

Subject: Antitrust Modernization Commission Request for Public Comment

Date: Monday, July 25, 2005 4:06 AM

From: Michael K. Kirk <[REDACTED]>

Reply-To: <[REDACTED]>

To: <comments@amc.gov>

To: Andrew J. Heimert,
Executive Director & General Counsel
Antitrust Modernization Commission

From: Michael K. Kirk
Executive Director
American Intellectual Property Law Association

Dear Mr. Heimert,

The Antitrust Modernization Commission has requested public comment on several questions relating to its New Economy Study Plan. I am forwarding the comments of the American Intellectual Property Law Association (AIPLA) in response to two of those questions.

Although comments on these questions were requested by July 15, 2005, it is my understanding that you agreed that AIPLA could submit its comments a few days after that deadline in order that AIPLA's Board of Directors could review and approve the comments with any amendments it believed necessary.

The attached comments, with certain edits, were approved by the Board on July 14. The amicus brief that AIPLA filed in the United States Supreme Court in support of the petition for certiorari in *Illinois Tool Works, Inc. v. Independent Ink, Inc.*, the AIPLA Response to the National Academies' Report entitled "A Patent System for the 21st Century," and the Federal Trade Commission's Report entitled "To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy" are embedded as Appendices A, B, and C, respectively, in the attached comments and are separately attached to this email.

Thank you for the opportunity to offer these comments. We look forward to working with you as the Commission's study proceeds.

Sincerely,

Mike Kirk

Contact Information:

Michael K. Kirk

Executive Director

American Intellectual Property Law Association

2001 Jefferson Davis Highway, Suite 203

Arlington, VA 22202

Tel. (703) 412-4349

Email: 

**AIPLA Response to the Antitrust Modernization Commission
Questions for Public Comment**

New Economy Issues

The Antitrust Modernization Commission has requested public comment on several questions relating to its New Economy Study Plan. AIPLA submits this comment in response to two of those questions:

- (1) What significance should be attached to the existence of a patent or copyright in assessing market power in tying cases and in other contexts, and
- (2) Specific comments on the reports on the patent system issued by the Federal Trade Commission and the National Academies Board on Science, Technology, and Economic Policy.

Presumption of Market Power From Patent or Copyright

On the significance of patents or copyrights to market power in antitrust cases, AIPLA believes strongly that the existence of a patent or copyright should not confer any presumption of market power in any relevant antitrust market. AIPLA recently reaffirmed this position in an amicus brief filed in the United States Supreme Court in support of the petition for certiorari in *Illinois Tool Works, Inc. v. Independent Ink, Inc.*, No. 04-1329, *petition docketed*, April 4, 2005, which has subsequently been granted.¹ In that case the Court of Appeals for the Federal Circuit had held that in antitrust tying cases, ownership of a patent confers a rebuttable presumption that the patent owner has market power. The AIPLA amicus brief, attached as Appendix A at the end

¹ The Court of Appeals decision is reported as *Independent Ink, Inc. v. Illinois Tool Works, Inc.*, 396 F.3d 1342 (Fed. Cir. 2005).

of this comment, argues that such a presumption is improper for numerous reasons, including the following:

- The presumption has no basis in fact. Virtually all patents cover modest improvements to existing products which typically compete with existing products that are already established in the marketplace.
- Federal courts, including the Federal Circuit, have consistently held in non-tying antitrust cases that a patent does not confer market power.
- Congress has expressly eliminated such a presumption from the analogous defense of patent misuse based on alleged tying. *See* 35 U.S.C. § 271 (d) (5).
- The Federal Trade Commission and Department of Justice have concluded as a matter of enforcement policy that market power cannot and should not be presumed from the ownership of an intellectual property right. United States Department of Justice and Federal Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property* § 2.2 (1995).
- The presumption of market power in tying cases, coupled with the application of the per se rule to tying, runs counter to the Supreme Court's recent jurisprudence that permits departure from the Rule of Reason only when experience has shown that a practice virtually always harms competition.
- Shifting the evidentiary burden on such a critical element of an antitrust tying claim to the patent owner will encourage the routine filing of antitrust counterclaims, which will increase the cost and risk of patent litigation, chilling the incentive of patent owners to enforce their patents in some cases.
- The presumption creates an anomaly in which the proof requirements for a misuse defense are more difficult than for an antitrust violation arising out of the same conduct -- a result that conflicts with the decisions of most courts.

It is not clear at this time how the Supreme Court will resolve this issue in the *Illinois Tool Works* case. If the Court fails to eliminate the presumption, AIPLA believes the

Commission could make a valuable contribution by urging Congress to eliminate any presumption of market power based on intellectual property rights. This would harmonize tying law with the rest of antitrust law and eliminate the current anomaly that exists between antitrust law and patent misuse by virtue of *Illinois Tool Works*.

Review of FTC and NAS Reports on the Patent System

One of the issues that the Commission has adopted for study is the effect of the current intellectual property regime on competition. On this subject the Commission has limited its solicitation to comments on recent studies of this subject by the Federal Trade Commission (FTC) and the National Academies Board on Science, Technology, and Economic Policy (NAS). AIPLA has previously published detailed critiques of both of these studies, which are attached as Appendix B (NAS) and Appendix C (FTC) to this comment. To aid the Commission in its review, we offer the following summary of the main points in these reports.

Flexible and Unitary Patent System (NAS Recommendation 1; FTC Recommendations 6 and 10)

AIPLA agrees with NAS'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. AIPLA also shares the perception in the NAS report that such a unitary system exists today, and that a variety of de facto mechanisms that provide flexibility to the system, such as different criteria for patentability for different technologies and variations in the level of ordinary skill applied to obviousness questions, do not detract from that uniform standard.

AIPLA disagrees with several points in the FTC Report that appear to contravene the notion of a unitary standard of patentability. AIPLA does not believe that the FTC's characterization of prior judicial decisions as improperly expanding the standard of patentability is correct. AIPLA also does not believe that decisions extending patentability to new subject matter should be based on economic criteria, such as an attempt to determine whether inventions in a particular subject area are likely to be forthcoming even without patentability. To depart from the uniform patentability standard would, in AIPLA's view, compromise the primary value of consistency and predictability that is crucial to stimulating invention and potentially conflict with treaty obligations under the TRIPS Agreement.

AIPLA agrees with many of the mechanisms recommended by the NAS to promote sound decision-making within a uniform patent system. AIPLA favors the continued use of Examination Guidelines, but cautions that they should not be given undue deference by the courts; acknowledges the benefits of amicus briefs in the Federal Circuit; and favors the continued practice of judges from other courts sitting by designation on the Federal Circuit. While agreeing that judges on the Federal Circuit should come from diverse legal backgrounds, AIPLA notes that the present make-up of that court already reflects such diversity and may in fact find patent law, and particularly patent litigation, under-represented.

*Changes To Non-Obviousness Standard (NAS Recommendation 2;
FTC Recommendation 3)*

AIPLA largely agrees with the broader thrust of both the NAS and FTC Reports on the subject of non-obviousness. AIPLA's position proceeds from two core principles. First, the non-obviousness standard should be applied with vigor and rigor. Second, there is no need to modify the statutory standard of non-obviousness to correct whatever shortcomings may exist in the current application of that standard. AIPLA believes that these shortcomings are largely the result of inconsistent application of the non-obviousness standard by the U.S. Patent and Trademark Office, which can be corrected by adequate funding, improved prior art search capabilities and an effective post-grant opposition procedure.

AIPLA's position differs from the NAS and FTC Reports in some details, however:

- The NAS Report recommends abandoning the per se rule that prevents consideration of the technical difficulty in obtaining pre-existing genetic sequences. To the extent that this recommendation could be read to advocate technology-specific application of the non-obviousness standard, AIPLA disagrees.
- AIPLA does not agree that the FTC's discussion of the "commercial success" test of non-obviousness warrants any change to current judicial practice. AIPLA also believes that the problem with the "suggestion" test perceived by the FTC is not prevalent and will be self-correcting without any need for legislation.

Effective Post-Grant Opposition Procedure (NAS Recommendation 3; FTC Recommendation 1)

AIPLA agrees with the recommendations of both the NAS and the FTC that Congress consider legislation to create an “Open Review,” or post-grant review, proceeding for third parties to challenge the validity of patents after issuance. The procedure should be adequately funded and 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 PTO.
- Requiring requesters to identify the real party in interest by 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 unless 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 raise any question of patentability, including double patenting and any of the requirements for patentability set forth in 35 U.S.C. §§ 101, 102, 103, 112, and 251(d). (This assumes passage of HR 2795, 109th Congress.)
- 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 against an opposer in any subsequent proceeding with respect to an issue of invalidity raised by an opposer, 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 an opposer and the patent owner, but if no opposer remains in the proceeding, permitting the panel to terminate the proceeding or issue a written decision in the absence of an opposer.

Strengthen PTO Capabilities (NAS Recommendation 4; FTC Recommendation 4)

AIPLA strongly supports the recommendations of both the NAS and FTC Reports, and of many other observers, that Congress should provide additional funding for the PTO to implement its 21st Century Strategic Plan, which AIPLA also supports. AIPLA believes there is no justification for the current practice of applying fees received by the PTO to fund non-PTO programs and that a first step toward adequately funding of PTO activities is to end that diversion of funds.

New Legislation To Codify The Exemption For Scientific Research And Experimentation

AIPLA agrees with the NAS recommendation that Congress act to exempt certain experimentation inventions from liability for patent infringement. The uncertain state of the law threatens numerous adverse consequences, including complicated licensing negotiations, compensation over-reaching, royalty stacking and delays in starting experiments until patent issues can be resolved. AIPLA has endorsed legislation, based on international precedents, that would exempt the following research activities from infringement liability:

- Evaluating the validity of the patent and the scope of protection afforded under the patent;
- Understanding features, properties, inherent characteristics or advantages of the patented subject matter;

- Finding other methods of making or using the patented subject matter; and
- Finding alternatives to the patented subject matter, improvements thereto or substitutes therefor.

AIPLA disagrees with the NAS's alternative remedy if Congress fails to enact exempting legislation of having the federal government 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.

Modify or Remove Subjective Elements From Patent Litigation (NAS Recommendation 6; FTC Recommendation 9)

Concerned that patent infringement litigation has been unnecessarily complicated and unpredictable as a result of issues that depend on assessment of a party's state of mind, the NAS Report recommends significant changes in three areas. These are willful infringement, which can give rise to treble damages, the "best mode" requirement, and inequitable conduct.

Willful Infringement

The NAS poses three alternatives for dealing with the problems associated with willful infringement: (1) abolishing the requirement that accused infringers obtain and disclose a written opinion of counsel as the only way of establishing due care; (2) limit inquiry into willful infringement to cases in which the defendant's infringement has already been established; and/or (3) require written notice of infringement and/or deliberate copying as a predicate for finding willful infringement (which the FTC Report also recommends).

AIPLA supports all three alternatives. AIPLA also suggests the following refinements to the third alternative: (1) reserve the issue of willfulness for the court, rather than the jury; (2) define a standard of due care to serve as a predicate for any finding of willful infringement; (3) specify that, absent deliberate copying, reasonable reliance on advice of counsel, offered in evidence, establishes due care; and (4) abolish any adverse inference based on the failure of the accused infringer to waive the attorney-client privilege.

Best Mode

AIPLA supports the NAS Report recommendation to eliminate the “best mode” requirement. AIPLA believes the “best mode” requirement should be removed as part of a coordinated effort to reform the U.S. patent laws in moving to a first-inventor-to-file system and because in any event it is beset with a host of practical problems that open it up to capricious and inconsistent application.

Inequitable Conduct

AIPLA supports elimination of the inequitable conduct defense to patent infringement except where actual fraud resulted in issuance of an invalid patent claim. This change would not disturb antitrust remedies for such conduct or for sham litigation, but would largely eliminate misconduct determinations, which the Federal Circuit has labeled an “absolute plague,”² from private litigation. The antitrust litigation would be streamlined by eliminating the issue of whether the conduct had been fraudulent. The private plaintiff would not be able to assert an antitrust claim based on PTO fraud absent an actual finding of fraud by the PTO. At the same time, collateral estoppel would presumably bar the patent owner from re-litigating a PTO finding of fraud. The antitrust plaintiff would still have to prove that the patent owner had knowledge of the misconduct, and that the misconduct was fraudulent, at the time that it prosecuted the infringement suit, as well as the other elements of an antitrust claim, such as market power, standing and damages.

As discussed in AIPLA’s comment to NAS, this procedure can only work effectively if it is coordinated with a number of the other changes recommended by NAS, including first-inventor-to-file (recommendation 7), more comprehensive post-grant opposition (Recommendation 3), and adequate PTO funding (Recommendation 7).

² See *Burlington Industries, Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988) (“[T]he habit of charging inequitable conduct in almost every major patent case has become an absolute plague.”)

International Harmonization (NAS Recommendation 7; FTC Recommendation 7)

AIPLA agrees with the NAS that redundancies should be reduced and inconsistencies should be eliminated among the world's patent systems. Accordingly, AIPLA endorses the following specific recommendations of the NAS Report:

- AIPLA strongly supports adoption of a first-inventor-to-file system of priority for U.S. patents as an international “best practice” that is better able to protect the interests of independent inventors and small entities.
- AIPLA also supports the NAS recommendation that any U.S. first-inventor-to-file system retain the one-year “grace period” which allows an inventor to file a patent application within one year of publication of its details without having the publication considered prior art precluding the patent grant.
- As indicated earlier, AIPLA supports elimination of the “best mode” requirement, which is an anomaly among the world's patent systems.
- AIPLA supports in concept the NAS recommendations for moving toward a more globally uniform prior art definition, but would refine those recommendations in the following ways: (1) treat patents, printed publications, and other public knowledge as prior art at the time they become reasonably and effectively accessible to persons skilled in the art, thereby eliminating the artificial prior art distinction in U.S. patent law under which knowledge existing in the United States constitutes prior art and knowledge existing elsewhere, even if readily available and effectively accessible, does not, and (2) treat applications that later issue as patents or that are otherwise published as 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 for patent.
- AIPLA has long advocated adoption of a requirement recommended by the NAS and FTC Reports to require publication of all U.S. patent applications after 18 months. Such a rule would minimize the uncertainty associated with submarine patents.

Enact Legislation To Create Intervening Or Prior User Rights (FTC Recommendation 8)

The purpose of a prior user right is to provide a safeguard against opportunistic broadening of claims to capture products after they have been developed by others at substantial cost. AIPLA supports the FTC's recommendation to the extent that it would provide prior user rights for products or processes before the effective filing date of a relevant patent application. Specifically, AIPLA recommends amending that provision to remove its current limitation to processes; to delete the requirement that the prior use be reduced to practice one year prior to the effective filing date; and to include "substantial preparation" as an act of prior use.

Modify Certain PTO Rules and Implement Portions of the PTO's 21st Century Strategic Plan (FTC Recommendation 5)

The FTC Report contains four specific recommendations to change PTO rules and procedures. AIPLA agrees with two of those recommendations, and disagrees with the other two.

- AIPLA **agrees** with the FTC recommendation (5c) that the PTO expand its "second pair of eyes" review in selected art areas -- a procedure which AIPLA has long advocated.
- AIPLA **agrees** with the FTC recommendation (5d) that the PTO forge a balance between the public's interest in intellectual property and each patent holder or applicant's interest in his or her patent or trademark -- a balance which AIPLA believes is best served by faithful adherence to the legislation which establishes governing patent policy.
- AIPLA **disagrees** with the FTC recommendation (5a) to require PTO applicants to submit a statement as to the relevance of a prior art reference upon request of an examiner. In AIPLA's view such a requirement will result in increased cost and time, and the likelihood that it will be used against the patent in subsequent litigation means that little or no useful information will be obtained.
- AIPLA also **disagrees** with the FTC recommendation (5b) to encourage greater use of PTO Rule 105, Examiners' Request for Information, to permit further examiner follow-up. In AIPLA's view expanded use of Rule 105 will introduce unnecessary

inefficiencies into the patent prosecution process and unnecessary obfuscation into the record, with little potential benefit.

Change The Burden of Proof of Invalidity From “Clear and Convincing Evidence” To Mere “Preponderance of the Evidence” (FTC Recommendation 2)

AIPLA **strongly disagrees** with the FTC’s recommendation for legislation to change the burden of proof of patent invalidity from “clear and convincing evidence” to a mere “preponderance of evidence.” AIPLA believes that such a change would undermine decades of well-reasoned precedent and open the door for patent invalidations based on allegations that are easily fabricated and almost impossible to disprove, typically consisting of uncorroborated oral testimony of prior uses or prior inventions. AIPLA believes that the FTC and, unfortunately, some courts, have failed to draw a distinction between the predicate facts underlying a claim of invalidity, which should be proven by clear and convincing evidence, and the legal conclusion of invalidity based on the persuasive force of those facts, which need only be demonstrated by a fair preponderance. Such a distinction, in AIPLA’s view, is most consistent with Supreme Court precedent and with the reward the patentee deserves for disclosing his or her invention to the public through the patent application process.

Conclusion

AIPLA appreciates the opportunity to present its views on these important subjects to the Commission. We direct the Commission’s attention to the documents provided in the three appendices for more detailed treatment of each of the subjects summarized above, and we hope that the Commission finds them useful. AIPLA would also be pleased to participate in the hearings which the Commission has planned to elaborate on these subjects and any others relating to intellectual property which the Commission would like to explore.

Appendix A

AIPLA_AmicusBrief-IndependentInk.pdf

Appendix B

AIPLA Comment on NAS Report.pdf

Appendix C

AIPLA Response To FTC Report.pdf

No. 04-1329

IN THE
Supreme Court of the United States

ILLINOIS TOOL WORKS, INC. AND TRIDENT, INC.,
Petitioners,

v.

