American Academics and the Biotechnology Revolution: Commercialization of Breakthroughs under Bayh-Dole

Good afternoon. It is wonderful to be in such illustrious and accomplished company at the Indian Science Congress here in Chandigargh. I would like to thank both Dr. Ananda Chakrabarty for inviting me to participate in today's session, as well as the organizers and hosts of this year's Indian Science Congress, the Panjab University, Chandigargh, the Institute of Microbial Technology, Changigargh, and the Indian Science Congress Association.

The theme for this year's session of the Congress: "Science and society in the Twenty-First Century: Quest for Excellence," is especially significant. As a non-scientist, here on behalf of PhRMA, the Pharmaceutical Research and Manufacturers of America, I view scientific achievement as a critical instrument for the benefit of society and humankind. PhRMA members work to develop scientific

discoveries into new therapies and cures to help patients live longer, better, and more productive lives. While this may appear self-evident, it does not happen by itself. I would like to discuss with you today a collaborative approach that has succeeded in the United States to helping ensure that this transformation actually takes place and that, in fact, society benefits from the potential that science has to offer.

Yes, the American experience is relevant to India. In the scientific and technological sectors, India and the United States have much in common. We both have world-class universities in which the most advanced research is undertaken. India ranks among the world's top ten largest industrializing nations and has the third largest pool of scientific and technical professionals in the world.[1] Traditionally, India's public institutions have actively engaged in and supported R&D. However, only a small percentage of this research

[1] Presentation of Jacques Gorlin, PhD, at the Rajiv Ghandi Institute for Contemporary Studies, New Delhi, India, August 29, 2002. (Dr. Gorlin concludes that: "India's cultural heritage and vast technology base provide unique advantages in the competition for global R&D needed for biotechnology and pharmaceuticals.")

reaches the marketplace in the form of new medicines and improved therapies for patients.

Over 25 years ago, the United States, the United States was faced with a similar challenge. I would like to discuss with you today how the United States responded over two decades ago to that challenge and some more recent developments as we consider the potential in India for a similar biotechnology revolution.

Two Landmarks in 1980

Nearly a quarter of a century ago in the United States, before the IT-revolution that has brought such benefits to India, two important events changed the face of science and its relationship with industry in the U.S. These are the U.S. Supreme Court case of *Diamond vs. Chakrabarty* that established the patentability of new life forms, and the passage in the U.S. Congress of legislation named after two prominent Senators, Birch Bayh and Robert Dole. The

Bayh-Dole Act provided incentives to encourage collaboration and to create new products and services from scientific breakthroughs in the area of biotechnology and beyond. And relying largely on these scientific breakthroughs that take place in universities and research institutes, PhRMA members will spend more than 32 billion dollars this year on development of new, innovative medicines for patients in the U.S. and around the world.

In his key note address at the Indian Government's Interactive Session on the upcoming patent amendments, Dr. Mashelkar cited the benefits of the American Bayh-Dole experience. In his presentation he contrasted the story of Indian science academia with the U.S. Bayh-Dole system as the "Continued Story of Missed Busses." Adoption of a Bayh-Dole system can help bring the benefits of scientific advances to society in the twenty-first century in India as in the U.S.

- **Chakrabarty vs. Diamond (1980)**

The organizer of this panel, Dr. Ananda Chakrabarty invited me to speak here today, but did not know that he would be featured in my talk. He is a mentor to me, as to so many others who look to him as a pioneer in biotechnology. In the mid-1970's Dr. Chakrabarty applied for a patent for a novel, engineered bacterium that was rejected by the patent office as a genetically engineered organism. His application was treated as a test case by the Patent and Trademark Office.

After several years of litigation, the Supreme Court eventually held in favor of Dr. Chakrabarty's invention in 1980, stating that "anything under the sun," including genetically engineered inventions, is eligible for a patent so long as it meets the standard definition of patentability (novelty, non-obviousness and commercially

[2] *Diamond v. Chakrabarty*, 447 U.S. 303, 100 S. Ct. 2204, 65 L.Ed.2d 144 (1980) Even in

applicability).[2] This ruling opened the pathway for biotechnology inventions in the United States.[3] On a personal level, Dr. Chakrabarty has told me how empowering it was for him, as an immigrant to the U.S. and a Non-Resident Indian (NRI) to be able to take his case to the highest court in the U.S., and to win.

