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From: Danielle Pasqualone [mailto:pasqualone.danielle@gene.com]
Sent: Monday, May 01, 2006 3:24 PM
To: AB93Comments
Subject: Comments on Notice of Proposed Rule Making, 71 Fed. Reg. 48

Dear Mr. Bahr,

Please see the attached comments from Genentech, Inc., on the Notice of Proposed Rule Making entitled "Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims," 71 Fed. Reg. 48 (January 3, 2006).

Thank you,

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May 1, 2006

By electronic mail – AB93Comments@uspto.gov

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

Re: Notice of Proposed Rule Making Entitled "*Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims*," 71 Fed. Reg. 48 (January 3, 2006)

Dear Mr. Bahr:

Genentech, Inc. ("Genentech") welcomes the opportunity to comment on the above-captioned Notice of proposed rule making. Considered the founder of the biotechnology industry, Genentech has been delivering on the promise of biotechnology for almost 30 years, using human genetic information to discover, develop, commercialize and manufacture biotherapeutics that address significant unmet medical needs. Today, Genentech is among the world's leading biotech companies, with multiple products on the market for serious or life-threatening medical conditions and over 40 projects in the pipeline. We are the leading provider of anti-tumor therapeutics in the United States. Of course, Genentech is not alone in its efforts to develop new biotherapeutics. Recent data from the Biotechnology Industry Organization indicates that there are currently more than 300 biotechnology-based products in clinical trials targeting more than 200 diseases, including various cancers, Alzheimer's disease, heart disease, diabetes, multiple sclerosis, AIDS, and arthritis.

Genentech invests over a billion dollars annually in its research and development programs. Strong patent protection is essential for recouping that investment, encouraging innovation, and sustaining future research and development. For a number of reasons, we believe that the proposed rule changes will have a profoundly negative impact on Genentech's ability to obtain commercially relevant patent protection for its discoveries. Indeed, we believe that the proposed rule changes will disproportionately harm the biotechnology industry as a whole.

Accordingly, we believe that the Office should not enact the proposed rules. If the Office does proceed with enacting rules changes of the type proposed, we respectfully request that it at

least make certain modifications to the proposed rules, as described below.[1] We believe that the modifications we are proposing here will lessen the adverse effect of the rule changes on the biotechnology industry and result in a more equitable and effective rule package. In particular, we set forth several specific circumstances that we believe the Office should recognize, and should explicitly identify in the rules, as examples of when it will be appropriate for applicants to file second or subsequent continuation applications and divisional applications. We also offer several suggestions for fostering more productive interactions between patent applicants and Examiners to reduce the need for filing continuing applications.

In providing the following comments on the proposed rules, we are mindful of the Office's goals of (1) decreasing the backlog of unexamined applications, (2) increasing public "certainty" as to the scope of patent protection, and (3) improving the quality of patent examination. We believe that our suggestions advance those goals and at the same time will help to ensure the continued availability of commercially relevant patent protection for biotechnology inventions and other inventions.

I. Brief Overview of Biotechnology Drug Development

The development of a biotech drug is a lengthy process that entails considerable cost and risk. This process starts with basic research into the molecular mechanisms of human disease. That research ultimately leads to the identification of a large number of unique, biologically active molecules as drug candidates. It is typically at this early phase in the drug discovery and development process that a biotechnology company will file patent applications disclosing those molecules. Such applications are often critical to secure funding from investors in the short term and to protect commercial products arising from that research in the long term.

After such patent applications are filed, many years of additional experimentation and testing are required to identify which of those molecules initially considered to be drug candidates is most likely to prove safe and effective when administered to humans. The development process involves extensive *in vitro* and *in vivo* testing, including the extensive human clinical trials that are required to obtain U.S. Food and Drug Administration approval to market a drug in the United States. A promising molecule will often pass scientific muster and clear preliminary regulatory hurdles only to be withdrawn from further development due to lack of efficacy or unexpected adverse effects discovered late in preclinical or clinical testing. In that event, the process may be repeated with an alternative molecule selected from amongst the numerous molecules sufficiently disclosed in the patent application filed many years before. In other cases, a molecule may initially prove ineffective in the treatment of a certain disease or

