



**RESPONSE TO THE RECOMMENDATIONS OF
THE NATIONAL RESEARCH COUNCIL OF
THE NATIONAL ACADEMIES ON
“A 21ST CENTURY PATENT SYSTEM”**

THE VIEWS EXPRESSED HEREIN ARE ON BEHALF OF THE AMERICAN BAR ASSOCIATION SECTION OF INTELLECTUAL PROPERTY LAW. EXCEPT WHERE NOTED, THEY HAVE NOT BEEN APPROVED BY THE AMERICAN BAR ASSOCIATION’S HOUSE OF DELEGATES OR THE BOARD OF GOVERNORS AND SHOULD NOT BE CONSTRUED AS REPRESENTING THE POLICY OF THE AMERICAN BAR ASSOCIATION.

OVERVIEW AND CALL TO ACTION

Three Recommendations of Overarching Importance to Improving the Patent Law

In its 2004 report on the U.S. patent system (“A Patent System for the 21st Century”), the National Research Council of the National Academies made seven principal recommendations. Since the publication of its report, NRC Recommendations 3, 6, and 7 have garnered particular attention. These recommendations respectively call for enhancing the post-grant review of patents, limiting subjective elements in patent litigation and making harmonizing changes to the patent laws, including the adoption of the first-inventor-to-file principle.

With respect to each of these three topics, the Section finds itself in substantial agreement with the recommendations made by the NRC. Of equal significance, the Section finds itself in substantial agreement with a number of other groups that have now taken public positions on these three NRC recommendations.

If a consensus were to develop on the merits of these recommendations, they could take on an overarching importance. Together they could define a path forward to the enactment into law of a set fundamental improvements to the U.S. patent system.

The Section’s response to the NRC recommendations will begin, therefore, with a discussion of these three recommendations and their collective significance.

First-Inventor-to-File: A Fairer and Simpler Patent System

A singularly important recommendation of the NRC is to seek greater harmonization between U.S. patent laws and those of countries outside the United States. An important thrust of this recommendation is that efforts be made to change and improve the operation of foreign patent systems. The Section supports harmonization efforts aimed at changing foreign patent laws so that they operate with greater effectiveness and fairness – and do so by incorporating existing features found in U.S. patent laws.

The NRC recommends one fundamental change to U.S. patent law as part of overall efforts at greater harmonization. NRC recommends that the United States change its patent law to guarantee the right to patent to the first inventor to file for a patent. Its report contains a cogent rationale for doing so. The American Bar Association, in February 2005, approved policy that supports making this change to the U.S. patent law. Both the NRC and the ABA see

IPL Section Supports Taking Action Now on Three NRC Proposals:

1. Adopt “first-inventor-to-file” system, including a one-year “grace period,” and protections against “self-collision.”
2. Eliminate or limit the “subjective elements” in patent litigation (“best mode,” “inequitable conduct,” and “willful infringement.”)
3. Create a window after a patent issues for an opposition procedure that would permit the correction of any mistake made in granting the patent.

changing to a first-inventor-to-file principle as the heart of creating a fairer and simpler patent system. The ABA has been joined by other leading U.S.-based non-governmental organizations that have reached the same conclusion. The time has come, therefore, for serious efforts to move forward with domestic legislation that would implement the NRC recommendation.

In the context of an international patent harmonization agreement, the Section has given detailed consideration to how such a fundamental change should be introduced into U.S. patent law. In this regard, the Section has identified a series of “best practices” – principles that should be followed in implementing the NRC first-inventor-to-file recommendation. Importantly, the Section’s support for a first-inventor-to-file rule is conditioned on retaining a one-year “grace period” in which pre-filing disclosures made directly or indirectly by the inventor cannot bar the inventor from obtaining a valid patent. The Section, moreover, opposes introduction of features of European patent law, such as “absolute novelty” (*i.e.*, any oral, non-confidential divulcation of an invention qualifies as prior art sufficient to bar its later patenting) and “self-collision” (*i.e.*, an inventor’s own prior-filed, copending patent applications can be cited as prior art against the inventor).

Instead the Section supports first-inventor-to-file legislation that would retain the existing features of U.S. law that provide fairness and balance. Importantly, the Section has endorsed retaining in the U.S. patent laws the requirements that disclosures must be publicly accessible (*i.e.*, reasonably and effectively accessible to persons of ordinary skill in the art) in order to qualify as prior art, protect patent owners against “self-collision,” and recognize the one-year “grace period” with respect to both direct and indirect disclosures by inventors.

Moreover, the Section has identified other important reforms to the U.S. patent laws that would further simplify the law, make patent validity assessments more certain, and eliminate subjective factors in determining patentability that currently complicate the patent laws. In this regard the Section has supported elimination of certain miscellaneous tests for patent validity that are unnecessary once a first-inventor-to-file rule is put into effect. Thus, the so-called “loss of right to patent” and related provisions (*i.e.*, abandonment of the invention, premature foreign patenting, use of the inventor’s personal and non-public knowledge gleaned from others as prior art, and forfeiture of the patent right based upon secret uses and/or secret placement of the invention “on sale”) should be eliminated from U.S. patent law. The use of so-called “secret prior art” (*i.e.*, prior inventions of others, not abandoned, suppressed or concealed) should likewise be eliminated. Finally, the “best mode” requirement should be repealed.

In brief, in carrying forth the NRC recommendations on the introduction of harmonizing changes into U.S. patent law, the Section has identified “best practices” that would allow a complete and accurate assessment of all issues of patent validity to be conducted in most situations solely by referencing publicly accessible information. Thus, the call for harmonizing changes to the U.S. patent law may represent the NRC recommendation of greatest potential benefit for inventors, patent owners, the United States Patent and Trademark Office and members of the public. Introducing a first-inventor-to-file system, done in accordance with the “best practices” supported by the Section in the context of an international patent harmonization agreement, would mean patent validity could be assessed more rapidly, less expensively, with

greater completely, with enhanced certainty, and at much reduced cost compared to the current U.S. patent law.

Limiting “Subjective Elements” In Patent Litigation

A second recommendation of the NRC with profound implications for the patent system is its proposal to eliminate – or at least limit – the so-called “subjective elements” often raised in patent litigation. The NRC report identifies three such elements that it recommends be eliminated and/or limited: the “best mode” requirement, the “inequitable conduct” defense, and the “willful infringement” allegations. The Section supports in principle the NRC recommendation as to each of these three elements

First, as described above, the Section favors outright elimination of the “best mode” requirement in the context of an international patent harmonization agreement. Without interrogating the inventor to learn what he or she contemplated as of the time the patent was sought, it cannot be known if the inventor’s “best mode” was disclosed and a patent is valid. Other major patent systems do not have this requirement. U.S. patent law introduced this requirement only in 1952. The remaining requirements for disclosing a patented invention assure that a complete description of a patented invention must be provided together with sufficient details to assure that the invention can be carried out, in order for a patent to be valid. Thus, on balance, the “best practice” for a patent system is to eliminate this requirement altogether, as the NRC recommends.

Second, the Section favors limitations on the “inequitable conduct” defense. Limiting this defense is in no way inconsistent with maintaining a comprehensive “duty of candor and good faith,” including a vigorous enforcement of the duty by the United States Patent and Trademark Office where a patent applicant is found to have violated the duty. Indeed, while the Section endorses limiting the unenforceability defense, it favors retaining the mechanisms already in the law that can deter and impose sanctions for misconduct, *e.g.*, criminal sanctions for making willful false statements and the like to the Office (18 U.S.C. §1001), disbarment of registered attorneys and/or agents based on intentional violations of professional conduct rules, and malpractice remedies against attorneys and agents engaged in unprofessional conduct before the Office. However, like the NRC, the Section believes that holding a patent unenforceable based upon alleged misconduct should be available as a sanction only if the decision to issue the patent was impacted in fact by the misconduct, *i.e.*, the patent issued with one or more invalid claims and, but for intentional misconduct, the patent not have issued with an invalid claim or claims.

Third, the Section favors limitations on allegations of “willful infringement” in patent litigation. The practical need to waive the attorney client privilege and rely upon an opinion of counsel to defend against an allegation of willful infringement has seriously eroded the important public purpose of that privilege, *i.e.*, “to encourage full and frank communications between attorneys and their clients.” *See Upjohn Co. v. United States*, 449 U.S. 383, 389 (1981). The Court of Appeals for the Federal Circuit recently has somewhat reduced the need to rely upon an opinion of counsel, but has not gone far enough. *See Knorr-Bremse Systeme v. Dana*

Corp., 383 F.3d 1337 (Fed. Cir. 2004). The Section proposes further limits on both the timing and the scope of waiver when an opinion of counsel is relied upon.

Post-Grant Opposition

The NRC made a third recommendation that also is of great importance, especially if it can be linked together with the harmonizing changes and the elimination and/or limitation on “subjective elements” in the patent law. This third recommendation of the NRC calls for an “open review” procedure that would permit the United States Patent and Trademark Office to promptly correct any mistakes made in the issuance of a patent. The Section supports such an “open review” procedure, *i.e.*, the introduction of a post-grant opposition system.

If a post-grant opposition system were to be coordinated with the harmonizing changes to the U.S. patent law described above, the Section would support making the post-grant opposition co-extensive with all issues relating to the validity of a patent. This would mean that any entity that is potentially adverse to a patent would have a very strong incentive to oppose the patent, in preference to holding back and waiting to mount a defense once sued. Under an appropriately structured opposition proceeding, the opposer could raise any issue it might later be able to raise in court, could do so without exposing itself to the patent owner’s choice of timing and forum, would not be subject to the patent owner’s demand for a jury trial, and could be assured that the proceeding would be promptly concluded. Thus, opening a limited window after the issuance of a patent for such an opposition to be requested holds the potential to correct errors in issuing a patent fairly, promptly, and comprehensively.

The Potential Synergy from Coupling Together These Three Recommendations

The potentially synergistic significance of these three recommendations of the NRC cannot, in the view of the Section, be overstated. Enacted together into law, they would mean that the work of the United States Patent and Trademark Office could be conducted with greater accuracy and completeness. Any mistakes made by the Office could be corrected promptly and comprehensively. A patent once issued – and especially a patent once vetted through an opposition procedure – would be more reliably enforceable. Patent litigation that today requires extensive discovery on issues of patent validity and enforceability would depend to a very large extent on publicly accessible information and upon wholly objective determinations.

The fundamental importance of these three NRC recommendations suggests that both the United States Patent and Trademark Office and the U.S. Congress should take a careful look at the steps needed to put these changes into the patent law. For the Office, it requires a careful look at the incremental resources and new areas of expertise needed to conduct post-grant oppositions. While some significant level of resource savings may result from the simplification of the patent law and practice resulting from the implementation of the first-inventor-to-file principle, these may likely not be sufficient to properly conduct substantial numbers of post-grant opposition proceedings.

The United States Patent and Trademark Office should also continue its laudable efforts to move forward with international patent harmonization agreements. This is especially

important in order to assure that the identified “best practices” envisioned for the U.S. patent system are incorporated outside the United States. The Section is aligned with many other U.S.-based organizations that have substantively identical views on the content of “best practices.” A domestic consensus among non-governmental organizations ought to strengthen substantially the leverage of the United States in international negotiations.

Finally, the Section believes that the time is ripe for active Congressional involvement in these recommendations. Again, the Section does not find itself alone in advocating that the United States move forward to adopt a first-inventor-to-file system as a means for making the U.S. patent operate with greater fairness, efficiency and effectiveness. A wide swath of the U.S.-based non-governmental organization community is seeking adoption of the Section-endorsed changes to U.S. patent law outlined above. Given the growing importance of the patent system, the many criticisms of the current operation of the system, and the apparent consensus within large parts of the user community that some corrective actions are essential, the Section supports taking these three NRC recommendations forward as the core of any effort at near-term reforms to the patent laws.