The second key enabling development for the biotechnology revolution in the United States was passage of the Bayh-Dole Act in 1980.[4]

- **The Bayh-Dole Act**

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advance of amendment of the Patent Act of 1970 in India, this same thing may now be happening in India where e "recently the Calcutta High Court held, in Dimminaco AG vs. Controller of Patents and Designs that a patent on a microorganism was valid. Dimminaco AG had applied to the Controller for a patent on the process for manufacturing a vaccine for infectious bursitis in poultry. The Controller had rejected the application because it involved a microorganism. In April 2002, Justice Ashok Kumar Ganguly of the High Court set aside the decision of the Controller of Patents and Designs. The Controller then accepted the application." Manisha Shridhar, "Gearing Up for Patents"; Terragreen, issue- 41, 31st July 2003, accessed December 17, 2003 at http://www.teriin.org/terragreen/issue41/essay.htm. The case cited is *Dimminaco AG vs. Controller of Patents and Designs* is A.I.D No.1 of 2001, Calcutta High Court.

[3] "Interestingly, before 1980, only a handful of biotech companies, including Genentech and Cetus/Chiron, were around. After *Diamond v. Chakrabarty,* the biotech industry grew phenomenally. Coincidence? Probably not." Speech: Anything Under the Sun Made by Man, Lila Feisee, Director for Government Relations and Intellectual Property, Biotechnology Industry Organization, Delivered at the Conference- Biotechnology in Northeast Ohio, Current Plans and Visions for the Future, At The Case Western Reserve School of Law, Law-Medicine Center, April 11, 2001, Accessed December 15, 2003 at http://www.bio.org/news/041101.html

[4] P.L. 96-517, the Patent and Trademakr Law Amendments Act, enacted into law in 1980.

In the United States in the 1960's and 1970's, there was a major concern in the United States, that despite increased funding for basic research by the U.S. Government, there was only very limited adoption of new technologies by industry.[5] In 1980, fewer than 5% of the 28,000 patents for which the U.S. held title were developed into commercial products by industry.[6] A large part of the problem was caused by the difficult and time-consuming process for companies interested in obtaining exclusivity rights to government inventions in the U.S.[7] Mainly, U.S. law provided for the grant of non-exclusive rights, but of course this failed to encourage companies to invest in and develop new products. In short, "taxpayers were supporting the

[5] "The Bayh-dole Act:A Guide to the Law and Implementing Regulation," Council on Government Relations (COGR), 1999, accessed at http://www.ucop.edu/ott/bayh.html

[6] Ibid, citing the U.S. Government Accounting Office (GAO) Report to Congressional Committees entitled "Technology Transfer, Administration of the Bayh-dole Act by Research Universities," May 7, 1998.

[7] "[B]y the late 1970s there was a growing dissatisfaction with federal policies on patenting the scientific knowledge resulting from the research. Many government officials, for example, believed that federal laboratories were keeping information away from those who could make use of it. There was also a concern that because the government had retained title to inventions, no one was bothering to advance the research. There was no incentive to do so. Further, with the maze of bureaucracy caused by lack of a uniform policy, made companies reluctant to deal with the government, even if they were interested in the research." Speech: Anything Under the Sun Made by Man, Lila Feisee, Director for Government Relations and Intellectual Property, Biotechnology Industry Organization, Delivered at the Conference- Biotechnology in Northeast Ohio, Current Plans and Visions for the Future, At The Case Western Reserve School of Law, Law-Medicine Center, April 11, 2001, Accessed December 15, 2003 at http://www.bio.org/news/041101.html. See also: "Innovation's golden goose," The Economist, December 12, 2002, noting that "inventions and discoveries made in American universities, teaching hospitals, national laboratories and non-profits institutions sat in warehouses gathering dust."

federal research enterprise, [but] they were not benefiting from useful products or the economic development that would have occurred with the manufacture and sale of those products."[8]

The new policy of Bayh-Dole provided the opportunity for universities and research institutes to become involved in the commercialization process by owning inventions and working with industry to bring products to market. Bayh-Dole also allows for exclusive licensing of inventions, with regulations that ensure that products are developed diligently and for the public good. University-industry partnerships allow researchers to participate in the development of a product or process, speeding up the commercialization process.[9] And income derived by the University goes back to fund additional research.

