

## **AIPLA Response to the National Academies Report entitled “A Patent System for the 21<sup>st</sup> Century”**

### **EXECUTIVE SUMMARY**

The National Academy of Sciences has completed a four-year study of the patent system. The NAS Report contains an impressive and comprehensive set of recommendations for reforming the U.S. patent system. The Report contains proposals that, if enacted into law, would change the patent statute in very significant ways. AIPLA has taken similar positions with regard to needed changes to U.S. patent laws. Thus, AIPLA commends the NAS effort and believes that the NAS Report deserves the most careful consideration by all the constituencies interested in the U.S. patent system. In addition, the Report merits serious consideration by the Congress. In brief, AIPLA endorses immediate and concrete efforts to see that the major NAS Report recommendations for statutory changes to U.S. patent laws are enacted into law.

AIPLA endorses the main thrust of the NAS Report in each of the seven areas where recommendations have been made:

- The patent system should remain open-ended, unitary and flexible so that, wherever “progress in the useful arts” might lead mankind, a vigorous and effective patent system can follow. No changes in the existing patent law are needed to achieve this end. Neither the AIPLA nor the NAS Report endorses any changes to the patent law in this regard.
- A core feature of the patent laws should be a set of vigorously applied criteria for patentability, and AIPLA agrees with the NAS Report that the non-obviousness standard should be vigorously applied. In this respect, however, non-obviousness is no different from the other patentability requirements; all must operate with vigor for the patent law to promote progress in the useful arts. That said, AIPLA does not agree that reinvigoration of the non-obviousness law is now necessary. Rather, what is needed is a *consistent* application of all the requirements for patent validity. Achieving this consistency depends in part upon a U.S. Patent and Trademark Office with sufficient resources and capabilities to guarantee that this can happen. The NAS Report does not recommend any statutory change to the

legal standard for assessing non-obviousness and AIPLA concurs that none is needed.

- Decisions of patent examiners to issue patents should be subject to an open review process in which the public can participate. AIPLA supports the conclusion of the NAS Report that an effective post-grant opposition system needs to be instituted. However, based upon global experience with such proceedings, a post-grant opposition mechanism must be carefully constructed, adequately resourced by the U.S. Patent and Trademark Office, and appropriately constrained. It should achieve a balance between the interests of the patent owner in a final determination of patent property rights and the interests of the public in the prompt elimination of erroneously granted patents.
- A predicate to the more effectively functioning patent system is a more effectively functioning U.S. Patent and Trademark Office. A key to a more effective Office lies in adequate funding levels, an improved mechanism for financing the operations of the Office, and a more effective business planning process. AIPLA wholeheartedly endorses the NAS Report recommendation that the Office's capabilities must be strengthened. Doing so depends upon funding and financing reforms that will make possible effective business planning. Creating and enhancing capabilities of the Office is essential to the successful implementation of a new post-grant opposition procedure.
- Scientific, research, or other experimental activities that allow a patented invention to be better understood, more fully developed, or further advanced should be exempt from patent infringement. Codifying such an exemption as recommended by the NAS Report, would remove the uncertainty that now exists over the manner in which a patented invention can be used to better understand and/or extend what is patented.
- The cost of patent litigation, which itself renders many patents *de facto* unenforceable, should be addressed through statutory changes recommended by the NAS Report. These changes include elimination, limitation or modification of current provisions of the patent law as they relate to willful infringement, inequitable conduct, and the requirement to disclose the inventor's contemplated best mode. While these changes may appear controversial to some inside and outside the IP community, radical changes in the patent law are needed to control the costs of all aspects of filing, procuring and enforcing patents.
- Substantive U.S. patent law should be radically simplified in the manner proposed by the NAS Report. AIPLA supports adoption of a "best practices" approach to modernizing the U.S. patent system. These include adoption of a first-inventor-to-file system, repeal of "loss of right to patent" provisions, ending the exclusions to

18-month publication of pending patent applications, and removal of the “best mode” requirement. Such changes to U.S. patent laws would also have the salutary effect of further harmonizing U.S. patent laws with those of other advanced industrialized countries. The NAS Report makes a persuasive case for the need to change U.S. patent laws and to seek patent law harmonization internationally.

As a final point, AIPLA supports taking a holistic and synergistic look at the recommendations contained in the NAS Report and the impact they would have on the U.S. patent system. The major statutory changes recommended in the NAS Report – instituting the post-grant opposition proceedings, eliminating subjective elements in patent litigation, and adopting harmonizing changes to U.S. patent law – could revolutionize the efficiency and effectiveness of U.S. patent system, if undertaken in a coordinated fashion.

While the more detailed and technical observations of AIPLA appear below, they should not obscure or dilute the essential conclusion reached after a careful study of the NAS work. *The NAS Report represents a major achievement in the continuing efforts directed towards improving the operation of the U.S. patent system.* The NAS Report should not only be carefully studied, but it should serve as a call to action by the Congress and other U.S.-based organizations interested in the future of the U.S. patent laws. Congress should look closely at improving the funding and financing of the U.S. Patent and Trademark Office, creating a balanced opportunity for post-grant opposition to all issued U.S. patents, barring patent infringement suits for certain research or experimental activities, eliminating subjective elements from patent litigation, and enacting a comprehensive set of “harmonizing” changes to the U.S. patent laws.

#### **RECOMMENDATION 1:**

##### **“Preserve an open-ended, unitary, flexible patent system.”**

*“The 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, for example in statutes that would be exceedingly difficult to draft appropriately and equally difficult to change if found to be antiquated or inappropriate for other reasons. Among the tailoring mechanisms that should be fully exploited is the USPTO’s development of examination guidelines for new or newly-patented technologies, as has been done for computer programs, superconductivity, and genetic inventions. In developing such guidelines, the office should seek advice from a wide variety of sources and maintain a public record of the submissions, and the results should be part of the record of any appeal to a court so that they can inform judicial decisions.*”

*“This information could be of particular value to the Court of Appeals for the Federal Circuit, which is in most instances the final arbiter of patent law. In order for judges to keep themselves well informed about relevant legal and economic scholarship, the court should encourage the submission of amicus briefs and arrange for temporary exchanges of members with other courts. Appointments to the Federal Circuit should include people familiar with innovation from a variety of perspectives, including management, finance, and economic history, as well as nonpatent areas of law that could have an effect on innovation.”*

## **AIPLA Response:**

### ***Flexible and Unitary System***

The NAS Report reflects a thoughtful examination of the U.S. patent system. It comments favorably on a number of aspects of the U.S. patent system, including its flexibility and open-ended character. AIPLA agrees with the Report’s recommendation that the United States retain a unitary patent system in which the same standards of patentability are applied flexibly to different subject matter inventions.

The NAS Report recommends increased use of Examination Guidelines. AIPLA agrees that Examination Guidelines may be valuable tools but cautions that they should not impair effective judicial review. The NAS Report recognizes that the Federal Circuit has substantially improved the quality of patent jurisprudence, and makes a series of recommendations regarding the composition of the Federal Circuit. AIPLA endorses these recommendations and urges that they be implemented in a manner that fosters uniformity and predictability in judicial decision-making.

The NAS Report observes that the present U.S. patent system has the flexibility to adapt to changing technologies, and, with few exceptions, has retained a unitary standard of patentability that has fostered predictability. AIPLA agrees with the observation that Congress has largely resisted making technology-specific distinctions in the standards for patentability. The exceptions that have been made, as noted in the NAS Report, are narrow, and Congress has maintained a unitary patent system. Yet, as the NAS Report points out, the system has remained open to technological change and has been able to adapt to new technologies without requiring substantial statutory revision. AIPLA agrees that this is one of the strengths of the U.S. patent system. The NAS Report also notes that obligations under the TRIPS Agreement prohibit members from discriminating in the grant of patents based on the technology involved.

The NAS Report observes that limited exceptions have evolved for various technologies, including: medical procedures; pharmaceuticals; and biotechnology. New statutory classes of intellectual property protection for semiconductor mask works, plants, and vessel hull designs are the only new examples of protection designed for particular

technologies. AIPLA agrees with the NAS Report that Congress has not and should not continually revisit the substantive standards for patentability each time a new technology appears. In this regard, the NAS Report notes that the U.S. patent system has remained flexible and receptive to new technologies through a variety of de facto mechanisms:

- maintenance fee lapse rates are different for patents in different technologies, reflecting variations in speed of innovation and product cycle time;
- pendency rates vary in the examination of different technologies;
- the criteria for patentability are applied differently in different technologies, such as the requirements for substantial utility in genomic inventions;
- experimental use is considered differently;
- the level of ordinary skill varies by technological discipline, as do secondary considerations of patentability;
- technological equivalents and pioneering inventions with broader scope vary by subject matter area, as do the applicability of the misuse defense and the availability of injunctive relief.

While not sharing the NAS view regarding utility in genomic inventions, as pointed out in the comments on the following Recommendation, AIPLA agrees with the NAS Report's observation that, in spite of the views of some observers, there is in fact a unitary standard of patentability for all technologies. AIPLA appreciates the NAS Report's perceptiveness in differentiating between the unitary standard and the de facto mechanisms that retain the system's flexibility to adapt to new technologies.

### ***Examiner Guidelines and Public Comment***

The NAS Report recommends that the USPTO continue this flexibility through more extensive use of Examination Guidelines. AIPLA notes that the Manual of Patent Examining Procedure already provides substantial guidance for examination of inventions in various technologies. Nonetheless, AIPLA concurs that Examination Guidelines have proved valuable in practice. AIPLA agrees that the use of Examination Guidelines should be continued and even extended in appropriate circumstances, yet, cautions that Examination Guidelines should not be given undue deference by the Courts.

Comments from diverse public sources garnered through notice and comment rulemaking may, as the NAS Report notes, provide a wealth of information from outside perspectives and may enrich the process. Caution, however, is required. Public comment cannot be given the same weight in statutory construction as legislative history from the

sponsor(s) of a bill. Nor can it substitute for a House or Senate conference report on what was intended by a specific provision. Rather, comments by the public are similar to questions from the floor of Congress or hearing testimony. They should be given appropriate weight, but their importance should not be overstated. Instead, it is comments by the sponsor(s) of a bill or from reports that provide guidance on Congressional intent. Administrative rulemaking cannot and should not subvert judicial decision-making. To the extent that administrative interpretation differs from the statutory requirements as determined by the courts, “it is emphatically the province and duty of the judicial department to say what the law is,” *Marbury v. Madison*, 5 U.S. 137 (1803). The Courts must exercise their independent judgment, without undue deference to comments memorialized through administrative rulemaking.

The NAS Report recognizes that the Constitutional authorization of Congress to promulgate intellectual property laws is broad: “to promote the progress of science and the useful arts.” Congress, in turn, has broadly exercised this authority in the current Patent Law. Specifically, as the NAS Report correctly points out, with few exceptions, patents may be granted for “anything under the sun that is made by man” that meets the statutory criteria of patentability, namely utility, novelty, non-obviousness, and the requirements for the disclosure itself. In contrast to the Federal Trade Commission Report (October 2003), which characterized prior judicial decisions as broadening the statutory criteria for patentability, the NAS Report correctly notes that prior USPTO and court decisions appearing to limit the scope of patentable subject matter were not consistent with the scope of patentable subject matter as determined by Congress. The NAS Report recognizes that, although many observers have considered certain recent judicial decisions as broadening the standards for patentability, they merely realize the full scope of patentable subject matter that Congress provided. AIPLA agrees with the NAS Report’s observations about the Constitutional mandate and Congressional policy decisions that define the scope of patentable subject matter under current patent law.

The NAS Report acknowledges the arguments that awarding patents may not be necessary to elicit the disclosure of certain inventions, and lists certain technologies in which some patents appear to have greater or lesser impact than in others. Although the FTC recommended modifying the patent system on that basis, AIPLA agrees with the NAS Report’s assessment that the same, unitary standards of patentability should be retained. Virtually every patentable invention may raise the question, in the words of Thomas Jefferson, whether or not the disclosure of the invention was “worth to the public the embarrassment of an exclusive patent.” That balance has been questioned since the earliest days of the Republic. Reasonable persons may disagree, and indeed do, with respect to specific individual inventions or categories of inventions. Nonetheless, the policy choice belongs to Congress, and AIPLA believes Congress has chosen correctly in this regard.

Care must be taken by the USPTO, therefore, to ensure that Examination Guidelines are consistent with Congressional policy and do not inject uncertainty into patent decision-making. Patentees and businesses seek certainty and predictability. Particularly at a time when the system is wrestling with substantial uncertainty over such fundamental issues as claim construction and the scope of equivalents, it would be counterproductive to introduce additional subjective and undefined standards through the use of Examination Guidelines. Hobbes's vision of life without effective government provides an apt analogy to the business patent user seeking predictability who would now be faced with such conflicting standards: "In such condition there is no place for industry, because the fruit thereof is uncertain . . . and which is worst of all, . . . the life of man, solitary, poor, nasty, brutish, and short."

