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From: JENJ (Jennifer Johnson) [mailto:johnsonj@zgi.com]
Sent: Wednesday, May 03, 2006 5:36 PM
To: AB94Comments
Subject: ZymoGenetics' Comments to Proposed Rules on Claim Practice
Importance: High

Attn: Robert A. Clarke
Deputy Director
Office of Patent Legal Administration
Office of the Deputy Commissioner for Patent Examination Policy

Dear Deputy Director Clarke,

Please post the attached .pdf on the Comments Regarding Proposed Rules for "Changes to Practice for the Examination of Claims in Patent Applications" 71 F.R. 61 (January 3, 2006).

Sincerely,

Jennifer K. Johnson

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ZYMOGENETICS

May 3, 2006

The Honorable Jon W. Dudas
Under Secretary of Commerce for Intellectual Property
and Director of the U.S. Patent & Trademark Office
Mail Stop Comments
P.O. Box 1450
Alexandria, VA 22313-1450

Attn: Robert A. Clarke
Deputy Director
Office of Patent Legal Administration
Office of the Deputy Commissioner for Patent Examination Policy

RE: Comments Regarding Proposed Rules for "Changes to Practice for the Examination of Claims in Patent Applications" 71 F.R. 61 (January 3, 2006).

Dear Under Secretary Dudas,

ZymoGenetics, Inc. appreciates the opportunity to offer comments concerning the Proposed Rules for "Changes to Practice for the Examination of Claims in Patent Applications" 71 F.R. 61 (January 3, 2006). We respectfully request consideration of the following comments.

A. The Financial Cost of Preparing Support Documents Would Adversely Impact Small and Mid-sized Biotechnology Companies.

The Small Business Administration (SBA) Office of Advocacy, in its comments to the Proposed Rule, states "Contrary to the PTO's estimates...completion of an examination support document could cost from $25,000 to $30,000 – a significant outlay." SBA Comments to 71 F.R. 61, page 3 (April 28, 2006). The costs to prepare a pre-Examination Support Document (hereinafter "Support Document") will be quite large in the biotechnology arts. Because of the numerous independent embodiments typically seen in a biotechnology application, and the complexity of the biotechnology arts, we would estimate that $30,000 would be a *minimum* cost for a Support Document. The level of involvement and potential liability risk for an outside firm (based on inequitable conduct concerns) could make compilation of a meaningful Support Document comparable to a full-blown legal opinion which typically runs between $50,000 and $100,000 per biotechnology opinion. For an innovative small- to mid-sized biotechnology company, such as ZymoGenetics Inc., the costs related to Support Documents could quickly escalate into several hundred thousand dollars or more per year. This is a cost that we simply cannot afford to have on a regular basis.

In our experience, our biotechnology applications often require more than ten representative claims to fairly encompass the entire scope of the invention. Prior to a restriction requirement, our biotechnology applications routinely provide numerous independent embodiments of an invention in a single application: e.g., polynucleotides, polypeptides, active fragments thereof, fusion proteins, antibodies, antibody derivatives, methods of making, methods

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of using, diagnostics, research tools, as well as method of treatment, and pharmaceutical formulations . of each the foregoing molecules. Coverage of these numerous embodiments necessitates an application with numerous independent claims (often in Markush-type format) to adequately cover the full scope of the described invention. These numerous independent embodiments are typically restricted by the USPTO into separate restriction groups on the basis that they are drawn to separate inventions. It is very difficult to protect the entire scope of the invention to which an applicant is entitled under law with less than ten independent claims prior to restriction. Consequently, biotechnology applicants will regularly be required to submit a Support Document, particularly if claim designation must occur prior to a restriction requirement.

As discussed above, we simply cannot afford to regularly prepare these Support Documents. Consequently, we would be caught in a predicament where we may be forced to accept less patent coverage than what we are entitled to under the U.S. Constitution and patent laws. The SBA shares this concern about the potential weakening of patents for small entities as a result the ten-claim limitation. SBA Comments to 71 F.R. 61, page 3 (April 28, 2006). In the biotechnology business, we need strong patent coverage. As a small business, our patents have enabled us to attract investors who believe in the pursuit of therapeutic drugs, and this investment has enabled us to advance drugs into the clinic. Without patents protecting biotechnology products, the enormous costs of research and development may not be recouped. Without meaningful drug patents, investors may no longer support biotechnology industry efforts needed to make drugs, which could seriously damage the business. Without a robust biotechnology industry, fewer new drugs would be developed to help patients fight their diseases.

