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From: Marcy_Rossell@hgsi.com [mailto:Marcy_Rossell@hgsi.com]
Sent: Tuesday, May 02, 2006 1:52 PM
To: AB94Comments
Subject: Comments on Proposed Rules

Attn: Robert A. Clarke
Office of Patent Legal Administration

Dear Mr. Clarke,

Please find attached a PDF file with comments from Human Genome Sciences, Inc. (HGS) regarding the U.S. Patent Office proposal to change practice for the examination of claims in patent applications as published at 71 Fed. Reg. 61 (January 3, 2006).

HGS is grateful for the opportunity to submit these comments.

Sincerely,

Kenley K. Hoover
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May 2, 2006

Via email to:
AB94Comments@uspto.gov

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

Attn: Robert A. Clarke
Office of Patent Legal Administration

Re: Comments on Proposed Rules: *Changes To Practice for the Examination of Claims in Patent Applications.* 71 Fed. Reg. 61 (Jan. 3, 2006).

Dear Under Secretary Dudas:

Human Genome Sciences, Inc. (HGS) is grateful for the opportunity to provide comments on the U.S. Patent Office (USPTO) proposal directed to changes to practice for the examination of claims in patent applications published at 71 Fed. Reg. 61 (January 3, 2006).

Please find enclosed herewith HGS' comments, suggestions, and alternative proposals with respect to the proposed rule changes (11 pages). HGS respectfully requests that the USPTO would fully consider the remarks submitted herein.

Sincererly,

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Associate General Counsel
Intellectual Property

Kenley K. Hoover, Ph.D., J.D.
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HGS

Human Genome Sciences, Inc.
May 2, 2006

Comments On Proposed *Changes To Practice for the Examination of Claims in Patent Applications* as published in Federal Register, Vol. 71, No. 1, pages 61-69, January 3, 2006.

Human Genome Sciences, Inc. (HGS) is grateful for the opportunity to provide comments on the U.S. Patent Office proposal *Changes To Practice for the Examination of Claims in Patent Applications.* 71 Fed. Reg. 61 (Jan. 3, 2006). HGS is an emerging biopharmaceutical company seeking to discover, develop, and manufacture protein and antibody drugs to treat significant unmet medical needs (such as, systemic lupus erythematosus, hepatitis C infection, and advanced-stage cancers). HGS appreciates and endorses the goals of the U.S. Patent Office to perform "better, more thorough and reliable" patent application examination. 71 Fed. Reg. at 61. However, HGS believes the currently proposed rule changes to claim examination practice in patent applications will not provide an efficient, reliable, or equitable means of accomplishing this objective. Accordingly, HGS respectfully opposes implementation of the proposed rules. Some of the reasons for which HGS is opposed to implementation of the proposed rules are discussed below. It is respectfully requested that the Office consider these suggestions and comments as part of its approach to achieving the improvements desired by both the Office and patent applicants.

I. Overview

The U.S. Patent and Trademark Office (hereinafter "USPTO" or "the Office") is proposing to limit initial examination of claims in a patent application to a set of "representative claims" to be selected by the patent applicant. 71 Fed. Reg. at 61; *esp.* proposed rules 1.104 and 1.75. In particular, the representative claims will be all independent claims and only the dependent claims that are "expressly designated" by the

applicant. 71 Fed. Reg. at 61. Moreover, if an application has more than ten independent claims, or if the applicant designates more than ten representative claims, the Office has proposed requiring applicants to submit an "examination support document" (hereinafter "ESD") to have the claims examined. 71 Fed. Reg. at 61; *esp.* proposed rule 1.75 (1) and 1.261. The Office's preference for limiting initial examination to ten (or fewer) representative claims is because:

> The Office's current practice for examination of claims in patent applications is less efficient than it could be because it requires an initial patentability examination of every claim in an application, notwithstanding that this effort is wasted when the patentability of the dependent claims stand or fall together with the independent claim from which they directly or indirectly depend.

71 Fed. Reg. at 62.

HGS is respectfully opposed to implementation of these rules for some of the reasons discussed below.