### ***Federal Circuit***

The NAS Report notes with approval the benefits of consistency and expertise that the Federal Circuit has provided, but cautions that as a specialized court, the Federal Circuit risks becoming insular. It notes that this risk is greater in the Federal Circuit than in the regional circuits, which are courts of general jurisdiction. Specifically, the NAS Report echoes the FTC's criticism that the Federal Circuit fails to give adequate weight to scholarship in its decision-making. Although AIPLA questions whether giving weight to outside scholarship is a valid goal in its own right, AIPLA agrees that the specific recommendations made by the NAS Report may enhance the quality of appellate decision making and should be pursued.

The NAS Report recommends three measures to improve the quality of Federal Circuit decision-making, namely: (1) greater reliance on amicus briefs to provide additional input to the court; (2) diversity of experience in Federal Circuit appointments; and (3) increased sitting by designation to diversify Federal Circuit panels.

**Amicus Briefs.** AIPLA agrees with the NAS Report that amicus briefs may provide the court with greater insight and improve appellate decision-making. At a minimum, they may offer context to the decision and its impact on others who are not parties to the proceeding. AIPLA notes that amicus briefs are frequently filed in the Federal Circuit by various bar and industry groups, even when not specifically requested by the Court itself. In addition, a number of these groups, as well as particular companies, monitor issues that are presented to the Court and regularly offer unsolicited amicus support. AIPLA agrees with the NAS Report that these diverse views have aided the Court in its decision-making and endorses additional amicus support on the issues confronted by the Court.

**Appointments and Patent Law Experience.** The NAS Report suggests that Federal Circuit appointments not be confined to patent practitioners and academics and that they include candidates with expertise in other disciplines, specifically, antitrust,

finance, and economics or economic history. Historically, appointments to the Federal Circuit have included persons with a wide variety of experiences. The Federal Circuit was formed in 1982, by merging the U.S. Court of Claims and the Court of Customs and Patent Appeals. During the first ten years of the Federal Circuit's existence, the Court had twenty-four active or senior judges. Of these, ten had prior experience in Government service, ranging from short terms as a prosecutor to at least one whose entire career was spent in Government service. Only five judges in this ten-year period had patent and/or trademark background before ascending to the bench. Three were in tax practice, two were in commercial practice, four were in trade, corporate or federal administrative law, and one was drawn from academia, with some administrative experience. Thus, the experience of the judges elevated to the Federal Circuit in its first ten years reflects diverse backgrounds in a wide variety of legal disciplines, not limited to patent law. Presently, only four of the twelve active judges sitting on the Federal Circuit had patent law experience before ascending to the bench. It could certainly be argued that additional patent expertise, especially experience in trying patent cases, would be helpful in assisting the Court to deal with many of the issues it confronts.

Although AIPLA believes that it is extremely valuable to have this expertise, AIPLA recognizes that patent jurisdiction is only one of the many subject matter areas of the Federal Circuit's jurisdiction. Patent cases make up a relatively small percentage of the Federal Circuit's total case load, which also includes the following areas: Merit Systems Protection Board, Tucker Act (government contract claims), Jones Act (seaman's claims); trade cases (Court of International Trade and International Trade Commission); Trademark Office; and veterans' appeals. Since 1982, Congress has broadened, not narrowed, the Court's jurisdiction. Although many of the NAS Report's recommendations may improve the Federal Circuit's ability to better consider technology cases, the recommendation to increase diversity of Federal Circuit judges would do little to enhance the court's expertise in the other aspects of its jurisdiction.

Although not a court of general jurisdiction, the Federal Circuit is also not a specialized patent court. Historically, this fact has been accommodated by the appointment of judges with experience as government lawyers, from corporations, and from private practice. AIPLA agrees with the NAS Report's recommendation that appointing judges with diverse experience is a worthwhile goal. Moreover, AIPLA agrees with the NAS Report's recommendation to appoint U.S. District Judges to the Federal Circuit, particularly those with patent experience.

Nonetheless, as with many things in life, timing is everything. Although AIPLA agrees that diversity is a laudatory goal in general, certain aspects of the Court's jurisprudence, in AIPLA's view, militate against greater diversity at the present time as noted above. The Federal Circuit is currently wrestling with doctrinal splits on a number of critical substantive patent issues: claim construction; the written description requirement; enablement; and the scope of equivalents, among others. The lack of

consensus on these issues and high reversal rates have contributed to uncertainty in the law increased the burden on and frustration of the district courts. Often the result in a particular case depends on the composition of the Federal Circuit panel hearing the appeal. Increasing diversity while such critical jurisprudential issues are in flux will only exacerbate these problems.

**Sitting by Designation.** The NAS Report recommends that the Federal Circuit expand the practice of its judges sitting by designation on other courts. AIPLA notes that statistics on this practice are available for the first ten years of the Federal Circuit's existence, and that new statistics are expected shortly for the most recent ten-year period. These statistics establish that Federal Circuit judges have regularly sat by designation on other courts, as have judges from other courts sat by designation on Federal Circuit panels.

During the first ten years of the Federal Circuit's existence, the Chief Justice has designated twenty-six Federal Circuit judges to sit by designation on regional circuits, and four Federal Circuit judges to sit by designation on District Courts. In addition, twenty-eight judges have been designated to sit by designation on Federal Circuit panels: six from other regional circuits and twenty-two from various district courts. Although data is not yet available for the most recent ten year period, the Federal Circuit has sat in other locations in the country and, time permitting, certain Federal Circuit judges have assisted the regional circuits in these instances by sitting by designation on regional circuits. In addition, Senior Federal Circuit judges have made themselves available to assist other courts, typically regional circuits.

AIPLA agrees that sitting by designation is valuable for both the Federal Circuit judges on other courts (district and appeals) and other judges on the Federal Circuit. For example, the Federal Circuit's high reversal rate on claim construction issues causes great confusion and frustration among district judges. Having district judges who hear patent cases sit on Federal Circuit panels, and having Federal Circuit judges sit by designation as trial judges, may inform the decision-making of both the district courts and Federal Circuit. At a minimum, it will provide a vehicle for exchanging information about the process and its effects.

## **RECOMMENDATION 2:**

### **“Reinvigorate the non-obviousness standard.”**

*“The requirement that to qualify for a patent an invention cannot be obvious to a person of ordinary skill in the art should be assiduously observed. In an area such as business methods, where the common general knowledge of practitioners is not fully described in published literature likely to be consulted by patent examiners, another method of determining the state of knowledge needs to be employed. Given that patent*

*applications are examined ex parte between the applicant and the examiner, it would be difficult to bring in other expert opinion at that stage. Nevertheless, the Open Review procedure described below provides a means of obtaining expert participation if a patent is challenged.*

*“Gene sequence patents present a particular problem, because of a Federal Circuit ruling that with this technology obviousness is not relevant to patentability. This is unwise in its own right and is also inconsistent with patent practice in other countries. The court should return to a standard that would not grant a patent for an innovation that any skilled colleague would also have tried with a ‘reasonable expectation of success.’”*

The non-obviousness requirement should be applied with vigor. The NAS Report and AIPLA appear to be in complete agreement on this critical point. AIPLA views the non-obviousness requirement as being no different from the other requirements to secure a valid patent. All requirements for obtaining a valid patent should be applied with equal vigor by both the U.S. Patent and Trademark Office and the courts.

AIPLA believes that the courts, including the Federal Circuit, have applied the standard of non-obviousness with both the needed rigor and the appropriate vigor, and they have done so with a commendable consistency over the past two decades. If a difficulty exists with application of the non-obviousness standard today, it does not lie in the patent statute or in substantive law of non-obviousness as applied in the courts. Thus, there is no need for either a judicial or congressional reassessment of the non-obviousness standard or its application.

Instead, any legitimate concerns over the application of the law of non-obviousness appear to AIPLA to arise from the potential for inconsistent application by the U.S. Patent and Trademark Office. The Office is charged with applying this standard to hundreds of thousands of patent applications that must be examined every year. If any reinvigoration is needed, it is in the capabilities of the U.S. Patent and Trademark Office to discharge this responsibility. Securing the needed capabilities is, of course, dependent upon more adequate and consistent funding for the U.S. Patent and Trademark Office. This appears to be a critical issue on which AIPLA and the NAS Report are in full agreement.

Adequate funding at the U.S. Patent and Trademark Office is critical to the ability of patent examiners to have access to – and sufficient time to carefully consider – the full scope and content of the prior art needed for assessing non-obviousness. Adequate levels of funding are also needed to assure that patent examiners can be well-trained, highly motivated, and effectively supervised so that consistent quality in patentability assessments can be realized.

As the NAS Report notes, ascertaining all the relevant prior art is not always a simple task. It is challenging in certain technical areas, such as patents related to business methods, that may not record the state of the art in patents and printed publications. AIPLA again agrees with the NAS Report that particular attention should be given to the need for consistent quality in prior art searching in all such areas of technology.

In addition, the public should have the ability to test the application of the non-obviousness standard – and other requirements for a valid patent – once the patent is issued. This should be done through an effective post-grant opposition system. As noted elsewhere in this report, AIPLA concurs with the NAS Report’s recommendation on post-grant opposition proceedings.

The two-prong effect of an adequately resourced Office and an effective post-grant opposition would assure that all issued U.S. patents can be adequately tested for non-obviousness – as well as the other requirements for a valid patent – in a manner that AIPLA believes should fully address the concerns expressed in recommendation two of the NAS Report. Thus, the concerns described in the NAS Report do not implicate – at least in AIPLA’s view – any lack of vigor in the non-obviousness standard itself or its applicability to any particular technology. Instead, AIPLA views those concerns as more reflective of the practical difficulties in delivering consistent quality, which can and should be addressed.

AIPLA takes particular note, as mentioned above, of the fact that NAS does not recommend any change to the statutory standard of non-obviousness as currently expressed in 35 U.S.C. §103. Nothing contained in the NAS Report would, in fact, support such a change. Likewise, AIPLA is opposed to any technology-specific changes to the statutory non-obviousness standard. Indeed, if any change in the statute were to discriminate against one field of technology vis-à-vis some other, it could implicate the obligations of the United States under the TRIPs Agreement as noted above. AIPLA, therefore, applauds the NAS for its restraint on the issue of possible statutory changes to the non-obviousness standard.

The commentary in the NAS Report on the judicial interpretation of non-obviousness law as applied to gene sequence patents requires a specific AIPLA response. First, AIPLA supports *consistent* application of all conditions for patentability – to all fields of invention – in order to protect the public from patents on subject matter that does not merit exclusive rights. Second, this position on the need for consistent application of the conditions for patentability applies as much to gene sequence patents as it does to other areas of technology. Third, to the extent that the commentary in the NAS Report can be construed to advocate that gene patents should not be subject to any *lesser standards* for patentability, including a lesser standard for non-obviousness, AIPLA would be in strong agreement. If this construction is given to the commentary in the

NAS Report on gene sequence patents, it would be consistent with AIPLA's position on non-discriminatory treatment for all areas of technology in which patents are sought.

However, if the commentary in the NAS Report on gene sequence patents is construed to go beyond merely arguing against a lesser standard of non-obviousness for gene product patents, then AIPLA must part company with that position. AIPLA would not concur with the proposition that the courts should rethink the standard for non-obviousness that has been applied to gene sequence inventions for more than the past decade or longer. If this is the intended conclusion from the commentary in the NAS Report, AIPLA finds it not well grounded in either law or policy.

Gene sequences are chemicals, specifically deoxyribonucleic acid compounds. The courts have correctly analyzed non-obviousness for gene sequence inventions in precisely the same manner as for other chemical substance inventions. The law of non-obviousness for chemical substance inventions has been systemically developed, particularly during the past 50 years. Today, it represents a consistent, coherent and complete body of law.

It could serve no sound policy purpose to create exemptions from existing non-obviousness principles for one type of chemical substance invention, much less recast those principles altogether. Indeed, it would be unprecedented in the patent law to look differently at the non-obviousness of a gene sequence invention crafted by a genetic engineer from the non-obviousness of the very same chemical substance had it been crafted by an organic chemist. Congress carefully codified in 1952 that patentability is not to be negated by the manner in which the invention was made.

As to any policy implications, AIPLA would strongly dispute that the existing non-obviousness law, as it applies to gene sequences, leads to a situation where too many and/or too broad patents may be issuing. In AIPLA's view, the non-obviousness requirement, taken together with the *remaining conditions for patentability*, is more than sufficient to provide effective, but properly constrained claims to gene product inventions.