***Improvements in the Operation of the United States Patent and Trademark Office:
Planning, Oversight, Accountability, and Financing***

The NRC has recommended that the capabilities of the United States Patent and Trademark Office be strengthened. It has particularly noted that the post-grant opposition system, particularly once fully phased into operation, may demand significant new resources and capabilities within the Office. The Section has been a strong and steady supporter of the NRC recommendations as they relate to adequate funding for the Office and the need to sustain that funding.

The Section would strongly urge that any effort to address the issue of resources and capabilities for the Office be undertaken in a holistic fashion. To simply provide the Office with a higher level of funding is not a guarantee that the underlying concerns expressed in the NRC report and elsewhere will be addressed. For the Section, implementing a holistic view requires undertaking a four-component effort. That effort must address planning, oversight, accountability, and – ultimately – financing.

Planning

Any effort at a more effective and efficient United States Patent and Trademark Office requires that the Office engage in comprehensive planning processes. These planning processes must be strategic, operational, and financial in character. They should operate over a five-year planning horizon. They should take account of all the constituencies in the patent system.

A successful strategic plan should address the needs of inventors for prompt, accurate and complete determinations of patentability. They should address then needs of those who may wish to challenge a patent with a prompt, efficient and complete mechanism by which errors in granting patents can be corrected. They should address the needs of technologists for rapid and complete access to the technical information contained in patents. They should address the

needs of Congress to exercise its responsibilities for oversight of the operations of the Office and its fidelity to its constitutionally driven mandate to promote progress in the useful arts.

The Section would support, therefore, as part of the efforts to reinvigorate the capabilities of the Office a statutory mandate that the Office undertake five-year strategic, operational, and financing plans for the Office, that these plans be developed in consultation with all the Office's relevant constituencies, and the plans serve thereafter as a framework for the oversight and accountability of the Office.

Oversight

Given the critical role of the United States Patent and Trademark Office today – and the recommendation that the Office's role be significantly expanded by hearing post-grant oppositions to the grant of patents – the existing oversight of the functioning of the Office should be reassessed. First and foremost, the work of the Judiciary and Appropriations Committees should remain as principal sources of oversight of the effectiveness of the Office. As the authorizers and appropriators of the Office, their oversight function has been critical to assuring accountability of the Office.

This Congressional oversight function could be strengthened, however, if the Patent Public Advisory Committee's role was enhanced to require the Office to consult with the PPAC in formulating its five-year plans and to require the PPAC to review and comment upon such plans before they are finalized by the Office. The Section recommends that Congress consider an enhanced role for the PPAC.

Accountability

Another facet of improving the functioning of the United States Patent and Trademark Office is keeping score – establishing numeric targets or metrics by which to assess whether the Office is meeting commitments in its five-year plans and improving its operational efficiency and effectiveness. Metrics should exist that reflect the accuracy, promptness, and efficiency by which the Office discharges its responsibilities.

The Section would support, therefore, a dialogue with the Judiciary and Appropriations Committees and the user constituencies that would determine how best to establish meaningful and appropriate metrics. As with the issues of oversight, it may be that the PPAC should play an ongoing role in developing and evaluating the appropriateness of suitable metrics.

Financing

The last leg of the four-legged foundation for a more effective and efficient United States Patent and Trademark Office is financing. The Section supports adequate financing of the Office – and appropriations mechanisms that create and can sustain adequate financing of the Office. However, for the Congress and for the user constituencies to be able to determine the appropriate level of funding and the effectiveness of the Office in using its resources, there must be contemporaneously put into place the improvements in planning, accountability, and oversight set out above.

If the Office is to take on the sobering responsibility of correcting its own mistakes in issuing patents through a post-grant opposition procedure that would encompass all patent validity issues, adequate and sustained financing will be crucial to building the capabilities necessary to effectively discharge this sobering responsibility.

IPL Section Supports the Call for a More Efficient and Effective United States Patent and Trademark Office:

1. Mandate the Office undertake a set of five-year strategic, operational, and financing plans.
2. Strengthen the existing Congressional oversight of the Office by mandating a new role for the Patent Public Advisory Committee in the five-year planning processes.
3. Establish new accountability measures through new metrics targeted to accuracy, promptness, and efficiency of the Office.
4. Address adequate and sustained financing for the Office in the context of the new planning, oversight and accountability mechanisms.

The Section Supports the Principle of a Unitary Patent System – Open to New Technologies and Underpinned by Legal Doctrines Flexible Enough to Apply Across the Useful Arts

The recommendation that appears first in the NRC report sets forth the basic principle of “one patent system” that applies across the useful arts, *i.e.*, the full sweep of subject matter that is eligible for patenting. At the level of this basic principle, the NRC and the Section are in substantial agreement.

The patent laws contain an existing collection of requirements that, if rigorously applied to any application for patent, should filter out of the patent system anything that, as a policy matter, should not be accorded patent-like exclusivity. With a set of stringent requirements for obtaining a valid patent – patent-eligible subject matter, practical and substantial utility in presently available form, novelty, non-obviousness, reasonable definiteness, complete written description and full enabling disclosure – the patent system should be open to all new technologies in all fields of endeavor. Moreover, across the useful arts, inventions should be capable of a thorough examination without engrafting new, technology-specific requirements for obtaining a patent.

In this respect, the Section was disappointed in one aspect of a further NRC recommendation relating specifically to the application of the non-obviousness requirement. The NRC specifically recommends that the courts look again at the application of the non-obviousness standard to gene patents. However, what the NRC proposes in this very specific recommendation for this very specific area of technology appears to the Section to be less than

fully consistent with the principle of a unitary patent system. Others have come to a similar conclusion in assessing this recommendation.

The Section's view and the NRC position may not reflect any practical differences. The fundamental principle of a unitary patent system is commonly shared. The need for vigorous applications of all tests for patentability appears to be a common objective. The absence of any perceived need for a change to the patent statute – including the statutory test for non-obviousness itself – is a view commonly held. Thus, both NRC and the Section appear to agree on the most fundamental point: the courts must apply a unitary law on non-obviousness, as reflected in the existing statute, to all fields of technology in a wholly non-discriminatory manner.

The “Experimental Use” Recommendation of the NRC Merits Serious Consideration

A final NRC recommendation calls for some clarification of the possible patent infringement issues that arise when an invention is used for research, scientific, or experimental purposes. Of concern to the NRC – and others – are the apparent differences expressed in opinions authored by judges of the Court of Appeals for the Federal Circuit.

One Federal Circuit judge has contended that no such common law exemption may exist, *i.e.*, “[I]n my judgment, the Patent Act leaves no room for any *de minimis* or experimental use excuses for infringement.” *Embrex Inc. v. Service Engineering Corp.*, 216 F3d 1343 (Fed. Cir. 2000). Another judge has taken the view that a limited exemption has historically existed in the common law, *i.e.*, “The subject matter of patents may be studied in order to understand it, or to improve upon it, or to find a new use for it, or to modify or ‘design around’ it. Were such research subject to prohibition by the patentee the advancement of technology would stop, for the first patentee in the field could bar not only patent-protected competition, but all research that might lead to such competition, as well as barring improvement or challenge or avoidance of patented technology.” *Merck v. Integra*, 331 F.3d 860 (Fed. Cir. 2003).

The Supreme Court has granted certiorari in the *Merck* case and it is possible that it may address the “experimental use” issue presented in the NRC recommendation. The Section does support clarification of the common law principle and looks forward to the development of a consensus on the best way forward to end the apparent uncertainty as reflected in judicial opinions over the past several years.

DETAILED DISCUSSION – SECTION RESOLUTIONS

RECOMMENDATION 1:

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

“The system should remain open to new technologies with features that allow flexibility in protecting new technologies.”

Section Response:

The Section agrees that the patent system should remain open to new technologies, giving full effect to Congress’s intent that anything under the sun that is made by man is patentable.

Discussion:

In *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) the Supreme Court held that the Constitution’s grant to Congress was very broad and that Congress intended that the patent laws be interpreted very broadly. Irrespective of this broad statutory mandate, various courts over the years narrowed the scope of the statutory subject matter to exclude such things as “phenomena of nature, abstract intellectual concepts, mental steps, mathematical algorithms with no substantial practical application, printed matter, and, for many years, business methods.” Many of these judicially-imposed restrictions now have been overturned. The courts have correctly determined that the judicially imposed limits on patentability were contrary to the law and to Congress’s clear intent. *See, e.g. State Street Bank and Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368 (Fed. Cir. 1998). The Section considers that to be appropriate.

As the Supreme Court has recognized on numerous occasions, the language of the patent laws already embodies policy determinations regarding the economic impact of patent scope. Congress has already spoken, and it has determined that the incentives of patent law work best when the scope of patentable subject matter is broad. Congress chose not to distinguish between specific categories of inventions beyond machines, manufactured articles, processes, and compositions of matter.

The Section suggests that the Patent and Trademark Office and courts vigorously pursue enforcement of the existing statutory criteria of patentability in order to effect the full scope of Congress’s policy decision that patent protection extends to “anything under the sun made by man.” *Chakrabarty*, 447 U.S. at 309.

“Among the features that should be exploited is the United States Patent and Trademark Office’s (USPTO) development of examination guidelines for new or newly patented technologies.”

Section Response:

The Section agrees that the use of examination guidelines by the USPTO should be continued and expanded, including guidelines for areas of new technology. Such guidelines, however, should continue to follow existing law for patentability and should not condone discriminatory treatment of patent applications based on the field of invention.

Discussion:

Guidelines are useful tools for teaching patent examiners how to consistently apply the patent law to new or newly patented technologies. New or newly patented technologies do not have the benefit of interpretation of the patent laws as applied to those technologies by either the Board or the Federal Circuit. Absent a set directive by the Patent and Trademark Office, inconsistent positions will likely be taken by the Examining corps regarding how the law should be applied to such technologies.

Guidelines were previously issued, for example, in the biotechnology area regarding written description and enablement under 35 U.S.C. §112, first paragraph. Prior to the guidelines, the scope of claims deemed allowable could vary greatly depending upon the Examiner assigned to the application. The Guidelines have a large number of examples that accurately set forth common claims in this technology. The Guidelines have a detailed explanation of how the patent law should be applied to the particular claims and what the shortcomings of the claims are. They also offer suggestions regarding what scope of claims could be found allowable and possible amendments. These Guidelines provided a much more consistent approach to patent prosecution in this area and continue to be used today even as the field has become more developed.

Thus, the Section agrees that examination guidelines are useful in new technologies as well as in more advanced technologies where inconsistent positions are common within the Examining corps.

“The Court of Appeals for the Federal Circuit (“Federal Circuit”) also should ensure its exposure to a variety of expert opinions by encouraging submission of amicus briefs and by exchanges with other courts. In addition to qualified intellectual property professionals, appointments to the Federal Circuit should include people familiar with innovation from a variety of perspectives—management, finance, and economics, as well as nonpatent areas of law affecting innovation.”

Section Response:

The Section agrees that the Federal Circuit should encourage submission of amicus briefs and encourage exchanges with other courts. The Section also agrees that the backgrounds and experience of men and women appointed to the court should reflect the diverse subject matter of the court, but the Section believes that court should include three or four active judges with patent law background and should include active judges with jury trial experience.

