



**RESPONSE OF**

**THE BIOTECHNOLOGY INDUSTRY ORGANIZATION**

**TO**

**THE NATIONAL RESEARCH COUNCIL**  
**OF THE NATIONAL ACADEMIES OF SCIENCES’**  
**REPORT ON**  
**“A PATENT SYSTEM FOR THE 21<sup>ST</sup> CENTURY”**

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In April 2004, the National Academies of Sciences (“NAS” or Academies’) issued a prepublication copy of a comprehensive report entitled “A Patent System for the 21<sup>st</sup> Century” (“Report”), setting forth seven recommendations for a 21<sup>st</sup> Century patent system. The Biotechnology Industry Organization (“BIO”) commends the Academies’ efforts and endorses many of the Report’s recommended reforms. BIO shares the Academies’ desire to encourage the innovation upon which our nation’s economic strength depends. Moreover BIO has long been in favor of reforms, including many of those recommended in the Report, that would strengthen, streamline and make the patent system more efficient. This document provides BIO’s views on the NAS Report’s recommended reforms to the U.S. patent system and includes suggestions about additional much needed reforms.

BIO is a trade association of more than 1,000 companies, universities, research institutions and affiliated organizations engaged in biotechnology research and development of medicines, diagnostics, agricultural products, pollution controls and industrial applications. Because the biotechnology industry depends on patents to protect truly breakthrough inventions, our members are important stakeholders in patent system reform. To understand the importance of the patent system to BIO’s constituents, it is important to understand the biotechnology industry.

## **ABOUT THE BIOTECHNOLOGY INDUSTRY**

Biotechnology, the combination of biology and technology, utilizes biological process to solve problems or make useful products such as therapeutics, diagnostic tools, environmental and agricultural products. According to the U.S. Department of Commerce, “at the dawn of the 21<sup>st</sup> century, no new area of science and technology holds greater promise or potential than biotechnology.”<sup>1</sup> Biotechnology activities occur in diverse and concrete categories: human health, animal health; agriculture and aquaculture; marine and terrestrial microbial; industrial and agriculture-derived processing; environmental remediation; natural resource recovery; and others. Biotechnology holds the promise of solving some of life’s most vexing problems: improving human health; ending hunger; meeting both energy and environmental needs; serving as a catalyst for new innovations; defending the homeland; and promoting economic growth and competitiveness.

Not surprisingly, due to its roots in science, the U.S. biotechnology industry is extremely research intensive, spending more than \$20.5 billion in 2002, with the top five companies spending an average of \$101,200 per employee.<sup>2</sup> The biotechnology industry is also a dynamic one as measured in terms of job growth, products and patents. In the United States, there are over 1,400 biotechnology companies employing over 190,000 people. As of the

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<sup>1</sup> Forward, “A Survey of the Use of Biotechnology in U.S. Industry,” U.S. Department of Commerce at vii (October 2003).

end of 2003, more than 370 biotechnology drug products and vaccines were approved by the FDA; in addition many more products are currently in late stage clinical trials targeting more than 200 diseases. Some biotechnology products – such as Erythropoietin (EPO), Herceptin® and Xigris® – have revolutionized the way society deals with cancer and other chronic diseases. Biotechnology is responsible for hundreds of medical diagnostic tests, which encompass such purposes as keeping the blood supply safe, AIDS testing and home pregnancy tests. Industrial biotechnology applications have led to cleaner processes that produce less waste and use less energy and water. Increased crop yields and decreased reliance on herbicides and pesticides benefit consumers through less expensive, safer foods. The biotechnology sector filed over 40,000 new biotechnology patent applications with the United States Patent and Trademark Office (“USPTO”) in 2003<sup>3</sup>; this demonstrates the strength of biotechnology’s research and development activities.

However, the nascent biotechnology community is just only entering the dawn of a new era. On balance, the industry itself is not yet profitable. Indeed, many biotechnology companies have yet to even bring a product to market. The full economic impact of new developments in biotechnology has yet to be realized.

