

# BIOTECHNOLOGY

Industrial College of the Armed Forces  
Industry Studies 2005

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## **ABSTRACT:**

The United States biotechnology industry has grown tremendously since 1992, with revenues increasing from \$8 billion in 1992 to \$39.2 billion in 2003. As a result, biotechnology has revolutionized the way scientists view living matter—their research and development efforts have led to the commercialization of many diverse products which have dramatically improved human and animal health, the world's food supply, and the quality of the environment. These successful applications of biotechnology are now viewed by private sector companies—as well as governments throughout the world—as being the catalysts of long-term economic growth, prosperity, and security. However, the United States, considered the current world leader in biotechnology, is being challenged by Asia for technological preeminence in this field. No longer content to dominate labor-intensive manufacturing, Asian governments are actively promoting biotechnology, nanotechnology, and information technology, and envision themselves becoming world leaders in these technologies—three areas that are likely to generate the next wave of global technological innovation. This report summarizes the current state-of-the-art in biotechnology—along with its economic and national security implications—and examines biotechnology in the broader global context.

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# Report Documentation Page

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**INTRODUCTION:**

*“Biotechnology will be essential to national long-term economic growth and leadership. From job creation to revenue generation, strength in biotech will be a core building block of America’s national competitiveness in the 21st century.”*

Excerpt from, “A Survey of the Use of Biotechnology in U.S. Industry,” United States Department of Commerce, October, 2003.

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 This industry study report provides an executive assessment of the biotechnology industry, and outlines its current status—to include such far ranging issues as bioethics, government regulation, intellectual property, the implications of nanotechnology, biodefense, the science and technology workforce, agriculture and genetically-modified foods, the pharmaceutical industry, biotechnology in Asia, as well as other relevant and compelling issues for the industry.

The biotechnology industry has grown tremendously since 1992, with revenues increasing from \$8 billion in 1992 to \$39.2 billion in 2003 (see Table 1). The industry is quite diverse; for example, molecular genetics provide products as varied as pharmaceuticals and motor fuels, while nanotechnology brings new capabilities to bone and tissue repair. The United States (U.S.) Office of Technology Assessment defined biotechnology (the name is typically foreshortened to “biotech”) in 1991 as, “...any technique that uses a living organism, or parts of organisms, to make or modify products, to improve plants or animals, or to develop microorganisms for specific uses.”<sup>1</sup> More recently, it has been defined as, “...engineering problems associated with the production and processing of substances obtained through the application of principles and techniques of modern molecular biology.”<sup>2</sup> The Biotechnology Industry Organization, which represents a wide range of business interests within the industry, has members in the agriculture, medicine, and animal science industries.<sup>3</sup> As of December 2003, the U.S. biotech industry employed 198,300 people, and is one of the most research-intensive industries in the world, spending \$17.9 billion on research and development. The top eight ranked biotech companies spent an average of \$104,000 per employee on R&D in 2003, and the U.S. Patent and Trademark Office granted almost 8000 patents in 2002. There are 1,473 biotech companies in the U.S., of which 314 are publicly held, with market capitalization (the total value of publicly-traded U.S. biotech companies at market prices) at \$311 billion as of mid-March 2004.<sup>4</sup>

**Table 1. U.S. Biotechnology Industry Statistics: 1994–2003 (U.S. dollars in billions).**

Year	2003	2002	2001	2000	1999	1998	1997	1996	1995	1994
Sales*	28.4	24.3	21.4	19.3	16.1	14.5	13	10.8	9.3	7.7
Revenues	39.2	29.6	29.6	26.7	22.3	20.2	17.4	14.6	12.7	11.2
R&D Expense	17.9	20.5	15.7	14.2	10.7	10.6	9.0	7.9	7.7	7.0
Net Loss	5.4	9.4	4.6	5.6	4.4	4.1	4.5	4.6	4.1	3.6
No. of Public Companies	314	318	342	339	300	316	317	294	260	265
No. of Companies	1,473	1,466	1,457	1,379	1,273	1,311	1,274	1,287	1,308	1,311
Employees	198,300	194,600	191,000	174,000	162,000	155,000	141,000	118,000	108,000	103,000

**Sources:** Ernst & Young LLP, annual biotechnology industry reports, 1993–2004. Financial data based primarily on fiscal-year financial statements of publicly traded companies.

**THE INDUSTRY DEFINED:**

While biotechnology has been practiced for the last 10,000 years, the term itself was first found in print in 1919.<sup>5</sup> However, today’s biotech economic sector is more often associated with the technological successes of the past two decades. This is the time period where scientists have been able to manipulate organisms at their genetic level in order to solve macro problems.

Biotechnology is expected to increase productivity for many industries—its impact on the economy is likely to be similar to that the information technology (IT) has had. In fact, with the specificity, precision, and predictability biotech can bring to an industry, perhaps it can even surpass the productivity gains of the IT revolution. When this productivity is coupled with the world’s demographic trends of an aging, longer-living population in the richest countries—and the growing populations in the poorest—the sector should continue to demonstrate strong economic growth far into the future. Simply put, biotechnology has the potential to fuel the next economic revolution.

The U.S. holds a significant advantage in the biotechnology sector (see Table 2). Because of the tremendous potential for economic growth, many countries are investing to cash in on these anticipated future benefits.

**Table 2. International Industry Profiles (As of 2002).**

	<b>Global</b>	<b>U.S.</b>	<b>Europe</b>	<b>Canada</b>	<b>Asia Pacific</b>
<i><b>Public Co. Data</b></i>					
Revenues (\$M)	41,369	30,266	8,262	1,466	1,375
R&D Expense (\$M)	22,012	16,272	4,989	555	197
Net Income (\$M)	-12,483	-9,378	-2763	-263	-79
Number of Employees	193,753	142,900	33,304	7,785	9,764
<i><b>Number of companies</b></i>					
Public	613	318	102	85	108
Private	3,749	1,148	1,776	332	493
Total	4,362	1,466	1,878	417	601

**Source:** Ernst and Young Report, “Global Biotech at a Glance.”

While biotechnology certainly has tremendous economic potential, there are also a few causes for concern. Continued access to sufficient capital and labor is challenging, especially for smaller firms. The costs in time and resources, quantity, and quality of government regulation are areas of friction and uncertainty. Within the U.S., the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the Department of Agriculture all regulate biotech; however, international standards do not exist for biotech. Unfortunately, the lack of sufficient intellectual property (IP) protection outside of the U.S. remains a serious concern to the industry. Increased competition, drug reimportation, biogenerics, and price controls are also likely to have negative impacts on future economic growth.<sup>6</sup> Additionally, there are concerns over whether a sufficient number of qualified scientific personnel exist to maintain U.S. competitive advantage in biotech.

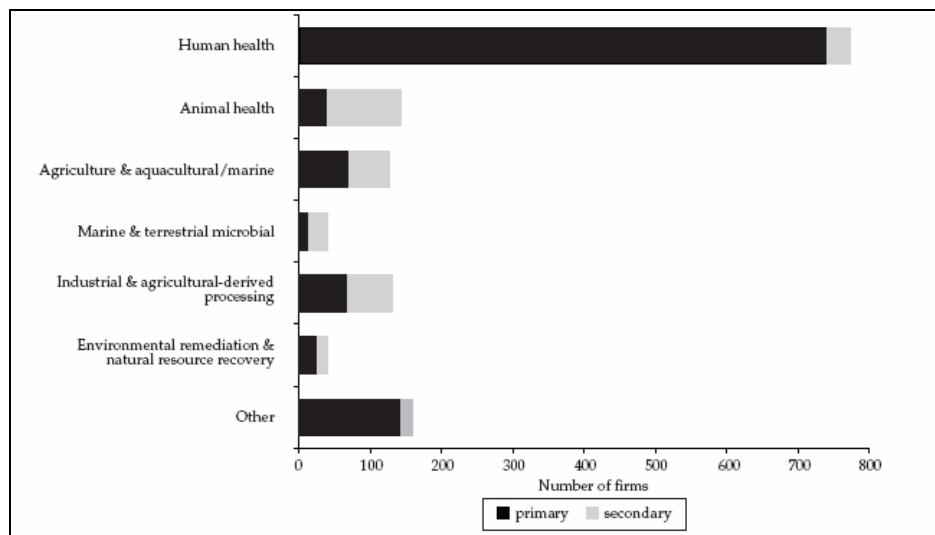
**Industry Measurement & Trends.** The biotech sector has experienced growth in economic and scientific applications throughout the 1990s and into this century. This growth can be quantified in many ways, demonstrating the rapid industry evolution that is underway. First,

U.S. revenues have increased from \$8 billion in 1992 to \$39.2 billion in 2003. That is nearly five fold from 1992 to 2002 with approximately 20% growth for the last three years. From 2001 to 2002 the growth in net sales for biotech firms was 10% as compared to 6% for the total U.S. market. Since 1982, when the FDA approved the first biotech drug or vaccine for public use, there have been approximately 285 approvals. There are currently more than 370 biotech drug products and vaccines in clinical trials targeting over 200 diseases.<sup>7</sup> This large number of drugs awaiting approval represents both growth in the sector, as well as the extended amount of time required for drug testing and approval. Furthermore, there are over 800 experimental medications in development.<sup>8</sup>

In the last quarter of 2002, respondents to a Department of Commerce survey indicated that they had pending U.S. patent applications for 33,131 new biotech-related products or processes, compared to 23,992 current U.S. biotech-related patents in their portfolios. Other survey data show that recent discovery, development, and application of biotechnologies are not only creating entirely new types of products and services, but that biotech processes and products are now applied in all types of manufacturing, agriculture, aquaculture, and even at the microbial and nanoscales.<sup>9</sup>

In 2002, the Department of Commerce divided the biotech sector into eight categories for their industry survey (see Figure 1 below): human health; animal health; agricultural and aquaculture/marine; marine and terrestrial microbial; industrial and agriculture-derived processing; environmental remediation; natural resource recovery; and “other”. In the survey of biotech industries, more than 75% of all respondents (780) selected “human health” as their primary or secondary application focus, while 12% to 14% of respondents chose one of three other categories—“animal health,” “agriculture and aquaculture,” or “industrial and agricultural-derived processing”—and 4% to 5% chose either “marine and terrestrial microbial” or “environmental remediation” or “natural resource recovery.” Sixteen percent of respondents (160) indicated “other” biotechnology applications as their business focus. Many of these companies develop and market tools to support biotech research and development.<sup>10</sup> As the sector grows and evolves into other industries in the future, this number of divisions is likely to grow.

