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To: AB93Comments
Subject: "Changes to Practice for the Examination of Claims In Patent Applications" (Fed. Reg. Vol. 71 No. 1 page 61, Jan. 3, 2006), and "Changes to Practice for Continuing Applications, Request for Continued Examination Practice, and Applications Claiming Patenta

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MDMA

MEDICAL DEVICE MANUFACTURERS ASSOCIATION
Innovation Today For Better Health Care Tomorrow™

May 3, 2006

The Honorable Jon W. Dudas
Undersecretary of Commerce for Intellectual Property
and Director of the U.S. Patent and Trademark Office
Mail Stop Comments – Patents
Commissioner for Patents
P.O. Box. 1450
Alexandria, VA 11313-1450

Attn: Robert W. Bahr
Senior Patent Attorney
Office of the Deputy Commissioner for Patent Examination Policy

Electronically submitted to: AB93Comments@uspto.gov

Dear Under Secretary Dudas:

On behalf of the Medical Device Manufacturers Association (MDMA), a national trade association representing the innovative sector of the medical device industry, I appreciate the opportunity to comment on the Patent Office rules proposed by the U.S. Patent and Trademark Office ("Patent Office") on "Changes to Practice for the Examination of Claims In Patent Applications" (Fed. Reg. Vol. 71 No. 1 page 61, Jan. 3, 2006), and "Changes to Practice for Continuing Applications, Request for Continued Examination Practice, and Applications Claiming Patentably Indistinct Claims", (Fed. Reg. Vol. 71 No. 1 Page 48, Jan. 3, 2006).

We understand that several life-sciences based organizations have submitted comments in reaction to these proposed rules. The potential negative impact is very similar across our extremely research-driven disciplines: the rule changes will cause significant and costly administrative burdens on patentees, decrease the level of protection for new inventions, thereby decrease the value of new inventions, decrease the level of investments in the industry, negatively influence industry's willingness to engage in fundamental R&D and quash innovation to the extent there is a perception by industry that IP rights are more onerous and costly to obtain.

Our purpose for submitting this letter, therefore, is twofold: (1) to strongly reaffirm and support the written comments provided by BIO and others focused on life sciences research and development, and (2) to point out particular characteristics present in the medical device sector that make application of these rules particularly problematic.

MDMA'S Background

MDMA is a national trade association that represents independent manufacturers of medical devices, diagnostic products and healthcare information systems. MDMA was created in 1992 by a group of medical-device company executives who believed that the innovative and entrepreneurial sector of the industry needed a strong and independent voice in the nation's capital. Our mission is to promote public health and improve patient care through the advocacy of innovative, research-driven medical device technology.

General Comments

The founders of the United States gave Congress the power to promote the "progress of Science and useful Arts, by securing for limited times to Authors and Inventors the exclusive right to their respective writings and discoveries." Accordingly, our government implemented a patent system that drives innovation and advances research and development to benefit society. The Patent system, in turn, stimulates job creation while bringing about new products and services. In the medical device industry, companies have been able to continually increase the quality of diagnosis and care of patients because of the availability of robust patent protection for their innovations. The medical device industry is one of the bright aspects of our economy and one of the biggest exporters.

The Patent Office's proposed rules are laudably intended to address patent application quality, pendency and backlog. The proposed rule changes, however, will severely limit the ability of medical device companies to secure appropriate patent protection on their inventions in exchange for the disclosing the technology to the public – the quid pro quo in the patent system. Without that patent protection, medical device companies will not be able to attract financing for products when the scope of protection is left diminished or ambiguous. Moreover, MDMA believes these rules, if adopted, will likely increase both the backlog and pendency of applications. The cumulative effect of these outcomes will be to chill medical device innovation which is characterized by a highly iterative and fast-paced product development process.

The Proposed Rules Will Negatively Affect The Scope of Patent Protection

The medical device industry is largely dependent upon patents. A medical device company starts with an idea. That idea coupled years of work by engineers, marketing, lawyers, etc. may ultimately result in a viable medical product. As a medical device company develops its idea into a clinical and commercial product, different aspects of the original idea or invention come to light. For example, a medical device company may decide that a particular sub-component of the broader original idea, fully supported in the original application, is going to be the key portion of the commercial product. The ability to obtain specific claims on that sub-component, years after already seeking claims in earlier application for other aspects of the original idea, is paramount in protecting the invention in the marketplace and obtaining investments.

