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From: Tom Hunter [mailto:thunter@quinelaw.com]
Sent: Friday, April 07, 2006 7:12 PM
To: AB93Comments
Subject: RE: Notice of Proposed Rulemaking Entitled "Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims" 71 Fed. Reg. 48-61

Please see the attached comments regarding Proposed Rulemaking Entitled “Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims” 71 Fed. Reg. 48-61

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April 7, 2006

VIA E-MAIL TO AB93Comments@uspto.gov

Robert W. Bahr
U.S. Patent and Trademark Office

RE: Notice of Proposed Rulemaking Entitled "Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims" 71 Fed. Reg. 48-61

Dear Sir,

We write in opposition to the "Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims" because these changes will have a devastating impact on the biotechnology industry and will not achieve the purported goals of the rule change.

The most problematic aspect of these rules is the requirement that divisional applications may only claim priority to a **single** nonprovisional application. Consequently, all desired divisional applications must be filed during the pendency of the first nonprovisional application related to an invention (*see* Proposed § 1.78(d)(1)(ii)).

In the biotech area, even for relatively simple cases, 10- to 20- or more-way restrictions are not unusual. Such restrictions result, *e.g.*, from the failure of the examining corps to follow MPEP § 803.04; *i.e.*, based on our prosecution experience, it appears that Group 1600 has determined that only 1 biological sequence will be examined per case, despite the stated rule that, in most cases, 10 sequences per case are to be examined. Indeed, Group 1600 has applied the "1 per case" rule even to related sequences, in violation of MPEP § 803.02 and In re Harnish 206 USPQ 300 (CCPA 1980).
Under the new rules, an applicant could have to file 10 to 20 or more divisional applications prior to issuance or abandonment of the first nonprovisional application to have the application fully examined. Applicants would also have to bear the costs of prosecuting these 10 to 20 or more applications simultaneously. Previously, applicants could prosecute divisional applications sequentially (*i.e.*, on allowance of the first case, a divisional was filed claiming priority to the first case, and on allowance of the second case, a divisional was filed claiming priority to both the first and second cases). Prosecuting divisional applications sequentially allowed applicants to spread filing and

prosecution costs over time during the early stages of product (*e.g.*, drug) development. The old regime thus allowed applicants to make decisions about which of the originally filed claims were most commercially relevant as more information accumulated during early product development.

Patents are the lifeblood of biotechnology and pharmaceutical companies. In this technology area, the time from invention to marketable product is long, often 5 to 10 years or longer. Product development is typically costly, on the order of a billion dollars for a new drug, for example. Any policy that impairs a company's ability to obtain commercially relevant patent coverage will undermine the company's willingness to invest in that product (*e.g.*, conduct clinical trials for FDA review) and will thereby restrict the progress of the biotech and pharmaceutical industries in bringing new human therapeutics to market.

The failure to obtain relevant patent coverage does not simply place a potentially lifesaving drug in the public domain. Absent relevant patent protection, a new drug simply **will not be submitted for FDA review**, and the American public will effectively be denied (perhaps forever) access to that potentially lifesaving drug.

The proposed rules impair a company's ability to obtain adequate patent coverage by forcing the company to choose between (1) devoting a much larger amount of money (*e.g.*, 10- to 20-fold more) to patent prosecution too early in product development to know what coverage will be commercially relevant or (2) giving up subject matter to which the company is entitled.

Moreover, the effect of these rules will, in fact, be contrary to at least one of the stated goals, namely that of reducing pendency by reducing the Patent Office's backlog. If the rules requiring the prosecution of divisional applications simultaneously is adopted, many applicants will file multiple divisional applications (perhaps 10 to 20 or more) prior to issuance of the first nonprovisional application. By contrast, under the old regime, applicants typically file no more than one divisional application prior to issuance of the first nonprovisional application.

Indeed, the practitioners in our firm will be reviewing all pending applications to identify cases in which it is advisable to file RCEs or continuing applications prior to the close of the comment period on these new rules. If others do so as well, the Patent Office could find itself with an increased backlog of cases similar to that incurred by the implementation of GATT.