[1] Although many of our suggestions are based on the assumption that the Office will ultimately enact the proposed rules in their present form or with modifications, we question the Office's authority to do so. We believe that the Office is attempting to limit applicants' statutory rights as expressly provided in 35 U.S.C. § 120 and as recognized by the Federal Circuit. *See Johnson & Johnston Associates Inc. v. R.E. Service Co.*, 285 F.3d 1046, 1055, 62 USPQ2d 1225, 1231 (Fed. Cir. 2002) ("A patentee who inadvertently fails to claim disclosed subject matter, however, is not left without remedy....[A] patentee can file a separate application claiming the disclosed subject matter under 35 U.S.C. § 120 (2000) (*allowing filing as a continuation application if filed before all applications in the chain issue*).") (emphasis added).

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patient population, only to demonstrate efficacy with another disease or patient population during additional clinical testing. Only if and when the FDA concludes that a molecule is clinically safe and effective for the treatment of a specific disease – many years after the filing of the first patent application disclosing that molecule – may an innovator biotechnology company begin to earn back those investments through the sale of a commercial product.

II. Comments on Proposed 37 CFR §§ 1.78(d)(1)(iv) and 1.114(f) Concerning Continuation Applications and Requests for Continued Examination (RCEs)

Strong patent protection for the commercial product – the approved biotech drug – is essential. The limited period of market exclusivity it provides gives a biotechnology company an opportunity to recoup the research and development costs incurred in bringing the product to market, and the incentive to undertake those expenses in the first place. Applicants, however, face some practical challenges in obtaining such patent protection. As described above, a patent application usually will be filed based on the results of early research, long before the FDA would consider approving a molecule disclosed in the application. Yet it is not realistic to expect applicants to present and pursue at the outset of prosecution claims covering each one of numerous biologically active molecules that are typically disclosed in such an application just to ensure patent protection for the one (or very few) that the FDA may approve many years later. The Federal Circuit recognized this "disconnect" between the point at which biologically active molecules are ready for filing in a patent application and the point at which such molecules are actually ready for therapeutic administration to humans:

> Usefulness in patent law, and in particular, in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans.

In re Brana, 51 F.3d 1560, 1568, 34 USPQ2d 1436, 1442 (Fed. Cir. 1995) (cited in MPEP § 2107, Part III).

Therein lies the importance of continuation application practice to Genentech and other biotechnology companies. Continuation applications have long provided a mechanism for applicants in the biotechnology industry to pursue claims covering biologically active molecules that are first disclosed in an early application but that are found to be commercially important only much later. Additionally, current continuation practice has allowed applicants to submit to the Office data generated during the course of lengthy preclinical and clinical studies to rebut claim rejections, e.g., obviousness, enablement, or utility rejections. The proposed rules would substantially limit those appropriate and well-justified uses of continuation applications. Accordingly, we ask that the Office modify proposed §§ 1.78(d)(1)(iv) and 1.114(f) by specifying that the following "showings" will support the filing of a second or subsequent continuation application or RCE.

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1. Affidavit or other showing that applicants are preparing to submit or have already submitted an IND or BLA

The regulatory approval process for a biotech drug involves multiple submissions of information, including preclinical and clinical data, to the FDA. When a product shows initial promise in preclinical studies, it may undergo clinical testing in humans only after an Investigational New Drug application (IND) has been submitted to and accepted by the FDA. The following information must be provided in an IND: (1) preclinical data from animal pharmacology and toxicology studies demonstrating that the product is reasonably safe for initial testing in humans; (2) information related to the manufacture of the product that will be administered to humans, including information related to its composition and stability; and (3) information on the investigators who will oversee the clinical testing and the protocols that will be used.[2] Obtaining that information, and then carrying out human clinical trials pursuant to an IND, takes considerable time and resources. If the human clinical trials yield favorable results, a Biologics License Application (BLA) with those results may be submitted to request FDA approval for marketing the product. The decision to enter a molecule into the regulatory approval process marks a point at which it is critical that applicants retain the opportunity to secure patent protection for their potentially marketable product.

