

# **AIPLA**

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AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION

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## **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

**AIPLA Response**  
**to the**  
**October 2003 Federal Trade Commission Report:**  
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**Table of Contents**

Acknowledgements.....	i
FTC Recommendation #1.....	1
FTC Recommendation #2.....	5
FTC Recommendation #3.....	17
FTC Recommendation #4.....	22
FTC Recommendation #5.....	24
FTC Recommendation #6.....	27
FTC Recommendation #7.....	33
FTC Recommendation #8.....	34
FTC Recommendation #9.....	36
FTC Recommendation #10.....	40

## **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.<sup>1</sup>
2. The burden of production and the burden of persuasion are on the party asserting invalidity.<sup>2</sup>
3. The burden of persuasion never increases, decreases, or shifts to the patentee regardless of what evidence is introduced at trial.<sup>3</sup>
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.<sup>4</sup>
5. Every fact used to overcome the presumption must be proven by clear and convincing evidence.<sup>5</sup>

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

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

<sup>3</sup> *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).

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

<sup>5</sup> *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.<sup>6</sup> 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."<sup>7</sup>

In *Radio Corporation of America v. Radio Engineering Laboratories., Inc.*<sup>8</sup> (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.

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[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.<sup>9</sup>

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.<sup>10</sup> An early Federal Circuit decision correctly recognized that "undoubtedly certain facts in patent litigation must be proved by clear and convincing evidence."<sup>11</sup>

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

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<sup>6</sup> 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).

<sup>7</sup> *Washburn*, 29 F. Cas. at 320.

<sup>8</sup> 293 U.S. 1 (1934).

<sup>9</sup> *Id.* at 8-9.

<sup>10</sup> 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).

<sup>11</sup> *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.<sup>12</sup> The decision maker must start from the position that the patent is valid.<sup>13</sup> It also establishes that the burden is constant, not increased or lessened by what evidence is produced during litigation.<sup>14</sup> It has no evidentiary value.<sup>15</sup>

The statute, created in the 1952 Patent Act, codified the common law presumption of validity and assignment of burden to some extent.<sup>16</sup> One common law justification for the rule was that an issued patent is *prima facie* evidence of inventorship and novelty.<sup>17</sup> 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.<sup>18</sup> 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.<sup>19</sup> This is the heart of the bargain between the patentee and the public.<sup>20</sup>

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<sup>12</sup> *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).

<sup>13</sup> *Stratoflex*, 713 F.2d at 1534.

<sup>14</sup> 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).

<sup>15</sup> *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.”).

<sup>16</sup> *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.”).

<sup>17</sup> *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).

<sup>18</sup> *The Barbed Wire Patent*, 143 U.S. at 292.

<sup>19</sup> *See* 35 U.S.C. § 112 ¶ 1.

<sup>20</sup> *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*<sup>21</sup>, 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.<sup>22</sup>

**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.<sup>23</sup> 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.*<sup>24</sup>, 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.<sup>25</sup>

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

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

<sup>21</sup> 143 U.S. 275 (1892).

<sup>22</sup> *Id.* at 292.

<sup>23</sup> 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).

<sup>24</sup> 261 U.S. 45 (1923).

<sup>25</sup> *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.<sup>26</sup>

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.<sup>27</sup>

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.”<sup>28</sup>

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.<sup>29</sup>

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*.<sup>30</sup> 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

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<sup>26</sup> *The Barbed Wire Patent*, 143 U.S. at 284.

<sup>27</sup> *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).

<sup>28</sup> *The Barbed Wire Patent*, 143 U.S. at 289.

<sup>29</sup> 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.

<sup>30</sup> 612 F.2d 546 (C.C.P.A. 1979).

patent must be clear and convincing to overcome the presumption of validity.”<sup>31</sup> Notably, the court also refused to consider the devices prior art for obviousness.<sup>32</sup> 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*<sup>33</sup> 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.”<sup>34</sup> 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.<sup>35</sup>

**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.<sup>36</sup> Assumed administrative correctness is certainly part of the reason for the clear and convincing standard, but it is not the entire explanation.<sup>37</sup> 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.<sup>38</sup>

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.*<sup>39</sup>, 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

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<sup>31</sup> *Id.* at 550.

<sup>32</sup> *Id.* at 551.

<sup>33</sup> 553 F.2d 69 (Ct. Cl. 1977).

<sup>34</sup> *Id.* at 75.

<sup>35</sup> *Id.* at 75.

<sup>36</sup> 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.”).

<sup>37</sup> 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.

<sup>38</sup> 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).