INDEPENDENT INK, INC.,
Respondent.

**On Petition for Writ of Certiorari to the
United States Court of Appeals for the Federal Circuit**

**MOTION FOR LEAVE TO FILE BRIEF AND
BRIEF OF *AMICUS CURIAE*
AMERICAN INTELLECTUAL PROPERTY LAW
ASSOCIATION
IN SUPPORT OF PETITIONERS**

AMERICAN INTELLECTUAL
PROPERTY LAW
ASSOCIATION
William C. Rooklidge, President
2001 Jefferson Davis Hwy.
Suite 203
Arlington, Virginia 22202
(703) 415-0780

*Patrick J. Coyne
Kenneth M. Frankel
FINNEGAN, HENDERSON,
FARABOW, GARRETT
& DUNNER, L.L.P.
901 New York Avenue, N.W.
Washington, D.C. 20001
(202) 408-4000

May 4, 2005

* Counsel of Record
Counsel for *Amicus Curiae*

**MOTION FOR LEAVE TO FILE
AMICUS CURIAE BRIEF**

The American Intellectual Property Law Association (“AIPLA”) respectfully moves for leave to file the attached *amicus curiae* brief, pursuant to Supreme Court Rule 37.2(b), in favor of granting the petition for a writ of *certiorari* to review *Independent Ink, Inc. v. Illinois Tool Works, Inc.*, 396 F.3d 1342 (Fed. Cir. 2005).

The AIPLA is a voluntary bar association of over 16,000 attorneys who daily work with patents, trademarks, copyrights, and trade secrets, and with the legal issues that the intellectual property presents. The AIPLA’s members include attorneys in private and corporate practice and in government service who secure, license, enforce, and defend against enforcement of intellectual property rights. They regularly counsel and advise their clients regarding, *inter alia*, the requirements of the antitrust laws for patent licensing arrangements. The arrangements include those that may be argued to tie the sale of patented and unpatented products. The Federal Circuit panel’s decision below materially impacts those licensing arrangements.

The Court should grant the AIPLA leave to file the attached *amicus curiae* brief, because, through its diverse representation of the intellectual property bar, the AIPLA brings a broad perspective and extensive experience to the important issues raised by the decision below. The AIPLA offers the Court a unique and balanced perspective, because the AIPLA’s members represent parties on both sides: (1) patent owners who license or enforce their intellectual property rights and, as a result, may find themselves accused of violating the antitrust laws; and (2) licensees or accused infringers who may respond to infringement threats or suits

with claims that the patent owner's licensing arrangements violate the antitrust laws.

Through their work, the AIPLA's members have practical experience with the factual predicate underlying the legal question that the Petition presents: whether the presumption of market power in a relevant market for the patented product—based solely on the existence of a patent—has a basis in fact.

In the AIPLA's practical experience, it does not. Instead, virtually all patents cover improvements to existing products that represent modest, incremental advances and rarely claim pioneering inventions that open new markets. Routinely, patents do not define relevant markets and do not provide substantial market power.

The AIPLA seeks to bring to the Court's attention information that should help the Court in resolving the split on this issue between the Federal Circuit panel decision, on the one hand, and decisions by other panels of the Federal Circuit and decisions by other circuit courts of appeals, on the other hand.

The AIPLA sought consent to file an *amicus curiae* brief from the counsel of record for all parties, pursuant to Supreme Court Rule 37.2(a). Counsel for Petitioner consented, but counsel for Respondent did not. Copies of the responses received from the parties are being filed with the Clerk.

Accordingly, the AIPLA respectfully requests that the Court grant the AIPLA's motion for leave to file the attached *amicus curiae* brief and that the Court grant the writ of *certiorari*.

Respectfully submitted,

Dated: May 4, 2005

AMERICAN INTELLECTUAL
PROPERTY LAW
ASSOCIATION
William C. Rooklidge, President
2001 Jefferson Davis Hwy.
Suite 203
Arlington, Virginia 22202
(703) 415-0780

*Patrick J. Coyne
Kenneth M. Frankel
FINNEGAN, HENDERSON,
FARABOW, GARRETT
& DUNNER, L.L.P.
901 New York Avenue, N.W.
Washington, D.C. 20001
(202) 408-4000

*Counsel of Record
Counsel for *Amicus Curiae*
American Intellectual Property Law Association

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<http://usdoj.gov/atr/public/guidelines/ipguide.htm>6

STATEMENT OF INTEREST¹

The AIPLA has no interest in any party to this litigation or stake in the outcome of this case, other than its interest in seeking a correct and consistent interpretation of the law affecting intellectual property.

SUMMARY OF ARGUMENT

In *Independent Ink, Inc. v. Illinois Tool Works, Inc.*, 396 F.3d 1342, 1352 (Fed. Cir. 2005), a three-judge panel of the Federal Circuit applied a presumption of market power in a relevant market. The panel applied the presumption in the context of an alleged Sherman Act § 1 antitrust violation based on tying of a patented product to an unpatented product. Specifically, the panel held that the mere existence of a patent on a product creates a rebuttable presumption that the patent owner has market power in the relevant market for the patented product itself. In so holding, the panel concluded that prior decisions of this Court require that presumption.

In reality, however, the mere issuance of a patent does not convey market power in a relevant market, except in very rare cases. Consequently, the presumption that patents nearly always define a market unto themselves and provide sufficient power to raise prices or restrict output is

¹ In accordance with Supreme Court Rule 37.6, the AIPLA states that this brief was not authored, in whole or in part, by counsel to a party to the instant Petition, and that no monetary contribution to the preparation or submission of this brief was made by any person or entity other than the AIPLA or its counsel.

not based on actual experience. Because the presumption does not reflect market realities, the Court should reject it.

Moreover, the presumption will encourage routine filing of tying antitrust claims, because the accusers would not need to confront market realities. Those filings may arise not only in cases of express ties, but also where a license arrangement may be argued to have a tying effect. The increased risk of treble-damage antitrust liability may discourage patent owners from enforcing their patent rights, and thus may lessen the value of those rights and the incentive to make and disclose innovations to the public.

The detrimental effect of the panel's decision extends to all antitrust tying allegations in the normal context in which patent claims are raised, *i.e.*, where the complaint raises claims of patent infringement, validity, or enforceability. Because the Federal Circuit has exclusive appellate jurisdiction in those cases, its presumption rule will apply.

Moreover, the treatment of market power by the panel below, in the context of tying under Sherman Act § 1, diverges from the treatment of that issue by other Federal Circuit panels that rejected or did not apply the presumption in related antitrust and misuse contexts. Because the panel below concluded that decisions of this Court require the presumption, only this Court can resolve that schism in the Federal Circuit's treatment of the identical issue. In addition, the panel's application of the presumption diverges from decisions of the Sixth and Seventh Circuits rejecting the presumption in related intellectual property areas.

The decision below addresses an issue of exceptional importance with widespread impact. It concerns not only the

administration of the antitrust laws but also the potential for overly aggressive private treble-damage antitrust enforcement that could lessen the incentives for innovation.

The AIPLA takes no position on the merits of this case or who should prevail on the present facts in the absence of a presumption of market power. Instead, the AIPLA urges the Court to grant the petition for *certiorari* and to hold that the mere existence of a patent should not create any presumption of a relevant market or of market power in a relevant market.

ARGUMENT

I. The Federal Circuit Panel's Decision Raises Issues of Exceptional Importance

The Petitioner set forth the facts of the case and described the trial court and appellate decisions below, which the AIPLA will not repeat. *See* Petition at 3-8.

Applying the presumption in the context of an alleged tying violation of Sherman Act § 1, the Federal Circuit panel held that:

[A] patent presumptively defines the relevant market as the nationwide market for the patented product itself and creates a presumption of power within this market. Once the plaintiff establishes a patent tying agreement, it is the defendant's burden to rebut the presumption of market power and consequent illegality that arises from patent tying.

Independent Ink, 396 F.3d at 1352. In applying this presumption, the panel relied upon and concluded that it was constrained by this Court’s decisions in *International Salt Co. v. United States*, 332 U.S. 392, 395-96 (1947), and *United States v. Loew’s Inc.*, 371 U.S. 38, 45-46 (1962). See *Independent Ink*, 396 F.3d at 1346-52.

A. The Presumption Has No Factual Basis, in the AIPLA’s Experience

The Federal Circuit panel’s decision actually applies two related presumptions: (1) that a patented product² defines a relevant market for the patented product itself in the United States; and (2) that the patent provides market power in that relevant market. See *Independent Ink*, 396 F.3d at 1352. The first presumption typically will control, because if the patented product were to define a product market unto itself, the patent likely would provide substantial economic power in that market.

This Court has instructed that “[l]egal presumptions that rest on formalistic distinctions rather than actual market realities are generally disfavored in antitrust law.” *Eastman Kodak Co. v. Image Technical Servs., Inc.*, 504 U.S., 451, 466-67 (1992). In the AIPLA’s practical experience, neither presumption rests on actual market realities.

In that experience, virtually all patents cover improvements to existing products that represent modest, incremental advances. Rarely do they claim pioneering inventions that open entirely new economic markets. Thus, the issuance of a patent, standing alone, only rarely affords

² Patents provide protection for both products and processes. For simplicity, this brief refers only to products.

its owner or licensor any appreciable market power in a relevant product market in the antitrust sense, *i.e.*, the power to raise prices or restrict output in that market. *See Kodak*, 504 U.S. at 464 (explaining that market power “has been defined as ‘the ability of a single seller to raise price and restrict output.’” (quoted source omitted).)

In the AIPLA’s experience, patented improvements typically compete with and provide alternatives to existing products that are already established in, or that may even dominate, the marketplace. Because they routinely are interchangeable with existing products, patented improvements seldom constitute a relevant product market unto themselves. *See Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962) (“The outer boundaries of a product market are determined by the reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it.”). Thus, the presumption that a patented product defines a relevant market for antitrust purposes has no basis in fact.

Routine interchangeability also precludes any factual basis for the presumption of market power in a relevant product market. In competing as an alternative to existing products, a patented product seldom dominates the marketplace.

As a result, contrary to the presumption, a patent rarely defines a relevant product market or creates market power in any relevant market, in the AIPLA’s practical experience.

Other Federal Circuit panels have recognized this economic reality in the contexts of other antitrust laws and patent misuse. *See, e.g., C.R. Bard, Inc. v. M3 Sys., Inc.*, 157

F.3d 1340, 1368 (Fed. Cir. 1998) (Sherman Act § 2; “It is not presumed that the patent-based right to exclude necessarily establishes market power in antitrust terms. The virtually unlimited variety and scope of patented inventions and market situations militate against *per se* rules in these complex areas.”); *Virginia Panel Corp. v. MAC Panel Co.*, 133 F.3d 860, 869 (Fed. Cir. 1997) (not applying presumption in patent misuse context; “[I]n the absence of market power, even a tying arrangement does not constitute patent misuse.”); *Abbott Labs. v. Brennan*, 952 F.2d 1346, 1354 (Fed. Cir. 1991) (Sherman Act § 2; “A patent does not of itself establish a presumption of market power in the antitrust sense. The commercial advantage gained by new technology and its statutory protection by patent do not convert the possessor thereof into a prohibited monopolist.”); *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 875 n.9 (Fed. Cir. 1985) (Sherman Act § 2; “[N]ot every patent confers market power.” (quoted source omitted)); *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1367 (Fed. Cir. 1984) (Sherman Act § 2; “[P]atent rights are not legal monopolies in the antitrust sense of that word.”).

Both the legislative and executive branches have indicated that the presumption is not factually supportable. In enacting 35 U.S.C. § 271(d)(5) (2000), Congress specifically required proof of market power in a relevant market to establish patent misuse or illegal extension of the patent right. Similarly, the Federal Trade Commission and the Department of Justice have concluded that market power cannot and should not be presumed. “Although the intellectual property right confers the power to exclude with respect to the *specific* product, process, or work in question, there will often be sufficient actual or potential close substitutes for such product, process, or work to prevent the exercise of market power.” United States Department of

Justice and Federal Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property* § 2.2 (Apr. 6, 1995), available at <http://www.usdoj.gov/atr/public/guidelines/ipguide.htm> (last visited May 3, 2005).

Thus, the essential factual premise of the Federal Circuit panel's decision, and of prior decisions by this Court in *International Salt*, 332 U.S. at 395-96, and *Loew's*, 371 U.S. at 45-46, has no factual basis, in the AIPLA's practical experience. Because the presumption does not rest on "actual market realities," the Court should reject it. See *Kodak*, 504 U.S. at 466-67.

B. The Market Power Presumption Eliminates a Critical Limitation on Application of the *Per Se* Rule, Which Should Not Be Compromised

The market power presumption can result in *per se* antitrust illegality if the patent owner does not rebut the presumption. This is because, once the plaintiff meets the market power element, the rest of the key elements of a tying offense may be undisputable or simply proved: two separate products that are tied together in an arrangement that affects a "not insubstantial" amount of commerce in the market for the tied product. *N. Pac. Ry. Co. v. United States*, 356 U.S. 1, 6 (1958) (concluding that tying arrangements are "unreasonable in and of themselves whenever a party has sufficient economic power with respect to the tying product to appreciably restrain free competition in the market for the tied product and a 'not insubstantial' amount of interstate commerce is affected."); see *Kodak*, 504 U.S. at 461-62. Thus, the presumption may shift certain cases from the Rule of Reason to *per se* standards for determining illegality of patent tying arrangements under Sherman Act § 1.

Such a result would run counter to the trend of this Court's antitrust decisions. Over the past thirty years, the Rule of Reason has developed into the preferred method for analyzing the potential for competitive harm in antitrust cases. *See, e.g., Continental T.V., Inc. v. GTE Sylvania, Inc.*, 433 U.S. 36, 49 (1977); *State Oil Co. v. Kahn*, 522 U.S. 3, 10 (1997). It affords substantial flexibility to prohibit practices that harm competition, while permitting practices that do not harm competition or that affirmatively enhance competition.

This Court has departed from the Rule of Reason and applied a *per se* rule to tying only in the narrow situation in which the seller is found to have market power in the relevant market for the tying product. *See, e.g., Kodak*, 504 U.S. at 464-78. In such cases, the antitrust plaintiff must (1) define the relevant market and (2) establish that the antitrust defendant has appreciable market power in the relevant market. *See Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 18 (1984); *Kodak*, 504 U.S. at 462 (explaining that “‘appreciable economic power’ in the tying product market” must be shown for a violation of Sherman Act § 1). This Court has recognized that tying is not necessarily *per se* unlawful. *See, e.g., Times Picayune Publ'g Co. v. United States*, 345 U.S. 594 (1953); *Standard Oil Co. v. United States*, 337 U.S. 293, 306 (1949); *Jefferson Parish*, 466 U.S. at 16-18. An accurate analysis of market power in a relevant market thus is critical to the proper application of the Rule of Reason.

The market power requirement guards against a rigid application of *per se* analysis in tying cases. Like any other limitation on the *per se* rule, it should be compromised only in rare instances, specifically where the challenged practice has been shown—through experience—to virtually always

harm competition. *See Continental T.V.*, 433 U.S. at 58-59 (explaining that any “departure from the rule-of-reason standard must be based upon demonstrable economic effect rather than . . . upon formalistic line drawing”); *N. Pac.*, 356 U.S. at 5 (explaining that *per se* analysis is appropriate only for practices that have a “pernicious effect on competition and lack of redeeming virtue”). The market power presumption applied by the Federal Circuit panel below, however, has not been validated by experience, as decisions of this Court require. *See, e.g., Kodak*, 504 U.S. at 466-67.

There is no reason why the Court’s approach to tying should be different where patent licensing is involved. The patent licensing context presents the same seller-buyer relationships as exist in typical tying cases under both the Rule of Reason and *per se* analyses: the patent owner sells licenses to its patents and the licensee buys those licenses. When the seller does not have market power in the tying product, the Rule of Reason is the proper mode of analysis even in tying cases. *See Jefferson Parish*, 466 U.S. at 29 (explaining that an antitrust plaintiff must prove a Rule-of-Reason violation in the absence of *per se* liability).

Moreover, positive benefits may flow from a variety of patent tying arrangements, such as efficiencies in ease of calculating license fees or in distribution. *See, e.g., Automatic Radio Mfg. Co. v. Hazeltine Research, Inc.*, 339 U.S. 827, 834 (1950) (holding non-mandatory package licensing of patents was not patent misuse), *overruled in part on other grounds by, Lear, Inc. v. Adkins*, 395 U.S. 653 (1969); *United States v. Jerrold Elecs. Corp.*, 187 F. Supp. 545, 555-58 (E.D. Pa. 1960) (holding tying was not antitrust violation for entrant into new industry), *aff’d per curiam*, 365 U.S. 567 (1961).

C. By Effectively Shifting the Burden to the Patent Owner, the Presumption Encourages Accused Infringers Routinely To Allege Tying Antitrust Counterclaims

Accused infringers routinely used to plead antitrust counterclaims. Those counterclaims have significantly diminished in frequency, however, as the Federal Circuit and this Court have narrowed the areas in which an antitrust violation can be pleaded and proven without spending the very substantial resources needed to analyze and prove market realities.

Patent litigation already entails serious risk for the patent owner. According to a recent study, at the district court level, patent owners win only about fifty-eight percent of all patent suits, only about two-thirds of patents are held valid and about the same portion are held infringed, and the patent owners' win rate varies significantly depending on the jurisdiction in which the suit is brought. *See* Kimberly A. Moore, *Forum Shopping in Patent Cases: Does Geographic Choice Affect Innovation?*, 79 N.C. L. Rev. 889, 915-17 (2001).