Finally, if the commentary in the NAS Report is construed to imply that the *O'Farrell* doctrine (*In re O'Farrell*, 853 F.2d 894 (Fed. Cir. 1988)) should be the only considerations applied to considering non-obviousness of gene product inventions, then AIPLA must part company with this conclusion. Gene sequence inventions, like all inventions, should have their non-obviousness determined based upon the "subject matter as a whole" of the claimed invention. This mandates consideration of the traditional criteria for non-obviousness of chemical products (*e.g.*, *In re Papesch*, 315 F.2d 381 (C.C.P.A. 1963)).

First, AIPLA notes that *O'Farrell* did not deal with gene products or other chemical substances. It did not purport to impact the longstanding precedent under which chemical products of all types are assessed for non-obviousness by looking at the “subject matter as a whole” of the claimed invention. This includes, of course, the motivation to make the specific molecular changes from the closest prior art to yield the claimed chemical product. “An element in determining obviousness of a new chemical compound is the motivation of one having ordinary skill in the art to make it.” *In re Gyurik*, 596 F2d 1012, 1018 (C.C.P.A. 1979).

Second, the entire body of Federal Circuit precedent indicates that when assessing the non-obviousness of process inventions it is critical to apply the “subject matter as a whole” of the claimed process to the determination of non-obviousness. In other words, the assessment of non-obviousness, even the determination of whether *prima facie* obviousness was established, must be undertaken by reference to the “subject matter as a whole.” The patent statute (35 U.S.C. §103(a)) requires no less.

Third, under the totality of Federal Circuit precedent, no *prima facie* obvious can be established for a claimed process using only the *O'Farrell* factors where the claimed process produces novel and non-obvious products. This result is mandated because of the Federal Circuit’s holdings in *In re Ochiai*, 54 F.3d 776 (Fed. Cir. 1995) and *In re Brouwer*, 77 F.3d 422 (Fed. Cir. 1996). These appeals involved *O'Farrell*-type process claims that the U.S. Patent and Trademark Office had determined were *prima facie* obvious under the limited criteria applied in *O'Farrell*. The Federal Circuit reversed in both appeals.

The Federal Circuit found in these appeals that limiting the non-obviousness inquiry to the *O'Farrell* factors violated the requirement in the patent statute (35 U.S.C. §103(a)) to assess non-obviousness based upon the subject matter as a whole of the claimed invention. The Federal Circuit expressly refused to limit the inquiry as to *prima facie* obviousness to the “obvious to try” and “reasonable expectation of success” criteria cited in the NAS Report. It found such a limited inquiry to be repugnant to the patent statute. Instead, the court indicated that the *prima facie* obviousness of the claimed process must be assessed by considering motivation to make the novel and non-obvious *products* produced by the processes. For a process to be even *prima facie* obvious, according to the court, the “subject matter as a whole” of the claimed process must be considered, including the novel and non-obvious products produced by the process.

AIPLA believes that the full explication of Federal Circuit jurisprudence can yield only one conclusion. The Federal Circuit’s application of the statutorily required “subject matter as a whole” inquiry has been consistently applied for both product and process inventions. If read to *necessarily* limit the non-obviousness inquiry of either a process or a product invention to the *O'Farrell* factors, the NAS Report is inconsistent with both the statute and with the totality of Federal Circuit precedent.

AIPLA believes that the NAS Report, had it taken the foregoing Federal Circuit precedent fully into account, would not have reached a conclusion different from that expressed by AIPLA herein. More importantly, had the NAS Report more fully considered the manner in which a consistent application of the remaining conditions for patentability today constrain the availability of gene product patents, AIPLA believes that NAS would have concluded that any possible policy concerns over gene patenting are being adequately addressed by the courts.

**RECOMMENDATION 3:**

**“Institute an Open Review procedure.”**

*“Congress should seriously consider legislation creating a procedure for third parties to challenge patents after their issuance in a proceeding before administrative patent judges of the USPTO. The grounds for a challenge could be any of the statutory standards – novelty, utility, non-obviousness, disclosure, or enablement – or even the case law proscription on patenting abstract ideas and natural phenomena. The time, cost, and other characteristics of this proceeding should make it an attractive alternative to litigation to resolve patent validity questions. For example, federal district courts could more productively focus their attention on patent infringement issues if they were able to refer validity questions to an Open Review proceeding.”*

**AIPLA Response:**

AIPLA agrees with the NAS Report that Congress should consider legislation creating an “Open Review,” or post-grant review, proceeding for third parties to challenge the validity of patents after their issuance. Such procedure should provide a balance between the cost and efficiency of removing invalid patents while protecting the rights of the requester and the patentee. General features of AIPLA’s recommended procedure include:

Allowing any person to request reconsideration of the grant of a patent by a panel of three Administrative Patent Judges by filing an opposition request with the USPTO.

Requiring requesters to identify the real party in interest but allowing the identity of the real party in interest to be kept sealed unless requested by a Government agency or a person showing good cause or the requester relies upon affidavits or exercises the right to appeal an adverse decision.

Requiring requests to be filed not later than nine months after the grant of the patent unless the patent owner consents in writing.

Allowing the opposition request to challenge validity based on double patenting and any of the requirements for patentability set forth in 35 U.S.C. §§ 101, 102 (except issues arising under §§ 102(c), 102(f) and 102(g)), 103, 112(¶¶ 1 and 2 (except for best mode)) or 251(¶4).

Allowing the patentee to narrow claims by amendment.

Allowing cross-examination of witnesses but no other discovery unless required in the interest of justice.

Basing the burden of proof on a preponderance of the evidence and applying the broadest reasonable construction of the claim.

Allowing a party to appeal a final decision to the Federal Circuit.

Applying preclusive effect on a requester in any subsequent proceeding with respect to an issue of invalidity raised by a requester, decided by the panel and necessary to the final determination.

Concluding the proceeding not later than one year after institution with a possible extension by not more than six months.

Allowing termination of the proceeding upon receipt of a joint request of the requester and the patent owner.

According to the NAS Report, a carefully designed and adequately funded post-grant procedure, addressing the entire range of patent quality issues, and not compromised by a conflict of interest, would represent a superior alternative to either re-examination or litigation.

AIPLA agrees. Such a process would provide significant opportunities for enhancing patent quality, thereby increasing business certainty, promoting competition, and fostering continued innovation. Therefore, AIPLA supports the creation of such a new administrative procedure in which the patentability of issued claims can be reviewed subsequent to the grant of a patent.

The NAS Report asserts that the details of design will determine whether the system is used, whether it is efficient and fair to all parties, and, importantly, whether it is subject to abuses that undermine its purpose.

AIPLA agrees. To that end, AIPLA supports legislation that addresses prompt filing of requests for review by a panel of three administrative patent judges, quick resolution of issues addressed, cost balancing limitations on issues addressed and

discovery, and limited estoppel provisions that apply only to those issues actually raised and decided.

General features of the NAS Report's recommended process include:

Any third party requesting a review should bear the burden of persuasion, subject to a preponderance of the evidence standard, that the claims of a patent should be cancelled or amended.

The Federal District Courts should be able to refer issues of patent validity raised in a lawsuit to a post-grant proceeding, confining themselves to resolving issues of infringement. The Department of Justice or the Federal Trade Commission should be able to request the director of the USPTO to initiate a review if they suspect that an invalid patent or patents are being used to adversely affect competition.

The requesting party would pay a fee, but the challenger and the patent holder would each pay their attorney fees and other costs.

The challenger would, of course, have access to the history of the patent's prosecution.

The proceeding would be conducted by an Administrative Patent Judge (APJ) or panel of judges of the U.S. Patent and Trademark Office.

The APJ would have discretion to allow limited discovery, live testimony of experts, and cross-examination.

Subject to the Administrative Procedures Act, the USPTO would have broad authority to design procedures drawing on the best practices of other countries but aimed at speed, simplicity, and moderate cost. It should do so in consultation with professionals steeped in the details of the current administrative proceedings – re-examination, re-issues, and interferences – and familiar with their drawbacks.

In rare cases, circumscribed in regulation, the USPTO should have discretion to continue a post-grant proceeding even if the parties decide to settle their disagreement.

The review procedure would substitute for inter partes reexamination and third-party-initiated ex parte reexamination.

AIPLA agrees with many of the general features of the NAS Report's recommended process. Specifically, AIPLA agrees that the party requesting a review

should bear the burden of persuasion subject to a preponderance of the evidence standard. AIPLA agrees that the requesting party should pay a fee, but the requesting party and the patent holder would each pay their own attorney fees and other costs. AIPLA agrees that the requester should have access to the complete history of the patent's prosecution. AIPLA believes that a proceeding should be conducted by a panel of not one, but three, Administrative Patent Judges (APJ) of the United States Patent and Trademark Office ("the panel") to promote uniformity in the decision making process. AIPLA agrees that the panel should have discretion to allow limited discovery in the interests of justice, but that such discovery should be limited to cross-examination by deposition of all affiants and declarants, including experts. The panel may also permit such cross-examination to take place live during an oral hearing before the panel. AIPLA agrees that the USPTO should have broad authority to design procedures aimed at speed, simplicity and moderate cost, and that fairness and the interest of justice must be high on the list of considerations when designing such procedures.

AIPLA disagrees with a few of the general features of the NAS Report's recommended process. In particular, AIPLA disagrees that Federal District Courts should be able to refer issues of patent validity raised in a lawsuit to a post-grant proceeding, thereby confining themselves to resolving issues of infringement. Often, patentability issues are extremely fact intensive and require more extensive discovery than should be accommodated in the proposed review. In such instances, parties should not be excluded from pursuing such challenges with the full benefit of discovery afforded in federal district court litigation, nor should the United States Patent and Trademark Office be burdened with affording the required discovery.

AIPLA further disagrees that the USPTO should have discretion to continue a post-grant proceeding even if the parties decide to settle their disagreement. Where the parties to an opposition proceeding request the termination of a proceeding and file a copy of their settlement agreement in the USPTO, the proceeding should be terminated. The threat of a continued proceeding could have a chilling effect on proposed settlement offers and, in effect, further burden the USPTO and parties with unnecessarily extended proceedings.

The success of any post-grant proceeding can only be proven in practice, and achieving a fair balance may well require adjusting the procedure or its relationship to ex parte and inter partes reexamination based on experience. However, AIPLA does not believe it should be done at this time since ex parte initiated reexamination will continue to be the lowest cost option for challenging the patentability of a claim, albeit on limited grounds. Thus, even where a party has instituted an opposition, there should not be a ban on that party filing an ex parte request for reexamination after the opposition has been terminated. On the other hand, AIPLA does believe that a patent for which a post-grant proceeding has been instituted should not thereafter be made the subject of a request for an inter partes reexamination by the same party who initiated the Open Review.

The NAS Report makes the following recommendations regarding the issues to be addressed and outcomes to be achieved:

Validity could be challenged on any ground – that the invention is not patentable subject matter, is not novel, is obvious, lacks utility, or is not properly disclosed.

Matters previously considered by the patent examiner could be reviewed.

The outcome would be a confirmation, cancellation, or amendment of the claims in dispute, but claims could not be broadened in a review proceeding, as distinct from a reissue proceeding.

Either party could appeal the APJ's decision, first to the Board of Patent Appeals and Interferences, and then to the Court of Appeals for the Federal Circuit. Appeal to the Federal Circuit would invoke estoppel.

AIPLA agrees with many of these recommendations concerning the issues to be addressed and outcomes to be achieved. For example, AIPLA agrees that the matters previously considered by the patent examiner could be reviewed. Further, AIPLA agrees that the outcome should result in confirmation, cancellation or amendment of the claims in dispute, but claims could not be broadened in a review proceeding.

However, AIPLA disagrees that validity should be allowed to be challenged on any ground. Instead, AIPLA believes that the grounds for requesting this new review proceeding should include all issues of utility, novelty, and nonobviousness under 35 U.S.C. §§ 101, 102 (with the exception of issues arising under §§ 102(c), 102(f) and 102(g)) and 103. AIPLA further believes that this new review proceeding should include issues of: (1) written description, enablement and definiteness under 35 U.S.C. § 112 (¶¶ 1 and 2, but excluding “best mode”); (2) non-statutory double patenting; and (3) broadening reissue under 35 U.S.C. §251, fourth paragraph. AIPLA believes that the excluded issues are highly fact intensive, with such facts typically solely in the possession of the patent owner, and require extensive discovery. Therefore, they are best left to the District Courts where full discovery is available.

AIPLA agrees that decisions of the panel should be appealed directly to the Court of Appeals for the Federal Circuit, as opposed to a district court.