II. SUBMISSION OF AN EXAMINATION SUPPORT DOCUMENT SHOULD NOT BE REQUIRED BECAUSE SUCH DOCUMENTS WILL IMPOSE UNWARRANTED BURDENS AND RISKS TO PATENT APPLICANTS.

The proposed rules would require submission of an Examination Support Document (ESD) if applicants wish to have more than 10 "representative" claims examined. 71 Fed. Reg. at 61; *see esp*, proposed rule 1.75(b)(1). The Office has indicated that introduction of the ESD requirement is appropriate because it shares the burden of examination with applicants who submit "more than a sufficiently limited number of claims." 71 Fed. Reg. at 62. HGS is opposed to the proposed requirement for submission of an ESD because the current claim fee structure already provides a sufficient deterrent to excessive claim filing *and* appropriate remuneration to the Office for the burden imposed in examining additional claims.

Furthermore, the ESD requirement is actually a requirement by the Office for applicants *to do the work of the Office.* The Office attempts to justify proposed rules

1.75(b)(1) and 1.261 on the basis that the proposed examination support document requirements "are similar" to MPEP requirements currently in place for requesting expedited examination of patent applications. In particular, the Office noted.

> The Office currently has a procedure for requesting accelerated examination under which an application will be taken out of turn for examination if the applicant files a petition to make special and (*inter alia*):
>
> Submits a statement(s) that a pre-examination search was made, listing the field of search by class and subclass, publication, Chemical Abstracts, foreign patents, etc. The pre-examination search must be directed to the invention as claimed in the application for which special status is requested. A search made by a foreign patent office satisfies this requirement if the claims in the corresponding foreign application are of the same or similar scope to the claims in the U.S. application for which special status is requested;
>
> Submits one copy each of the references deemed most closely related to the subject matter encompassed by the claims if said references are not already of record; and
>
> Submits a detailed discussion of the references, which discussion points out, with the particularity required by 37 CFR 1.111 (b) and (c), how the claimed subject matter is patentable over the references.
>
> See, Manual of Patent Examining Procedure § 708.02 (8th ed. 2001) (Rev. 3, August 2005) (MPEP).

71 Fed. Reg. at 63. It should be noted, however, although *all* of the required elements for requesting expedited examination *are* included in proposed rule 1.261, this rule *also adds* a number of substantive new requirements. For example, an examination support document as required by proposed rule 1.261 must include all of the following items (*none of which are required by MPEP § 708.02*):

> (1) ...for database searches, the search logic or chemical structure or sequence used as a query, the name of the file or files searched and the database service, and the date of the search;
> (2) an information disclosure statement in compliance with 1.98...
> (3) For each reference cited, an identification of all the limitations of the independent claims and designated dependent claims that are disclosed by the reference...
> (5) A concise statement of the utility of the invention as defined in each of the independent claims; and

> (6) A showing of where each limitation of the independent claims and the designated dependent claims finds support...in the written description of the specification.

71 Fed. Reg. at 61 (proposed rule § 1.261).

Furthermore, the accelerated examination procedure under MPEP § 708.02 VIII (C) also provides that "A search made by a foreign patent office satisfies this requirement if the claims in the corresponding foreign application are of the same or similar scope to the claims in the U.S. application for which special status is requested". In marked contrast, however, the Office has stated that under proposed rule 1.261 "A search report from a foreign patent office will not satisfy the requirement in § 1.261(a)(1) for a preexamination search unless the search report satisfies the requirements for a preexamination search set forth in § 1.261." Hence, under proposed rule 1.261 it will be significantly easier for an applicant to obtain advanced application examination (*i.e.*, out-of-turn examination over prior filed applications) than it will be for an applicant to obtain initial examination of 11 claims!

Another important distinction between the proposed ESD requirement and the requirement for expedited examination is that a request for expedited examination is *voluntary and optional*. In contrast, from a pragmatic intellectual property perspective, the ESD requirement is not optional. Although the proposed rules provide that an applicant could file 10 or fewer independent claims, or designate 10 or fewer "representative" claims, in order to avoid the ESD requirement, most contemporary, technologically complex inventions (especially biotechnology inventions) cannot be adequately protected by 10 or fewer claims. Hence, from a practical perspective the ESD becomes a mandatory requirement for any applicant in need of initial examination of 10 or more "representative" claims.

