-----Original Message-----
From: JMcLaughlin@isisph.com [mailto:JMcLaughlin@isisph.com]
Sent: Thursday, May 04, 2006 9:55 AM
To: Clarke, Robert
Cc: AB93Comments
Subject: Comments from Isis Pharmaceuticals regarding Proposed Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims (71 Fed. Reg. 48)

Mr. Clarke:
I copied you when I sent these comments on Tuesday, but for some reason there was an error in delivering the comments to the AB93comments@uspto.gov email address (I received a routing failure notice). Please confirm that the comments will be considered as timely submitted and that you received the copy when they were submitted.
Thank you,
Joshua McLaughlin

----- Forwarded by Joshua McLaughlin/ISIS on 05/04/2006 06:53 AM -----

Joshua McLaughlin/ISIS

05/02/2006 04:25 PM

To AB93Comments@uspto.gov
cc Robert.Clarke@uspto.gov
Subject Comments from Isis Pharmaceuticals regarding Proposed Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims (71 Fed. Reg. 48)

To Whom it May Concern:

Please accept the attached comments from Isis Pharmaceuticals, Inc. on the *Proposed Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims, Notice of proposed rulemaking* as published in 71 Fed. Reg. 48 (03 January 2006).

Please contact us if you have questions or trouble opening the attached document.

Respectfully submitted,

Joshua McLaughlin, J.D., LL.M.

Patent Licensing Counsel
Isis Pharmaceuticals, Inc.
1896 Rutherford Road
Carlsbad, CA 92008
760-603-2767 (p)
760-603-3820 (f)

jmclaughlin@isisph.com

Isis Pharmaceuticals, Inc. appreciates the opportunity to provide comments on the *Proposed Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims, Notice of proposed rulemaking* (the "Notice") as published in 71 Fed. Reg. 48 (03 January 2006) and supports the goal of the United States Patent and Trademark Office (the "Office") to streamline the patent examination process and improve patent quality.

Isis Pharmaceuticals, Inc. ("Isis") is a small entity pharmaceutical company (less than 300 employees) focused on the discovery and development of drugs to treat a variety of human diseases. Isis primarily develops what are known as "antisense" oligonucleotide drugs which are the first class of drugs targeted to control expression of genes, through interactions with RNA, to inhibit the production of proteins involved in human diseases. Like many biotechnology companies Isis invests heavily, both in time and money, to develop drugs to treat life threatening diseases. To attract investors and drug development partners, Isis depends upon the value generated by the strength of its patent portfolio which reflects the investment in its research and development activities. Licensing of such patents generates income which is needed to bring drug products through the lengthy and expensive preclinical and clinical development process.

Summary

Isis is concerned about the impact that the proposed rule changes contained in the Notice will have on its ability to obtain patent protection for its innovation. The proposed rule changes contain provisions which will have a disparate impact on the biotechnology industry and will have, what appear to be, unintended consequence to patent applicants and the Office.

- The proposed rules regarding divisional applications will place an undue burden on patent applicants, particularly small entities in the biotechnology industry. The manner in which the Office issues restriction requirements in biotechnology applications, combined with the requirement that all divisional applications be filed at the same time, will lead to many applicants being deprived of the right to obtain patent coverage for many aspects or embodiments of their invention; or make it so financially burdensome that it is cost prohibitive to obtain such patents.
- The proposed rules regarding divisional applications do not contemplate the scenario in which a divisional or continuation application may be subject to a further restriction, different from the restriction requirements received in the earlier filed application. This situation is fairly common in the prosecution of biotechnology patent applications. This will deprive applicants from the ability to obtain patent coverage on their inventions.
- The ability to file such divisional applications serially under the existing rules, rather than in parallel under the proposed rules, allows applicants to minimize the financial impact of such restriction requirements and the costs associated with filing divisional applications in any given year. This will cause a significant burden on many patent applicants, particularly

small entity biotechnology companies whose patent applications receive a disproportionate number of restriction requirements and thus would be forced to file a larger number of divisional applications. Further, the ability to file such divisional applications serially allows an applicant to file the divisional applications to commercially important restricted inventions as a technology develops rather than filing all possible divisional applications prior to the issuance of the prior filed application.

- The proposed rules regarding continuation applications will increase costs for patent applicants, particularly small entities, because rather than continuing the prosecution of an application through filing a Request for Continued Examination, many applicants will be forced to appeal patent applications which have received a final rejection.
- The proposed rules will have a disparate and negative effect on the biotechnology industry where patent applications must be filed years before a product can be commercialized due to the long approval process.
- Less burdensome and problematic alternatives are available to the Office which will be less burdensome on applicants and are more likely to resolve the issues raised by the Office.

