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President

**Re: Request for Comments on Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility, 70 FR 75451-2, & 71 FR 34307-8**

The Association of American Medical Colleges appreciates this opportunity to comment on the interim guidelines referenced above that will assist patent examiners in determining whether patent applications are directed to eligible subject matter under Federal patent law. The AAMC makes these comments on behalf of our member organizations, including all 125 U.S. allopathic medical schools, nearly 400 teaching hospitals, and 94 academic medical societies. Our members include the nation's leading performers of biomedical and health sciences research and are drivers of innovation and new biomedical technologies. Many hold extensive patent portfolios. Above all, these institutions are devoted to the improvement of public health through education and the discovery and translation of new knowledge in the biomedical and health sciences. Our comments on the draft interim guidelines focus on their treatment of eligible subject matter under 35 U.S.C. section 101.

Patent protection is essential to much development and innovation in medicine, especially in the successful realization of new biopharmaceuticals and medical devices. However, the academic medical community also recognizes that patent protections must not inappropriately limit access to fundamental scientific or medical knowledge, or to understanding of the natural principles underlying human health and disease.<sup>1</sup>

Historically, the courts, and most notably the U.S. Supreme Court, have sought to ensure that patent protections be extended only to useful, novel, non-obvious inventions—machines, manufactures, compositions of matter, or processes—that may well employ scientific or technical principles, but that patent exclusivity should never extend to laws or principles of nature, natural phenomena, or abstract ideas themselves. These “judicial exemptions” under section 101 are entirely in keeping with, and necessary to accomplish, the Constitution’s mandate to promote progress in science and technology. Last month,

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<sup>1</sup> This argument was central to the concerns raised by the American Medical Association, the AAMC, and other medical organizations as amicus curiae to the U.S. Supreme Court in *Laboratory Corporation of America (LabCorp) v Metabolite*, December, 2005.  
<http://www.aamc.org/advocacy/library/research/corres/2005/122305.pdf>

Justice Breyer, joined by Justices Stevens and Souter, concisely and eloquently reaffirmed the rationale for the distinctions in patent eligibility under section 101:

Patent law seeks to avoid the dangers of *overprotection* just as surely as it seeks to avoid the diminished incentive to invent that underprotection can threaten. One way in which patent law seeks to sail between these opposing and risky shoals is through rules that bring certain types of invention and discovery within the scope of patentability while excluding others [emphasis added].<sup>2</sup>

Patents on, for example, natural laws or principles are inherently overbroad and would preempt innovation. This crucial point is not sufficiently conveyed in the draft guidelines. In Section IV A on the breadth of the controlling law, the draft emphasizes the Supreme Court's statement in *Diamond v Chakrabarty*<sup>3</sup> that Congress intended section 101 to include "anything under the sun that is made by man." The phrase is repeated in several places, noting its legislative history of the 195[2] Patent Act. The draft then quotes at length the Federal Circuit's decision, *In re Alappat*:

The use of the expansive term "any" in section 101 represents Congress' intent not to place any restrictions on subject matter for which a patent may be obtained beyond those specifically recited in section 101 and the other parts of Title 35.... Thus, it is improper to read into section 101 limitations as to the subject matter that may be patented where the legislative history does not indicate that Congress clearly intended such limitations.<sup>4</sup>

However, the Federal Circuit's interpretation in *Alappat* appears at odds with the *Chakrabarty* decision itself.<sup>5</sup> In *Charkrabarty*, the Supreme Court relied heavily not on legislative but on case law precedent, in its statements strongly supporting limitations on patentable subject matter. For example:

This is not to say that section 101 has no limits or that it embraces every discovery....Einstein could not patent his celebrated law that  $E=mc^2$ ; nor could Newton have patented the law of gravity. Such discoveries are "manifestations of...nature, free to all men and reserved exclusively for none."<sup>6</sup>

The case law precedent extends over more than 150 years, including for example, *LeRoy v. Tahtam* (1852), *Mackay Radio & Tel. Co. v. Radio Corp. of Am.* (1939), and *Funk Bros. Seed Co. v. Kalo Inoculant Co.* (1948). These distinctions have been reaffirmed by the Supreme Court in *Charkrabarty*, as noted above, and *Diamond v. Diehr* (1981).

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<sup>2</sup> *LabCorp v Metabolite*, docket 04-607, 2006; dissent to dismissal on improvident grounds.

<sup>3</sup> 447 U.S. 303 (1980).