The Proposed Rules Will Negatively Affect Investments

A medical device's company obviously needs money to support its product development. In order to justify an investment from an individual or corporation in this development, a medical device company typically relies heavily on patents. Indeed, investors in the medical device

sector expect a patent portfolio that protects the idea on several different levels and directions before funding the development. Moreover, investors expect that a medical device company will be able to modify the patent claims it seeks as different aspects of its original idea manifest themselves during development. These expectations are a necessary part of the equation an investor uses to determine the likelihood of making money on the investment. Because of these expectations and the fierce competition for investment dollars, medical device companies typically file for patents as early as possible and as often as possible.

The Patent Office's proposed rules, however, would make it difficult for medical device companies to meet these investor expectations and thus gain the funding needed to bring innovative and live-saving technologies to fruition. Without the potential for strong protection for medical inventions, investors will go elsewhere to spend their dollars.

The Proposed Rules Will Increase Costs

The proposed rules regarding continuation practice and the limit on the number of claims to be initially examined will result in substantial and immediate increased costs. Specifically, medical device companies seeking patent protection will have to expend time and money working with attorneys to formulate new prosecution strategies in light of the new changes.

The Proposed Rule Changes Will Increase The Uncertainty Of Patents

The Patent Office's rule changes are likely to be challenged in the courts for years thereby increasing the degree of uncertainty for patent applicants. During the period of uncertainty, while the legal system addresses the legality of these rules, applicants will be required to follow the rules. As argued above, , a medical device company will likely obtain a lesser scope of patent protection for its invention under the proposed rules. Indeed, many company may forgo seeking patent protection for aspects of its inventions altogether. Without the ability to obtain robust patent protection, smaller medical device companies would be crippled in their ability to obtain financing while at the same time striving to adequately protect their inventions. The protection provided by initial patents to smaller, newer medical device companies is often their most valuable and only asset. These initial patents are also the standard by which venture capitalists evaluate investment candidates.

The Patent Office's Authority To Adopt Proposed Changes

MDMA believes, as other commentators do, that the Patent Office may lack the authority to adopt such sweeping rules. For example, in the proposed § 1.78(d)(1), the Patent Office would limit applicants to a single continued examination application unless an applicant can show, to the satisfaction of the Patent Office, why any amendment, argument, or evidence to be presented in a second or subsequent continued examination filing could not have been previously submitted. Though the Director of the Patent Office certainly has the authority to "...establish regulations not inconsistent with law..." pursuant to 35 U.S.C. § 2(b)(2)(D), the proposed rule directly undermines §§ 120, 121, and 365(c) of Title 35.

Sections 120, 121, and 365(c) each provide for the filing of continuing applications. Each section sets forth certain conditions that, when met, mandate that an application "shall have the

same effect" or "shall be entitled" to the benefit of the earlier filing date of a parent application. These statutory provisions do not give or suggest any basis for any authority of the Patent Office to add additional requirements for obtaining the benefit of the earlier filing date in continuation applications. Thus, the Patent Office's rules would take away a right given to applicants by Congress.

Case law suggests that the Patent Office has no authority to place any such restrictions on the number of continuing applications originating from an original application. See In re Henriksen, 399 F.2d 253, 261 (C.C.P.A. 1968); In re Hogan, 559 F.2d 595, 603-05 (C.C.P.A. 1977). Both cases find that any restriction on the number of continuing applications cannot be imposed by the Patent Office. Rather, the cases conclude that it is an issue for the Congress to decide.

The Patent Office may contend that its proposal does not run afoul of the statutory provision or judicial precedent because it only places an additional requirement on continuation practice rather than place an absolute limit on the number of continuing applications. Such a contention, however, would be simply playing semantics. The practical and intended effect of the proposed rules would be to limit the number of continuing applications. This effect unjustifiably denies applicants a right granted by statute.

Conclusion

MDMA appreciates the opportunity to provide comments on the proposed rules. The proposed rules will not result in the Patent Office's stated objectives. Rather, the new rules would decrease the value of new inventions and influence industry's willingness to engage in fundamental R&D by making the process more costly, uncertain and burdensome. MDMA certainly appreciates the challenges before the Patent Office and recognizes the need for improvements to the patenting process. But it is vital that any change to the system does not disproportionately affect one sector over another. Given that these proposed changes are dramatic t, MDMA recommends that the Patent Office not implement the proposed rules, but rather recommend them to Congress and allow Congress the opportunity to consider changes of this magnitude and engage industry and the public in the process.

Respectfully Submitted,

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