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<sup>2</sup> BIO Editor and Reporters Guide, [www.bio.org](http://www.bio.org).

<sup>3</sup> [www.uspto.gov](http://www.uspto.gov), Technology 1600 Vital Statistics.

The biotechnology industry operates in an ecosystem of federal funding of basic and applied research, intellectual property law (particularly patent law), technology transfer, collaborative activities, joint ventures and private investments for financing. Patent protection, which serves as a stimulus for inventiveness and creativity, is critically important to biotechnology. Investors recognize patents as important benchmarks of progress in developing product lines and revenues. Investment of risk capital provides the life-blood of a research-intensive industry, and intellectual property protection serves as the enticement for private financing. The promise of a return on investment, rooted in patents on biotechnology inventions, helps to attract the capital required to discover and develop high-risk biotechnology products.

Indeed, many start-up biotechnology companies have been created based solely on the promise of their patent portfolios. The vast majority of biotechnology companies have only patents on what may eventually become a commercially viable product or technology. Patents protect the assets that entice investment, facilitate licensing, encourage collaborations and joint ventures, and promote technology transfer for further development of a promising technology or product. The capital generated as a result of this intellectual property supports companies as they invest the hundreds of millions of dollars and the decades necessary to successfully develop a commercial biotechnology product.

Strong domestic and international intellectual property protections have been, in large measure, responsible for the growth and development of today's biotechnology sector. Confidence in the patent system by the innovation sector, the investment community and the consuming public is especially important. Therefore, BIO is not only attuned to the merits of the patent system but recognizes the importance of patent quality improvements as well. BIO believes that an effective patent system stimulates innovative biotechnology discoveries and inventive activities that benefit the American public and people around the world, be it patients, farmers, consumers of food products or industrial workers.

#### **THE NATIONAL ACADEMIES' REPORT**

##### **Seven Recommendations for a 21<sup>st</sup> Century Patent System**

The NAS Report recommends seven steps to ensure the vitality, and improve the functioning, of the patent system: (1) preserve an open-ended, inventory, flexible patent system; (2) reinvigorate the non-obviousness standard; (3) institute an open-review procedure; (4) strengthen USPTO capabilities; (5) shield some research uses of patented inventions from liability for infringement; (6) modify or remove the subjective elements of litigation; and (7) reduce redundancies and inconsistencies among national patent systems. BIO has adopted positions on many of these recommendations and BIO's views are set forth in the order of BIO's priorities.

##### **a. Strengthen USPTO Capabilities**

BIO supports the NAS' observation that more resources are needed by the USPTO, and that the USPTO's budget should be determined based on the resources needed for the Office to function effectively and efficiently. NAS Report at 84.

BIO is a strong advocate of adequate USPTO funding and believes that a fundamental change is needed in the method through which the USPTO is funded. Most importantly, BIO supports legislation to end the diversion of patent user fees. For over a decade, the funding of the USPTO has been accomplished through annual appropriations measures that, because of the availability of USPTO user fees for diversion to non-USPTO uses, have led to both inconsistent and inadequate levels of USPTO funding. Funding problems have frustrated the USPTO's strategic planning and contributed to increasing concerns that the USPTO is issuing poor quality patents. The U.S. House of Representatives recently passed a fee bill that will provide necessary funds to the USPTO and end fee diversion. *See* H.R. 1561, 108<sup>th</sup> Cong., 2d Sess. (2004). Similar legislation has been favorably reported by the Senate Committee on the Judiciary. BIO will continue to support enactment of legislation ending the diversion of fees intended for using in reviewing patent applications.

The NAS Report sets forth several recommendations designed to improve USPTO capabilities regarding personnel, electronic processing and analytical capability with which BIO agrees. For example, the NAS report recommends having adequate numbers of trained personnel with adequate

time to review patent applications. The NAS report also recommends continued movement toward the European Patent Office-style electronic filing, with patents published after 18-months being made publicly accessible. Finally, the NAS report recommends a robust multidisciplinary analytical capability with economic, statistical, management, and program evaluation expertise. BIO agrees.