Discussion:

The Section agrees that the establishment of the Court of Appeals for the Federal Circuit in 1982 has resulted in a vast improvement over adjudication in the regional circuit courts of appeals and has achieved many of the goals set for the court, including but not restricted to greater consistency in the interpretation and application of the patent law. The Section also agrees that – consistent with the assignment to the Federal Circuit of jurisdiction over a wide variety of subject matters to avoid insularity and other perceived disadvantages of specialized courts – the court should be exposed to insights from a wide spectrum of thought and experience.

Toward this end, the Federal Circuit should continue its practice of seeking amicus input into its more important cases. To the extent appropriate to the particular case, this amicus input should draw upon insights from other judicial decisions, independent scholarly analysis, and available and relevant empirical evidence. It is the Section’s view, however, that the court’s current amicus brief practice satisfies these goals, and should be continued. The Section sees no need to urge the court to expand its amicus practice to encourage “economic analysis in areas of innovation-related law.”

The Section agrees with the NRC Report that (1) judicial appointments to the Federal Circuit should be made with particular care (as should the appointment of all judges to all courts), (2) Federal Circuit judicial appointments should not be confined to intellectual property practitioners and academics, (3) Federal Circuit judicial appointments should include men and women with diverse experience and backgrounds appropriate to the court’s diverse subject matter jurisdiction, and (4) in particular, some appointments to the court ought to be from the ranks of Federal district court judges with extensive jury trial experience, including patent jury trial experience. It is also important, however, that – given the importance and scope of the court’s patent jurisdiction – the Federal Circuit’s complement of active judges always include three to four judges with extensive pre-court patent experience. Notwithstanding the foregoing,

however, the Section sees no need to appoint judges to the Federal Circuit “with backgrounds in antitrust or finance law or in economics or economic history.” On the contrary, given the tension that has often existed between the antitrust and patent laws, the Section feels that a focus on antitrust or economics would tend to undermine the twin goals of uniformity and predictability in the judicial application of the patent laws.

Finally, the Section agrees that encouraging Federal Circuit judges (as some now do) to sit by designation on other courts and vice-versa would be beneficial, at the very least because it will give the judges a better sense of how patent law fits in with other laws influencing innovation. Particular benefit would be achieved, however, if Federal Circuit judges received greater exposure to patent jury trials, either through designation to serve on district courts or through the designation of district court judges to serve on the Federal Circuit.

RECOMMENDATION 2:

“Reinvigorate the non-obviousness standard.”

“The requirement that to qualify for a patent an invention cannot be obvious to a person of ordinary skill in the art should be assiduously observed. In an area such as business methods, where the common general knowledge is not fully described in published literature that is likely to be consulted by patent examiners, another method of determining the state of general knowledge needs to be employed. Given that patent applications are examined ex parte between the applicant and the examiner it would be difficult to bring in other expert opinions at that stage. Nevertheless, the Open Review procedure described next provides a means of obtaining expert participation after a patent issues.”

Section Response:

The Section agrees with the NRC that the obviousness standard should be assiduously observed and that an Open Review procedure would assist the USPTO by making available relevant prior art not presently available to the USPTO. This is discussed further in the response to Recommendation 3 below.

*“With respect to gene-sequence-related inventions, a low standard of non-obviousness results from Federal Circuit decisions making it difficult to make a case of obviousness against a genetic invention (for example, gene sequences). In this context the court should return to a stricter standard, which would also be more consistent with other countries’ practices in biotechnology patenting The committee therefore recommends that the USPTO and the Federal Circuit abandon the per se rule announced in *Bell and Deuel*”*

Section Response:

The Section agrees that the obviousness standard should apply equally to all technologies, but disagrees with the suggestion by the NRC that the standard of non-obviousness is low with respect to gene-sequence-related inventions, or that the Federal Circuit in *Bell and Deuel* established a different obviousness standard for gene-sequence inventions.

Discussion:

The Section disagrees with the assertion in the NRC report that a change must be made based upon the Federal Circuit precedent of *Bell* and *Deuel*. The NRC report suggests eliminating the alleged “*per se* rule” relating to the non-obviousness of the sequence. First, the NRC report does not suggest making any statutory changes to § 102 and/or § 103. The IP Section would be adverse to any changes specific to biotechnology inventions since the laws should apply equally to all technologies and should not be more stringent for any particular technology. It is believed that the current legal precedent applies § 102 and § 103 in the genetic sequence area just as it does in the chemical area as well as the electrical and mechanical arts.

Secondly, the application of *Bell* and *Deuel* is consistent with the application of § 112 in *Regents of the University of California v. Eli Lilly & Co.* While the NRC report mentions the *Lilly* decision, it states that the fact that *Lilly* results in “narrowing the scope of some gene patents to the actual sequence disclosed” and may “inherently prevent patents on some technologically obvious genes for which *Bell* would otherwise permit a patent ... is not an adequate solution.” The legal precedent in these cases does go hand-in-hand. Changing the standard for obviousness would require a change in what is described to a person skilled in the art. The end result, however, may be the same. While a broader claim may be held “described” by the specification, the broader claim may be “obvious” under a more stringent standard relating to genetic sequences.

Generally, in light of the written description requirement, genetic sequence claims are limited to a particular sequence or closely related sequences thereof. Under Federal Circuit precedent, the sequence as a whole should be evaluated. Would one skilled in the art have reasonably expected the particularly claimed sequence based upon the available prior art? This is the test suggested by the NRC report at pages 77-78. That is the correct test and is what is currently being used. If one skilled in the art would not have expected the particularly claimed sequence, then that sequence should not be found obvious based upon the prior art. No changes are needed to the law in this regard.

What is needed is more consistent application of the law. It is possible that some of the concerns reflected in the NRC report could be remedied if the turnover in the examining corps in Technology Center 1600 were reduced and more effective training and supervision were able to produce greater consistency. Further, other quality measures could further the goal of a consistent application of the existing standard for non-obviousness.

Moreover, some patent application claiming gene sequences are very large and especially complicated to examine. Patent examiners reviewing these applications might achieve greater consistency if given more time and more credit commensurate with the greater complexity of that work.

RECOMMENDATION 3:

“Institute an Open Review procedure.”

“Congress should seriously consider legislation creating a procedure for third parties to challenge patents for a limited period after their issuance in an administrative proceeding before administrative patent judges of the USPTO. The speed, cost, and design details of this proceeding should make it an attractive alternative to litigation to determine patent validity and be fair to all parties.”

Section Response:

The Section agrees, in principle, with the recommendation of the NRC for creation of a new administrative procedure to allow post-grant review of patents.

Discussion:

There are several mechanisms by which the Patent and Trademark Office can review issued patents:

- When an applicant files an application to reissue a patent and requests correction of at least one error in the patent,
- When an interference is declared between the patent and a pending application,
- When a patent owner or third-party requests reexamination of the patent, and
- When the Director initiates reexamination of a patent on his own initiative.

However, most of these procedures have significant substantive limitations. For example, most are limited to grounds based on prior art patents or printed publications and, outside of interference proceedings, the decision is not made by administrative patent judges. There is a general recognition that some type of more meaningful, cost effective, post-grant review process is important to sustaining the viability of the U.S. patent system.

The Section favors the NRC’s recommendation of an administrative post-grant review and opposition procedure that would provide a more balanced proceeding than the present Patent and Trademark Office review procedures. The Section agrees that a properly implemented post-grant review process would provide significant opportunities for enhancing patent quality, thereby increasing business certainty, promoting competition, and fostering continued innovation. Therefore, the Section supports the creation of a new administrative review procedure that includes the provisions to:

[1] permit the filing of an opposition by any person, upon a suitable threshold showing, within a limited period of time not greater than 1 year after the date of the patent grant;

[2] permit as grounds for opposition a broader scope of invalidity issues under 35 U.S.C. §§ 102 (except 102(c), (f) and (g)), 103 and 112 (except for the best mode requirement), than is available in reexamination proceedings;

[3] permit a limited opportunity for amendment of the patent claims during the opposition;

[4] provide completely *inter partes* proceedings, including the right of any party thereto to appeal an adverse decision to the Court of Appeals for the Federal Circuit;

[5] provide that all evidence other than patents and printed publications be presented through affidavit or declaration, and that affiants and declarants be subject to cross-examination;

[6] limit discovery to cross-examination of affiants, unless otherwise required in the interest of justice;

[7] provide authority to the Board of Patent Appeals and Interferences to hear and decide all such post-grant review proceedings;

[8] put the burden of proof on the Opposer to show invalidity by a preponderance of the evidence; and

[9] require that the proceeding be completed within a specified period of time.

In order to be effective, such a post-grant review proceeding must be truly *inter partes*. Moreover, the opposition should be heard and decided by a panel of administrative patent judges (“APJ’s”), such as the Board of Patent Appeals and Interferences. Such APJ’s have training and experience in contested proceedings, whereas the Examiners currently handling re-examinations do not.

The proceeding should permit assertion of a broader scope of invalidity grounds than prior art patents and printed publications as currently available in reexamination proceedings. If the institution of the post-grant opposition system is coordinated with the so-called “harmonizing” reforms that the Section supports, then the scope of the post-grant opposition could be made co-extensive with all the issues of validity that a challenger might later raise in court as a defense to infringement.

The Section proposes that all prior art available under 35 U.S.C. §§ 102 and 103 be eligible for assertion in an opposition, but, absent enactment of the “harmonizing” changes, would oppose an opposition proceeding that would deal with issues of § 102(c) (abandonment), § 102(f) (derivation), and § 102(g) (first to invent). Those excepted grounds likely would require more discovery and more difficult determinations of what was in the mind of the inventor, thereby unduly increasing cost and delay. Thus, if the opportunity for post-grant opposition is to be optimized – both in providing a challenger a full opportunity to correct error made in granting the patent and to provide the patent owner assurance that a patent surviving an opposition is highly likely to be validly enforceable – the Section urges Congress to link post-grant oppositions to the first-inventor-to-file changes to the patent law.

The Section also proposes that indefiniteness of the claims, and lack of a written description of the invention or an enabling disclosure under § 112 be permitted as grounds which can be asserted. However, the failure to disclose the best mode of practicing the invention known to the inventor should not be available as a ground of opposition because of the difficult fact and discovery issues raised by inquiry into the state of mind of the inventor. This issue,

however, would be eliminated as a basis for invalidating a patent if the “harmonizing” changes are adopted.

To avoid harassment and unreasonable burden on the patentee, the opposer should be required to make a threshold showing of invalidity before the proceeding is instituted.

Discovery must be stringently limited so as to avoid the time delay and huge costs often associated with patent infringement litigation in the courts. Such costs would create an unreasonable burden for a patent owner who may not have even asserted that the opposer has infringed. Accordingly, the Section proposes that all evidence other than patents and printed publications be presented through affidavit or declaration, and that discovery be limited to cross-examination of affiants, unless otherwise required in the interest of justice.

The Section proposes that all oppositions be filed within a limited period, not greater than one year, after the patent issues. Further, the Section proposes that the entire proceeding be completed within a specified period of time, e.g., one year after it is instituted unless extended for an additional six months in unusual circumstances. Such time limitations will provide competitors and the public with an early opportunity to correct improperly granted patents, while providing the patentee with greater certainty within a reasonable time after the patent issues.

The Section believes that such a post-grant review proceeding would provide a prompt and cost-effective procedure for determining the patentability of the issued claims without creating an undue burden on patentees to defend their patents against frivolous assertions, repeated challenges and harassment. However, such a post-grant review proceeding will require additional funding for the PTO, and the Section’s proposal is conditioned upon a commitment for adequate funding.

RECOMMENDATION 4:

“Strengthen USPTO capabilities.”