While AIPLA generally agrees that some type of estoppel is appropriate, AIPLA supports application of a limited estoppel that prevents the requester from later challenging in a civil action any finding of fact or conclusion of law incorporated into the panel's final determination, absent a showing that additional factual evidence exists that could not reasonably have been discovered at the time of the post-grant proceeding

because of the limited discovery permitted. This limited estoppel would apply when the time for appeal has expired or any appeal proceeding has terminated. AIPLA further believes that the reasons for creating this new administrative procedure, and the public's interest in having only valid patents granted, are best served by not creating any other statutory estoppels based upon a party's participation in the review proceeding, particularly where the proceeding is initiated within nine months of the patent grant.

The NAS Report noted that there was not one view on the important issue of whether patents should be subject to challenge and review for only a limited time after they are issued, as is the practice in Europe, or for as long as they remain in force. A majority favored limiting the window for challenge to one year from the date of grant to reduce uncertainty later in the life of the patent, but to allow a challenge thereafter if the patent owner has alleged infringement.

AIPLA believes that, as a means of motivating challenges for early resolution of uncertainties regarding a patent's validity, there should be a limited time period during which third parties may avail themselves of this new review proceeding. Preferably, this time period should be no more than nine months from the date that the patent issues. AIPLA also believes that both the patentee and a third party requester should be able to utilize this new administrative proceeding at any time by mutual agreement.

The NAS Report recognizes there is a strong theoretical case for the welfare gains of adopting a post-grant review proceeding. These include the prevention of unwarranted monopoly profits, the alignment of patent costs and benefits to genuine novelty and utility, and the reduction in uncertainty for all participants in the relevant market. These benefits depend heavily on two effects or characteristics of the system – first, that it tends to substitute for, rather than lead to, litigation and second that it is less expensive and faster than litigation.

AIPLA believes that such a review proceeding must be implemented with sufficient mechanisms in place to achieve a reasonably prompt and cost-effective procedure for determining the patentability of one or more issued claims without creating an undue burden on patentees to defend their patents against frivolous assertions, and with adequate procedures designed to protect a patentee from harassment. Therefore, to aid in preventing the review proceeding from becoming a vehicle for harassing patentees, AIPLA believes that strict time limits should apply and be adhered to by the administrative patent judges.

In particular, the review proceeding should normally be completed within one year from the date it is instituted, with a six-month extension possible upon a showing of good cause. If multiple requests are filed, they should be combined into a single proceeding unless the panel decides, in appropriate cases, to institute separate proceedings. After the panel institutes the opposition, the patent owner should be afforded the option to respond

to the request and provide any factual evidence or expert opinions (in the form of affidavits or declarations) that rebut the request. As part of its response, the patent owner should have an opportunity to narrow its claims as a matter of right. Additional briefing, or further amendments by the patentee, should be permitted only upon a showing of good cause. The requester should be given an opportunity to exclude an amended claim from the proceeding or to address any new issues of patentability raised by an amended claim. Both the patentee and the requester should have the same right to appeal the panel's final determination to the Court of Appeals for the Federal Circuit as in the current *inter partes* reexamination.

The NAS Report observes that it will certainly require additional resources – money, infrastructure, people, and space – to achieve an effectively functioning review procedure in the USPTO. AIPLA agrees that an Open Review process will require additional resources. While the Board of Patent Appeals and Interferences should be commended for improving efficiency and reducing its backlog, it cannot be expected to take on the responsibility of this significant and important change in the law without additional resources.

The NAS Report notes that, in the past, adoption by the United States of a post-grant proceeding comparable to an opposition has been opposed by the “independent inventor” community as a potential weapon of large businesses against individuals and small enterprises. However, the NAS Report points out, and AIPLA agrees, that individuals and small businesses will not be harmed by an Open Review system, but rather will be beneficiaries of an alternative, cheaper, and faster system of resolving patent validity questions. AIPLA also believes that the interests of the “independent inventor” community are best served by prompt, cost-effective resolution of patentability issues with necessary safeguards in place to protect the patent owner from harassment.

#### **Recommendation 4:**

##### **“Strengthen USPTO capabilities.”**

*“To improve its performance, the USPTO needs additional resources to hire and train additional examiners and implement a robust electronic processing capability. This has been a consistent recommendation of review of the patent system dating back to 1919. Further, the USPTO should create a strong multidisciplinary analytical capability to assess management practices and proposed changes, provide an early warning of new technologies being proposed for patenting, and conduct reliable, consistent, reputable quality reviews that address office-wide and individual examiner performance. The current USPTO budget is not adequate to accomplish these objectives, let alone to finance an efficient Open Review system.”*

## **AIPLA Response:**

The NAS Report adds a voice to a widening chorus of observers who have recognized the harm done to the USPTO by the decade-long political plundering of its financial resources, and who support additional resources for the USPTO to improve its performance. AIPLA supports providing additional funding for the USPTO to support the 21<sup>st</sup> Century Strategic Plan developed by the USPTO in 2002 and specifically the pending Fee Legislation, provided that all of the fee revenues generated are either made fully available to the USPTO, or that any amount not made available is refunded to those who paid the fees.

AIPLA has consistently believed that the USPTO should receive all of its fees as evidenced by the following resolutions:

Fee diversion – “RESOLVED, that the AIPLA favors in principle that all revenue generated by fees paid by users of the services of the USPTO for application processing be made promptly available to the USPTO without limitation to provide such services, and Specifically, AIPLA opposes the withholding or diversion of any such revenue to fund any non-USPTO programs.” (July 10, 2000)

Fee Diversion – “RESOLVED, that AIPLA supports H. Res. 110 introduced on April 3, 2001, that would make it out of order for the House of Representatives to consider any bill, joint resolution, amendment, motion, or conference report that makes available funds to the USPTO for any fiscal year, or for any other period for which the funds are provided, in amounts less than the total amount of patent and trademark fees collected by the USPTO in that fiscal year or during that other period (as the case may be).” (July 11, 2001)

There are three principal aspects of USPTO performance that require evaluation - patent quality (i.e., will competitors and the courts respect the patent grant), early clarification of rights (i.e., how long will it take to grant the patent), and cost-effectiveness in USPTO operations. Questionable patents are being issued due to many reasons addressed in the 21<sup>st</sup> Century Strategic Plan. Patent application pendency will soon be at the highest level in more than twenty years unless the USPTO receives requested funding. The backlog of pending patent applications is at an all-time high. Cost effectiveness of the USPTO has been compromised because it has had to forego critically needed investments in e-processing to focus on current workload.

AIPLA supports the 21<sup>st</sup> Century Strategic Plan, which depends on enactment of pending fee bill, HR 1561, for its funding. This bill increases user fees by some 15 to 25% - an amount users are willing to pay for better service, provided the USPTO receives all of its fees. The fee bill, as amended, has passed the House on March 3, 2004, ensures that all of the fee revenue generated by patent and trademark fees will go to the USPTO

or be refunded to the users. While not guaranteeing that all fee revenues will go to the USPTO, the amended fee bill at least provides a solution to the fee diversion problem, which has resulted in more than \$650M of patent and trademark fees being diverted to other government programs since 1992. It does this by providing, as noted, that any revenues collected in excess of the amount appropriated to the USPTO will be refunded to users. It is hoped that, since the fee revenues would no longer be available to the appropriators to spend elsewhere, they will appropriate all fee revenues to the USPTO.

AIPLA supports the significant progress that has been demonstrated by the USPTO in adapting its operations to an electronic operating environment. For the most part, the initiatives already introduced by the USPTO have improved its operations, improved access to information in the USPTO for both the examining staff and the public, and provided opportunities for greater efficiencies in processing patent and trademark applications. We support efforts being made to establish user-friendly options for patent application filing and electronic access to file wrapper contents. These efforts, which are finally starting to show signs of real success after many years of development, also require additional financial resources to complete, and be maintained and improved on a continuing basis.

AIPLA supports a robust multi-disciplinary analytical capability within the USPTO to provide guidance on future needs and information on current programs. Public Advisory Committees were established in 1999 under 35 U.S.C. § 5 to advise the Director on policies, goals, performance, budget and user fees of the USPTO with respect to both patents and trademarks. The USPTO has had internal staff devoted to analysis and projections of future needs and development of program options, but is continually hampered by the lack of funds to support such a capability in addition to more prominent and immediate goals.

AIPLA has supported a robust quality review system within the Patent and Trademark Office. Specifically it has supported a second pair of eyes review that allows USPTO to quickly flag issues that need further attention by the examiner or the examiner's supervisor. The USPTO first used this method to improve the quality of business method patents, and it received some good reviews from participants in the patent system, although there is some concern that apprehension over issuing a bad patent is preventing the grant of patents on inventions that do meet all criteria for patentability. If it is found that this program is effective for both preventing the grant of bad patents while not preventing the grant of patents on inventions that should be patented, the AIPLA believes that the expansion of this program to fields with substantial economic importance, as well as other new technologies as they emerge, could help to boost patent quality in areas where it will make the most difference.

## **RECOMMENDATION 5:**

### **“Shield some research uses of patented inventions from liability for infringement.”**

*“In light of the Federal Circuit’s 2002 ruling that even noncommercial scientific research conducted in a university enjoys no protection from patent infringement liability and in view of the degree to which the academic research community especially has proceeded with their work in the belief that such an exception existed, there should be limited protection for some research uses of patented inventions. Congress should consider appropriate targeted legislation, but reaching agreement on how this should be done will take time. In the meantime the Office of Management and Budget and the federal government agencies sponsoring research should consider extending ‘authorization and consent’ to those conducting federally supported research. This action would not limit the rights of the patent holder, but it would shift infringement liability to the government. It would have the additional benefit of putting federally sponsored research in state and private universities on the same legal footing. A recent Supreme Court ruling shielded state universities from damage awards in patent infringement suits.”*

### **AIPLA Response:**

AIPLA agrees with the recommendation of the NAS Report that Congress act to exempt certain experimentation on patented inventions from liability for patent infringement. However, the NAS Report’s proposal for “liability shifting” as an alternative – if Congressional action on an exemption is not forthcoming – represents neither a feasible nor a desirable alternative.

The NAS Report starts with the premise that:

Ultimately, the test of a patent system is whether it enhances social welfare, not only by encouraging invention and the dissemination of useful technical information but also by providing incentives for investment in the commercialization of new technologies that promote economic growth, create jobs, promote health, and advance other social goals.

AIPLA wholeheartedly agrees with the NAS Report’s assessment of the principal goals of the patent system. The patent system, in the words of the Constitution exists “to promote the progress of the useful arts.” Such progress means that the patent system, functioning properly, will advance social welfare through encouraging both innovation and dissemination of knowledge. Fostering more innovation and greater dissemination of

technical knowledge should instruct the policy choices that are made in crafting patent laws.

It is with this philosophic understanding of the patent system's role that AIPLA endorses the NAS Report's call for a statutory experimental use exemption. Some exemption for experimentation on patented inventions must be part and parcel of an effectively functioning patent system.<sup>1</sup>

The exemption is inherent to a properly functioning patent system at least where experimentation is required to understand *what is patented, whether the patent is valid, what basic properties or characteristics the patented invention might have, and to improve upon the invention*. In brief, a patent system operates in an appropriate and balanced fashion when what is patented is reserved for the inventor to exclusively commercialize and given to the public to both further examine and improve upon. The inventor need not be denied the former when the public has a limited exemption to accomplish the latter.

The NAS Report cites the recent Federal Circuit decisions in *Duke v. Madey* and *Integra v. Merck KGaA* and notes that these decisions have created an undesirable degree of uncertainty over where the line is to be drawn as between the inventor's exclusivity in commercialization and the public's right to engage in legitimate experimentation.<sup>2</sup> The

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<sup>1</sup> Although no explicit statutory exemption from infringement is found in the patent statute itself, some commentators have found logical support in the statute for the proposition that not all activities or "uses" connected with a patented invention should be found infringing:

If the public had absolutely no right to make, use, or sell the patented invention until the *end* of the patent term, it would be somewhat puzzling to require that the patentee give the public an enabling disclosure of the invention at the *beginning* of the patent term. The requirement of early disclosure suggests that certain uses of patented inventions during the patent term do not constitute patent infringement.

Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology*, 97 Yale L.J. 177, 218 (1987).