To ensure that applicants in the biotechnology industry are able to obtain that patent protection, we propose that the Office should allow applicants to file a second or subsequent continuation application that claims a molecule (or an invention related to that molecule, such as a method of treatment) that will be entering, or has already entered, the regulatory approval process. Accordingly, we propose that applicants could satisfy the requirement for a "showing" under §§ 1.78(d)(1)(iv) in one of two ways. First, applicants could provide an affidavit or other statement to the Office confirming that they are presently engaged in obtaining information, such as data from preclinical animal studies, needed for submitting an IND for that molecule. Second, applicants could provide evidence to the Office that they have already submitted an IND or BLA (or an amended IND or amended BLA) for the particular molecule.

By the time an applicant is preparing to submit, or has already submitted, an IND or BLA covering a particular molecule, it is quite possible that a prior-filed patent application disclosing that molecule will no longer be pending. In the absence of such a pending application, a continuation application claiming that molecule cannot be filed. To address this situation, we propose that the Office allow applicants to file a second or subsequent continuation application at a time when a parent application is still pending and then immediately suspend action on the continuation. Suspension of action is permitted under the present rules "for good cause" and for a limited period of time (no more than six months). *See* 37 C.F.R. §1.103(a). We propose that the Office revise or adopt a modified version of §1.103(a) that would allow applicants to suspend action as a matter of right for up to 5 years.[3] Action on the continuation application would resume only upon request by applicants, and only if applicants are able to make a showing that

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[2] *See* http://www.fda.gov/cder/regulatory/applications/ind_page_1.htm for the requirements for submitting an IND application.

[3] This period of time is consonant with deferred examination in various foreign countries.

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they are preparing to submit, or have already submitted, an IND or BLA for a molecule disclosed in the continuation. At the same time, applicants would amend the claims of the continuation to correspond to the subject matter of the IND or BLA. By allowing applicants to suspend action under these circumstances, the Office will ensure that applicants in the biotechnology industry are able to file continuation applications to obtain patent protection for their actual commercial products.

2. Submissions that obviate rejections or otherwise respond to an Examiner's request for information

During prosecution, it is sometimes necessary for applicants to submit data or other evidence to obviate a rejection or to otherwise respond to an Examiner's request for additional information. The necessity to submit such evidence should justify the filing of a second or subsequent continuation application or RCE if the evidence is not readily available and/or is the result of lengthy experimentation. For example:

Evidence or data useful to obviate rejections under 35 U.S.C. § 103

The Office should allow applicants to submit evidence or data in response to a rejection under 35 U.S.C. § 103, provided the evidence or data were not obtained in time for submission in the parent application. Such data may include, for example, evidence of unexpected or synergistic effects or inadequacy of the cited art. Although the Office has represented in its "Town Hall" meetings that it would allow applicants to submit such data, the Office further indicated that such submissions would be limited to data that "just became available" and "is the result of lengthy experimentation that was started after the applicant received the rejection for the first time."[4] Such limitations, however, are unduly restrictive.

The Office should allow applicants to submit data regardless of the starting date of experimentation, so long as the data were not obtained in time for submission in the parent application. For example, a course of experimentation might be started before any obviousness rejection is imposed or even before the filing date of the application, but ultimately, that experimentation might coincidentally produce information relevant to the rejection, such as unexpected results.

Furthermore, it is not reasonable to assume that relevant experimental data will "become available" during the four-month time frame in which an applicant would be required to file a petition under proposed § 1.78(d)(1)(iv). Certain experiments, such as animal studies, often span many months or more. Thus, the Office should accept an interim statement from the applicant that experimentation is underway but not yet completed, and the nature of the experimentation is such that it requires an extended period of time to complete.

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[4] *See* slide no. 60 from the Office's presentation at the Town Hall Meeting on Proposed Rules on Claim and Continuation Practice, held at Berkeley, CA, on February 28, 2006.

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"Confirmatory" evidence or data to obviate rejections under 35 U.S.C. §§ 101 and 112, first paragraph (enablement)

The Office should allow applicants to submit "confirmatory" evidence to obviate rejections under 35 U.S.C. §§ 101 and 112, first paragraph (enablement), if that evidence was not available in sufficient time for submission in the parent application. This suggestion is consistent with the Office's current practice of accepting evidence or data confirming that an asserted utility is substantial, specific, and/or credible in response to rejections under 35 U.S.C. §§ 101 and 112, first paragraph (enablement). If, as in the above example, applicants are conducting experiments to obtain data that will obviate those rejections, but those experiments are not completed in time for submission by way of a petition under § 1.78(d)(1)(iv), then the Office should accept a statement from the applicant that experimentation is underway but not yet completed, and the nature of the experimentation is such that it requires an extended period of time to complete.