<sup>39</sup> 93 U.S. 489 (1876).



as *prima facie* evidence of novelty and inventorship.<sup>40</sup> 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.”<sup>41</sup>

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.<sup>42</sup>

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.<sup>43</sup> 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.<sup>44</sup>

### **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 &*

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<sup>40</sup> *Id.* at 498.

<sup>41</sup> *Id.* at 499.

<sup>42</sup> *RCA*, 295 U.S. at 8.

<sup>43</sup> 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.*

<sup>44</sup> *See SSIH*, 718 F.2d at 375.

*Co.*,<sup>45</sup> 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.”<sup>46</sup>

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

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.<sup>48</sup>

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.*”<sup>49</sup> Some district courts have misconstrued the requirement that facts be proved by clear and convincing evidence to include the persuasive force of those facts.<sup>50</sup> 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.<sup>51</sup>

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<sup>45</sup> 722 F.2d 1542 (Fed. Cir. 1983).

<sup>46</sup> *Id.* at 1549.

<sup>47</sup> 718 F.2d 365 (Fed. Cir. 1983).

<sup>48</sup> 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.”).

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

<sup>50</sup> *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).

<sup>51</sup> *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.”<sup>52</sup> 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.”<sup>53</sup> The modern clear and convincing evidence standard is the most consonant with *RCA*.<sup>54</sup>

### **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.<sup>55</sup> 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*.<sup>56</sup> 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

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<sup>52</sup> *RCA*, 293 U.S. at 8-9.

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

<sup>54</sup> 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).

<sup>55</sup> 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.

<sup>56</sup> 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

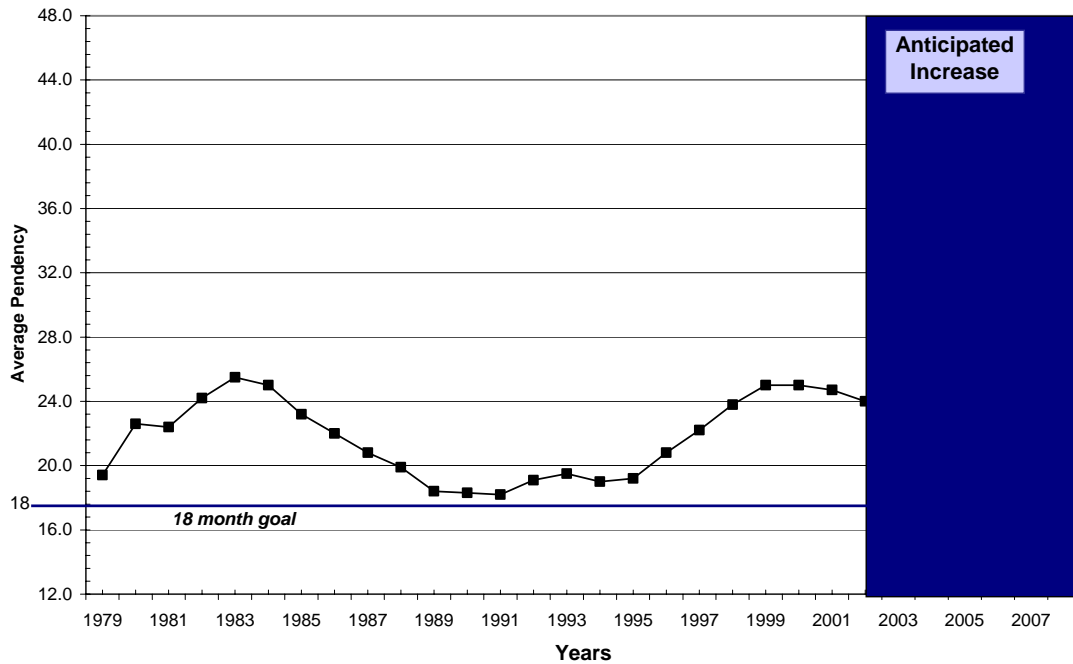
application processing be made promptly available to the USPTO without limitation to provide such services, and Specifically, AIPLA opposes the withholding or diversion of any such revenue to fund any non-USPTO programs.” (July 10, 2000)

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) ostensibly<sup>57</sup> makes willfulness strictly an issue for the Court to decide, (2) predicates willful infringement liability

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<sup>57</sup> The language “the court may consider the willfulness of any infringement” can arguably be construed to permit the Court to consider an advisory jury finding of willfulness in making its determination as to whether to increase damages. Under existing Federal Circuit precedent, the Court can consider the jury’s finding of willfulness in determining whether the

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

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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, 2<sup>nd</sup> paragraph (additions underlined, deletions stricken), as follows:

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

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.