“To improve its performance the USPTO needs additional resources.”

Section Response:

The Section agrees that the Patent and Trademark Office needs additional resources and should be adequately funded.

Discussion:

The Section agrees that the USPTO capabilities should be strengthened, and has consistently supported adequate funding for the Patent and Trademark Office. Most importantly, the ABA and the Section have urged that some financing means be found that will assure the Office receiving sufficient, predictable funding for it to carry out urgently needed improvements in the efficiency and effectiveness of its operations.

There is a growing public perception that there are an increasing number of lower quality patents issued. Many of the reasons that underlying that perception are outlined in the Patent and Trademark Office’s 21st Century Strategic Plan. One major reason is the increase in number of patent filings. From 1997 to 2001 the number of filings increased from 237,045 to 344,717. There has also been an increase in the number of patents issued. From 1997 to 2001 the number of patents issued increased from 122,977 to 187,822. This problem is amplified in art areas where references other than printed publications constitute the bulk of the relevant art, *e.g.*, business method patents. Despite these major problems and the need for greater funding, user fees continue to be diverted and funding shortfalls have persisted.

The Section supports providing predictable and sustained funding at adequate levels for the Patent and Trademark Office to be able to carry out strategic and operational plans to enhance the quality of patent examination and to adequately perform the tasks assigned to it – and to have the mechanisms for oversight and accountability to assure that it does so efficiently.

“These funds should enable implementing a robust electronic processing capability.”

Section Response:

The Section agrees that the USPTO should enhance its electronic processing capability.

Discussion:

The Section reaffirms its longstanding support for use of electronic tools to assist in the patent examination process. The exponential decay in the cost of computing and the exponential rise in the depth and breadth of electronically searchable prior art information affords a continuing set of opportunities for more effective and pervasive use of electronic tools in the patent procurement process.

The NRC its report that the USPTO pre-search the subject matter of a patent application using a sophisticated, automatic text-search program that searches the prior art. The Section supports this recommendation. It appears to represent a cost-effective technology given that the USPTO already uses optical character recognition in order to process patent applications within the Application Branch, maintains a number of text-search prior art databases, and should be able to rely on a number of highly sophisticated technologies that currently exist for text-searching large databases.

While not all patents in all areas of technology may be equally amenable to this type of electronic searching, the USPTO should be able to continually assess the effectiveness of this type of searching to determine where it provides incremental improvement in the efficiency and effectiveness of patent examination. Given that the full-text for all U.S. patent applications exists shortly after filing and that text-searchable databases similarly exist, the incremental costs for devising search algorithms and delivering search results to patent examiners should be modest, justifying at least an early pilot program.

“These funds should enable . . . creating a strong multidisciplinary analytical capability to assess management practices and proposed changes.”

Section Response:

The Section agrees that funds should be used to assess management practices and proposed changes.

Discussion:

The Section agrees that the Patent and Trademark Office funds should be used to create a strong multidisciplinary analytical capability to assess management practices and proposed changes. The specific needs of the Patent and Trademark Office fluctuate with the economy and with the development of new technologies. The Patent and Trademark Office should use its resources to analyze statistics and thus the needs of the Office. Being able to analyze and respond to trends quickly allows the Office to promote the progress of Science and the useful Arts, as dictated by the Constitution.

A review of pendency statistics of the Office illustrates the need for such analytical capabilities. The areas of growth in the economy are usually the areas of the longest pendency, e.g., Art Unit 1600 (biotechnology and organic chemistry) in the 1990s and Art Units 2100 (Computer Architecture Software and Information Security) and 2600 (Communications) in 2005. Not only does this shorten the life of the patent in these areas, but it also affects business and development in these areas of growth. For example, it delays the issuance of the patents at times where many companies are developing and thus looking for patents to use for generating the interest of investors. Further, as competitors develop their business, a delay in issuance of patents provides uncertainty regarding what they are excluded from pursuing. Without knowledge of what patent claims will ultimately issue, competitors cannot attempt to design around the future claims. The Office should have the capabilities to evaluate trends and compensate accordingly so that public interest is best served.

“These funds should be used to . . . conduct reliable, consistent, reputable quality reviews that address office-wide as well as subunit and examiner performance.”

Section Response:

The Section supports expanding the current USPTO quality review program.

Discussion:

The USPTO currently randomly evaluates 2–4% of all allowed patent applications to determine the quality of the examination. In their evaluation, the USPTO’s Office of Quality Review considers such quality indicia as whether relevant art was applied, whether the search that was conducted was sufficient, and whether additional rejections should have been made. The USPTO maintains Office-wide statistics such as the number of allowed patent applications that were allowed with one or more claims a court would likely hold invalid. However, it seems that the USPTO does not maintain records of quality indicia on an art-unit or tech-center-by-tech-center basis.

The National Research Council of the National Academies recommends in their report, *A Patent System for the 21st Century*, to strengthen the capabilities of the U.S. Patent and Trademark Office by developing a reliable, consistent, reputable quality assurance process. Such process would include determining a sampling rate for reviewing allowed patent applications and using that process to inform decisions about hiring, training, reassigning supervisors and examiners.

The Section of Intellectual Property Law agrees with the National Academies that the USPTO can use the Office of Quality Review more effectively to optimize training and hiring. By using data from the quality review process, the USPTO can improve quality by locating specific areas needing improvement and without wasteful duplication of effort. Also, by collecting data more specifically and using the data to influence hiring and training, the USPTO can improve quality without substantially increasing its costs.

Several years ago, the USPTO instituted a program of “second pair of eyes review” of patent applications largely in the business methods patents art area. That was done at a time when the PTO was receiving considerable criticism for issuing certain patents that were considered by many to be highly questionable. The program was considered to be successful generally in reducing the number of such questionable patents thereafter, though not eliminating them. However, the improvement in quality was not without cost in terms of utilization of PTO resources and in terms of pendency of all applications in that art area. At the time that the program was installed there was a perception that the business methods patents area was new and that training of examiners in that area was difficult under all of the circumstances.

Rather than adopt an expansion of the program on such infirm ground, it is desirable that the program be expanded only as needed to address circumstances akin to those extant in the business methods patents at the inception of the program. In view of the existing efforts to raise quality in the PTO and to reduce pendency, the overall principle of “do it right the first time” should be kept in mind. The PTO should not design its programs to utilize extra resources to achieve the levels of patent examination quality that could and should otherwise be achieved more efficiently by proper training and examination process control.

Accordingly, while the Section has long supported various ideas and programs to improve quality in the USPTO, the resolution supports the expansion of the program of second examiner review only in those art areas and for such time as necessary to bring examination processes and training into compliance in those art areas.

“[O]ne of the common occurrences in patent prosecution that should be much better documented is in-person or telephone negotiations between examiners and applicants’ representatives.”

Section Response:

The Section supports complete documentation of interviews, but believes that the present USPTO requirements for documentation are sufficient if consistently followed.

Discussion:

The Section believes that further requirements for documentation of in-person or telephone negotiations between examiners and applicants’ representatives are not required. If the current dictates of the Patent Office are followed, sufficient documentation of the substance of examiner interviews will be provided in the prosecution file history.

Under MPEP § 713.04, a “complete written statement as to the substance of any ... interview” must be made of record in the prosecution file history of a patent application. If an applicant requests an interview, the “Applicant Initiated Interview Request Form” must be submitted to make of record what will be discussed. According to the MPEP, a written record should be made of any interview and should provide a “complete and proper recordation of the substance of any interview.” The written record should include a description of any exhibits, identification of claims and prior art discussed and identification of “the principal proposed amendments of a substantive nature discussed.” In addition, the “general thrust of the principal arguments of the applicant and the examiner should also be identified.” Further, a general indication of other matters, the general results or outcome of the interview, and, if it is an “interview” by email, a copy of the email should be made of record.

If these dictates are consistently followed by the Patent Office, a sufficient documentation of in-person and telephone negotiations between examiners and applicants’ representatives will be provided in each prosecution file history where an interview has occurred.

RECOMMENDATION 5:

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

“In light of the Federal Circuit’s 2002 ruling that even noncommercial scientific research enjoys no protection from patent infringement liability, and in view of the academic research community’s belief in the existence of such an exemption, and behavior accordingly, there should be some level of protection for noncommercial uses of patented inventions. Congress should consider appropriately narrow legislation, but if progress is slow or delayed the Office of Management and Budget and the federal government agencies sponsoring research should consider extending “authorization and consent” to grantees as well as contractors, provided that such rights are strictly limited to research and do not extend to any resulting commercial products or services. Either legislation or administrative action could help ensure preservation of the “commons” required for scientific and technological progress.”

Section Response:

The Section agrees with the NRC recommendation that some research uses of patented inventions should be shielded from liability for infringement.

Discussion:

Some exemption for experimentation on patented inventions must be part and parcel of an effectively functioning patent system. Although no explicit statutory exemption from infringement is found in the patent statute itself, some commentators have found logical support in the statute for the proposition that not all activities or “uses” connected with a patented invention should be found infringing:

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

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

The exemption is inherent to a properly functioning patent system at least where experimentation is required to understand what is patented, whether the patent is valid, and what basic properties or characteristics the thing patented might have. In brief, a patent system should operate in an appropriate and balanced fashion by protecting the ability of the patent owner to prevent unauthorized commercial uses of the patented invention while protecting the ability of the public to evaluate, study and improve upon the patented invention. The Section believes that the ability of a patent owner to effectively commercialize its patented invention would not be compromised by a statutory exemption from infringement that is carefully and narrowly crafted to enable third parties to conduct research on the patented invention.

The Section believes, however, that certain premises in the NRC recommendation should not be relied upon in designing such an exemption. For example, the NRC makes a distinction between research performed by “non-commercial” entities, such as universities, and research performed by “commercial” entities. In practice, the experience of members of the Section is that such a distinction is nearly impossible to draw in practice, and should be immaterial to the question of whether the research activities are shielded from infringement or not. The Section observes that the motivation of an entity performing bona fide research on a patented invention – i.e., research to ascertain how the invention works, to design around the patent claims, or to evaluate and study the teachings of the patent – should not subject the party performing those acts to potential infringement liability.

The NRC report also cites the recent Federal Circuit decisions in *Duke v. Madey* and *Integra v. Merck KgaA* for the proposition that there is greater uncertainty in the public regarding research uses of patented technology. Another such decision is *Embrex, Inc. v. Service Engineering Corp*, 55 USPQ2d 1161, 216 F.3d 1343 (Fed. Cir. 2000). In that appeal, Judge Radar in a concurring opinion stated that he wished the majority would have held that “the Patent Act leaves no room for any *de minimis* or experimental use exemption from infringement.” Such an extreme interpretation would preclude any activity with patented subject matter qualifying as exempt from infringement and permit the activities to be enjoined. The concurring decision does, however, underscore the possible need for a Congressional response to what are apparently varying views at the Federal Circuit of what the controlling common law principles are or should be.

The NRC suggests that these decisions have created an undesirable degree of uncertainty over where the line should be drawn as between the inventor’s exclusivity in commercialization and the public’s right to engage in legitimate experimentation.

While the Section does not necessarily agree that there is a substantially increased degree of uncertainty, or that universities are only now attuned to possible risks of infringement from the actions of university researchers, legitimate concerns do exist over what are acknowledged to be *de minimis* uses of the patented invention. The fact that the costs of obtaining a patent license for such *de minimis* uses to authorize any necessary experimentation are generally available for nominal sums does not mitigate these legitimate concerns. Indeed, the evidence suggests the contrary may be the case. In any event, threatened patent litigation, complicated licensing negotiations, efforts to secure compensation based upon the fruits of any experimentation, and delays in starting experiments until patent issues can be resolved are all potential adverse

consequences of not having a definitive provision in the patent law exempting bona fide experimentation activities.

