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**From:** Licad, Esperanza [mailto:Esperanza_Licad@chiron.com]
**Sent:** Wednesday, May 03, 2006 9:54 PM
**To:** AB93Comments
**Subject:** AB93 Comments from Novartis Vaccines and Diagnostics, Inc.

Dear Sirs,
Please find attached in pdf format our comments for your attention. Please acknowledge safe receipt.

Best regards,

**Esperanza Licad**
**On behalf of Alisa A. Harbin**
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Office of the Deputy Commissioner for Patent Examination Policy
Mail Stop Comments-Patents
Commissioner for Patents
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May 3, 2006

Gentlemen:

These comments are presented on behalf of Novartis Vaccines and Diagnostics, Inc., formerly known as Chiron Corporation, relating to the United States Patent & Trademark Offices Notice of proposed rule making entitled "Changes to Practice for Continuing Applications . . . " published January 2, 2006 at 71 Fed. Reg. 48. Novartis Vaccines and Diagnostics, Inc. opposes the adoption of the proposed rules.

Under the proposed rules, an applicant will only be entitled to file one continuation application from a single utility filing. Any additional continuation applications are subject to the applicant making the requisite showing: that the amendment, argument, or evidence that the claims could not be submitted earlier.

The U.S. PTO has stated that the proposed rules are needed to reduce application backlog and pendency times. In addition, according to the U.S. PTO, the new rules would reduce "submarine patents" and give the public more effective notice of claim scope.

Adoption of the proposed rules would be devastating to the biotechnology and pharmaceutical industries while failing to significantly impact backlog/application pendency and public notice function of applications.

The proposed rules will cripple the biotechnology/pharmaceutical industry's ability to protect their innovations in a commercially meaningful manner. Ultimately, adoption of those proposed rules would discourage investment in research and development of new biotechnology and pharmaceutical products vital for national and international health and welfare. That result is contrary for the reasons that the U.S. patent system exists: "to promote The Progress of Science and useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their respective . . . Discoveries." U.S. Constitution, art. I, sec. 8.

Moreover, the proposed rules will disproportionately impact the biotechnology and pharmaceutical industries. Limiting continuation practice might have minimal effect on the ability for the electrical, software, and mechanical industries to protect their intellectual properties. However, with the biotechnology/pharmaceutical industries' long product cycles and high development costs, the inability to obtain appropriate patent protection from later filed continuations could be debilitating.

Continuation practice is a right established by statute. 35 U.S.C.§ 120. The PTO cannot abrogate a right granted by statute. Congress, not the PTO, should decide whether to change continuation practice.

Also, based on the U.S. PTO's own presentations, restricting biotechnology and pharmaceutical continuation practice will have only a small effect to backlog and pendency.

For a number of reasons, U.S. patent law and U.S. PTO practice render the proposed rules particular unfair to patentees.

The U.S. PTO has also stated that the proposed rules would prevent abuse of the continuation and practice and "submarine patents." However, the twenty-year term and application publication provide for adequate public notice and have eliminated "submarine patents." Other changes to the patent laws and U.S PTO practice could effectively address those concerns.

Biotechnology/Pharmaceutical industry product development cycle/commercialization issues

Unlike other industries, such as electronics and software, a biotech or pharmaceutical product often take many years and hundreds of millions of dollars before commercial launch. Product development is also very high risk compared to most other industries: many products never successfully reach the market even after years of work and millions of dollars of investment.

Also, given the enormous complexity of biotechnology and the long development times, which aspect of an invention disclosed in application will become the commercial embodiment is often unknown four, five, or even ten years after the applicant files an application.

For a company to embark on such a long, expensive, and risky product cycle, it must have some assurance that it will be able to have some exclusivity in the market. Patents are critical for that type of protection. If a competitor could simply copy the innovator company's work and then market the same or similar product without undertaking such large costs and risks, biotechnology/pharmaceutical companies will not continue to invest in research and development.

1. The Proposed Rules

- According to the proposed rules the "second and subsequent continued examination filings, whether a continuation application, a continuation-in-part application, or a request for continued examination, be supported by a showing as to why the amendment, argument, or evidence presented could not have been previously submitted."
- The proposed rules further state that "when an applicant (or assignee) files multiple applications with the same effective filing date, a common inventor and overlapping disclosures, the Office will presume that the applications contain patentably indistinct claims." In such situations, therefore, the U.S. PTO proposes that applicants "include either an explanation of how the claims are patentably distinct, or a terminal disclaimer and an explanation of why there are patentably indistinct claims in multiple applications."