[8] The Bayh-dole Act:A Guide to the Law and Implementing Regulation," Council on Government Relations (COGR), 1999, accessed November 2003 at http://www.ucop.edu/ott/bayh.html, p. 2. The Economist notes that, "[a]lthough taxpayers were footing the bill for 60% of all academic research, they were getting hardly anything in return." "Innovation's golden goose," The Economist, December 12, 2002.

[9] "Bayh-Dole Act," Cornell Research Foundation, Inc., accessed at http:://wwww.crf.corell.edu/bayh-dole.html

The combined impact of these two nearly simultaneous developments on bringing science to the marketplace was nothing short of amazing. In 1999 alone, the licensing and development of these discoveries added $40 billion to the U.S. economy and supported more than a quarter of a million jobs,[10] the same number employed by the entire IT sector in India. The social benefits of these two developments include the launching of the biotechnology revolution that has brought so much hope of new cures and therapies for diseases in our lifetime. The majority of commercialization of scientific breakthroughs under Bayh-Dole have been in the life-sciences, where products and processes reduce pain and suffereing and save lives.[11] There are thousands of new products on the market due to Bayh-Dole. These include technologies instrumental to the biotechnology industry like recombinant DNA technology, the process for inserting DNA into cells, and new and more effective tests and therapies for cancer and osteoporosis, new vaccines, environmentally sound technologies and even safer guardrails for our

[10] Id.

[11] The Bayh-dole Act:A Guide to the Law and Implementing Regulation," Council on Government Relations (COGR), 1999, accessed at http://www.ucop.edu/ott/bayh.html

highways.[12] And Bayh-Dole generates continuing streams of income for Universities and Research Institutes, leading to increased funding for scientific research.[13] Over two hundred research institutes in the U.S. report more than 37 billion dollars in funding in FY- 2002.[14]

Chakrabarty, Bayh-Dole and the American Biotech Revolution

Lila Feisee of the Biotechnology Industry Organization or BIO has noted the combined synergistic effect of these two critical events:

> With the help of the Supreme Court decision of *Diamond v. Chakrobarty* and the Bayh-Dole Act, the biotech industry sky-rocketed. Today there are over 1,300 biotechnology companies in this country [the U.S.] . . . developing effective new therapies and cures for . . . our most intractable illnesses such as heart disease, all forms of cancer, Alzheimer's, Parkinson's, osteoporosis; almost

[12] Ibid., Op. Cite

[13] "Running royalties on product sales were $1.005 billion," in FY 2002, according to Patricia Harsche Weeks, 2003 – 2004 President of the Association of University Technology Managers (AUTM), and Vice President, Planning and Business Development, Fox Chase Cancer Center, Philadelphia, PA, A Message from the President, AUTM Licensing Survey, FY 2002.

[14] AUTM Licensing Survey, FY 2002, p. 1.

every disease is under assault by biotechnology companies.[15]

But not content to remain a pioneer of the biotech patent, Dr. Chakrabarty now joins the ranks of biotechnology entrepreneurs with the establishment of CDG Therapeutics. In recent months, Dr. Chakrabarty and his colleague Dr. Das Gupta have negotiated exclusive rights to their path-breaking cancer research at the University of Illinois to try to bring new cancer therapies to market through CDG therapeutics. Thus a new chapter begins in the continuing history of biotechnology.

