-----Original Message-----
**From:** Leda Trivinos [mailto:leda.trivinos@biogenidec.com]
**Sent:** Tuesday, May 02, 2006 5:57 PM
**To:** AB93Comments; AB94Comments
**Cc:** Ray Arner; Leda Trivinos
**Subject:** Comments re: Notice of Proposed Rulemaking (71 Fed. Reg. 48; 71 Fed. Reg. 61)

**Commissioner for Patents**
**Attn: Robert W. Bahr**
**Attn: Robert A. Clarke**

On behalf of Biogen Idec Inc., please consider the attached comments on the Office's proposed rules regarding changes to practice for the examination of claims and for continuing applications.

Thank you,

Leda Trivinos, Ph.D., J.D.
Assistant General Counsel
BIOGEN IDEC INC.
14 Cambridge Center
Cambridge MA 02142
T: 617.914.7766 F: 617.679.2838

# BIOGEN IDEC COMMENTS ON USPTO RULE PROPOSALS

## I. Introduction

Biogen Idec, Inc. thanks the Under Secretary for this opportunity to comment on the Office's proposed regulations for patent examination and continuation practice.[1] This comment addresses both proposals and is being submitted in duplicate.

Biogen Idec is a global biotechnology corporation, headquartered in Cambridge, Massachusetts. Biogen Idec markets leading therapeutic biologic products in oncology, neurology and immunology. For more than 25 years, the company has grown through the discovery, development and commercialization of its own innovative products and through scientific and strategic collaborations. Patent protection is vital to Biogen Idec's business, as it is to research and discovery throughout the biotechnology industry.

Biogen Idec appreciates the Office's efforts to improve the quality of examination and to reduce pendency times. These comments identify specific problems with the proposed rules, which unfairly burden the biotechnology industry, and suggest procedures that could alleviate some of the Office's administrative problems, especially those in the 1600 Art Unit.

## II. The proposed limits on continuations unfairly burden the biotechnology industry

Due to several factors unique to the biotechnology industry, the proposed regulations are unfairly burdensome to this industry.

***Complexity of technology and law necessitates comprehensive examination.***

New inventions in all arts are likely to be technically complex. However, in the biotechnological arts, the complexity of both the technology and the law[2] makes for particularly difficult prosecution. At times, a single claim -- one that may eventually issue as written -- stands initially rejected under § 101 for lack of utility, § 102 for anticipation, § 103 for obviousness, § 112 for lack of written description, § 112 for lack of enablement, and § 112 for indefiniteness. This slew of rejections would be unusual in the predictable arts. Typically (and perhaps largely because Examiners may not have sufficient time for initial examination), multiple exchanges are required for the Examiner to fully understand the invention, to clarify the issues for both parties, and to develop a factual record that addresses all the Examiner's concerns. Accordingly, applicants are unlikely to successfully traverse all these rejections in a single response. The Office's proposal to limit continuations severely limits the possibility of engaging in a searching analysis of the issues on the record since this discourse depends on extending examination using

[1] 71 Fed Reg. 61 (January 3, 2006); 71 Fed Reg. 48 (January 3, 2006)

[2] For example, the Federal Circuit has recently reconsidered the standards in biotechnology inventions for utility (*In re Fisher*, 421 F.3d 1365 (Fed. Cir. 2005)), enablement (*Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318 (Fed. Cir. 2005)), and written description (*Univ. of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916 (Fed. Cir. 2004)). The Supreme Court has granted certiorari on the question of whether a claim to a broad diagnostic correlation is valid (*Laboratory Corp. of America v. Metabolite Laboratories, Inc.*, 126 S.Ct. 601 (2006))



Biogen Idec 14 Cambridge Center Cambridge, MA 02142 Phone 617 679 2000 www.biogenidec.com

RCEs and continuations. To invoke the Office's metaphor: if the apple is a pithy varietal, two bites of the apple will not provide adequate sustenance.

If RCE and continuation practice is restricted, more thorough discussion needs to take place earlier. The current "count" system is not amenable to such expeditious dispatch. Because the current system awards examiners credit for the filing of continuations and RCEs, examiners often compel applicants to file RCEs or continuations, so as to accrue more counts, rather than engage in good faith consideration of applicants' arguments.

Without modifying current examiner incentives, the Office's proposal will merely shift the burden of evaluating the complex technical and legal issues common in biotechnology applications to other Office staff – namely senior examiners handling pre-appeal procedures and the administrative law judges of the Board of Patent Appeals and Interferences.

