From: Jackson, Jimmy
Sent: Tuesday, April 08, 2008 3:14 AM
To: Markush-irfa.comments
Cc: Reiter, Stephen; Aranaz, Kelly
Subject: uspto comments

BIOCOM

Via E-mail: *Markush-irfa.comments@USPTO.gov*
Via Facsimile: 571-273-7754

Mail Stop Comments--Patents
Commissioner for Patents and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Attn.: Kathleen Kahler Fonda, Legal Advisor
Office of Patent Legal Administration

RE: Alternative Claims Notice--Initial Regulatory Flexibility Analysis

Dear Sir:

BIOCOM appreciates the opportunity to provide comments on the initial regulatory flexibility analysis (IRFA), as published in 73 Fed. Reg. 12679-12684 (March 10, 2008), with respect to the changes proposed by the Alternative Claims Notice of Proposed Rule Making (the "Notice"), as published in 72 Fed. Reg. 44992-45000 (August 10, 2007).

BIOCOM is a regional advocacy organization representing more than 550 dues paying life science companies and service providers in Southern California. Strong intellectual property protection is important to attract the substantial investment required to bring new life-saving therapeutics to the market. Toward that end, BIOCOM and its member companies have a keen interest in potential changes to the patent examination process which may substantially increase the cost of obtaining patents, increase the risk of challenge to the resulting patents, and consequently reduce the ability of small companies which do so much of the innovative research in this country to raise the capital necessary to pursue their goals.

BIOCOM supports the goal of improving patent examination by the United States Patent and Trademark Office (USPTO), especially the goals of making the decision-making process more efficient, thereby minimizing the pendency of applications before the Office. However, a realistic evaluation of the economic impact of the changes proposed by the Alternative Claims Notice of Proposed Rule Making warrants a closer look.

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As a preliminary matter, the standards set forth in the Notice are vague and ambiguous, making it impossible to reasonably assess the economic impact of the proposed new rules on any users of the patent system, much less small entities. The proposed new rules allow examiners to require patent applicants to simplify the presentation of claims with alternative language so that:

--the number and presentation of alternatives in a single claim are not "difficult to construe," or

--no alternative is itself defined as a set of further alternatives within the claim.

The "difficult to construe" standard is not only vague and ambiguous, it also leaves far too much discretion in the hands of the individual patent examiners, who have every motivation to make their task easier by simply limiting the scope of the claims being actively considered in a given patent application. Furthermore, the requirement that no alternative can itself be defined as a set of further alternatives is far too overreaching, as such a requirement would apply to claims which contemplate even simple alternatives.

Thus, as a result of the vague and ambiguous standards set forth in the Notice, and the selection criteria employed by the USPTO for the IFRA, the number of affected cases has been underestimated. According to the Notice, "the Office screened these published applications for commonly used alternative language (e.g., 'contains one selected from the group consisting of') . . ." (see page 12681, col. 3, lines 1-5 of the Notice). The phraseology "selected from the group consisting of" is but one of many ways to introduce alternative claim language. For example, section 2173.05(h)II of the Manual of Patent Examining Procedure states that "expressions using 'or' are acceptable" alternative claim language. By focusing on the presence or absence of only "commonly used" alternative language, the USPTO has unduly limited the identification of cases to which the proposed new rules will apply. Contrary to the assertions of the USPTO, it is expected, based on the collective experience of practitioners who regularly service the biotechnology/chemistry segment of the USPTO user base, that the incidence of alternative claim language is actually much higher than estimated by the USPTO, especially by true small entities which do not have the sophistication to employ the "commonly used" alternative language referred to in the Notice. This is readily confirmed by examining a sample of 34 U.S. patent applications published on March 27, 2008 with claims directed to nucleotide or amino acids sequences--approximately half of which have claims employing alternative claim language other than the "commonly used" format.

