awareness about IPR should be a continuing process
2. IP and technology licensing would be situation, institution and technology specific. Therefore each institution should workout its own policy for valuation, license negotiations and identification of companies

3. There are many groups in the country working in the fields of IPR and technology management in different universities and R&D institutions. There is a need for more interactions among these groups. It is recommended that these group can form a society of IP and technology managers (Indian Society of Technology Managers (ISTM))
4. A portal may be created which should act as a virtual discussion forum through which participants of this workshop could share their experience, case studies, different types of model agreement (licensing, MTA, etc.) and any other topic of benefits to participants. The portal will be available to people from other institutions working in this field.
5. More such workshops should be conducted involving many more institutions and practicing IP and technology managers, occasionally also with research directors from companies in research-intensive industries (Agriculture, Health, electronics, etc.). These may be organized jointly by TIFAC and US Department of State (Subject to availability of funds).
6. IPR culture must be integrated as an essential component of R&D efforts of an institution. Each academic and research institution should create an enabling mechanism for undertaking IPR activities.
7. Identification of inventions in these institutions should be given utmost importance, which would necessitate extensive training of research faculty and professionals involved in IPR and technology management in patent searches. Such expertise should be developed in all institutes.
8. Scientist-scientist and scientist-student contacts were considered- important parameter for facilitating IP and technology licensing. Each academic institution should develop a dynamic database of its alumni, which should be used for identifying licensees.
9. In order to facilitate licensing of IPR and technology from University/R&D institutions to industry, a need for evolving common principles and formats for licensing was strongly felt.

D. 2003 Government of India Science and Technology Policy

Selected Highlights on IP Management

Policy Objectives:

- To encourage research and innovation in areas of relevance for the economy and society, particularly by promoting close and productive interaction between private and public institutions in science and technology.
- To establish an Intellectual Property Rights (IPR) regime which maximises the incentives for the generation and protection of intellectual property by all types of inventors. The regime would also provide a strong, supportive and comprehensive policy environment for speedy and effective domestic commercialization of such inventions so as to be maximal in the public interest.

Implementation Strategy:

- A comprehensive and well-orchestrated program relating to education, R&D and training in all aspects of technology management will be launched.
- Every effort will be made to achieve synergy between industry and scientific research. Autonomous Technology Transfer Organizations will be created as associate organizations of universities and national laboratories to facilitate transfer of the know-how generated to industry. Increased encouragement will be given, and flexible mechanisms will be evolved to help, scientists and technologists to transfer the know-how generated by them to the industry and be a partner in receiving the financial returns.

- Intellectual Property Rights (IPR), have to be viewed, not as a self-contained and distinct domain, but rather as an effective policy instrument that would be relevant to wide ranging socio-economic, technological and political concepts. The generation and fullest protection of competitive intellectual property from Indian R&D programs will be encouraged and promoted.
- The process of globalization is leading to situations where the collective knowledge of societies normally used for common good is converted to proprietary knowledge for commercial profit of a few. Action will be taken to protect our indigenous knowledge systems, primarily through national policies, supplemented by supportive international action.
- For this purpose, IPR systems which specially protect scientific discoveries and technological innovations arising out of such traditional knowledge will be designed and effectively implemented.
- Our legislation with regard to Patents, Copyrights and other forms of Intellectual Property will ensure that maximum incentives are provided for individual inventors, and to our scientific and technological community, to undertake large scale and rapid commercialization, at home and abroad.
- The development of skills and competence to manage IPR and leveraging its influence will be given a major thrust. This is an area calling for significant technological insights and legal expertise and will be handled differently from the present, and with high priority.

E. Setting up of the IPR and tech transfer activities at the Indian Council of Medical Research, New Delhi

The Indian Council of Medical Research (ICMR) is the premier agency in India for the formulation, promotion and conduct of biomedical research in India. The ICMR, established in 1911, is one of the oldest medical research agencies in the world and was set up a year before Medical Research Council (MRC) of the United Kingdom. The ICMR has a network of 27 research institutes spread all over India that address disease-specific and discipline activities.

During its 90 odd years of existence, scientists of ICMR have made several significant contributions to advancing frontiers of medical research and find solutions to serious public health problems. However, in common with other scientists in India ICMR researchers also have traditionally held strong belief that new information and knowledge should be freely and widely disseminated. More so, if the research happens to be supported with public funds and is expected to be of direct or indirect impact on public health. Not surprisingly, the moment there is an exciting finding; it would be immediately published in a learned journal to enable its widest dissemination. That new knowledge generated could be protected through instruments of intellectual property rights has been rather alien to many established scientists in the best of institutes. In addition, having any systems of monopoly over new knowledge which restricts free access to others has been not very palatable, until very recently. In that sense, patents and other forms of protection were never considered as serious options to publication among the scientific community.