Furthermore, the rules make no provision for existing portfolios of cases in which applicants are in the process of prosecuting divisional applications sequentially. Assume, for example, that an original application received a 5-way restriction relating to inventions A-E, invention A was prosecuted to allowance in the original application, and invention B is being prosecuted in a first divisional application in which an RCE has been filed when the rules go into effect. It is entirely unclear how applicants are to obtain examination or issuance of claims to inventions C-E. Under proposed § 1.78(1)(ii), no

further divisionals may be filed of right that claim the benefit of the first nonprovisional application

In the real world, particularly in the biotech sector, the ability to claim priority to the first application disclosing an invention is essential. Under proposed § 1.78(d)(1)(i), **no further RCE, continuation, or continuation-in-part may be filed of right**. Under proposed § 1.78(d)(1)(iv), applicants may file another continuing application **only** to obtain consideration of an amendment, argument, or evidence that **could not have been submitted** in the prior application. It is unclear that these grounds will encompass the filing of claims that were not previously considered due to a restriction requirement. In the absence of an explicit statement from the Patent Office (prior to May 3, 2006) that petitions for continuing applications will be granted in this situation, applicants must consider filing all possible divisional applications before the new rules go into effect.

The rules also make no provision for the possibility of a "late" restriction, for example in a continuation or divisional. In this situation, it appears that the applicant has no right to file an additional divisional application to prosecute claims to the non-elected invention.

Unless the foregoing issues are addressed in a way that takes real-world considerations into account, the Patent Office can expect an exponential increase in the number of petitions filed. In the past, biotech applicants have tended to acquiesce to improper restriction requirements because the stakes were not high enough to warrant the preparation of a petition. The new rules raise the stakes to the point that petitions (and subsequent court actions upon petitions that are improperly decided) will likely be the rule rather than the exception). Additionally, Appeal Briefs addressing improper restriction *rejections* will also become the rule, rather than the exception (restriction of a claim away from itself is a per se claim rejection for misjoinder and is appealable, rather than petitionable).

The Patent Office can also expect a dramatic increase in petitions for withdrawal of the finality of Office Actions improperly made final. Presently, it is less expensive to file an RCE than to file such a petition. Under the new rules, applicants will be forced to file such petitions when an Office Action is improperly made final.

Finally, the petitions office will also have to decide petitions under § 1.78(d)(1)(iv), for which the standards are not yet clear. Given that the petitions office has, in numerous cases, taken at least a year to decide petitions to reverse a simple improper holding of abandonment (*e.g.*, where the Patent Office lost an Office Action Response or misplaced formal drawings), the new rules will unquestionably introduce more confusion, uncertainty, and delay into prosecution.

The second most problematic aspect of the proposed new rules is the limitation of applicants to one RCE or continuing application for a given first nonprovisional or divisional application. Contrary to the Patent Office's contentions, this will unduly burden and limit applicants and examiners and will likely increase pendency.

This limitation burdens applicants by requiring them to respond to a first Office Action by preparing what will *de facto* be an Appeal Brief with all necessary supporting documentation including declarations. Because the filing of an RCE or continuation application cuts off an applicant's right to any further prosecution, RCEs and continuations can only be filed as a last resort, *i.e.*, after appeal to the Board. Furthermore, because the examiner can refuse to consider any evidence filed after a Final Office Action, all evidence necessary to support an appeal must be filed in response to the first Office Action.

The requirement for a *de facto* Appeal Brief in response to a first Office Action ignores the reality that many rejections can be overcome by simply explaining the distinctions between the invention and the cited art to the examiner. In other words, many rejections can be overcome without the need for the applicant to prepare, and the examiner to review, declaration evidence. But applicants faced the inability to predict that the examiner will be unpersuaded by simple explanation, and only one opportunity to submit additional evidence, will be forced to submit such evidence in response to the first Office Action to ensure that it is part of the record for appeal. In the event of a Final Office Action, applicants will file an appeal, which will transmute the current backlog of "rework" applications to a backlog of appeals. When the applicants that are currently prosecuting RCEs or continuing applications in an effort to obtain issuance of commercially relevant claims are instead prosecuting appeals, the time to decision will increase, which will increase pendency.

Furthermore, the proposed rules would eliminate legitimate and beneficial uses of RCEs and continuing applications. A common strategy, which is critical to start-up companies, in particular, is to prosecute an application to the point of an indication of allowable subject matter. The non-allowable subject matter can be canceled from the application and pursued in a continuation application, allowing the first application to issue. This strategy is especially important in the area of biotech, where complex § 112 (description/enablement) issues make it difficult to obtain the patent coverage to which the applicant is entitled in the first application. The ability to obtain more limited coverage initially while still preserving the ability to pursue broader, more commercially relevant, coverage is often essential to a start-up attempting to obtain funding. However, under the proposed new rules, as explained above, continuations will only be filed after appeal, eliminating this valuable strategy, which will hinder, not promote, innovation.