High costs to litigate infringement cases already prevail. The AIPLA conducts an annual economic survey of its members, which litigating parties regularly use as a basis for budgeting infringement litigation, as well as in determining the reasonableness of attorney's fees and costs. *See, e.g., View Eng'g, Inc. v. Robotic Vision Sys., Inc.*, 208 F.3d 981, 987-88 (Fed. Cir. 2000) (citing survey for attorney's fees); *Yurman Designs, Inc. v. PAJ, Inc.*, 125 F. Supp. 2d 54, 56 (S.D.N.Y. 2000) (same). The 2003 survey, the most recent year for which results are available, shows the median costs for an infringement suit are approximately

\$4,000,000 and the top twenty-five percent of the suits cost about \$6,000,000. *See* Appendix attached hereto at A2, American Intellectual Property Law Assn., *2003 Report of the Economic Survey* 94 tbl. 22 (2003).

In the AIPLA's experience, antitrust litigation costs add substantially to the total. Discovery alone in a typical antitrust case often involves hundreds of thousands of documents. The magnitude of these costs represents a substantial burden on any company, regardless of size. They may be crippling to a mid-sized company, and prohibitive to small businesses, start-up companies, and individual inventors.

A tying antitrust claim without the presumption necessarily requires both sides to explore market issues. But the presumption shifts the bulk of the costs of the antitrust litigation to the patent owner. The presumption thus unfairly handicaps the patent owner by easing the burden for the antitrust plaintiff, thereby increasing the risk to the patent owner.

The presumption imposes a substantial evidentiary burden for the patent owner, because the Federal Circuit panel's decision limits the proof that can be offered. Specifically, the panel held that, to rebut the presumption, it is not enough to show the availability of alternatives to the tying arrangement. Rather, the patent owner must establish the price elasticity of the relevant products, which typically is expensive and time consuming. "The presumption can only be rebutted by expert testimony or other credible economic evidence of the cross-elasticity of demand, the area of effective competition, or other evidence of lack of market power." *Independent Ink*, 396 F.3d at 1352.

Thus, although the market power presumption may simplify that issue for the antitrust plaintiff, it forces the patent owner to introduce substantial, complex, and costly proof just to survive summary judgment. Yet, that shifting of cost and risk is not justified by practical experience.

Moreover, the presumption may provide an incentive to circumvent the limitations of a misuse defense by repackaging it as an antitrust claim. Under 35 U.S.C. § 271(d)(5) (2000), to establish misuse, the accused infringer must establish market power and would not receive the significant benefit of the presumption.

The combined effect of these factors skews the balance of power between the patent owner and the antitrust plaintiff substantially in favor of the antitrust plaintiff. This can have widespread implications for many patent owners, because numerous arrangements involving patents can be characterized as ties. Licensing of numerous patents for a royalty based on total sales, for example, is a common practice that courts have subjected to an antitrust tying analysis. *See, e.g., Automatic Radio*, 339 U.S. at 834; *Zenith*, 395 U.S. at 137-39.

The increased cost and risk flowing from the presumption can coerce patent owners into compromising valid infringement claims and settling cases for less than they otherwise would. According to a recent study, about 95 percent of patent cases settle before the end of trial. *See* Jean O. Lanjouw & Mark Schankerman, *Protecting Intellectual Property Rights: Are Small Firms Handicapped?*, 47 J.L. & Econ. 45, 56 (Apr. 2004). Worse yet, in view of the enhanced risk of treble damage liability, the presumption may compel some patent owners not to enforce their rights at all. That would diminish the value of the exclusive rights

afforded by a patent, which in turn may impair the willingness of inventors to innovate and disclose their inventions to the public through the patent system. The effect is not limited merely to cases of express ties, but includes licenses in which the practical effect of a restriction may arguably create a tie.

II. Reversal Would Resolve Divergences Between Federal Circuit Panels' Decisions, and Between the Federal Circuit and Other Circuits

The Federal Circuit panel's decision diverges not only from decisions by other Federal Circuit panels that rejected or did not apply the presumption in related contexts, but also from decisions of other circuit courts of appeals that have declined to apply such a presumption.

The Federal Circuit is uniquely positioned among the circuit courts of appeals to handle patent-antitrust cases. Vested by Congress with sole nationwide jurisdiction over patent appeals in cases initiated with patent claims—which are the vast majority of cases involving patents—the Federal Circuit receives appeals that would otherwise have been decided by regional circuit courts of appeals. *See* 28 U.S.C. § 1295(a)(1) (2000). All appealed cases that raise a patent claim in the complaint will flow to the Federal Circuit. *See Holmes Group, Inc. v. Vornado Air Circulation Sys., Inc.*, 535 U.S. 826, 829 (2002). Thus, divergence between the law applied by different panel decisions of the Federal Circuit is akin to diverging decisions among the regional circuits.

A dominant factor in creating the Federal Circuit was to bring uniformity to the treatment of patent cases, including cases involving antitrust claims that are within its jurisdiction. *See Noblepharma AB v. Implant Innovations*,

Inc., 141 F.3d 1059, 1068 (Fed. Cir. 1998); *Panduit Corp. v. All States Plastic Mfg. Co.*, 744 F.2d 1564, 1574 (Fed. Cir. 1984). Yet, a substantial contrast now exists between Federal Circuit panels' decisions on the question of whether a patent creates a presumption of market power in a relevant market. Specifically, the decision below stands out from other Federal Circuit panels' decisions that hold that the market power presumption does not exist in the context of attempted or actual monopolization under Sherman Act § 2, or that did not apply the presumption in the context of patent misuse. *See, e.g., Bard*, 157 F.3d at 1368 (Sherman Act § 2); *Virginia Panel*, 133 F.3d at 869 (misuse); *Abbott Labs.*, 952 F.2d at 1354 (Sherman Act § 2); *Loctite*, 781 F.2d at 875 n.9 (Sherman Act § 2); *Am. Hoist*, 725 F.2d at 1367 (Sherman Act § 2).

In the decision below, the panel recognized the contrast, but concluded that controlling precedent of this Court constrained it to follow the presumption. *See Independent Ink*, 396 F.3d at 1349 n.8, 1351. If that precedent is controlling, the Federal Circuit, even acting *en banc*, cannot cure this schism without guidance from this Court.

This divergence at the Federal Circuit has practical effects that increase the risk to the patent owner even further. It can create confusion in the trial of patent and antitrust issues. For example, where an accused infringer also asserts a Sherman Act § 2 attempted monopolization claim, the jury will be asked to apply the presumption to the Sherman Act § 1 tying claim, but not to the Sherman Act § 2 attempted monopolization claim. *See Independent Ink*, 396 F.3d at 1353. The same can occur where an accused infringer asserts a misuse claim.

In addition, the shifting of burdens of initial proof may create an anomaly that it would be more difficult to establish the equitable defense of patent misuse than an affirmative antitrust violation. Yet, misuse encompasses conduct broader than an antitrust violation. “[A]s the Supreme Court has said, the patentee’s act may constitute patent misuse without rising to the level of an antitrust violation.” *Senza-Gel Corp. v. Seiffhart*, 803 F.2d 661, 668 (Fed. Cir. 1986), citing *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 140 (1969). Moreover, misuse cannot exist where the effect of the licensing does not improperly restrain competition. “To sustain a misuse defense involving a licensing arrangement not held to have been *per se* anticompetitive by the Supreme Court, a factual determination must reveal that the overall effect of the license tends to restrain competition unlawfully in an appropriately defined relevant market.” *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 706 (Fed. Cir. 1992), quoting *Windsurfing Int’l, Inc. v. AMF, Inc.*, 782 F.2d 995, 1001-02 (Fed. Cir. 1986).

The Federal Circuit panel’s decision below also contrasts with decisions of other circuit courts of appeals that have rejected the presumption in related intellectual property contexts. While the Federal Circuit panel below adhered to the principles articulated more than 50 years ago, other circuits have declined to continue to follow *International Salt* and *Loew’s* regarding the treatment of tying arrangements involving patent rights, as the Federal Circuit panel recognized. See *Independent Ink*, 396 F.3d at 1350. In the context of Sherman Act § 1 tying cases, the Sixth and Seventh Circuits have recognized that the presumption is not justified by substantial economic experience and declined to apply any presumption. See *A.I. Root Co. v. Computer/Dynamics, Inc.*, 806 F.2d 673, 676 (6th Cir.1986)

(copyright antitrust); *USM Corp. v. SPS Techns., Inc.*, 694 F.2d 505, 511 (7th Cir. 1982) (patent misuse). The Federal Circuit panel also noted that the Second, Ninth, and Eleventh Circuits have indicated the opposite. *See Independent Ink*, 396 F.3d at 1352, citing *MCA Television Ltd. v. Pub. Interest Corp.*, 171 F.3d 1265, 1276-79 (11th Cir. 1999) (copyright antitrust), *Digidyne Corp. v. Data Gen. Corp.*, 734 F.2d 1336, 1344 (9th Cir. 1984) (copyright antitrust), and *Susser v. Carvel Corp.*, 332 F.2d 505, 521 (2d Cir. 1964) (trademark antitrust). *See also* Petition at 22-23 (citing other appellate and district court cases).

Review by this Court would resolve these diverging rules, both between Federal Circuit panels and among circuit courts of appeals.

III. Conclusion

For the foregoing reasons, the AIPLA respectfully requests that the Court grant *certiorari* to review the Federal Circuit panel's decision. The Court should grant that review to clarify that tying arrangements involving patent and other intellectual property rights are assessed under the Rule of Reason without any presumption of market power in a relevant market arising merely from the issuance of a patent.

Respectfully submitted,

Dated: May 4, 2005

AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION William C. Rooklidge, President 2001 Jefferson Davis Hwy. Suite 203 Arlington, Virginia 22202 (703) 415-0780	*Patrick J. Coyne Kenneth M. Frankel FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P. 901 New York Avenue, N.W. Washington, D.C. 20001 (202) 408-4000
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*Counsel of Record
Counsel for *Amicus Curiae*
American Intellectual Property Law Association



AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION

2001 JEFFERSON DAVIS HIGHWAY ■ SUITE 203 ■ ARLINGTON, Virginia 22202

AIPLA Response to the National Academies Report entitled “A Patent System for the 21st 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 APLA questions whether giving weight to outside scholarship is a valid goal in its own right, APLA 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. APLA 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. APLA 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. APLA 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 F.2d 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 21st 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 21st 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 21st 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.¹

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.² The

¹ 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).

² 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.³ 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

³ 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, 101st 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.

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 7th 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 7th 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.⁴ 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.

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

⁴ 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) ostensibly⁵ make willfulness an issue

⁵ 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, 2nd 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.⁶

⁶ 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.”

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 that 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

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.

AIPLA

AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION

2001 JEFFERSON DAVIS HIGHWAY ■ SUITE 203 ■ ARLINGTON, Virginia 22202

AIPLA Response

to the

October 2003

Federal Trade Commission Report:

*“To Promote Innovation: The Proper Balance of
Competition and Patent Law and Policy”*

April 21, 2004

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.

AIPLA Response
to the
October 2003 Federal Trade Commission Report:
“To Promote Innovation: The Proper Balance of
Competition and Patent Law and Policy”

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Acknowledgements

In October of 2003, the Federal Trade Commission issued a report entitled *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*. This comprehensive report was a wide-ranging look at issues at the intersection of intellectual property law and competition law which had been the topic of a series of hearings conducted by the Commission and the Department of Justice throughout the preceding year. The Commission made a number of findings concerning intellectual property law, and offered ten specific recommendations for consideration. Representatives and members of the American Intellectual Property Law Association participated in a number of those hearings, and we take this opportunity to thank each of those individuals for their efforts.

Shortly after taking office, I convened a Special Committee to Study the FTC Report to analyze and comment on the recommendations of the Commission. The mission of the Special Committee was to evaluate the policy implications contained in the report, reach out to the substantive committees of the Association for their input, and present a comprehensive response to the various proposals for the Board of Directors.

AIPLA wishes to acknowledge the tremendous work of the Committee and recognize the indispensable contributions of its members:

Gary Griswold, Chair

**Bob Baechtold
Roger Parkhurst
Ed Poplawski
Paul Prestia**

**John Wiedemann
Patrick Coyne
Ken Frankel
Bill Rooklidge**

AIPLA particularly acknowledges the effort and leadership of the Chair of the Special Committee, Gary Griswold. His continued service to this Association surely benefits the entire intellectual property community.

In addition, thanks and appreciation are also due to the Patent Law, Patent Litigation, Patent-Relations with the USPTO, and Interference Committees for their review and comments on the Special Committee's Report and to the Board of Directors for their thoughtful review of the proposals of the FTC and the recommendations of the Special Committee to formulate the response to the FTC Report which serves as an important policy statement on behalf of the Association.

Finally, AIPLA would like to express its appreciation to the Commissioners of the Federal Trade Commission, and particularly to Chairman Muris, for their interest in these very significant issues and for dedicating the considerable resources of the Commission to this effort. We would particularly like to acknowledge the tremendous work of the staff of the Commission, for their hard work and receptiveness to our views and positions.

**Rick Nydegger
President, AIPLA**

AIPLA Response to the FTC Report

Recommendation 1:

“As the PTO Recommends, Enact Legislation to Create a New Administrative Procedure to Allow Post-Grant Review of and Opposition to Patents.”

“The PTO discusses patent applications only with the patent applicant. Until recently, third parties could only bring certain relevant documents to the attention of, and, in limited circumstances, file a written protest with, an examiner or to request the PTO Director to reexamine a patent. To address this situation, Congress passed legislation to establish limited procedures that allow third parties to participate in patent reexaminations. Recent amendments have improved those procedures, but they still contain important restrictions and disincentives for their use. Once a questionable patent has issued, the most effective way to challenge it is through litigation. Litigation generally is extremely costly and lengthy, and is not an option unless the patent owner has threatened the potential challenger with patent infringement litigation.”

“The existing procedures attempt to balance two perspectives. On the one hand, third parties in the same field as a patent applicant may have the best information and expertise with which to assist in the evaluation of a patent application, and therefore might be useful participants in the process of deciding whether to grant a patent. On the other hand, the limited involvement of third parties in the issuance and reexamination of patents reflects genuine concern to protect patent applicants from harassment by competitors. This remains an important goal. To continue to protect against the possibility of competitors harassing patent applicants, any new procedure should be available only after a patent issues.”

“Because existing means for challenging questionable patents are inadequate, we recommend an administrative procedure for post-grant review and opposition that allows for meaningful challenges to patent validity short of federal court litigation. To be meaningful, the post-grant review should be allowed to address important patentability issues. The review petitioner should be required to make a suitable threshold showing. An administrative patent judge should preside over the proceeding, which should allow cross-examination and carefully circumscribed discovery, and which should be subject to a time limit and the use of appropriate sanctions authority. Limitations should be established to protect against undue delay in requesting post-grant review and against harassment through multiple petitions for review. The authorizing legislation should include a delegation of authority permitting the PTO’s conclusions of law to receive deference from the appellate court. Finally, as is the case with settlements of patent interferences, settlement agreements resolving post-grant proceedings should be filed with the PTO and, upon request, made available to other government agencies.”

AIPLA Response:

Under this recommendation, the Federal Trade Commission (“FTC”) advocates creating a new administrative procedure for post-grant review of patentability determinations that allows for meaningful challenges to patent validity short of federal court litigation. To make challenges meaningful, the FTC proposes that the post-grant review should address, at a minimum, patentability issues relating to novelty, nonobviousness, written description, enablement and utility, but only after the review petitioner has first satisfied a suitable threshold showing. An administrative patent judge would preside over the proceeding, which would include cross-examination and appropriate, “carefully circumscribed discovery.” The review proceeding would be conducted within defined time limits and under sanctions authority necessary to control proceedings of this nature. The FTC also advocates establishing limitations to protect against undue delays in requesting post-grant review, and against harassment through repetitive petitions for review. The PTO’s conclusions of law should receive deference from the appellate court, and settlement agreements resolving post-grant review proceedings should be filed with the PTO and, upon request, be made available to other government agencies under terms comparable to those currently applicable to settlements of interferences.

AIPLA agrees that a post-grant review 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 a new administrative review procedure in which the patentability of issued claims can be reviewed by an administrative patent judge.

Such a proceeding should be post-grant, identify the real party-in-interest, and be completely *inter partes*. The identity of the real party-in-interest should be allowed to be kept separate from the file of this proceeding only where the requester does not rely upon factual evidence or expert opinions presented in the form of affidavits or declarations and does not become a party to an appeal. The requester should be required to provide a complete disclosure of the basis for the request, including any factual evidence or expert opinions relied upon which should be provided in the form of affidavits or declarations. AIPLA believes that the grounds for requesting this new review proceeding should be enlarged from those permitted in reexamination to include all issues of novelty and nonobviousness under 35 U.S.C. §§ 102 and 103 that are based upon patents or publications, as well as the issues of written description and enablement under 35 U.S.C. § 112 paragraphs 1 and 2 (excluding “best mode”), utility, subject matter eligibility for patenting (35 U.S.C. 101), and non-statutory double patenting. All parties would be subject to a duty of candor and good faith, and the requester would have the burden of proving, by a preponderance of the evidence, that an issued claim is invalid.

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 judge.

In particular, the review proceeding should normally be completed within one year from the date of the filing of a petition requesting review, with a six (6) month extension possible upon a showing of good cause. If multiple requests are filed, they should be combined into a single proceeding. After the administrative patent judge 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 administrative judge's final determination to the Court of Appeals for the Federal Circuit as in the current *inter partes* reexamination.

AIPLA also 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 (9) 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. As one example, if the parties involved in federal court infringement litigation mutually agree, they should be permitted to file a petition in the PTO requesting a review under this procedure of the patentability of one or more claims of the patent(s)-at-issue in the litigation for some limited period of time, *e.g.*, three months, following the filing of an Answer to the Complaint in the litigation. Whether or not the federal court infringement litigation is stayed thereafter during the conduct of the review proceeding should be in the discretion of the District Court Judge.