Evidence, data, or other information requested by the Examiner

If an Examiner expressly requests that an applicant submit certain evidence, data or information for any reason during prosecution, for example, under 37 C.F.R. § 1.105(a)(1), and the requested evidence, data, or information is not readily available to an applicant, the Office should afford the applicant a reasonable opportunity to submit the requested information in an additional continuation application or RCE if it cannot be provided earlier.

Additionally, we propose that the Office revise or adopt a modified version of 37 C.F.R. § 1.103(a) that would allow applicants to suspend action in the continuation application or RCE in any of the above circumstances until the necessary experimental data is obtained.

3. Declarations under 37 C.F.R. §§ 1.131 and 1.132

The Office should consider declarations under §§ 1.131 and 1.132 as acceptable "showings" under proposed §§ 1.78(d)(1)(iv) and 1.114(f). Applicants often initially attempt to obviate rejections under 35 U.S.C. §§101, 102, 103, and 112 by arguing against those rejections or by submitting non-declaratory extrinsic evidence. If those efforts are unsuccessful, applicants may need to file declarations under §§ 1.131 and 1.132. Accordingly, applicants may not even seek to obtain declarations under §§ 1.131 and 1.132 until after a second or subsequent Office action on the merits. Furthermore, the preparation of such declarations typically requires considerable time and effort. For declarations under § 1.131, adequate time is needed to locate inventors and laboratory notebooks containing information for antedating the cited art. Likewise, for declarations under § 1.132, suitable declarants must be identified, and any necessary experiments conducted and reported. Accordingly, the Office should acknowledge this practice by allowing the filing of an additional continuation application or RCE to provide applicants with the time needed to prepare and have executed suitable declarations under §§ 1.131 and 1.132. Alternatively or additionally, the Office should allow those declarations to be submitted as a matter of right after a final Office action has issued.

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4. Provoking an interference

The Office should deem it acceptable for applicants to file a continuation application for the purpose of provoking an interference. Under 35 U.S.C. §135(b), an applicant must present one or more claims to provoke an interference with an issued patent or published application within one year of the issue or publication date. It may be preferable or even required to present such claim(s) in a new continuation application, for example, if presenting such claim(s) in an existing application would unreasonably complicate or delay the prosecution of that application or if prosecution of that existing application has already closed. Accordingly, we propose that an applicant be permitted to file one or more claims in a second or subsequent continuation to provoke an interference with an issued patent or published application if the applicant provides a statement that 1) identifies such patent or published application and 2) asserts that the newly presented claim(s) are directed to substantially the same subject matter as at least one of the claims in such patent or published application. If the applicant ultimately amends the claim(s) in the continuation application, and the Office makes a determination that the requirements of 35 U.S.C. § 135(b) are no longer met, the applicant would lose its claim for priority to any prior application(s) under 35 U.S.C. §120 or §119(e).

5. Response to a new ground of rejection

The Office has stated that proposed § 1.78(d)(1)(iv) would be satisfied if a "final rejection contains a new ground of rejection *that could not have been anticipated by the applicant* and the applicant seeks to submit evidence which could not have been submitted earlier."[5] The Office should eliminate the requirement that the new ground of rejection "could not have been anticipated by the applicant." That requirement is unduly vague and subjective. If the evidence in question is relevant to a new ground of rejection and could not have been submitted earlier, there is no reason to condition its submission on an arbitrary "foreseeability" standard. Moreover, newly available evidence should support the filing of a continuation or RCE if it responds not only to a rejection expressly identified as a "new ground" of rejection, but also to a newly raised basis or rationale for maintaining a previously issued rejection.

6. Claims to species or subgenera within a genus previously found to be patentable over the prior art

The Office should allow applicants to file a continuation application as a matter of right if that application claims a species or subgenus that falls within a generic claim allowed or issued in at least one of the priority applications. If a disclosed genus has already been found patentable over the prior art, then all of the species and subgenera within that genus are likewise free of the prior art. Consequently, claims to any such species or subgenus in a subsequent continuation application need only be examined for compliance with 35 U.S.C. § 112, thereby posing little burden on the Office. Furthermore, the allowance or issuance of a generic claim in a prior-filed application, together with the disclosure in that application of the species or subgenus falling

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[5] *See* slide no. 61 from the Office's presentation at the Town Hall Meeting on Proposed Rules on Claim and Continuation Practice, held at Berkeley, CA, on February 28, 2006 (emphasis added).