Comments on Changes to Divisional Applications

Proposed §1.78(d)(1) provides that a divisional patent application may only claim priority to a single prior-filed application if (i) the prior application was subject to a requirement of unity of invention under PCT Rule 13 or a requirement for restriction under 35 U.S.C. 121, and (ii) the divisional application contains only claims directed to an invention or inventions which were identified in such requirement for unity of invention or for restriction but were not elected for examination in the prior filed application (see proposed §1.78(d)(1)(ii)).

One initial concern regarding the proposed rules is that they do not contemplate the scenario wherein a divisional or continuation application may be subject to a further restriction, different from the restriction requirement received in the earlier filed application. There are a number of ways that this can happen, for example an examiner may alter their thinking in how to group inventions; a different examiner may view the invention differently and restrict the invention differently from how the earlier filed application was restricted; or a CIP may be filed which contains additional subject matter which the examiner may find necessary to restrict. It is fairly common for divisional or continuation applications to be assigned to a different examiner than the first filed application, and applicants often receive restriction requirements in divisional or continuation applications which are different than the restriction imposed in the first filed application.

The proposed rules provide that a divisional application may only claim priority to a single-prior filed application If a divisional or continuation application is subject to a restriction requirement there is no provision allowing an applicant to file divisional applications which claim priority to the first prior filed application. Since there is

significant variability in the way that restriction requirements are imposed on biotechnology applications by different examiners, this will lead to a situation where patent applicants are not able to file applications to protect their inventions ultimately leading to a loss of rights through no fault of the applicant.

Due to the complex nature of biotechnology inventions, patent applications in this field receive a disproportionate number of restriction requirements which necessitates the filing of multiple divisional patent applications. The way in which biotechnology patent applications are restricted by examiners under 25 U.S.C. 121 is very inconsistent and difficult to determine prior to filing the application, each examiner may view an application differently and may issue different restriction requirements. There is little that an applicant can do to either minimize or alter how any particular application may be restricted by an examiner.

This situation is particularly onerous for patent applications drawn to oligonucleotide-based therapeutics. Such patent applications often exemplify a significant number of active antisense oligonucleotides which are part of the same invention, all resulting from the same discovery. Patent applications claiming antisense oligonucleotides targeting a single mRNA are often restricted to a single antisense oligonucleotide compound in a given application, even though for a given therapeutic target multiple disclosed antisense oligonucleotides may work through the same mechanism (hybridizing to the target mRNA sequence), target the same mRNA sequence, and share the same basic structure.

The Office's practice of restricting such applications to a single oligonucleotide sequence appears to be contradictory to the unity of invention standard described in *In re Harnisch* and MPEP Section 803.04 which states that "It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction." Ten sequences are still far fewer than are routinely identified through modern high throughput screening techniques in this field and the interpretation of this standard by the Office currently places a significant financial burden on applicants. The current internal practice of the Office in not adhering to this standard by itself imposes a great financial burden on applicants. This, when combined with the proposed rules relating to divisional applications will lead to an even greater financial burden on applicants, and for many it may lead to a loss of patent rights for significant aspects or embodiments of their inventions.

Since it is the Office that imposes restriction requirements on patent applications, applicants should not be required to bear the burden of filing multiple simultaneous divisional applications to ensure that the full scope of their invention is examined. Divisional applications are different from voluntary continuation applications because the applicant has very little control over how the examiner will view his invention and what restrictions may be imposed, once a restriction requirement has been imposed by the

Office there is little choice for an applicant but to file divisional applications drawn to each of the restricted inventions.[1]

The current rules allow a patent applicant to file divisional applications serially, thus minimizing the financial burden of filing multiple divisional applications in any single year. The proposed rule changes would require an applicant to file all divisionals simultaneously and thus bear the significant costs associated with such filings. It is important to note that the Office filing fees are not the only costs associated with filing patent applications, such filing fees are often a minor portion of the overall costs related to the preparation, filing and prosecution of a patent application.

It appears obvious that the proposed rules requiring that all divisional applications be filed prior to the issuance of the single-prior filed application would increase the total number of applications being filed at the Office in any given year. The increased number of patent applications filed may, in fact, lead to increased workload at the Office and a concomitant increase in the pendency of applications. The Office has stated in many presentations that they do not have enough examiners to keep pace with the number of applications being filed each year and cannot hire enough examiners to keep pace. The proposed rule changes will only exacerbate this situation.