While AIPLA is in general agreement with the FTC's Recommendation for a new administrative post-grant review procedure, the Recommendation leaves open issues concerning the scope of the proceeding and necessary safeguards to protect the patent owner from harassment. AIPLA recognizes that the scope and level of inquiry must be sufficiently broad to ensure broad use of such a post-grant review proceeding and to provide sufficient advantages over federal court litigation. At the same time,

the costs must be kept sufficiently low while maintaining a sufficiently speedy outcome.

However, AIPLA has concerns regarding the extent of discovery that should be allowed as that will affect both the length of the proceeding and its cost, which are two of the major criticisms leveled against federal court litigation today. The more discovery permitted, the longer and costlier the proceeding, and the more it will begin to resemble federal court litigation. Similarly, while sanctions for failure to make required disclosures or cooperate in discovery are appropriate, the manner of applying sanctions can also lead to delay in obtaining a timely resolution. Very strict controls must be placed on the availability and extent of permitted discovery to control the costs of the review proceeding and avoid delays in obtaining a timely resolution. Because a competitor generally is in the best position to probe beneath the surface of a patentee's affidavits, AIPLA believes that cross-examination by deposition of witnesses who submitted an affidavit or declaration in support of the patentee or the requester is the only discovery that should be permitted. No other discovery should be allowed except upon an express finding by the administrative patent judge that additional discovery is required in the interest of justice. Oral argument before the administrative patent judge should also be a part of the review proceeding if requested by either party, but live testimony should not be permitted.

This limitation on discovery also affects the question of estoppel, i.e., whether or not a third party requester should be barred from asserting in a later civil action, or in a subsequent review proceeding, the invalidity or unpatentability of any claim finally determined to be valid and patentable.

AIPLA supports application of an estoppel that prevents the requester from later challenging in a civil action any finding of fact or conclusion of law incorporated into the administrative patent judge's final determination, absent a showing that additional factual evidence exists that could not reasonably have been discovered because of the limited discovery permitted. However, AIPLA 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 (9) months of the patent grant.

Finally, AIPLA also agrees that settlements resolving such post-grant review proceedings should be filed with the PTO and made available to other government agencies in the same manner as the current interference practice.

Recommendation 2:

“Enact Legislation to Specify That Challenges to the Validity of a Patent Are to be Determined Based on a ‘Preponderance of the Evidence.’ ”

“An issued patent is presumed valid. Courts require a firm that challenges a patent to prove its validity by ‘clear and convincing evidence.’ This standard appears unjustified. A plethora of presumptions and procedures tip the scales in favor of the ultimate issuance of a patent, once an application is filed. In addition, as many have noted, the PTO is underfunded, and PTO patent examiners all too often do not have sufficient time to evaluate patent applications fully. These circumstances suggest that an overly strong presumption of a patent’s validity is inappropriate. Rather, courts should require only a ‘preponderance of the evidence’ to rebut the presumption of validity.

“The PTO works under a number of disadvantages that can impede its ability to reduce the issuance of questionable patents. Perhaps most important, the courts have interpreted the patent statute to require the PTO to grant a patent application unless the PTO can establish that the claimed invention does not meet one or more of the patentability criteria. Once an application is filed, the claimed invention is effectively presumed to warrant a patent unless the PTO can prove otherwise.

“The PTO’s procedures to evaluate patent applications seem inadequate to handle this burden. The patent prosecution process involves only the applicant and the PTO. A patent examiner conducts searches of the relevant prior art, a focal point of the examination process, with only the applicant’s submissions for assistance. The patent applicant has a duty of candor to the PTO, but that duty does not require an applicant to search for prior art beyond that about which the applicant already knows. If the patent applicant makes assertions or files documentary evidence regarding certain facts, the PTO does not have facilities with which to test the accuracy or reliability of such information.

“Moreover, presumptions in PTO rules tend to favor the issuance of a patent. For example, ‘[i]f the examiner does not produce a prima facie case [of obviousness], the applicant is under no obligation to submit evidence of nonobviousness.’ Similarly, ‘[o]ffice personnel...must treat as true a statement of fact made by an applicant in relation to [the asserted usefulness of the invention], unless countervailing evidence can be provided that shows that one of ordinary skill in the art would have a legitimate basis to doubt the credibility of such a statement.’ Likewise, ‘[t]here is a strong presumption that an adequate written description of the claimed invention is present when the application is filed.’

“The PTO’s resources also appear inadequate to allow efficient and accurate screening of questionable patent applications. Patent applications have doubled in the last twelve years and are increasing at about 10% per year. With yearly

applications approximating 300,000, they arrive at the rate of about 1,000 each working day. A corps of some 3,000 examiners must deal with the flood of filings. Hearings participants estimated that patent examiners have from 8 to 25 hours to read and understand each application, search for prior art, evaluate patentability, communicate with the applicant, work out necessary revisions, and reach and write up conclusions. Many found these time constraints troubling. Hearings participants unanimously held the view that the PTO does not receive sufficient funding for its responsibilities.

“Finally, the PTO grants patents based only on the ‘preponderance of the evidence.’ This standard applies in the context of an underlying presumption that the patent should be granted unless the PTO can prove otherwise. It does not seem sensible to treat an issued patent as though it had met some higher standard of patentability.

“Defenders of the application of the ‘clear and convincing’ evidence standard urged that a finding of patent validity by a neutral government agency using a knowledgeable examiner justifies placing a heavy burden on those who challenge a patent’s validity. We disagree. Presumptions and procedures that favor the grant of a patent application, combined with the limited resources available to the PTO, counsel against requiring ‘clear and convincing evidence’ to overturn that presumption. We believe the ‘clear and convincing evidence’ burden can undermine the ability of the court system to weed out questionable patents, and therefore we recommend that legislation be enacted to amend the burden to a ‘preponderance of the evidence.’”

AIPLA Response:

AIPLA opposes the FTC proposal for legislation to reduce the burden of proof on facts leading to invalidity as flawed and unnecessary. It would undermine decades of well-reasoned precedent that have rejected attempts to invalidate patents based on allegations that are easily fabricated and almost impossible to disprove, typically uncorroborated oral testimony of prior uses or prior inventions.

The requirement that the factual predicate for a finding of invalidity be proved by evidence that is clear and convincing is entirely appropriate and imposes no unfair burden on the party challenging the patent. A prior printed publication or prior patent, on its face, constitutes clear and convincing evidence of its content. An alleged prior use or prior invention, on the other hand, does and should require similarly convincing evidence of its substance.

It appears that the FTC has misunderstood the scope and motive of the “clear and convincing evidence” standard. This misperception is fostered by a lack of precision in many decisions, but the remedy should be clarifications by judicial interpretation, not legislation.

What the well-reasoned precedent holds is that it is the underlying *facts* that must be proven by clear and convincing evidence, i.e., what is the content of the prior art and the level of skill in the art. That does not apply, and should not apply to the *legal conclusion* of invalidity, e.g., obviousness. It is only those predicate facts, not their persuasive force, which must be clearly and convincingly established.

Clarification of those basic principles, and the correct ambit of the “clear and convincing evidence” standard should, we believe, be addressed by the courts, not Congress. When correctly applied as described above, the standard is appropriate and will not make patent challenges unduly difficult or unfairly tilt the playing field.

The Current Law

Under 35 U.S.C. § 282, “[a] patent shall be presumed valid. . . . [and t]he burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.” Judge-made law defines the quantum of proof required to establish invalidity. Currently:

1. The presumption of validity attaches to issued patents.¹
2. The burden of production and the burden of persuasion are on the party asserting invalidity.²
3. The burden of persuasion never increases, decreases, or shifts to the patentee regardless of what evidence is introduced at trial.³
4. The PTO examiner’s decision to allow a patent is entitled to some deference, making the persuasive burden easier or more difficult to carry depending on the specific facts.⁴
5. Every fact used to overcome the presumption must be proven by clear and convincing evidence.⁵

¹ *Solder Removal Co. v. United States Int’l Trade Comm’n*, 582 F.2d 628, 632-33 (C.C.P.A. 1978).

² *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360 (Fed. Cir. 1984).

³ *Lindenmann Maschinentabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1459 (Fed. Cir. 1984); *Stratoflex v. Aeroquip Corp.*, 713 F.2d 1530, 1534 (Fed. Cir. 1983); *SSIH Equip. S.A. v. United States Int’l Trade Comm’n*, 718 F.2d 365, 375 (Fed. Cir. 1983).

⁴ *Astra-Sjuco, A.B. v. United States Int’l Trade Comm’n*, 629 F.2d 682, 688 (C.C.P.A. 1980).

⁵ *Connell v. Sears Roebuck & Co.*, 722 F.2d 1542, 1549 (Fed. Cir. 1983).

The Historical Development and Bases of the Invalidity Rules

Many Supreme Court decisions recognized that a heightened burden should be applied to at least some potentially invalidating facts in patent litigation.⁶ As early as 1844, Justice Story held that the proof of the facts showing anticipation were the defendant's burden to prove "beyond a reasonable doubt . . . because the plaintiff has the right to rest upon his patent, till its validity is overthrown."⁷

In *Radio Corporation of America v. Radio Engineering Laboratories., Inc.*⁸ (RCA) the Court synthesized many prior decisions, explaining that:

Through all of the verbal variances, however, there runs this common core of thought and truth, that one otherwise an infringer who assails the validity of a patent fair upon its face bears a burden of persuasion, and fails unless his evidence has more than a dubious preponderance.

* * *

[T]he requirement of evidence sufficient to carry conviction to the mind is little more than another form of words for the requirement that the presumption of validity shall prevail against strangers as well as parties [to prior litigation] unless the countervailing evidence is clear and satisfactory.⁹

After *RCA*, but prior to the creation of the Federal Circuit, many Circuits held that the facts relating to invalidity were to be proved by a heightened burden.¹⁰ An early Federal Circuit decision correctly recognized that "undoubtedly certain facts in patent litigation must be proved by clear and convincing evidence."¹¹

The pre-Federal Circuit invalidity rules developed from three distinct sources, as discussed below.

⁶ See, e.g., *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45, 60 (1923) ("[E]vidence to prove prior discovery must be clear and satisfactory."); *The Barbed Wire Patent Case*, 143 U.S. 275, 284 (1892) ("[T]he proof shall be clear, satisfactory and beyond a reasonable doubt."); *Cantrell v. Wallick*, 117 U.S. 689, 695-96 (1886); *The Corn-Planter Patent*, 90 U.S. 181, 227 (1874); *Coffin v. Ogden*, 85 U.S. 120, 124 (1873) ("The burden of proof rests upon [the defendant] . . . and every reasonable doubt should be resolved against him."). See also *Washburn v. Gould*, 29 F. Cas. 312, 320 (C.C. Mass. 1844) (No. 17,214).

⁷ *Washburn*, 29 F. Cas. at 320.

⁸ 293 U.S. 1 (1934).

⁹ *Id.* at 8-9.

¹⁰ See 2 DONALD S. CHISUM, CHISUM ON PATENTS § 5.06[2][d][ii], at 5-691 – 92 & nn. 18 – 20 (2003 main vol.) (collecting cases).

¹¹ *SSIH*, 718 F.2d at 375.

1. Section 282 and the common law presumption of validity. The statutory presumption is a procedural device that assigns the burden of production and persuasion to the party seeking to establish invalidity and does not permit it to be shifted.¹² The decision maker must start from the position that the patent is valid.¹³ It also establishes that the burden is constant, not increased or lessened by what evidence is produced during litigation.¹⁴ It has no evidentiary value.¹⁵

The statute, created in the 1952 Patent Act, codified the common law presumption of validity and assignment of burden to some extent.¹⁶ One common law justification for the rule was that an issued patent is *prima facie* evidence of inventorship and novelty.¹⁷ The patent itself is very strong evidence of the date of invention and of inventorship.

The presumption is a patentee's procedural reward for going through the patent process and assuring that the invention will be disclosed to the public, even if the patent later turns out to be invalid.¹⁸ The rule is justified, in part, by the benefit the patentee gives to the public by filing a patent application that issues into a patent. A patent applicant must put the invention in the possession of the public by describing the invention, by disclosing the best mode for practicing it, and by enabling a person of skill in the art to practice the invention.¹⁹ This is the heart of the bargain between the patentee and the public.²⁰

¹² *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1534 (Fed. Cir. 1983); *Solder Removal*, 582 F.2d at 632 n. 8 (Section 282 “requires that a party asserting invalidity bear not only the presumption-generated burden of going forward with proof but also the burden of persuasion on that issues. . . . To hold otherwise would involve total disregard of last sentence of the first paragraph of § 282.”). Of course, the burden of producing evidence — as opposed to the burden of persuasion — can be placed on the patentee after the party seeking invalidity has brought forth some evidence., e.g. after a *prima facie* case of obviousness is made. *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 291-92 (Fed. Cir. 1985).

¹³ *Stratoflex*, 713 F.2d at 1534.

¹⁴ Prior to the creation of the Federal Circuit, some other circuits had the burden being destroyed or changed based on whether the evidence introduced in litigation was more or less relevant than that considered by the patent examiner. *See Solder Removal*, 582 F.2d at 633 (citing cases).

¹⁵ *Stratoflex*, 713 F.2d at 1534; *W.L. Gore & Assocs, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553 (Fed. Cir. 1983) (“The presumption has no separate evidentiary value.”).

¹⁶ *See American Hoist*, 725 F.2d at 1358-59 (“The presumption was, originally, the creation of the courts and was a part of the judge-made body of patent law when the Patent Act of 1952 was written. That act, for the first time, made it statutory in § 282, first paragraph.”).

¹⁷ *See e.g., Cantrell*, 117 U.S. at 695 (citing *Smith v. Goodyear Dental Vulcanite Co.*, 93 U.S. 486, 498 (1876)). *See also Washburn*, 29 F. Cas. at 320 (“[T]he plaintiff has the right to rest upon his patent till its validity is overthrown.”). Novelty, prior to the Patent Act of 1952, included both anticipation and nonobviousness. *See Goodyear*, 93 U.S. 486, 497 (1876).

¹⁸ *The Barbed Wire Patent*, 143 U.S. at 292.

¹⁹ *See* 35 U.S.C. § 112 ¶ 1.

²⁰ *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 142 (2001); *Bonito*

Prior art may be technically invalidating, yet may not effectively put the invention in the possession of the public. For example, in *Barbed Wire Patent Case*²¹, the allegedly invalidating prior art was the public use of various wire fences on farms and at fairs. Although there was some chance that the public uses, technically, invalidated the patent, none of the prior uses truly put the invention in the possession of the public. The Court said:

It is possible that we are mistaken in this; that some of these experimenters may have, in a crude way, hit upon the exact device patented . . . [B]eyond question, [the patentee] . . . first published the device; put it upon record; made use of it for a practical purpose; and gave it to the public . . . [W]e think the doubts we entertain concerning the actual inventor should be resolved in favor of the patentee.²²

2. Trustworthiness of evidence. Most of the Supreme Court decisions requiring a heightened standard of proof dealt with oral evidence of prior use or inventorship. In earlier days patents were routinely challenged by uncorroborated oral evidence.²³ The Supreme Court was reluctant to invalidate patents based on oral testimony alone, even though such testimony is accepted in other, even criminal, cases. In *Eibel Process Co. v. Minnesota & Ontario Paper Co.*²⁴, the Court explained:

The temptation to remember in such cases and the ease with which honest witnesses can convince themselves after many years of having had a conception at the basis of a valuable patent, are well known in this branch of law, and have properly led to a rule that evidence to prove prior discovery must be clear and satisfactory.²⁵

Earlier, in *Barbed Wire Patent Case*, the Court had explained:

Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 151 (1989).

²¹ 143 U.S. 275 (1892).

²² *Id.* at 292.

²³ See, e.g., *Smith v. Hall*, 301 U.S. 216, 232-33 (1937); *Eibel Process Co. v. Minn. & Ontario Paper Co.*, 261 U.S. 45, 60 (1923); *T.H. Symington Co. v. National Malleable Castings Co.*, 250 U.S. 383, 386 (1919); *Deering v. Winona Harvester Works*, 155 U.S. 286, 300 (1894); *The Barbed Wire Patent*, 143 U.S. 275 (1891); *Cantrell*, 117 U.S. at 695-96; *Coffin*, 85 U.S. at 124 (1873).

²⁴ 261 U.S. 45 (1923).

²⁵ *Id.* at 60 (citing *Barbed Wire Patent*, 143 U.S. at 284 and *Loom & Co. v. Higgins*, 105 U.S. 580, 591 (1881)).

In view of the unsatisfactory character of testimony, arising from the forgetfulness of witnesses, their liability to mistakes, their proneness to recollect things as the party calling them would have them recollect them, aside from the temptation to actual perjury, courts have not only imposed upon defendants the burden of proving such devices, but have required that the proof shall be clear, satisfactory, and beyond a reasonable doubt.²⁶

This special concern has carried through to the modern rule that corroboration is required for evidence by an alleged prior inventor to meet the clear and convincing standard.²⁷

Critically, none of these cases was concerned with the persuasive force of the invalidating facts. The Court was always concerned with the existence and availability of those facts — the scope and content of the potentially invalidating prior art. For example, in *Barbed Wire Patent Case*, the Court was convinced that a wire fence had been used in public, but it was “far from being satisfied that it was the [patented] . . . device, or so near an approximation to it as to justify us holding that it was an anticipation.”²⁸

Documents such as patents and printed publications, once authenticated, normally constitute clear and convincing evidence of their substantive content. However, if a document is ambiguous, it too may not meet the clear and convincing standard. The Court often reviewed prior art patents and other documentary evidence without describing what burden or factual standard it was applying.²⁹

The Federal Circuit’s predecessor courts applied the rule in this manner. A good example from the Court of Customs and Patent Appeals is *Stevenson v. International Trade Commission*.³⁰ At issue was the availability and relevance of prior art relating to a skateboard for anticipation and obviousness purposes. Uncorroborated oral testimony was offered about two allegedly anticipating skateboards. The court refused to consider them anticipating. It stated that “[t]he evidence presented is insufficient to establish the existence of any anticipating devices. Proof of such devices, alleged to be complete anticipations of the subject

²⁶ *The Barbed Wire Patent*, 143 U.S. at 284.

