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From: Joel Rarang [mailto:jrarang@ceres-inc.com]
Sent: Tue 5/2/2006 9:08 PM
To: AB94Comments; AB93Comments
Cc: Clarke, Robert
Subject: RE: Proposed PTO Rule Changes

Dear Mr. Bahr and Mr. Clark,

With this e-mail, please find attached my comments to the following proposed rule changes:

1) Changes to Practice for the Examination of Claims In Patent Applications (Fed Reg. Vol 71 No. 1 page 61, Jan. 3, 2006), and

2) 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).

I appreciate the opportunity to offer my comments and would appreciate an acknowledgement that my comments have been received by the USPTO.

Best Regards,

Joel Cruz Rarang

Joel Cruz Rarang
1535 Ranch Conejo Blvd.
Thousand Oaks, CA 91320

May 2, 2006

The Honorable Jon W. Dudas
Under Secretary of Commerce for Intellectual Property
and Director of the United States Patent and Trademark Office

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

Robert A. Clark, Deputy Director
Office of Patent Legal Administration
Office of the Deputy Commissioner for Patent Examination Policy

To the Honorable Jon Dudas, Director of the USPTO:

I appreciate the opportunity to comment on the PTO's proposed *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). I was recently admitted to practice before the USPTO as a patent agent and I am concerned about the effects the proposed rule changes will have on the inventive spirit of our nation. The impact of the proposed rule changes will adversely affect the field of biotechnology, as well as jeopardize the viability of small inventive entities. I fear that the proposed rule changes could impede the progress of science and useful arts by stifling the development of useful technologies derived from biotechnological research.

Innovations in Biotechnology have improved the overall quality of life and have proven to be a valuable resource in the development of new technologies. With the

discoveries from biotechnological research, the public is supplied with knowledge that can be used to increase the yield of arable land, reduce damage to the environment by industrial processes, decrease the economic cost of manufacture, discover alternative sources of energy, and understand the relationship between genetics and specific disorders. It is the responsibility of the USPTO to ensure that the benefits accorded to the public by innovations in the biotechnological field are maintained.

Intellectual property is the primary product of many biotechnology-based companies. Patent applications are filed to attract funding from potential business partners, investors and collaborators. This strategy has allowed small biotech companies to research solutions to many of the most prevalent problems facing our society. It is therefore essential that the patent prosecution process be reliable, predictable and affordable for biotech companies to obtain intellectual property protection commensurate with discoveries to which they are entitled. Without such a process, the viability of many biotech companies would be jeopardized by the uncertainty in obtaining intellectual property protection for discoveries. Unfortunately, the question of how biotech companies are going to fully protect their intellectual property has been left unanswered by the proposed rule changes.

The practice of filing continuation applications or Request for Continued Examination (RCE) is necessary to fully cover many biotechnology-based discoveries. It is often the case where the concept of a marketable product is disclosed in a first filed patent application, but supporting data is required by the examiner during patent prosecution. The data required by the examiner might take years to generate because of the nature of the experiments to be conducted. In this instance, an applicant would file

continuing applications or Request for Continued Examination (RCE) to acquire sufficient the time to gather data in support of the product concept.

The time and cost to effectively respond to an office action can also be substantial to the patent applicant. When a discovery is made, the commercial value of the discovery remains uncertain. A small inventive entity will not actively pursue patent protection for a discovery that has little perceived commercial value. The decision to actively pursue patent protection for a discovery is subject to market fluctuations and investor interest. Rather than expend limited resources in pursuing protection for a discovery that has little commercial value, small biotech companies would defer the cost of prosecution by filing continuing applications. If the discovery proves to be commercially valuable, the small inventive entity has the right to claim the benefit of the first filed application through continuing applications.

Under the current USPTO restriction practice, the claims to an inventive concept can be restricted into different groups, each restriction group comprising a different aspect of the same inventive concept. Examples of separate restriction groups can include groups of claims directed toward a useful nucleic acid sequence, a vector comprising the nucleic acid sequence, a cell comprising the nucleic acid sequence, and a method of using the nucleic acid sequence in a process. Because of the loosely followed independent and distinct criteria and the variation in the restriction practice between different examiners, a patent applicant may have to file multiple inventions to protect the concept of a discovery.

Different product concepts can lie within different restriction groups for particular discovery. The decision for which restriction groups to elect and actively prosecute is

dependent upon the perceived commercial value of a product concept. Since the determination of the commercially valuable product concept may change over time, it is important for small biotech companies to be able to adjust to these fluctuations in order to remain attractive to investors. By filing a divisional application directed to the restriction group of interest, the applicant can adjust to market fluctuations and changes in investor interest.

The limitations to the practice of filing continuing applications and RCEs, imposed by the proposed rule changes, coupled with a restriction practice that requires multiple applications to cover a single inventive concept will make it virtually impossible for some biotech companies to obtain full coverage of their discovery. The proposed rules would limit the filing of continuing applications and RCEs by requiring a showing of cause after the first request for a continuing application or RCE. When an inventive entity files a discovery in a patent application, the benefit of the first filed application can be obtained only while the first filed application is still pending. Also, a third or succeeding application filed in series can only claim the benefit of the previous application in the series.

Under the proposed rules, the applicant could no longer file serial divisional applications and still claim the benefit of the first filed application in which the discovery was disclosed. This would cause the applicant to either file multiple stand alone cases for all embodiments of an inventive concept, or file sufficient divisional applications in parallel to cover the inventive concept. The effect would be a “front loading” of potential prosecution cost to obtain ample intellectual property protection. Small biotech

companies do not have the capital to file applications on each restriction. The result would be a piecemeal coverage for their discoveries.

An increase in the cost of obtaining full patent protection on the different restriction groups will cause some companies to cut back funding for research in favor of patent prosecution. Companies may decide to focus on the development of predictable technologies and mere proofs of product concepts. This would greatly hinder innovation because it is the patent incentive to do innovative research that has paved the way for the emergence of new technologies.

The proposed rules would limit the time available to generate data in support of a patent application. If data to support a patent application is not generated in time to refute an examiner's rejection or disclose in the appeal process, the applicant may be forced to accept patent protection for less than what the applicant is statutorily entitled. The failure of the PTO to understand the value of a discovery may not be corrected in time by confirmatory data. This error will be at the expense of the applicants who develop innovative solutions to the more intractable problems.

The publication of a first filed patent application could result in unintended prior art complications if the benefit of the first filed patent application cannot be claimed. If a valuable commercial embodiment of a discovery has been disclosed in a first filed patent application published more than one year ago, the first filed application would pose as a 35 U.S.C § 102 (b) statutory bar prior art against any patent application claiming the product concept. The applicant could unwittingly dedicate a valuable commercially embodiment of an inventive concept to the public.

Unintended prior art complications would cause a decrease in the dissemination of important discoveries which are presently perceived to have little commercial value. Inventive entities would be wary of publication of their discoveries since they could, in some instances, be creating their own 35 USC § 102 (b) prior art on a possible important commercial embodiment. The significant contributions of the small inventive entities to the public coffers of knowledge would dwindle in light of the proposed rules.

The climate the proposed rules would create would not be conducive to innovation in the field of biotechnology. Advances in technologies stemming from biotechnological research would be hindered due to the delays in the dissemination of knowledge and the redirection of capital intended for research.

Since it is the public that benefits from advances in the field of biotechnology, it is the public that would be affected by delays in the availability of new technology.

I urge the patent office to reconsider and to withdraw the proposed rules.

Sincerely,

Joel Cruz Rarang
Patent Agent
Reg. No. 58,489