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Report of AIPLA Special Committee to Study the National Research Council's Report on Reaping The Benefits of Genomic and Proteomic Research

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Introduction

The National Academy of Science ("NAS") report is 144 pages in length and deals with many topics that are not addressed in the report's Recommendations. Because of this, AIPLA decided to comment only on the actual Recommendations and not on the background discussions which resulted in the ultimate Recommendations. This lack of comment should not be interpreted to mean that AIPLA necessarily agrees with everything that is in the body of the Report.

The Committee commends the NAS for reviewing the interfaces between intellectual property, innovation, and public health. The AIPLA Special Committee concluded that the NAS recognizes, in general, the value of intellectual property in this area and appreciated that without such protection much valuable research would not have been conducted.

Recommendation 1:

NIH should continue to encourage the free exchange of materials and data. NIH should monitor the actions of grantees and contractors with regard to data and material sharing and, if necessary, require grantees and contractors to comply with their approved intellectual property and data sharing plans.

AIPLA Response

AIPLA agrees that the NIH has a right and responsibility to ensure that the public receives the greatest benefit from its investment in biomedical research. Accordingly, there is an expectation that NIH funded grantees and contractors will comply with the Guidelines[1] on exchange of materials and data. Consistent with those Guidelines, grantees and contractors

[1] See Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources ["Guidelines"].

should continue to seek patent protection for therapeutic and diagnostic inventions.

AIPLA agrees that "monitoring" the activity of grantees is important to ensure compliance with the existing federal funding Guidelines. This need not be a complicated undertaking, and could consist of a few questions to be included at the front of every grant application, as shown in attached Exhibit A.

Recommendation 2:

NIH should adapt and extend the "Bermuda Rules" to structural biology data generated by NIH-funded centers for large-scale structural genomics efforts, making data promptly and freely available in a database via the Protein Data Bank (PDB).

AIPLA Response

AIPLA agrees that structural data otherwise available to the public should be promptly available in the most useful format, particularly in a format that is searchable and facilitates patentability analyses. However, the Bermuda Rules were created to foster a spirit of collaboration and safety among separate laboratories working toward the goal of sequencing the human genome. Absent the need to create a collaborative, safe environment to foster some similar goal, AIPLA supports the right of grantees and contractors to seek appropriate patent protection for discoveries prior to making structural information available to the public.

Recommendation 3:

The PDB should work with USPTO, the European Patent Office (EPO), and the Japanese Patent Office (JPO) to establish mechanisms for the

efficient transfer of structural biology data in published patent applications and issued patents to the PDB for the benefit of the larger scientific community. To the extent feasible within commercial constraints, all researchers, including those in the private sector, should be encouraged to submit their sequence data to GenBank, the DNA Databank of Japan, or the European Molecular Biology Laboratory and to submit their protein structure data to the PDB.

AIPLA Response

AIPLA agrees that PDB deposit should be an acceptable mechanism of disclosure for applications. However, compliance should be attested to by declaration or affidavit, as is done with ATCC culture deposits. This ensures efficient deposit and conserves scarce patent office resources. AIPLA would support a standardized format for the entry of structural data in a searchable database of patent documents.

Recommendation 4:

The committee endorses NIH's Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources and Best Practices for the Licensing of Genomic Inventions. Through its Guide for Grants and Contracts, NIH should require that recipients of all research grant and career development award mechanisms, cooperative agreements, contracts, institutional and Individual National Research Service Awards, as well as NIH intramural research studies, adhere to and comply with these guidance documents. Other funding organizations (such as other federal agencies, nonprofit and for-profit sponsors) should adopt similar guidelines.

AIPLA Response

AIPLA agrees with the principles of the Guidelines, and refers the reader to Recommendation 1 and Exhibit A for its views on compliance.

AIPLA notes that, contrary to the Guidelines, universities seek exclusive licenses for DNA-based inventions as noted in the NRC report on pages 98-100 and elsewhere, and that these activities limit accessibility of the DNA-based inventions to both research institutions and industry. Exempting research on inventions from liability for patent infringement, Proposal 10, may not address all situations where access to DNA-based inventions would advance research. Accordingly, requiring adherence to the Guidelines would further alleviate the problem of access to DNA-based inventions created through research supported by NIH and other funding organizations with similar goals.

Recommendation 5:

Universities should adopt the emerging practice of retaining in their license agreements the authority to disseminate their research materials to other research institutions and to permit those institutions to use patented technology in their nonprofit activities.

