ZYMOGENETICS

April 28, 2006

Jon W. Dudas
Under Secretary of Commerce for Intellectual Property
and Director of the U.S. Patent & Trademark Office
Mail Stop Comments
P.O. Box 1450
Alexandria, VA 22313-1450

Attn: Robert W. Bahr
Senior Patent Attorney
Office of the Deputy Commissioner for Patent Examination Policy

RE: Comments Regarding Proposed Rules for "Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims" 71 F.R. 48 (January 3, 2006).

Dear Under Secretary Dudas,

ZymoGenetics, Inc. appreciates the opportunity to offer comments concerning the Proposed Rules for "Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims" 71 F.R. 48 (January 3, 2006). We respectfully request consideration of the following comments.

A. The Proposed Rules Are Against The Public Interest As They Disparately Impact The Biotechnological Arts

The Proposed Rules limiting continuing applications are particularly harmful with respect to the biotechnological arts where the inventions are complex and there are practical considerations in bringing a product to market that necessitate the need for multiple continuation and divisional applications. Product development times for therapeutic biotechnology products are long; the average time to advance a new drug from discovery to FDA approval is 10 to 15 years. See, Tufts Center for the Study of Drug Development reported in November 2001. During this long product development cycle, complex experiments are often required to determine the commercial embodiment of an invention and to address patentability issues arising during prosecution. The final commercial product may be a single embodiment among a number of embodiments in a patent application that discloses it, and that embodiment may not be known for years after the filing date.

Limits on continuing application practice will have a detrimental effect on U.S. biotechnology businesses. Biotechnology companies like ZymoGenetics have used multiple continuing applications to obtain a meaningful scope of drug patents that both narrowly cover a drug itself and that more broadly cover an area of protection surrounding the drug. Biotechnology companies often need to obtain issued patents quickly, e.g., on narrow

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embodiments of an invention, in order to raise essential investor capital. For this reason, broader and follow-on claims are pursued in continuations after issuance of a patent claiming narrower embodiments of the invention. Multiple continuing applications allow us the opportunity to provide specific data and information to the PTO as we advance a drug from discovery into clinical trials and eventually to patients. If we are denied this opportunity, we could be caught in a predicament where we cannot obtain needed scope of patent protection for drugs because continuing applications have been denied; and we are forced to accept very narrow patents prior to knowing the precise form of the therapeutic drug. Resulting patents might not cover the actual form of the therapeutic drug used in patients nor provide adequate broader protection against potential infringers making minor modifications to the drug.

If enacted, the Proposed Rules would create uncertainty in the biotechnology industry as to whether the full scope of the invention could be protected with a single continuation. As a small business, our patents have enabled us to attract investors who believe in the pursuit of therapeutic drugs, and this investment has enabled us to advance drugs into the clinic. Moreover, without patents protecting biotechnology products, the enormous costs of research and development may not be recouped. Without meaningful drug patents, investors may no longer support biotechnology industry efforts needed to make drugs, which could seriously damage the business. Without a robust biotechnology industry fewer new drugs would be developed to help patients fight their diseases.

Applicants in the biotechnological arts often submit multiple continuing applications to obtain the full scope of the invention(s) described and claimed in an application; i.e., the entire scope of the invention as entitled under law. Denying continuing applications unless "amendment, argument, or evidence *could not have been* submitted" could effectively limit biotechnology applications to a single continuing application. In so doing, the United States Patent and Trademark Office (PTO) would be denying an applicant's right to obtain claims to the full scope of their invention, to which an applicant is entitled by law.

We ***oppose*** the promulgation of these Proposed Rules. The limitation on continuing application practices under these rules would negatively impact the biotechnology industry and ultimately the availability of therapeutic molecules that may benefit the public. These outcomes would be against the public interest.

B. Proposed Rule 37 C.F.R. §1.78(d)(1) Is Unlawful Because It Is Beyond The PTO's Rulemaking Authority And Is Against Public Interest Because It Is Contrary To 35 U.S.C §120

Proposed Rule §1.78(d)(1) limits the number of nonprovisional applications from which a nonprovisional application may claim benefit. Such a limitation is contrary to both the statute and the case law. 35 U.S.C. §120 states, "An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title . . . *shall* have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application *or on an*

application[1] *similarly entitled to the benefit of the filing date of the first application . . .*" (Emphasis added). The statute is unambiguous—applicants have a right to claim priority to an earlier filed application that discloses the claimed invention.