With the large number of restrictions imposed in biotechnology patent applications, the cost to applicants for protecting their inventions will skyrocket. The filing fees for patent applications are currently $790 per application ($395 for small entities), which does not include any other expenses associated with the filing (such as attorney fees), given these dollar amounts and internal Office practices on restriction requirements it is easy to see the significant financial impact the proposed rule changes will have on patent applicants. For example, if a patent applicant receives a restriction requirement indicating that there are 10 groups of inventions in one application, rather than being able to spread the $7900 in filing fees to cover each restricted invention over a span of years (plus all of the costs associated with the prosecution), the applicant will be required to incur all of the expenses up front in a single year. Applicants' patent expenditures will grow significantly and may require a choice between patenting their inventions or investing in research and development. Small biotechnology companies

[1] The Court of Appeals for the Federal Circuit (CAFC) has indicated that divisional applications are a necessary part of the patent system stating:

> Filing a divisional application in response to a requirement for restriction is one such legitimate reason for refiling a patent application. Given one's entitlement to claim an invention in various ways, and the PTO's practice of limiting its examination of an application to only one of what it considers to be several inventions, it cannot, without more, be an abuse of the system to file divisional applications on various aspects that the PTO has considered to be separate and distinct from each other. See 35 U.S.C. § 121 (2000); 37 C.F.R. § 1.142 (2005); see also Manual of Patent Examining Procedure §§ 803, 818 (8th ed., rev. 2 2004).

Symbol Technologies v. Lemelson Medical,Education & Research Found. , No. 04-1451, 2005 WL 2173572 (Fed. Cir. Sept. 9, 2005)

may be forced to decrease their research expenditures in order to obtain adequate patent protection on their inventions. These results seem contrary to the public interest and contrary to the purpose of the patent system.

Conclusion to Proposed Changes on Divisional Applications

Representatives from the Office have indicated that the reasons for the proposed rule changes to divisional applications are (i) to provide certainty to the public as to the scope of inventions being claimed, and (ii) to decrease the pendency of applications under examination. As stated before, divisional applications are different from voluntary continuation applications because the applicant has little control over how the examiner will view his invention and what restrictions may be imposed, and once a restriction requirement has been imposed there is little choice but to file divisional applications.

Regarding the Office's stated goal of improving public certainty on the scope of a claimed invention, the proposed rules specify that a divisional application must contain only claims directed to an invention or inventions which were identified in such requirement for unity of invention or for restriction but were not elected for examination in the prior filed application. Certainty for the public, in the context of divisional applications, could be easily resolved by publishing the claim set as examined for restriction (which is often already done), this would provide the public with information on what claims the applicant may be entitled to pursue in divisional applications and would not cause a burden on applicants.

Regarding the Office's stated goal of reducing pendency for applications under examination, rather than accomplishing this goal the proposed rules for divisional applications may inadvertently lead to an increase in the pendency of applications due to the requirement that multiple divisional applications be filed prior to the issuance of the single-prior filed application. This will necessarily lead to an increase in the total number of applications for each applicant pending at any one time as applications will be filed concurrently to protect each invention which was subject to the restriction requirement.

Isis respectfully submits that the proposed rules regarding divisional applications should not be implemented as written because (i) there are alternative means for accomplishing the stated goals of the Office; (ii) there are internal policies and procedures at the Office which should be examined regarding restriction practice prior to enacting any limitations on divisional applications; (iii) the proposed rules as written may preclude applicants from their right to have the full scope of their invention examined and obtain patent protection for their inventions; (iv) the proposed rules will have a disproportionate impact on the biotechnology industry; and (v) the proposed rules will cause an undue burden and significant financial hardship on small entities in the biotechnology industry .

Comments on Changes to Continuation Applications

Proposed §1.78(d)(1) provides that a continuation application (including continuation applications, continuation-in-part applications and requests for continued examination) may claim priority only to a single-prior filed application.

First, in discussing continuing applications it is worth noting that different types of continuing applications (continuation applications, continuation-in-part applications (CIPs), and requests for continued examination (RCEs)) may serve very different and legitimate purposes for a patent applicant.[2] It is also worth noting that the filing of continuing applications after June 8, 1995 (post-GATT) does not act to extend the patent term for any patented inventions, this has limited the overall impact of such continuation applications.

Continuation applications often serve as a mechanism to allow applicants to pursue claims which were cancelled in the prior filed application or to pursue claims of a different scope or drawn to a different aspect of the invention.[3] These are legitimate uses of continuation applications and are particularly necessary in the biotechnology industry where prior art searching is difficult, and companies have a need to respond to industry and product developments during the lengthy drug development process.