²⁷ *Juicy Whip v. Orange Bang, Inc.*, 292 F.3d 728, 741 (Fed. Cir. 2002); *In re Reuter*, 670 F.2d 1015, 1021 & n.9 (C.C.P.A. 1981) (listing a series of factors that must be considered for oral testimony to satisfy the clear and convincing burden).

²⁸ *The Barbed Wire Patent*, 143 U.S. at 289.

²⁹ See, e.g., *Eibel Process*, 261 U.S. at 58-60; *Deering*, 155 U.S. at 291-99; *The Corn-Planter Patent*, 90 U.S. at 189-90, 206-09.

³⁰ 612 F.2d 546 (C.C.P.A. 1979).

patent must be clear and convincing to overcome the presumption of validity.³¹ Notably, the court also refused to consider the devices prior art for obviousness.³² But once the state of the prior art was effectively established, the court freely compared the art to the claims.

Similarly, the Court of Claims in *Lockheed Aircraft Corporation v. United States*³³ held that the conception and reduction to practice necessary to invalidate a patent for prior inventorship must be established by “clear and satisfactory proof beyond a reasonable doubt.”³⁴ Here, again, the court applied the high burden only to the existence of the potentially invalidating art. Because the evidence offered was oral, the court also required corroboration. When the court reached obviousness, it applied no such high burden in its discussion of the scope of the prior art or its application to the claims of the patent.³⁵

3. Administrative law deference. It is often, but erroneously stated that the presumption of validity and the heightened burden derive from solely from the assumption that the Patent Office did its job correctly.³⁶ Assumed administrative correctness is certainly part of the reason for the clear and convincing standard, but it is not the entire explanation.³⁷ The presumption of validity arises from the mere fact of issuance of the patent, whereas deference depends on the specific facts considered by the PTO and those raised in litigation.³⁸

The Supreme Court’s decisions recognize this difference between the presumption of validity and the assumption of administrative correctness. In *Smith v. Goodyear Dental Vulcanite Co.*³⁹, the defendant raised the defense of lack of novelty and the defense that the reissue patent was for a different invention than the original patent. First, the Court discussed the presumption of validity arising from the patent

³¹ *Id.* at 550.

³² *Id.* at 551.

³³ 553 F.2d 69 (Ct. Cl. 1977).

³⁴ *Id.* at 75.

³⁵ *Id.* at 75.

³⁶ See *American Hoist*, 724 F.2d at 1359 (“Behind it all, of course, was the basic proposition that a government agency such as the then Patent Office was presumed to do its job.”). Compare *Solder Removal*, 582 F.2d at 633, n. 10 (“Application of § 282 in its entirety has suffered from analogy of the presumption itself to the deference due administrative agencies.”).

³⁷ The administrative deference justification is generally thought to derive from *Morgan v. Daniels*, 53 U.S. 120 (1894). See *American Hoist*, 725 F.2d at 1359; *Solder Removal*, 582 F.2d at 633 n.10. As explained above, the presumption of validity and the heightened burden long predate *Morgan*. See *supra* nn. 8, 9 & 19 and accompanying text.

³⁸ See, e.g., *SSIH*, 718 F.2d at 375 (“We do not agree that the *presumption* is affected where prior art more relevant than that considered by the examiner is introduced, rather the offering party is likely to carry its burden of persuasion with such evidence.”) (emphasis in original).

³⁹ 93 U.S. 489 (1876).

as *prima facie* evidence of novelty and inventorship.⁴⁰ Later, discussing the allegedly defective reissue, the Court explained that the defendant “must overcome the presumption against him arising from the decision of the Commissioner of Patents in granting the issue . . . [The defect] must plainly appear before we can be justified in pronouncing the reissued patent void.”⁴¹

The Court in *RCA* appeared to recognize the different roles of the presumption of validity and the assumption of administrative correctness:

A patent regularly issued, and even more obviously a patent issued after a hearing of all the rival claimants, is presumed to be valid until the presumption has been overcome by convincing evidence of error. . . . If it is true where the assailant launches his attack with evidence different, at least in form, from any theretofore produced in opposition to the patent, it is so a bit more clearly where the evidence is verbally the same.⁴²

The Federal Circuit has acknowledged that the substantive effect to be accorded administrative correctness is a function of the factual foundation of the administrative decision. It has inherent evidentiary value that the trier of fact may credit, and the trier of fact determines that value.⁴³ If evidence more relevant than that previously considered is introduced, that does not change the presumption of validity, the burden of proof on any particular fact, or the overall burden. As a practical matter, though, it makes the overall burden more likely to be carried.⁴⁴

The Federal Circuit

The Federal Circuit decisions have, unfortunately, not always maintained a clear distinction between the proof of a *fact* by clear and convincing evidence as distinguished from the persuasive force of those facts. In *Connell v. Sears Roebuck &*

⁴⁰ *Id.* at 498.

⁴¹ *Id.* at 499.

⁴² *RCA*, 295 U.S. at 8.

⁴³ For example, the Federal Circuit has approved the following jury instruction:

Because the deference to be given the Patent Office’s determination is related to the evidence it had before it, you should consider the evidence presented to the Patent Office during the reissue application process, compare it with the evidence you have heard in this case, and then determine what weight to give the Patent Office’s determinations.

Mendenhall v. Cedarapids, Inc., 5 F.3d 1557, 1563-64 (Fed. Cir. 1993). A separate instruction had described the presumption of validity. *Id.*

⁴⁴ *See SSIH*, 718 F.2d at 375.

Co.,⁴⁵ the court said, correctly, that “[t]he patent challenger may indeed prove *facts* capable of overcoming the presumption [of validity], but *the evidence relied on to prove those facts* must be clear and convincing.”⁴⁶

As Judge Nies explained regarding obviousness in *SSIH Equipment S.A. v. United States International Trade Commission*⁴⁷:

With respect to the Commission’s statement that there must be “clear and convincing evidence of *invalidity*” (our emphasis), we find it inappropriate to speak in terms of a particular standard of proof being necessary to reach a legal conclusion. Standard of proof relates to specific factual questions. While undoubtedly certain facts in patent litigation must be proved by clear and convincing evidence . . . the formulation of a legal conclusion on validity from the established facts is matter reserved for the court.⁴⁸

Sometimes, the Federal Circuit’s language describing the burden blurs the distinction between the existence of the facts and the persuasive force of the facts. For example, the court has stated “a challenger must establish facts, by clear and convincing evidence, *which persuasively lead to the conclusion of invalidity.*”⁴⁹ Some district courts have misconstrued the requirement that facts be proved by clear and convincing evidence to include the persuasive force of those facts.⁵⁰ The careful distinctions required between the proof of fact and persuasive force of the facts can sometimes be confusing, particularly because legal conclusions, like obviousness, may be tried to a jury along with the underlying facts.⁵¹

⁴⁵ 722 F.2d 1542 (Fed. Cir. 1983).

⁴⁶ *Id.* at 1549.

⁴⁷ 718 F.2d 365 (Fed. Cir. 1983).

⁴⁸ 718 F.2d at 375. *See also Railroad Dynamics, Inc. v. A. Stucki Co.*, 727 F.2d 1506, (Fed. Cir. 1984) (“The burden . . . is to prove *facts* supporting defenses . . . not to prove the legal conclusion (patent invalidity) sought by those defenses.”)(emphasis in original); *Newell Cos., Inc. v. Kenney Mfg Co.*, 864 F.2d 757, 767 (Fed. Cir. 1988) (“Quantum of proof relates to facts, not legal conclusions. . . . Our precedent holds that the disputed facts underlying the legal conclusion of obviousness must be established by clear and convincing evidence, not the ultimate legal conclusion of obviousness itself.”).

⁴⁹ *Avia Group Int’l, Inc. v. L.A. Gear, Inc.*, 853 F.2d 1557,1662 (Fed. Cir. 1988) (emphasis added).

⁵⁰ *See Smith v. M & B Sales & Mfg’g*, 13 U.S.P.Q. 2d (BNA) 2002, 2003 (N. D. Cal. 1990) (“First, he must establish the facts on which he relies by clear and convincing evidence. Second, he must persuade the court that the facts that are proved to this level of certainty *persuasively* demonstrate [invalidity]”) (emphasis in original).

⁵¹ *Connell*, 722 F.2d at 1547.

RCA undoubtedly required a heightened burden for proof of facts, and the Federal Circuit correctly applies the modern clear and convincing standard. *RCA* used language to describe the standard of proof such as “clear and satisfactory”, “more than a dubious preponderance” and “convincing evidence of error.”⁵² Until relatively recently there was no fixed verbal formula for the heightened standard of proof of facts used in civil cases. Various terms were used to describe the standard, such as “clear, cogent and convincing” or “clear, unequivocal and convincing” — all of which meant “a higher probably than is required by the preponderance-of-the-evidence standard.”⁵³ The modern clear and convincing evidence standard is the most consonant with *RCA*.⁵⁴

The Federal Trade Commission’s Proposed Change

The FTC would reduce the burden of proving all facts relating to invalidity from clear and convincing to a mere preponderance in all circumstances.⁵⁵ In making its proposal, the FTC looked only to the prosecution side of patent law and appeared to focus solely on the shortcomings of the administrative process and thus the administrative correctness theory.

Unfortunately, the FTC’s solution is too broad because its analysis is too narrow. Apparently, the FTC believes that the clear and convincing standard is based entirely on administrative deference and that it was the wholly novel creation of the Federal Circuit in erroneous reliance on *RCA*.⁵⁶ As explained above, that is not accurate. The heightened burden on proof of facts has been a consistent element of U.S. patent law since at least Justice Story’s time.

The presumption of validity does not derive exclusively from the presumption of correctness of the PTO’s actions; nor is the requirement that the predicate facts be shown by clear and convincing evidence rooted solely in those administrative concerns. The rule recognizes that the applicant of a granted patent is presumptively

⁵² *RCA*, 293 U.S. at 8-9.

⁵³ *California ex rel Cooper v. Mitchell Bros.’ Santa Ana Theater*, 454 U.S. 90, 93 & n. 6 (1982).

⁵⁴ For an excellent discussion of the various standards of proof and the propriety of the clear and convincing standard in patent litigation, see *Price v. Symsek*, 988 F.2d 1187, 1191-94 (Fed. Cir. 1993). There have been occasional disputes as to whether *RCA* required the criminal standard of “beyond a reasonable doubt” for proof of some facts. See *id.*; *Juicy Whip*, 292 F.3d at 741; *George v. Bernier*, 768 F.2d 1318, 1321 (Fed. Cir. 1985). Cf. *California*, 454 U.S. 94, 97 n. 5 (Stevens, J. dissenting) (reasonable doubt is used to prove invalidity of a patent; citing *RCA*, 293 U.S. at 7-8).

⁵⁵ It is unclear if the FTC believes that there should be any deference to any of the decisions of the PTO. The logic of the FTC’s report would suggest no deference, but it did not recommend changing that aspect of the law.

⁵⁶ FTC REPORT, Ch. 5, § IV, B., p. 26 n. 183.

the first inventor, and that presumption should not be overturned by flimsy and easily manufactured evidence.

Longstanding and well-reasoned precedent establishes that the existence and substance of prior art must be established by clear and convincing evidence. This burden is not particularly difficult to meet when the evidence is documentary. Patents are particularly good evidence because of the disclosures they are required to contain. Since they are, by definition, designed to meet the technical requirements and proof standard of patent law, patents are *per se* clear and convincing proof of their contents.

And, of course, the burden of proof is not on the issue of invalidity — the persuasive value of facts to the trier of fact. Instead, the burden of proof is on the individual facts that may lead to the conclusion of invalidity.

The FTC's analysis is concerned solely with the procedural advantages that a patent applicant may enjoy during *ex parte* prosecution. These concerns can be adequately addressed by the presentation of evidence during trial. The party asserting invalidity is free to point out any flaws in the PTO procedures, both in general and in the prosecution of a particular patent. The trier of fact is free to come to its own conclusion about the evidentiary value of the administrative proceedings.

The FTC did not adequately consider litigation-specific issues that make a heightened burden appropriate. For example, prior use sought to be proved by oral evidence should be established by clear and convincing evidence. Nor did it appreciate that meeting a clear and convincing standard is not a hardship when the challenger relies on the content of documentary evidence such as a patent or printed publication. These are good rules that should not be changed by a blanket preponderance requirement.

The Appropriate Rules

The FTC's concerns would be appropriately and adequately addressed if the Federal Circuit consistently applies the clear and convincing evidence standard only to the proof of predicate facts, and not to their persuasive force.

The general rule most consistent with Supreme Court precedent is the following: (1) the existence, authentication, availability and scope of evidence should be established by clear and convincing evidence, but (2) once such predicate facts are so established, the burden should be that the persuasive force of such facts demonstrates patent invalidity by a fair preponderance, not some elevated standard.

Recommendation 3:

“Tighten Certain Legal Standards Used to Evaluate Whether a Patent is ‘Obvious.’”

“Patent law precludes patenting if the differences between the claimed invention and the prior art are such that ‘the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art.’ ‘Nonobviousness asks whether a development is a significant enough technical advance to merit the award of a patent.’ A proper application of this statutory requirement is crucial to prevent the issuance of questionable patents, including trivial patents and patents on inventions essentially already in the public domain. The courts have developed a variety of tests to evaluate the obviousness of a claimed invention. Two in particular – the ‘commercial success test’ and ‘the suggestion test’ – require more thoughtful application to weed out obvious patents.

- “a. In applying the ‘commercial success’ test, 1) evaluate on a case-by-case basis whether commercial success is a valid indicator that the claimed invention is not obvious, and 2) place the burden on the patent holder to prove the claimed invention caused the commercial success.*

“The Supreme Court has advised that, in some circumstances, courts may consider the commercial success of a claimed invention to indicate that it was not obvious. For example, in some cases early in the twentieth century, courts found the commercial success of an invention that satisfied a long-felt need that had resisted the efforts of others to solve the problem tended to show the claimed invention was not obvious.

“Commercial success can result from many factors, however, some of which have nothing to do with the claimed invention. For example, marketing, advertising, or an incumbent’s unique advantages may cause commercial success. An undue reliance on commercial success to show nonobviousness can raise a number of competitive concerns. Commercially successful inventions may be more likely than others to occur even without the prospect of a patent. Patents on commercially successful products are more likely to confer market power than those on less successful products.

“Certain patent experts and other Hearings participants expressed concern that courts and juries sometimes fail to use a sufficiently searching inquiry when they conclude that commercial success demonstrates a claimed invention is not obvious. Under current standards, if the patent holder shows that the claimed features of the patent are coextensive with those of a successful product, then it is presumed that the invention – rather than other factors – caused the commercial success. The burden shifts to the challenger to present evidence to rebut that presumption.

“This test fails to ask, first, whether factors other than the invention may have caused the commercial success. By contrast, the PTO properly requires that commercial success be ‘directly derived from the invention claimed’ and not the result of ‘business events extraneous to the merits of the claimed invention.’ Second, the judicial standard too easily shifts the burden to the challenger. The patent holder is the best source of information on what has caused the commercial success of its product and should be required to show that, in fact, the claimed invention caused the commercial success.

“b. In applying the ‘suggestion’ test, assume an ability to combine or modify prior art references that is consistent with the creativity and problem-solving skills that in fact are characteristic of those having ordinary skill in the art.

“If the prior art already would have suggested the claimed invention, then the claimed invention is obvious. If not, then the claimed invention is not obvious. The ‘suggestion test’ thus asks a helpful question – that is, to what extent would be prior art ‘have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success.’ The Federal Circuit justifiably has sought to protect inventors from findings of obviousness based purely on hindsight. ‘Good ideas may well appear ‘obvious’ after they have been disclosed, despite having been previously unrecognized.’ The Federal Circuit also has sought to ensure that the PTO provides an administrative record susceptible to judicial review.

“Hearings participants expressed concern, however, with some recent applications of the suggestion test. To show that a claimed invention is obvious, some cases seem to require the PTO to point to particular items of prior art that concretely suggest how to combine all of the features of a claimed invention. Such an application of the suggestion test may have found that the claimed invention of the Selden patent – that is, putting a gasoline engine on a carriage – was not obvious, because there was no document that suggested that combination. The invention likely was obvious, however; ‘[e]verybody seemed to know that if you got a new engine of any kind, you would put it on a carriage.’

“It is important to protect against the issuance of obvious patents that may confer market power and unjustifiably raise costs. Requiring concrete suggestions beyond those actually needed by a person with ordinary skill in the art, and failing to give weight to suggestions implicit from the art as a whole and from the nature of the problem to be solved, is likely to result in patents on obvious inventions and is likely to be unnecessarily detrimental to competition. The Federal Circuit’s most recent articulations of the suggestion test seem to signal greater appreciation of these issues and would better facilitate implementation of the test in ways sensitive to competitive concerns.”