But a series of events in the recent past that pushed the world towards a new global economic order triggered new thinking among the society at large including the scientific community. The signing of the GATT treaty by India in 1996 and the eventual membership of the World Trade Organisation is perhaps first event. The signing of the GATT treaty that contained the contentious Trade Related Intellectual Property Rights (TRIPS) set off a fierce national debate on the IP rights. Several non-Governmental organizations in India expressed serious reservations on what is the first step of India's hesitant attempt towards globalization. One of the major concerns was the fear and apprehension that the new IPR regime would drive the drug prices beyond the reach of the common people. Also, the deadline of 2005 for India to become fully WTO compliant with appropriate amendments to the prevailing patent regimes and apprehension that multinational drug companies will monopolize the public health system increased the anxiety levels of the Indian public, and the policy makers. It had an interesting spin-off; enhancing the awareness of the scientific community, including ICMR scientists of the protection of new knowledge and its associated benefits and drawbacks. There were other events that brought things to a boil of the

need to protect indigenous knowledge from being exploited by others. The abortive attempt to patent the wound-healing properties of turmeric by two US-based Indians underlined the need for vigilance to and the urgency to find means of protecting knowledge through legal instruments. The legal battle in the US resulted in the revocation of this patent as it documented evidence was presented to show that turmeric was used for centuries in India for wound healing. The patenting of a plant with proven hepato-protective properties again in the US reinforced the thinking that intellectual property protection is an intrinsic component of doing science in a globalized world and India would perhaps only stands to gain by putting some legal framework on intellectual property rights in place. By late 1990s, there was a favorable climate for initiative steps towards IP protection and new technology generation.

The first step taken by the ICMR was the drafting a policy for working with industry and the transfer of new technology generated on commercial terms – the first attempt towards public-private partnership in its 90 year old history. A policy document was generated which envisaged working with industry. This policy document outlines modalities with which the ICMR scientists could interact with the industry and the terms and conditions on which new knowledge generated by ICMR scientists could transfer to industry, both on an exclusive or non-exclusive basis and the associated licensing issues. As a follow-up of the approval by the Government of India, a Technology Transfer Unit (TTU) was set up in 1996 at the ICMR headquarters to centrally promote, co-ordinate and monitor this first ICMR-industry partnership. In addition, the policy of rewarding inventors through a royalty-sharing policy on the revenue generated helped scientists recognize that new knowledge with potential industrial application can also have commercial value. Simultaneously, steps were taken to sensitize scientists of the need to identify new intellectual property and protect the new knowledge and that disclosure through publication would mean loss of their IP rights. They were made aware of the need to keep appropriate records of data generated as a mandatory protective measure against possible legal challenges and claims of priority. The ICMR researchers realized in a very over a short period that new IP and technology could be major driving forces for the overall development of the country besides benefiting them. A single window approach by the TTU to facilitate smooth transition of laboratory knowledge to industry encouraged many ICMR scientists to protect and exploit their new knowledge.

As a natural extension of the encouraging response to these initiatives, a full-fledged IPR Unit was set-up at the ICMR Headquarters in 2000 to take care of all IP-related activities of the Council. During this period, through the initiative of the Science Office of the US Embassy, services and advice of a senior technology manager of the National Institutes of Health, Bethesda, were made available to the IPR Unit of ICMR. The IPR policy of ICMR then being drafted was finalized. This policy document was released by the federal Minister of Health & Family Welfare, Govt of India. These new policy initiatives were widely appreciated by scientists within and outside the ICMR as it recognizes the importance of new knowledge besides outlining steps towards protection and eventual commercialization.

These new policy initiatives appear to have a snowballing effect on the scientists of the Council. Over a ten year period (1990-99) just 10 patents were filed by the ICMR scientists. But over the last two and a half years (2000-2003) as many as 19 patents including 5 international patents were filed. Over half a dozen technology negotiations were held and some products transferred to the industry. It has been very exciting to both the scientists and the IPR staff to be part of this new and very rewarding experience The new found vigor among ICMR scientists to recognize IPR as a legitimate tool for furthering science goes to show that what it was perhaps knowledge-gap that dissuaded them from exploiting new knowledge. More recent experience with a new HIV/AIDS vaccine initiative with public (India) - Private (US industry partner, Therion) – an international NGO (International AIDS vaccine Initiative, IAVI) showed that it is the generation cutting edge technology that can help a country acquire self-sufficiency in health care besides helping India become truly globally competitive.

In this brief period of less than eight years, there has been a perceptible change in the mind-set of scientists and a lot of skeptics have turned believers. This includes a large number of scientists and a handful of bureaucrats, who were initially rather cool to the setting up of minimal IP infrastructure at

the ICMR. No major concessions were made nor serious impediments created. Two significant factors, more by chance helped these new initiatives take off ground smoothly. When the first technology transfer policy document was taken before the Governing Body of ICMR, the highest policy making body in 1996, it was cleared with surprising ease. This was because the then federal Minster of Health & Family Welfare was an industrialist-politician who understood the language of new technology, commercialization and how new knowledge could be converted into money. His unflinching support virtually preempted any possible serious and normal bureaucratic road-blocks. The second major significant historical event has been the presence of a dynamic Director-General of ICMR during these exciting times. He virtually guided and strongly supported the IP activities smoothly to its present stage. It is due to his encouragement and unstinted support that the Council which at one time was a publication-oriented agency has become patent savvy and a vibrant technology-generating organization. The DG very strongly supported the policy as he believed that to remain globally competitive, ICMR scientists should not only do research that pushes the frontiers of science but generate create cutting-edge technology and in the bargain generate wealth for the Indian Council of Medical Research and India.