Not only have the total number of applications affected by the proposed rules been under-estimated, the categories into which the identified cases have been assigned are further evidence of the non-representative nature of the selection criteria employed by the Office. The Notice sets forth the following four categories of cases:

1) Category 1: Small entity applications with acceptable alternative language (alleged to comprise 82% of biotechnology/chemical applications);
2) Category 2: Small entity applications with alternative language that claim multiple inventions in a single claim (alleged to comprise only 11% of biotechnology/chemical applications);

3) Category 3: Small entity applications with alternative language that have claim(s) in an improper format (alleged to comprise only 3% of biotechnology/chemical applications);
4) Category 4: Small entity applications with alternative language that claim multiple inventions in a single claim and have claim(s) in an improper format (alleged to comprise only 4% of biotechnology/chemical applications).

The representation that 82% of biotechnology/chemical applications employ acceptable alternative claim language is beyond belief. Moreover, the representation that only 7% of biotechnology/chemical applications employ alternative claim language of improper format is equally beyond belief. Indeed, the basis on which the USPTO selected applications for review (i.e., cases which contain "commonly used alternative language") appears to have purposefully understated the nature of the problem by understating categories (3) and (4).

The USPTO categorization of applications (and percentages assigned thereto) are especially suspect given the Patent Office's policy of treating individual nucleotide and amino acid sequences as independent inventions, taken together with the common practice by patent applicants of using alternative claim language to group related sequences together in a single claim. More importantly the percentages presented by the Office are impossible to verify given the vague and ambiguous "difficult to construe" standard.

Even with the likely under-estimation of the impact of the proposed new rules on the biotechnology/chemistry segment of the USPTO user base, the Notice still acknowledges that nearly half (43%) of small entity applications in the biotechnology/chemical space contain claims with alternative language (see Table 1 at page 12681 of the Notice). Clearly, any change which impacts such a large portion of USPTO customers must be undertaken with care.

Regardless of the number of divisional applications which may be required to fully protect an invention, the costs associated with the filing of additional applications are substantially understated in the Notice (see Table 2 at page 12682 of the Notice). Focus is given primarily to the filing of a single divisional application, and the added cost of response to a single Office Action. This is not realistic for several reasons. First of all, it is unlikely that a highly sophisticated invention in the biotechnology/chemical space will be considered to embrace only two separate and distinct inventions. As acknowledged in the Notice "some applications would have required more than 100 divisional applications to maintain scope." See page 12683, col. 1, end of second paragraph of the Notice. While the need for 100 divisional applications may not be the norm, it is much closer to reality than the single divisional application used by the USPTO for purposes of the IRFA.

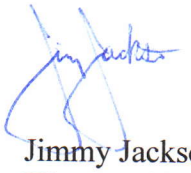
It is also unrealistic to assert that a highly sophisticated invention in the biotechnology/chemical space will advance to allowance based on only a single response. A more realistic estimate would be 2.5 responses required per application, at a correspondingly higher cost to the applicant.

Moreover, additional official expenses, such as issue fees and maintenance fees, are completely ignored by the IRFA. In addition, administrative expenses related to the need to coordinate multiple filings spawned by a single parent filing, must also be considered.

BIOCOM believes that the disproportionate added burdens of the proposed rules on life science companies will dramatically reduce the ability of smaller companies (who make up the majority of BIOCOM's membership) to file and successfully prosecute patent applications of fair and reasonable scope to allowance and grant. Moreover, the additional costs imposed on those who must resort to filing multiple patent applications in order to obtain patent coverage of a scope commensurate with their contribution to the art disproportionately effects the patent portfolios of smaller companies, with the potential to significantly reduce the ability of BIOCOM members to obtain patent protection of the scope necessary to facilitate raising the capital necessary to pursue their goals.

BIOCOM appreciates the opportunity to comment on the proposed changes and to suggest alternative approaches to addressing USPTO concerns. BIOCOM welcomes the opportunity to work with the USPTO to develop a fair set of rules regarding the use of alternative claim language that address USPTO concerns without unduly increasing the costs and risks inherent in the exercise of obtaining patents.

Respectfully submitted,



Jimmy Jackson
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