The statute also gives applicants a right to claim priority back through a series of applications so long as the chain of copendency has not been broken. The CCPA stated in *In re Henriksen*, "We agree with appellant's analysis to the effect that the statute provides no limit to the number of applications that may be copending." *In re Henriksen*, 399F.2d 253, 261, 158 USPQ 224 (CCPA 1968). The court went on to explain that conditions for patentability are set forth in 35 U.S.C. §§102 and 103, and that the Office's attempt to limit claims to earlier filing dates "circumscribed a meaning of long standing attributed to 102(b)." *Id.* The court concluded by stating that any limitation on priority claims "is for the Congress to decide." *Id.* at 262. See also, *In re Hogan*, 559 F.2d 595, 604, 194 USPQ 527 (CAFC 1977) ("[A] limit upon continuing applications is a matter of policy for the Congress, not for us."). Moreover, the Board of Patent Appeals and Interferences has recognized the Henriksen court's stricture on limiting continuing applications. In *Ex parte Hull* the Board stated, "[*Henriksen*] established that the Office cannot deny an applicant the benefit of the filing date of his earliest filed case no matter how many intervening continuing applications when no other pertinent facts are involved." 191 USPQ 157, 159 (CCPA 1975). The Board also stated, "It is not the number of continuing applications which is determinative, but the overall course of conduct by an applicant which may result in the forfeiture of a right to a patent." *Id.* at 160. Consequently, the limitation in the rules for a priority claim benefiting only a "single-prior filed" application has no basis in law and is in fact contradictory to established law.

It is acknowledged that the Office has a legitimate need to reduce the burden caused by processing unnecessary applications and eliminate unreasonable delays in prosecution. It has been established that unreasonable delays may result in forfeiture of the right to a patent. *In re Bogese*, 303 F.3d 1362, 64 USPQ2d 1448 (Fed. Cir. 2002). However, any solution must address the actual problem of unreasonable prosecution delay or prosecution laches without limiting the rights of applicants to obtain claims to the full scope of their invention. These aims can be achieved by limiting the filing of continuing applications only when applicants fail to make a good faith effort to advance prosecution through the filing of amendments or additional argument or evidence.

It is also unclear how limiting claims to priority aids the PTO in solving its examination burden. The PTO's own statistics show that the "problem" of multiple continuing applications (i.e., second or subsequent continuation/CIP or RCE) is limited to less than 4% (11,800 out of 317,000) of all applications and about 20% (10,000/52,000) of RCEs. 71 F.R. 48-61, 50 (January 3, 2006). Consequently, there is no clear nexus between this limitation of priority claims imposed by the Proposed Rules and the problem of examination burden.

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[1] The phrase "on an application," which is in the singular, should be read to include the plural. *In re Henriksen*, 399F.2d 253, 158 USPQ 224 (CCPA 1968).

C. Proposed Rule 37 C.F.R. §1.78(d)(1) Is Unlawful Because It Is Beyond The PTO's Rulemaking Authority And Is Against Public Interest Because It Is Unconstitutionally Vague

The proposed rule states that a second continuation would be allowed if applicant can "show to the *satisfaction of the Director* that the amendment, argument, or evidence *could not have been submitted* during the prosecution of the initial application." 71 F.R. 48-61, 50 (January 3, 2006) (emphasis added). The Proposed Rule is beyond the Office's rulemaking authority because a standard based on a showing *"to the satisfaction of the Director"* or on evidence that "*could not have been submitted*" is arbitrary and capricious, and therefore unconstitutionally vague. There is no guidance in the rule or elsewhere as to what may or may not "satisfy" the Director or as to what type of evidence "could not have been submitted" during the prosecution of the initial application.

The courts have found that an agency rule that is so vague and ambiguous as to defy reasonable efforts to predict how it will or may be applied is arbitrary and capricious and thus unlawful under the Administrative Procedure Act, 5 U.S.C. §706(2)(A). Where the government's "interpretation of a regulation is either unconstitutionally vague as applied or unreasonable given the regulated activity, we may refuse to accept the [government's] interpretation." *Vencor, Inc. v. Shalala*, 988 F. Supp. 1467, 1472 (N.D.GA 1997) quoting *Georgia Pacific Corp. v. OSHRC*, 25 F.3d 999, 1004 (11th Cir. 1994). More importantly, a statute is unconstitutionally vague "if it forbids or requires the doing of an act in terms *so vague that men of ordinary intelligence must necessarily guess at its meaning and differ as to its application*" *Id.* (emphasis added) quoting *Connally v. General Constr. Co.*, 269 U.S. 385, 391 (1926). It is unclear what burden an applicant must meet in order to file an additional continuation application. One would necessarily guess at what evidentiary burden an applicant must meet to "satisfy the Director" or that "could not have been submitted" to the PTO to meet the burden. It is thus unclear what the Proposed Rule means and hence it is unconstitutionally vague.