The Role of Milestones in Licensing Deals to Assure Access to Health Products in Developing Countries [1]

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Executive Summary

IP management to optimize public sector benefits needs to balance the commercial interests of private sector manufacturers with the needs of the public sector to obtain access to products at lowest possible costs. Most of the intellectual property (IP) oriented towards generating public sector benefits in the healthcare sector and biotechnology results from R&D in public-sector research centers and international organizations. Through adequate management of the resulting IP the public sector can benefit from its R&D investments through availability of the most modern products at conditions that are beneficial for the developing world, thus eliminating the otherwise significant access barriers.

An important tool of adequate IP management between public sector and private sector partners is the detailed definition of contractual milestones when it comes to licensing out IP from the public sector to private sector companies with the goal of producing products based on or incorporating the IP. This article describes in detail the considerations that lead to successful milestone definitions and discusses

[1] Oehler J. 2004. The Role of Milestones in Licensing Deals to Assure Access to Health Products in Developing Countries. *IP Strategy Today* No. 10-2004. Pp. 59-70. www.bioDevelopments.org/ip

important factors related to pricing to the public sector; territory and exclusivity; regulatory work and data; time to market; royalties; and terms and termination of licensing agreements.

One of the underlying assumptions for everything that is outlined above is that milestones are not cast in stone. Milestones should and need to remain adjustable throughout the lifetime of a license agreement according to project development, changes in the market environment, and other factors that can't be anticipated completely. When it comes to the detailed specifications of individual milestones, it does not really matter if you are choosing an absolute or a relative goal, and which definitions to finally select. What matters is to get the commitment of a private sector company to realize public sector targets. It is important to have a working set of adequate milestones in place, to define review periods for performance assessment by your contract partner, and to be ready to be open to and to accept milestone revisions when new, solid evidence requires a change of rules to keep the product and public sector goals alive. Such result oriented milestones require very intensive preparations, detailed knowledge of processes related to the development and marketing of the product, detailed knowledge of markets, realistic anticipation and forecasting of product potential, the persistence for quantitative forecasting and for establishing a master plan for the entire product roll-out, and a mission-driven mindset to establish the optimum public sector goals and to prevent the public sector from losing out to commercial thinking.

Successful public-private partnerships are being built on value propositions from the public sector to the private sector partners that take advantage of the inherent capabilities of public sector organizations. It is the task of the public sector IP manager to identify the relevant capabilities that are important to a particular public-private partnership, and turn these capabilities into specific value propositions that help the private sector partner to realize its commercial goals, but without sacrificing any potential benefit to the public sector. In this context, it is especially important to overcome the common phenomenon of further "marginalization of the poor" in the small and smallest countries of the developing world. In a commercial environment it is market attractiveness that rules priorities. In a public-sector context, the poor in the smallest countries have the highest needs to get access to affordable products. Adequate and successful IP management of public-sector generated IP needs to bridge these two opposites. The experiences of the Concept Foundation, which are the platform for this article, show that this is possible.

1. Introduction: The Importance of Contracts

For parties entering into agreements of any kind, the primary assumption of contractual relationships is that the principal subject of their deal will be realized successfully. In terms of assumptions and remedies, contractual agreements differ considerably in quality and substance for cases when unforeseen and adverse effects prevent the contractual partners from reaching their goals. Too many contractual relations go sour because when everything seems predictable partners rush into agreements without carefully thinking about contingencies.

Without an early elaboration of clear provisions for contingency planning and crisis management, this "honeymoon" trap is why many contractual agreements contain unclear, foggy language and omit definitive, detailed, and enforceable conditions concerning not only the contractual rights but also the obligations of each partner and the specific countermeasures to be taken should one party run into difficulties in fulfilling its part of the deal. Instead, "best efforts" clauses or provisions for consultations to solve problems case by case are used so as not to spoil the initial enthusiasm when the agreement is being established. This can be a sure recipe for disaster when the unforeseen strikes, especially if the mechanisms to settle disputes over differing opinions about contractual performance are not clearly specified.

A typical contract specifies the subject matter, the rights and obligations of each party under the agreement, and the duration and terms. Licensing agreements between two organizations identify, among many issues, the nature and scope of the intellectual property or product that is licensed, spec-

ify the territorial grant to the licensee where the licensed product would be made available, and the terms under which the Licensor receives financial compensation from its licensee(s).

A practical example is the use of technical know-how or the results of scientific research that represents the particular intellectual property of a Licensor and is to be licensed out to a commercial company able to create a product from this IP and to distribute this product to consumers and users. The interests of both parties in this arrangement are straightforward and advantageous for each partner—it is a win-win situation. This ordinary, idealistic assumption prevails at the beginning of any licensing deal. All too often, however, reality thwarts the goals of the initial agreement for the times planned or forecasted, and the contractual partners are left with a subset of the original targets.