Although BIO agrees with many aspects of the report designed to strengthen USPTO capabilities, BIO strongly disagrees with the assertion that the USPTO's current discretionary practice of dividing a single discovery into multiple applications ("restriction practice"), has any place in a 21<sup>st</sup> century patent system. Requiring patent applicants to file multiple applications to protect a single discovery results in unnecessary expenses for patent applicants (additional filing, prosecution, issue, and maintenance fees), and further results in an unnecessary proliferation of issued patents that must be reviewed and searched by third parties to understand a patent landscape. BIO believes that augmented funding should be used to implement the USPTO's 21<sup>st</sup> Century Strategic Plan which includes restriction practice reform as a key element. The need to reform USPTO restriction practice is addressed in detail later in this document.

**b. Institute a Post-Grant Open-Review Mechanism**

BIO agrees with the NAS recommendation that Congress should consider legislation creating a post-grant review procedure, that would enable third parties, for a limited period, to challenge the validity of issued



patents in an administrative proceeding within the USPTO. See NAS Report at 78. BIO also agrees with the NAS recommendation that any post-grant review system must be more timely, less expensive, and more efficient than reviews the courts typically provide. BIO firmly believes that a post-grant administrative mechanism would be valuable to the biotechnology industry only if it allowed challenges to the validity of a patent without the expenses and delays associated with district court litigation. A post-grant opposition system must not become an additional means to challenge a patent and harass patent owners. To avoid this unintended outcome, a post-grant opposition system must include certain procedural safeguards to ensure the proper balance between the interests of the patent owner and the interests of the public in eliminating improperly issued patents. See <http://www.bio.org/ip/action/20040708.pdf>.

BIO is further concerned that the USPTO may not have adequate resources to implement a fully effective post-grant review system. The USPTO must have available to it – on a consistent year-in, year-out basis – the assured resources needed to conduct potentially *thousands* of contested post-grant proceedings. If this is not accomplished, the USPTO will not be able to implement a fair, balanced and prompt post-grant review system.

Furthermore, as aptly noted by the NAS, additional reforms will be necessary and in fact, in some instances would become more urgent if a post-grant system is implemented. Many of these reforms will be addressed in the remainder of this statement.

**c. Limit the Subjective Elements of Patent Litigation**

The NAS Report makes a compelling case for three reforms to reduce the cost and to increase the predictability of patent infringement litigation.

See NAS Report at 95.

i. *“Willful” Infringement and Enhanced Damages.* One mechanism to decrease costs of patent litigation is to eliminate claims that depend on determining a party’s state of mind (and therefore greatly increase discovery and associated litigation expenses). The NAS recommends the modification of the common law principle of “willful” patent infringement, which if proven, exposes an infringer to potential treble damages. In BIO’s view, the current standard for willful infringement causes unusual negative repercussions (such as businesses having a policy of not reviewing patent literature for fear of gaining knowledge of a competitor’s patent, the need to generate costly legal opinions solely to defend against allegations of willful infringement and the potential for treble damages). The U.S. Court of Appeals for the Federal Circuit reviewed *en banc* the law of willful infringement in the case of *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*<sup>4</sup> BIO filed a brief of *amicus curiae* in the case. The Court’s decision did not change the position that BIO set forth in its brief of *amicus curiae*, and BIO will continue to seek appropriate statutory reform.

ii. *“Best Mode” Defense.* Second, the NAS recommends reform of the “best mode” defense, which addresses whether an inventor has disclosed in a

patent application what she or he considered to be the best way to make and use the invention.