**Figure 1. Biotech Industry Sectors.**



**Source:** U.S. Department of Commerce Technology Administration and Bureau of Industry and Security, “*Critical Assessment of Technology in U.S. Industry*,” p. vii, August 2002.



While the "average" biotechnology company is small, private, and unprofitable, several are large multinational corporations with products generating huge revenues and the financial standing of top pharmaceutical firms. For example, the top 10 biotech firms in terms of sales posted around 50% of the revenues from the entire sector. The pharmaceutical industry is dominated by a shrinking group of large, global corporations that continue to merge with or acquire one another in an effort to create mass, reach more markets, enhance product pipelines, and increase in-house research capabilities. The significant growth in the size of participants in the closely-tied biotech and pharmaceutical segments is generating new opportunities as outsourcing activities create demand for specialized laboratory and testing facilities and IT providers.<sup>11</sup>

The human disease and genomics areas of biotechnology typically get the majority of the press and prestige; meanwhile, the field of agricultural biotech has quietly become very robust. Transgenic crops—engineered to withstand weather and insects, have existed for more than a decade. Significant acreage is farmed utilizing genetically engineered or modified plants, fertilizers, and seeds. The International Service for the Acquisition of Agri-Biotech Applications (ISAAA) reported that biotech crop plantings increased 20 % globally from 2003-2004.<sup>12</sup> However, the expanding production and exporting of these crops has caused concern over the safety of the food supply, as well as any long term problems associated with consuming genetically-engineered products. Nonetheless, it would seem that there will continue to be great potential for economic growth in this sector, as these unsubstantiated political concerns are allayed over time.

## **INDUSTRY CHALLENGES:**

In the Department of Commerce survey, a majority of biotech firms identified some type of impediment to the advancement of their research or product commercialization. Three of the impediments that were most cited are: regulatory approval process and costs (59%), research costs, and access to start-up capital (53% each). Firms working in the area of Agri/Aquaculture and Marine biotechnology are concerned about unfair foreign laws and public acceptance concerning ethical considerations. Companies engaged in environmental remediation and natural resource recovery applications are most concerned with antiquated rules and regulations, and unfair U.S. laws.<sup>13</sup>

A major area of controversy, public debate, and barriers surrounds the ethical application of biotechnology. Currently, political, religious, and bioethics groups are trying to control the exploitation of embryonic stem cells. On August 9, 2001, President Bush placed limitations on stem cell research programs with only 78 stem cell lines worldwide meeting eligibility criteria for U.S. federal funding. Of those lines, 51 were either developed by foreign institutions and/or foreign institutions retain the intellectual property rights associated with the lines.<sup>14</sup> Federal funding is very important to scientific research, as investors are currently more focused on financing late product development to minimize their exposure to risk. Without government funding, U.S. scientific research on embryonic stem cells has already fallen behind that of countries that support this type effort, such as South Korea, China, Hong Kong, and Singapore.

**Access to Capital.** Among all but the very largest firms, access to capital is a major challenge. Smaller firms (those with 500 or fewer employees) are more reliant on venture and angel capital as important sources of funds for their research and development activities. Federal and state government loans and grants are very important. For reasons discussed below, increased government support for basic research is imperative for continued U.S. competitive advantage.

Although the amount of venture capital invested in biotechnology firms declined in both 2001 and 2002, biotech firms received an increasing percentage of venture capital funds. The stage

at which investors support biotech firms is important—most venture capital money is flowing to late-stage product development and less to technology platforms that may be used to develop multiple therapeutics. However, the focus on quickly putting “product on market” is having a negative impact on R&D and innovation within the industry.

In addition, there is intense pressure to get products developed, through testing and approval, and to the market.<sup>15</sup> The recent backtracking by companies and regulators on previously approved drugs is indicative of this serious problem. As a result of these drugs being pulled from the marketplace, the public’s perception of the industry and the regulators is at an all time low. The drug industry spent \$18.5 billion on marketing last year to the public and medical professionals, which has added to the public criticism. The FDA is under scrutiny as well, accused of placing priority on new drug approvals “funded by the industry” before drug safety. There are currently several bills before Congress to improve drug-safety monitoring.<sup>16</sup>

**Intellectual Property (IP).** Intellectual property rights—through the patent process—are the engines providing investment funding for biotech R&D. However, patent fees, the patent approval process, and patent rights held by third parties are serious barriers to getting a product to market. Managing IP rights imposes significant complexity and costs on smaller research and development firms.<sup>17</sup> Ongoing patent litigation has special significance for the whole industry, not just the individual companies involved. Generic drug makers are challenging companies in court over three blockbuster drugs. These lawsuits question the original “composition of matter” patents on products, not just the industry’s efforts to spin out protection for a few more years of profit. If any one of these decisions were to go against the big companies, it would affect the whole industry.<sup>18</sup>

Several developments in IP have increased the time and resources required to continue research and development efforts, placing a drag on innovation. As entities aggressively pursue protection under U.S. laws, researchers are often required to make agreements with other patent holders to access necessary technology or to form collaborative research and business teams. At the same time, contests for IP rights have become more competitive and increased the number of legal claims, counterclaims, and infringement suits. More broadly, the way in which long-standing IP laws intersect with new biotech-related products and processes uncovered through research and development is a matter of growing controversy. The products of modern genetic research may be considered, depending on their application, either as revealed aspects of nature (which generally are not protected by U.S. patent law) or as inventions and useful devices (which are protected).<sup>19</sup>

A more balanced IP protection system is required. A system that provides market incentives that can facilitate research, but not restrict dissemination, hinder the circulation of ideas, or promote ownership such that the use of underlying scientific and technological advances is slowed. This updated system should exclude basic research from patent protection to encourage innovation. The present legal debate on patent policy and biotech research and development, and the lack of consensus on viable solutions, create uncertainties for biotech businesses. Evidence indicates that investment in biotechnology firms is particularly sensitive to capital and equity markets’ perceptions of national patent policy.<sup>20</sup>

**Workforce.** The population of companies engaged in biotechnology is dynamic and growth in the biotechnology-related workforce has been vigorous, averaging 12.3% annually for 2000–2002. Companies with 50 to 499 employees experienced the fastest growth, with an annual increase of 17.3%, while growth among larger responding firms was 6.2%. These figures compare to essentially no growth in U.S. non-farm payroll employment during this same period. Smaller companies (those with fewer than 50 employees) reported difficulty in filling positions. Nearly half of these firms reported that more than 20% of their biotech-related positions had been unfilled for more than three months. This was true for only 1% of firms with more than 50 employees.<sup>21</sup>

## **GOVERNMENT: GOALS AND ROLE:**

Nowhere else is the industry debate more prominent than in the establishment of appropriate government policy and regulations for biotechnology. Most of the industry's regulatory guidance within the U.S. emanates from the government through the U.S. Department of Agriculture (USDA), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA). Many of the regulations established as governance for the biotech industry centers around what the government and the general public consider matters of ethics, morality, and safety. The industry tests the limit of our current views on human advancement, and the potential for R&D to generate unintentional consequences that may unleash some form of uncontrollable agent(s) on the general population. Therefore, legislators enact policies that, among others, things try to reduce consumer fears.<sup>22</sup>

Unlike the industrial revolution where new discoveries brought advancements in industrial capacity and improvements in business processes, or the IT revolution that ushered in a new era of computer technology that allowed for faster and more efficient processing of information, hence the Information Age, the biotech revolution is challenging the core knowledge of our existence and the ability to sustain ourselves over longer periods of time. Not only that, it is challenging whether or not we should move beyond reproduction as we know it to creating replicas of ourselves or recreating ourselves in newer and more enhanced forms. Of course, this brings about discussions on the extent to which we will allow various forms of animal (to include human) and plant experimentation. While the latter issue has been a source of debate for hundreds of years, today's biotech research takes the issue to an entirely new level. These and other issues, concerns, attitudes and beliefs, along with the drive, desire, and the basic capacity for human comprehension, give rise to policies and regulations designed to allow for biotech research and development but at a pace that accounts for safety, caution, and limits on every aspect of the business. Both sides, in the biotech regulatory debate, desire to ensure the longevity of human existence.