Such contracts between private and public sector entities must also consider that the commercial interests of private sector companies are on the whole oriented towards maximizing profitability. Accordingly, it should not be expected that private sector businesses will automatically provide the best services to the public sector or that they will focus on the generation and use of intellectual property to maximize public sector benefits. To prepare for situations when the original targets of a license agreement are delayed or not achieved, and to avoid situations when projected public sector benefits are delayed or unrealized, it is good practice to establish contractual milestones that regulate target achievement under the license and set incentives for keeping to timelines and performance goals. This allows both the Licensor and licensee(s) to focus resources on their efforts to perform as initially agreed.

Additionally, it is very useful to spell out the level and conditions of fines (monetary or otherwise) to be paid when a partner does not fulfill obligations. This should include a mechanism to prevent prolonged periods of quarreling over differing opinions and arguments over performance that would halt product development or marketing efforts and ultimately hurt the public sector.

Most important milestones cover:

- Pricing to the public sector
- Territory and exclusivity
- Regulatory work and time to market
- Royalties
- Terms and termination of the license agreement

2. The Great Divide in Business Models: Public Sector–Industry

The discussion between the public sector and industry is a cross-cultural event, no matter how well public sector players think they understand industry. In such a cross-cultural environment, there is nothing more dangerous and productive of misunderstanding than to "assume the obvious", since what is obvious for one person with a public sector background will not necessarily be the same for the other partner. Do not leave obligations and contractual performance to "best efforts" and "common sense"! It is much better for both partners to specify in writing exactly what the public sector wants to achieve with a commercial partner, detailing when and how this will be achieved and specifying related penalties. If the agreement specifies only best efforts and unspecified performance, disaster threatens!

Value Propositions Stimulate Collaboration

To manage intellectual property for maximized public sector benefits requires balancing the expectations of the public sector to obtain products at the lowest possible prices, excellent quality, and in sufficient quantities, with the expectations of private sector companies to generate a satisfactory rate of return on their manufacturing and marketing efforts.

Important value propositions for pharmaceutical companies are:

- *Save time to market*: An earlier market entry means higher market share opportunities for the company and ultimately more sales. Example: Pharmaceutical and/or clinical research using an existing network of public-sector institutions in parallel speeds the generation of results needed for drug regulatory approval without the lead time required to approach new, unfamiliar trial sites and train in GCP (Good Clinical Practices).
- *Save resources*: Reduced need for internal company resources means a lower cost burden for the licensee and improves the bottom line. On the other hand, when investment levels are maintained more parallel activities are possible with the same amount of resources, helping to increase the company's commercial output. Example: existing public-sector distribution networks, formal or informal, allow a product to reach a large public-sector market very quickly without the costly build-up of a supply chain.
- *Save investments*: A reduced need for investments means better cash flow utilization within the company, which is very important for investors.

Any plan for a value proposition must deal specifically with the nature of the partnership, and a successful proposal must present an **authentic and actual value** to a potential partner. These authentic and actual values need to be based on the set of capabilities, which actually are the platform for all actions that results in value creation, that the public-sector organization could offer and on what needs of the private-sector partner could be met by a public-sector partner. Such genuine values include the examples above: "save time to market", "save resources", and "save investments." As these demonstrate, it is important to look behind the immediate and apparent "face" value of individual capabilities in the public sector to be able to identify and compose the true value contributions. Indeed, an authentic value proposition is more often composed of several contributions from various capabilities than a single value factor.

It is very helpful to understand all the specific values at a very early stage of approaching potential licensing partners that drive an industry and that are particularly important for the potential licensee. A detailed analysis of these values and alignment with existing public-sector capabilities help to identify the value propositions that public-sector organizations could offer their private sector partners.

3. The Most Important Milestones

3.1 Principles

The management of intellectual property for maximized public sector benefits has three key aspects:

- Definition of the geographic coverage for marketing the product (i.e., territory)
- The claim for product exclusivity by the private sector licensee(s)
- The definition of the preferred public sector price or other public sector benefit

These headlines seem very straightforward. It is easy to imagine that the partners in a license arrangement agree on a set price for the product for public sector distribution, agree on the names of the countries where the product could be sold, and that as a result the private sector company as licensee obtains the exclusive rights to marketing and sales of the product in this territory. However, in real life, this does not necessarily mean a maximization of public sector benefits.

Some key questions need to be answered to safeguard the maximization of public sector benefits:

- How well will we reach smaller countries with our product?
- How well will we reach the rural population in developing countries that, by all experience, normally remains underserved?

- Who will be the beneficiaries that can obtain the product at a special public sector price?
- How can we assure that we obtain the product at prices that public sector agencies can afford?

The principal way to address these issues is to set contractual milestones that prevent the marginalization of the poor in smaller countries, regulate public sector access, and set the geographic coverage for all countries in a territory (even in countries and regions that commercially are not interesting enough to generate sizeable returns on investments and would therefore normally not be served). Finally, there needs to be a clear framework to compute the manufacturing cost.

Due to commercial pressures, there is an inherent danger of putting the private sector and its commercial interests before those of the public sector. This danger mainly results from attempts to simplify the private sector partner's participation because of fears about failing to make a deal. While simplifying agreements is good practice, establishing specific contractual milestones and clarifying them under the terms of an agreement are not necessarily complications. Success requires focusing on the targets to achieve and on the issues to exclude. A tight focus will secure simplicity of the provisions and regulations without overburdening an agreement.