Furthermore, the proposed requirements for submission of an ESD actually constitutes preparation of a patentability opinion such as are sometimes requested by patent applicants from independent counsel. Preparation of such opinion documents by legal counsel, however, is quite expensive. As such, the proposed ESD requirements will present a substantial financial burden on applicants desiring to have more than 10 claims

considered in their application. The Office itself has acknowledged that according to an American Intellectual Property Association survey, a typical patent novelty search analysis could be expected to cost $2500. 71 Fed. Reg. at 66. Based on this figure, the Office concludes "the Office does not consider the additional cost of providing an examination support document to be a significant economic impact on an applicant who is submitting an application containing more than ten independent claims." 71 Fed. Reg. at 66 (emphasis added). This conclusion, however, overlooks the fact that a patent "novelty analysis" is only one part of the requirements mandated by proposed rule 1.261. In fact, the remaining legal analyses and exposition required by rule 1.261 would be significantly more costly than $2500. Additionally, the Office is also concluding that an applicant who can afford to file "more than ten independent claims" can afford preparation of an ESD. This assumption, however, overlooks the fact that proposed rule 1.261 *also* applies to applicants who merely wish to have more than 10 total claims examined (independent or dependent; *without paying for any additional independent claims*). Hence, the Office incorrectly assumes that ESD's will only be required of applicants who can afford paying for preparation of such documents.

Finally, requiring ESDs will also serve to unfairly set applicants up for losing patent rights in litigation, such as through charges of inequitable conduct or fraud, in the event that they fail to disclose or mistakenly mischaracterize, no matter how unintentionally, any relevant subject matter or prior art. 37 C.F.R. § 1.56. For example, the PTO has extensive search tools which may not be available to patent applicants, however, failure to find a prior art reference for lack of resources is not likely to shield an applicant from charges of inequitable conduct because opponents will almost certainly argue that a reasonable person would have found the relevant reference. Moreover, the requirement for a variety of additional statements by applicants in ESD documents will expose applicants to many litigation risks should a challenge to their patent arise. For example, proposed rule 1.261 would require applicants to submit, "[a] detailed explanation of how each of the independent claims and designated dependent claims are patentable over the references cited with the particularity required by § 1.111(b) and (c)..." 71 Fed. Reg. at 69 (proposed rule 1.261 (a)(4)). However, submitting such

"detailed statements" poses a virtually insurmountable challenge to applicants who must be absolutely certain that they make neither any unintentional mischaracterizations nor could any statements they offer be mischaracterized by a challenging party.

HGS is opposed to proposed rules 1.75(b) and 1.261 requiring applicants to submit an examination support document merely to obtain initial examination of more than 10 claims. HGS respectfully submits that the current fee structure (requiring payment of $200 for each independent claim in excess of 3 independent claims, and $50 for each dependent claim in excess of 20 total claims) is both sufficient deterrent to excessive claim filing and also appropriate remuneration to the Office for the burden imposed in examining additional claims.

III. PATENT APPLICANTS SHOULD NOT BE REQUIRED TO DESIGNATE "REPRESENTATIVE CLAIMS" BECAUSE SELECTIVE DESIGNATION OF CLAIMS WILL CREATE NUMEROUS UNCERTAINTIES DURING PROSECUTION; MOREOVER, APPLICANTS CURRENTLY PAY THE STATUTORY FEES MANDATED TO HAVE ALL CLAIMS EXAMINED.

HGS also opposes the proposed rule change wherein only ten "representative" claims will be initially examined without submission of an ESD. 71 Fed. Reg. at 61 (proposed rules 1.104 and 1.175 (b)). The proposed "representative" claim practice forces applicants into a triple-jeopardy situation for losing patent rights. First, by not requiring Examiners to consider all initially filed claims, applicants are immediately placed in jeopardy of being required to file continuing applications because, after a final office action, applicants can only get the previously unexamined claims in a subsequent continuation (RCE, Con or Div). Second, if an applicant chooses to have more than 10 claims initially examined by designating more than 10 "representative" claims, the applicant risks charges of inequitable conduct in view of the risks associated with submitting the required ESD (as discussed above). Third, if only ten claims are pursued to avoid both of the first two consequences, many applicants will be unable to properly claim and, thereby, protect the invention which they have chosen to trade to the public in return for a limited time in which to exclusively benefit from that disclosure.