AIPLA Response:

Recommendation 3 advocates that,

(a) in determining “obviousness” under 35 USC §103, (1) evaluate “commercial success” on a case by case basis to determine whether the commercial success is a valid indicator that a claimed invention is not obvious, and (2) place the burden on the patent holder to prove the claimed invention caused the commercial success; and

(b) in applying the “suggestion” test (to determine whether it would have been obvious to combine or to modify prior art references), assume an ability to combine or modify consistent with the creativity and problem-solving skills that in fact are characteristic of those having ordinary skill in the art.

Standing alone, these recommendations are not objectionable, except to the extent that they imply a need to change existing law. AIPLA does not read the recommendations as advocating such a change, and thus agrees with them.

The commentary which follows the recommendations, however, contains several statements which do require a response.

Commercial Success Test

Regarding the nexus between commercial success and unobviousness (Recommendation 3 a.), the commentary indicates that

1. A showing of commercial success gives rise to a presumption (of such a nexus) and places a burden on a patent opponent to rebut that presumption.
2. The test fails to ask whether other factors may be responsible for that success.
3. The burden is shifted too easily since it is the patent holder who is the best source of information on what has caused the commercial success and the patent holder should be required to show that the claimed invention caused the commercial success.
4. As opposed to this “judicial standard,” the patent office requirement, which the commentary favors, is that “commercial success” be “directly derived from the invention claimed” and not the result of “business events extraneous to the merits of the claimed invention.”

The last point is a non-sequitur. The patent office standard is necessarily and properly based on the case law, and does not differ from the case law on commercial success.

The commentary otherwise takes issue with what courts have established as the logical procedure for the presentation of evidence pertaining to commercial success, as opposed to the procedure by which the same evidence is called for by the patent office. In the patent office there is no procedural order for the presentation of evidence since it is an ex parte proceeding. Rule 56 in the patent office requires that an applicant disclose any evidence contrary to that which it urges. In the inter partes environment, discovery and adversarial advocacy perform this function.

AIPLA finds no basis for any inference that “commercial success” is not evaluated on a case-by-case basis to determine whether that commercial success is a valid indicator of unobviousness. See, for example, *J.T. Eaton & Co. v. Atlantic Paste & Glue Co.*, 106 F.3d 1653, 41 USPQ 2d 1641 (Fed. Cir. 1997) (Affirmed as to presence of commercial success and opponents failure to prove other factors as a cause of that success, but remanded for reconsideration of whether a prima facie case of nexus had been shown.); *Brown and Williamson Tobacco Corp. v. Phillip Morris Inc.*, 229 F.3d 1120, 56 USPQ 2d 1456 (Fed. Cir. 2000) (Affirmed rejection of commercial success on the basis that patent opponent had proved commercial success was not necessarily due to the patented feature; also considered possibility that commercial success of the infringing product might also show unobviousness, but refused to remand in view of strong evidence of obviousness.).

Nor does AIPLA see any need to modify the judicial approach to commercial success evidence, particularly insofar as the cases reflect the procedure used in terms of “presumptions” and “burdens.” That this procedure is fair and logical is well illustrated by the Federal Circuit opinion in *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 7 USPQ 2d 1223 (Fed. Cir. 1988).

As fully explicated in that case, when a patent proponent asserts that commercial success supports its contention of nonobviousness, a causal nexus between the commercial success and the claimed invention must be shown and the burden of proving that nexus lies with the party asserting it.

As stated by the court, “In meeting its burden of proof, the patentee in the first instance bears the burden of coming forward with evidence sufficient to constitute a prima facie case of the requisite nexus. . . . A prima facie case of nexus is generally made out when a patentee shows both that there is commercial success, and that the thing (product or method) that is commercially successful is the invention disclosed and claimed in the patent” (intervening citations of authorities omitted). After describing examples of facts in which nexus has not been shown, the court goes on, “When the patentee has presented a prima facie case of nexus, the burden of producing contrary evidence then shifts to the challenger, as in other civil litigation

[and] Once a prima facie case of nexus is made the court must consider the evidence adduced on both sides of the question, with such weight as is warranted.” Id, 851 F.2d. at 1392, 7 USPQ 2d at 1226 (emphasis added).

The explanation for this procedural rule is best summed up with a further quote from the *Demaco* opinion,

A patentee is not required to prove as part of its prima facie case that the commercial success of the patented invention is *not* due to factors other than the patented invention. It is sufficient to show that the commercial success was of the patented invention itself. A requirement for proof of the negative of all imaginable contributing factors would be unfairly burdensome, and contrary to the ordinary rules of evidence, *See 9 Wigmore* [J. Wigmore, *Evidence*, 3d ed. 1940] §2486 at 291 (“Thus, in most actions of *tort* there are many possible justifying circumstances ...; but it would be both unfair and contrary to experience to assume that one of them was probably present and to require the plaintiff to disprove the existence of each one of them”) (emphasis in original)

(emphasis on “not” in first sentence, also in original). 851 F. 2d at 1394, 7 USPQ 2d at 1227

Shifting the burden of coming forward with evidence should not be confused with shifting the burden of proof. Nor should making a prima facie case be confused with shifting the burden of proof. That is made clear by a further quote from *Demaco*, in turn quoting the Supreme Court's definition of “prima facie,”

The phrase “prima facie case” ... may be used by courts to describe the plaintiff's burden of producing enough evidence to permit the trier of fact to infer the fact at issue.

851 F.2d at 1392, 7 USPQ 2d at 1226, citing *Texas Dept. of Community Affairs v. Burdine*, 450 U.S. 248, 254 n. 7 (1981), in turn citing *Wigmore* and *McCormick on Evidence*, the leading treatises on evidence.

In summary, AIPLA sees no need for any change regarding the rules for proving commercial success and the relevance of that success to the unobviousness of an invention. Obviousness does not and should not hinge only on the commercial success test.

Suggestion Test

Regarding the “suggestion” test (Recommendation 3. b), the commentary noted concern with “some recent applications of the suggestion test” while also observing that “The Federal Circuit’s most recent articulation of the suggestion test

seems to signal greater appreciation of these issues [the requirement of “concrete suggestions” in the prior art to combine or to modify references beyond those needed by a person with ordinary skill in the art] and would better facilitate implementation of the test in ways sensitive to competitive concerns.”

Suggestion or motivation for combination or modification must be clearly present and based on concrete evidence in the prior art. The Federal Circuit’s articulation of this test consistently recognizes the necessary consideration of the level of skill in the art when determining if the art provides sufficient motivation for combination or modification of prior art references. However, it may be that, in certain cases, an insufficient motivation is found because the level of skill has not been given adequate consideration. We believe these cases are the exception rather than the rule. To the extent this may be a problem, it appears to be self-correcting through the traditional evolution of case law as applied in specific fact situations.

In summary, AIPLA sees no need for any legislative change regarding the suggestion test.

Recommendation 4:

“Provide Adequate Funding for the PTO.”

“Participants in the Hearings unanimously expressed the view that the PTO lacks the funding necessary to address issues of patent quality. Presidential patent review committees have long advocated more funding for the PTO to allow it to improve patent quality. As recently as 2002, the Patent Public Advisory Committee stated that the PTO “faces a crisis in funding that will seriously impact...the quality of ...issued patents.” The FTC strongly recommends that the PTO receive funds sufficient to enable it to ensure quality patent review.”

AIPLA Response:

AIPLA supports providing additional funding for the PTO to support the 21st Century Strategic Plan developed by the PTO in 2002 and specifically the pending fee legislation. It does not support any fee increases unless those fees are provided to the PTO and opposes any increase in fees unless it is guaranteed that all the fees that are provided for the PTO go to the PTO in order to improve its operations.

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

Fee Diversion – “RESOLVED, that the American Intellectual Property Association favors in principle that all revenue generated by fees paid by users of the services of the United States Patent and Trademark Office for

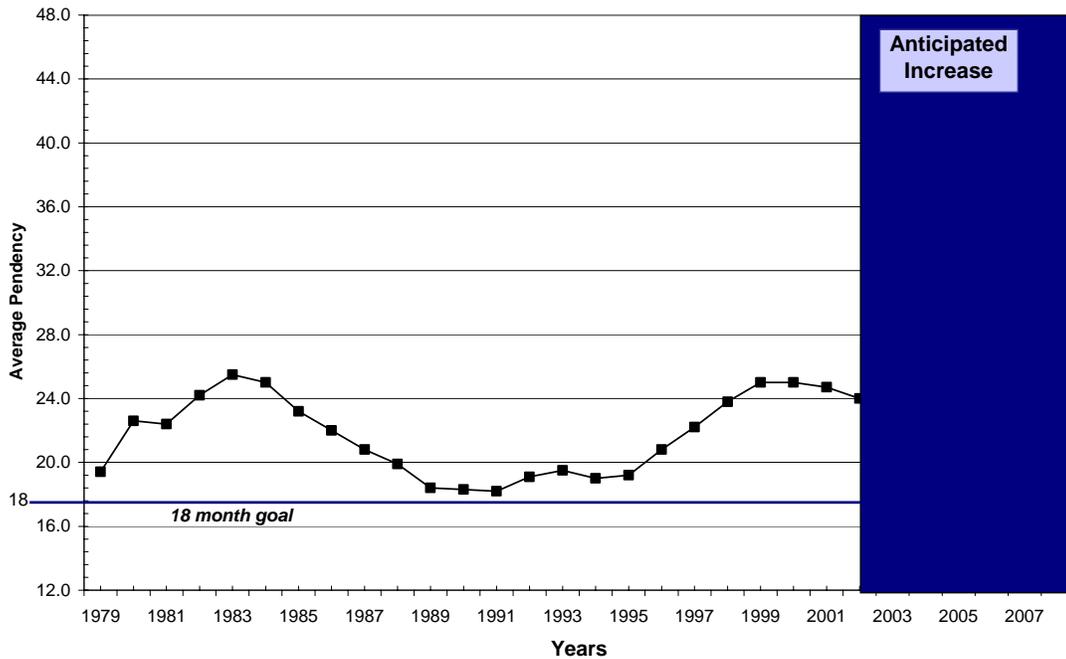
application processing be made promptly available to the USPTO without limitation to provide such services, and Specifically, AIPLA opposes the withholding or diversion of any such revenue to fund any non-USPTO programs.” (July 10, 2000)

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 United States Patent and Trademark Office 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 United States Patent and Trademark Office in that fiscal year or during that other period (as the case may be). (July 11, 2001)

There are three main factors for judging the performance of the PTO – patent quality, early clarification of rights, and cost-effectiveness in PTO operations. Questionable patents are being issued due to many reasons addressed in the 21st Century Strategic Plan. As can be see in the attached graph, patent application pendency will soon be at the highest level in more than twenty years unless the PTO receives funding for its Strategic Plan. The backlog of pending patent applications is approaching an all-time high of one-half million cases. Cost effectiveness of PTO has been compromised because the PTO has had to forego critically-needed investments in e-processing to focus on current workload.

AIPLA supports the 21st Century Strategic Plan, which depends on enactment of the pending fee bill for its funding. This bill increases user fees by some 15 to 25 percent – an amount users are willing to pay for better service, provided the PTO receives all of its fees. The fee bill, as amended, that passed the House of March 3, 2004, ensures that all of the fee revenue generated by the fee bill will go to the PTO or be refunded to the users. The amended fee bill provides a solution to the fee diversion problem, which has resulted in more than \$650 million 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 PTO will be refunded to users. It is believed that since the fee revenues will no longer be available to the appropriators to spend elsewhere that they will appropriate all fee revenues to the PTO.

Patent Application Pendency
(1979 - 2008)



Source: USPTO

Recommendation 5:

“Modify Certain PTO Rules and Implement Portions of the PTO’s 21st Century Strategic Plan.”

“a. Amend PTO regulations to require that, upon the request of the examiner, applicants submit statements of relevance regarding their prior art references.

“Some Hearings participants asserted that, far from holding back information, patent applicants tend to provide an examiner with numerous prior art citations, resulting in lots of ‘information,’ but little ‘knowledge.’ The 2002 version of the PTO’s 21st Century Strategic Plan proposed requiring applicants that cited more than 20 prior art references to provide statements to explain the relevance of references, but the PTO has now withdrawn that proposal. The FTC’s proposal is more modest than the PTO’s original proposal; it would require relevance statements only when the examiner requests them. These statements could materially enhance examiners’ ability to provide quality patent examinations by drawing more fully on the patent applicant’s knowledge base to identify the most relevant portions of prior art references.

“b. Encourage the use of examiner inquiries under Rule 105 to obtain more complete information, and reformulate Rule 105 to permit reasonable follow-up.”

“PTO Rule 105 permits examiners to request ‘such information as may be reasonably necessary to properly examine or treat the matter [under examination]. The Commission recommends that the PTO make a concentrated effort to use examiner inquiries more often and more extensively. As one panelist emphasized, ‘to get better quality and shrink the amount of work,’ there is a need to seek more knowledge in the possession of applicants, who typically ‘know more about the technology than the examiner does, and [know] where you might find something that might be relevant.’ To be fully effective, however, Rule 105 should be amended so that applicants who reply that they do not know the answer to the examiner’s inquiry, or that the necessary information ‘is not readily available to the party or parties from which it was requested’ are not accepted as a complete reply, as they are now, but rather are treated as responses on which the examiner may follow up.”

“c. Implement the PTO’s recommendation in its 21st Century Strategic Plan that it expand its ‘second-pair-of-eyes’ review to selected areas.”

“Second-pair-of-eyes review allows the PTO quickly to flag issues that need further attention by the examiner or the examiner’s supervisor. The PTO first used this method to improve the quality of business method patents, and it received good reviews from participants in the patent system. The Commission believes that expanding this program to fields with substantial economic importance, such as semiconductors, software, and biotechnology, as well as other new technologies as they emerge, could help to boost patent quality in areas where it will make the most difference.”

“d. Continue to implement the recognition that the PTO ‘forges a balance between the public’s interest in intellectual property and each customer’s interest in his/her patent and trademark.’”

“The PTO functions as a steward of the public interest, not as a servant of patent applicants. The PTO must protect the public against the issuance of invalid patents that add unnecessary costs and may confer market power, just as it should issue valid patents to encourage invention, disclosure, and commercial development.”

AIPLA Response:

Recommendation 5 includes four sub-sections, two with which we can agree (5c and 5d) and two which we oppose (5a and 5b).

Subsection 5a proposes a requirement that PTO applicants submit a statement as to the relevance of a prior art reference upon request of an examiner. Subsection

5b recommends increased use of PTO Rule 105, Examiners' Requests for Information. AIPLA strongly opposes these two recommendations.

Regarding the proposed requirement for statements of relevance (Recommendation 5a), we believe past experience substantiates the basis for our opposition. Whether required generally, or on some limited basis as the FTC proposes, it is a virtual certainty that the result will be the same as when such statements were required generally for a number of years. That is: little or no useful information will result.

The risk that whatever an applicant includes in such a statement will likely be used against the patent in any subsequent litigation and the increased time and cost implicated by such a requirement greatly outweighs whatever utility an examiner might find in these statements. Inasmuch as they were not found to be of much use in the past, there is no reason to think that will change just because the requirement of such statements is limited to specific circumstances, such as when an examiner makes a specific request.

Regarding the recommendation to encourage use of PTO Rule 105, Examiners' Request for Information and reformulation of that rule to permit follow-up (Recommendation 5b), AIPLA has opposed this Rule both in its present form and in the proposed amended form now pending in rule changes proposed to implement the PTO 21st Century Plan. AIPLA also opposes the reformulation proposed by the FTC and the increased use of Rule 105 Requests as recommended.

This opposition is based on the pernicious effect which is certain to follow from any procedure which further complicates and extends the communications process necessary for efficient and effective determination of what is patentable and what is not patentable without a corresponding benefit to the system. AIPLA foresees essentially no benefit to the system by virtue of examiners' requests for information and certainly none from increased emphasis on such requests.

To the extent any such request may, in some specific situation, serve some useful purpose, that request can be made under Rule 132. By far the greater likelihood is that such questions, and the answers to such questions, will be open to different interpretations, thus further obfuscating the record of how and why a patent was granted and inviting still more charges of fraud on the patent office.

One need only look to the ineffectiveness of interrogatories as a means of obtaining useful information in civil litigation to see how such questions would be similarly ineffective in patent prosecution.

Recommendation 5c advocates that the PTO expand its "second-pair-of-eyes" review in selected art areas. AIPLA has long been on record as favoring this procedure. We are not aware, however, of any study of the efficacy of this procedure,

which has been in place now for some time in at least one art area. It may be useful to consider such a study so as to ensure that PTO resources committed to this program are justified.

Recommendation 5d advocates continued implementation of the recognition that the PTO “forges a balance between the public’s interest in intellectual property and each customer’s interest in his/her patent and trademark.” AIPLA has long been on record in favor of this recognition.

This is a balanced interest, however, and the PTO’s functioning “as a steward of the public interest” should not overlook the interest of its users, whose rights are set forth in legislation which establishes the governing policy. The PTO’s stewardship is best served by faithful implementation of that legislation, and the concern for issuance of invalid patents, serious as that concern is, should not cause the PTO to err on the side of failing to issue patents which are fully justified under the governing legislation.

Nor should the balanced approach of the PTO objective be thrown out of balance by an unwarranted perception of what is in the public’s best interest. This could be the result if, as is implied in FTC Recommendation 10, the public interest is perceived as involving “the incorporation of economic insights” into PTO decision making. For reasons fully explicated in response to Recommendation 10, AIPLA is strongly opposed to this view. For the same reasons, AIPLA opposes any interpretation of the PTO’s objective, to forge “a balance between the public's interest in intellectual property and each customer’s interest in his/her patent and trademark,” which implicates consideration of economic insights into PTO decision making.

Recommendation 6:

“Consider Possible Harm to Competition – Along with Other Possible Benefits and Costs – Before Extending the Scope of Patentable Subject Matter.”