AIPLA Response

AIPLA suggests that dissemination to research institutions is acceptable, provided that those research institutions are prevented from further dissemination to industry and the non-profit activities exclude obtaining and managing patents in a manner that would restrict the use of the research tool in the future (absent the same terms as provided in the non-exclusive

license or a grant-back of rights, including commercial rights, in any such patent).

Recommendation 6:

In cases in which agreements are needed for the exchange of research materials and/or data among nonprofit institutions, researchers and their institutions should recognize restrictions and aim to simplify and standardize the exchange process. Agreements such as the Simple Letter Agreement for the Transfer of Materials or the Uniform Biological Material Transfer Agreement (UBMTA) can facilitate streamlined exchanges. In addition, NIH should adapt the UBMTA to create a similar standardized agreement for the exchange of data. Industry is encouraged to adopt similar exchange practices.

AIPLA Response

AIPLA agrees that simple agreements facilitate access to research materials subject to observance of intellectual property rights owned in the research material and/or data and consistent with the Guidelines. The existing Simple Letter Agreement appears sufficient for this purpose, and can be adapted for data with minimal modifications.

Recommendation 7:

USPTO should create a regular, formal mechanism, such as a chartered advisory committee or a regularly scheduled forum, comprising leading scientists in relevant emerging fields, to inform examiners about new developments and research directions in their field. NIH and other relevant federal research agencies should assist USPTO in identifying experts to participate in these consultations.

AIPLA Response

AIPLA agrees that educating examiners about new developments in their fields would promote better decisions and improve patent quality. Rather than create another chartered advisory committee, however, the curriculum of the existing Patent Academy should be expanded to incorporate lectures on recent developments by leading scientists. AIPLA is already exploring ways to work with the USPTO to provide education on the impact which examiners' work has on R&D incentives and litigation. Technical education would provide a necessary and useful compliment.

Recommendation 8:

In determining nonobviousness in the context of genomic and proteomic inventions, USPTO and the courts should avoid rules of nonobviousness that base allowances on the absence of structurally similar molecules and instead should evaluate obviousness by considering whether the prior art indicates that a scientist of ordinary skill would have been motivated to make the invention with a reasonable expectation of success at the time the invention was made.

AIPLA Response

AIPLA disagrees with this Recommendation. The NAS's position is very similar to that espoused in its previous report on the patent system, "A Patent System for the 21st Century." AIPLA's position in response is unchanged. A copy of the AIPLA position is attached as Exhibit B.[2]

The National Academy's Recommendation regarding obviousness appears to be a solution to a problem that doesn't

[2] Since the AIPLA position in Exhibit B was developed, the Supreme Court has granted a *writ of certiorari* from the decision in *Telefelx Inc. v. KSR International Co.*, 04-1152 (Fed. Cir. 2006)(unpublished)

really exist. Little evidence supports the notion that the above-stated Recommendation is required to prevent stagnation in research related to genomics and proteomics. Indeed, the report itself states: "The committee found that the number of projects abandoned or delayed as a result of difficulties in technology access is reported to be small, as is the number of occasions in which investigators revise their protocols to avoid intellectual property issues or in which they pay high costs to obtain intellectual property. Thus, for the time being, it appears that access to patented inventions or information inputs into biomedical research rarely imposes a significant burden for biomedical researchers." The paper goes on to cite an inchoate fear that investigators' ignorance of intellectual property is the reason patents are not more broadly thwarting research.

A report of a very recent exhaustive empirical study by Adelman and DeAnglis demonstrates that the frequently stated concerns of the "anti-commons" are misplaced.[3] The paper states that the "lack of concentrated control, rising number of patent applications, and the continuous influx of new patent owners suggest that overall biotechnology innovation is not being impaired by the growth in patents issued each year."[4] Thus, there is insufficient evidence to justify a different approach to the obviousness of biotechnological inventions than that dictated by the relevant statute and associated jurisprudence.