Allegations in patent litigation that an inventor has failed to disclose the best mode are often unsuccessful. However, because of the subjective nature of the inquiry (involving the state of mind of the inventor and whether the inventor actually believed there was a preferred method of making and using an invention at the time the application was filed), such allegations are commonplace and expensive to rebut. “Best mode” defenses often lead to considerable discovery and create unnecessary uncertainty regarding patent validity. BIO agrees with the NAS that the defense should be statutorily reformed.

Specifically, the requirement that a “best mode” be disclosed in the patent application should be repealed. At the same time, the inventor should remain obligated to provide both a written description of the invention and a full enabling disclosure for carrying out the invention. If these reforms are accomplished, patent litigation would become dramatically simplified.

iii. *Inequitable Conduct Reform.* Third, the NAS recommends reforming the law of “inequitable conduct,” relating to whether the applicant’s attorney or anyone substantively involved in prosecuting the patent application intentionally misled the USPTO when prosecuting the original patent. As is the case with the “best mode” defense, allegations of “inequitable conduct” are made in almost every U.S. patent litigation

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<sup>4</sup> Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp., Docket No. 01-1357, -1376, 02-1221,

infringement lawsuit and frequently result in a subjective “state of mind” based inquiry that often leads to significant discovery and expense. In general, one of two allegations is made: first, too little information was disclosed to the USPTO such that material information was withheld; or, second, too much information was disclosed to the USPTO in a manner that material information was effectively concealed in the mass of disclosed information. The court then considers the materiality of the withheld or effectively concealed information and attempts to determine whether there was an intent to deceive or mislead the USPTO.

BIO agrees with the NAS that “inequitable conduct” law and practice should be modified. BIO supports adoption of a statutory provision that prevents the pleading of “inequitable conduct” in any patent infringement action unless and until a court has entered a judgment that one or more patent claims are invalid. Once pled, no finding of inequitable conduct should be permitted without proof that an invalidated claim would not have been granted, but for the misconduct. In addition, reform should accomplish the following four objectives: (1) eliminate the inference of intent from the materiality of the information that was withheld; (2) award attorney’s fees to a prevailing patentee; (3) eliminate the permanent unenforceability of the patent as the sole, automatic remedy for inequitable conduct, except in cases of actual fraud; and (4) provide *de novo* appellate court review of a district court finding of inequitable conduct.

**d. Harmonize the U.S., European, and Japanese Patent Examination Systems**

The NAS recommends that the United States, Europe and Japan continue to harmonize patent examination procedures and standards to reduce redundancies in search and examination and eventually achieve mutually advantageous results. NAS Report at 101. In a global environment, BIO believes that harmonization is especially important between and among industrialized nations and can result in eliminating or at least reducing the number of redundant tasks performed by patent office personnel.

Several areas for harmonization are identified by the NAS with which BIO agrees and they are listed below.

i. *First-to-invent versus first-inventor-to-file priority.* The conversion of the United States system to a “first to file” system is, as a practical matter, a prerequisite to any serious effort to harmonize substantive standards of patent law. See NAS Report at 102. BIO supports awarding the right to patent to the “first-inventor-to-file” for a claimed invention that provides an adequate disclosure. The complexity, expense, unpredictability and delay in the “proofs of invention date” system in the United States are in direct conflict with BIO’s goal of promoting clarity and consistency in the law. Pursuing first inventor-to-file reform also is consistent with BIO’s position in support of international patent law harmonization. By taking a lead in offering to jettison an outmoded feature of U.S. patent law, the United States

will enhance its ability to convince other countries, primarily significant European nations and Japan, to make mutually beneficial changes in their systems.

ii. *Grace Period.* The NAS Report proposes retention by the United States and adoption by other countries of a grace period for prior art determinations that are personal to the patent applicant. BIO supports a grace period for disclosures emanating from the patent applicant, rather than one that would provide for an “absolute” grace period. A grace period linked to information emanating from the applicant is more consistent with the first-to-file standard, and is a reasonable standard that would protect the inventor from what are in essence his own disclosures.