Continuation applications also allow applicants the ability to resolve issues that have arisen due to the holdings in case law in the federal courts, thus ensuring the enforceability of their patents. Continuation applications may serve as an alternative to reissue or reexamination proceedings where newly discovered prior art can be considered in relation to the novelty or obviousness of a claimed invention (e.g. prior art cited in corresponding foreign patent prosecution).

RCEs are relatively new for the patent office (implemented as part of the *American Inventor Protection Act* in 2000). Patent applications under examination generally receive only one substantive office action and if the rejections are not immediately overcome the applicant receives a final office action. In many instances, a meeting of the minds between an applicant and an examiner cannot be reached in a response to a single office action. RCEs are often filed in order to encourage the examiner to consider amendments after a rejection has been made final. RCEs are

[2] The CAFC has indicated that there are legitimate grounds for refiling a patent application which are not merely abuses of the patent system. See *Symbol Technologies v. Lemelson Medical,Education & Research Found,.* supra.

[3] The CAFC has stated that "one might legitimately refile an application containing rejected claims in order to present evidence of unexpected advantages of an invention when that evidence may not have existed at the time of an original rejection. Commonly, and justifiably, one might refile an application to add subject matter in order to attempt to support broader claims as the development of an invention progresses, although entitlement to an earlier filing date for any claimed subject matter may of course be necessary to avoid a statutory bar created by intervening events outlined in 35 U.S.C. §§ 102 and 103. One may also refile an application even in the absence of any of these reasons, provided that such refiling is not *unduly* successive or repetitive." See *Symbol Technologies v. Lemelson Medical,Education & Research Found,.* supra. (emphasis added)

generally used to advance the prosecution of an application and serve as a cost-effective alternative to placing the application on appeal. Adopting the proposed rules with regard to RCEs will eviscerate RCE practice which helps the applicant and examiner to reach agreement on the scope of allowable claims.

One of the primary concerns associated with the proposed rules on continuation applications is the current practice of examiners to issue final rejections at a very early stage in patent prosecution coupled with a refusal to consider arguments or amendments after making a rejection final – this leads applicants to file RCEs or other continuation applications, which may not be necessary otherwise, in order to have their arguments or amendments considered. The primary reason for this practice appears to be the Office's internal system of examiner production goals. Under this system, examiners have a production goal and only receive credit for First Actions on the Merits (FAOM) and disposal, abandonment, allowance, or examiner's answer.[4] This system provides a perverse incentive for examiners to (i) issue final rejections at an early point in prosecution; (ii) refrain from working with patent applicants to come to agreement on claims of commensurate scope with the applicant's invention; and (iii) encourage applicants to file RCEs.

Examiners are disinclined to consider amendments made after a final rejection (even if the amendments and arguments would move the application forward in prosecution or put it in condition for allowance), but often suggest that they would be happy to consider the amendment if an RCE is filed. This allows the examiner to obtain at least 2 points under the Examiner Production System when they consider the proposed amendments after the RCE is filed.[5] It is fairly common for the application to proceed fairly quickly to allowance after the filing of the RCE once the examiner has considered the arguments or amendments submitted by the applicant. The proposed rule changes, limiting the number of RCEs (or other continuing applications) available to an applicant, will cause significant hardships on applicants if there are not significant changes made within the Office to provide for a more equitable and thorough examination process in the first-filed application prior to the implementation of any changes to the current rules governing the number of continuation applications available to an applicant.

The proposed changes, particularly the rules limiting the number of RCEs available to an applicant, are also likely to lead to an increase in the number of applications for which final rejections are appealed. Increasing the number of appeals may lead to an increase in the pendency of cases on appeal and lead to a *de facto* increase in patent term beyond 20 years for a significant number of cases.[6] It is unclear as to how the Office plans to address the significant increase in the number of applications which will be appealed or whether there was any consideration of the public policy implications of extending the terms for large numbers of patents.

---

[4] See the description of Examiner Production System as described in the *US Department of Commerce Office of Inspector General Final Report 15722 dated September 2004.*

[5] Examiners receive 1 point for disposition of the case and 1 point for a FAOM.

[6] See 35 U.S.C. 154(b)(1).

Given the pendency issues the Office is experiencing, if an applicant needs to obtain patent coverage to pursue an infringing competitor there is often need to streamline prosecution on a narrow set of claims to protect their business, without impairing the ability to pursue broader claims to cover the full scope of their invention. Thus it is often more expedient for a patent applicant to pursue an initial claim scope which is narrower than the full scope of the applicant's invention, and in a subsequent filed application pursue a set of claims which are commensurate with the full scope of the applicant's invention. Small entities are likely to disproportionately be impacted by the limitation on Continuation applications as they have more limited budgets and are more vulnerable to competition where infringing products are being made by a competitor.