Biotechnology Today and Tomorrow

Let me now turn to the future of biotechnology. As we all know,

[15] Lila Feisee, Director for Government Relations and Intellectual Property, Biotechnology Industry Organization, Delivered at the Conference- Biotechnology in Northeast Ohio, Current Plans and Visions for the Future, At The Case Western Reserve School of Law, Law-Medicine Center, April 11, 2001, Accessed December 15, 2003 at http://www.bio.org/news/041101.html

in the Spring of 2003, the complete sequencing of the human genome became known. This will have a major impact on the way that new diagnostic tools and new medicines are developed. PhRMA member companies and Indian firms alike are using the basic research data of the Human Genome, to understand the associations that exist between genes and diseases. This will translate into new diagnostic options and medicines -- including genetic tests, pharmacogenomics, and gene therapy. We are on the threshold of a new era in medicine. "Today, physicians have at their disposal more than 140 biotech-based medicines and vaccines, in addition to a raft of genetic tests. These medicines have benefited an estimated 325 million people worldwide and are part of the medical mainstream, used both in emergency situations - such as heart attacks and sepsis - and to slow progression of previously intractable chronic diseases, like rheumatoid arthritis and multiple sclerosis."[16]

[16] Carl Feldbaum, President of the Biotech Industry Organization (BIO), "It was 20 years ago today . . .," U.S. Biotechnology Trends, Fall 2002, BioIreland, Dublin, Ireland, November 14, 2002, accessed December 15, 2003 at http://www.bio.org/news/speeches/20021114.asp

We have seen a consistent pipeline of biotechnology products moving towards regulatory approval, with biotechnology therapies for over 200 diseases representing roughly a third of the more than 1,000 medicines in human clinical testing. And this year, the 50th anniversary of the discovery of DNA, the FTA received more submissions for biotechnology drugs than for traditional pharmaceutical medicines.[17]

So far, 95 biotechnology drugs, most developed by PhRMA member companies, have received marketing approval. Another 371 are in the pipeline.[18] Companies today also have already mastered the duplicating of individual body cells, tissues and genes into new biotechnology medicines that are often safer and more effective than older, conventional chemical compounds.

[17] "Biotech reaches a turning point in its evolution," The Financial Times, December 17, 2003.
[18] PhRMA, Pharmaceutical Industry Profile 2003 (Washington D.C.: PhRMA, 2003): 16.

Intellectual Property Elements of Bayh-Dole

When Bayh-Dole was adopted in the United States, of course there was already a long-standing commitment to patent protection, rooted in the U.S. Constitution.[19] And one of the most positive developments in the last two years has been the recognition that India, as a knowledge economy, must protect its intellectual patrimony through strong protection of the intellectual property associated with pharmaceutical and biotechnology inventions. This includes protecting patents, assuring data exclusivity, and creating linkages between health regulatory officials and industrial property offices to provide needed incentives for commercialization of products to benefit patients.

[19] "The Congress shall have the Power . . . to promote the Progress of Science and useful arts, by securing for limited Times to Authors and Inventors the exclusivity Right to their respective Writings and Discoveries." U.S. Constitution, Article I, Section 8.

With the upcoming parliamentary debate of the Third Amendment of India's 1970 patent law, India has an excellent opportunity to gain maximum value from the best and brightest scientific minds trained by Indian universities that currently apply their genius both within India and in Western laboratories.

We have seen that good ideas have no nationality. In this context, India's best minds need the legal infrastructure to bring their ideas into the marketplace, and to bring India into the patent mainstream as the last major market to adopt patent protection for pharmaceutical products.[20]

We need to provide a transparent and predictable commercial

[20] The 34th Annual Report 1999 – 2000 of the Organization of Pharmaceutical Producers of India (OPPI) notes that since the late 1980's, "The following developing countries extensively changed and improved their patent systems: Korea (1987), Czech and Slovak Republics (1990), Mexico, Bulgaria, Indonesia, Chile, Belarus (1991), Romania Taiwan, Russia Ukraine, Thailand (1992), China, Yugoslavia, Philippines, Poland, Slovenia, Macedonia (1993), Andean Pact, Hungary (1994), Brazil (1996) and Jordan (2000). All of them introduced product patents for pharmaceuticals." OPPI 34th Annual Report 1999 – 2000, p. 6.

environment that will encourage greater foreign investment, partnerships, and technology transfer. Recognizing this need, the Government of India has already initiated the process of amending the Patents Act of 1970 to allow product patent protection for pharmaceutical products, which it must enact by January 1, 2005.