iii. *Best Mode Requirement.* Because the “best mode” requirement has no analog in foreign law, the NAS Report recommends its removal from U.S. patent law. NAS Report at 103-104. BIO agrees, and opposes a requirement to disclose the best mode, framed either as a subjective or objective obligation. The best mode requirement imposes undue burdens on a patent applicant, and, as discussed above, gives rise to groundless challenges to patents.

iv. *Application Publication.* BIO agrees with the NAS Report that the United States should abandon its exception to the rule of publication after 18 months for applicants who do not intend to patent abroad. NAS Report at 104. “Submarine” patents (patent applications that pend for years until a practical implementation of the invention appears) can be detrimental to the

progress of research and innovation. By promoting disclosure, publication of patent applications effectively minimizes the uncertainties of submarine patents.

One area of harmonization important to the biotechnology industry and dismissed by the NAS report is directed to needed reforms to USPTO restriction practice. Although not a specific NAS reform recommendation, the NAS report makes an unfortunate and misinformed statement about a potential benefit from the USPTO's practice of dividing a single discovery into multiple patent applications: by "simplifying the task of examiners it is more likely to enhance the quality of the results than to degrade it." [P. 58] BIO strongly disagrees with this characterization and believes that restriction practice reform has at least two benefits: reforming USPTO's restriction practice will aid in improving patent quality and efficiency, and will also be a necessary part of any harmonization process. The United States practice for restricting U.S. national applications is substantially different than that followed by other countries. Under those practices, patent examiners receive a certain time credit for the examination of each application. If two inventions presented in an application are examined in that application, the examiner receives one time credit. If the examiner requires restriction of the application, he or she can receive two full time credits. The USPTO also receives one full set of fees in the first scenario, versus two full sets of fees in the second. This system incorporates strong

incentives for the USPTO and for individual examiners to impose restriction requirements.

These incentives have led to significant problems in the biotechnology sector, where examiners impose restriction requirements freely and frequently, often with the result that closely related aspects of a single invention are split into five or more separate applications. The adverse effects of this overly restrictive standard are numerous. One significant problem is the proliferation of unnecessary applications, each of which implicates significant additional administrative and legal costs for patent applicants and for the USPTO. Multiple co-pending applications directed to closely related aspects of an invention are frequently assigned to different examiners, which can result in inconsistent patentability opinions from the USPTO. Multiple co-pending applications also create chaos in the market, as claims that relate to a single inventive concept issue over a period of multiple years, rather than in a single patent.

BIO has proposed, and will continue to advocate for, restriction practice reform, in particular a move towards a unity of invention style standard for restriction practice that will improve the efficiency of the U.S. patent system and bring the U.S. more in line with other countries, including European countries, Canada and Japan.

**e. Preserve a Flexible, Unitary, Open-Ended Patent System**

BIO agrees with the NAS that the patent system “should remain open to new technologies and the features that allow somewhat different



treatment of different technologies should be preserved without formalizing different standards....” NAS Report at 4. An open system involving increased public participation, particularly in new technology areas, would be beneficial to USPTO personnel as well as the public. Through openness, including the increased use of USPTO guidelines promulgated with the benefit of public input, the public would be apprised of the USPTO’s interpretations of the law and its internal policies and procedures and the USPTO would also be kept abreast of cutting-edge technological advances. However, although it is reasonable for courts to give “appropriate consideration” to USPTO guidelines and consider the rationale for their creation (including the public record, as suggested by the NAS Report), courts should not be required to “defer” to an administrative guideline. Guidelines are often no more than the Director’s current understanding of a law or policy or the perceived most efficient way for the USPTO to conduct its business. A formal rulemaking process that requires notice to the public and receipt of comments is the appropriate mechanism both to receive public input and the USPTO’s response through incorporation in the Code of Federal Regulations.

