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From: Licad, Esperanza [mailto:Esperanza_Licad@chiron.com]
Sent: Wednesday, May 03, 2006 9:55 PM
To: AB94Comments
Subject: AB94 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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NOVARTIS

VIA EMAIL-AB94Comments@uspto.gov

Office of the Deputy Commissioner for Patent Examination Policy
Mail Stop Comments-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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 Examination of Patent Claims.. ." published January 2, 2006 at 71 Fed. Reg. 61. Novartis Vaccines and Diagnostics, Inc. opposes the adoption of the proposed rules.

Under the proposed rules, examination of most dependent claims would be delayed until an application is in condition for allowance. They would permit the U.S. PTO to limit its initial examination to representative claims including all independent claims and those dependent claims designated by an applicant.

Adoption of the proposed rules would be burdensome to the biotechnology and pharmaceutical industry 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.

The biotechnology/pharmaceutical industries' long product cycles and high development costs require appropriate patent protection. Sometimes that requires filing an application with more than ten independent claims.

Biotechnology/Pharmaceutical industry product development cycle/commercialization

Unlike other industries, such as electronics and software, a biotech or pharmaceutical product often take 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.

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.

The proposed rules

The PTO proposes to delay examination of most dependent claims until an application is in condition for allowance, and to permit the PTO to limit its initial examination to representative claims including all independent claims and those dependent claims designated by an applicant. The proposed rule would limit an applicant to no more than 10 independent claims in any application, or to no more than 10 "representative" claims, i.e., the independent claims plus the number of dependent claims designated for initial examination.

To obtain examination of more than ten claims (whether independent or "representative"), an applicant would be required to submit an "examination support document" including a statement that a search was conducted and an explanation of the search, an information disclosure statement, an explanation of how the claims are patentable over the references cited, a statement of utility, and a showing of where each claim limitation is supported in the written description. The proposed rule would impose this burden on any applicant for normal examination of more than 10 claims. Moreover, failure to supply an examination support document "when necessary" will result in a reduction by the PTO of any patent term adjustment to which an application might otherwise be entitled.

The proposed rules and biotechnology innovation

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

Biotechnology science and inventions are often very complex. Numerous claims are needed to fully cover such complex inventions. The extra claims in such applications are not an "abuse" of the system, but a legitimate means of protecting intellectual property.

As noted above, biotechnology research is very expensive in part because of the long development times. 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.

The proposed rules are unfair to applicants

The U.S. PTO has already instituted extra fee payments for claims beyond a certain number to limit the number of claims prosecuted, but has not waited for a sufficient time for these payments to effect the desired change of reducing the number of claims.

The review of a limited number of "representative claims" is particularly problematical when combined with the limited continuation practice. The limited continuation practice encourages applicants to claim their inventions in as many forms as possible because they may not be able to file a continuation to pursue other forms and embodiments.

The U.S. PTO's position that limiting examination to representative claims is analogous to the BPAI's group of claims is inapt. First, the claim grouping for the BPAI occurs for the purpose of review. The BPAI reviews a record that has been developed by the examiner and the applicant. BPAI review occurs after one or more rounds examination, allowing the applicant to have a better understanding of the patentability issues for all claims. By contrast, there is no such information available at the beginning of examination; it is a blank slate.

Further, for the BPAI, claims are grouped for the purpose of appeal based upon the nature of the rejections being appealed. Thus, claims for which a rejection applies equally may be grouped together. For example, claims rejected based upon an obviousness rejection may fall into two groups, one of which has claims where all the elements are disclosed in the prior art and one of which has claims with elements not disclosed. Arguments such as lack of motivation to combine would likely apply to both groups. However, in the absence of a rejection, an applicant won't necessarily know which claims are "representative claims." The claims that are before the BPAI might be narrower than the claims as submitted initially for examination.

Although we appreciate the U.S. PTO's attempt to reduce backlog and increase quality of examination, we do not think the proposed rules advance those goals. Adoption of the proposed rules would undermine the U.S. PTO's mission to promote investment in research.

Very truly yours,

NOVARTIS VACCINES AND DIAGNOSTICS, INC.

Alisa A. Harbin
Head of Global Patents, Vaccines and Diagnostics