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within that generic claim, reasonably places the public on notice that the applicant may wish to claim such species or subgenus in a further continuation application.

7. Claims finally rejected in a case having other allowed claims

The Office should allow an applicant to cancel rejected claims from an otherwise allowable continuation application and pursue only those claims or claims of narrower scope in a further continuation application. This will permit applicants to avoid delay in the issuance of allowable claims while the rejected claims undergo further prosecution or appeal in the further continuation application. Under these circumstances, the Office may permit Examiners to issue a first final Office action in the further continuation application if the claims presented in that further continuation were under final rejection in the parent application. Alternatively, the Office may require that the finally rejected claims proceed directly to appeal in the further continuation application. Prompt issuance of the allowable claims would serve the public interest by providing clear notice regarding what claims are actually issued.

8. Newly found information that could not have been cited in the prior application or art not considered

The Office should permit applicants to submit any material information in a continuation application if applicants did not become aware of that information until after allowance of the prior-filed application. For example, new art may be cited, e.g., in a foreign counterpart application, that was unknown to, and thus could not have been anticipated by the applicant. If this art is found after allowance of the application, applicants should be permitted to file a continuation application to have it considered by the Office. Specifically, a further continuation application or RCE should be allowed upon a showing that the art (or any other information that applicant has a duty to disclose under 37 C.F.R. § 1.56) was not known to the applicant to the best of its knowledge in time to file it in the parent application. The same showing should be allowed where the Examiner did not consider art cited in an Information Disclosure Statement filed in an existing continuation, and the applicant brought the omission to the attention of the Examiner before prosecution is closed. Likewise, the Office should permit applicants to file continuation applications solely for the purpose of effecting a change in inventorship, should the need for such a change come to light after prosecution of the prior-filed application is closed. In each of these situations, the claims in the continuation application would remain the same as in the prior-filed application.

III. Comments on Proposed § 1.78(d)(1)(ii) Concerning "Involuntary" Divisional Applications

Proposed § 1.78(d)(1)(ii) provides that a divisional application can claim the benefit of only a single non-provisional application. In practice, this means that any divisional application will have to be filed during the pendency of the application in which a restriction requirement was imposed.

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Changing divisional application practice in this manner would contradict the long-settled expectations of applicants in the biotechnology industry. Current practice allows applicants to claim patentably distinct embodiments of an invention over a commercially realistic period of time by filing divisional applications "in series." This current practice is good for the industry, as it enables applicants to manage costs. It also provides applicants with sufficient time to assess the commercial viability of various patentably distinct inventions before expending resources prosecuting applications that cover those embodiments. And, given the lengthy time for product development in this industry, it would be unfair to force applicants to abandon those patentably distinct embodiments.

The proposed rule would also impose unreasonable financial burdens on applicants. The expense of filing all divisional applications during the pendency of an original non-provisional application might prove economically infeasible for applicants with limited resources. Indeed, the proposed changes in divisional practice would have a harsh impact on the biotechnology industry in particular. Examiners frequently impose what we believe to be unreasonable and often improper restriction requirements on applications directed to biotechnology inventions, necessitating the filing of numerous divisional applications. For example, it is common practice for Examiners to restrict examination to only a single biological "sequence," (i.e., a nucleotide sequence or an amino acid sequence), even though the MPEP permits examination of up to 10 biological sequences in an application. *See* MPEP §803.04. Accordingly, under the proposed rules, applicants in the biotechnology industry would have to simultaneously file numerous divisional applications claiming biological sequences that should have been examined in the parent application.

Finally, we believe that the proposed rule would exacerbate, not alleviate, the Office's backlog of unexamined applications. For applicants with the resources to file a full suite of divisional applications, the proposed rule is likely to result in a net increase in new application filings. Many of the divisional applications that would be filed under the rules as proposed would not be filed at all if applicants had sufficient time to identify the most commercially valuable embodiments and file divisional applications covering only those embodiments.