“Section 101 of the Patent Act states, ‘Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent.’ Despite this broad mandate, courts have long held certain types of inventions unpatentable. Traditional common law exceptions include phenomena of nature, abstract intellectual concepts, mental steps, mathematical algorithms with no substantial practical application, printed matter, and, for many years, business methods.

“Over the past twenty-five years, however, the scope of patentable subject matter has expanded significantly. For example, the Supreme Court, through two landmark decisions in 1980, held that both man-made, living organisms and computer

software constitute patentable subject matter pursuant to Section 101. In 1999, the Federal Circuit ruled that business methods can be patented. Some Hearings participants claimed that patents on computer software and business methods are not necessary to spur the invention, commercial development, or public disclosure of software or business methods. Others disagreed. Some Hearings participants contended that software and business method patents can raise significant competitive concerns and deter innovation, especially because so much of the innovation in those fields builds incrementally on preceding work. This may raise the potential for thickets of patents to hinder, rather than accelerate, innovation and commercial development.

“The constitutional intention that patents ‘promote the Progress of Science and useful Arts’ should be taken into account in interpreting the scope of patentable subject matter under Section 101. Decisionmakers should ask whether granting patents on certain subject matter in fact will promote such progress or instead will hinder competition that can effectively spur innovation. Such consideration is consistent with the historical interpretation of patentable subject matter, which implicitly recognizes that granting patent protection to certain things, such as phenomena of nature and abstract intellectual concepts, would not advance the progress of science and the useful arts. For future issues, it will be highly desirable to consider possible harms to competition that spurs innovation – as well as other possible benefits and costs – before extending the scope of patent subject matter.”

AIPLA Response:

The FTC Report begins from the premise that the Constitutional authorization of Congress to promulgate intellectual property laws is broad: “to promote the progress of science and useful arts.” The Report further notes that Congress has broadly affected this mandate in the current Patent Law. Specifically, patents may be granted for any machine, manufacture, composition of matter, or process that meets the remaining statutory criteria of patentability, namely novelty, obviousness, and the requirements for the disclosure itself.

The FTC correctly notes that prior judicial decisions have narrowed that scope, substantially in some instances. The FTC correctly points out that, in spite of the broad statutory mandate in the Patent Act, district and appeals courts have in a number of prior decisions restricted the scope of statutory subject matter to less than the full scope of patentable subject matter authorized by the Congress.

AIPLA agrees with the FTC’s observation that “traditional common law exceptions include phenomena of nature, abstract intellectual concepts, mental steps, mathematical algorithms with no substantial practical application, printed matter, and, for many years, business methods.” In addition, these judicially created restrictions on the scope of patentable subject matter also previously included software, business methods, and man-made or modified living organisms.

Some of those judicially imposed restrictions have been relaxed in recent years, in effect broadening the scope of patentable subject matter relative to what it had been under these restrictions. The Report goes on to note that some of these decisions eliminating prior judicial restrictions, and in particular the restriction on business method patents, have caused substantial problems for not only the PTO and the courts, but also for competitors. The FTC suggests that awarding patents for business methods may not have been necessary for the particular inventions to emerge in roughly the same time frame. Yet, the FTC notes that it has been particularly difficult to locate relevant prior art from the time before patents were allowed for business methods. Certain of these recent judicial decisions eliminating past judicial restraints were criticized by witnesses at the FTC's hearings last year. The FTC, therefore, recommends that the PTO and the Courts consider possible harm to competition before extending the scope of patentable subject matter in the future.

Although AIPLA agrees with the FTC's observations regarding the scope of both the Constitutional mandate and Congressional policy decisions regarding the scope of patentable subject matter under the current patent law, AIPLA respectfully disagrees with the FTC's reasoning, with its assessment of the existence and nature of the problem created by these recent judicial decisions, and with its recommendation.

AIPLA respectfully submits that there are three discrete problems with the FTC's views and recommendation in this regard:

- (1) the FTC's focus on the recent decisions reversing some of these restrictions, instead of on the propriety of the earlier decisions imposing those restrictions, is inappropriate;
- (2) the decisions reversing these restrictions were based upon statutory authority and were not policy decisions within the courts' discretion, and as such, left little room for injecting the possible harms, benefits, and costs factors that the FTC recommends for the future; and
- (3) it is unclear how the FTC proposes to implement such policy considerations, leaving the issue open-ended.

The patent laws already embody ample statutory criteria effecting Congressional policies regarding the scope of patentable subject matter. AIPLA respectfully submits that the FTC's efforts would be more productively focused on improving consistency of application of these existing statutory criteria, rather than implementing additional policy concerns.

First, the FTC fails to examine the fundamental question whether the prior decisions, which created these prior judicial restrictions on the scope of patentable subject matter, were valid or authorized in the first instance. The FTC does not appear to be taking the position that the courts have improperly extended the scope of patentable subject matter beyond the statutory bounds set by Congress. Rather, the

Report appears to agree that in each of the examples cited, the effective “expansion” is expressly within the original statutory scope of patentable subject matter, as construed by the judiciary over the nearly three decades.

The FTC cites with apparent approval the Supreme Court’s statement in the *Chakrabarty* case that Congress, in the legislative history of the current patent law, expressly stated that “anything under the sun made by man” is patentable. In spite of that foundation, the FTC never questions the propriety of the prior judicial decisions that eroded that statutory subject matter and resulted in the “traditional common law exceptions [that] include phenomena of nature, abstract intellectual concepts, mental steps, mathematical algorithms with no substantial practical application, printed matter, and, for many years, business methods” being unpatentable subject matter.

Yet, in making its recommendation that courts expand patentable subject matter only in certain instances where informed by economic policy, the FTC appears to be endorsing the restrictions of the past. The FTC appears to be asking that the courts reverse those restrictions only where those restrictions fail to that serve economic policy goals, regardless whether or not those restrictions have any legitimate statutory or other legal basis in the first instance.

Further, if an on-going cost-benefit policy debate is necessary for statutory subject matter and new technical areas, why focus only on economic policy and competition that spurs innovation? Other policy considerations are also relevant, such as fairness, evening the market playing field, and enhancing the potential for creating new markets.

AIPLA respectfully submits that the statute already provides concise but ample guidance. In each of the instances cited by the FTC, the court reversed a prior judicial restriction based upon the holding that the restriction was not in accordance with the statutory criteria of patentability. Although the decisions may, as a practical matter, have effectively expanded the judicially limited scope of patentable subject matter, the courts addressed the statutory language of the 1952 Patent Act, as they understood Congress intended it. The courts’ retreat from their earlier, perceived restrictions on the scope of statutory subject matter was compelled in each instance by the language of the statute itself.

Second, AIPLA asserts that the statute does not authorize or recommend, and thus leaves no room for, economic policy considerations by the courts. The FTC notes that expansion of the scope of patentable subject matter may not have been necessary to induce the disclosure of these inventions, and questions whether or not the public has benefited adequately from the perceived expansion. AIPLA advises against assuming that these judicial restrictions were correct and using economic policy considerations to decide whether they should be reversed. Instead, AIPLA submits that the proper framework for debate over harms, benefits, and costs to

“innovation and commercial development” is in Congress during consideration and passage of a statute. Here, the policy decisions have already been made by Congress.

The FTC does not appear to question these facts directly but, rather, appears to seek to preserve potentially unjustifiable restrictions where they may serve other economic policy goals. Specifically, the FTC questions whether or not the “extensions” in two specific fields, namely, software and business methods, were necessary to spur innovation “because so much of innovation in those fields builds incrementally on preceding work.”

AIPLA respectfully submits that all innovation builds on preceding work. No such analysis was conducted by the FTC about other perceived “extensions,” such as patents for biological inventions, based on the *Chakrabarty* decision. The FTC focuses only on certain of these “extensions” effected by the Federal Circuit. In so doing, the FTC overlooks these other “extensions,” apparently based upon the belief that such subject matter does not similarly offend these economic principles. The FTC’s choice of subject matter — software and business methods and not genetic inventions — may reflect more the FTC’s own policy decisions rather than the statutory criteria.

Third, virtually every patentable invention may raise the question whether or not the rewards of the patent system and concomitant costs to society were necessary to induce the disclosure. This 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. Virtually every invention could be questioned to assess whether or not the inventor would have disclosed it, absent the rewards offered under the patent laws.

Yet, the Patent Code already incorporates such considerations on a macroeconomic level. Congress chose not to distinguish between specific categories of inventions beyond machines, manufactured articles, processes, and compositions of matter. More importantly, Congress chose not to engage in a microeconomic analysis on a case-by-case basis but, rather, to sanction broad categories of patentable subject matter. To inject these economic considerations on a microeconomic level in the context of particular inventions or specific sub-categories that appear nowhere in the statute, invites inconsistent and arbitrary decision-making, threatens to undermine the policy decisions that Congress has already made, and injects an undesirable degree of uncertainty. Although the FTC feels comfortable with undertaking this type of economic analysis, AIPLA respectfully submits that the courts and PTO should not be asked to do so.

The FTC notes with approval the ascendancy of economic thought, guided by the Chicago School of Economics, in the development of antitrust policy over the past few decades. Such principles presumably are cited as providing the degree of refinement necessary to implement this policy inquiry.

Although AIPLA agrees that these influences have in many instances improved substantially antitrust decision-making, AIPLA seriously questions whether comparable benefits could be derived from injecting the same economic principles in decisions regarding whether or not to issue individual patents, or even to allow categories of patentable subject matter. In any event, Congress has already made its decision on these issues, leaving no flexibility in that analysis for considerations of the type urged by the FTC.

Whereas the rule of reason evolved to meet a specific need in the Sherman Act that was deliberately left unmet by Congress, no such gap exists in the patent law. Section 1, 15 U.S.C. § 1, is vague, and the Rule of Reason evolved to fill that gap. In the patent laws, however, Congress expressly provided specific statutory criteria to guide analysis: utility, novelty, non-obviousness, and written description. 35 U.S.C. §§ 101, 102, 103, 112.

AIPLA submits that making these assessments on a case-by-case, or even category-by-category basis, creates at least three additional problems.

First, neither the FTC, nor the PTO, nor the courts have the statutory authority to do so. Congress has already made the policy decision that “anything under the sun made by man” is patentable subject matter. Within that scope, the courts should not establish additional restrictions nor should they for economic policy reasons perpetuate judicially created, common law restrictions that have no statutory basis.

Second, AIPLA questions whether such an inquiry can be implemented effectively. The FTC’s proposal is vague in this regard and provides no standards or guidelines for implementation. Nor does it explain how such analysis is compatible with the statutory criteria.

Third, and perhaps most important, such a policy inquiry would inject substantial uncertainty into patent decision making. Patentees and businesses who use technology seek certainty and predictability from the patent system. Particularly at a time when the system is wrestling with substantial uncertainty over such fundamental issues as claim construction and the scope of equivalents, the quality of patent decision making would not be improved by introducing additional subjective and undefined standards, without any statutory basis and requiring new or additional skill sets or expertise. It would instead inject an unacceptable degree of uncertainty into the system.

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 a standard: “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.”

Instead of injecting additional criteria, AIPLA suggests that the PTO and courts pursue improvement and enforcement of the existing statutory criteria of patentability, namely utility, novelty, obviousness, and the statutory requirements for the disclosure itself, 35 U.S.C. §§ 101, 102, 103, and 112, in order to effect the full scope of Congress's mandate that all man-made machines, manufactured articles, processes, and compositions of matter are appropriate subject matter. These are concrete, ascertainable objectives that will clearly improve the quality and predictability of patent decision-making.

Recommendation 7:

“Enact Legislation to Require Publication of All Patent Applications 18 Months After Filing.”

“Until relatively recently, patents were published only when issued; patent applications were not published. During the time that would pass between the filing of a patent application and the issuance of a patent, an applicant’s competitor could have invested substantially in designing and developing a product and bringing it to market, only to learn, once the patent finally issued, that it was infringing a rival’s patent and owed significant royalties. This scenario disrupts business planning, and can reduce incentives to innovate and discourage competition.

“A relative new statute requires that most patent applications – all except those filed only in the United States – be published 18 months after filing. Patent applicants are protected from copying of their inventions by statutory royalty rights, if the patent ultimately issues. This new procedure appears to have increased business certainty and promoted rational planning, as well as reduced the problem of unanticipated “submarine patents” used to hold up competitors for unanticipated royalties. For these reasons, Hearings participants advocated expanding the 18-month publication requirement to include patents filed only domestically, because such patents may well have competitive significance. Protection from copying similar to that already available for other published applications should be extended to those filing domestic patent applications as well, and any necessary protections for independent inventors also should be considered in terms of their likely costs and benefits.”

AIPLA Response:

AIPLA believes 18-month publication of patent applications represents an appropriate balance between the interests of the applicant and the public. With publication, provisional statutory rights for damages for infringement from publication to patent grant may be granted to the applicant, and those working in the field are given notice of the patent protection being sought by others. Those working

in the field can avoid infringement and conducting research in an area that may be precluded. It also reduces the opportunity for patent applications to lie quietly in the USPTO and issue years later after an industry has developed relative to a technology.

When the American Inventors Protection Act was passed in 1999, it allowed persons to withdraw their applications from publication if they were going to be filed in the United States only without seeking corresponding foreign protection. AIPLA supports publication of all patent applications. Publication reduces uncertainty about pending patent rights, results in earlier dissemination of technology to the public, and eliminates the administrative burden on the USPTO of determining which applications to publish. Redaction in applications runs counter to this policy and should be eliminated as an option for published applications.

However, 18-month publication should not extinguish the applicant's ability to abandon the application (terminate the pending status of the application) before publication. In such a case, no publication should result.

Recommendation 8:

“Enact Legislation to Create Intervening or Prior User Rights to Protect Parties from Infringement Allegations That Rely on Certain Patent Claims First Introduced in a Continuing or Other Similar Application.”

“After publication of its patent application, an applicant may continue to amend its claims. Through this claim amendment process, a patent that states broader claims than those published at 18 months can still emerge. If the applicant uses procedures such as continuing applications to extend the period of patent prosecution, the potential for anticompetitive hold up increases. Indeed, several panelists asserted that some applicants keep continuing applications pending for extended periods, monitor developments in the relevant market, and then modify their claims to ensnare competitors' products after those competitors have sunk significant costs in their products. Patent reform efforts have long focused on how to remedy opportunistic broadening of claims to capture competitors' products.

“Legitimate reasons exist to amend claims and use continuing applications. Any proposed remedy for the opportunistic broadening of claims should also protect such legitimate uses. Creating intervening or prior use rights would most directly achieve this balance; it would cure potential competitive problems without interfering with legitimate needs for continuations. Such rights should shelter inventors and users that infringe a patent only because of claim amendments following a continuation or other similar application, provided that the sheltered products or processes are developed or used (or the subject of substantial preparation for use) before the amended claims are published.”

AIPLA Response:

AIPLA supports the FTC's recommendation to the extent it would provide a prior user right for products or processes used (or the subject of substantial preparation for use) before the effective filing date of the individual application.

The FTC Report also proposes that a prior use or intervening right be established that would allow others to have a defense akin to a prior use for claims that appear later in the chain of a patent application, such as a continuation or other type of continuing application.

If all patent applications are published within 18 months, the likelihood of rights appearing in subsequent applications broader in scope, which would surprise follow-on inventors or developers, would be reduced but not eliminated. The possible extent of a patentee's rights are confined by the disclosure in the patent application and the prior art. Claims cannot be added which are not supported by the disclosure or which encompass the prior art. Thus, publication of applications at 18 months provides competitors with notice of the extent of possible rights, even if the published claims are narrower than those to which the patentee may be entitled. Legitimate reasons exist for presenting narrower claims with a patent application and presenting broader claims in a continuation or similar application.

While AIPLA supports existing law concerning intervening rights and prosecution laches, the difficulty of providing an intervening right that would allow one to obtain a right to continue for the subject matter not covered by the claims of the published application could cause substantial unintended consequences. Thus, AIPLA believes that the critical date for the prior use is the effective filing date, not a later date.

The existing prior user right is set forth in 35 U.S.C. § 273 (attached). It has certain limitations relating to subject matter as well as other aspects that have reduced the effectiveness of the prior user right. Specific issues are the scope of coverage, which is limited to "methods of doing business," the requirement that the prior use be reduced to practice one year prior to the effective filing date of the involved patent application and the failure to include "substantial preparation" as an act of prior use. AIPLA supports amending 35 U.S.C. § 273 to remove the limitation to processes, to delete the requirement that the prior use be reduced to practice one year prior to the effective filing date, and to include "substantial preparation" as an act of prior use.

Recommendation No. 9

“Enact Legislation to Require, as a Predicate for Liability for Willful Infringement, Either Actual, Written Notice of Infringement from the Patentee, or Deliberate Copying of the Patentee’s Invention, Knowing it to be Patented.”

“A court may award up to three times the amount of damages for a defendant’s willful infringement of a patent – that is, the defendant knew about and infringed the patent without a reasonable basis for doing so. Some Hearings participants explained that they do not read their competitors’ patents out of concern for such potential treble damage liability. Failure to read competitors’ patents can jeopardize plans for a noninfringing business or research strategy, encourage wasteful duplication of effort, delay follow-on innovation that could derive from patent disclosures, and discourage the development of competition.

“It is troubling that some businesses refrain from reading their competitors’ patents because they fear the imposition of treble damages for willful infringement. Nonetheless, infringers must not be allowed to profit from knowingly and deliberately using another’s patented invention due to a low likelihood that the patent holder can afford to bring suit or obtain substantial damages. The FTC’s recommendation would permit firms to read patents for their disclosure value and to survey the patent landscape to assess potential infringement issues, yet retain a viable willfulness doctrine that protects both wronged patentees and competition.”