Recommendations:

- Examiners should be encouraged (and preferably required) to interview with applicants prior to writing a first office action. At this time, trivial issues can be resolved and examiners can ask for clarification of aspects of the invention as needed. Such a process would reduce the Office's workload by avoiding the very common rejections based on a misunderstanding of the invention. Early discussion of substantive matters has the potential to rapidly streamline prosecution so that the first office action immediately and more fairly confronts the real issues.
- The examination "count" system for continuations and RCEs should be abolished to remove the incentive for examiners to prematurely close prosecution and compel refilings. In addition, examiners should be given credit for quality first office actions so that examiners have incentives to spend an adequate number of hours on initial examination.
- If the current proposal is adopted, petitions to file a second RCE or continuation should operate as a notice of appeal when finally denied. Alternatively, applicants should be allowed additional time after final denial of the petition to file a Notice of Appeal
- The Office should consider opening satellite offices in other major cities to increase the pool of qualified applicants for examiner positions.

***Lengthy product cycles require lengthy prosecution.***

Unlike high technology or mechanical products, for example, biologic therapeutics require lengthy development times, including several years of clinical trials, to reach a stage at which they can be marketed. Ten to fifteen years is the norm, and the majority of potential products fail in the clinic for reasons unrelated to patentability. Therefore, although a patent application covering a particular product may be filed very early in the development process, FDA approval to sell the product often does not come until the twilight of patent term. Continuation applications that focus on different aspects of the invention or pursue claims of different breadth during the life of the patent term are necessary to protect the full scope of an invention as a product matures. Forcing applicants to conclude prosecution long before regulatory approval



**Biogen Idec** 14 Cambridge Center Cambridge, MA 02142 Phone 617 679 2000 www.biogenidec.com

leaves applicants with the real possibility that their patents may not adequately protect the ultimate therapeutic product or use.

***Continuations guard against exploitation of the "limits of language."***

The need for continuations with new claims is a natural result of the limitations of language. As Justice Kennedy aptly noted:

> [T]he nature of language makes it impossible to capture the essence of a thing in a patent application. The inventor who chooses to patent an invention and disclose it to the public, rather than exploit it in secret, bears the risk that others will devote their efforts toward exploiting the limits of the patent's language.[3]

Thus, if inventors are restricted to their original claims, competitors can appropriate the intellectual contributions in the patent specification by devoting their resources to wiggling out of claim language. Although the doctrine of equivalents was one protection from such exploitation, recent case law has severely limited the scope of the doctrine.[4] The only sure protection against such copying is the opportunity to draft claims with full knowledge of a competitor's product. Without this opportunity, patents would be reduced to a semantic exercise in which competitors inspect a file history and find a claim limitation that is barred from equivalents in order to copy an inventor's ideas. Accordingly, the drafting of claims that cover another party's product has been condoned by the Federal Circuit.[5] It is wholly outside of the Office's authority to overrule the courts on this issue.

***Concerns about "late claiming" are unfounded.***

A frequent criticism of continuations with new claims is that they allow companies to lie in wait and then later surface with a previously unseen patent that ensnares unsuspecting competitors. These "submarine" patents garnered notoriety for their artificially extended patent terms. However, it is important for the public and for the Office to understand that, since the enactment of provisions that fix patent term to one's original filing date and that require the publication of applications, this practice has been extinguished.[6]

Besides, **current law protects the public from abusive continuations**.[7] Late claims filed in a continuation application, like all claims, must satisfy the requirements of patentability. In particular, they must be described and enabled in the *original* parent application as required by 35 U.S.C. § 112 and 35 U.S.C. § 132(a) (prohibiting new matter). Thus, patentees who successfully secure late claims are merely obtaining exclusive rights to their original

---

[3] *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 731 (2003).

[4] *Id.*; *Johnson & Johnston Assoc. Inc. v. R.E. Serv. Co.*, 285 F.3d 1046 (Fed. Cir. 2002) (en banc) (finding no equivalents for disclosed but unclaimed embodiments)

[5] *PIN/NIP, INc. v. Platt Chemical Co.*, 304 F.3d 1235 (Fed. Cir. 2002)

[6] American Inventors Protection Act, Pub. L 106-113 (1999); Uruguay Round Agreements Act, Pub. L. 103-465 (1994) (providing 20 year terms from original filing date as codified at 35 U.S.C. § 154(d)(2))

[7] The law of prosecution laches provides further protections against true abuse. *See Symbol Technologies v. Lemelson Medical, Education & Research Found.*, 429 F.3d 1051 (Fed. Cir. 2005)

contributions, and for a term no longer than 20 years from the filing date of the original parent application. This is no more than executing on the original *quid pro quo* in which inventors receive rights in exchange for public disclosure.