Moreover, the filing of many divisional applications "in parallel" will likely lead to more inefficient prosecution, particularly if multiple parallel applications are distributed to different Examiners (and perhaps different art units) who apply inconsistent standards for restriction or examination on the merits.

To address these concerns, we propose the following rules: Applicants should be permitted to continue the practice of filing "serial divisional applications" (i.e., divisional applications claiming the benefit of *more than one non-provisional application*). To discourage what the Office regards as "late claiming," however, the claims pursued in a continuation of any serial divisional application must be of the same scope as, or of a narrower scope than, the claims presented in that serial divisional application. This is consonant with European divisional practice, thus harmonizing USPTO practice with EPO practice. Further, such a rule would promote the "certainty" that the Office seeks, in that the public is "on notice" that applicants

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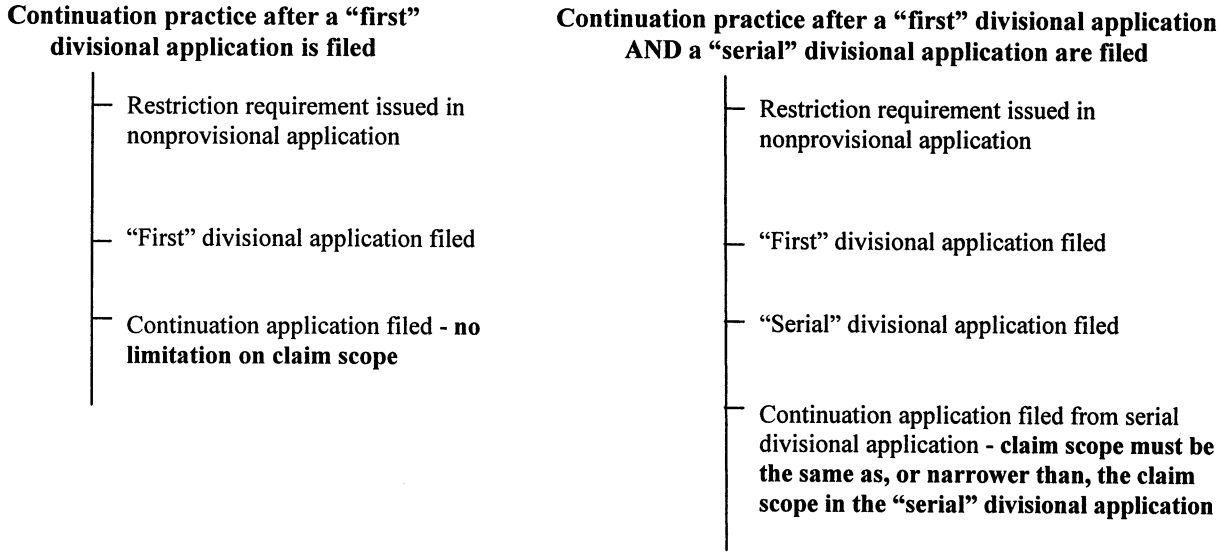
intend to pursue the claims presented in their original restricted claim set and potentially any claims of the same scope as, or of narrower scope than, that of the original claim set.

Under this proposed solution, a continuation of a divisional application that claims the benefit of only a single non-provisional application (i.e., a "first" divisional application) may contain claims outside the scope of the claims in that divisional application, as currently permitted by the proposed rules.

The following timelines illustrate these different scenarios:



IV. Transitional Provisions

Many applicants (not just those in the biotechnology industry) have implemented patent prosecution strategies based on current rules relating to continuation and divisional applications. For example, in a patent application having both allowed and rejected claims, it is currently common practice to cancel the rejected claims and pursue those claims in a continuation application so that the allowed claims can issue. Likewise, it is currently common practice to file a single divisional application claiming only one of several non-elected inventions from a parent application, with further divisional applications being filed "in series" if necessary to cover other commercially relevant embodiments of the invention. The proposed rules will change all that. Applicants will need to revise their practices to comply with the new rules, and may incur significant expenses in doing so. Accordingly, we urge the Office to include in the proposed rules "transitional provisions" that will allow applicants adequate time to implement the new rules, and that will reduce the incentive applicants may otherwise have to preemptively file numerous continuation and divisional applications before the new rules go into effect.