Accordingly, the Section supports the general proposition that Congress act to create an exemption in the patent law for certain acts of research or experimentation that are done on subject matter protected by a patent from liability for patent infringement. The Section supports the general assessment of the NRC that such an exemption from liability is entirely in line with the goals of the patent system. As the Constitution specifies, the Congress is given the authority to provide a patent system that will “promote the progress of the useful arts.” Such progress means that the patent system, made to function properly, will advance social welfare through both innovation and dissemination of knowledge. Fostering both more innovation and greater dissemination of technical knowledge have paramount roles in the policy choices that are made in crafting patent laws.

The Section recognizes that the task of legislatively defining an exemption from infringement for *bona fide* research will be extremely difficult. For example, the exemption, if it is to operate as intended, must be drawn in precise and clear terms that enable a third party to appreciate without substantial effort whether the acts it intends to perform will give rise to potential liability. A standard that requires extensive litigation to ascertain whether actions undertaken by a third party will or will not give rise to liability would frustrate the purpose of the legislation.

The proposed exemption is consistent with legislation in other countries. Most other industrialized countries have provisions permitting research and experimentation uses of a patented invention. See, e.g., Article 69(1) of the Japanese Patent Act (“[t]he effects of the patent shall not extend to the working of the patent right for the purposes of experiment or research.”). Provisions modeled generally on Article 27(b) of the Community Patent Convention (“acts done for experimental purposes relating to the subject-matter of the patented invention” are exempted) also can be found in most European nations. In addition, the WTO Agreement on Trade Related Aspects of Intellectual Property (TRIPS) provides expressly provides for the possibility of a research exemption through Article 30 of the Agreement (“Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.”).

The continued absence of a statutory research exemption from U.S. patent law could have the unintended effect of making it more expedient to conduct certain types of experimental work in foreign countries where the threat of patent infringement litigation would not exist. Promoting the progress of the useful arts *outside the United States* should not be advantaged simply because of the lack of a comparable provision in U.S. patent law.

Finally, the codification of an experimental use doctrine is especially important today given the reach of the patent law to permit the patenting of “anything under the sun made by man.” Because of the patent eligibility of all man-made products and process, an exemption would ensure that products discovered in nature and patented as man-made compositions, *e.g.*,

genetic material, hormonal substances, and organisms, can nonetheless be fully studied and examined.

RECOMMENDATION 6:

“Modify or remove the subjective elements of litigation.”

“Three provisions of patent law that are frequently raised by plaintiffs or defendants (rarely by the courts) in infringement litigation depend on determining a party’s state of mind, and therefore generate high discovery costs. These provisions are (1) “willful infringement,” which if proven, exposes an infringer to possible triple damages; (2) the doctrine of “best mode,” which addresses whether an inventor disclosed in an application what the inventor considered to be the best implementation of the invention; and (3) the doctrine of “inadequate conduct,” concerning whether the applicant’s attorney intentionally misled the USPTO in prosecuting the original patent. To reduce the cost and increase the predictability of patent infringement litigation outcomes, and to avoid other unintended consequences, these provisions should be modified or removed.”

Section Response:

While the NRC recommendation at first blush may seem radical to some steeped in the intricacies of the patent law, the points made in the NRC report bear serious consideration. The statistics in the NRC report reflect accelerating, out-of-control costs for patent litigation. Much of the costs are tied to enormous amounts of information that must be produced during discovery because it is of potential relevance to the contemporaneous state of mind of the inventor and/or others at the time the invention was made, the patent was sought, and/or the patent was being examined.

The experience outside the United States validates the possibility of running a patent system in which the issues in litigation are fundamentally objective determinations based principally on publicly accessible information. Under such a system, only limited discovery is needed in litigation and greater prospective certainty about the enforceability of the patent can be had absent *any* discovery.

Thus, the Section supports in principle moving ahead with the NRC recommendation and to identify the extent to which these issues can be limited in most patent litigation.

Allegations of Willful Infringement

“Lacking evidence of its beneficial deterrent effect but with evidence of its perverse antidisclosure consequences, the committee recommends elimination of the provision for enhanced damages based on a subjective finding of willful infringement ... A modest step is to abolish the effective requirement that accused infringers obtain and then disclose a written opinion of counsel. Another possibility is to limit inquiry into willful infringement to cases in which the defendant’s infringement has already been established. A third alternative that preserves a viable willfulness doctrine but curbs its adverse effects is to require either actual, written notice of infringement from the patentee or deliberate copying of the patentee’s invention, knowing it to be patented, as a predicate for willful infringement.”

Section Response:

The Section favors substantial changes to the law of willful infringement. The Section proposes reforms to the scope and timing of the waiver of privilege when an attorney opinion is relied upon in defense of willfulness allegations. The Section is considering additional proposals that have emerged from the Business Software Alliance, the AIPLA and a Section Task Force.

Discussion:

On September 13, 2004, the Court of Appeals for the Federal Circuit, *en banc*, held that the trier of fact cannot draw an adverse inference with respect to willful infringement when the attorney-client privilege and/or work product privilege is invoked by a defendant in an infringement suit. *See Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337 (Fed. Cir. 2004). The Federal Circuit further held that the trier of fact cannot draw an adverse inference with respect to willful infringement when the defendant has not obtained legal advice. Finally, the Federal Circuit held that the existence of a substantial defense to infringement is not sufficient alone to defeat liability for willful infringement even if no legal advice has been secured.

The Section has long favored elimination of the adverse inference, and urged that position in an amicus brief in *Knorr-Bremse*. However, *Knorr-Bremse* treated only some of the problems existing in the law of willful infringement. The Section proposes legislation to further alter the law regarding the waiver of privilege.

The Federal Circuit in *Knorr-Bremse* recognized the importance of the attorney-client privilege, stating:

The Supreme Court describes the attorney-client privilege as “the oldest of the privileges for confidential communications known to common law,” and has stressed the public purpose to encourage full and frank communication between attorneys and their clients and thereby promote broader public interests in the observance of law and administration of justice. The privilege recognizes that sound legal advice or advocacy serves public ends and that such advice or advocacy depends upon the lawyer’s being fully informed by the client.

Upjohn Co. v. United States, 449 U.S. 383, 389, 101 S.Ct. 677, 66 L.Ed.2d 584 (1981). Professor Wigmore has elaborated:

The lawyer must have the whole of his client’s case, or he cannot pretend to give any useful advice That the whole will not be told to counsel unless the privilege is confidential, is perfectly clear. A man who seeks advice, seeks it because he believes that he may do so safely; he will rarely make disclosure which may be used against him; rather than create an adverse witness in his lawyer, he will refuse all private arbitration, and take the chance of a trial.

8 J. Wigmore, *Evidence in Trials at Common Law* § 2291 at 548 (McNaughton rev. 1961). See *Hunt v. Blackburn*, 128 U.S. 464, 470, 9 S.Ct. 125, 32 L.Ed. 488 (1888) (the attorney-client privilege is designed to encourage candid exchange of information).

383 F.3d at 1344.

Consistent with those statements by the Supreme Court, The Court of Appeals for the Federal Circuit, and Professor Wigmore, the Section submits that an accused infringer should not be required to waive the attorney-client privilege prematurely. Accordingly, it is the position of the Section that discovery on opinions of counsel should be stayed until after a finding of liability for infringement. Thus, the privilege would only need to be waived in those cases where liability actually is found. Because only about 5% of the patent infringement cases filed in district courts go to trial, and liability at the trial court level is found only in about 60% of those cases that do go to trial, delay of the requirement to waive privilege until after liability has been established would greatly reduce the number of unnecessary waivers of the privilege. See Kimberly A. Moore, *Judges, Juries, and Patent Cases: An Empirical Peek Inside the Black Box*, 98 Mich. L. Rev. 365, 383-385 (2000).

Under the Section’s proposal, expedited discovery regarding the issue of willful infringement based on a privileged opinion of counsel would occur during a 30-60 day period immediately after liability is found. Trial of the willful infringement issue would follow promptly after that expedited discovery period.

The Section also favors limitations on a waiver of privilege for a willfulness defense extending to litigation counsel. At present, the scope of the waiver is uncertain. The privilege

between a client accused of patent infringement and that client's litigation counsel may be waived by the mere reliance upon an opinion prepared by other counsel. The possibility of the waiver extending to communications between litigation counsel and the client severely restricts those communications in a manner inconsistent with the public interest.

Accordingly, the Section proposes that the attorney-client privilege protecting communications between a client accused of patent infringement and that client's litigation counsel not be waived with respect to litigation counsel where the client has asserted the defense of reliance on advice of counsel in response to an allegation of willful infringement and where (1) the litigation counsel was at no time involved in rendering the advice upon which the client has asserted reliance; and (2) the opinion relied upon was rendered prior to the service of any summons and complaint alleging infringement.

Additional proposals for reform of the law relating to willful infringement have recently emerged from the Business Software Alliance, the AIPLA, and a Task Force of the Section. The Section is studying those proposals and will supplement this response, if appropriate, after that study is complete.

Best Mode Elimination

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

Section Response:

The Section agrees that the best mode requirement should be eliminated as part of a harmonization package. This is discussed in more detail in the Section’s response to Recommendation 7.

Inequitable Conduct Defense in Patent Infringement Litigation.

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

Section Response:

The Section agrees that changes in implementation of the inequitable conduct defense should be enacted in order to drive down the costs and complexity of patent litigation.

Discussion:

Inequitable conduct is frequently pled, but seldom proven. *E.I. DuPont de Nemours & Co. v. Phillips Petroleum*, 849 F.2d 1430 (Fed. Cir. 1988). Over pleading of inequitable conduct has been labeled a “plague” on the patent system by the Court of Appeals for the Federal Circuit. It appears “in nearly every patent suit, and is cluttering up the patent system.” *Burlington Industries, Inc. v. Dayco Corp.*, 849 F.2d 1418 (Fed. Cir. 1988). Changes are required.

Under present law, a finding of unenforceability of even one claim of a patent will render all claims of the patent unenforceable, even when some of those claims are free of any direct taint from the inequitable conduct. An entire patent can become permanently unenforceable because of conduct that relates solely to a claim that covers an invention that may not be commercially significant and, indeed, may never have been asserted or relied upon by the patent owner. As stated in *J.P. Stevens & Co., Inc. v. Lex Tex, Ltd., Inc.*, 747 F.2d 1553, 1561 (Fed. Cir. 1984), *cert. denied*, 474 U.S. 822 (1985):

Once a court concludes that inequitable conduct occurred, all the claims—not just the particular claims to which the inequitable conduct is directly connected—are unenforceable.

Inequitable conduct is separate and distinct from invalidity even though the defenses might depend on the same prior art reference. See *Minnesota Min. and Mfg. Co. v. Johnson & Johnson Orthopedics, Inc.*, 976 F.2d 1559, 24 USPQ2d (BNA) 1321 (Fed. Cir. 1992) (“[P]roving inequitable conduct does not ‘invalidate’ a patent. Rather, it renders the patent unenforceable. Although the practical effects may be the same, the legal concepts are quite different.”). Because inequitable conduct and invalidity are different, a patent may be unenforceable even though information, such as prior art, withheld from the PTO does not render the claims in the patent invalid. See *Li Second Family Limited Partnership v. Toshiba Corp.*, 231 F.3d 1373, 56 USPQ2d (BNA) 1681 (Fed. Cir. 2000) (“Information concealed from the PTO may be material even though it would not invalidate the patent.”); *Merck & Co. v. Danbury Pharmacal, Inc.*, 873 F.2d 1418, 10 USPQ2d (BNA) 1682 (Fed. Cir. 1989) (same). Thus, under current law, it is easier for a party to assert inequitable conduct since the party alleging inequitable misconduct merely needs to show that withheld information, such as a prior art reference, should have resulted in a *prima facie* case of unpatentability and, therefore, was material. Such party, however, is not required, under current law, to prove that the patent claims are invalid in the light of the withheld information.