The USDA, EPA, and FDA individually and collectively (depending on the overlap) encompass and regulate an array of fields within the biotech industry, some with similar goals that drive competition, and some with their own unique set of goals or desired end-states that may result in some new product or discovery that will further advance the field. Federal management and regulatory policies have tried to encircle any potential residual discoveries that might serve as building blocks for further biotech-related R&D and/or product manufacturing for public or specialized consumption. Today, U.S. government regulations apply to biotech in the following areas: agriculture (genetically enhanced crops, etc); intellectual property/patents; funding; morals/ethics; safety; biodefense/bioterrorism/national security; human genome study and implications; cloning (human/animal); embryonic/stem cell research; nanotechnology (although some consider this on the fringes of biotechnology); environment/bioremediation (bio-environmental cleanup, etc.); and medicine (pharmaceuticals/drugs). This list continues to evolve. In March 2005, the FDA issued guidelines intended to encourage pharmaceutical companies to study how genetic variations affects the way people respond to their drugs. These new guidelines are paving the way for yet another field under the umbrella of biotechnology called pharmacogenomics.<sup>23</sup> The terms pharmacogenomics and pharmacogenetics are used interchangeably to describe this science, although the former refers to the general study of all of the many different genes that determine drug behavior, while the latter refers to the study of inherited differences (variation) in drug metabolism and response.<sup>24</sup>

## Intellectual Property

Another government role necessary for the health and survival of the U.S. biotechnology industry is protecting intellectual property (IP) through the use of patents, copyrights, and trademarks. Promoting the necessary domestic legal reforms to streamline the application process are critical to improving access to the innovator—whether that is an individual, a commercial entity, or a government agency. The current set of U.S. legal precepts which govern IP must evolve to protect and promote the diverse innovations within the industry. This legal evolution must remain inclusive of the broad spectrum of participants, and must serve as a standard for negotiation and inclusion within the World Trade Organization (WTO) to promote and protect fair trade practices for U.S. commercial interests. While this report addresses biotech IP under two broad geographic spheres—domestic and foreign, both are increasingly intertwined due to the changing views of international commerce, sovereign borders, the role of the WTO, and a host of related friction points.

The rate of ongoing commercial competition, legal change, and innovation throughout the global biotechnology industry is increasing in intensity and becoming more complex. The legal strictures within sovereign regimes and within the international marketplace can not adjust to the speed of innovation brought about by competing commercial interests. In some sense, it is a form of intellectual and economic warfare in which varied commercial and government interests compete for a share of the market place with little to no consideration accorded the small individual innovator. The legal precedents within the U.S., the European Union, Asia, and the WTO lack standardization to enforce and protect intellectual property (IP).<sup>25</sup> In many instances this global competition has become so cutthroat, complex and convoluted that the individual inventor has little chance of filing for or protecting his patents due to legal challenges, rising costs, complexity, copyrights, and trademarks.<sup>26</sup>

**Domestic Considerations.** The protection of IP through the vast web of U.S. federal regulations (patents, copyrights and trademarks) has been useful in promoting innovation. In broad terms these “rule sets” have been protectionist in nature with a monopolistic flavor aimed at protecting the broad demographics of our society (from the individual inventor to a commercial entity, or a government agency). These regulations have fostered a unique and delicate environment geared towards rewarding risk. “*Never mind that the U.S. patent system stimulates 10 times the significant discoveries of other nations’ systems combined, that it is the world’s most reliable engine for technological advance and job growth.*”<sup>27</sup> While this system has worked well in the past, the present system holds real challenges. The current methodology of protecting IP involves filing for a patent, trademark or copyright through a 13 step process with the U.S. Patent and Trademark Office (PTO; a sub-agency of the U.S. Department of Commerce).<sup>28</sup> Successful negotiation through the heavy bureaucratic red tape results in a 20 year protection from the time of award. In the realm of bio-development part of this time is consumed in product test and approval, which could take as long as 7-10 years. The end result is to encourage and reward the risks of innovation; but the current rule set fails to account for the long lead time to bring a product to market and the requisite open sharing of technical information (the very openness of the procedure leaves the discovery accessible to competitive forces which may gain competitive advantage through exploiting similar ideas not within the realm of the current patent).<sup>29</sup>

Domestic legislation has also been enacted to further protect intellectual property. The Bayh–Dole Act of 1980 states that its purpose is “...to use the patent system to promote the utilization of inventions arising from federally funded research or development.”<sup>30</sup> The Public Health Security and Bioterrorism Preparedness Act of 2002, the Small Business Technology

Reauthorization Act of 2001, and thirteen other bills are further legislative measures to protect and promote domestic IP.<sup>31</sup>

**Foreign Considerations.** The “extraterritorial reach” of U.S. patent law is limited to the geopolitical borders of the U.S.<sup>32</sup> At issue, is how sovereign countries define IP and the application of common rules.<sup>33</sup> The inability to enact common rule sets which recognize IP and to enforce these rules remains problematic. U.S. Biotech firms must take a calculated risk and determine to what extent they will introduce IP within foreign regimes. This very action breeds distrust between peer competitors, within the host country, between regimes, and across the Biotech Industry.<sup>34</sup> Each geographical region presents diverse challenges and further complicates establishing common ground to gain international consensus.

One of the greatest challenges to protecting IP resides within the third world, especially China. The root factors consist of: a poor transition from government to private ownership; no infrastructure for private research and development (to include funding); poor understanding of the exclusivity of patents; a fledgling legal system; government corruption; and extreme competition between new startup firms all desiring to compete in the global economy.<sup>35</sup> Another challenge resides in an unfair competitive advantage accorded privileged firms seeking to exploit gaps and grey areas within the still immature legal system. Lawyers who represent Western companies embroiled in intellectual property disputes in China, however, point to major loopholes in Chinese law and in the country’s trademark and patent system as parts of the problem. Many Chinese patents, for example, are granted without examination of their originality, making it easy for local companies to claim others’ innovations as their own.<sup>36</sup> Counterfeiting of IP remains one of the most prevalent threats to foreign direct investment in China. “When the joint venture dissolves, or sometimes even while it remains active, the Chinese allegedly make use of the technology or manufacturing processes illegally.”<sup>37</sup>

While the challenges remain in China, new hope for improved opportunity within the biotech investment and development community awaits in India. Recent patent reforms within India signal clearly that the WTO’s rule sets can have a positive effect. “The new Ordinance, issued by the government for amending the Patents Act, 1970, is likely to affect the farm sector as it extends the product patent regime to agro-chemicals, food and biotechnology products, apart from drugs and pharmaceuticals.”<sup>38</sup> Stronger and more precise regulations will level the competitive playing field and serve to encourage increased foreign investment.<sup>39</sup>

Disagreement over patent standards, rights to genetic material, and the effect of biotechnology patents will continue to generate friction in the global market place. The Federal Trade Commissions 2003 report offered 9 recommendations to protect domestic IP, but could just as easily translate or apply these same standards within the WTO. These interests continue to offer a common way ahead and highly useful to garnering consensus within the WTO.<sup>40</sup>

## **ESSAYS ON MAJOR ISSUES:**

### **Bioethics:**

The discussion of ethics in the biotechnology field is growing in importance, in light of new advances in technology, biology, and the publication of sequenced DNA through The Genome Project.<sup>41</sup> The impact on agriculture, pharmacogenetics, nanotechnology, and tissue cloning and cell replacement can barely be assessed due to the unknown realm of possibilities. The challenge is what are the ethical boundaries? Who determines the ethical boundaries—individuals, peer groups, governments, or an ethical board? There may not be one clear answer, but we have an obligation as a society to do so. To understand why ethics is important in biotechnology industry, “...we need to

be aware that it faces challenges unlike those faced in other sectors. Few industries conduct research so likely to become front-page news, or so likely to face intense scrutiny by peers, academics, government and consumers.”<sup>42</sup>

Within the biotechnology industry, there are unique technical challenges, which will require an examination of the individual parts: agriculture with genetically modified (GM) crops, gene testing/profiling and the right of privacy, cloning and stem cell research with its applications, and pharmacology. Upon examination of the individual sectors we will have a framework that applies to the sum of all parts of the industry.

**GM Foods.** At a glance, it seems to make sense that GM crops benefits society as a whole by preserving the environment, increasing the yield and nutritional value of crops that combat famine and malnourishment, not to mention the financial benefits. Nevertheless, GM crops have had a tremendous resistance by the European Union (EU) since the late 1990's.<sup>43</sup> The EU's point of view, however, "...taking genes from one species and putting them into another is seen as 'unnatural' or unethical".<sup>44</sup> However, if we go back to the Hippocratic Oath, "...to do no harm,"<sup>45</sup> presently there are no adverse effects as a result of consuming GM foods. This is an example of the wrongful application of ethics to impose one's bias or to limit the economic well-being of other countries.

**Gene Testing/Profiling and the Right of Privacy.** Is probably the most controversial area in biotechnology is where the ethical boundaries can be too broad or too narrow with great physiological, social and economical impact. The issue can be broken down into two major issues: gene testing and what to do with the information; and the protection and privacy of access of this information by third parties, which potentially could create employment or insurance discrimination.