An additional beneficial use of RCEs has been to allow examiners more time to consider the issues in a case. Under the old regime, applicants could simply file an RCE if the examiner believed that a response after a Final Office Action raised new issues. Under the proposed rules, applicants will file more petitions in this situation in an effort ensure that the examiner considers, where obligated to, arguments or evidence filed after final rejection and that evidence necessary for appeal is made of record. Such petitions will further burden the Petitions Office and create confusion as to the content of the record in cases that proceed to appeal.

Where petitions are granted, examiners will be forced to give further consideration to cases without the benefit of an RCE. If examiners are pressured to maintain the same appearance of productivity as under the old regime, quality of examination will be compromised, not enhanced, as the Patent Office claims.

In addition, the United States has always been a "first to invent" rather than a "first to file" country, and the interference proceeding in the Patent Office was provided by statute to permit resolution of priority of invention between competing applicants. Previously, where claims were allowed that included multiple claim sets, only one of which might form the basis for an interference, a common practice was to cancel the potentially interfering claims, allow the non-interfering claims to issue, and prosecute the potentially interfering claims in a continuation. Under the proposed rules, if a continuation or RCE has already been filed, it may be impossible for the applicant to file an application simply for the purpose of copying claims and provoking an interference. If so, the applicant is, in effect, denied a statutory right.

Finally, it is incumbent on the Office to consider the real-world effects on practitioners and applicants that will occur as a result of the proposed changes. It is plain that the proposed rule changes, which are deceptively simple on the surface, will result in significant, though still not fully understood, shifts in how applications are to be filed and prosecuted. The potential implications for practitioners and applicants of the practice changes necessitated by the rules are profound. Years, or even decades of practitioner experience and two centuries of public expectation regarding continuation and divisional practice will be overturned. There will be significant court challenges to determine whether the Office even has the authority to make the proposed changes (and there are clearly strong arguments that the Office lacks this authority). It will, for some time, be unclear what should constitute standards of practice for patent drafting and prosecution as a result of the proposed rule changes and uncertainty surrounding the legality of the rule changes. Experienced practitioners will not, at least for some time, be sure how to advise clients in complex cases. The net effect of this uncertainty will ultimately be very costly to the public at large.

In view of the problems with the rules as proposed, we suggest the following modifications.

(1) **Do not modify divisional practice**. Allow applicants to continue to file divisional applications in series. This will prevent the Patent Office from being overwhelmed with divisional filings and will likely reduce the total number of applications filed in a given patent family. For example, in the case of a 6-way restriction, an applicant may file 5 divisional applications if forced to decide on filing prior to issuance of the first application. If, however, the applicant can prosecute the divisional applications serially, rather than in parallel, the applicant may decide after one or two divisional applications that the coverage obtained is sufficient in light what has been learned over time about the commercial importance of the inventions to the applicant's business. In this example, serial prosecution would reduce the total number of cases pending in the Patent Office by half.

(2) **Give applicants two unrestricted opportunities to have amended claims, arguments, or evidence entered and considered** and to interview the case with the examiner. The expectation that the applicants and examiner should be able to resolve the issues in biotech cases in one exchange simply does not comport with reality, even when both parties are competent and motivated. In our experience, the European model for patent prosecution is far superior to that in the United States in that the applicant and examiner have, on average 2-3 exchanges followed by an oral hearing, if necessary, to resolve outstanding issues. If applicants' efforts to overcome the rejections set forth in a first Office Action are unsuccessful, and applicants have a second unrestricted opportunity to respond to the rejections, including the opportunity to interview the case, we believe applicants will be more able to obtain meaningful coverage without the need for appeal, RCE, or continuing applications. Simply put, the reality is that we need two real bites at the apple. This policy would also ensure that, in the event of an appeal, applicants would have a fair opportunity to prepare the record. This could readily be accomplished by providing a second non-final office action as of right, or, alternatively, by adopting mandatory entry and consideration of amendments, arguments, and/or evidence (*e.g.*, declarations) filed after final rejection.

3) **Provide an expedited review process for petitions to withdraw finality** so that applicants have an answer to the petition before the deadline for filing an Appeal Brief.

4) **Provide an explicit and unequivocal right to file a continuation for the purpose of copying claims to provoke an interference**.

We submit that the suggested modifications of the proposed rules will help the Patent Office achieve the goal of reduced pendency, while avoiding the most serious of the adverse affects of the proposed rules on applicants.

Sincerely,

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