The Section proposes that a “but for” standard should be applied by the courts in determining inequitable conduct (*i.e.*, the misconduct caused the issuance of one or more invalid patent claims). The “but for” standard is applied in other areas of the law in fraud cases, where materiality is an essential element requiring proof. In such cases, misrepresentations or failures to fulfill a duty to speak is material *only when* the outcome of the case was affected. The law in patent litigation should be the same. Misstatements or failures to disclose that do not affect the outcome of the case, even though reprehensible, have not inflicted any harm on the accused infringer because they have not caused issuance of patent claims that would otherwise have been properly rejected if all the facts had been made known to the USPTO.

The Section contemplates an entirely *objective* standard for determining whether a “but for” relationship exists between the culpable conduct and the consequence. That objective standard would be keyed to how a hypothetical examiner should have treated the examination of the patent. It would be based upon consideration of the prosecution history as a whole, objectively considered. It would, thus, address what such a hypothetical examiner should have done in disposing of the application for patent in light of the omission of material information or the reliance on a material misrepresentation of information.

The broader materiality rule of USPTO Rule 56 may be beneficial in setting the USPTO standard for disclosure. That broader obligation to disclose can be enforced by the USPTO under its disciplinary authority or otherwise. However, there appears to be no cogent public policy reason for the broader standard in court proceedings. Adoption of the “but for” standard would make it unnecessary for courts to consider the intent element of inequitable conduct in those cases where the claims are found valid (*i.e.*, not proved to be invalid by clear and convincing evidence). It should reduce the cost and complexity of patent litigation.

The Section also proposes that the “all or nothing” rule be abolished. The ability to render all claims of a patent unenforceable by proving inequitable conduct as to any claim has become a prime motivator for many litigants in asserting inequitable conduct as a defense.

In many situations, a single patent may contain claims to related but distinct subject matter. For example, a patent may include claims to a manufacturing process, to an apparatus designed for carrying out the process, and for the resulting product. The failure to disclose prior art or other information that provides the basis for a finding of inequitable conduct may be material only as to some, but not all, of the claims. Under these circumstances, the question as to whether or not to render unenforceable all claims of the patent should be determined by the Court, based upon the equities of the particular case.

The reach of inequitable conduct may even extend to related patents. *Consolidated Aluminum Corp. v. Foseco Int’l Ltd.*, 910 F.2d 804 (Fed. Cir. 1990).

The Federal Circuit in *FMC Corp. v. Manitowoc Co., Inc.*, 835 F.2d 1411 (Fed. Cir. 1987), held that inequitable conduct is an equitable doctrine and to be guilty of inequitable conduct, “one must have intended to act inequitably. *Id.* at 1415. Changing the law to permit the maintenance of objectively valid claims despite the existence of one or more other unenforceable claims, would be desirable. Moreover, the charges of inequitable conduct would be more properly focused on the claims in suit, rather than on unasserted claims of the patent in suit.

The present rule of unenforceability as to all claims, as well as associated patents, sweeps too broadly and lacks proportionality. Because it can be somewhat fortuitous whether certain claims are included in one application, the present law can result in the same conduct being treated differently if the claimed subject matter is included in one application instead of two. While the law clearly should discourage all forms of dishonesty and misrepresentation in dealing with the PTO, the “penalty” now being assessed goes too far. The Federal Circuit’s decision in *Rohm & Haas Co. v. Crystal Chemical Co.*, 722 F.2d 1556, 1571 (Fed. Cir. 1983), provides support for balancing these interests. Instead of the “all or nothing” rule, inequitable conduct should be penalized in proportion to the seriousness of the offense and the relationship between the conduct and the patent claims. The Sections submits that placing the burden on the patentee to prove that a certain claim was not tainted by the inequitable conduct is appropriate in these circumstances.

RECOMMENDATION 7:

“Reduce redundancies and inconsistencies among national patent systems.”

“The United States, Europe, and Japan should further harmonize patent examination procedures and standards to reduce redundancy in search and examination and eventually achieve mutual recognition of results. Differences that among others are in need of reconciling include application priority (“first-to-invent” versus “first-inventor-to-file”), the grace period for filing an application after publication, the “best mode” requirement of U.S. law, and the U.S. exception to the rule of publication of patent applications after 18 months. This objective should be pursued on a trilateral or even bilateral basis as well as a multilateral basis.”

Section Response:

The Section agrees that the United States should change its patents laws, including by adoption of the first-inventor-to-file principle to achieve greater harmonization with the patent laws in Europe and Japan and, conversely that Europe and Japan should make significant changes to their patent laws, including adoption of a one-year “grace period,” abolishing the “self-collision” rule, ending “novelty-only” uses of prior art, and ending “absolute novelty” rules that allow a single, oral, non-confidential divulcation of an invention to bar its later patenting.

Discussion:

The Association favors legislation to adopt the first-inventor-to-file principle in the United States. Doing so will produce greater harmonization among the world’s leading patent systems and facilitate efforts at concluding international harmonization agreements that may produce even more significant harmonizing changes to the patent laws. However, the Section does not support harmonization for its own sake. Rather, it supports harmonization when and if the resulting changes can produce improvements to the patent system, *i.e.*, constitute so-called “best practices.”

The “Best Practices” Foundation for “First Inventor to File” Principle

In recent harmonization discussions – and parallel efforts to devise domestic legislative reforms – an emerging principle is that so-called “best practices” among global patent systems and incorporated into domestic patent law reforms. A “best practices” patent system presumably would achieve, among other objectives—

- Predictability in assessments of what inventions will be validly patentable.
- Simplicity in the legal principles and concepts that underlie the system.

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

Efforts at greater international harmonization of patent laws based upon “best practices” has taken on critical importance during the past decade. Unlike the decade that preceded it, numerous critics of the operation of the patent system become vocal about the need for the patent system to operate more effectively in each of the dimensions used to define “best practices.”

The “Best Practices” for Implementing a First-Inventor-to-File System

The Section also favors, in the context of an international patent harmonization agreement, the adoption of a coordinated set of specific changes to the patent statute. These provisions are offered as a set of proposed “best practices” for the implementation of a first-inventor-to-file system.

1. Elimination of the Best Mode Requirement

The Section favors removal of the “best mode” requirement as part of the adoption of a first-inventor-to-file system. Since 2001, repeal of the “best mode” requirement has been viewed as a “best practice” in the context of harmonizing U.S. patent law by BIO, NAM, IPO, and AIPLA. More recently, AIPLA and BIO have reaffirmed their support for the repeal of this requirement as part of the adoption of the first-inventor-to-file rule.

The NRC Report has now adopted the identical recommendation, support the elimination of the “best mode” requirement from U.S. patent law:

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

The NRC rationale for removing the requirement is persuasive, but other considerations also support the repeal. While the NRC cites the burdens and uncertainties for foreign inventors, the same is true for U.S.-based inventors and, as discussed, below is at least as important a factor in supporting repeal of this requirement. Further, the inherent uncertainties – and the greater consequences of an uncertain patent system as patents have grown in economic value and importance – not only further justifies the change but also makes the change a priority. Finally, both the Section and NRC envision coordinating this reform with adoption of a first-inventor-to-

file system. Such coordination serves to magnify the importance of removal of this requirement from the U.S. patent laws.

On the issue of coordination of “best mode” with other harmonization-related changes, such coordination could produce a patent system in which there would be no issues of patent validity that would require discovery of inventor records and inventor intentions in most patent infringement litigations. Except in a few situations where ownership of a patent is at stake and the ownership determination depends upon the individuals named as inventors, the right combination of coordinated reforms – including elimination of the “best mode” requirement – would render irrelevant the personal knowledge or contemplations of an inventor from relevance in patent validity determinations.

The patent validity issues that would remain would be related exclusively to *what the public knew* (prior art), and *what the patent taught* persons skilled in the art (adequate disclosure) relative to the claimed invention. Thus, the potential advantages of elimination of the “best mode” requirement in easing the discovery burdens in patent litigation are more than incremental in the context of a coordinated set of reforms. The result of a packaged set of changes could mean that all inventor-focused discovery could be eliminated in many patent litigations.

It is for this reason that the Section supports a coordinated set of reform to U.S. patent law that includes repeal of the “best mode” requirement. The NRC report appears to reach the same conclusion on the coordination issue based upon the elements of its harmonization-related recommendations.

Thus, the Section to fully endorses the NRC recommendation on elimination of the “best mode” requirement as part of the package of harmonization-related changes to U.S. patent law.

2. Reform of the “In Public Use or On Sale” Bar

The Section also supports, in a harmonization context, repeal of the aspect of the “in public use or on sale” bar to patenting except where the activities at issue (*i.e.*, use, sale, or offer for sale) make the invention “reasonably and effectively accessible” to persons of ordinary skill in the art. Thus, non-informing activities, such as non-informing commercial uses of an invention, are excluded from the reach of the bar.

a) Policy Drivers Underlying a “Forfeiture Bar” – Differences Between a First-to-Invent vs. First-Inventor-to-File System

For a first-to-invent system to operate effectively, it *must* include substantial incentives to file promptly after an invention has been made. The needed incentives to file promptly are particularly important where an invention can be kept secret while it is being commercialized. Absent some patent law doctrine that makes a longstanding non-informing and/or secret commercial use of an invention a bar to patenting, the inventor, in a first-to-invent system, would have a compelling incentive to defer seeking a patent. The inventor could wait until the

invention became public, either through another's public disclosure of the invention or efforts to seek and/or obtain a patent for the invention.

In such situations, the first-to-invent system allows a commercial user that has not abandoned, suppressed or concealed an invention to rely on its early invention date proofs to remove the public disclosure of another as prior art and/or establish priority over the rival inventor and obtain the patent for the invention. If a non-informing commercial use gives the public the benefit from the invention, the commercial user has an argument that there is no abandonment, suppression or concealment. See *Oak Industries v. Zenith Electronics*, 726 F.Supp. 1525, 14 USPQ2d 1417, 1424-25 (N.D. Ill 1989). ("We believe that in order to avoid a finding of suppression or concealment, Zenith need only show that the public enjoyed the use and benefits of the Seattle converters. See *Friction Division Prods., Inc. v. E.I. DuPont de Nemours & Co.*, 658 F.Supp. 998, 1013, 3 USPQ2d 1775, 1786 (D. Del. 1987), aff'd, 883 F.2d 1027 (Fed. Cir. 1989) (unpublished opinion). A noninforming public use, as opposed to a secret public use, will defeat a claim of concealment, at least where the public benefits.")

The incentive to delay filing in a first-to-invent system becomes a compelling one whenever the underlying invention can be practiced on a non-informing basis, *i.e.*, without providing the public a description of the invention and/or enabling it to be reproduced. This arises in part because deriving value from patenting an invention of this type is invariably problematic. Unlike a non-informing use, patenting the invention provides the entire world a disclosure of the otherwise inaccessible technology. It allows competitors to copy and commercialize the invention on a like non-informing basis, *i.e.*, without affording the patent owner a ready means for detecting an infringing commercialization. Moreover, the economic value from patenting the invention may be lost if it can be infringed in any location (*e.g.*, such as by building a single large manufacturing facility in a foreign country where no valid patent has or can be issued). Thus, the incentive to use the patent system to secure an early filing must overcome the potential disadvantage that the invention must be clearly patentable, patented, and enforceable under dozens of patent laws in order to secure meaningful economic value from patenting.