2. Proposed rules and biotechnology innovation

The proposed rules will severely limit the ability of biotechnology and pharmaceutical companies to adequately protect their products.

- Biotechnology related inventions typically take years to commercialize. The limited continuation practice could limit the ability to have claims that are reasonably directed to the final format of the invention. The availability of continuation applications years after the priority filing is critical to being able to claim embodiments disclosed in those early filings that later turn out to be commercially relevant.
- Biotechnology science and inventions are often very complex. Continuations and numerous claims are needed to fully cover such complex inventions.
- As noted above, biotechnology research is very expensive in part because of the long development times and high risk of failure. In order to raise the capital to see new products to market, biotechnology companies rely upon their intellectual property as their most valuable asset to demonstrate to venture capital firms and larger partner biotech/pharmaceutical companies that their investments will see a return. Indeed, for most start-up biotechnology companies, their only asset is their intellectual property. Enacting the proposed rules will hamper their ability of such start-ups to protect their inventions, raise venture capital, or partner with pharmaceutical companies or larger biotech companies.

3. Congress is the proper forum for making the changes proposed by the rules

Congress, and not the PTO, has authority to change continuation practice.

- The U.S. PTO does not have the authority to refuse to accept a continuation application. 35 U.S.C. 120 states an application may claim priority to an earlier application. Nothing in the language suggests that the U.S. PTO has any discretion to decide whether to examine the application, only whether to respect

the priority claim. The U.S. PTO cites to 35 U.S.C. 2 as providing authority for it to decide whether or not to examine an application. However, that general provision does not trump Congress's specific statement in 35 U.S.C. § 20.

- Last year, Congress considered the changes similar to the proposed rules in H.R. 2765. H.R. 2795 provided express language that granted the U.S. PTO Director the right to limit the circumstances under which a continuation application may be applied.
- The House IP Subcommittee held hearings on An Amendment in the Nature of a Substitute. This substitute H.R. 2795 bill no longer included the language granting the Patent Office Director the right to limit the circumstances under which an applicant can file a continuation application.

Therefore, Congress clearly does not believe that the U.S. PTO was granted this ability to make such a change in PTO practice.

4. The proposed rules will do little to lower backlog and pendency

A major reason set forth by the U.S. PTO for the proposed changes is to reduce backlog and pendency. However, the proposed changes will only make a small dent.

- James Toupin, General Counsel for the U.S. PTO, presented a slide entitled "Pendency Reduction Action Plan at the February 2006 town hall meeting in Berkeley. That slide showed the projected lengths of application pendency from 1982 to 2010. The length of pendency from 2006 to 2010 were projected on the following: (1) no changes are made to current procedures and hiring at the U.S. PTO; (2) 1000 new examiner hires and low attrition; and (3) adopting the proposed continuation and claim rules in addition to 1000 new examiner hires and low attrition. There was relatively small change in the curves between option (2) and option (3). Therefore, the proposed rules will not have a significant impact on backlog and pendency.
- Another set of slide presented by Mr. Toupin at that town hall shows that TC1600 (biotechnology) has highest percent of continuations. However, the TC1600 has a much shorter pendency than other art units, such as TC2600 or TC3600.
- The U.S. PTO has asserted that without the continued examination filings, it "could have issued an action for every new application received in 2005 and reduced the backlog by issuing actions in 35,000 older cases." But this ignores the fact that only a small minority is "abusing" the continuation examination filing procedure and therefore little efficiency is to be gained if applied fairly. Even if the U.S. PTO acted to stop all continued examination filings, given the narrow restriction practice in the TC1600 group is unlikely to reduce the backlog.
- The U.S. PTO's cited examples of abuses amount to a small fraction of those using the continuation process. Specifically, the U.S. PTO cites to applicants submitting literal translations of foreign applications that are corrected through multiple rounds of Office Actions and response, which common sense dictates must be a small minority, and to applicants which misuse the process to keep applications pending until the relevant industry develops the technology, which the U.S. PTO admits represents a small minority. Thus, the U.S. PTO is

proposing to enact rules to that would adversely impact those who are using continuation practice for bona fide purposes to prevent a small minority from misusing the practice.

- The U.S. PTO could reduce backlogs in TC1600 by reforming the currently burdensome restriction practice. Currently, many TC1600 are subject to a multiplicity of restriction requirements.

5. The proposed rule would unfairly penalize applicants in to accommodate changes in PTO practice, case law, and competitive landscape

The proposed rules will have unfair consequences for applicants.