Furthermore, the proposal to limit initial examination to ten "representative" claims will introduce numerous additional problems and questions which must be addressed. As a few examples, consider the following:

(A) The Office has proposed that "examination of the dependent claims that are not designated for initial examination will be deferred until the application is otherwise in condition for allowance." 71 Fed. Reg. at 62. However, what happens if the examiner initially rejects all ten initially designated representative claims (*i.e.*, the application is not deemed in condition for allowance)? Would this rejection constitute a first action on the merits such that applicants would have only one opportunity *to perfectly amend* their claims so as not to receive a second action final rejection?

(B) At what stage in the examination process will applicants be afforded opportunity to have additional claims considered? If a second action final rejection is issued based on the initially examined claims, is an applicants only recourse to file an RCE or continuation (if still permissible in view of proposed rules 1.78 (d)), in order to have initially non-designated claims examined?

(C) Are claim fees going to be charged for additional claims filed, but not designated as representative, and not examined? This would be equivalent to collecting a fee for services not rendered.

(D) Will claims which were not designated as representative be reviewed by Board of Patent Appeal and Interferences (BPAI) upon appeal?

(E) Will "representative" claims be sufficient to satisfy 35 U.S.C. 135(b)?

(F) Limiting the number of initial claims examined produces piecemeal examination; which the M.P.E.P. currently advises against. *See*, M.P.E.P. § 707.07 (g) (Rev. 3, August 2005).

These are but a few of the immediately apparent problems and issues that will arise should the Office proceed in adopting limited initial examination of claims. HGS

respectfully submits that the current fee structure (requiring payment of $50 for each dependent claim in excess of 20, and $200 for each independent claim in excess of three) is both sufficient deterrent to excessive claim filing and also appropriate remuneration to the Office for the burden imposed in examining additional claims.

IV. TREATMENT OF MARKUSH STYLE CLAIMS

The Office has requested comments on how claims written in alternative Ex Parte Markush format should be considered under proposed rule 1§ 1.75(b)(1). 71 Fed. Reg. at 64. HGS respectfully submits that Markush format claims should be treated as a single claim, not multiple claims, in accord with the long-standing precedent and principles relied upon for this type of claim. HGS reserves its right to comment further upon any specific proposals regarding Markush style claims.

V. ALTERNATIVE PROPOSAL: MAKE APPROPRIATE AND NECESSARY REVISIONS TO CLAIM RESTRICTION PRACTICE AND POLICIES.

The restriction requirement practices of the Patent Office have directly contributed to patent applicant's need to file multiple divisional applications. The Office's current restriction requirement practices partition single inventions or discoveries into numerous application filings (*i.e.*, divisional applications). This practice appears to result from an overly-exacting application of restriction practice standards.[1] As such, examiners typically justify office actions with multiple restriction groups by stating that searching all of the groups would constitute an undue burden. However,

[1] "United States restriction practice is based on 35 U.S.C. 121, which provides that: '[i]f two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions.' This allows examiners to limit applicants to one set of patentably indistinct inventions per application. The USPTO may 'restrict' the application to one set of patentably indistinct inventions: (1) If the application includes multiple independent and patentably distinct sets of inventions, and (2) if there is an undue burden to examine more than one invention in the same application. Restriction practice was designed to balance the interest of granting an applicant reasonable breadth of protection in a single patent against the burden on the USPTO of examining multiple inventions in a single application." Official Gazette Notice, No. 24 (June 17, 2003).

when a reasonable number of inventive embodiments are closely related, a search broad enough to cover all of them should ordinarily not be considered an undue burden.

Therefore, the trend toward increasingly narrow restriction requirements has, unfortunately, created the need for applicants to file, and the Office to examine, numerous divisional patent applications. It has also made it difficult for inventors to obtain full intellectual property protection for their inventions. Zealous application of restriction practice is particularly noticeable in the biotechnology industry where applicant's claims are commonly restricted into 10, 20, 30 and even hundreds of different groups.[2] As such, under current restriction practice, if an applicant seeks patent coverage for related embodiments of a *single discovery*, the applicant must file *multiple divisional applications* just to have the examiner to consider the merits of each related embodiment. For example, in the case of a therapeutic gene product (*i.e.*, a biotechnology invention), applicants are required to file separate applications for nucleic acids encoding the gene product, anti-sense molecules to inhibit the gene product, methods of detecting the gene product, therapeutic use of the gene product (or anti-sense molecules thereto), antibodies against the gene product, diagnostic and therapeutic uses of said antibodies, and so forth.