Surprise is also no longer an element. Third parties have adequate notice of possible late claims because applications are published at 18 months (except for a small minority that have sacrificed international rights). Even if the published application does not include claims to a particular embodiment, the specification is available and provides exact boundaries for what might be later claimed in any continuation. Applicants are obliged to disclose all relevant art that they know of in the public file wrapper, and the public is free to search for and contribute other relevant material.[8] If there is any uncertainty as to what claims might issue, the remedy is more consistent and diligent examination.

Recommendations:

- True continuations should not be limited. The current law already protects the system from abuses of continuation and RCE filings and applicants already have many incentives to conclude prosecution.[9] The Office should recognize the legitimate need for a flexible continuation practice in biotechnology for the reasons described above.
- The Office should implement an optional system of **deferred examination** for a fee. Many patents expire because their maintenance fees are not paid, even just four years after issuance.[10] The reason for this phenomenon is that patentees are unable to fully appraise a patent's value at the time of issuance if the commercial strategy is still nascent. Deferred examinations would save the Office of the effect of examining and issuing patents that are not ultimately of value. Deferred examination also benefits patentees because it enables them to coordinate prosecution with product cycle. As long as only published applications can be deferred, the public is not harmed since publication provides adequate notice.
- If limits on continuations are implemented, the Office should promulgate a rule that expressly and unconditionally permits continuations for the following purposes:
    - triggering an interference;
    - citing newly found art; and
    - submitting post-filing evidence to confirm enablement of the claimed invention. If animal testing or clinical testing is requested by the Examiner, no constraint should be placed on the amount of time available.

[8] 21 C.F.R. § 1.56(a) (describing duty of disclosure); 21 C.F.R. § 1.99 (providing for third party submissions)
[9] Delays and refilings work against any patent term adjustment under 35 U.S.C. § 154(b). Moreover, it is critical for a patent related to an approved product issue before drug approval as no patent term extension is available if the patent issues after approval. 35 U.S.C. § 156(a). Applicants also do not get credit for regulatory delay prior to issuance of the patent. 35 U.S.C. § 156(c).
[10] See Moore, Kimberly A. "Worthless Patents," 20 Berkeley Tech. L.J. 1521 (2005) (estimating from an empirical study that about 53%of U.S. patents expire for non-payment of maintenance fees and nearly one in six expire just four years after issuance).



**Biogen Idec** 14 Cambridge Center Cambridge, MA 02142 Phone 617 679 2000 www.biogenidec.com

***Rampant Restriction Practice in Technology Center 1600 is the cause of many filings.***

Many pending applications are divisionals. These applications are the product of the Office's own discretion, usually exercised against the wishes of applicants. Here again biotechnology is unique. Biotechnology applications are almost exclusively examined in TC 1600. In this TC, more so than in any other, restriction requirements are the norm, and it is not uncommon to have applications restricted into 10, 20, or even hundreds of restriction groups.

Current rules allow the filing of serial divisionals directed to different restriction groups. The option to employ sequential prosecution spreads the costs of such filings across a number of years. In contrast, proposed § 1.78(d)(1)(ii) requires that all divisional applications be filed during the pendency of the original parent application. Thus, all divisional applications would be prosecuted *concurrently*. This rule would increase the number of pendencies at the Office and defeat the Office's avowed purpose of reducing pendency time. The costs and problems this rule creates for inventors are immense. If applicants must pursue divisionals to all groups before the original application issues as a patent, the Office will be flooded with applications.

This rule alone will severely squeeze the biotechnology industry, which is overwhelmingly comprised of small companies. Filing and prosecuting even a few divisionals from *one* application as required by the proposed rule could expend a small company's patent budget and prevent filings on new inventions. Even for Biogen Idec, one of the largest biotechnology companies in the United States, the costs would be prohibitive.

Not only is it ungrounded in policy, but the requirement for parallel divisional prosecution is unworkable in cases where the Office requires a species election in a first divisional application. The rule prevents further divisionals from being filed to protect the unelected species. The rule is also unworkable where the Office issues a second restriction requirement, for example, in a first divisional application.

Recommendations

- The rules should explicitly permit serial divisionals, as they do today.
- The Office should implement **restriction reform** in TC 1600. Many restriction requirements define different groups that could be searched with identical searches, imposing no additional burden on the Office if they were searched together. Currently, applicants do not contest many improper restrictions because the cost of filing a divisional is less than petitioning to traverse a restriction. This practice is certain to change if parallel divisionals are required. Implementing a "unity of invention" standard as in the PCT, for example, would reduce restriction groups and divisional filings.
- If § 1.78(d)(1)(ii) is adopted, the Office should be bound by its initial restriction requirement and rule § 1.146 authorizing species elections should be repealed.