Additional commentary in the current NAS report merits mention. The report calls for the obviousness inquiry with respect to biotechnology product inventions to delve into the process by which the invention was derived, which would single out biotechnology for special treatment. The NAS's Recommendations would discriminate against biotechnological

[3] Adelman, David E. and DeAnglis, Kathryn L., "Patent Metrics: The Mismeasure of Innovation in the Biotech Patent Debate" (January 29, 2006). Arizona Legal Studies Discussion Paper No. 06-10 Available at SSRN: http://ssrn.com/abstract=881842

[4] *Id*. at 58.

chemical inventions as compared to small molecule chemical inventions. Importantly, this would be in violation of the statutory mandate, "Patentability shall not be negatived by the manner in which the invention was made."[5] In fact, the United States is required to avoid discriminating with respect to patentability based on technological field of invention pursuant to the TRIPS agreement.[6] Thus, neither the courts nor the USPTO are free to act on the NAS's Recommendation.

The report indicates that such an approach would be consistent with the Federal Circuit's earliest jurisprudence with respect to biotechnology, citing *Amgen v. Chugai*[7] and *Hybritech v. Monoclonal Antibodies.*[8] The reliance on these two cases is misplaced. Footnote 3 of the *Amgen* case states, "We note that both the district court and the parties have focused on the obviousness of a process for making the EPO gene, despite the fact that it is products (genes and host cells) that are claimed in the patent, not processes. We have directed our attention accordingly, and do not consider independently whether the products would have been obvious aside from the alleged obviousness of a method of making them."[9] Thus, the court expressly disapproved of the approach of basing an obviousness determination on the process by which the invention was derived, but its hands were tied because the parties and the district court approached the question incorrectly. The *Hybritech* case is also inapt, because the claimed invention in that case was a process.

The concerns of the NAS seem to be almost entirely based on the cases of *In re Deuel*[10] and *In re Bell.*[11] In both cases, the

[6] 35 U.S.C. §103.
[6] Trade-Related Aspects of International Property Rights Agreement Article 27(1).
[7] 927 F.2d 1200 (Fed. Cir. 1991).
[8] 802 F.2d 1367 (1986).
[9] 927 F.2d at 1207.
[10] 51 F.3d 1552 (Fed. Cir. 1995).
[11] 991 F.2d 781 (Fed. Cir. 1993).

Federal Circuit overturned the USPTO's determination that the claimed DNA sequences were obvious in view of partial (*Deuel*) or full (*Bell*) amino acid sequences and known cloning methodology. The claimed DNA sequences could not be envisioned without carrying out the work of actually isolating them, hence fulfilling the truism articulated in *Deuel* that "[w]hat cannot be contemplated or conceived cannot be obvious."[12] The report asserts that, in *Deuel* and *Bell*, the "court refused to see that there is a known relationship between a gene and the protein it encodes."[13] This is a baffling comment in view of the extensive discussion in both cases regarding proteins and the DNA encoding them. In *Bell*, the court simply recognized the lack of impact of that relationship to the claimed specific, natural nucleic acid sequence given the degeneracy of the genetic code. But the existence of the prior art still had a significant effect—it prevented the patentee from receiving claims of much broader scope. In *Deuel*, the court recognized that a short and partial amino acid sequence did not render obvious the DNA encoding the full-length protein.

The report demonstrates awareness that small molecule chemical inventions are never examined with respect to the manner in which the invention was derived.[14] This despite the fact that chemical inventions often have their origin in high-throughput screening not unlike the manner in which some biotech product inventions are made. For almost any field of invention it would be possible to critically dissect how the invention was created if that information were available to the examiner. "To the contrary, patent acquisition does not require any threshold level of effort or ingenuity."[15] The method of making is simply not part of the inquiry.

[12] 51 F.3d at 1558.
[13] 2005 NAS Report at 9.
[14] 2005 NAS Report at 70.
[15] CFMT, Inc. v. YieldUp Int'l Corp., 349 F.3d 1333 (Fed. Cir. 2003).

Nor should Congress change the statute so that it is. As stated previously, the TRIPS agreement requires that no discrimination based on technological field occur. Opening all inventions up to such an analysis would render an already overtaxed USPTO incapable of functioning. The PTO usually doesn't have the information available to it to make such an assessment and, even if it did, the inquiry would be so subjective as to be useless. In the late 80's and early 90's the PTO was operating under just such a standard. Applicants were invited to submit declarations as to why "cloning the gene was difficult." Invoking the competence (or not) of the scientists involved in the experimentation would hopelessly muddle the whole process.

In summary, while AIPLA strongly believes the nonobviousness requirement must be vigorously applied, that does not equate to discrimination against biotechnological inventions. The statutory mandate with respect to obviousness that "[p]atentability shall not be negatived by the manner in which the invention was made" is completely appropriate.