When it comes to public sector benefits, making a product available or how quickly it reaches markets does not constitute progress. It is how many people the product will reach, how easily it will be available, and who can afford the product at what pricing level that defines success. The goal is to reduce morbidity and mortality to the greatest possible extent. For the public sector, This is the ultimate benefit of product development. The necessary achievements for obtaining this outcome need to be clearly specified as milestones in the agreement. Accordingly, we will take a closer look at territory, exclusivity, and pricing.

3.2 Territory and Related Aspects

A typical license agreement will specify the grant of the license in one of its early paragraphs. Language such as "LICENSOR grants COMPANY the rights to manufacture and sell the PRODUCT into the PRIVATE SECTOR and PUBLIC SECTOR markets of the TERRITORY" is commonly used. The terms LICENSOR, COMPANY, PRODUCT, PRIVATE SECTOR, PUBLIC SECTOR, and TERRITORY are used according to the definitions in the introductory "Whereas" chapter to the agreement.

Under this wording, the license grant is established as a right of the licensee to the product. However, it doesn't specify the obligation to sell into the territory. This is a very important issue of practical IP management for public sector benefits. While it is reasonable to assume in case of a "one-product, home market" manufacturer that the licensee will introduce the product into this (single) market, it is not necessarily true that a licensee will introduce the product into all markets of a multi-country territory, especially the public sector. This failure to reach all the desired markets may result from various factors that were not known or were underestimated at the time when the license agreement was established.

Between the signing of a license agreement and the commercial rollout of the product, a considerable period of time may be needed for product development, manufacturing scale up, and drug regulatory approval for a pharmaceutical. Depending on the capabilities of the licensee, this time period may well extend over several years. During this time the company's business and the business environment may change significantly, and resources that originally were available for dealing with the product may have been partially redirected to other, possibly more profitable, products and projects. Markets that initially seemed very attractive may lose their appeal over time compared to other opportunities since recognized by the company.

Changes in the business environment and business focus may affect the licensee's commitment to serve the public sector as originally envisioned for the entire territory. To avoid negative consequences for

public sector availability and public sector access to the product in the territory, it is only prudent to establish the license grant as an obligation to sell the product into the public sector of the territory—not just as a right of the licensee. This can be accomplished in various ways:

- One possibility is to separate the grant of the "rights to manufacture the product" from the "obligation to sell the product into all countries of the territory". Emphasis here should be on *all countries* in the territory.
- Another possibility is to assign milestones to the execution of the sales rights for the product under which the licensee would gain access to other countries. Only after showing defined success according to the milestones the licensee would be granted additional sales rights for other countries.
- Public and private sector rights to selling the product could be dealt with in separate regulations that capture the priority for the public sector organization of having the product introduced into the public sector to a satisfactory level (to be defined by an adequate milestone) in one country before additional rights to markets – public and private- in other countries would be granted.

The license grant could specify, as example, the rights of a Brazilian manufacturer to produce and sell the product in Brazil, its home market, and the rights to sell it in other Latin American countries when certain conditions are met. A wide range of options for these conditions are available and could be specified in the license agreement, such as:

- *Market share*: licensee will gain the rights to sell into other countries after establishing a market share of 20% in the specific market segment, as reported by IMS[2].
- *Market position*: licensee will gain the rights to sell into other countries after positioning the product among the top 3 products within its category in the Brazilian market, as measured by analyst reports.
- *Sales volume*: licensee will gain the rights to sell into other countries after an annual sales volume of 5 million units is realised in the Brazilian market, as measured by cumulative sales reports from distribution agents.
- *Public sector penetration*: licensee will gain the rights to sell into other countries after the total output/annual output into the public sector in Brazil has reached 10 million units, as measured by procurement orders from public sector agencies.

In addition to the milestones for gaining the rights to sell in additional countries, the remaining countries in the licensed territory could be prioritized in order of importance for the licensee, or eventually the Licensor as well. Each country on the list will then be characterized by individual milestones that need to be reached by the company before it could sell in an additional country. These country priorities and milestone definitions should be set initially when signing the license agreement, with the option to revise the priorities and milestones after a certain period.

It is unwise to leave country priorities or milestone definitions open and uncovered for the sake of higher flexibility (e.g. saying, that the next country priority will be set shortly before reaching the last defined milestone in the actual country of activity, or a similarly flexible model that postpones decision-making). This carries the risk that it might get more and more difficult to reach the necessary consensus between licensor and licensee about country priorities and milestone definitions, especially the closer the country of choice is to the bottom of the priority list. The licensee might then no longer desire to sell in a particular country, and especially into the public sector, due to various, possibly hidden reasons, which would run contrary to the goals of the public sector organization at that time. In a flexible licensing model, if milestones had not been mutually defined before such a situation emerges, the private-sector company would not violate the license agreement if the necessary consensus about mile-

[2] IMS is an international firm that publishes reports on pharmaceutical sales by conducting pharmacy audits and other means.

stone definitions cannot be reached between the contract partners, and could walk away from its responsibilities to serve a particular country.

