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BRIGHAM AND WOMEN'S HOSPITAL
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May 3, 2006

Robert A. Clarke
Mail Stop Comments-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Mr. Clarke:

The recent attempt by the United States Patent and Trademark Office (the Office) to address the resource depletion associated with the examination of applications containing a substantial number of claims that is reflected in the Proposed Changes to Practice for the Examination of Claims in Patent Applications (The Proposed Changes), Notice of proposed rulemaking as set forth in the Federal Register at 71 Fed. Reg. 61 (January 5, 2006) is acknowledged and appreciated by the Corporate Sponsored Research and Licensing Offices (CSRL) at the Brigham and Women's Hospital (BWH).

As a non-profit academic teaching hospital that engages in a high volume of internally and externally funded research, BWH regularly generates discoveries (Discoveries, singularly referred to as Discovery) that have the potential to improve healthcare. CSRL functions to support such research and enable the translation of each of the Discoveries into products that can potentially improve patient care. In most cases, enabling translation of a Discovery requires filing at least a U.S. patent application(s) on the discovery (the Application) and then subsequently licensing the Application to entities deemed best suited to successfully translate the Discovery.

At the time of preparing and filing the Application and in most instances, it is uncertain whether the Application will ever be licensed, and if so, which claims of the Application will be most attractive to potential licensees. This is especially true for an Application that is prepared and filed on a Discovery that is biotechnological given the evolving nature of the biotechnological industry and the recognized complexity and flux of the biotechnological patent law. In view thereof, it may occasionally be prudent to include multiple claim sets in the Application to cover various aspects of the Discovery thereby increasing the likelihood that at least one of the multiple claim sets will attract licensing interest. Depending on the specifics of the Discovery, multiple claim sets could conceivably comprise more than ten (10) independent claims. In such cases, prohibitions on the number of independent claims that could be drafted to cover the various aspects of the Discovery would negatively impact the overall licensing appeal of the Application.

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It is the opinion of CSRL that, if adopted, the rules set forth in the Proposed Changes (the Proposed Rules) would impose a *de facto* prohibition on at least the number of independent claims that could be filed in an Application by imposing a "duty to search" on an applicant who has filed an application containing greater than ten (10) independent claims that have been presumably drafted to optimally cover various aspects of his/her/its invention. The "duty to search" would require the applicant to at least conduct a search for documents having relevance to the filed claims and then submit detailed, affirmative representations to the Office regarding how the documents were uncovered and why the applicant believes the claims to be patentable in view of the documents. Recognizing that such representations are routinely attacked in litigation to support unenforceability assertions, an applicant would arguably be forced to utilize a less optimal claim drafting strategy that includes the filing of ten (10) or less independent claims to obviate the "duty to search". In such a case, the forced utilization of the less optimal claim drafting strategy is arguably tantamount to prohibiting the applicant from filing more than ten (10) independent claims.

In view of the foregoing, CSRL is opposed to the adoption of the Proposed Rules in their entireties as it believes such adoption would impose a *de facto* prohibition on at least the number of independent claims that could be filed in an Application. The *de facto* prohibition would compromise CSRL's ability to broaden the overall appeal of the Application to licensees in instances where prudence dictates the filing of more than ten (10) independent claims to cover the aspects of a Discovery. Lessened licensee appeal to the Application will result in a decreased likelihood that aspects of the Discovery claimed in the Application will be successfully translated into products that have the potential to improve patient care.

Despite the above, CSRL is cognizant of and sympathetic to the operational issues that have resulted from the filing of applications containing substantial numbers of claims. It is CSRL's belief that if the Office: 1) created and adopted rule(s) that would allow deferred examination of applications; and 2) granted authority to the examiners of crowded art units to delegate their search duties to employees that have been specifically retained by the Office to conduct prior art searches on the claims the operational issues confronting the Office would, at least partially, be resolved.

Respectfully submitted,

Richard L. Stevens, Jr.
Intellectual Property Manager