There are pros and cons in gene testing and the ethical implications along with it. The pro on gene testing is that such testing has already resulted in dramatically improvements in our lives. Some testing is used for diagnosis and direct physicians appropriate treatments, while others allow families to avoid having children with devastating diseases, or identifying people at high risk for conditions that may be preventable.<sup>46</sup> The cons are gene testing—as well as medical testing in general—suffers from the possibility of laboratory errors. Many in the medical establishment feel that the uncertainties around test interpretations, the current lack of available options for these diseases "...has the potential for provoking anxiety, and the risk for discrimination and social stigmatization could nullify the benefits of testing.”<sup>47</sup>

This leads to the issue of discrimination and the right of privacy to one's gene inheritance. Currently there is no federal legislation relating to genetic discrimination in individual insurance coverage or to genetic discrimination in the workplace.<sup>48</sup> Now the only citizens protected in the U.S. are the federal employees by executive order signed on February 8, 2000, by President Clinton.<sup>49</sup> This executive order was endorsed by the American Medical Association, the American College of Medical Genetics, the National Society of Genetic Counselors, and the Genetic Alliance.<sup>50</sup>

**Cloning and Stem Cell Research.** This ethical issue is the most divisive of all sectors in biotechnology. One of the reasons is the "biopolitics" surrounding this subject in the U.S. Even though there is stem cell research currently underway, the source and application of the research creates great controversy in the U.S., and no clear consensus around the world. An example of this was demonstrated with the selection of "Baby Adam", from among 15 healthy embryos, because he had the right bone marrow to help his sister, who had a rare disease."<sup>51</sup> Such selection would have been illegal in Britain, but not in the U.S. since there was use of public money.<sup>52</sup>

In the area of cloning, the ethical issue not only pertains to human cloning but to animals as well. In November 2004, the ethics committee of the American Society of Reproductive Medicine

said that cloning for fertility treatment “did not meet standards of ethical acceptability”.<sup>53</sup> While a poll by Time/CNN found that 67% of people said that animal cloning was a “bad idea,”<sup>54</sup> the ethical debate comes down to a fundamental division on how we see life: viewed through the prism of its intrinsic value vs. its utilitarian value, while cynics say it is a growing war between commerce and culture.<sup>55</sup>

**Pharmacogenetics.** Pharmacogenetics is the study of how genes influence an individual’s response to drugs.<sup>56</sup> This topic necessarily brings up the allocation of scarce resources, fair distribution and burdens and benefits in developing the field of pharmaeconomics, individualized medicine, and individual rights.<sup>57</sup> The first consideration is resource allocation—should research be pursued in this field or allocated for a greater humanitarian need? However, just in the U.S. every year, adverse reaction to drugs possibly kills 100,000 patients.<sup>58</sup> One can argue that the elimination of adverse affects reduces unwarranted cost that consequently will free up resources for other endeavors. The second ethical issue is who benefits from this technology and whom it discriminates against. Because any new technology or procedures are costly, only those who can afford it are the beneficiaries. Policies to remedy this problem may also come at a higher cost for the government in the healthcare sector. Thirdly, individualized medicine may lead the medical community to take shortcuts in diagnosis and treatment. This creates delays in providing adequate treatment with potential harmful consequences. Lastly, because pharmacogenetics addresses predisposition diseases, which patients do we protect? Do we protect the patients who initially received the diagnosis or the sibling and parents that share the same genetic traits? Unfortunately, the lack of privacy protection laws put the family members at risk for discrimination.

**Dual Use and National Security.** There is no greater fear or danger than the potential dual use of biotechnology and its impact on U.S. national security. The development of biotechnology is intended for the betterment of humanity, but at the same time this technology may fall in the hands of rogue states, transnational terrorist and criminals, or even disenchanted individuals. Because of this threat, there are many challenges for the industry, scientists, and the government. It has an impact on how the industry goes about conducting R&D and marketing to maintain competitive advantage. While for scientists, it affects the culture of open source, peer reviews and the sharing the information across national boundaries in the name of advancing science. The government has the regulatory obligation and constitutional obligation to safeguard its citizens. Too much regulation may restrict competitive advantage of corporations and limit the scientist’s ability to do meaningful research. On the other hand, insufficient regulation and oversight may endanger the very citizens that it seeks to protect.

### **The Science and Technology Workforce:**

The U.S. biotechnology industry is heavily dependent on R&D for its continued growth and success. The U.S. has for many years benefited from minimal competition in the global markets for scientists. However, the ready availability of scientific talent from domestic and foreign sources to supply the U.S. biotechnology industry is no longer assured. If labor needs cannot be satisfied by these two sources, U.S. firms may feel compelled to outsource their R&D. Conceivably, either one of these scenarios could effectively reduce U.S. competitiveness in the global biotechnology industry. Along with the rapid growth of the industry, the biotech workforce has also experienced substantial growth over the last 10 years. In fact, this workforce has more than doubled during the last decade from approximately 80,000 employees in 1992 to the current estimate of almost 200,000 employees.<sup>59</sup> This industry growth and subsequent demand for workers is likely to continue—with conservative estimates of 500,000 workers needed by 2012.<sup>60</sup>

With the industry relying so heavily on R&D, satisfying the industry's growing intellectual capital needs presents a tremendous challenge. Eighty-six percent of the biotech workforce possesses an education level well beyond secondary school. In fact, statistics indicate 36% of the workforce has advanced graduate degrees (Ph.D.—19%, M.S.—17%), and the majority of the remaining percentage hold at least a bachelor's degree (B.S.—50%), with the remaining workers being employer trained (14%). Furthermore, due to the highly technical nature of the work, it is difficult for workers from other U.S. industries to transfer into the biotech workforce. Consequently, the biotech industry places a heavy burden on the U.S. education system to provide the necessary scientific expertise—especially in the microbiology, biochemistry, and molecular biology disciplines.

Due to the growth of the industry and its need for highly educated workers—and in particular, in the biological and life sciences—there is increasing pressure on this input market. Unfortunately, the scientific and technical workforce in the U.S. is in a general state of decline, and has been so for a number of years. Because of the industry's growing intellectual capital needs, and the general inability of the U.S. workforce supply pool to satisfy the growing demand for workers, the industry also relies on foreign workers with the necessary scientific skills. There are potential problems however—both economic and security-related—with having significant numbers of foreign workers employed in the industry. The origins and causes for the decline of the U.S. scientific workforce, along with the impacts of foreign workers on the biotechnology industry, are explored in more detail below.

**Root Causes of the Science and Technology Workforce Problem:** There are a number of possible causes for the decline of the scientific and technical workforce in the U.S. The principal reasons include: a long-term decline in the overall federal investment in R&D as a percentage of gross domestic product; a general lack of interest amongst young people in pursuing education in the physical and biological sciences at both the undergraduate and graduate levels; an educational environment where foreign graduate students are earning a significant percentage of the scientific and technical degrees granted by American universities; and long delays involved in recruiting and training a highly-educated workforce with the required skills needed to replace the scientists of the current baby-boom generation who are just now retiring.<sup>61</sup>

With regards to reallocation of the labor market from other industrial sectors, the education requirements seem to preclude easy transfer of this labor into the biotech sector. There also appears to be unwillingness in the workforce to commit to the additional years of technical training—even when supplied by the employer—to facilitate the transition.

**Role of Foreign Workers in the U.S. Biotechnology Industry.** Under current U.S. immigration law, foreign workers with unique skill sets that are not available in the existing domestic labor pool may obtain permission to stay and work in the U.S. for up to six years. These workers are designated as H-1B visa holders; current federal law caps the number of H-1B visas at 65,000 per year. The annual limit for this controversial “guest worker” program has already been met for fiscal year 2005—U.S. Citizenship and Immigration Services, which processes the applications for the H-1B program, is no longer accepting petitions for visas for initial employment for this fiscal year.<sup>62</sup>

Biotechnology companies have frequently used workers with H-1B visas, since their skills frequently matched the most pressing employment needs of the industry—such workers are considered critical to industry success and competitiveness. Skilled foreign workers are typically paid salaries comparable to American workers in the same jobs. Estimates indicate that between 7%-10% of the biotech workforce hold H-1B visas; this percentage increases if bioinformatics is included.<sup>63</sup> However, foreign workers only provide a temporary solution to shortages in the domestic labor force—shortages that point out the inadequate production of appropriately trained U.S. citizens.



**Implications for the U.S. Biotechnology Industry.** While a large proportion of the H-1B workers remain in the U.S. for the entire six years, that trend may not continue in the future. As increasing numbers of international biotechnology firms develop and mature outside of the U.S., increasing numbers of these foreign nationals may feel compelled to return to their countries of origin to work in their native biotech industries. In addition, other countries may recruit them to work in their biotech industry. If industry labor needs cannot be satisfied by either domestic or foreign worker sources, U.S. firms may feel compelled to outsource their R&D in order to remain competitive.

Conceivably, any one of these scenarios could reduce U.S. competitiveness in the global biotechnology industry. Furthermore, since so much of the industry is knowledge-based, any reduction in the workforce—U.S. or foreign—would mean not only the loss of workers, but also the loss of intellectual property, since this knowledge is worker-transportable. This scenario is especially problematic on the foreign worker side, since many countries do not necessarily adhere to international patent and trademark laws.