**Biogen Idec** 14 Cambridge Center Cambridge, MA 02142 Phone 617 679 2000 www.biogenidec.com

## III. The proposed limits on the examination of claims are unworkable

In a typically complex biotechnology application, many different claims are needed to adequately claim an invention, including large numbers of dependent claims. Often, prior art is identified by the examiner that was previously unknown to the applicant. Applicants cannot anticipate *ab initio* which limitations (which may be in dependent claims or in the specification) may be needed to overcome such art. Under the proposed rules, adding a limitation from a claim not initially selected for examination in a response to a rejection may be sufficient to trigger a final Office Action because the amendment "could have been presented earlier". Thus, Applicants are unfairly prejudiced merely because they understandably lacked the foresight to designate these claims as "representative."

The proposed Examination Support Document (ESD), which must be filed to initially examine more than 10 claims, would also pose an undue burden. Based on an AIPLA Report, the Office estimates that the cost for an ESD would be around $2,500. However, the AIPLA Report referred to the cost of a patent novelty search and analysis, which typically focuses on a single point of novelty of a broadly defined invention and is quite narrower than the extensive claim-by-claim, reference-by-reference analysis contemplated by the proposed ESD. Based on extensive experience, Biogen Idec estimates that the cost of a prior art search and analysis that meets the requirements of the proposed ESD for even a simple biotechnology invention would easily average over $20,000. Furthermore, Biogen Idec is unaware of any jurisdiction which places the onus of patent examination on the applicant.

Recommendations:

- If the proposal is adopted, the limit on initial examination to 10 claims should only be applied after election following restriction.
- Applicants must be allowed to amend claims by adding a limitation from a claim not initially selected for examination without triggering a final office action.
- The Office has solicited comments on how to treat Markush claims. To evaluate patentability of a Markush claim, an examiner need only search the art for each species encompassed by the claim. However, this burden is equally present if the claim recites a generic term since a generic term still embraces a host of different species. If anything, Markush claims are narrower and more specific than a claim reciting a generic term and therefore require less extensive examination. Accordingly, the Office should not count each alternative as a separate claim.
- Multiple dependent claims should be encouraged, not discouraged as they are more concise. Particularly where all the claims referenced in a multiple dependent claim depend from the same independent claim, **examining a multiple dependent claim is no additional work than examining a singly dependent claim**. If the multiple dependent claim adds a novel and non-obvious feature, it would be patentable regardless of however many claims from which it depends. If it does not, the examiner can simply reject the claim if any of the claims from which it depends is rejected.



**Biogen Idec** 14 Cambridge Center Cambridge, MA 02142 Phone 617 679 2000 www.biogenidec.com

## IV. Other Concerns

***Choking off biotechnological continuations will not reduce pendency in high-tech arts.***

Above Biogen Idec clarified the practical, technical, and regulatory reasons why continuations are an integral component of protecting biotechnological innovations. Therefore, it should be no surprise that continuations are most prevalent in TC 1600. TCs in which high-technology and computer inventions are examined have a much longer average pendency, and a much lower rate of continuations. Thus, limiting continuations will only punish the biotechnology industry for its complexity without delivering any substantial benefit to solving the Office's root problem – overly long pendencies in the computer and electronic arts.

***APA Rulemaking cannot be used to subvert legislative intent or judicial rules.***

The Office recognizes that Federal Circuit case law condones drafting of claims after filing of an application to cover competitor's products. Thus, the courts have expressly approved procedures in which claims are prosecuted in a third or later continuation. As noted in *Rowe v. Dror*, the Office is not free to administratively set aside judicial rules.[11]

Moreover, in this last year, Congress considered a bill that would limit the right to file continuations, § 8 of H.R. 2795. After much discussion, this provision was discarded from H.R. 2795, as it is from the current proposal H.R. 5096.[12] The Office should not presume to alter the law by administrative *fiat* when Congress contemporaneously deemed the proposal untenable. A sudden and drastic change in policy by the agency at a time when Congress is itself actively reforming the patent laws may violate the separation of powers doctrine.