Further, since most applications publish within 18 months from the priority date, the public has adequate notice of what the patent application is drawn to. Limiting continuing applications will not act to provide any further certainty to the public on what the applicant believes his invention is.

The Office may, in some instances, actually receive an efficiency advantage in having a family of related divisional or continuation applications; an examiner may only need to review a common specification once since it is used in the several related applications. This may result in an economy of examination of these related applications. If two applications are filed on the same day but are not crossed referenced as being related to one another, the examiner needs evaluate the full specification of each since there may be some differences. If each application were independent, the examiners would not receive the benefit of this "economy of scale."

Further, the proposed rules appear to be in response to the actions of a small number of applicants who delay prosecution or allowance of applications for unreasonable periods through the filing of continuation applications. While alternative mechanisms exist to deal with such abuses of continuation application practice, such as prosecution laches, the proposed rules will unintentionally punish those applicants whose patents cover complex technologies.

Conclusion to Proposed Changes on Continuing Applications

Unless, and until, certain internal practices at the Office are modified, these proposed rules will impose great hardships on the patent applicants and will not address the issues that the Office has put forth. Some of the internal practices which should be evaluated prior to enacting the proposed rules are: (i) revising guidelines for examiners to determine when it is proper to make a rejection final, (this may necessitate a review of Examiner Production System or other alterations to examination procedures) (ii) ensuring that applicants are provided with examination of the full scope of their inventions, (iii) improving the impartiality and review process in pre-appeal conferences, and (iv) pre-examination interviews to allow applicants the opportunity to put the invention in context for the examiner.

Alternative Proposals and Suggestions to Proposed Rule Changes

There are a number of other actions that the Office can take to improve patent quality while streamlining the examination process. Examples of alternative changes which would be less burdensome on applicants while addressing the issues raised by the Office are:

a) Reexamine Office policies relating to the finality of rejections. By issuing improper final office actions, the Office is propagating a system wherein continuation applications are necessary in order to have an invention adequately examined.

b) Improve examiner training. This affects not only efficiency of the office, but also patent quality. Further, steps should be taken to decrease examiner attrition rates.

c) Revise restriction practice. The Office is unduly restricting patent applications which provides for piecemeal examination of inventions and is very burdensome on patent applicants. Further, examiners are currently issuing restriction requirements which are not in accordance with published guidelines from the Office.

d) Improve cooperation with foreign patent offices. The ability to coordinate searches of the same invention and rely on searches from foreign patent offices would greatly streamline the prosecution of many patent applications. This could also be done by accelerated examination of applications entering the US through the PCT where a search had already been conducted.

e) Create deferred or accelerated examination systems. Systems such as this would provide for more flexibility in Office workload by allowing applicants who require immediate examination of their applications to take precedence over those requesting deferred examination. The publication of applications at 18 months and the 20 year patent term would continue to provide certainty to the public under such a system.

Conclusions

While Isis understands the Office's concerns relating to the pendency of patent applications and recognizes the need for change to resolve these issues, we must protest the implementation of the proposed rules as published. We have particular concerns related to the implementation of these rules as applied to applications which are already on file – patent strategies may have been developed based on existing rules which may lead to significant loss of rights to a large number of patent applicants.

The language of the patent statutes suggests that a patent is a property right that the inventor is entitled to for any new and non-obvious invention as long as the patent application meets the standards for patentability.[7] The proposed rules impair this right and may deprive inventors (particularly small entities) from having the full breadth of their inventions examined, or otherwise make it so cost prohibitive to file the necessary number of distinct applications in a short time period so that the applicants are *de facto* deprived from having the full scope of their inventions examined.

[7] See 35 U.S.C. 101 and 102.

Prior to implementation of any rule changes as proposed in the Notice, there are a number of internal Office practices which should be evaluated and considered as described above which could lead to a resolution of many of the concerns put forth by the Office and not impair the rights of inventors to obtain a patent or make the process unduly burdensome on applicants. Further, it is of interest to note that the question of whether there should be a limitation on the number of continuation applications that an applicant may file is currently being discussed in Congress, which may imply that this issue may be better left to the elected officials in the legislature rather than through rule making by the Office.[8]

Respectfully Submitted,

Joshua McLaughlin, J.D., LL.M.
Patent Licensing Counsel
Isis Pharmaceuticals, Inc.
Reg No: 50,455

[8] See H.R. 2795 and H.R. 5096.