Recommendation 9:

Principal investigators and their institutions contemplating intellectual property protection should be familiar with the USPTO utility guidelines and should avoid seeking patents on hypothetical proteins, random single nucleotide polymorphisms and haplotypes, and proteins that have only research, as opposed to therapeutic, diagnostic, or preventive, functions.

AIPLA Response

AIPLA agrees with the Report that the law on utility in the United States requires at least one specific and substantial practical utility of an invention in order for a patent to issue and that the current USPTO utility guidelines generally reflect this

requirement. AIPLA agrees that patents should not issue on inventions that do not have a specific and substantial utility and that proteins and DNA of unknown function or use may lack such utility. AIPLA further agrees that potential patent applicants should be familiar with the law on utility and refrain from filing for patents on inventions that do not meet the utility standard.

AIPLA is uncertain what is meant by the comment in the Recommendation that implies there can be no utility for proteins that have "only research, as opposed to therapeutic, diagnostic, or preventive, functions." AIPLA opposes a blanket prohibition against patents on research tools. On the other hand, AIPLA agrees that patents should not be granted on materials which themselves are useful only as objects of further research or as tools of research to discover other substances whose utility is not yet known.

Furthermore, it is well settled that invention requires a complete conception of an operative mode of making and using an invention, but does not require actual reduction to practice of the invention. AIPLA opposes an effort to eliminate "constructive reduction to practice" based on the technology involved.

Recommendation 10:

Congress should consider exempting research "on" inventions from infringement liability. The exemption should state that making or using a patented invention should not be considered infringement if done to discern or to discover:

a) the validity of the patent and scope of afforded protection;

b) the features, properties, or inherent characteristics or advantages of the invention;

c) novel methods of making or using the patented invention; or

d) novel alternatives, improvements, or substitutes.

AIPLA Response

The NAS's position in this Recommendation is very similar to that espoused in its previous report on the patent system, "A Patent System for the 21st Century." AIPLA's position on this issue is virtually unchanged. A copy of the AIPLA position on the earlier report is attached as Exhibit B.

AIPLA agrees that scientific research or other experimental activities that allow a patented invention to be better understood, more fully developed, or further advanced should be exempt from patent infringement. Codifying such an exemption, as recommended by the NAS Report, would remove the uncertainty that now exists over the manner in which a patented invention can be used to better understand and/or extend what is patented.

Recommendation 11:

NIH should undertake a study of potential university, government, and industry arrangements for the pooling and cross-licensing of genomic and proteomic patents, as well as research tools.

AIPLA Response

AIPLA agrees that data on pooling and similar mechanisms is needed in the genomics and proteomics arena in order to formulate wise policies. Further, the NIH is well suited for performing such a study. AIPLA believes pooling strategies are worth further study and exploration.

AIPLA knows of an example in the biotech area: A non-assert pledge has been published by Massachusetts Institute of Technology, Max Planck, the Whitehead Institute for Biomedical

Research, and The University of Massachusetts as relates to the siRNA patents by Tuschl. The pledge provides that the patents will not be asserted against research uses.

Also, Dow Chemical Co. and Monsanto Co. have entered into a cross licensing arrangement for genes used in connection with plant herbicide resistance. The stated objective is to provide more products to farmers.

Recommendation 12:

Courts should continue to decline to enjoin patent infringement in those extraordinary situations in which the restricted availability of genomic or proteomic inventions threaten the public health or sound medical practice. Recognition that there is no absolute right to injunctive relief is consistent with U.S. law and with the Agreement in Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement).

AIPLA Response

The Committee acknowledges that it "was unable to find any evidence of systematic failure of the licensing system" and that only "a few cases of restrictive . . . license practices by some companies have generated controversy . . . because of the potential adverse effect on public health." Nevertheless, Recommendations 12 and 13 suggest the need to protect the public health from the patent system. AIPLA disagrees that anything new needs to be done to the current patent system to protect public health. The current patent system has all of the necessary safeguards to address the points raised by the report.

Recommendation 12 appears to have been made in light of the Federal Circuit decision in *MercExchange, L.L.C. v. eBay, Inc.*, 401 F.3d 1323 (2005). This issue was argued before the U.S. Supreme Court. On May 15, 2006 the Court held:

"___ that the decision whether to grant or deny injunctive relief rests within the equitable discretion of the district courts, and that such discretion must be exercised consistent with traditional principles of equity, in patent disputes no less than in other cases governed by such standards. "*Ebay Inc. v. MercExchange, L.L.C.*, 547 U.S. ___, 126 S.Ct. 1837 (2006).

