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From: Lawrence Linn [mailto:linnl@aradigm.com]
Sent: Thursday, May 04, 2006 7:33 PM
To: Clarke, Robert
Cc: AB93Comments
Subject: Re: Comments on Proposed Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims, Notice of proposed rulemaking

Dear Mr. Clarke:

We submitted yesterday (05/03/06 11:32 PST) our comments from Dr. V. Bryan Lawlis on the proposed changes via Internet mail as described in the posting directions to AB93Comments@uspto.gov , yet we do not see that the comments have been posted to the Public Commentary section of the website. This should appear under the "**B. Corporations**" sub-heading. Could you please advise me of the status of the posting or if any additional steps are necessary.

For convenience, I have attached a copy of our comments in .pdf format.

Thank you in advance,

-Lawrence Linn

May 3, 2006

Re: Proposed Changes To Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims.

In regard to the proposed changes described in 71 Fed. Reg. 48 (January 3, 2006), I and others at our organization believe that these changes, should they be enacted, will needlessly obstruct innovation in the biotechnology, biopharmaceutical, and drug delivery industries by seriously limiting the ability of innovators to obtain adequate patent protection on their inventions and also by escalating the costs of securing patent protection.

While we wholeheartedly agree with the overall intention of USPTO to "…become more efficient, to ensure that the patent application process promotes innovation, and to improve the quality of issued patents", we are convinced that the proposed changes, should they be enacted, will *not have the intended effect* but rather will create a cascade of adverse consequences for both patentees as well as the patent office. We believe that the solution for addressing the "backlog of unexamined applications" is internal to the USPTO and not to place increasingly heavy and overly burdensome restrictions on the ability of applicants to freely, fully, and flexibly conceive and further develop their intellectual property.

We recognize the need for patent reform, but the way in which it is implemented is crucial. It has certainly been the subject of much debate in Congress. However, the USPTO is attempting to deal with its inefficiencies and avert criticism for the quality of its production by restricting the very features of patent applications (continuations, CIPs, RCE's, and claims) that are crucial to the flexible development of strong intellectual property, and provide an ongoing source of critical intellectual capital. Patent rights are critical to all industries but are particularly critical to start-up ventures, technology-based companies, and a broad array of small businesses. In the pharmaceutical industry in particular, smaller companies are to a large part driving the innovations that will make future improvements in health care possible.

The proposed rules includes a limitation of a single continuation application. Particularly in the highly complex, pioneering world of biotechnology, drug discovery, and medical devices, inventions by necessity evolve over time as new therapeutic applications are discovered, refinements to formulations or molecular entities become apparent, or continually improved methods and techniques of treatments and drug delivery are found. Often the optimum chemical structure or delivery regimen can only be determined through extensive clinical testing that this completed after a patent application receives its first examination. A single continuation application does not provide an adequate opportunity nor the flexibility to secure claims for an invention disclosed in a parent patent application. Such a policy will potentially stifle the enterprise of innovation, as more potential innovators rely on trade secrets rather than risk disclosing information, or avoiding investments all together, for which there is no guarantee of protection.

In the biopharmaceutical industry, the drug discovery and testing process and the eventual approval of a therapy or a drug delivery device is a notoriously long-term affair that occurs only after years, frequently a decade or more, of very heavy investment. The looming possibility of

being unable to secure and maximize important patent protection because of severe limitations placed on claims or the ability to file continuations would undermine the industry.

Additionally, beyond the common use of allowing an innovator to evolve the claims of an evolving technology, continuation applications make it possible to partition highly complex and integrated inventions into sub-parts, as are common in the medical device industry or as may be found in the area of immunologic sciences or molecular biology, which can potentially yield enormous healthcare benefits into the future; indeed, the most adverse consequences of the proposed changes would impact applications involving science & technology where the practical value of inventions may not be realized until some years later.

Without adequate patent protection in place, companies cannot attract investors and without investors healthcare products cannot be developed. Obtaining funding can take quite a lot of time -- especially in our high-risk, expensive, and research-intensive area. High quality patent rights and their accompanying exclusivity also are critical to the position of smaller pharmaceutical companies in the business negotiation process, the very companies that will drive many of the innovations that will lead to future improvements in health care, including better outcomes, higher qualities of life, and longer life spans.

If the current continuation practice is changed pursuant to the current rule changes proposed by the USPTO, it will be substantially more difficult for companies to obtain patent protection that truly protects the innovations most likely to improve patient outcomes. This will slow investments which will ultimately impact the economy and decrease the amount of new and innovative products brought into the marketplace. In perhaps the worst possible potential outcomes, companies will be forced to clinically test and market products that are not the best embodiments for curing patients with minimal side effects, but rather those that were the best embodiments known at the time the patent was filed.

The tactics or workarounds that patentees will be forced to resort to in the wake of any such changes (e.g., filing numerous initial patents covering every conceivable embodiment or clogging the Board of Patent Appeals with appeals) would invariably have the effect of badly defeating the intended purpose; the patent office work load would surge even more and push up costs for all parties involved.

The USPTO is an administrative agency chartered to serve the public under the Department of Commerce and as such it should never lose sight of its primary obligation to the public or its vital role in the health of the economy. The proposed changes would not serve benefit of industry, the USPTO, or ultimately the public. I urge you to reconsider these proposed changes.

Sincerely,

V. Bryan Lawlis, Ph.D.
President and Chief Executive Officer
Aradigm Corporation
Hayward, CA