<sup>2</sup> Another such decision is *Embrex, Inc. v. Service Engineering Corp*, 55 USPQ2d 1161, 216 F.3d 1343 (Fed. Cir. 2000). In that appeal, Judge Rader in a concurring opinion stated that he wished the majority would have held that "the Patent Act leaves no room for any *de minimis* or experimental use exemption from infringement." Such an extreme interpretation would preclude any activity with patented subject matter qualifying as exempt from infringement and permit the activities to be enjoined. Moreover, this interpretation runs counter to longstanding judicial and treatise commentary supportive of the vitality of this exemption. The concurring decision does, however, underscore the importance of a Congressional response to what are apparently varying views at the Federal Circuit of what the controlling common law principles are or should be.

concern has not been diminished by suggestions that the “experimentation” issue is a *de minimis* one because patent licenses for any needed experimentation are generally available for nominal sums. Indeed, the evidence suggests the contrary may in fact be the case. In any event, failing to have a definitive provision in the patent law exempting experimentation can create many potential adverse consequences, including threatened patent litigation, complicated licensing negotiations, efforts to secure compensation based upon the fruits of any experimentation (including “reach-through” royalties), royalty stacking, and delays in starting experiments until patent issues can be resolved.

Thus, AIPLA endorses the NAS Report’s recommendation that a legislative solution be expeditiously sought. AIPLA is developing such a legislative solution that is discussed in greater detail below. AIPLA is endeavoring to craft a narrow, statutory exemption for experimental use for a patent invention that would not impinge upon an inventor’s exclusive right to commercialization, but would open the way for an appropriate range of experimentation on the patented invention.

AIPLA does not share the view expressed in the NAS Report that Congress would have insufficient interest in this issue to promptly pursue legislation providing such an exemption. The alternative remedy proposed in the NAS Report is that the “federal government could assume liability for patent infringement by investigators whose work it supports under contracts, grants and cooperative agreements.” AIPLA believes this remedy could prove unworkable and is at best insufficient.

First, while the biomedical industry is where the issue most frequently arises, the remedy must address all areas of research no matter where carried out or how funded. The proposal in the NAS Report would not apply to vast amounts of research, much of which is as important as federally funded biomedical research.

Second, the NAS Report expresses the view that the preemption remedy can be implemented much more quickly than legislation could be enacted. The recent experience, however, with the CREATE Act would suggest otherwise, particularly if a cogent legislative proposal can be assembled and concerted resources are placed on vetting the proposal. In this regard, AIPLA will offer its proposal for legislation that is being crafted to achieve just this objective.

AIPLA has specifically endorsed legislation which would serve to exempt from infringement research that is directed to any of the following activities: (1) evaluating the validity of the patent and the scope of protection afforded under the patent; (2) understanding features, properties, inherent characteristics or advantages of the patented subject matter; (3) finding other methods of making or using the patented subject matter; and (4) finding alternatives to the patented subject matter, improvements thereto or substitutes therefor. Such a proposal, although narrowly crafted, will provide a sufficient

safe harbor for experimentation to encompass all the activities that NAS believes should be exempt from the scope of the patent rights.

The proposal advanced by AIPLA is based upon international precedents. An exemption for experimentation not only exists outside the United States, but also is recognized as part of the statutory patent law.<sup>3</sup> Its continued absence from U.S. patent law could have the unintended effect of making it more expedient to conduct certain types of experimental work in foreign countries where the threat of patent infringement litigation would not exist. Promoting the progress of the useful arts *outside the United States* should not be encouraged simply because of the lack of a comparable provision in U.S. patent law.

Finally, the codification of an experimental use doctrine is especially important today given the broad reach of the patent law to “everything under the sun that is made by man.” *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980). Because of the patent eligibility of all man-made products and processes, the doctrine assures that products discovered in nature and patented as man-made compositions, *e.g.*, isolated and purified genetic material, hormonal substances, and organisms, can nonetheless be fully studied and examined during the patent term, whether for purposes of improving or designing around the patented subject matter.

Hence, the enactment of the statutory “experimental use” exemption recommended by NAS Report would reduce and eventually remove the substantial uncertainty over what is and is not an infringing use of a patented invention in a manner

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<sup>3</sup> Other industrialized countries have provisions on non-infringing uses, including Article 69(1) of the Japanese Patent Act (“[t]he effects of the patent shall not extend to the working of the patent right for the purposes of experiment or research.”) and Article 27(b) of the Community Patent Convention (“acts done for experimental purposes relating to the subject-matter of the patented invention” are exempted). In 1990, the House of Representatives considered the desirability of codifying a similar statutory research exemption by adding a 35 U.S.C. § 271(j):

(j) It shall not be an act of infringement to make or use a patented invention solely for research or experimentation purposes unless the patented invention has a primary purpose of research or experimentation. If the patented invention has a primary purpose of research or experimentation, it shall not be an act of infringement to manufacture or use such invention to study, evaluate, or characterize such invention or to create a product outside the scope of the patent covering such invention. This subsection does not apply to a patented invention to which subsection (e)(1) applies.

See Section 402, H.R. 5598, 101<sup>st</sup> Congress, September 12, 1990.

that would demonstrably promote progress in the useful arts, while assuring that the United States would remain a prime location for the experimentation required to do so.

#### **RECOMMENDATION 6:**

##### **“Modify or remove the subjective elements of litigation.”**

*“Among the factors that increase the cost and decrease the predictability of patent infringement litigation are issues unique to U.S. patent jurisprudence that depend on the assessment of a party’s state of mind at the time of the alleged infringement or the time of patent application. These include whether someone ‘willfully’ infringed a patent, whether a patent application included the ‘best mode’ for implementing an invention, and whether an inventor patent attorney engaged in ‘inequitable conduct’ by intentionally failing to disclose all prior art when applying for a patent. Investigating these questions requires time-consuming, expensive, and ultimately subjective pretrial discovery. The committee believes that significantly modifying or eliminating these rules would increase predictability of patent dispute outcomes without substantially affecting the principals that these aspects of the enforcement system were meant to promote.”*

#### **AIPLA Response:**

##### **I. Willful Infringement:**

*“Lacking evidence of its beneficial deterrent effect but with evidence of its perverse antidisclosure consequences, the committee recommends elimination of the provision for enhanced damages based on a subjective finding of willful infringement; but we recognize that this is a matter of judgment and that there are a number of alternatives short of elimination that merit consideration. A modest step is to abolish the effective requirement that accused infringers obtain and then disclose a written opinion of counsel. Another possibility is to limit inquiry into willful infringement to cases in which the defendant’s infringement has already been established. A third alternative that preserves a viable willfulness doctrine but curbs its adverse effects is to require either actual, written notice of infringement from the patentee or deliberate copying of the patentee’s invention, knowing it to be patented, as a predicate for willful infringement (Federal Trade Commission, 2003; Lemley and Tangri, 2003). If some form of willfulness doctrine is retained, there is the question by how much should damages be enhanced. One answer is by the least amount needed to deter deliberate copying and make the victims whole. Lemley and Tangri suggest that in most instances awarding successful plaintiffs*

*their attorney fees will suffice as an adequate penalty. Finally, modification or elimination of willful infringement raises questions about the status of the “duty of care” to avoid patent infringement. This is a matter we did not address that merits further consideration.”*

### ***Elimination of “Willful Infringement” as a Doctrine in Patent Law***

AIPLA agrees with the observation in the NAS Report that the effect of the elimination of the doctrine of willful infringement would be to remove from patent litigation an issue of intent that can produce a significant discovery burden, introduce an element of substantial uncertainty, and complicate much patent infringement litigation. However, AIPLA also acknowledges, as does the NAS report, that the questions of whether to eliminate willful infringement as a doctrine of patent law and the degree to which “enhanced” damages should be used as a tool to deter willful infringement are difficult questions that raise strongly competing policies.

AIPLA had been hopeful that these problems would have been obviated in whole or in part by the *en banc* Federal Circuit in the pending case of *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.* 344 F3d 1336 (Fed. Cir. 2003). With the *en banc* decision of the Federal Circuit handed down on September 13, 2004, however, it is now clear that most of the problems raised by this difficult area of the law remain unanswered by the court’s decision, and will thus require further thought and study as suggested by the NAS report. With respect to the three alternatives specifically raised in the NAS report, our comments are as follows.

#### ***First Alternative: Eliminate Relevance of “Opinions of Counsel” to Willfulness***

AIPLA agrees with the First Alternative to abolish the requirement that accused infringers obtain and disclose a written opinion of counsel as the only way of establishing due care. AIPLA took this position in its amicus brief in the *Knorr-Bremse* appeal which may be found at:

[http://www.aipla.org/Content/ContentGroups/Issues\\_and\\_Advocacy/Amicus\\_Briefs1/knorr\\_bremse.PDF](http://www.aipla.org/Content/ContentGroups/Issues_and_Advocacy/Amicus_Briefs1/knorr_bremse.PDF).

Thus, as stated in the AIPLA brief, whether or not legal advice was sought, whether or not an opinion of counsel was received, and whether or not attorney-client privilege is waived, there should be no adverse inference with respect to the issue of possible willfulness. The Federal Circuit clearly agreed with this position in its answers to Questions 1 and 2.

Although abandoning the presumptions flowing from claiming the privilege or not obtaining an opinion, the Federal Circuit in *Knorr-Bremse* left intact the duty of due care,

that is, the affirmative duty to exercise due care to determine whether or not one is infringing, including the duty to seek and obtain competent legal advice from counsel before the initiation of any possible infringing activity. Thus, this case did not eliminate the relevance of opinions of counsel to willfulness. Therefore, recognizing that the Federal Circuit has in the past affirmed findings of no willfulness even where the infringer did not obtain an opinion of counsel, AIPLA urges that if the duty of due care is to be retained, it should be clarified that, while reasonable reliance on an opinion of counsel can establish due care, it is not the only way of establishing due care.

***Second Alternative: Limit Inquiry into Willful Infringement to Cases Where Defendant's Infringement Has Already Been Established***

AIPLA believes that the Second Alternative would reduce the discovery burden in the vast majority of patent infringement cases and, to that extent, have a salutary effect. While willful infringement is alleged in 92% of patent cases, Kimberly A. Moore, *Empirical Statistics on Willful Patent Infringement*, 15 Fed. Cir. Bar. J. \_\_\_ (forthcoming in October 2004), relatively few patent cases are tried, *id.* (6.2% of patent cases are tried), so that delaying discovery until a liability determination would provide a benefit—at least in terms of reduced discovery costs—in most patent cases. Additional salutary effects that would flow from this alternative in the relatively few cases that are actually tried would be that the trier of fact on willfulness would be more likely to treat willfulness as an “exceptional case” rather than simply a corollary to liability for infringement (which statistics suggest is the current treatment, particularly in jury trials, *see id.* (from 1983–2000, willfulness found in 67.7% of jury trials and 52.6% of bench trials), and that the trier of fact on liability would not be swayed in making that decision by facts relevant only to willfulness. The traditional objection to this alternative is that delaying discovery and trial on willfulness would violate the patentee’s 7<sup>th</sup> Amendment right to jury trial by forcing consideration of willfulness by a trier of fact other than the jury that tried liability. As explained below in connection with the Third Alternative, however, AIPLA believes that there should be no right to jury trial on willfulness, a position with which several scholars have agreed. *See* Janice M. Mueller, *Commentary: Willful Patent Infringement and the Federal Circuit’s Pending En Banc Decision in Knorr-Bremse v. Dana Corp.*, 3 J. Marshall Rev. Intell. Prop. L. 218 (2004); John B. Pegram, *The Willful Patent Infringement Dilemma and the 7<sup>th</sup> Amendment*, 86 J. Pat. & Trademark Off. Soc’y 271 (2004).

Another oft-cited drawback to the separate discovery and trial alternative is that separate discovery and trials could add a measure of expense, complexity and delay to those cases where infringement was found and a second trial on the issue of willfulness was required. This drawback is considered by trial courts now on a case-by-case basis, and courts bifurcate willfulness from patent infringement liability, at trial at least, surprisingly often: in 34.5% of all patent cases that go to trial, 48.6% of the bench trials

and 21.7% of the jury trials.<sup>4</sup> See Kimberly A. Moore, *supra*. These detriments would have to be weighed, however, against the other benefits in both the cases that were tried and those in which liability was not found or the case did not proceed to such a second trial, particularly in light of the relatively few patent cases that actually proceed to trial. This weighing process will need to be the subject of considerable further study.

***Third Alternative: Written Notice of Infringement and/or Deliberate Copying Predicate***

AIPLA supports the Third Alternative to require, as a predicate for willful infringement liability, either actual written notice of infringement from the patentee, or deliberate copying of the patentee's invention, knowing it to be patented. The NAS recommendation is substantially the same as a recommendation made by the FTC in its 2003 report on the patent system. AIPLA supported the FTC recommendation in the AIPLA written comments to the FTC which may be found at:

[http://www.aipla.org/Content/ContentGroups/Issues\\_and\\_Advocacy/Comments2/Patent\\_and\\_Trademark\\_Office/2004/ResponseToFTC.pdf](http://www.aipla.org/Content/ContentGroups/Issues_and_Advocacy/Comments2/Patent_and_Trademark_Office/2004/ResponseToFTC.pdf).