That is the holding of the Supreme Court and the Supreme Court's decision should address any concern raised by Recommendation 12.

Recommendation 13:

Owners of patents that control access to genomic or proteomic based diagnostic tests should establish procedures that provide for independent verification of test results. Congress should consider whether it is in the interest of the public's health to create an exemption to patent infringement liability to deal with situations where patent owners decline to allow independent verification of their tests.

AIPLA Response

The emphasis on the patent owner in this Recommendation is misplaced. A genetic test consists of tangible reagents and materials. Any test, whether patented or not, should be perfected with respect to the actual reagents and materials before it is used to predict diseases in patents. At page 56 of the report the current procedure for quality control of genetic testing is outlined. There are several existing checks on genetic testing (CLIA and FDA). If the genetic test is accurate, independent verification would not be needed. That use can be and is regulated and should address the verification issue raised by the Recommendation. Furthermore, continued testing of reliability and accuracy of an approved test occurs through use and acceptance in the market. The issue of the reliability of a

test, genetic or otherwise, is more appropriate for regulators and should not be addressed by tinkering with the patent system.

AIPLA's Response to Recommendation 10 outlines its position with respect to a research exemption. Note, however, that any exemption would only apply to the issue of patent infringement. It would not exempt one from the requirement to actually purchase the approved test kit or materials. Indeed, it is likely that testing on an approved test, if one were inclined to do such testing, could be accomplished simply by purchasing the test kit or materials. Such a purchase may in and of itself exhaust the patent rights in the test, further negating any need for adopting the NSC's Recommendation.

Exhibit A: Survey Questions for Grant Applications

The following or similar questions can be included in the front of every grant application and proposals scored, in part, based on the answers. The scoring should be weighted sufficiently to strongly encourage compliance with the Guidelines. The Survey questions should be marked Confidential to prevent their dissemination under FOIA, and separated from the grant proposals (once evaluated) to prevent their accidental disclosure.

□ Yes □ No	Have you shared any materials relating to the subject matter of this grant application?
□ UBMTA □ NSLA □ Other □ N/a	Was the transfer of materials made under the Uniform Biological Materials Transfer Agreement (UBMTA) or the NIH Simple Letter Agreement (NSLA)?
□ Yes □ No □ N/a	Have you followed the NIH Guidelines and NIH Best Practices by avoiding reach-through royalties and by limiting exclusive licenses to appropriate fields of use and by ensuring dissemination for research uses?
□ Yes □ No	Are there any patents or patent applications relating to the subject matter of this grant application?
□ Yes □ No □ N/a	Is the technology associated with a grant of rights to a third party?

Exhibit B:

AIPLA'S Response to National Academy of Sciences' "A Patent System for the 21st Century

Recommendation 2:

"Reinvigorate the non-obviousness standard."

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

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

AIPLA Response

The non-obviousness requirement should be applied with vigor. The NAS Report and AIPLA appear to be in complete agreement on this critical point. AIPLA views the non-obviousness requirement as being no different from the other requirements

to secure a valid patent. All requirements for obtaining a valid patent should be applied with equal vigor by both the U.S. Patent and Trademark Office and the courts.

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

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

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

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

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

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

AIPLA takes particular note, as mentioned above, of the fact that NAS does not recommend any change to the statutory standard of non-obviousness as currently expressed in 35 U.S.C. §103. Nothing contained in the NAS Report would, in fact, support such a change. Likewise, AIPLA is opposed to any technology-specific changes to the statutory non-obviousness standard. Indeed, if any change in the statute were to discriminate against

one field of technology vis-à-vis some other, it could implicate the obligations of the United States under the TRIPs Agreement as noted above. AIPLA, therefore, applauds the NAS for its restraint on the issue of possible statutory changes to the non-obviousness standard.

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

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

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

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

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

Finally, if the commentary in the NAS Report is construed to imply that the *O'Farrell* doctrine (*In re O'Farrell*, 853 F2d 894 (Fed. Cir. 1988)) should be the only considerations applied to considering non-obviousness of gene product inventions, then AIPLA must part company with this conclusion. Gene sequence inventions, like all inventions, should have their non-obviousness determined based upon the "subject matter as a

whole" of the claimed invention. This mandates consideration of the traditional criteria for non-obviousness of chemical products (*e.g.*, *In re Papesch*, 315 F.2d 381 (C.C.P.A. 1963)).