Under a first-inventor-to-file standard, part of the incentive to delay seeking patents for the subject matter while engaging in a non-informing commercial use disappears. If someone else makes the invention public or a rival inventor seeks a patent for it, the delay in seeking a patent by a non-informing or secret commercial user is fatal to the ability of the user to patent the invention – the public disclosure of another immediately bars the secret commercial user's ability to seek a valid patent. Invention date proofs cannot be used to establish priority and allow belated efforts to patent to succeed.

More importantly, a rival inventor who could be victimized by the delay of the secret commercial user in seeking a patent under the first-to-invent system (*i.e.*, who could not successfully establish a defense of abandonment, suppression or concealment) becomes a guaranteed victor under the first-inventor-to-file standard. The unfairness that could result from allowing the commercial user to delay seeking a patent and then snatch patent rights away from a rival inventor who promptly seeks a patent is eliminated and, instead, it is the rival inventor that can obtain global patent priority.

Thus, under a first-inventor-to-file system the incentive for early filing inherently exists and the ability to “game the system” by deferring the filing of a patent is inherently eliminated. For this reason the policy drivers for retaining (or removing) bars to seeking a valid patent in a first-inventor-to-file system are largely turned on their head.

Whereas extended secret commercial use must bar the commercial user from seeking a valid patent in a first-to-invent system, the first-inventor-to-file standard does not need such an incentive. What becomes important in the situation where one or more inventors are engaged in a non-informing or secret commercial use of an invention is to maintain an incentive for at least one such inventor to come forward and seek a patent.

First-inventor-to-file systems address this issue by *preserving* the right to patent an otherwise patentable invention so long as the invention has not been publicly disclosed or divulged by anyone. Patentability is potentially preserved even if the invention is the subject of a longstanding secret commercial use. The rule preserving potential patentability rather than forfeiting the right to patent, coupled with the threat of a rival inventor filing first, provides a continuing incentive to disclose the invention.

This policy choice means that the subject matter secretly commercially used, once disclosed through the patent system, can be improved upon and/or designed around by others. These activities flowing from the disclosure result in progress in the useful arts in a manner that may not happen or happen more slowly if the subject matter is maintained in secret.

Thus, under a first-inventor-to-file standard, the reasons for barring an inventor from seeking a valid patent after a prolonged period of non-informing or secret commercial use not only disappear, but actually reverse. Maintaining the right to validly patent subject matter even after its secret commercial use provides a continuing incentive to disclose an invention that can then be more readily and rapidly improved by others and otherwise progress the useful arts. Keeping the forfeiture would mean introducing an incentive for perpetual secrecy, impairing what otherwise might be accelerated progress in the useful arts.

b) Metallizing Engineering’s Rationale Supports Incentives for Early Filing, But Solely Based Upon the Operation of a First-to-Invent Standard

Removing the forfeiture represents a “best practice” for handling in the patent laws the factual situation described in *Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516, 68 USPQ 54 (2d Cir. 1946). In *Metallizing Engineering*, the patent owner put a trade secret process into a non-informing commercial use in the United States. The commercial use had continued for more than one year before the patent owner had sought and obtained a patent for the trade secret subject matter. When the patent owner attempted to enforce the patent, the court ruled the patent owner had forfeited the right to patent the invention that had been placed in a non-informing commercial use. The statutory basis for the court’s holding was that the patented trade secret had been “in public use or on sale” under the precursor to the provisions of law now codified in 35 U.S.C. § 102(b).

Judge Learned Hand authored the *Metallizing Engineering* decision. He explicitly grounded the decision on the importance of securing a disclosure of the invention at the earliest possible time. The full policy rationale cited by Judge Hand for the forfeiture doctrine was the following:

[I]t is a condition upon an inventor's right to a patent that he shall not exploit his discovery competitively after it is ready for patenting; he must content himself with either secrecy, or legal monopoly. It is true that for the limited period of two years he was allowed to do so, possibly in order to give him time to prepare an application; and even that has been recently cut down by half. But if he goes beyond that period of probation, he forfeits his right regardless of how little the public may have learned about the invention; just as he can forfeit it by too long concealment, even without exploiting the invention at all. *Woodbridge v. United States*, 263 U.S. 50, 44 S.Ct. 45, 68 L.Ed. 159; *Macbeth-Evans Glass Co. v. General Electric Co.*, *supra*, 6 Cir., 246 F. 695. Such a forfeiture has nothing to do with abandonment, which presupposes a deliberate, though not necessarily an express, surrender of any right to a patent. Although the evidence of both may at times overlap, each comes from a quite different legal source: one, from the fact that by renouncing the right the inventor irrevocably surrenders it; the other, from the fiat of Congress that *it is part of the consideration for a patent that the public shall as soon as possible begin to enjoy the disclosure*. [Emphasis supplied.]

153 F.2d 520.

As noted above, the principle policy driver for the forfeiture under a first-to-invent system is that absent a forfeiture, a trade secret holder would be free to wait until another inventor had sought a patent on the same subject matter and only then apply for a patent. The trade secret holder could rely on its earlier reduction to practice to establish its status as the first to invent. It could argue that its longstanding commercial use established that it had not “abandoned, suppressed or concealed” the trade secret technology. If such delaying tactics were permitted, they would arguably be unfair and contrary to a host of policy considerations.

Thus, the first-to-invent system makes an unequivocal forfeiture based upon prolonged secret commercial use an essential feature of the system. An inventor that long delays patent filing while undertaking commercial use of an invention must fail at attempted patenting either because the law finds the activity to represent abandonment, suppression or concealment or a forfeiture under section 102(b). Otherwise, the first to invent would have a risk-free opportunity for delaying filing indefinitely to the public detriment, and then snatch back the patent from anyone else later making the invention and seeking a patent for it.

On the other hand, the first-inventor-to-file system puts every inventor at equal risk of losing the right to patent unless and until a patent filing date is secured. The person who is the first to invent and then delays filing while pursuing a commercial use cannot use the early invention date to frustrate a later inventor that files a patent application first. Instead, the later inventor will be able to obtain a valid patent.

This difference between a first-inventor-to-file standard and the first-to-invent system is fundamental and profound. This difference requires a careful reassessment of the role of the forfeiture provision in the context of moving to the first-inventor-to-file standard, even if patent harmonization does not accompany the move to the new standard.

A careful analysis of the facts of *Metallizing Engineering* in the context of a first-inventor-to-file standard indicates the better policy choice is to eliminate the forfeiture so that the patent incentive remains for all inventors to become the first inventor to file – and make the earliest possible disclosure of new technology. Indeed, it is only this policy choice under a first-inventor-to-file standard that motivates an early disclosure of the invention and it is the patent-incented disclosure that can most readily and rapidly produce progress in the useful arts.

Strong policy reasons, important economic factors, and sound practical considerations argue for removing the forfeiture from the patent law once a first-inventor to file standard is adopted.

3. Elimination of Derivation-Based Prior Art

The Federal Circuit has interpreted existing 35 U.S.C. § 102(f), barring a patent when the patent applicant “did not himself invent the subject matter sought to be patented” to mean that an inventor’s personal knowledge learned from another can represent “prior art” that must be taken into account in determining if an invention is non-obvious. *OddzOn Products Inc. v. Just Toys Inc.*, 122 F.3d 1396 (Fed. Cir. 1997).

This decision has proven controversial and has led Congress to consider reversal of the *OddzOn* holding in situations where the knowledge of the invention is obtain through a joint research agreement. The so-called “CREATE Act” was drafted to address and reverse the *OddzOn* holding.

The Section favors, in a harmonization context, a solution to the *OddzOn* situation that consists of two parts. First, codification that the right to seek and obtain a patent is the inventor’s right. This eliminates the possibility that a person who derives an invention can be entitled to patent the invention. Because such a non-inventing patent applicant “did not himself invent the subject matter sought to be patented,” the “right to patent codification accomplishes literally and precisely what the language of 35 U.S.C. § 102(f) provides.

With the codification of the “right to patent” added to the patent statute, the provision in subsection (f) of section 102 (“he did not himself invent the subject matter sought to be patented”) is simply repealed. With the repeal of this section, an inventor’s personal knowledge is unavailable for determining obviousness under 35 U.S.C. § 103. Thus, the *OddzOn* holding is overruled.

Policy considerations that support overruling *OddzOn* include the following:

- It unfairly punishes a true inventor for what he knows. Any other person making the same invention could be entitled to a valid patent for the same invention.
- It encourages ignorance, rather than communication. It makes no policy sense to deny an inventor a patent because he had a private communication with another scientist.
- It obviates the need to make complicated remedial changes to the patent law to eliminate untoward effects, including the CREATE Act.
- It avoids the need in patent litigation to proceed with discovery related to the issue of “what did the inventor know and when and from whom did he learn it”?
- It provides the patent owner a greater degree of certainty and reliability that the patent will not be invalidated because some personal knowledge of the inventor is deemed to render a patented invention obvious.
- It avoids the potential for unrecognized “inequitable conduct” issued based upon a later contention that the inventor had personal knowledge that might have rendered to the invention obvious, but was withheld from the PTO.

This principle continues the protect an inventor against derivation, but does not then punish a true inventor of a claimed invention from validly patenting an invention that is otherwise non-obvious simply because of personal knowledge of the true inventor.

4. Repeal of Other “Loss of Right to Patent” Provisions

The Section favors, in a harmonization context, repeal of the two remaining provisions in 35 U.S.C. § 102 that relate to loss of right to patent. These are 35 U.S.C. § 102(c) (abandonment) and 35 U.S.C. § 102(d) (premature foreign patenting).

The move to a “first-inventor-to-file” system makes it desirable, to remove a set of either little used, increasingly archaic and/or clearly unnecessary or undesirable provisions affecting the right to patent in 35 U.S.C. § 102. This includes removal of the obscure provisions on loss of right based upon “abandonment” and premature foreign patenting under 35 U.S.C. §§ 102(c) and (d). Today, 35 U.S.C. § 102(c) (abandonment) and 35 U.S.C. § 102(d) (premature foreign patenting) are essentially “dead letters.” Over the past several decades, no patent has been invalidated for “abandonment” and in fewer than a handful of situations has an issue under 35 U.S.C. § 102(d) even arisen in reported patent cases.

5. Elimination of Use of Invention Dates.

The adoption of a first-inventor to file system necessarily eliminates the use of invention date proofs to antedate a prior-filed application for patent that would otherwise be prior art. This is the mechanism by which the first inventor to file has a right to secure a valid patent that cannot be patented a second time by a later-filing inventor.

The Section further supports, in a harmonization context, the principle that invention date proofs cannot be used in a 35 U.S.C. § 102(a) context. This permits an inventor making an invention to dedicate the invention to the public through publication of an invention. If

invention dates could be used to eliminate such prior art, this ability to dedicate an invention to the public could be frustrated.

More importantly, it would impact on the ability of an inventor to make use of the grace period. If after the publication of an inventor, another inventor could file an application for patent and use invention dates to antedate the inventor's publication, the antedating inventor would be entitled to the patent as the first inventor to file.

For these and other reasons, the "best practice" under a first-inventor-to-file system is to eliminate the use of invention dates for any and all purposes.

6. Prior Art Definition; Elimination of Geographic Considerations in Determining Prior Art

The Section offers, in a harmonization context, a specific definition of prior art.