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At a minimum, we suggest the following transitional provision: "A non-provisional application filed after the effective date of the rules may claim the benefit of more than one prior-filed application without the requisite showing under proposed § 1.78(d)(1)(iv), if at least one of the prior-filed applications was filed before the effective date of the rules, and no more than one of the prior-filed applications was filed after the effective date of the rules." This provision would allow applicants to file, as a matter of right, a first continuation and a second continuation of *any* application pending before the effective date of the rules. A showing under § 1.78(d)(1)(iv) would only be required for a third or subsequent continuation application.

We also urge the Office to adopt the following transitional provision to allow applicants to continue the practice of filing "serial" divisional applications: "An involuntary divisional application (i.e., a divisional application necessitated by a restriction requirement) may claim priority to more than one prior-filed application if at least one of the prior-filed applications was filed prior to the effective date of the rules."

This provision will eliminate the need for applicants to file a wave of divisional applications immediately before the effective date of the rules, particularly in those situations where applicants have already abandoned the non-provisional application that was initially subjected to a restriction requirement.

V. Suggestions Regarding the Efficiency of Examination Procedures

Genentech believes that appropriate modifications, such as those discussed above, will lessen the adverse impact of the proposed rule changes on patent applicants, particularly those in the biotechnology industry. However, to further reduce that impact, we encourage the Office to adopt policies that will foster more productive interactions between applicants and Examiners.

The Office should give Examiners greater discretion in conducting prosecution. For example, the Office should encourage Examiners to issue second and subsequent, non-final Office actions if the Examiner decides, in her/his discretion, that progress is being made in bringing the claims to allowance and agreement between the Examiner and applicant is anticipated, but additional time is needed for the Examiner to apprehend the invention fully and/or resolve outstanding issues with the applicant. Accordingly, the Office should ensure that there are no disincentives for Examiners to issue second and subsequent non-final actions. This suggestion is consonant with European patent practice, which gives Examiners substantial latitude in deciding whether to continue prosecution on the merits or issue a final action.

The Office should also provide expanded opportunities for Examiner interviews. In our experience, interviews are often the most effective and efficient way to resolve issues, particularly where there is simply a barrier to getting a point across. Pre-examination interviews should be permitted as a matter of right. Such an interview, conducted after the Examiner has reviewed the application, would allow an interchange with the applicant to clarify any uncertainties and resolve minor issues in advance of the preparation of a first action on the merits. Further, we believe that after-final interviews should be permitted as a matter of right, particularly if the Office adopts the proposed rules.

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Additionally, applicants should have the right to request that a supervisor attend any interview after a first action. Supervisors are best positioned to facilitate the interaction between an Examiner and an applicant's representative, and their presence can ensure quality control.

VI. Alternative Solutions

In addition to the rule changes that the Office has proposed for continuation, divisional, and RCE application practice, we believe the Office should consider alternative reforms that would effectively address the concerns that gave rise to the proposed rules. Such reforms might include, for example, (1) instituting a deferred examination system, (2) increasing the two-year time period for filing "broadening" reissue applications, (3) implementing reforms to harmonize restriction practice with PCT "unity of invention" practice, and (4) discouraging "late claiming" by placing limits on the belated presentation of claims unrelated to claims previously pending in an application. Genentech intends to elaborate upon these views in its response to the Office's request for comments on its new 21st Century PTO Strategic Plan.

VII. Conclusion

Genentech appreciates the opportunity to provide these comments to the Office. We support the Office's goals of enhancing the efficiency of its examination operations and increasing public certainty as to the scope of patent protection. However, those goals should not come at the expense of applicants' reasonable opportunity to secure commercially relevant patent protection for their inventions. Applicants in the biotechnology industry, more so than any other industry, face a unique set of challenges because of the long product development cycle and regulatory approval process that is required to bring a biotech drug to market. For that reason, we believe that the proposed rules would disproportionately harm the biotechnology industry.

Enacting the proposed rules in their present form would result in significant loss of patent rights and irreparable harm to many applicants in the biotechnology industry. Accordingly, we urge that the Office not enact the proposed rules, and alternatively that the Office modify the proposed rules along the lines that we have recommended.

Sincerely,
GENENTECH, INC.

/s/

Sean A. Johnston
Vice President – Intellectual Property

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