On the other hand, priorities and milestone definitions may change over time in a fast moving business environment and they might not be considered valid after several years in the lifetime of a license agreement. This is a common perception when it comes to the definition of priorities and milestones, especially among advocates of "real-time" implementation. Given the need to eventually define priorities and milestones, to protect public sector access to the product everywhere as far as possible, and the inherent dangers of leaving important parts of an agreement initially undefined pending a mutual understanding at a later time, it is close to irresponsible to skip over these definitions and omit them from the initial version of the signed license agreement. One can provide for a regular update of the details of these conditions, when a changed environment, for example, calls for revisions. At that time, however, it would be up to the licensee to demonstrate the need for changes and to prepare a detailed proposal of what to change and how to change it. Unless the proposed changes bring up compelling and convincing reasons for the licensor, the original definitions of priorities and milestones will prevail. The originally anticipated public sector goals and benefits remain in force without alteration and are still to be realized by the licensee.

Initially defining contractual priorities and detailed milestones is, of course, a painful process that requires very intensive preparations so that the essential aspects of public sector needs are not overlooked. This phase of desk research and information collection is among the most important phases for adequately preparing license agreements serving public sector interests. For initial negotiations between parties, it is most appropriate to roll out the terms of a licensing arrangement in all related details, even though it may be difficult and resource-intensive to formulate all of them. Calls from the contract partner or one's own tendencies to postpone detailing specifications or omit the necessary depth of description for the benefit of simplifying and quickly reaching an agreement are not beneficial for establishing the necessary framework of an efficient and ultimately effective public sector oriented licensing arrangement. If it is not possible to reach an agreement on staggered priorities with detailed milestones in the beginning of the contract relationship, how can these differences satisfactorily be ironed out later?

3.3 Avoiding the Marginalization of the Poor in Small Countries

For commercial companies, large markets dominate priorities and occupy the top spots of territorial ranking, while small countries regularly end up at the bottom of the priority list. In a commercial environment, market attractiveness rules priorities. The needs of the poor and of public sector agencies in small countries do normally not represent attractive markets for companies that are expecting to generate sizeable commercial returns out of their manufacturing and marketing efforts. It is necessary for a Licensor to ensure that product access is not limited to larger markets only and that small countries will also be covered to avoid further marginalizing the poor.

When it comes to the territorial grant of a license agreement aimed at maximizing public sector benefits, this particular issue needs to be considered thoroughly by the licensor. The prospect of substantial profits from product sales into the private markets of any territory is an important issue for awarding the licensee commercial advantages under the license agreement. However, the territorial grant must not only cover large countries and their sizeable private markets -as main incentive that the public sector would be reached as well -, but needs to also include small countries and their public sector markets that normally would remain uncovered by the private sector partner. It is vital for an effective territorial grant to contain a mix of large and small markets to balance the commercial potential for the licensee against the humanitarian need of the public sector to provide access for the poor to affordable and effective products also in those countries that are commercially not attractive. This particular need is left to the protection of the licensor as the guardian of public sector interests.

It is a good practice, therefore, not to grant sales rights in large countries to a single licensee without including the obligation to also serve the markets and the public sector in the smallest countries. Should a single licensee be unable to cover all the markets of a region, an appropriate segmentation of the entire region needs to ensure that two or more licensees each get a profitable share of it to assure that the public sector in the smallest countries will also be served. As outlined above, this goal needs to be adequately supported by specific milestones.

The upfront definition of territorial milestones is often skipped or neglected to the public sector's disadvantage. One very common reason for this is that the primary needs of the public sector are spread over a wide territorial area and/or over a variety of minority groups in dire need for services. Satisfactory coverage requires a multitude of distinctive priorities and characteristic milestone definitions, which places a burden of initial definition on the license partners, especially the licensor as guardian of the public sector interests.

One strategy for expanding territories is for the licensor to generate sales to public sector agencies in countries that are not covered by the initial territory grant but very much need the product. This approach has the following advantage: the licensee can focus on the obligations and related milestones under the license agreement without dilution through multiple targets, while the licensor seeks to serves public sector agencies outside the territory. If desired, this additional market may be assumed by the licensee.

An issue for special consideration is the setting of a quantitative goal for public sector sales. The licensor could use absolute or relative target figures for the size of the public sector sales. A good target figure is the market share percentage reached after a certain time from product launch. Another possibility is to define the sales growth reached in the first years on the market. You could use the sales volume after 1, 3, or 5 years on the market to characterize the expected—and initially agreed upon—success of product introduction. You could specify, for example, that the product should be among the top three products within the specific market segment in its third year of introduction.

Competitiveness in the private sector is an important success factor for any product. Licensees need to gain highest levels of competitiveness in private sector markets for being able to reach their commercial objectives. This will –in return- support a very competitive manufacturing cost structure, which ultimately provides the public sector with lowest possible cost. It is therefore adequate to also express public sector goals by measuring private market targets.

Another way to set milestones for performance in the public sector would be to set sales volumes in the private and public sector in relation to each other. A powerful milestone definition is to specify, for example, that public sector sales reach 40% (or any other agreed upon ratio) of the sales volume for the private market within three years after product launch.