For completeness, the substance of the AIPLA response is reiterated here.

During the hearings conducted by the FTC, it was revealed in testimony that one company forbade its engineers from reading patents for fear that such acts might be used by a patentee to allege that the company willfully infringed the patent. This fear, whether well founded or not, forcefully demonstrated that the law on willfulness has effectively undermined the Constitutional purpose of the patent system. Other witnesses underscored the need to revise the law regarding willfulness. This concern was one of the driving motivations underlying a proposed amendment to 35 U.S.C. § 284 developed by AIPLA.

As set forth in AIPLA's Spring 2003 Bulletin, AIPLA's proposed amendment concerning enhanced damages for willful infringement provides:

“For purposes of determining whether to increase damages under this section, the court may consider the willfulness of any infringement.

“A finding of willfulness requires that the infringer failed to exercise due care to determine whether the infringer would be liable for infringement. A duty to exercise due care under this subsection shall only arise upon (i) written notice by or on behalf of the patentee of specific acts of infringement or (ii) the deliberate copying of a patented invention with knowledge that it is patented. Proof by clear and convincing evidence that an infringer deliberately copied

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<sup>4</sup> Another drawback, one rarely discussed by the bar, is the district courts' likely adverse reaction to having their case-management discretion limited and having discovery and trial procedures imposed upon them.

the patented invention with knowledge that it is patented and without due consideration of whether the patent may be infringed, unenforceable, or invalid, establishes that the infringer failed to exercise due care. Reasonable reliance on advice of counsel, offered into evidence, shall establish due care.

“Under this section, no adverse inference may be drawn from an assertion of attorney-client privilege or other immunity as a basis for not revealing advice of counsel.”

As indicated in AIPLA’s Spring 2003 Bulletin, the proposed amendment would be a “meaningful reform that would promote the patent system’s Constitutional role of promoting science and the useful arts without crippling enhanced damages as a deterrent to the abject copyist” and would constitute the “best way” to address the problem of enhanced damages for willful infringement.

Since AILPA has adopted a position on willfulness, a comparison of AIPLA’s position with the Third Alternative is made to determine whether they are consonant with each other. As explained below, the Third Alternative effectively incorporates the predicate test contained in AIPLA’s proposed amendment, but is silent as to the interplay between the duty of care and willfulness and as to whether willfulness is an issue for the by jury.

AIPLA’s proposed amendment would: (1) ostensibly<sup>5</sup> make willfulness an issue

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<sup>5</sup> The language “the court may consider the willfulness of any infringement” can arguably be construed to permit the Court to consider an advisory jury finding of willfulness in making its determination as to whether to increase damages. Under existing Federal Circuit precedent, the Court can consider the jury’s finding of willfulness in determining whether the case is an exceptional one so as to warrant an award of enhanced damages. However, the AIPLA Board of Directors adopted the following Resolution on October 30, 2003:

**RESOLVED**, that the American Intellectual Property Law Association (AIPLA) favors, in principle, revising the current damages statute to require that all findings necessary to support an award of enhanced damages shall be made by the court and not by the jury.

Specifically, AIPLA supports revising the first two sentences of 35 U.S.C. § 284, 2<sup>nd</sup> paragraph (additions underlined, deletions stricken), as follows:

When the actual damages are not found by a jury, the court shall assess them. In either event the court may thereafter increase the ~~damages~~ amount awarded in exceptional cases up to three times the amount of actual damages found or assessed; with all necessary further findings to be made by the court.

for the Court; (2) predicate willful infringement liability on the infringer's failure to satisfy a duty of care; (3) delineate exactly when the duty of care arises; (4) identify one way to prove failure to satisfy the due care standard ("deliberate copying"), but specify that "reasonable reliance on advice of counsel, offered into evidence, shall establish due care"; and (5) abolish the adverse inference rule where the accused infringer asserts the attorney-client privilege/work product immunity "as a basis for not revealing advice of counsel."

While the Third Alternative does not address it, the Resolution adopted by AIPLA would change Federal Circuit precedent by making willfulness an issue for the court. With the addition of the proposed language to 35 U.S.C. § 284, the Court would make findings on inherently factual issues, such as whether the infringer copied the patented invention. Federal Circuit jurisprudence has effectively made willfulness a mixed issue of law and fact, by mixing state of mind with legal issues (e.g., the closeness of the case) that should only come into play when the court considers whether to enhance damages. Unfortunately, existing Federal Circuit law on willfulness fosters burdensome satellite litigation because it promotes extensive probing of non-liability opinions and opinion counsel's actions. Removing the issue of willfulness from jury consideration is one part of an overall solution to the problem of the enormous expense and delay normally associated with willful infringement related discovery.

While the Third Alternative does not expressly mention the duty of care, the two alternative predicate acts that it identifies are virtually identical to the two alternative predicate acts identified in AIPLA's proposed amendment. There are three differences in detail: (1) for the first alternative predicate act (i.e., written notice), AIPLA's proposed amendment requires written notice of "specific acts" of infringement; (2) for the second alternative predicate act (i.e., deliberate copying), AIPLA's proposed amendment indicates that adequate proof of deliberate copying of the patented invention establishes lack of due care; and (3) AIPLA's proposed amendment expressly provides that "reasonable reliance on advice of counsel" establishes due care.

Notwithstanding the specific details in AIPLA's proposed amendment that are not contained in the Third Alternative, it is believed that the thrust of the Third Alternative is fully compatible with AIPLA's proposed amendment.

Notwithstanding the recommendations in the NAS Report and the convergence of the Third Alternative with AIPLA's proposed amendment concerning enhanced damages, this issue should be further reviewed in light of the Federal Circuit's *en banc* decision. The need for further review is emphasized by Judge Dyk's partial dissent questioning whether the due care requirement is consistent with the Supreme Court cases holding that punitive damages can only be awarded for reprehensible conduct.

## **II. Best Mode Elimination**

*“Given the cost and inefficiency of this defense, its limited contribution to the inventor’s motivation to disclose beyond that already provided by the enablement provisions of Section 112, its dependence on a system of pretrial discovery, and its inconsistencies with European and Japanese patent laws, the committee recommends that the best-mode requirement be eliminated.”*

AIPLA endorses the NAS Report’s recommendation to eliminate the “best mode” requirement. The substantive position of AIPLA in support of this recommendation is set out in connection with the discussion related to Recommendation 7.

## **III. Inequitable Conduct Defense in Patent Infringement Litigation**

*“In view of its cost and limited deterrent value the committee recommends the elimination of the inequitable conduct doctrine or changes in its implementation. The latter might include ending the inference of intent from the materiality of the information that was withheld, de novo review by the Federal Circuit of district court findings of inequitable conduct, award of attorney’s fees to a prevailing patentee, or referral to the USPTO for re-examination and disciplinary action. Any of these changes would have the effect of discouraging resort to the inequitable conduct defense and therefore reducing its cost.”*

After careful consideration of this recommendation, its rationale, and the overall policy implications, AIPLA concurs with the recommendation that the “inequitable conduct” defense to the enforceability of a patent be removed from patent litigation. However, this concurrence is conditioned on enactment of a new administrative enforcement mechanism providing that determinations of inequitable conduct would be undertaken by an adequately funded (and otherwise fully capable) office in the U.S. Patent and Trademark Office and that the USPTO would impose appropriate sanctions for misconduct, including – in the case of an actual fraud on the USPTO – canceling the patent. In AIPLA’s view, this change to “inequitable conduct” law should be undertaken together with (or subsequent to) other AIPLA-supported changes to the patent law that the NAS has recommended. In particular, any change to “inequitable conduct” law should be coordinated with the adoption of AIPLA-supported changes based upon NAS Recommendation 7 (“first-inventor-to-file” and other harmonizing changes to U.S. patent law), Recommendation 3 (post-grant opposition opportunity under which an opposer is

permitted to raise all issues of patent validity), and Recommendation 4 (addressing U.S. Patent and Trademark Office funding and financing issues to assure that the Office can effectively and efficiently discharge all its responsibilities).

AIPLA is mindful of the essential role that the “duty of candor and good faith” plays in assuring high quality and complete patent examination and the role that the unenforceability defense based upon inequitable conduct has played in deterring misconduct. Moreover, AIPLA believes that an appropriate deterrent to misconduct before the U.S. Patent and Trademark Office should remain part of any reform to the existing law on “inequitable conduct.” In short, the existing duty should remain undiminished and sanctions for misconduct should be crafted that would continue to function as an effective deterrent. However, the role of “inequitable conduct” in patent infringement litigation should end.

To achieve these ends, AIPLA is currently developing a proposal that would replace the “inequitable conduct” defense with an administrative enforcement process within the USPTO. The administrative enforcement process would authorize the Office to investigate and sanction violations of the duty of candor and good faith in the procurement of a patent, as well as violations of any other proceedings before the USPTO involving a patent. Through this new mechanism, the venue for determining whether misconduct had occurred would change, but an effective forum for misconduct determinations would remain as would sanctions sufficient to deter misconduct.

With very limited exceptions, the proposed changes contemplated by AIPLA would remove any misconduct determinations from litigation between private litigants and place them exclusively in the new administrative process. Consistent with notions of administrative due process, the person to be held accountable for the misconduct would retain the ability to have judicial review (Federal Circuit appeal) of any misconduct determination made by the U.S. Patent and Trademark Office. The person so accountable would be the patent owner (if the individual involved in the conduct was associated with the patent owner) or the party adverse to the patent (if the misconduct involved an individual in a contested proceeding associated with the party adverse to the patent).

Equally significantly, an adjudication of misconduct through the new administrative process would provide a predicate for possible liability in situations other than a patent infringement case. Causes of action based upon adjudicated misconduct that would not be preempted under this proposal are those based upon invalid patent claims that were obtained as a consequence of the adjudicated misconduct. However, unlike current law, the determination of whether misconduct occurred would reside solely in the U.S. Patent and Trademark Office administrative process and court review of that process, preempting all other inquiries into and adjudications of an issue of misconduct itself.

More specifically, AIPLA contemplates codifying the law related to inequitable conduct, fraud, or other misconduct in the procurement of a patent and other proceedings before the U.S. Patent and Trademark Office by adding a set of explicit provisions to Title 35. The codification would require the Office to establish a duty of candor and good faith in connection with the patenting process. It also would define the standard for determining whether inequitable conduct, fraud, or other misconduct has taken place. The contemplated standard for the duty of candor and good faith is that currently set forth in Rule 56 of the Office's regulations, 37 C.F.R. §1.56, and individuals subject to the duty would be the same individuals currently subject to the duty.

The codification would require those individuals bound by the duty to timely disclose information they know to be material to patentability (or to the other issues in the proceeding in which the patent is involved). It also would enjoin these individuals from knowingly and materially misrepresenting material information. The underlying standard of materiality would remain the same as under current Rule 56.

The U.S. Patent and Trademark Office would establish a special office with exclusive authority to investigate any allegations of possible violations of the duty. The special office would have subpoena powers to enable it to thoroughly investigate possible misconduct. The special office would allow persons who are the subjects of an investigation to obtain relevant evidence through subpoenas, using the existing provisions in Title 35 applicable to contested cases.

Where the U.S. Patent and Trademark Office finds misconduct following an investigation, the new provision would authorize civil monetary penalties. Penalties would be assessed in amounts sufficient to serve as a deterrent to misconduct. Patent owners and others subject to the penalty would have the right to contest the penalty through a hearing with evidence before the Office's Board of Patent Appeals and Interferences. A person subject to the penalty could also appeal to the Federal Circuit. In addition, in the case of an actual fraud on the U.S. Patent and Trademark Office, the Office would be required to cancel the claims of any involved patent.

By empowering the U.S. Patent and Trademark Office with the authority and resources to investigate and penalize misconduct occurring before it, AIPLA believes that this administrative process would provide a fully effective deterrent to that misconduct. At the same time, it would remove the issue of possible misconduct from most private litigation, thereby eliminating the routine assertion of this issue and the accompanying higher litigation costs. Finally, it would not disturb the additional private remedies for cases where adjudicated misconduct produced additional public or private harm because such misconduct resulted in the issuance of a wholly or partially invalid patent. Thus, bad faith enforcement or attempted enforcement constituting a violation of the antitrust laws is not preempted. See *Handgards, Inc. v. Ethicon, Inc.*, 743 F.2d 1282, 1294 (9th Cir. 1984), *cert. denied*, 469 U.S. 1190 (1985).