If the Office genuinely desires to reduce patent application pendency and backlog by reducing the number of "re-work" applications, it should seriously investigate, and ultimately adopt, examination practices that permit applicants to claim related embodiments of an invention in a single application or, *at least*, fewer applications such as is currently accomplished in other international patent offices (*e.g.*, Canada, Europe, and Japan). Adopting such practices would not only expedite pendency but would also better serve public notice by creating fewer issued patents which the public must discover and assess to avoid involvement in infringing activities. Accordingly, the Office should strongly consider adopting a unity of invention standard of claims examination practice.[3]

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[2] HGS will gladly supply the Office with numerous examples of such situations upon request.

[3] For example, under a "[u]nity of Invention standard, restriction would, as a general rule, no longer be permitted between certain related inventions that currently may be restricted under United States restriction practice. Some examples of related inventions that are often filed together and typically can be restricted under current United States practice before a prior art search is conducted, but do not lack unity under the Unity of Invention standard, include: (1) A process, and the apparatus for carrying out the process; (2) a process for making a product, and the product made; (3) an apparatus, and the product made by the apparatus; (4) a product, and the process of using the product. A lack of Unity of Invention is different

As part of such consideration, the Office should investigate the examination and art searching techniques already practiced and achieved (apparently without any "undue burden") by foreign patent offices operating under a unity of invention standard (*e.g.*, Canada, Japan, and Europe). Consequently, another component of revising restriction practice should include allowing multiple dependent claims *and* multiple-multiple dependent claims (without charging exorbitant fees[4]) as is currently practiced in other international patent offices (again, without any apparent "undue burden"). It is important to note that the Office does not have to create, *de novo*, the means and methods for examining claims to related, though perhaps patentably distinct, inventions in a single application. Foreign patent offices are currently practicing just such broad scope claims examination. Therefore, the USPTO should be able to investigate, tailor, and adopt those practices from foreign patent office that best allow the U.S. Office to achieve examination of broad scope claim embodiments in a single patent application. Hence, adoption of an international unity of invention standard will not only produce fewer divisional application filings, but will also accomplish an additional step toward the international harmonization of patent law.

Finally, the Office must create a fair and equitable system for awarding examiner disposal credits in order to reduce the number of claim groups created by an examiner in each restriction requirement. For example, the Office should provide examiners with disposal credits based on the *number of claims* examined, not based on the number of applications examined.

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from restriction practice in some major aspects. Unity of Invention is practiced, with slight variations, in PCT applications and in applications examined by the European Patent Office (EPO) and the Japan Patent Office (JPO). The primary consideration for establishing Unity of Invention is that the claims are entitled to be examined in a single application if the claims are so linked together as to form a single general inventive concept, premised on the concept of a common feature (referred to as a 'special technical feature' in the context of PCT Rule 13) that can be present in multiple inventions within a single application. As long as the same or corresponding common feature is found in each claim and that common feature makes a contribution over the prior art, the claims comply with the requirement for Unity of Invention." Official Gazette Notice, No. 24 (June 17, 2003).

[4] The standard (large entity) fee for a multiple dependent claim is currently $360 plus an additional claim fee for each claim upon which the claim depends. 37 C.F.R. §§ 1.16(j) and 1.175(c). High fees should not be necessary for multiple dependent claims, however, because a claim fee (search fee) was paid for each preceding claim upon which a given multiple dependent claim relies. Hence, for multiple dependent claims, it is only necessary to perform a search and examination of the claim with respect to the additional limitation found in the given multiple dependent claim.

V. CONCLUSION

In view of the explanations, comments, and arguments discussed herein, and otherwise, HGS respectfully requests the Patent Office not to implement the proposed rule changes to claim examination practice in patent applications.