With respect to public sector availability, it is mandatory to specify expected launch dates for the product. For example, the license agreement could stipulate that the product be made available in the public sector not later than two years after signing the agreement. In case a product requires initial sales in the private market for any reason, an adequate requirement for public sector introduction could be "*…not later than X years after private sector launch.*" For multi-country territories, individual requirements for each country would need to be established and defined.

Remedies for unmet milestones need to be part of the license agreement. One effective remedy is to significantly increase royalties on sales in the private market when a milestone has not been reached.

3.4 Exclusivity

Exclusivity is one of the first things that companies ask for. It is important to link such requests with specific milestones. Such milestones can be:

- The volume of sales reached in (a) market(s) after a certain time period from launch or signing the agreement.
- The level of market share reached against competition.
- The level of market share established in a new market segment, measured against the total product potential.
- The level of coverage of different regions in a large market or across different countries of a region.
- The latest date of product launch into a market that will secure product/technology exclusivity for the company in general, for a selected territory, etc.

Equally important to setting specific milestones is to specify penalties and fines for the licensee if these milestones haven't been reached. Examples are:

- Temporary increase of royalties on private sector sales until the milestone condition has been reached.
- Loss of exclusivity for the product or technology and conversion to a non-exclusive license in general or for a specific territory.
- Loss of exclusivity and territory to a competitor.
- Payment of a fine in a predefined amount for the failure to introduce a product into a country under exclusivity for the licensee.

It is good practice to evaluate the request for exclusivity against the level of public sector benefits that a potential licensee could deliver. Again, it is unreasonable to expect that a private sector company will concentrate major resources on serving the public sector as long as there are no specific obligations in a license agreement or adequate milestones have not been defined. Since the request for exclusivity is made to protect the commercial potential of a market place, the public sector partner has the right in a *quid pro quo* to ensure the protection of public sector needs. It is especially important for the public sector partner to understand, and eventually to regulate in the license agreement, what kind of resources-qualitatively and quantitatively-the private sector company will make available and mobilize to work in the public sector segment of the exclusive territory.

3.5 Pricing for the Public Sector

A key issue for the public sector in developing countries is the affordability of products that are brought into the market. Prices must ensure the widest possible availability. Price calculations are done differently in the pharmaceutical industry than in the public sector. Pharmaceutical companies commonly use a retrograde calculation scheme. They base product prices on the perceived purchasing power of the target segment in a market. Manufacturing costs are not a major factor for the price calculation. Overhead and marketing costs are usually higher than production costs and need to be well offset by product pricing. Adequate product positioning into affluent markets to a large extent determines achievable margins and operating profitability. The public sector, in contrast, mostly uses the cost-plus model for price determination. Manufacturing and organizational infrastructure contribute significantly to costs. Sales and marketing costs are kept at the lowest possible levels so as not to burden the product price. A reasonable but small rate of operating profit is added on top of these costs to determine the product price. With the purchasing power of the public sector under severe limitations, a price determination along the lines of a cost-plus model is the method of choice.

An effective license agreement needs to employ a detailed cost calculation model. The aim of this cost calculation model is to understand all directly and indirectly attributed product costs that contribute to final cost. By applying this tool and marking up the ex-factory product price with a mutually accepted profit margin for sales into the public sector, a reasonable platform for the determination of the lowest possible public sector price can be achieved. For indirect costs it is necessary to determine if the cost

burden on the product is fairly allocated. Private sector pricing of the product is entirely up to the discretion of the manufacturer and not a public sector concern.

It is good practice to mandate the regular submission of manufacturing cost reports and product cost calculation details on an annual basis. Furthermore, it is important for the Licensor to reserve the rights to have these cost reports audited by independent auditors.

Should a manufacturer be unable to match expected price levels for the public sector when the company begins manufacturing and is still at the beginning of the learning curve, it is necessary to set a definite time line for when expected price levels must be reached. Adequate penalties have to be in place for this case. It is important to recognize that a license agreement can not be a tool to force a manufacturer to produce a product below cost, however, the detailed agreement on the manufacturing cost calculation model and the overall pricing structure for the product will eliminate related concerns.

The licensor should define which institutions are the public sector organizations that can obtain the product at the preferred price. For pharmaceutical products, it should be clearly defined if these public sector organizations are only ministries of health, government purchase organizations, public sector hospitals, and similar institutions, or if non-government agencies with charitable functions, social marketing organizations in a country, international organizations with a humanitarian mission, and other institutions are also potential beneficiaries. The license should define how these agencies and organizations will be informed about the availability of a preferred public sector price for the product.

3.6 Regulatory Work and Time to Market

Pharmaceuticals are subject to drug regulatory approval by health authorities. The time needed for the regulatory approval process prolongs the period for a product to reach a market. It is a good practice to stipulate in the license agreement when the licensee must bring the product forward to registration, and it is best is to specify within what time period after signing the license agreement the licensee has to forward a complete registration filing to the relevant authorities. For a multi-country territory it is vital to specify the sequence of registration filings in the various countries and the maximum time allowed between individual filings.

It is also advantageous to specify how much time may pass after a registration approval has been obtained until the product is actually launched into the public sector. This prevents the unusual, but realistic scenario of a licensee “sitting” on its rights and not utilizing them for the benefit of the public sector.