There is also a potential security issue associated with foreign nationals in the biotech industry. Considering the list of countries that supply H-1B visa holders—such as India, China, Pakistan, et al., one cannot easily dismiss the notion that some of the foreign nationals who return to these countries may be compelled by their governments to use their knowledge and skills for more sinister purposes. This is a concern not only for the biotech industry, but also for U.S. national security policymakers.

### **Nanobiotechnology:**

The biotechnology industry is clearly a research-driven enterprise that solves “macro” problems with “micro” sciences—and more recently—with “nano” sciences. The nexus between biotechnology and nanoscale science and technology, commonly referred to as “nanoscience” or “nanotechnology,” has grown significantly. In fact, the term “nanobiotechnology” was coined to describe the merger of these two disciplines. This integration of nanotechnology with biotechnology—as well as with information technology is expected to further accelerate over the next decade. While many definitions for nanotechnology exist, the National Nanotechnology Initiative (NNI) has defined it in three parts: research and technology development at the atomic, molecular, or macromolecular levels, at the length scale of approximately 1-100 nanometers (1-100 x 10<sup>-9</sup> meters or 1-100 nm) range; creation and utilization of structures, devices, and systems that have novel properties and functions because of their small size; and the ability to control or manipulate on the atomic scale.<sup>64</sup> An additional caveat imposed by the NNI definition is all three of these guidelines must be present for the technology to qualify as nanotechnology.

Nanobiotechnology, on the other hand, has been defined as, “...a field that applies nanoscale principles and techniques to understand and transform biosystems (living or nonliving), or uses biological principles and materials to create new devices and systems integrated from the nanoscale.”<sup>65</sup> Since many of the basic life processes occur at the sub-cellular level—i.e., the nanoscale—understanding the fundamental structure and design of these biological systems has the potential to significantly influence medicine and the life sciences. Development of this fundamental understanding at the nanoscale holds great promise for the synthesis and fabrication of devices for measuring the characteristics of these cells and sub-cellular components—which some biologists now refer to as “functional nanosystems.”<sup>66</sup>

**Applications of Nanotechnology to the Field of Biotechnology:** The increasing scientific interest in the intersection of these two fields is based on the idea that nanotechnology offers biology new tools, and that biology offers nanotechnology access to new types of functional nanosystems—i.e., components of the cell.<sup>67</sup> The merger of these two disciplines to create the field of

nanobiotechnology reflects the increasing importance of nanoscience in the creation of novel types of biomaterials. These new materials could be used in such things as: tissue engineering and cell patterning, sensors that rely on conformational changes in macromolecules for use in diagnostics, “nanopores” that allow the passage of single molecules for sequencing deoxyribonucleic acid (DNA), nanomaterials for use in imaging single molecules or cells, and new materials or devices for use in drug delivery or as therapeutics.<sup>68</sup>

For example, researchers are currently exploring how DNA can be used for non-biological applications, such as the building of structures and devices whose essential elements and mechanisms range from 1-100 nanometers—i.e., the nanoscale. Because of the inherent size of DNA (e.g., the width of the DNA helix is approximately two nanometers and it twists a full revolution every 3.5 nanometers), it is considered a versatile framework for making these devices and structures. Depending on its sequence of base pairs, DNA has highly specific interactions with other chemicals. Biologists have exploited the use of these “sticky ends” in genetic engineering for years.<sup>69</sup>

Because of this feature, DNA is considered an ideal molecule for building nanoscale structures, since strands of DNA can be “programmed” to assemble into complex arrangements simply by producing the strands with the appropriate combinations of sticky ends. Novel uses of this technique include DNA “scaffolds” that hold “guest molecules” in orderly arrays for crystallography, or used to build materials with precise molecular configurations. X-ray crystallography—used to determine molecular structure, is an important step in the design process of new drugs. In addition, new materials could be constructed—either made by the DNA or made of it—with exacting molecular precision. DNA machines with actual moving parts could be employed as nanomechanical sensors, switches, and tweezers.<sup>70</sup>

**Changes in Physical Properties at the Nanoscale—Why the Familiar Rules Don’t Apply:**

Major changes in the physical properties of ordinary materials occur when it is reduced to the molecular dimension. For example, nanomaterials have vastly increased surface area—often by a factor of million(s). This fact alone makes these materials considerably more reactive—they are quicker to ignite, melt, and absorb. These unique properties also lead to new concepts such as more efficient drug dosages—delivered in quantities of “nanospecks,” or highly responsive sensors which can detect individual molecules. New generations of prosthetic and medical implants whose surfaces are “molecularly designed” to interact with the body could be developed, along with the ability to attract and assemble the raw materials in body fluids that can regenerate bone, skin, or other missing or damaged tissues.<sup>71</sup>

**Nanotechnology Question Marks:** The public’s general misunderstanding of nanotechnology—fueled by imaginative science fiction, has distorted the truth about the technology. Such inaccurate portrayals not only threaten public confidence in the integrity of the science, but could also precipitate a global backlash amongst activists, similar to the reaction against genetically modified food. Already, such groups as the “Friends of the Earth” have warned of the dangers of nanotechnology, even calling for a global moratorium on the production of all nanomaterials.<sup>72</sup>

A more legitimate challenge for the nanobiotechnology industry is to ensure that these nanomaterials are safe for the human body and the environment. Worries grew in the spring of 2004 when researchers at Southern Methodist University reported brain damage in a large-mouth bass that had been swimming in an aquarium stoked with these carbon-based nanoparticles known as buckyballs. Although far from conclusive findings, such findings raised scientific concern worldwide.<sup>73</sup>

In response to these as well as other safety concerns, the Environmental Protection Agency has started an assessment of the effects of nanoparticles on biological systems to ascertain whether they do indeed present unique health and environmental risks. At the same time, the U.S. National

Institute of Standards and Technology is developing new means of measuring nanotechnology product dimensions, behaviors, and properties, in order to establish standards for quality assurance and control of future nanotechnology products.<sup>74</sup>

### **The Pharmaceutical Industry:**

The U.S. pharmaceutical industry occupies a critical sector of biotechnology. Using genetic engineering techniques, biomedicine can produce an increasing number of drugs and diagnostics derived from human genes. This is known as biologics—these medicines are generated from biofermentation techniques that use microbial or animal cell cultures.<sup>75</sup> The biotech and pharmaceutical drug products are frequently referred to as “biotechnology medicines.” For instance, according to the Boston Business Journal, “...*the Tufts Center for the Study of Drug Development says that advances in biotechnology research and development will result in nearly 50 new biotechnology medicines gaining marketing approval from the U.S. Food and Drug Administration (FDA). That’s out of about 250 protein-based biotechnology therapeutic products in development worldwide.*”<sup>76</sup>

Drug prices are difficult to rationalize without a full understanding of what is included in the cost. Prices in other countries generally reflect the low incomes and the highly politicized nature of most foreign health care systems that rely on price controls and access restrictions. For example, drug prices are low in Mexico compared to those in the EU and the U.S. because Mexico has a much lower per-capita income and spends far less on health care and pharmaceuticals. The Mexican government also regulates drug prices and provides only limited patent protection for pharmaceuticals.<sup>77</sup> On the surface, Canada appears to have lower drug prices but the reasons for this are the slow growth of the Canadian economy and the recent decline of their dollar. As a result, many goods, not just prescription medicines, are cheaper than in the U.S. Moreover, Canadians have the advantage of having fewer and less costly product liability lawsuits and litigation than the U.S in this market.<sup>78</sup>

Health care cost is undeniably increasingly expensive, but the alternative of not treating illnesses and not having access to critical medications are even more costly. In fact, new pharmaceuticals are responsible for almost half of the reduced disease mortality between 1970 and 1991. Furthermore, some health care professionals believe that every new drug approved during that time saved over 11,000 life-years annually. In addition, today’s physicians/doctors have at their disposal medications and technologies that provide for the immediate diagnosis and treatment of most of the disorders that affect modern man. Hundreds of new medicines are in development for cancer, heart disease, strokes, Alzheimer’s, infectious diseases, and AIDS. A couple of decades ago treatment for AIDS was non-existent; by 1987, there was one drug, AZT. Now, there are at least 74 anti-AIDS drugs available and still more under development.<sup>79</sup>

The incentives for the Pharmaceutical companies to take high risks in investing capital for high cost pharmaceutical R&D are primarily the IP protection of exclusive patent rights. These rights protect them and promise potential rewards and high profits to cover their investment costs of R&D and provide returns on their capital for future R&D efforts. From “...*the time research begins to develop a new prescription medicine until it receives approval from the Food and Drug Administration (FDA) to market the drug in the United States, a drug company typically spends approximately \$802 million over the course of 10 to 15 years.*”<sup>80</sup> Even such substantial investments by pharmaceutical firms do not guarantee results and return on investments. “*Of every 5,000 to 10,000 substances reviewed by FDA, only about 250 make it to the animal-testing stage. Around 5 of them go on to human clinical trials. Only one, on average, makes it into the market. Even at that*

*point, only 3 out of 10 new drugs actually make money. Those few must pay for everything—research, administration, regulatory delays, and failures.”<sup>81</sup>*