By coordinating the change in the law relating to inequitable conduct with other reforms, the concerns of patent owners that patent oppositions would create new and troublesome opportunities for allegations of inequitable conduct in patent litigation (based upon the patent owner's conduct during the opposition) would be addressed. Post-grant oppositions – because they could address all issues of patentability – would serve instead to provide patent owners greater certainty as to the validity and enforceability of a patent in any later litigation.

Lastly, AIPLA recognizes the intimate relationship between the ability of the U.S. Patent and Trademark Office to discharge the responsibility of effectively and efficiently enforcing its rules relating to candor and the financing needed by the Office in order to secure and sustain the facilities, the capabilities and the competencies for undertaking these required efforts. Thus, the steps that AIPLA has described in response to NAS Recommendation 4 are a critical predicate in order for the Office to discharge these responsibilities.

#### **RECOMMENDATION 7:**

##### **“Reduce redundancies and inconsistencies among national patent systems.”**

*“The United States, Europe, and Japan should further harmonize patent examination procedures and standards to reduce redundancy in search and examination and eventually achieve mutual recognition of results. Differences that need reconciling include application priority (“first-to-invent” versus “first-inventor-to-file”), the grace period for filing an application after publication, the ‘best mode’ requirement of U.S. law, and the U.S. exception to the rule of publication of patent applications after 18 months. This objective should be pursued on a trilateral or even bilateral basis if multilateral negotiations are not progressing.”*

#### **AIPLA Response:**

AIPLA is a longstanding supporter of greater international harmonization of patent laws. Its position is grounded on the benefits that harmonization will bring to U.S.-based inventors. Thus, it fully endorses and supports the principle expressed by the NAS Report that redundancies should be reduced and inconsistencies should be eliminated among the world's patents systems.

AIPLA has led the way in defining the manner in which these objectives ought to be carried out. In the Association's view – which appears to be consistent with the NAS Report – the so-called “best practices” analysis should be used to guide the world's patent systems to greater consistency and harmony.

The NAS Report makes a number of specific recommendations that AIPLA endorses as entirely consistent with its long-held views on “best practices” for making needed reforms to U.S. patent laws. On one issue – defining prior art – AIPLA would take the principles expressed in the NAS Report to a higher level of refinement that more closely aligns with the emerging consensus of U.S.-based NGOs. These areas of alignment between AIPLA and the NAS Report include:

***A. First-To-Invent Versus First-Inventor-To-File Priority.***

Like the NAS Report, AIPLA supports adoption of a first-inventor-to-file system as a “best practice” for operating the U.S. patent system. The NAS Report concludes that:

The United States should conform its law to that of every other country and accept the first-inventor-to file system. There are several reasons for this shift. First, the discrepancy means not only that in some cases different people will own patents on the same invention in different countries but also that there are radical differences in procedure. The United States has an elaborate legal mechanism, both in the USPTO and in the courts, for determining who was the first to invent. Because the rest of the world has no analogous process, foreign patent applicants are subject to uncertainty and perhaps challenges that are entirely unfamiliar. The governments tend to view U.S. acquiescence to the first-to-file as the cornerstone of international harmonization.

Work within AIPLA over recent years has created a compelling rationale for moving forward with this cornerstone change to U.S. patent law. In addition, AIPLA is among the strongest supporters of moving on a parallel (and hopefully synergistic) track to achieve greater international harmonization of patent laws, most especially rules on determining prior art. Importantly, AIPLA has addressed the concerns noted in the NAS Report over the impact of a first-inventor-to-file rule on small entity inventors and the potential for untoward consequences on patent filing strategies.

*The First-to-Invent, Not a First-Inventor-to-File, System is Fundamentally and Necessarily Unfair to the Independent Inventor and Inherently Favors “Large Entity” Inventors*

Many factors drive adoption of a first-inventor-to-file system, with or without harmonization. The most important is that the first-inventor-to-file system is best able to

protect the interests of independent inventors and other small entities. What should motivate the change is the current system's demonstrable *unfairness to small entities*.

The current system does *not* award patents to the first to invent. It uniformly awards patents to the first-inventor-to-file for a patent except in rare instances where sufficient invention date proofs can be marshaled to demonstrate that a second-to-file inventor had a sufficiently corroborated set of proofs on the date of invention to overcome the presumption that it was *not* the first to invent.

The resulting expense and complexity of the first-to-invent system mean that an inventor can be first to make the invention and first to file a patent application claiming the invention, but still forfeit the right to a patent because it cannot sustain the cost of the "proof of invention" system. Those costs – where proofs must be marshaled and considered by the U.S. Patent and Trademark Office – amount to hundreds of thousands of dollars. It is this aspect of the current law that produces *an inherent and fundamental unfairness to small entities*.

The only way for the law to guarantee the first to invent the right to patent is through a first-inventor-to-file rule, not through a first-to-invent system. Thus, it is changing, not sustaining, current law that would most consistently reward the first to invent with the assured right to patent.

The past several decades have only made the imperatives for moving to a first-inventor-to-file system more clear. These have included the skyrocketing costs of patent interferences, the ease and inexpensiveness of provisional patent application filing, and the new right of foreign-based inventors to introduce invention date proofs. While a decade ago a U.S.-based inventor might have had some advantage because of the bar against relying on a foreign date of invention, this provision of U.S. patent law was outlawed by TRIPS. Thus, a host of factors have now presented themselves that make adoption of a first-inventor-to-file system a compelling proposition for all U.S.-based inventors – small entities more than all others.

Statistical analyses now confirm the existing disadvantage that independent inventors face in losing more patents than they gain. The Mossinghoff analysis notes that, even before the floodgates to foreign invention date proofs were opened, independent inventors over two decades managed to lose a net of 17 patents because of the first-to-invent principle – notwithstanding investing millions of dollars in patent interferences.<sup>6</sup>

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<sup>6</sup> These most salient statistics relate to the number of interferences won by junior party independent inventors and the number of interferences lost by senior party independent inventors, *i.e.*, the net "gain" for independent inventors compared to a first-inventor-to-file system. According to Gerald J. Mossinghoff, *The First-to-Invent System Has Provided No*

Another factor not to be overlooked is that, in a less politically charged climate, small entities have historically *avored* a first-inventor-to-file system. In an earlier and less costly era for patent interference contests, the inventors proclaimed to Congress that:

“Our information is that costs average \$5000 per applicant per interference, and that one case in four is won by the second-to-file. These are not very good odds. One inventor would have to conduct not four but eight cases for one victory he would not have won under a first-to-file system. At \$40,000, this is too dear a victory.

“But there is another, more subtle economic factor. This is the cost of worldwide patenting when the rest of the world uses a first-to-file system. If it can be shown that a first-to-file principle in the United States would reduce the cost of typical worldwide coverage—presently on the order of \$1000 per country for fees and translations only, or from \$5,000 to \$30,000 for reasonable worldwide coverage—then we have an additional reason for adopting first-to-file. **On this combination of grounds, we endorse a first-to-file rule.** We also encourage any other steps taken, not necessarily toward a universal patent, but at least toward a universal patent application, advisory assistance from the Department of Commerce, and other means of reduction in the cost of worldwide patent protection.”

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*Advantage to Small Entities*, 88 J. Pat & Trademark Off. Soc’y 425 (2002), there was no *net gain* for independent inventors, but rather a *net loss* of 17 patents from 1983 through 2000. This was before the Uruguay Round Agreements Act took hold, which will further disadvantage small entities. The Mossinghoff analysis has recently been confirmed by Mark A. Lemley and Colleen V. Chien, *Are U.S. Patent Priority Rules Really Necessary?*, 54 Hastings Law Journal 1299, 1323 (July 2003), who note:

[I]nterference proceedings are more often used by large entities to challenge the priority of small entities, not the reverse. This evidence further supports Mossinghoff’s conclusion that the first to invent system is not working to the benefit of small entities. If anything, ***small entities are getting bogged down in interference proceedings initiated by larger companies.*** This makes some intuitive sense. ***Large, sophisticated entities are more likely to understand the patent system, including the rather arcane interference process, and use it to their advantage.***

Statement of Burke E. Wilford, National Director, the American Society of Inventors, Exhibit D, Hearings before the Subcommittee on Patents, Copyrights and Trademarks of the Committee on the Judiciary, United States Senate, 90th Congress, May 17-18, 1967, p.291.

Another important fairness consideration lies in the essential and irreducible complexity of determining if an inventor is first to invent. This complexity is best reflected in the number of ways in which the first inventor – even a first-to-file first inventor – can forfeit the right to patent:

- The “conception” of the invention is deemed to be “incomplete” or otherwise inadequate,
- The required “independent corroboration” of the conception is found to be inadequate,
- The proffered proofs of diligence are rejected because the conception was incomplete, inadequate, or uncorroborated,
- Interruptions in the continuity of diligence in a “reduction to practice” cannot be explained or excused,
- The required records needed to establish the invention dates and diligence dates may be unavailable.
- The “reduction to practice” does not demonstrate the required operability for the intended purpose for the invention,
- The invention is deemed to have been “abandoned, suppressed or concealed,”
- Patent claims of the rival inventor are not timely “copied” in the manner required by law,
- Proper preliminary motions are not made to allow use of the inventor’s “best proofs” of invention dates, or
- Interference “estoppel” applies.

*Adoption of the First-Inventor-to-File Principle Cannot Produce Untoward Consequences on an Inventor’s Patent Filing Strategies Because Almost All U.S. Patent Procurement Today Already Operates on a De Facto First-to-File Basis*

In considering the impact on patent filing practices if a first-inventor-to-file system were adopted, a practical reality of current law and practice is sometimes overlooked. All inventors using the patent system who are not U.S.-based operate under a *de jure* first-inventor-to-file rule. This accounts for about 50% of all originally filed U.S. patent applications. Further, many U.S.-based inventors have an interest in using U.S. patent filing as a basis for establishing global patent priority and must act accordingly.

A third class of U.S.-based inventors are both large and small entity inventors that – on account of the operation of the “proofs of invention” rules under current U.S. law – affirmatively conduct their patent operations under a first-to-file principle. In other words, they prepare and file patent applications today as though the right to a patent was awarded to the first-inventor-to-file.

This leaves – theoretically at least – a small number of U.S.-based inventors whose patent filing practices reflect neither the *de jure* nor *de facto* first-to-file rule. However, these inventors that delay or defer patent filing that they might otherwise have undertaken are unlikely to change these tactics. They already run the risks of the “in public use or on sale” and other statutory bars arising, as well as the discovery of intervening art that will require marshalling expensive invention date proofs during *ex parte* examination. In addition, these inventors could become embroiled in patent interferences that they might otherwise have avoided, and could be forced to sustain the burden or proof in an interference that might otherwise have required no resort to affirmative proofs of the invention date. This does not even include the possible forfeiture of all foreign patent rights.

Thus, it is unlikely that any move from a first-to-invent system to a first-inventor-to-file principle would impact patent filing practices. It is equally unlikely that it would produce a substantial number of sloppily drafted patent applications.

Rather, it will free inventors from the dual burden of meeting both the *de facto* requirement to undertake patent filing practices seeking to be the first inventor to-file and the parallel burden of maintaining and asserting invention date proofs when the status of as the first inventor comes into question. Being the first-inventor-to-file alone will be enough to secure the right to patent.

## **B. *Grace Period.***

The NAS Report proposes a “first-inventor-to-file” system that is unlike those existing in most countries outside the United States. The NAS Report recognizes the desirability of maintaining a one-year “grace period” that insulates an inventor from the patent-defeating effects of a disclosure made directly or indirectly by the inventor before a patent application is filed. In this sense, the NAS Report is unlike earlier proposals, *e.g.*, the Johnson Commission, that would not have provided this important protection for inventors.

In addition, the NAS Report supports another long-held view of APLA that a “grace period” should be internationalized – all countries should adopt a one-year “grace period counted back from the Paris Convention priority date. This form of “grace period” would optimize the ability of U.S. inventors to take global advantage of the period of grace.

The NAS Report has specifically endorsed:

The United States should retain and seek to persuade other countries to adopt a grace period, allowing someone to file a patent application within one year of publication of its details without having the publication considered prior art precluding a patent grant. This provision encourages early disclosure and is especially beneficial for dissemination of academic research results that may have commercial application. As other countries try to accelerate the transfer of technology from public research organizations to private firms via patents and licensing, the idea of a grace period is likely to become more widely accepted. Germany recently adopted such a provision.

The NAS Report's recognition of this important feature of the patent law and its encouragement of the international adoption of a "grace period" is to be applauded.

### ***C. Best Mode Requirement Elimination.***

The NAS Report makes a singularly important recommendation, again supported by AIPLA, that the so-called "best mode" requirement be eliminated from U.S. patent law:

The "best mode" requirement, having no analog in foreign patent law, imposes an additional burden and element of uncertainty on foreign patentees in the United States. This, in addition to its dependence on discovery aimed at uncovering inventor records and intentions, justifies its removal from U.S. patent law.