The USPTO is tasked with encouraging small entities to obtain patents at a reasonable cost. According to 35 U.S.C. § 2 (2000), the USPTO "shall recognize the public interest in continuing to safeguard broad access to the United States patent system through the reduced fee structure for small entities...." Where small entities, such as small- to mid-sized biotechnology companies, are already tasked with increased patent fees based on extensive restriction practice and fee increases generally, such businesses might not be able to obtain the entire scope of their inventions because they cannot afford to prepare the necessary Support Documents. The resulting effect is a no-win situation: The applicant's patent rights and businesses dependent on those rights are potentially weakened; and the public is potentially deprived of valuable inventions and industry arising from such businesses.

B. Treatment of Independent Claims: Restriction Election; Markush-Type Claims; and Species Elections

In light of the above concerns, particularly with respect to biotechnology applications, in the event the Proposed Rules are enacted, designation of claims for examination ***should not occur until after a formal restriction requirement*** under 35 USC §121 has been received by the applicant. The USPTO considers each restriction group by definition as an independent and distinct invention. 35 U.S.C. §121; MPEP §802. It is therefore only reasonable that applicants designate claims for examination in conjunction with the election of a restriction group in response to such restriction requirement, or for each independent and distinct invention filed in a

divisional application. Allowing designation after restriction would certainly alleviate some of financial burden related to Support Documents for small- to mid-sized biotechnology companies.

The USPTO requested specific comments regarding how Markush-type claims should be counted for purposes of Proposed Rule 1.75(b)(1). 71 F.R. 61, 64 (January 3, 2006). We urge that the Office count each Markush-type claim as a separate single claim and ***does not*** count each alternative within the specified genus as a separate claim for the purposes of the rule. Likewise, with regards to species election, we believe that each species within a claim ***does not*** count as a separate claim for the purposes of the rule. That is, the current definition of an independent claim should not be changed.

Requiring that each member of a Markush group or each elected species be a separate "claim" counted in the designated claim set only further stretches the negative effects of the Proposed Rules described in Part A above: namely, the high costs of Support Documents, and the weakening of patents for small entities as a result of the ten-claim limitation.

C. The Support Document is Against the Public Interest Because it Shifts the Burden of Examination of a Patent Ppplication from the Patent Examiner to the Applicant.

For all intents and purposes the Support Document is an examination of the claims of the application on the merits. The Support Document under Proposed Rule §1.261(a) includes a detailed search statement, an information disclosure statement (IDS), identification of all claim limitations for all independent claims and designated claims disclosed by the references, a *detailed explanation of how the claims are patentable* over the references cited, a concise statement of utility, a showing of where each limitation of the independent claims and the designated dependent claims finds support under the first paragraph of 35 U.S.C. §112. 71 F.R. 61, 65. This is a succinct summary of what an examiner at the USPTO basically does when examining a patent application. In effect, any time a Support Document is submitted to the USPTO, an applicant will be examining his/her own application.

This development would be to both statute and case law. "The Director shall cause an examination to be made of the application . . ." (35 U.S.C. §131), and "[w]henever, on examination, any claim for a patent is rejected, or any objection or requirement made, the Director shall notify the applicant thereof, stating the reasons for such rejection, or requirement, together with such information and references as may be useful in judging of the propriety of continuing the prosecution of his application . . .." (35 U.S.C. §132). The meaning of these statutes read together is clear. Congress assigned to the USPTO, not to the applicant, the responsibility for examining the patentability of an application.

However, the Proposed Rules circumvent this central function of the USPTO. Whenever a Support Document is required, the applicant will effectively perform an initial examination on the merits of his/her claims creating a conflict of interest for the applicant. This conflict raises the issue as to whether it is in the public interest to require a Support Document. Shifting an impartial patent prosecution system to one performed by the very party that is seeking patent protection is against the public interest.

D. The Proposed Rules do not Solve the USPTO's Problem of Excessive Examination Burden.

(1) The Proposed Rule may result in more applications being filed, each with fewer claims.