Steady increases in the demand for new drugs that result in higher prices and health care costs reflect America’s desires for improved medications, health and longer life. The highest-priced drugs do not represent luxury goods but address serious and painful health conditions. About half (50.6%) of the \$22.5 billion increase of the prescription drug spending in 2001 occurred among just nine categories of medicines—those used to treat depression, high cholesterol, diabetes, arthritis, high blood pressure, pain, allergies, ulcers, and other gastrointestinal ailments.<sup>82</sup> The increase in demand is also a product of today’s lifestyle—fast food, two income families and the aging baby boom generation. To feed this growing demand, we need to ensure continued innovation and breakthrough development of new drugs are encouraged and incentivize companies to invest in R&D. Furthermore, there is a critical need for the continuous increase in medical innovation and government policy/support to encourage and foster the collaboration and joint R&D ventures between biotech and pharmaceutical firms and other research institutions to develop and produce biotechnology medicines to prevent, cure sickness and improve wellness. Any government intervention or legislative initiatives to reduce prices would definitely take away companies’ incentive to invest in new drug development, limiting production of and access to new, life-saving compounds.<sup>83</sup>

### **Agriculture and Genetically Modified Foods:**

The U.S. is by far the world’s leader in the bio-agriculture industry with more than half the world’s total genetically modified (GM) crop production in 117.6 million acres.<sup>84</sup> According to the U.S. Department of Agriculture, this is an 11% increase over 2003 which is due primarily to increased planting of GM corn and soybeans. Ninety percent of the world’s GM crops are dominated by four countries: United States (59%), Argentina (20%), Canada (6%), and Brazil (6%). There was an increase in global GM crop acreage of 20%, 32.9 million acres between 2003 and 2004.<sup>85</sup> The predominant GM crops are herbicide-tolerant (HT) and insect-resistant (Bt) soybeans, corn, cotton, and canola. In 2004, HT crops dominated U.S. biotech crop acreage. Specifically, HT soybeans reached 85% of U.S. total soybean acreage; HT cotton reached 60% and HT corn reached 18% of their respective total crop acreages.<sup>86</sup> In 2004, the share of total U.S. corn acreage for Bt corn increased from 29% to 32% largely due to the introduction of a new Bt corn variety that is resistant to the corn rootworm, a pest that may be more destructive to yield than the European corn borer.<sup>87</sup> Several companies are working on the next generation of GMOs which will benefit consumers directly and will involve improvements in food quality, safety, and nutrition.<sup>88</sup> It is expected that oil crops with enhanced levels of healthy oils like omega-3 will reach the market in the next five to seven years.<sup>89</sup> Other examples of GM foods with increased health and nutritional value that are in development include golden rice and canola oil with high vitamin A and potatoes with a 30% increase in protein content.

In recent years, GM foods have stirred a debate among politicians, activist groups, and consumers, particularly in Europe, concerning the benefits and risks of GM foods, with more focus on the risk side of the equation. The EU’s concerns have impacted U.S. ability to market and export GM foods to the EU. Since May 2003, the U.S. and EU have been in WTO litigation over the EU’s 1999 suspension of consideration and approval of GM products for planting and import. EU consumers fear GM foods as a result of their experience with the “mad cow” crisis, creating a lack of confidence in the government and regulatory system to protect the food supply. The EU incorporates the precautionary principle in its Regulation on General Food Law to ensure that precaution is used within the overall framework of risk analysis. Precaution is relevant when there

is a circumstance in which science lacks the ability to ensure that there will not be harmful health effects. But, precautionary measures shall be applied only as necessary for health protection while restricting trade as little as possible.<sup>90</sup> Opponents of the precautionary principle, including the U.S., argue that its application to GM foods is problematic. Using the precautionary principle establishes a regulatory framework based on verifying that a new product or technology causes no harm. This essentially means that perhaps the farmer, the regulating agency, or maybe even the biotechnology company must prove a negative, a logical impossibility.<sup>91</sup>

During the moratorium, the EU established regulations for the labeling of GM foods. The EU believed that more extensive labeling information would help restore consumer confidence in the food regulatory system, providing consumers greater choice about what they eat and build confidence in GM products.<sup>92</sup> The Traceability and Labeling Regulation requires that biotech products be traced throughout the commercial chain, and that food containing biotech products comply with certain labeling requirements. The Genetically Modified Food and Feed Regulation provides new approval procedures for biotech food and feed products.<sup>93</sup> U.S. government officials, farm groups, and biotechnology companies regard the rules as costly, unworkable, unenforceable, unnecessary and discriminatory against U.S. agriculture products.<sup>94</sup> Since the U.S. commodity grain system routinely mixes in GM varieties with conventional varieties, producers and farmers will have to segregate crops and foods derived from GM crops at every step of the harvesting and food production processes. Further, labels that identify foods as derived from biotechnology are likely to be seen by consumers as “warning labels” which would decrease the demand for the products.<sup>95</sup> The U.S. prefers and uses a voluntary labeling policy. The labeling debate indicates the need for internationally agreed to standards for GM products being traded globally because there are different approaches being used around the world. The United Nations international food standards body, Codex Committee on Food Labeling, has been unable to reach consensus on GM food labeling. They will address it again at their meeting in Malaysia in May 2005.<sup>96</sup>

Although the WTO dispute has not been settled, the EU has recently taken steps to open up trade and acceptance of GM foods. The EU’s moratorium was lifted by default when the European Commission approved two new crops, Syngenta’s Bt11 sweetcorn for human consumption and Monsanto’s NK603 maize, in May and October 2004, respectively.<sup>97</sup> However, public opposition to GM foods remains strong in the EU. A recent survey by the European Commission found that 70.9% of European shoppers were hostile to foods containing GM ingredients.<sup>98</sup> In addition, farming groups, regional bodies and local politicians have established GM-free zones, raising the question as to whether there can be coexistence; that is, the regulation of GM crops so that they do not cross pollinate and contaminate conventional agriculture. The EU commissioner has requested a report by the end of 2005 on how different countries have approached coexistence to determine if the EU framework can learn any lessons for adoption.<sup>99</sup>

There is divided state opinion within the EU regarding the role that GM products can play in European society. Therefore, the Commission has called for a study on the cumulative long-term effects of GM crops on human and animal health. The objectives of the project include: assessing and documenting the adequacy of existing risk assessment methodologies and protocols for judging the impact of GM crops; and to identify any possible gaps in knowledge.<sup>100</sup>

### **Biological Warfare:**

The threat of bioterrorism is no longer limited to just the potential for state sponsored attacks. The primary threat is likely to come from terrorists, non-state actors, and individual operators who may have gained access to dangerous pathogens. The threat posed by dangerous pathogens also appears to be changing. Bioweapons could become increasingly diverse and potent

as a result of discoveries in the life sciences (e.g., medicine, and agriculture).<sup>101</sup> A panel convened by the National Academy of Sciences noted that the genomic revolution could produce biologically engineered agents, or unconventional pathogens that could be combined with known pathogens to produce virulent “designer” BW agents.<sup>102</sup> We also need to be concerned about the remnants of the Soviet offensive biological weapons program that produced strains of antibiotic resistant anthrax and hemorrhagic fever viruses (e.g., Marburg).<sup>103</sup> The Soviets are known to have tested and weaponized these novel agents.<sup>104</sup>

In April 2004, President George W. Bush issued a Presidential Directive (PD) “Biodefense for the 21st Century” aimed at addressing the unique, growing threat presented by the application of biotechnology to weapons development. The PD breaks biodefense into four pillars: threat awareness, prevention and protection, surveillance and detection, and response and recovery. Broadly, these four pillars span intelligence-based, pro-active posturing; multi-dimensional, multi-national diplomatic prevention; defense via surveillance and detection; and a national response plan based in pharmaceutical protection and post-exposure treatments.

**Biodefense.** Following the October 2001 anthrax letter attacks, the U.S. government realized there was no market for the products that it now needed. As a result, President Bush announced “Project Bioshield” in his January 2003 State of the Union address. Project Bioshield is a comprehensive effort to develop modern, effective drugs and vaccines to protect against biological as well as other weapons.<sup>105</sup> In July 2004, President Bush signed Project Bioshield into law. Bioshield authorizes and appropriates up to \$5.593 billion over 10 years (through 2013) for the purchase of vaccines, drugs, and diagnostic tools for the Strategic National Stockpile (SNS).<sup>106</sup> The primary component of SNS is development and purchase of vaccines for anthrax, smallpox, and plague.

To date, only a small amount of Bioshield money is obligated. Major U.S. biotechnology firms appear content to remain on the sidelines. A survey of 30 expert leaders from academia, government, and industry (17 from the pharmaceutical and biotech industries), concludes that Bioshield, is necessary, but not sufficient to entice industry leaders to enter the biodefense industry.<sup>107</sup> There are essentially four reasons for this, including; no product turnover or opportunity to replenish the stocks; lack of sufficient intellectual property protections; insufficient indemnification protection; and, no guaranteed government funding for development of experimental biodefense vaccines and drugs. Senators Lieberman and Hatch recognized the deficiencies of Bioshield; on March 19, 2003, they proposed “Bioshield II.”<sup>108</sup> The purpose of Bioshield II is to provide additional incentives for biotechnology companies to enter the biodefense market. A major incentive currently contained in Bioshield II is to provide increased liability protection. Currently, Bioshield II is in draft legislation before the Senate.