AIPLA endorses the NAS Report's recommendation, though for somewhat different reasons. AIPLA's longstanding view – in the context of patent harmonization efforts – has been that the "best mode" requirement should be eliminated. Recently, AIPLA determined that the requirement should be removed as part of a coordinated effort to reform U.S. patent laws in moving to a first-inventor-to-file system. In this respect, the considerations that led the Association to this conclusion were strikingly similar to the NAS Report's observations and conclusions.

AIPLA's observations about the application of the "best mode" requirement that drove its deliberations on this issue included the following:

- Patent examiners cannot effectively examine for “best mode” compliance. The last USPTO challenge to an inventor’s “best mode” disclosure may have been *In re Bundy*, 642 F.2d 430, 434, 209 USPQ 48, 51 (C.C.P.A. 1981).
- Patent reexamination and/or opposition cannot satisfactorily address the issue of adequacy of “best mode” disclosure.
- A person skilled in the art cannot determine if the “best mode” requirement has been met until he or she has been sued and the lawsuit is deep into discovery. The public cannot rely on this as a basis for acting free from the patent.
- The issue, therefore, can be effectively addressed only in patent litigation, years or even a decade or more after the relevant contemplations took place.
- The “best mode” can be based on knowledge that the inventor gained from any source before filing. This can open up the work of an entire research organization to discovery and makes discoverable anything potentially communicated to an inventor about carrying out the invention.
- By its nature, this requirement can be raised in virtually any litigation by simply alleging that some known and omitted detail of carrying out the invention is a concealed “best mode.” Indeed, for this reason it is pled far more often than it is ever proven. Considerable expense and effort have been invested over the past decades to invalidate very few patents on this basis.
- As the NAS Report points out, this is precisely the type of issue that gives patent litigation a bad name among those paying the bills because it makes patent litigation needlessly complex, expensive, and unpredictable.

A number of further observations can be made:

- The requirement was not a part of U.S. patent law for its first 163 years. It was adopted only as part of the 1952 Patent Act. Some of the greatest inventions known to mankind were patented and contributed to the progress of the useful arts without the “best mode” requirement in the patent laws.
- Those tending the patent laws of other industrialized nations have not seen a need for a “best mode” disclosure and they have not adopted it in their own laws. Indeed, if this experiment had succeeded – like the relatively recent practice of 18-month publication of published applications has done – then some industrialized country would have embraced it over the last five decades.

- The remaining disclosure requirements in section 112 are more than adequate to assure that the public gets the full benefit from a patent disclosure. When properly applied, a claimed invention must be completely described in terms adequate for the full scope of what is claimed so that it can be practiced by ordinarily skilled persons without any need for undue experimentation.

The efficacy of the defense is constrained by the further reality that it is far more difficult to prove if the inventor is deceased or otherwise not available to for discovery.

Determining “best mode” is inherently open to capriciousness and inconsistency, as the above examples indicate. What rational basis can exist for disadvantaging U.S.-based inventors, inventors who make themselves freely available for discovery, and inventors most honest and forthright about what they recall about what they knew and thought at the time the patent was sought? Indeed, its application turns upside down the notion of providing incentives for fair play.

The 1952 experiment to introduce this requirement, as its full implications have played out, has imposed too great a price for any benefits it has achieved. Patent applications are filed early – sometimes just before or just after an invention has first been reduced to practice. This will remain the case under a first-inventor-to-file system. Any perceived benefits received by the public from the imposition of this requirement are offset by the burden on the patent system created by requiring this type of disclosure at a time when the invention may be far from any commercial form. This is because the best mode may change again and again as further refinements and developments are made to permit it to be commercialized.

Thus, AIPLA endorses the NAS Report’s proposal to eliminate this requirement from the patent law.

#### ***D. Prior Art Rationalization and Simplification.***

The NAS Report has made some proposals for rationalizing and simplifying prior art as part of the movement to the first-inventor-to-file rule. Its principal recommendations are reflected in the following:

In the interest of arriving at a uniform definition of prior art, the United States should remove its limitation on non-published prior art and its rule that foreign patents and patent applications may not be recognized as prior art as of their filing dates. In connection with moving to a first-inventor-to-file system, the foreign patent prior art rule for unpublished prior patent applications should also be adopted. A common misconception about the EPO and other foreign systems like

that of the EPO is that they are winner-take-all systems similar to the U.S. interference proceeding. A difference in prior art treatment, however, prevents this from occurring. Abroad an unpublished prior patent application is available for prior art purposes only under the novelty standard. It cannot be used in a non-obviousness (or equivalent) rejection. This allows the later filing applicant to obtain claims to a disclosed aspect of the invention that is novel with respect to the prior application even if it would have been obvious. This has the affect of giving some reward to near simultaneous inventors. Where the second to file is first with a commercially important embodiment of the invention, the foreign rule increases cross licensing and enhances competition in the marketplace.

While AIPLA applauds the NAS Report's suggestion to move to a more globally uniform prior art definition, the specifics of its proposal differ from what AIPLA now advocates as a set of "best practices" for a harmonized patent system. In this regard, other U.S.-based groups share the current AIPLA position, including the Intellectual Property Owners Association, the National Association of Manufacturers, and other U.S.-based NGOs, in advocating a highly simplified definition for prior art.

Thus, an emerging consensus of U.S.-based NGOs, which would take the NAS Report's proposals for harmonizing prior art to the next level of effectiveness, now include the following refinements to what NAS Report proposes—

- Patents, printed publication, and other public knowledge would become prior art at the time they became reasonably and effectively accessible to persons skilled in the art, eliminating the increasingly arbitrary and artificial distinction between knowledge existing in the United States from knowledge readily and effectively accessible elsewhere.
- The filing of applications that later issue as patents or that are otherwise published would create prior art, with no distinction between the use as prior art for novelty or for non-obviousness purposes and, with no distinction between the filing of a national or an international application (*i.e.*, PCT application) for patent.

The latter rule, *i.e.*, that the filing of a later-published patent application creates prior art for both novelty and non-obviousness purposes, best reflects a principle that has been long embodied in U.S. patent law: delays in the publication of patent applications (or delays in U.S. Patent and Trademark Office processing that results in the issuance of a patent) should not result in a delayed effectiveness of the published patent application or in the prior art effect of a patent as of the filing date. Moreover, the ability to make

complete use of the filing of a published patent application as prior art, including for non-obviousness purposes, avoids the potential of a multiplicity of patents that are adversely owned. A more restrictive “novelty-only” rule means valid (and adversely held) patents can issue on mere obvious variations of the same patentable invention.

### ***E. Application Publication.***

The NAS Report endorses publication of pending applications for patent at 18 months, a position long endorsed by AIPLA:

The United States should abandon its exception to the rule of publication after 18 months for applicants not intending to patent abroad. This, too, would promote the disclosure purpose of the patent system. Eliminating the non-publication option would minimize the uncertainty associated with submarine patents, which remain a problem as a consequence of the continuation practice, enabling an applicant to abandon one application and file a continuation or pursue an application to issue while maintaining a continuation on file—in either case in the hope of winning a better patent eventually. Moreover, universal publication would extend to all patentees the provisional rights under 35 U.S.C. Sec. 154(d) (2000) that give a patentee a reasonable royalty for infringement that occurs after publication but before patent issuance under certain conditions (Lemley and Moore, 2004).

The position expressed by NAS Report has been the position of AIPLA since 1990. One significant objection to universal publication of pending applications disappears with the adoption of the first-inventor-to-file rule. Under first-to-invent practice, the publication of a patent application allows a competitor to file its own application for patent on the same or a similar invention, and to “swear behind” the published application. Through the “swearing behind” process, the competitor can get its own patent or—even worse—provoke an interference with the first inventor to file. The interference, once provoked, may cost the first-inventor-to-file the right to patent the invention.

This “spurring” of the filing of a patent application on the same or a similar invention is impossible under the first-inventor-to-file rule. Indeed, the publication of the patent application has the salutary effect of placing all competitors on notice that they cannot then file a patent application on the same or a similar invention. The “swearing behind” option is unavailable.

Thus, as AIPLA looks to define a coordinated set of reforms to U.S. patent law along the lines recommended by the NAS Report, it endorses that Report's position. The adoption of the first-inventor-to-file rule now facilitates the 18-month publication of pending applications for patent by removing the principal objection to doing so.

#### *F. Overarching Impact*

The NAS Report anticipates some criticisms of its proposals for reform-minded changes to U.S. patent laws with the suggestion that it might be viewed as favoring a "Europeanization" of U.S. patent laws. The NAS Report offers the following as a defense to such a potential charge:

The committee recognizes that its proposals, apart from foreign adoption of a grace period, would represent U.S. conformity with other patent systems and may be subject to the charge that we favor "Europeanizing" the U.S. patent system. That is a narrow view. It presumes that only the items enumerated are part of a negotiated package. It implies that the U.S. system features we propose changing are important to its integrity. We disagree. Most important, it ignores what we expect to be the benefits of harmonized priority and examination procedures for U.S. inventors, whether large or small entities—first, faster, more predictable determinations of patentability; second, simplified, less costly litigation; and third, less redundancy and much lower costs in establishing global patent protection.

While the NAS Report's defense on this point is, in AIPLA's view, a convincing one, it perhaps understates the importance of two aspects of the NAS Report's recommendations. First, the NAS Report's recommendations are generally consistent with an "Americanized" patent law since they keep a one-year "international grace period" and define prior art according to traditional U.S. patent law principles that emphasize the role of the inventor and the patent owner.

Second, the benefits from the patent law simplification proposed by the NAS Report could be decisively important to the more efficient operation of the U.S. patent system in a fair and balanced manner. The NAS Report's proposals are consistent with what AIPLA has come to believe should be the overarching principle for reforming patent law. That principle can be concisely stated:

**A person of ordinary skill in the art with sufficient training in the patent law should be able to —**

**(1) pick up a patent or published application for patent,**

- (2) read through it and its prosecution history,**
- (3) compare the claims to readily accessible prior art, and**
- (4) make a complete and certain determination of the validity of the claims.**

Under this overarching principle, patent validity would not depend upon—

- What *the inventor knew* and when he knew it.
- What *the inventor contemplated* and when those thoughts occurred.
- What *the inventor did* to create the invention and when the inventor did it.

Instead, patent validity would be solely determined based upon—

- What *the public knew* and when the knowledge became public.
- What *the patent teaches* and how broadly the teachings apply.

After using these two inquiries to assess the scope and content of the prior art and the sufficiency of the disclosure relative to what is claimed, the person skilled in the art and sufficiently trained in the patent law could assess novelty, utility, enablement, written description, subject matter eligibility, definiteness, and non-obviousness for the claimed invention. Nothing else would or should bear on the right to enforce the patent.

Why the overarching principle? It was formulated as a shorthand way of capturing all the features of a patent system that are relevant to whether a feature of patent law is a so-called “best practice.” In recent harmonization discussions – and in parallel efforts to devise domestic legislative reforms – an emerging principle is that so-called “best practices” among global patent systems should be adopted for a harmonized system and incorporated into domestic patent law reforms. A “best practices” patent system presumably would achieve, among other objectives—

- Predictability in assessments of what inventions will be validly patentable.
- Simplicity in the legal principles and concepts that underlie the system.
- Reliability of U.S. Patent and Trademark Office determinations once made.
- Stability in legal doctrines defining patent validity and enforceability.
- Economy in the patent procurement and enforcement processes.
- Promptness in final determinations of patentability and validity.
- Fairness to all categories of inventors, whether individual inventors or inventors affiliated with either small or large entities.
- Balance between providing strong protection for patentable innovations and preserving unfettered freedom to use unpatentable and unpatented subject matter.

This overarching principle – and the “best practices” notions that underlie them – lead necessarily to the core reform prioritized by the NAS Report: elimination of invention date proofs as a touchstone for determining what is prior art and what is not. No longer would *every* patent be potentially invalid because a prior, but *entirely secret*, invention made by another not abandoned, suppressed or concealed can be uncovered as prior art. Instead, prior art for the first-inventor-to-file would be only what is public knowledge prior to the filing date.

The bottom line is a simple one. Given that the two systems – first-inventor-to-file and first-to-invent – produce nearly identical results in fact (*i.e.*, the first-inventor-to-file for a patent is virtually always awarded the right to patent when invention dates are used to determine priority), why not obtain the advantages of a *fairer, less expensive, more prompt, more certain, and more predictable* standard by awarding the right to patent to the first inventor to file? The answer the NAS Report offers is a thoroughly American one that is demonstrably in the best interests of the United States and its inventor communities.