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

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

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

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

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

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

would have concluded that any possible policy concerns over gene patenting are being adequately addressed by the courts.

Recommendation 5:

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

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

AIPLA Response:

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

The NAS Report starts with the premise that:

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

AIPLA wholeheartedly agrees with the NAS Report's assessment of the principal goals of the patent system. The patent system, in the words of the Constitution exists "to promote the progress of the useful arts." Such progress means that the patent system, functioning properly, will advance social welfare through encouraging both innovation and dissemination of knowledge. Fostering more innovation and greater dissemination of technical knowledge should instruct the policy choices that are made in crafting patent laws.

It is with this philosophic understanding of the patent system's role that AIPLA endorses the NAS Report's call for a statutory experimental use exemption. Some exemption for experimentation on patented inventions must be part and parcel of an effectively functioning patent system. [16]

The exemption is inherent to a properly functioning patent system at least where experimentation is required to understand *what is patented, whether the patent is valid, what basic properties or characteristics the patented invention might have, and to improve upon the invention*. In brief, a patent system

[16] 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).

operates in an appropriate and balanced fashion when what is patented is reserved for the inventor to exclusively commercialize and given to the public to both further examine and improve upon. The inventor need not be denied the former when the public has a limited exemption to accomplish the latter.

The NAS Report cites the recent Federal Circuit decisions in *Duke v. Madey* and *Integra v. Merck KGaA* and notes that these decisions have created an undesirable degree of uncertainty over where the line is to be drawn as between the inventor's exclusivity in commercialization and the public's right to engage in legitimate experimentation.[17] The concern has not been diminished by suggestions that the "experimentation" issue is a *deminimis* one because patent licenses for any needed experimentation are generally available for nominal sums. Indeed, the evidence suggests the contrary may in fact be the case. In any event, failing to have a definitive provision in the patent law exempting experimentation can create many potential adverse consequences, including threatened patent litigation, complicated licensing negotiations, efforts to secure compensation based upon the fruits of any experimentation (including "reach-through" royalties), royalty stacking, and delays in starting experiments until patent issues can be resolved.

Thus, AIPLA endorses the NAS Report's recommendation that a legislative solution be expeditiously sought. AIPLA is developing such a legislative solution that is discussed in greater detail

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

below. AIPLA is endeavoring to craft a narrow, statutory exemption for experimental use for a patent invention that would not impinge upon an inventor's exclusive right to commercialization, but would open the way for an appropriate range of experimentation on the patented invention.

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

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

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

AIPLA has specifically endorsed legislation which would serve to exempt from infringement research that is directed to any of the following activities: (1) evaluating the validity of the patent and the scope of protection afforded under the patent; (2) understanding features, properties, inherent characteristics or

advantages of the patented subject matter; (3) finding other methods of making or using the patented subject matter; and (4) finding alternatives to the patented subject matter, improvements thereto or substitutes therefor. Such a proposal, although narrowly crafted, will provide a sufficient safe harbor for experimentation to encompass all the activities that NAS believes should be exempt from the scope of the patent rights.

The proposal advanced by AIPLA is based upon international precedents. An exemption for experimentation not only exists outside the United States, but also is recognized as part of the statutory patent law.[18] Its continued absence from U.S. patent law could have the unintended effect of making it more expedient to conduct certain types of experimental work in foreign countries where the threat of patent infringement litigation would not exist. Promoting the progress of the useful arts *outside the United States* should not be encouraged simply because of the lack of a comparable provision in U.S. patent law.

Finally, the codification of an experimental use doctrine is especially important today given the broad reach of the patent law to "everything under the sun that is made by man." *Diamond v. Chakrabarty,* 447 U.S. 303, 309 (1980). Because of the patent eligibility of all man-made products and processes, the doctrine assures that products discovered in nature and patented as

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

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

See Section 402, H.R. 5598, 101st Congress, September 12, 1990.

man-made compositions, *e.g.*, isolated and purified genetic material, hormonal substances, and organisms, can nonetheless be fully studied and examined during the patent term, whether for purposes of improving or designing around the patented subject matter.

Hence, the enactment of the statutory "experimental use" exemption recommended by NAS Report would reduce and eventually remove the substantial uncertainty over what is and is not an infringing use of a patented invention in a manner that would demonstrably promote progress in the useful arts, while assuring that the United States would remain a prime location for the experimentation required to do so.