<sup>4</sup> Interim guidelines, p. 12, quoting *Alappat*, 33 F.3d at 1542, 31 USPQ2d at 1556.

<sup>5</sup> This argument is described at length by the Public Patent Foundation as amicus curiae in *LabCorp v Metabolite*, . [http://www.pubpat.org/assets/files/AmicusBriefs/PUBPAT\\_LabCorp\\_SCt\\_Brief.pdf](http://www.pubpat.org/assets/files/AmicusBriefs/PUBPAT_LabCorp_SCt_Brief.pdf)

<sup>6</sup> *Chakrabarty*, quoting *Funk Bros. Seed* 333 U.S. 127 (1948).

Perhaps one of the more famous cases—and a landmark decision underscoring the doctrine that patent law should not preempt subsequent innovation—is the Court’s 1853 rejection of a claim in Samuel Morse’s patent on the electro-magnetic telegraph. While Morse’s first seven patent claims appropriately included the apparatus and process for his telegraph, the eighth claim embraced the use of electric current “however developed” for telegraphy:

The Court recognized that Morse’s eighth claim, if allowed, would effectively grant Morse ownership of the idea of using electric current to print at a distance...Claim 8 would thus cover the work of “some future inventor” who, “in the onward march of science, may discover a mode of writing or printing at a distance by means of the electric or galvanic current, without using any part of the process or combination set forth in the plaintiff’s specification.”<sup>7</sup>

Patent examiners should remain confident that long-standing judicial exemptions under section 101 remain strongly in force, as reaffirmed in the Breyer-Souter-Stevens opinion (which was a minority “dissent” on a procedural question, but might well reflect the majority in substance, as it so accurately recites prior Supreme Court rulings).

Question (4) of the *Federal Register* notice asks, “What role should preemption have in the determination of whether a claimed invention is directed to a practical application of a 35 U.S.C. 101 judicial exemption?” We believe that the extent to which follow-on innovation is preempted by a patent claim should play a decisive role, as in *O’Reilly v Morse*, in determining the extent to which that claim falls within a 101 judicial exemption. The Association believes that the final PTO guidelines should underscore the legal and economic policy rationale for the judicial exemptions under section 101, as the current draft does not, given the critical role such exemptions play in assuring the effectiveness of the patent system. On balance, and notwithstanding its rhetoric, we believe the draft guidelines do provide comprehensive and systematic information to help patent examiners make such determinations.

An instructive example of our concern is claim 13 of the patent<sup>8</sup> currently under challenge in *LabCorp v Metabolite*, which unlike the antecedent claims that recite the steps of a novel process, embraces the abstract concept of correlating blood homocysteine levels and possible deficiency in B vitamins, a factor in cardiovascular and other disorders. As upheld by the lower courts, the claim provides the patent holder and licensee the right to exclude others from performing this correlation, no matter what methods are used to measure blood homocysteine levels. A physician who merely performs the mental act of correlating a test result with the vitamin deficiency should not be liable for patent infringement, nor should a laboratory testing company that makes known the availability of this diagnostic measurement be liable for inducement to infringe. As the AMA, the AAMC and other medical organizations noted in their brief

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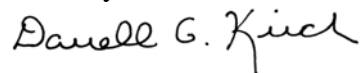
<sup>7</sup> The quotation is from the amicus brief of the AMA et al., op cit.

<sup>8</sup> Patent no. 4,940,658.

supporting certiorari, "A physician who learns - from the medical literature, colleagues, continuing medical education, or other public sources - of the naturally occurring association between homocysteine and vitamin deficiency cannot put that knowledge out of mind. Knowledge of basic scientific facts such as a correlation between a test result and a possible disease state is essential to the practice of medicine."<sup>9</sup>

As medical science and practice together enter the still dawning "Age of Genomics," progress in both will increasingly require unfettered access to and understanding of information describing a vast number of correlations and associations between genomic variations and diverse pathological phenotypes. The patent system that will best promote this research and thereby further the national priority of improving the health of the public is one that unambiguously fosters free exchange of fundamental scientific and medical information by scrupulously respecting the boundaries of eligible subject matter, and one that reserves the privileges of appropriation and exclusivity for truly novel, non-obvious, and useful innovations.

Sincerely,

A handwritten signature in black ink that reads "Darrell G. Kirch". The signature is written in a cursive style with a prominent initial 'D' and 'K'.

Darrell G. Kirch, M.D.

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<sup>9</sup> Quotation also from the AMA et al. brief, op cit.