Because of the high financial cost of compiling and filing a Support Document, it is likely that the Proposed Rules will result in many more cases being filed, each with smaller claim numbers, thus increasing the PTO's burden of documenting, tracking, assigning and examining even more applications. The cost of filing several individual applications (e.g., even 12 or more applications at $2000 per application) would be far less costly for an applicant than submitting a single Support Document. This will be particularly true for biotechnology applications with numerous independent embodiments that would require Support Documents that are anticipated to be extremely expensive as discussed above.

This increased filing will do nothing to decrease the examination burden of the USPTO but will instead increase the backlog of unexamined cases.

(2) The Proposed Rule may decrease the efficiency of examination.

The examination of many applications having less than ten independent claims, for example, those with a number of dependent claims not examined the first time, will go from being a one-step search and examination process to a two-step process. A significant amount of time will likely be spent by the examiners re-familiarizing themselves with the claimed subject matter, and redoing searches that could have more easily been done at the time of first review.

(3) The Proposed Rules address a small problem.

The Office's own comments indicate that a very small number of applications include more than ten independent claims. 71 F.R. 61-69, 62 (January 3, 2006). Given this, it seems unlikely that changes aimed these small number of applications will truly reduce the USPTO's examination burden. Instead, it is more likely that a large number of applications with ten independent claims or less will consume whatever time saved. So, one must question whether applications with excessive numbers of claims actually pose a problem that justifies the promulgation of these rules.

(4) If the Proposed Rules are imposed retroactively, it would overwhelm both applicants and the USPTO.

We note that the Proposed Rules will be particularly burdensome and detrimental to efficiency if they are applied retroactively, as many applications will have been drafted without the suggested ten claim limit in mind. A retroactive application will force consideration of the production of many Support Documents which many small- to mid-sized businesses cannot afford. To avoid filing such a document, it is much more likely that an applicant will chose either to file several continuing and divisional applications prior to enactment of the rules, and appeal existing applications, rather than fronting the large financial burden of providing Support Documents. This would further clog the Office with pending cases and increase the examination burden, rather than reduce it.

E. Proposed Alternatives for Easing the USPTO Examination Burden.

(1) Let the fee increases of 2004 do their job. As noted by many commentators, the Proposed Rules have not taken into account the inevitable reduction of the number of applications with excessive claims due to the December 8, 2004 increase in application claim fees. It is probable that this increase has already served to reduce the number of new patent applications filed that contain more than the three independent claims ($200 each for every independent claim over 3) and seventeen dependent claims ($50 each for every claim over 20). Thus, we would first propose to let the proposed fee increases of 2004 continue to winnow away applications with numerous claims.

(2) Do not change the definition of what comprises an independent claim, and ensure that designation of claims occur after restriction required by the USPTO.

(3) Revamping of the restriction rules and permitting the examination of more claims each time a case is reviewed (similar to European Patent Office practice) may be the best solution to the efficiency problem. Examiners would spend less time re-familiarizing themselves with the claimed subject matter, and redoing searches that could have more easily been done at the time of first review.

(4) Increase fees related to filing a new patent application with excessive independent claims. The USPTO could assert even larger fee increases for the initial examination of more than 20 claims, correlating to the increased USPTO examination time, which may address this problem more thoroughly than the proposed limitation of the number of examined claims. The fee increase of 2004 has already shown a tendency to reduce in the number of applications with excessive claims -- it is entirely uncertain whether the Proposed Rules will be effective in reducing examiner burden at all.

(5) Adopt a request for examination requirement, whereby applicants must request examination within a certain time frame and pay an examination fee. This would reduce the number of applications that must be examined by placing the burden on applicants to decide what applications, and more specifically which claims within those applications, are of sufficient interest to warrant examination. Examination of claims of questionable value could be deferred; many of them would be allowed to go abandoned.

(6) Charge additional fees for an expedited review of all claims in an application. As noted above, this additional fee would serve to offset the additional USPTO costs relating to increased examination time, and may address this problem more thoroughly than the proposed limitation of the number of examined claims. This would ensure equality of service by the USPTO, and ensure the public that examination was fair.

Again, we appreciate the opportunity to provide comments on the proposed rules.

Sincerely,

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