AIPLA Response:

AIPLA strongly supports Recommendation 9 in the FTC’s report to enact legislation to require, as a predicate for liability for willful infringement, either actual written notice of infringement from the patentee, or deliberate copying of the patentee’s invention, knowing it to be patented.

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 “To promote the progress of ... useful arts ...” 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 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 constitutes 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 FTC’s Recommendation 9 is made to determine whether they are consonant with each other. As set forth below, the FTC’s Recommendation 9 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.

Comparison of the FTC and AIPLA positions necessitates consideration of four fundamental precepts of existing Federal Circuit jurisprudence:

burden of proof – a patentee must show willful infringement by clear and convincing evidence that the infringer did not have a reasonable basis for believing it had a right to engage in the infringing acts See, *Electro Med. Sys., S.A. v. Cooper Life Sciences*, 34 F. 3d 1048, 1056 (Fed. Cir. 1994)

the fact finder – willfulness is a question of fact triable to a jury. See, e.g., *National Presto Industries, Inc. v. West Bend Co.*, 76 F.3d 1185, 1192-93 (Fed. Cir. 1996)

totality of the circumstances test for willfulness – the fact finder considers the “totality of the circumstances” to determine “whether a prudent person would have had sound reason to believe that the patent was not infringed or was invalid or unenforceable, and would be so held if litigated.” *SRI Int’l, Inc. v. Advanced Technological Lab., Inc.*, 127 F. 3d 1462, 1468-69 (Fed. Cir. 1997). In this regard, the Federal Circuit has articulated at least seven non-exclusive factors that can be considered in applying the test. The majority of these factors (e.g., copying, design around and formation of good faith based on a non-liability opinion) are demonstrably factual, but a few are palpably legal (e.g., the closeness of the legal and factual questions, and whether infringement is solely based on the Doctrine of Equivalents). In that sense, it has analytical similarity to an obviousness inquiry, although the ultimate issue of obviousness is one of law (yet, often submitted to a jury in special interrogatories with the underlying factors submitted in the jury instructions).

duty of care and the adverse inference rule – Once a potential infringer has actual notice of a pertinent patent, it has an affirmative duty to investigate the scope of the patent and form a good faith belief that the patent is invalid, non-infringed or unenforceable. *Botts v. Four Star Corp.*, 807 F. 2d 1567, 1572 (Fed. Cir. 1986). Moreover, the existence of a timely obtained and reasonable relied on competent non-liability opinion is often an important factor in satisfying the duty of care and thereby avoiding willful infringement. Conversely, assuming that the duty of care is triggered, the failure to obtain a non-liability opinion or the refusal to waive the attorney-client privilege/ work product immunity and produce the opinion(s) permits the fact finder to draw an adverse inference against the accused infringer. In light of the pending *Knorr-Bremse* en banc case, the adverse inference rule may be overturned. Another interesting question in the *Knorr-Bremse* case is whether the Federal Circuit will adopt a *per se* rule that a “substantial defense” to infringement defeats liability for willful infringement even if no legal advice has been secured.

Preliminarily, if *Knorr-Bremse* adopts the aforementioned *per se* rule, and particularly if its adoption entails eviscerating or abolishing the duty of care as relates to the need to get non-liability opinions, then the FTC’s Recommendation 9 may accomplish its purpose without the need for legislative action. Correspondingly, AIPLA’s proposed amendment would also be substantially mooted except for the issue of whether the Court or the jury is to decide willfulness.

AIPLA’s proposed amendment (1) ostensibly⁵⁷ makes willfulness strictly an issue for the Court to decide, (2) predicates willful infringement liability

⁵⁷ 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

on the infringer's failure to satisfy a duty of care, (3) delineates exactly when the duty of care arises, (4) identifies one way to prove failure to satisfy the due care standard ("deliberate copying"), but specifies that "reasonable reliance on advice of counsel, offered into evidence, shall establish due care," and (5) abolishes 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 FTC's recommendation does not address whether the issue of willfulness should be solely for the court to decide, the Resolution adopted by AIPLA would make willfulness an issue for the court and, would change existing Federal Circuit jurisprudence. 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. Of course, Federal Circuit jurisprudence has effectively made willfulness a mixed issue of law and fact, by inappropriately conflating 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 FTC recommendation 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

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, the AIPLA supports revising the first two sentences of 35 U.S.C. § 284, 2nd 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.

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. Ultimately, the efficacy of using the "duty of care" language in AIPLA's proposed amendment may well depend on the outcome of the Knorr-Bremse case. Presumably, if the Court does change its existing precedent, it will only eliminate the duty of care as it relates to the need to seek and obtain a competent and timely non-liability opinion, rather than abolish the general duty to form a good faith belief that conduct is lawful under the totality of the circumstances.

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

Recommendation 10:

"Expand Consideration of Economic Learning and Competition Policy Concerns in Patent Law Decisionmaking."

"The Supreme court has made clear in several decisions that there is room for policy-oriented interpretation of the patent laws. Indeed, to find the proper balance between patent and competition law, such policy-oriented interpretations are essential. Over the patent twenty-five years, the incorporation of economic thinking into antitrust has provided significant insights that have substantially improved the development of antitrust law and competition policy. The Federal Circuit and the PTO may also benefit from much greater consideration and incorporation of economic insights in their decisionmaking."

AIPLA Response:

AIPLA questions the FTC recommendation that the Federal Circuit and PTO adopt and incorporate policy-oriented principles and economic thinking in their decision-making.

This recommendation is based upon the FTC's experience "[t]hat antitrust law develops largely through case law[, which] gives it flexibility to incorporate the goals of patent law." Yet, this parallel is seriously strained when the respective frameworks of the two sets of laws are considered in context. The antitrust laws contain relatively few *per se* rules. *Per se* rules are generally disfavored, except in situations in which they have been shown over time to be valid predictors of competitive harm. Instead,

the basic framework for application and interpretation of the antitrust laws has been the Rule of Reason, based upon an intensive factual and policy assessment of competitive harm.

It is believed that attempts to draw parallels between antitrust law and patent law are inapposite. Although the Supreme Court adopted the Rule of Reason to resolve the uncertainty of the Sherman Act, it took an entirely different approach to obviousness. It set out several specific factors: level of ordinary skill, scope and content of the prior art, and differences between the art and the invention as a whole, in view of certain specific “secondary considerations.”

The criteria for utility, novelty, and disclosure are each *per se* standards and no factors are evaluated for their reasonableness. Although flexibility has enhanced the administration of the antitrust laws, flexibility for its own sake is not a legitimate goal. Rather, applying a comparable level of flexibility in the patent context would simply introduce uncertainty and unpredictability into a system that is striving for greater certainty and predictability.

Ultimately, AIPLA agrees with the FTC that “[u]ncertainty interferes with efficient business activity, and the value of uniformity in the application of patent law is clear.” Certain of the means proposed by the FTC — strengthening the implementation and enforcement of the existing statutory criteria of patentability and increased communications between patent institutions and antitrust agencies — may prove to be valid and useful exercises. Others, however, such as injecting economic theory into the interpretation and application of clearly defined statutory criteria, will simply result in greater uncertainty.

AIPLA believes that Congress, and not the PTO or the courts, is the proper authority to consider economic theory and competition policy-oriented principles. For the reasons discussed below, the PTO and the courts should not inject these theories and principles into their decision-making.

Consumer welfare is a goal of both the antitrust and patent laws. Enhanced competition is presumed to benefit consumers. Similarly, broadening the scope of public disclosure under the patent laws, thereby enhancing the competition among ideas, is presumed to enhance consumer welfare.

However, consumer welfare is fostered in starkly different ways in the two statutory schemes. Under the antitrust laws, challenged practices are evaluated directly for their impact on competition and their impact on consumers. Under the patent laws, in contrast, every patent has the potential to increase prices and constrain supply of the patented technology in the short term, potentially harming consumers. The patent system enhances consumer welfare in different ways, by generating additional new technologies, products, and services, and creating new markets or expanding or enhancing old markets.

The tools of the antitrust laws that may enhance price competition are not aligned with a patent system, in which price competition on the patented invention is decidedly not the goal. Rather, the patentee is permitted to charge whatever the market will bear, consistent with the remaining restrictions of the antitrust laws. Moreover, patents rarely define economic markets. The public derives several discrete benefits in return for allowing the patentee to exploit the invention exclusively: after expiration, all members of the public are free to use the invention and competitors may copy the invention, driving the price of the technology down to commodity levels, if they have not done so already; and during the life of the patent, others are free to employ the disclosure of the innovation to develop competing, non-infringing inventions.

Fostering and maintaining effective price competition for the patented invention are simply not goals of the patent laws. Instead, the goal is to induce the flow of new and additional innovations. In return, the consumer bears the higher prices the patentee may be able to charge in the short term, as a spur to additional disclosure and additional competition through further innovation and disclosure. Price competition necessarily reduces the potential reward to the patentee and the incentive to disclose additional innovations. Thus, the tools that are effective at maintaining price competition are irrelevant to, and may affirmatively harm, the policies underlying the patent laws.

The FTC notes a number of areas where economic policy has come to accept various practices that were once thought unacceptable with respect to patents: grant backs; addressing the free-rider effect; compulsory licensing; combining complimentary means of production; and patent pools, among others.

AIPLA agrees that these are all effective and worthwhile developments. AIPLA recognizes further that economic policy played an essential role in implementing a more reasonable approach to each of them. These salutary developments in antitrust law flow from the Rule of Reason. Nevertheless, these developments do not command a *quid pro quo* that the patent laws would reap comparable benefits from economic theory. Nor do these developments necessarily mean that comparable gains could be realized in the vastly different framework of the patent laws.

AIPLA recognizes as valid the FTC's criticism that "patent institutions [presumably the PTO and courts], however, have not always brought this goal [of policy-oriented interpretation of the patent laws] to the forefront in interpreting and applying the underlying policies." The FTC does not appear to be stating that the current statutory criteria of patentability are insufficient, but rather that their implementation and enforcement by the PTO and courts have, at times, lagged. AIPLA respectfully submits that the statutory standards have proved effective over

two hundred years of administration of the patent laws. The FTC appears to agree, in that its overall conclusion is that the patent system, as a whole, functions well.

To the extent any deficiencies exist, they reside in the proper enforcement and implementation of the existing statutory criteria. The solution, therefore, resides in the more effective implementation and enforcement of those criteria — not in injecting additional, undefined criteria to the mix.

Nonetheless, the FTC takes the position that “sharper focus on policy choices ... would yield substantial public benefit.” It is unclear from the FTC’s Report what benefits the FTC perceives, how great the perceived benefits are, and how these measures would be implemented. The FTC concedes that the patent system, overall, already delivers substantial public benefits: enhanced disclosure of new ideas; enhanced innovation; and the substantial leverage that may flow from the disclosure requirements that typically require the patentee to disclose the invention in greater detail than the scope of the claims.

If the sought-after “public benefit” is to distribute to the public all or some portion of a perceived “windfall” a patentee receives from exploiting a relevant market for a patented invention, or to drive down prices by introducing price competition on the patented subject matter, AIPLA opposes such measures. The potentially substantial rewards offered by the exclusive use of an invention are perhaps the most powerful motivator for further innovation and disclosure. In the words of President Lincoln (a patentee himself), the rewards offered by the system “add the fuel of interest to the fire of genius.” The competition that the Founders and Congress chose to foster through the patent system is competition for new ideas, not price competition.

Shifting to the existing criteria of patentability, the FTC notes that errors in the determination of obviousness are a substantial problem. Most inventions that are found to be unpatentable do not precisely replicate the prior art. Obviousness is the primary engine by which the patent system avoids granting patents on inventions that do not contribute new knowledge and ensures a flow of new disclosures that add substantively to the public domain. Granting patents on obvious improvements allows private gain at the public expense, while contributing no new disclosure to the public.

On the other hand, overly aggressive application of the statutory standards of patentability frustrates and stifles invention and deprives the public of potentially valuable patent disclosures. AIPLA submits that the patent system in particular and economy in general benefit directly from fair, consistent, and uniform application of the statutory standards over time.

The FTC suggests that the PTO adopt a role as a policy-setting agency, contending that its interpretative role is “insufficient.” AIPLA strongly opposes this

recommendation for two reasons. First, Assistant Commissioner Kunin is correct that the statutory mission of the PTO is fundamentally different than that of the Federal Trade Commission. The FTC is vested with the responsibility to effect and enforce antitrust policy based on economic principles, through a Rule of Reason analysis. The PTO, in contrast, interprets and applies specific, concise, statutory criteria of patentability, more akin to a *per se* analysis. AIPLA submits that there is no role in the PTO's patentability analyses for policy considerations of the type the FTC would have it inject.

Second, the PTO may not possess the skills, resources, and experience needed to implement such an analysis. In addition, it lacks the track record to do so. With very limited exceptions, Congress is the body most apt to make policy-oriented changes to the Patent Act.

The FTC also implies that the Federal Circuit appears to have betrayed Congress's trust that "the Federal Circuit would strictly construe its own jurisdiction and that its jurisdiction would not be easily manipulated." To support its assertion, the FTC cites: (1) the Supreme Court's *Holmes Group v. Vornado* decision; (2) *dicta* in Federal Circuit opinions regarding the scope of its jurisdiction in *Intergraph v. Intel* and *CSU v. Xerox*; and (3) the Federal Circuit's holding regarding choice of law in *Nobelpharma v. Implant Innovations*. Certainly, the Federal Circuit has wrestled with these difficult questions, as do all courts. The Supreme Court, however, has provided and will continue to provide clarification, when needed.

In conclusion, the statutory requirements for patentability are based upon mandatory authority of the statute itself, regulations, and prior court decisions, not economic journals and law review articles. Whereas, these sources may inform economic decision theory based upon a Rule of Reason analysis, they are irrelevant to the statutory criteria of patentability.

35 U.S.C. 273

Defense to infringement based on earlier inventor

(a) *Definitions.*—For purposes of this section—

(1) the terms “commercially used” and “commercial use” mean use of a method in the United States, so long as such use is in connection with an internal commercial use or an actual arm’s-length sale or other arm’s-length commercial transfer of a useful end result, whether or not the subject matter at issue is accessible to or otherwise known to the public, except that the subject matter for which commercial marketing or use is subject to a premarketing regulatory review period during which the safety or efficacy of the subject matter is established, including any period specified in section 156 (g), shall be deemed “commercially used” and in “commercial use” during such regulatory review period;

(2) in the case of activities performed by a nonprofit research laboratory, or non profit entity such as a university, research center, or hospital, a use for which the public is the intended beneficiary shall be considered to be a use described in paragraph (1), except that the use—

(A) may be asserted as a defense under this section only for continued use by and in the laboratory or nonprofit entity; and

(B) may not be asserted as a defense with respect to any subsequent commercialization or use outside such laboratory or non-profit entity;

(3) the term “method” means a method of doing or conducting business; and

(4) the “effective filing date” of a patent is the earlier of the actual filing date of the application for the patent or the filing date of any earlier United States, foreign, or international application to which the subject matter at issue is entitled under section 119, 120, or 365 of this title.

(b) *Defense to infringement.*—

(1) *In general.*— It shall be a defense to an action for infringement under section 271 of this title with respect to any subject matter that would otherwise infringe one or more claims for a method in the patent being asserted against a person, if such person had, acting in good faith, actually reduced the subject matter to practice at least 1 year before the effective filing date of such patent, and commercially used the subject matter before the effective filing date of such patent.

(2) *Exhaustion of right.*—The sale or other disposition of a useful end product produced by a patented method, by a person entitled to assert a defense under this section with respect to that useful end result shall exhaust the patent owner’s rights

under the patent to the extent such rights would have been exhausted had such sale or other disposition been made by the patent owner.

(3) *Limitations and qualifications of defense.*—The defense to infringement under this section is subject to the following:

(A) *Patent.*—A person may not assert the defense under this section unless the invention for which the defense is asserted is for a method.

(B) *Derivation.*—A person may not assert the defense under this section if the subject matter on which the defense is based was derived from the patentee or persons in privity with the patentee.

(C) *Not a general license.*—The defense asserted by a person under this section is not a general license under all claims of the patent at issue, but extends only to the specific subject matter claimed in the patent with respect to which the person can assert a defense under this chapter, except that the defense shall also extend to variations in the quantity or volume of use of the claimed subject matter, and to improvements in the claimed subject matter that do not infringe additional specifically claimed subject matter of the patent.

(4) *Burden of proof.*—A person asserting the defense under this section shall have the burden of establishing the defense by clear and convincing evidence.

(5) *Abandonment of use.*—A person who has abandoned commercial use of subject matter may not rely on activities performed before the date of such abandonment in establishing a defense under this section with respect to actions taken after the date of such abandonment.

(6) *Personal defense.*—The defense under this section may be asserted only by the person who performed the acts necessary to establish the defense and, except for any transfer to the patent owner, the right to assert the defense shall not be licensed or assigned or transferred to another person except as an ancillary and subordinate part of a good faith assignment or transfer for other reasons of the entire enterprise or line of business to which the defense relates.

(7) *Limitation on sites.*—A defense under this section, when acquired as part of a good faith assignment or transfer of an entire enterprise or line of business to which the defense relates, may only be asserted for uses at sites where the subject matter that would otherwise infringe one or more of the claims is in use before the later of the effective filing date of the patent or the date of the assignment or transfer of such enterprise or line of business.

(8) *Unsuccessful assertion of defense.*— If the defense under this section is pleaded by a person who is found to infringe the patent and who subsequently fails to demonstrate a reasonable basis for asserting the defense, the court shall find the case exceptional for the purpose of awarding attorney fees under section 285 of this title.

(8) *Invalidity*.—A patent shall not be deemed to be invalid under section 102 or 103 of this title solely because a defense is raised or established under this section.