- There are many legitimate reasons for an applicant to file continuing applications. For example, an applicant, particularly a biotech applicant, is often trying to disclose and claim many aspects of a complicated invention. Often, an applicant will accept relatively narrow claims allowed by an examiner to pursue broader claim. Or, perhaps a new piece of prior art is has recently been identified that should be addressed by a continuation application.
- The U.S. PTO has acknowledged that continuation practice is abused by only a small number of applicants. It is unreasonable for the U.S. PTO to respond to those exceptions by penalizing legitimate use of continuation practice.
- Limitation on the continuation practice also impairs the ability of the patentee to accommodate changes in the interpretation of patent law from legal jurisprudence. For example, cases such as Eli Lilly have clarified the written description requirement in a way that has dramatically altered the way that a biotech patent attorney claims inventions. Cases such as Festo have altered both how patent attorneys claim inventions and how they prosecute applications. Particularly in biotechnology, there are many unanswered questions about enablement, utility, and written description. The U.S. Court of Appeals for the Federal Circuit might not take up those issues until years after an application has been filed and examined.
- The new rules would limit the ability to copy claims for interference purposes. It is conceivable that claims to interfering subject matter would not be presented until after one party had exhausted its allotment of continuations and has no cases pending. That party would be unable to copy claims to provoke an interference although their patents disclosed the invention and they were, in fact, the first to invent.
- Including RCE's in attempts to limit continuation practice raises additional concerns. Given the limited time permitted a U.S. PTO Examiner to review responses after a final Office Action and the limited ability to have amendments and declarations entered after a final office action, an applicant is essentially limited to making one response and one set of amendments.

- The retroactive application of the proposed changes unfairly and adversely affects applicants who have been prosecuting applications in good faith under the present rules. Many applicants would not have been willing to cancel broad claims in order to have narrower claims allowed because they would not want to have used up their one free continuation application.
- The proposed rules allow an applicant to file additional continuation applications an applicant can show that the amendment, argument, or evidence that the claims could not be submitted earlier. Making that showing will be an additional burden on an applicant and generate more work for the examiners that review those showings. Also, we are concerned about the lack of consistency among examiners reviewing the showings for adequacy. There are no standards yet for what constitutes an appropriate showing that would allow an applicant to file additional continuation applications.
- The reality is that quality and fairness of an examination varies considerably from examiner to examiner. Continuation practice allows the applicant more flexibility in responding to examinations of lower quality. Finally, considering the proposed rules on limiting continuation practice together with the proposed rules with limiting the number of claims for examination would place biotechnology applicants in a very difficult position. They will be limited to the number of claims that can be examined in an application as well as the number of applications that could be filed to an invention.

6. The proposed new rules do little to reduce "uncertainty" or "submarine patents"

The U.S. PTO has stated that the new rules will help reduce "submarine patents" and promote the notice function of patents. However, the new rules will have only a limited impact on minimizing "submarine patents" and notifying the public of claim scope.

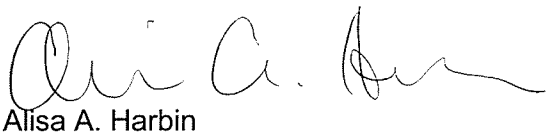
- Most applications are publicly accessible and therefore the public is capable of assessing the potential scope of the claims that may issue. Patent attorneys are routinely asked by their clients to make such assessments. Further, the entire prosecution history is now available online, therefore increasing the public's awareness of the patent application's progress. The fact that a patent attorney is typically needed to review a pending application to determine the scope of what could be claimed does not diminish the public's notice since even determining
- The scope of what is claimed in an issued patent requires that a patent attorney review and construe the claims.
- Even if certain applications are not published, the case law has provided a laches defense for unduly long delays in the prosecution of patent applications. Symbol Technologies v. Lemelson, 277 F.3d 1361 (Fed. Cir. 2002).
- The post-GATT 20 year term of patents also limits the impact of unduly delayed patent prosecution as such delays no longer extend the life of the patent and therefore merely reduce the patent's enforceable term.

7. More effective options for addressing the U.S. PTO's concerns about public notice, certainty, and backlog

- To lower backlog and lower the amount of biotech applications, the PTO should revise restriction practice. TC1600 issues burdensome restriction requirements. Restriction requirements result in divisional applications. Often, the restriction requirements break out claims that could easily be examined together.
- Offer the option to defer examination. Many biotech/pharmaceutical companies would choose to defer examination on applications covering early stage products.
- To give more public certainty about patent scope and to ensure stronger patents the U.S. PTO should encourage Congress to pass legislation providing for
    - publication of all patent applications, and
    - institution of opposition proceeding following grant.

Very truly yours,

NOVARTIS VACCINES AND DIAGNOSTICS, INC.



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