**Military Vaccines.** Health experts believe that immunization is the most effective means of preventing infectious diseases.<sup>109</sup> Vaccines have two significant advantages for military readiness—the first is that preventative vaccination reduces readiness-associated impact on troop strength through death or illness vice reliance on post-event treatment. Secondly, “...*vaccines are the most cost effective way to protect service members from potential disease*”.<sup>110</sup> The U.S. military’s vaccine problems, however, are symptomatic of the larger vaccine issues confronting public health, homeland defense and military vaccine requirements (e.g., time, and intellectual property).

DoD vaccine R&D priorities are: vaccines for threat agents for which a vaccine currently doesn’t exist (e.g., avian flu, Marburg, Ebola); vaccines that need improvement and are slow to achieve immunological response or requiring multiple shots; and development of multi-valent vaccines.<sup>111</sup> As we move forward, military vaccine requirements are likely to change from multi-valent to multi-pathogenic vaccines in order to develop immune response to the broad array of infectious disease threats. The technologies for these vaccines will require a greater understanding

of the immune system and bio-informatics in order to drive to a greater immune response while identifying the best antigenic targets; advances in vaccine production and delivery methods will further enhance this invisible weapon system's utility.<sup>112</sup>

**Surveillance and Detection.** Surveillance and detection focuses on attack warnings. A requirement for an effective defensive network is one that can detect agents, assess the associated threat and mobilize the appropriate resources to counter it. The speed at which the detection, identification, and defensive actions occur will likely limit the scope of the damage and lessen the impact of the bioattack. The combined initiatives of BioWatch,<sup>113</sup> and BioSurveillance,<sup>114</sup> among others, provide fundamental building blocks for ensuring a national surveillance and detection program.

Syndromic surveillance is the ongoing, systemic collection, analysis, interpretation, and application of real-time indicators for detecting disease outbreaks *before* public health authorities discover it.<sup>115</sup> It applies automated data analysis tools to screen generic clinical illness symptoms (e.g., fever, rash, and respiratory complaints) to detect unexpected patterns, or illness clusters, that warrant investigation.<sup>116</sup> It is based on the theory that screening for certain symptoms can provide public health officials with the earliest evidence of a bioterror attack *before diagnoses* are confirmed and reported to public health agencies.<sup>117</sup> Syndromic surveillance can buy critical time to *mobilize* the public health system<sup>118</sup>

### **Unconventional Applications of Biotechnology:**

Unconventional applications of biotechnology include pharmaceuticals, marine biotechnology, genetic engineering, bio-energetics, biomimetics, biomaterials, and environmental biotechnology. Examples include:

**Pharmaceuticals.** *Cocaine Vaccine:* An immunotherapeutic approach to treating cocaine dependence in the form of a vaccine has recently been developed. The vaccine induces the patient's immune system to produce antibodies that bind the cocaine molecules to antibodies upon entering the bloodstream thereby preventing cocaine from crossing the blood-brain barrier to act on receptor sites in the brain. The impact of this promising application is that it can be an effective treatment for million of cocaine addicts who wish to end their dependence on the drug.

**Marine Biotechnology.** *Treatment of Mucociliary Disease:* Researchers working with red tide toxin at the University of North Carolina's Wilmington's Center for Marine Science have discovered two new compounds that improve the flow of mucus through the respiratory tract, allowing airways to clear more quickly and efficiently for victims of cystic fibrosis and similar lung diseases.<sup>119</sup> Impacts of this application is that the doses required to gain beneficial effects are much lower using this technology than the current treatment resulting in greatly reduced negative side effects.

**Genetic Engineering.** *Mammal Parthenogenesis:* Scientists have produced a mouse through parthenogenesis, a process whereby the genetic exchange between sperm and egg is circumvented and the egg becomes the sole source of genetic material in creating a new embryo. Until now, it had been considered biologically impossible for two mammals of the same sex to combine their genomes and produce viable offspring. This research will impact areas of study such as embryology, assisted reproduction, and even cloning. In the future it may even allow two women to have a biological child without the participation of a male.<sup>120</sup>

**Bio-Energetics.** *Microbial fuel cell:* Environmental engineers at Penn State University have generated electricity from a microbial fuel cell without adding any other bacteria. The naturally occurring bacteria in wastewater drive power production via a reaction that allows them to transport electrons from the cell surface to an anode. Through this application microbial fuel cells would

make the process of purifying wastewater much more economical for companies operating sewage treatment plants and provide access to sanitation technologies to developing countries throughout the world.<sup>121</sup>

**Biomimetics.** *Self Cleaning Materials—The Lotus Effect:* A group of German scientists have developed materials that mimic the surface of the lotus plant. These materials have a self-cleaning surface that resist adherence by any other material. Possible applications include paints, roof tiles, textiles and material coatings. One interesting application is aircraft skin paint.

**Biomaterials.** *Spider's Silk from Goat's Milk:* Nexia Biotechnologies has developed a method to introduce silk-producing genes called fibroins into New Zealand miniature goats.<sup>122</sup> Given the difficulty with harvesting spider's silk from spiders, these genetically enhanced goats can produce up to 15 grams of spider silk per liter of milk, significantly more than what a spider could make. With these increased quantities, commercial applications such as brake pads, surgical sutures, lightweight bulletproof vests and clothing, and even arresting cables for aircraft become cost effective.

**Environmental Biotechnology.** *Phytoremediation:* Phytoremediation is a type of bioremediation that uses genetically modified plants and trees to clean up contaminated sites. Contaminants such as mercury and arsenic are absorbed by the plants and either metabolized into a less harmful substance or stored in the leaf and root system. By harvesting the latter, contaminants can be more safely disposed of or collected for further processing or recycling. The impact of this technology is that it could prevent or minimize site contamination before it even begins thereby reducing stress on the environment. *Biofilm Protection:* Biofilms are bacterial slime layer which naturally develop on any submerged structure. They form on almost any material including stone, metal or wood. They constitute a major problem for any industry that deals with flowing water systems. Scientists are developing paints and other coatings made with biological ingredients to control biofilm formation on submerged surfaces. These coatings blend metabolically active bacteria (living paints) or enzymes into coatings.<sup>123</sup> These bacterial coatings produce enzymes that enable it to feed on the biofilm. Since they contain live bacterial organisms, these coatings can regenerate indefinitely. Another innovative application is to use the bacteria in developing a non-toxic "biocement" material which can be used to build structures that inhibit biofilm formation. This application of biotechnology can greatly benefit water treatment plants, the oil industry, the military, and even the recreational boater.

## **BIOTECHNOLOGY IN ASIA: CHINA, HONG KONG, AND SINGAPORE:**

**China.** China has been aggressively investing in biotech since 1999. The seeds for this added investment and focus were made in the 1996-1998 863 Programs. The 15th and 16th People's National Congress generated numerous science and technology initiatives—specifically in biotech—to establish Chinese institutional and intellectual capacity. Their goal was and is to compete regionally and then globally, specifically with the U.S., for eventual dominance in the biotech market. The government decided to invest in biotech as a priority since the U.S. government was so heavily invested in information and software technologies.<sup>124</sup> The Chinese biotech market earned \$3 billion in 2003 and is projected to earn \$9 billion by 2010.<sup>125</sup> China and India are now leading the Asia-Pacific biotech industrial effort which outperformed Europe by 40% in 2003 according to the United Nation's Industrial Development Organization.<sup>126</sup> China's main sources of biotech growth will be in bio-agriculture, genomic sequencing, biochips, traditional Chinese medicines, bioinformatics, stem cell research, and bio-manufacturing.<sup>127</sup>

Chinese investment strategies reflect the continued growth and importance of biotech as a staple in China's quest for high-tech competitiveness. China invested \$180 million in biotech



between 1996-2000, but dramatically increased that rate by 400% from \$100 million annually in 2001 to \$1.2 billion by 2005.<sup>128</sup> Their current 5-year plan projects an annual investment rate of \$8.8 billion by 2010.<sup>129</sup> In aggregate, they have approximately 500 biotech firms, of which 39 are publicly traded.<sup>130</sup> The U.S., in comparison, has 1,466 biotech companies of which 318 are publicly traded.<sup>131</sup> China has approximately 300 publicly funded laboratories and 50 start-up companies with over 20,000 researchers in life sciences—located mainly around Beijing, Shanghai, and Shenzhen.<sup>132</sup> China's current annual biotech investment is small compared to the U.S.'s \$15.7 billion. The U.S. also employs over 200,000 people in biotech as compared to China's 50,000.<sup>133</sup>

China can also leverage several competitive advantages in the global biotech market. First, the protracted drug research and developmental process is very expensive.<sup>134</sup> China is well positioned to benefit from the pre-clinical, non-human testing of drugs because their testing and research costs are less than one-fifth U.S. costs.<sup>135</sup> Second, China has significantly lower scientific labor costs—the annual salary for a U.S. Ph.D. researcher is \$85,000 as compared to China's \$25,000. This is one of the primary reasons large pharmaceuticals like Novartis and Pfizer established research facilities in China.<sup>136</sup> Third, China currently lacks many of the ethical constraints restricting controversial genetic research and experimentation.