***The proposed rules will have serious legal consequences for innovators.***

Under current law, applicants must carefully measure every statement advanced before the Office. This is because almost any claim amendment bars the possibility of equivalents during litigation. Statements that explain an invention to an examiner can give rise to argument-based estoppel and alter claim interpretation. While these comments may see appropriate at the time, applicants will typically not be aware of infringing products. Without this prior knowledge, applicants' arguments are likely to be interpreted and distorted in unforeseen ways. Thus, good prosecution practice advances only one argument at time.

By limiting continuation practice, applicants will suffer on two counts – they will be forced to place more statements on the record than needed, and they will be unable to rectify inadvertent problems in later continuation applications. Any disclosed subject matter that applicants were unable to claim because of the procedural pressure of the current proposal becomes dedicated to the public.[13]

Applicants will rapidly appreciate that rules limiting continuation practice and the number of examined claims create a very limited opportunity to secure claims. The reaction will have two

[11] 112 F.3d 473, 479 n. 2 (Fed. Cir. 1997)
[12] *See* Industry Coalition Print (September 1, 2005).
[13] *Johnson & Johnston Assoc. Inc. v. R.E. Serv. Co.*, 285 F.3d 1046 (Fed. Cir. 2002)



Biogen Idec 14 Cambridge Center Cambridge, MA 02142 Phone 617 679 2000 www.biogenidec.com

simple consequences. First, applicants will disclose far less to minimize the risk of dedicating material to the public without the benefit of patent rights. Besides the obvious loss of information for the public, reduced disclosure will also chill collaborations and damage partnerships as more information is preserved as trade secret. Second, applicants will raise the level of advocacy before the Office. Thus, applicants will frequently petition to remove finality of office actions and to traverse restriction, and will always appeal to the Board and the Federal Circuit. Such practice will only benefit lawyers, and it will exact a huge monetary cost on innovators and on the Office.

Standard continuation practice enables the early issuance of narrow claims. There is no reason to delay issuance of the narrow claims in one patent while the applicant appeals the rejection of the broader claims. In effect, limiting continuations punishes an applicant by either (i) delaying issuance of the allowed narrow claims or (ii) requiring forfeiture of the broader claims to expedite issuance of the narrower claims.[14] Traditionally, continuations have enabled applicants to protect their core invention with narrow claims and then to work with the Office in later applications to determine the outer bounds of their contributions. The limit to ten claims hampers securing the core invention, while the limitation on continuations forecloses later opportunities.

***The current proposal will extract a huge cost from small and large companies.***

If implemented in their current form, the proposed rules will substantially increase the cost of obtaining patent protection for intellectual property since patent prosecution will necessitate more costly appeals, petitions to the commissioner, concurrent multiple divisional prosecution, and, in some cases, detailed and expensive ESDs. Although Biogen Idec is a large entity, over 90 percent of biotechnology companies are small businesses. Therefore, the significant increase in prosecution costs implicated by the proposed rules are unfairly burdensome on this industry as a whole.

***Such drastic rule changes require further discussion and public comment.***

Because the proposed rules comprise such a drastic change in patent practice, there should be an extended period of review. In contrast to the present proposed rules, the Office spent several years studying a single, much narrower issue: restriction reform in TC 1600. The Office's analysis of potential solutions to a "broken" restriction practice included at least **two** periods of public comments, and still has not generated a final policy. For the pre-appeal brief conference, the Office instituted a period of "beta testing" of the process to evaluate if it improved practice. The Office should take at least that level of care to understand all the implications of the much broader rules that are currently proposed, and to ensure their fair application. Biogen Idec strongly encourages the Office to at least publish interim rules prior to any final rulemaking here.

[14] Patent term adjustment (PTA) is not always a solution, for example, where a patent must issue before FDA approval to receive patent term extension, 35 U.S.C. § 156(a), or where the claims are directed to early stage activities (e.g., screening methods and research tools) and extensions to the end of the patent term have little value.



Biogen Idec 14 Cambridge Center Cambridge, MA 02142 Phone 617 679 2000 www.biogenidec.com

## V. Conclusion

In closing, Biogen Idec appreciates that the Office is faced with a difficult problem and that solutions that burden applicants may be inevitable. However, it is unclear if and how the current proposal alleviates the Office's workload. What is clear is that the current proposal will severely and disproportionately burden biotechnology companies with negative consequences to the public.

The Office can and should consult with Congress before radical reformation. Patents are critical to innovation and the American economy. The patent system should not be thrown into chaos unilaterally by the agency when Congress is on the cusp of reforming the statute. Biogen Idec is willing to work with the Office to develop a strategy that fairly protects innovation and thereby advances the interests of the public.



**Biogen Idec** 14 Cambridge Center Cambridge, MA 02142 Phone 617 679 2000 www.biogenidec.com