Desirability of elimination of geographic considerations in determining whether knowledge of an invention is sufficient to qualify as prior art. The "in this country" limitation that U.S. law imposes on non-published prior knowledge should be repealed. This limitation has become increasingly untenable as jet travel has removed geographic barriers on the geographic mobility of persons skilled in the art and modern means of electronic communication have decimated other geographic barriers to information flow. Thus, a more contemporary standard is essential to distinguish knowledge arising from some form of disclosure that ought to constitute prior art from knowledge whose character is such that an invention should nonetheless be regarded as novel and patentable.

In Europe, any divulgation of an invention that is deemed to have been non-confidential can represent a disclosure that constitutes prior art. Such a standard, applied globally, leads to transparently nonsensical and unacceptable results. Entirely secret and inaccessible information to persons skilled in the art nonetheless qualifies as a patentability-destroying disclosure. A number of additional hurdles beyond a single, non-confidential "divulgation have been proposed. One such hurdle would be to impose a requirement that accessibility of the information should be "reasonably possible." The Section does not support a "reasonably possible" standard because of the lack of clarity in the manner this would operate.

The emerging consensus position, while recognizing the desirability of removing artificial geographic limitations, nonetheless retains the essential rationale for imposing such limitations – the more inaccessible the information, the greater the policy interest in disregarding a remote and inaccessible disclosure as prior art. Hence, the emerging consensus standard focuses not on attempting to make increasingly meaningless geographic limitations, but by on a standard requiring both reasonable and effective accessibility of information to qualify as prior art.

The Section proposes that both concepts – reasonable accessibility and effective accessibility – be separately defined and independently applied to assure a complete and objective limitation on the scope of activities that can constitute prior art. Together, the two

concepts – one of reasonableness and the second of effectiveness – are designed to prevent a substantially unavailable and/or unintelligible or non-informing disclosure from qualifying as patent-defeating prior art:

Under the proposal, a disclosure cannot be considered to be “reasonably accessible” unless the efforts required to secure access to the disclosure by a person of ordinary skill in the art are not unreasonable or undue. At one extreme, a disclosure in a database or other searchable repository, such as a cataloged disclosure in a library, would be deemed reasonably accessible. At the other extreme, an unrecorded, oral divulgence whispered by one individual to another that occurred once in a remote and isolated locale, without more, would not by itself establish reasonable accessibility.

A disclosure cannot be considered to be “effectively accessible” unless a person of ordinary skill in the art would be able to comprehend the disclosure and discern its technical import. At one extreme, a publication in the English language appearing in a reputable professional journal would be regarded as effectively accessible. At the other extreme, the subject matter contained in an encrypted electronic file, even if reasonably accessible for downloading on the Internet through a search engine, would not be regarded as being effectively accessible absent the ability to unencrypt its technical contents using reasonable efforts.

This standard has the further advantage of being capable of application in a uniform and harmonized manner by patent offices throughout the world. Thus, it represents a desirable outcome of any negotiations that might lead to a globally applied standard for prior art.

7. Filing of Patents and Published Patent Applications As Prior Art

The Section supports a simplified treatment of the filing of patents and published patent applications as prior art. Published U.S. patent applications become prior art as of their effective filing dates and are available for use in either novelty or non-obviousness rejections. Published PCT applications are treated no differently. U.S. patents are treated no differently from published patent applications.

Because the United States is a signatory to both the Paris Convention and the Patent Cooperation Treaty, the provisions in both these treaties must be observed the determination of prior art based upon a first-inventor-to-file principle. The Paris Convention creates a so-called “right of priority.” The United States is obligated to make the determination of a first-filed application for “first-inventor-to-file” purposes by taking into account any foreign-filed application of an inventor if entitled to the right of priority. Thus, in determining whether a patent or published application for patent is earlier filed, the Paris Convention priority filing date must be used. In contrast, under existing 35 U.S.C. § 102(e), Paris Convention priority filings are ignored in giving prior art status to a patent or published application for patent as of the filing date for the patent or application. See *In re Hilmer*, 149 USPQ 480 (C.C.P.A. 1966).

Second, the Section supports the proposition that an international patent application, published under the Patent Cooperation Treaty, need not have been published in the English language in order for the publication application to represent prior art as of the international

filing date under the Treaty. The existing requirement for an English-language publication cannot be maintained in a first-inventor-to-file context and must be removed.

This language limitation on the qualification of a PCT application as prior art was permitted under the reservation taken by the United States with respect to Article 64(4) of the PCT. (In pertinent part, “[a]ny State whose national law provides for prior art effect of its patents as from a date before publication, but does not equate for prior art purposes the priority date claimed under the Paris Convention for the Protection of Industrial Property to the actual filing date in that State, may declare that the filing outside that of an international application designating that State is not equated to an actual filing in that State for prior art purposes.”) However, the reservation only applied to a country operating a so-called “first-to-invent” system, *i.e.*, where the *Hilmer* doctrine can be observed so that the Paris Convention priority date need not be used as the date a patent or published application has prior art status.

In addition, the invention date for the claimed invention is no longer used as the reference point for what can be considered prior art. Instead, a patent or a published patent application becomes prior art if the patent or published application for patent is *effectively filed* before the *effective filing date* of the claimed invention instead of before the *invention date* of the claimed invention.

The original rationale for treating patents (and, by extension, published applications for patent) as prior art from the filing date of the patent or application in the first-to-invent system was offered by the Supreme Court in *Alexander Milburn v. Davis-Bournonville Co.*, 270 U.S. 390 (1926). The rationale in part was that the prior art status of the patent or application for patent is to be determined independently of the period of delay in the issuance of the patent (or delay in the publication of the application for patent) once filed. This rationale necessitated the prior art status reach back to the filing date of the patent or applications, *i.e.*, the applicable date had *no delay* existed between the filing and the issuance of the patent or publication of a pending application for patent. For this same policy rationale, the first-inventor-to-file uses the effective filing date as the date prior art status is accorded for both novelty and non-obviousness.

Because the determination of when a patent or application for patent was effectively filed requires consideration of prior-filed applications, not all subject matter in the patent or published application for patent may have the same effective filing date. When the description is effectively filed depends on whether the subject matter described was carried over from an earlier-filed patent application. Some decisions of the courts, however, ignore subject matter from an earlier-filed priority application that is carried over into a later-filed patent or published application in assessing the effective filing date for the “carried over” subject matter. *See In re Wertheim*, 209 USPQ 554 (CCPA 1981). The Section is not intended to follow the *Wertheim* decision, but adopts a simple “whole contents” approach that is contrary to the holding of the court (*i.e.*, the holding from *Wertheim* that is inconsistent with the “whole contents” approach, stating: “While some of the reference patent disclosure can be traced to [the priority application], such portions of the original disclosure cannot be found ‘carried over’ for the purpose of awarding filing dates, unless that disclosure constituted a full, clear, concise and exact description in accordance with § 112, first paragraph, of the invention claimed in the reference

patent, else the application could not have matured into a patent, within the *Milburn* § 102(e) rationale, to be “prior art” under § 103.”)

In a nutshell, the proposed treatment of PCT applications permits finality in the scope and content of the relevant prior art to be ascertained sooner (*i.e.*, immediately upon publication of an application for patent), permits a global application of a common prior art standard that would not be possible if National State entry were required for a prior art effect, and permits the inventor to dedicate an invention to the public in a more full and certain manner if a decision is reached not to seek the issuance of patents in the United States and other countries.

The only alternative would be to require National Stage entry under the PCT before a published PCT application would have a prior art effect from its effective filing date. As noted above, this would frustrate and early and final determination of the scope of the prior art, a globally common standard for treating published PCT applications, and the ability to dedicate the invention to the public without the expense of country-by-country National Stage Entry.

Finally, treating published PCT applications in a non-discriminatory manner compared to published U.S. patent applications creates little or no incremental examination burden. The issue of affording foreign language prior art for PCT applications exists in a nearly identical measure even if the English language publication requirement could be maintained in a first-inventor-to-file system. *Every* foreign-language PCT published application constitutes prior art that must be applied to later-filed applications of U.S. inventors. The only issue is the 18-month delay issue: Are later-filed applications of U.S. inventors later than the filing date or the publication date of the foreign language PCT application?

8. Exclusion for Commonly Owned Inventions for Disclosures Made Directly or Indirectly by the Inventor

The Section supports without substantive change two principles of existing U.S. patent law. Unless a statutory bar, *i.e.*, 35 U.S.C. § 102(b), the inventor’s own disclosures do not create prior art, whether the disclosure of the inventor alone or through another person. Thus, the so-called one-year “grace period” is preserved, although the inventor will not be able to resort to use of invention dates to remove a pre-filing disclosure made by a third party as prior art.

Second, the Section supports without substantive change the amendments to 35 U.S.C. § 103 made as part of the Patent Law Amendments Act of 1984, excluding as prior art certain commonly owned inventions. Moreover, because of the changes to derivation law supported by the resolution, it accomplishes – but with greater thoroughness and completeness, the changes to the patent law sought by the sponsors of the so-called CREATE Act.

9. International Grace Period

As under existing U.S. patent law, the Section supports continuation of the so-called “grace period” as a domestic grace period. Thus, it requires that an application for patent be filed within the one-year period in the PTO (or through the Patent Cooperation Treaty). Priority

application filing does not qualify as a filing for the purpose of determining whether the filing was within the grace period.

However, the proposal of a Paris Convention priority application would be sufficient to satisfy the one-year requirement, but only if part corresponding changes in the patent laws in Europe and Japan. In this sense, the possibility of an international grace period provides a *quid pro quo* among parties to any harmonization agreement.

10. Obviousness-Type Double Patenting

The proposal makes any new statutory provisions that would create a “first-inventor-to-file” system subject to the existing judge-made law on “obviousness-type double patenting.” Thus, the same inventor would not be entitled to obtain multiple patents for the same patentable invention, except by making an appropriate disclaimer of independent terms and separate ownership for the patent deemed to be the second patent for the same patentable invention. Similarly, an assignee taking advantage of the provisions that preclude using certain earlier-filed applications for patent for being applied as prior art against later-filed applications for patent would be subject to the same double patenting considerations that are applied under existing patent law.

CONCLUSIONS

The five-year study of the operation of the U.S. patent system by the NRC has produced a report that challenges the reader to rethink some of the most fundamental precepts that have undergirded the patent law for generations. In most of the areas where the NRC has recommended changes to the patent laws, its reasoning is sound and its perspective disarmingly refreshing. As the Section has worked through the issues raised by the NRC, it has become clear that the package of three principal reforms – first-inventor-to-file and other simplifications of the law of patent validity, elimination of “subject elements” from most patent litigations, and a post-grant opposition that would allow a challenger to seek correction of any mistakes made in issuing a patent – would together have the potential to work a near revolutionary improvement in the efficiency and effectiveness of the operation of the U.S. patent system.

The Section, therefore, would urge the Congress, the United States Patent and Trademark Office, and the various constituencies interested in the operation of the patent system to answer a simple question. Whether inventor, patent owner, or patent challenger, would the benefits of these reforms – the simplification, the elimination of subjective elements, the ability to rely almost exclusively on publicly accessible information in evaluating the patentability of an invention – make the U.S. patent system better or worse?

The essence of a fair and balanced package of reforms is that every constituency finds some feature that is potentially troublesome, but not so troublesome that the benefits of the package do not more than counterbalance any negatives. The best tribute that the Section could offer to the NRC would be to note that, while everyone may object to something in the report, few can rationally question the overall advantages that would flow from prompt enactment of its three fundamental proposals for reforming the patent statute.