India should complete all legislative action needed by 2005 to be fully compliant with its international obligations, including those TRIPS provisions that, to date, it still has not implemented.

Stated simply, India needs to introduce a product patent system that conforms to international standards. Included should be:

- a streamlining of the application process, that is, elimination of pre-grant opposition and

shortening of the application time period.

- introduction of TRIPS due process requirements in the areas of compulsory licensing, with removal of the numerous triggers and low hurdles that eat away at the innovators' rights, and

- elimination of provisions that are clearly inconsistent with minimum international obligations, like patentability standards that go beyond novelty, obviousness and commercial applicability.

But more needs to be done to ensure that India becomes the major biotech hub it deserves to be. India does not yet provide protection for the commercially valuable, confidential clinical dossier

information that is disclosed to regulatory authorities as a condition for obtaining marketing approval. This is known as data protection or data exclusivity. WTO members are obligated to provide this as a TRIPS obligation (TRIPS Article 39.3) from January 1, 2000. Countries with data exclusivity include the U.S. and nearly all other OECD-level economies, Jordan, Singapore, Chile, Morocco, and others.

Within India, there is growing recognition that data exclusivity is a separate and independent form of intellectual property protection from patents that is also critical to innovation and technology transfer in the pharmaceutical and biotech fields. The Government of India should be encouraged to resolve this well ahead of the January 1, 2005 deadline for introduction of product patents.

Data Exclusivity brings multiple benefits, allowing the Ministry

of Health to better track applications for marketing approval, provide transparency on the registration process, safeguard the confidentiality of the data and prevent registration of unauthorized products that rely, directly or indirectly, on the data provided by the innovator or his agent or licensee. We see the possibility for positive spill-over effects that will improve the drug registration process, provide better care for patients, and assist all legitimate drug manufacturers.

Finally, PhRMA members also seek linkage in India. Patent linkage refers to the obligation to delay the approval of marketing applications for generic drugs until after the expiration of patents that cover the drug product or its approved use. It is a way of ensuring that one governmental agency does not undercut the efforts of another agency to provide effective intellectual property protection.

To date, India does not provide any mechanism to ensure linkage. It is critical that there be communication between the Patent Office and the Ministry of Health to ensure that the health regulatory authority does not provide market authorization for unauthorized copies of products subject to patent protection. Governments, not patents offices, are bound by WTO TRIPS Agreement, and it is the responsibility of all relevant Government agencies to ensure that TRIPS obligations on patent protection and data exclusivity are met.

Patent linkage is most important in countries like India that have just adopted or are in the process of adopting product patent protection for pharmaceutical products. Several OECD-level and/or middle-level developing countries do now provide linkage, including Canada, Mexico, Jordan, Chile, China and Singapore.

If the regulatory constraints are minimized and other forms of

regulation streamlined in India, the Indian Biotech industry can easily surpass the Indian IT industry and even the bio-informatics sector through the adoption of legislation similar to Bayh-Dole.

Based on the experience of the United States, both Japan and Taiwan have now passed legislation modeled on Bayh-Dole in recent years, and in the future should also benefit from greater public/private partnerships in research.[21] I have spoken frequently of India's vast reservoir of scientific talent and established global pharmaceutical industry. I believe that once India establishes a strong platform of effective patent and data protection, India will be uniquely positioned to benefit from similar legislation, to bring the benefits of collaborative relationships between research institutions and industry to light, and to speed India's own biotechnology revolution.

[21] Patricia Harsche Weeks, 2003 – 2004 President, AUTM, Remarks on the 23rd Anniversary of the Implementation of Bayh-Dole, December 12, 2003, Washington, DC.

Thank you.