BIO further agrees with the NAS recommendation that the judicious use of *amicus curiae* briefs provides an important opportunity for members of the public to inform the judiciary about a broader array of issues. The Federal Circuit is comprised of judges with diverse backgrounds some of whom, prior to their appointment to the bench, may not have been experienced in the unique field of patent law. In order to realize the advantages of a specialized

court to resolve patent appeals (*e.g.*, greater consistency and, therefore, greater guidance to the patent community), care should be taken to retain a core group of judges who have practical experience in patent law. The opportunity to file *amicus* briefs provides opportunity for educating the judges.

Finally, BIO notes that several exceptions to a unitary patent system – the Plant Patent Act of 1952 (35 U.S.C. §§161, 164) and the Plant Variety Protection Act of 1970 (U.S.C. §2321 *et seq.*) – have served well elements of the biotechnology industry that focus on plants, and plant varieties. Despite the NAS recommendation for a unitary patent system, these exceptions should be retained.

**f. Reinvigorate the Non-Obviousness Standard**

The non-obviousness requirement in U.S. patent law requires that an invention not just be new, but also that it be more than a minor, “obvious” advance over prior technology when viewed by a person of ordinary skill in the art. BIO agrees that the non-obvious standard should be consistently applied to determine the patentability of all inventions. Consistent application of the non-obviousness standard by USPTO examiners depends, in part, on providing the USPTO with adequate resources to train examiners, allowing examiners the appropriate time to assess patentability of an application, and providing appropriate quality review of patentability determinations.

Although the NAS does not recommend statutory changes to the current standard for assessing non-obviousness, the NAS does suggest applying a heightened standard for non-obviousness determinations for biotechnology-related inventions. BIO agrees that a statutory change is unnecessary, but does not agree that a new patentability standard should be adopted for assessing the patentability of biotechnology-related inventions.

As the NAS Report observes, high rates of innovation show that the patent system is working well and that fundamental change is not necessary. This is consistent with the growth of the biotechnology industry and the development of new and life-enhancing products. The Federal Circuit should not overrule carefully considered precedent and adopt a heightened standard with respect to determining whether biotechnology inventions are non-obvious.

**g. Shield Some Research Uses of Patented Inventions from Infringement Liability**

Research and intellectual property protection drive the biotechnology industry. The NAS recommends that Congress consider, in the wake of several recent Federal Circuit decisions, legislation to create a research exemption to patent infringement liability. *See* NAS Report at 88. The NAS recognizes that establishing a political consensus on the parameters of appropriate legislation will take time.

Congress has already created statutory research exceptions in a handful of occasions: (1) solely for uses reasonably related to the

development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products (*see* 35 U.S.C. §271(e)(1); (2) “bona fide” research on plant varieties subject to the Plant Variety Protection Act of 1970; (3) research for use of copyrighted material under certain circumstances; (4) fair use in copyright law; and (5) semiconductor chip protection. In addition to these statutory provisions, the courts have developed common law exceptions that some believe do not offer the clarity and consistency so necessary to an effective patent system.

While BIO favors improved certainty to enable researchers to more easily determine whether a proposed application of a patented invention is or is not an infringement of a U.S. patent, BIO also recognizes the importance of providing inventors the right to exclude others from practicing an invention for the term of a patent. BIO is actively considering the various implications of a research exception to patent infringement for experimental uses.

## **CONCLUSION**

BIO commends the Academies’ efforts, through publication of its Report on “A Patent System for the 21<sup>st</sup> Century,” to promote an effective patent system and agrees with many of the Report’s recommendations. The biotechnology industry is dedicated to developing the most innovative products and processes to address modern-day challenges in health care, agriculture, energy and the environment, and homeland security. To fulfill

its enormous promises, the industry must be able to rely on a strong and predictable patent system. BIO is confident that the net result of a strong and predictable patent system will be continued breakthrough inventions, job creation and stimulation of the American economy. BIO looks forward to working with Congress, the National Academies, and the USPTO in strengthening the U.S. patent system and ensuring that it meets the needs of the American public in the 21<sup>st</sup> Century.