However, China has a number of challenges that must be overcome before it can obtain its current goals of regional dominance and global competitiveness. The number one impediment is the lack of adequate intellectual property (IP) rights, and more importantly, enforcement mechanisms. Second, and a related factor, is their poor record to adopt World Trade Organization (WTO) standards. Third, in part due to the first two factors, China does not have the foreign direct investment (FDI) and private investment growth needed to incentivize its biotech industry. Lastly, China is a centralized communist society with rampant corruption at the federal and provincial levels down.<sup>137</sup> The Chinese need to remedy these problems to attain their goals of further economic liberalization, gains in domestically-generated high-tech products, and prioritized self-sufficiency.

**Hong Kong.** At the stroke of midnight on July 1, 1997, Hong Kong's rule was returned to the People's Republic of China (PRC), ending 156 years of British Rule.<sup>138</sup> Hong Kong's aggressive, western-oriented community realized the potential effects of these changes in 1988, began the development of modern high-tech R&D facilities with a focus on information technology and biomedical sciences which rivaled those of its competitors in Shanghai and Singapore. This situation literally placed Hong Kong in a biotechnological "catch-up" mode which still continues today. As a British colony, Hong Kong was not available to receive earlier investments from the PRC in high-tech R&D facilities such as The Shanghai Zhangjiang Hi-Tech Park established in July of 1992.<sup>139</sup> However, Hong Kong's biggest asset—its human capital—has made a Herculean effort, through investments and intelligent process management, to meet and manage the challenge of bringing its biotech community to world-class status. Today, after receiving many groundbreaking biotechnology patents for discoveries ranging from skin care gels, to pig growth hormones, Hong Kong and its resident companies are beginning to reap the benefits of its efforts, as the city has achieved an acknowledged status as a world leader in several advanced biotech areas such as genomic research and human vaccine development.

Hong Kong has developed a well-known and well-earned position as the "Gateway to China." Its traditional economic pillars, banking, finance, service and manufacturing industries had been engrained in the culture of the city and consequently, there was very little focus on the biotech industry. With China's entry into the World Trade Organization, and the change to Chinese rule, Hong Kong's traditional role was no longer needed, as Chinese mainland companies could be directly contacted by western organizations. However, the combined leadership of Hong Kong and the PRC provides access to many of the elements which has allowed Hong Kong to quickly

restructure itself, and pursue leadership in information technology and biotechnological research and development via: access to astounding levels of capital; an aggressive, profit-oriented intellectual base of government and private leaders; a system of laws (the Basic Law of Hong Kong) which will prevail for the next 50 years by agreement with the British government and the PRC, maintaining the rights to property ownership and personal freedoms, and; access to western specialists in all areas of technology, and finance and academia.

Hong Kong's aggressive approach towards the development and funding of its biotechnological research industry has already begun to bear fruit. While the process of producing vaccines and drugs for human use is expensive and extended, Hong Kong's understanding of the outsourcing approach to R&D has placed it in a strategic position in the biotech industry.

**Singapore.** Singapore, a small city-state in S.E. Asia, has virtually no natural resources. Its future growth depends heavily on domestic human capital to maintain technological advantage over its neighbors. Singapore lost some of its early lead in computer technology that offered cheaper labor for manufacturing and assembly.<sup>140</sup> To slow the loss of manufacturing jobs, Singapore plans to make biomedicine the fourth pillar of its economy alongside electronics, chemicals, and precision engineering. The Singapore government believes that because of the complexity of the industry, the infrastructure for biotechnology cannot easily be transplanted to a cheaper offshore location.

In 1999 the Singapore Economic Development Board (EDB) canvassed the leading multinational pharmaceutical and biotech companies and asked them what it would take for them to invest in Singapore. The companies wanted tough patent protection; lengthy and considerable tax breaks, and government investment.<sup>141</sup> The EDB worked to address these issues in order to lure multi-national companies to Singapore. The early results are impressive—the biomedical sciences industry has doubled in size since 2001.<sup>142</sup> Singapore's growth is forecasted at 9%, second only to China in Asia. In 2004 Singapore's Biomedical Sciences (BMS) industry grew to S\$15.8 billion, a 33.2% increase over 2003 and surpassing the goal of S\$12 billion.<sup>143</sup> Much of this growth is attributed to manufacturing exports and in particular, pharmaceuticals. However, expectations for 2005 are not as good, with pharmaceutical output likely to be flat due to pressure from generic firms.<sup>144</sup> The combination of intellectual property laws, corporate tax breaks, and an educated workforce has driven this growth.

Singapore's overall economic goal is to develop the life sciences industry to the point where it can achieve the same level of success as the other three major economic sectors: electronics, chemicals, and engineering.<sup>145</sup> Leading the initiative is the EDB and Singapore's Agency for Science, Technology, and Research (A\*STAR) under the Ministry for Trade and Industry. A\*STAR is a government agency in charge of overall coordination of Singapore's Biotechnology initiatives. The long-term plan is to move Singapore from manufacturing drugs to inventing and testing them.

## **CONCLUSIONS:**

The great potential for biotech breakthroughs is close enough and/or seemingly real enough for vast programs with billion dollar budgets to be put in place. Regulatory, structural and labor issues still exist in many locales that serve to impede the entrepreneurial and technology transfer efforts so crucial to bringing scientific research into the commercial marketplace. The world is still in the early days of the biotechnology revolution. The increasing size of biotech companies, the breadth and depth of current research efforts, and the tremendous advances made in the field of genomics serve to motivate countries around the globe as they rush to jump on to this fast moving train.<sup>146</sup> The U.S. has a significant competitive advantage in biotechnology primarily due to its economic power and efficiency, coupled with its massive science & technology capability.

The seemingly unchecked and rapidly rising cost of healthcare is likely to cause a change to U.S. government policy regarding the drug industry. A likely goal might be to reduce the percentage of the cost for drug research and development paid by the U.S. consumer. Unless changes to the IP regulations are instituted, it's likely to have a large negative impact on the profitability of products within the biotech sector. Promoting the necessary domestic legal reforms to streamline the patent application process are critical—this legal evolution must remain inclusive of the broad spectrum of participants, and must serve as a standard for negotiation and inclusion within the World Trade Organization to promote and protect fair trade practices for U.S. commercial interests. Any change that erodes the potential profits of the biotechnology industry will require careful consideration, as the likelihood of damaging the sector's ability to gain access to necessary capital is large. The current market system and the access to capital it provides are instrumental to the U.S. ability to maintain a competitive global advantage in biotechnology.

As U.S. labor rates continue to outpace the world, the U.S. science and technology workforce contracts, and the foreign science and technology workforce expands, more biotech firms will rely on outsourcing to satisfy their research and development needs. This appears to be a significant negative trend for continued U.S. competitive advantage. Because of the investment in time required to change this trend, the U.S. government must work with industry to quickly address this problem through more investment and targeted education tax credits.

The U.S. continues to lead the world in biotechnology, but the rest of the world is working hard to catch up. Over-regulation and a declining technical workforce require immediate attention by U.S. policymakers. This sector is too important to the health of the national economy for the U.S. to not maintain its competitive advantage in biotechnology.

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<sup>2</sup> UniGuide, Academic Guide to the Internet, <<http://www.aldea.com/guides/ag/biotx.html>> (accessed 12 March 2005).

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<sup>6</sup> Standard & Poor's Industry Surveys, *Biotechnology*, 23 December 2004, New York, NY.

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<sup>22</sup> Shelton, Jeffery, "Emerging Biotech Regulatory Policy," The Industrial College of the Armed Forces Student Paper, Fort McNair, Washington DC, AY 2004-2005, 1. [Note: submitted as a spring semester economics paper, 21 March 2005.]

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<sup>24</sup> "One Size Does Not Fit All: The Promise of Pharmacogenomics," National Center for Biotechnology Information, *A Science Primer*, (rev 31 March 2004): 1-2, <<http://www.ncbi.nlm.nih.gov/About/primer/pharm.html>>.

<sup>25</sup> Jackson, John H., William J. Davey, and Alan O. Sykes, Jr., *Legal Problems of International Economic Relations, Cases, Materials and Text*, 4<sup>th</sup> Edition, (St. Paul: West Group, 2002): 1-2.

<sup>26</sup> Nguyen, Thi C., "Seeds of Change," *The Implications of Biotechnology Patents*, 1 (Boston: Harvard University Press, Spring 1996).

<sup>27</sup> Kaltenheuser, Skip, "Patents, Why Change A System That Fuels Invention?," *Los Angeles Times*, 12 October 1997. It was James Madison and the framers of the Constitution who reasoned that the U.S. government should grant the creator of an invention an exclusive property right for a limited but definite period of time, currently 20 years from the date of application. Upon grant, all patent details would become public knowledge. After the term expires everyone can freely use the

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invention. The details of nearly 6 million inventions are now available to everyone, and the world's economy sails on the wind of ideas conceived in the U.S.

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<sup>38</sup> Sharma, Ashok B., "New Amendments to Patents Act, 1970 to Affect Farm Sector," *The Financial Express*, 3 January 2005 <<http://www.financialexpress.com>>.

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in millions of dollars of new foreign investment in research out-sourcing in India.... With the stronger patent protection, more international companies will use India's relatively inexpensive engineers, scientists... for development and clinical testing...."

<sup>40</sup> Federal Trade Commission, "To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy," Washington, DC, October 2003, 12.

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