4. Conclusions

4.1 Setting Tough Milestones for a Tough Industry

Finally, some thoughts about milestones for the cautious few who feel uncomfortable with the idea of setting tough milestones in a tough industry.

One of the underlying assumptions for everything that is outlined above is that milestones are not cast in stone. Milestones should and need to remain adjustable throughout the lifetime of a license agreement according to project development, changes in the market environment, and other factors that can’t be anticipated completely. When it comes to the detailed specifications of individual milestones, it does not really matter if you are choosing an absolute or a relative goal, and which definitions to finally select. What matters is to get the commitment of a private sector company to realize public sector targets. It is important to have a working set of adequate milestones in place, to define review periods for performance assessment by your contract partner, and to be ready to be open to and to accept mile-

stone revisions when new, solid evidence requires a change of rules to keep the product and public sector goals alive.

Such result oriented milestones require:

- Very intensive preparations
- Detailed knowledge of processes related to the development and marketing of the product
- Detailed knowledge of markets
- Realistic anticipation and forecasting of product potential
- The persistence for quantitative forecasting and for establishing a master plan for the entire product roll-out
- A mission-driven mindset to establish the optimum public sector goals and to prevent the public sector from losing out to commercial thinking

In a process oriented sense, milestones represent and define the Standard Operating Procedures (SOPs) of organizations that have voluntarily subjected themselves to certification procedures, such as ISO. Why shouldn't the public sector also define such SOPs for important targets of a license agreement? It is crucial to recognize that public-private partnerships are NOT the magic solution for tasks that have not been well enough specified! In this sense, public-private partnerships (PPPs) should not represent a poor substitute in absence of specific targets for public sector benefits.

4.2 Achievements of the Public-Private Partnership Model:

The Work of the Concept Foundation to Close the Medicines Access Gap Specific to Developing Countries

The role of Public-Private-Partnerships (PPPs) as an innovative approach to the discovery, development and distribution of health products, drugs and vaccines for developing countries has been emphasized repeatedly in various publications, and around 86 PPPs (see www.ippph.org for a complete list) have been established worldwide in the meantime. However, PPPs' accomplishments as indicators for the PPP model to succeed in its goal are rarely publicized, partly because most of these entities are relatively young. Half of these partnerships have been established in the past few years since 1999 (www.ippph.org). This is a very short period of time in a pharmaceutical R&D or health care environment where normally times to market are ranging from not less than 10 to around 12-15 years on average.

The Concept Foundation (www.ConceptFoundation.org) was established in 1989 through an initiative funded by WHO's Special Programme of Research, Development and Research Training in Human Reproduction (WHO/HRP), with the support from PATH/PIACT and additional funding by the World Bank and the Rockefeller Foundation. The mission is to "Provide access to top quality reproductive-health products for developing countries at lowest possible prices and realize maximum public sector benefits through the management of intellectual property and technology transfer for contraceptives and pharmaceuticals that otherwise would not be available to the public sector with the intended quality and prices". Concept Foundation has accumulated extensive experience with project management of health technologies development and with technology transfer to roll-out new technologies in the developing world.

The R&D process for product development of new drugs, vaccines and also diagnostics in the diseases of poverty is a crucial step towards ultimately eradicating the disease burden in the poorest regions of the world. Many PPPs concentrate their efforts on the product development approach, and the largest product development PPPs have successfully raised (in combined figures) more than half a billion US dollars in recent years to acquire the R&D funds needed to fuel their development work. However, product delivery is an equally important, if not even a more decisive, factor of access to medicines, and

most product development PPPs are not active in delivery of their products into local health infrastructure. There are no significant experiences reported with the downstream issues involved in bringing products into markets there where they are most needed.

Future concerns for product development PPPs to solve will be how to handle and finance downstream issues for introduction and launching new products in diseases of poverty to close the medicines access gap for public health services when public health factors, such as:

- adequate health infrastructures,
- disease surveillance,
- compliance monitoring,
- education and training of health workers and medical staff,
- improving health care facilities,

and similar issues come into play, besides further important soft factors such as

- physical distribution networks,
- satisfactory supply volumes,
- adequate volume forecasting,
- minimizing product waste at the point of treatment,

and others, to name but a few of the most important issues to deal with.

As we know well from the experiences in pharmaceutical industry, a significant and decisive part of the cost structure for new medicines is related to bringing a new product to markets through effective and successful programs of marketing and distribution. While nobody would expect the need to create market demand (= invest marketing dollars) for new products to fight diseases of poverty, the inability of the poorest regions high in demand for effective medicines to pay for new products and the supply, distribution, as well as surveillance problems to reach all who need treatment, will demand huge additional investments and other type of public-private partnerships at work on the downstream issues before all goals are being reached.

These efforts must include reaching lowest possible manufacturing costs for the ability to forward preferential pricing to public health services and closing the medicines access gap in the developing world, establishing sustainable manufacturing with a continuous system for quality monitoring and creating a business model, financially attractive to private pharmaceutical companies, to overcome the disincentives from poor expected return by operating in public sector markets. The achievements of the PPP business model exercised by Concept Foundation to realize these goals, dealing with the downstream issues around product delivery, demonstrate broad success in the principal goal to close the medicines access gap for developing countries.

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