A retrospective standard based on a showing that "amendment, argument, or evidence *could not have been submitted"* would effectively not allow more than a single continuing application to be filed because of what an applicant "could have claimed" in the prior application. For example, an applicant seeking narrow claims in a first continuation would presumably be prohibited from seeking broader claims in a second continuation, even though the applicant *is entitled to the full scope of their invention under law*. The standard should include, as acceptable grounds for filing a continuation, the rejection and cancellation of a broad claim followed by presentation of that claim (in original or amended form) in a continuation. Under the Proposed Rules, what new argument or new claim *could not have been* presented earlier? What arguments, if any, can one present that will *satisfy the Director* to allow a second or subsequent continuation? The standard to be met under these Proposed Rules is so nebulous that it is impossible to answer these questions – one must necessarily guess. Requiring a hindsight justification that the "amendment, argument, or evidence *could not have been* submitted" in the initial application is vague at best. Consequently, such a standard is nebulous and does not offer applicant sufficient guidance.

A continuation or RCE does not present new matter. Therefore, it is unclear what new amendments, arguments, or evidence can be presented in a continuation or RCE that "could not have been submitted" earlier or what arguments can be presented that will *satisfy the Director* to allow a second or subsequent continuation. For example, under the Proposed Rule it is unclear whether a continuation or RCE would be allowed based on a different scope of invention, a change in commercial embodiment of the invention, or other business considerations.

The meaning and application of the Proposed Rule is nebulous at best and is too vague to be anything but arbitrary and capricious, a violation of the Office's rulemaking powers.

D. Proposed Rule 37 C.F.R. §1.78(d)(1) Is Unlawful Because It Is Beyond The PTO's Rulemaking Authority And Is Against Public Interest Because It Sets a *Per Se* Limit on the Number of Continuing Applications

The PTO has suggested that the Proposed Rule §1.78(d)(1) is not beyond its rulemaking authority because the Proposed Rule does not set a *per se* limit on the number of continuing applications because any second or subsequent continuing application may be allowed if the applicant can "show to the *satisfaction of the Director* that the amendment, argument, or evidence *could not have been submitted* during the prosecution of the initial application." 71 F.R. 48-61, 50 (January 3, 2006) (emphasis added). However, because proposed 37 C.F.R. §1.78(d)(1) is so vague as to how an applicant would meet a showing that evidence *could not have been submitted* during the prosecution of the initial application, as discussed in Part C above, applicants can only reasonably rely on a *single* continuing application to be allowed under the Proposed Rule. Submission of a second continuing application would presumably be denied. Consequently, the Proposed Rule effectively creates a *per se* limit on the number of continuing applications to that single allowed continuing application. Such a *per se* limit is clearly arbitrary and capricious, a violation of the Office's rulemaking powers.

E. This Proposed Rule 37 C.F.R. §1.78(f)(2) Is Unlawful Because It is Beyond The PTO's Rulemaking Authority And Is Against Public Interest Because It Requires An Applicant To Examine The Patentability Of His Or Her Own Application and the Basis for Double Patenting Presumption is Contrary to Law

Proposed 37 C.F.R. §1.78(f)(2) requires an applicant to examine the patentability of his or her own application. Such a prescription is contrary to both statute and case law. "The Director shall cause an examination to be made of the application . . ." (35 U.S.C. §131), and "whenever, on examination, any claim for a patent is rejected, or any objection or requirement made, the Director shall notify the applicant thereof, stating the reasons for such rejection, or requirement, together with such information and references as may be useful in judging of the propriety of continuing the prosecution of his application . . ." (35 U.S.C. §132). The meaning of these statutes read together is clear. Congress assigned to the PTO, not to the applicant, the responsibility for examining the patentability of an application.

In addition, the second circuit has recognized the impropriety of a rule that creates a conflict of interest by requiring the regulated party to self regulate. "The only way that broadcasters can operate in the 'public interest' is by broadcasting programs that meet somebody's view of what is in the 'public interest.' That can scarcely be determined by the broadcaster himself, for he is in an obvious conflict of interest." *National Ass'n. of Indep. Television Producers & Distrib's et al. v. FCC*, 516 F.2d 526, 536 (2d Cir. 1974). As Congress has charged the PTO to protect the public's interest, the PTO, not the applicants, is obligated to examine the patentability of applications.

Proposed 37 C.F.R. §1.78(f)(2) establishes that a rebuttable presumption of double patenting exists when there is a "substantial overlapping disclosure" between a nonprovisional application and one or more other pending or patented nonprovisional applications or patents that share the same filing date and name at least one inventor in common." In order to rebut the presumption, applicant must submit to the satisfaction of the Director "how the application contains only claims that are *patentably distinct* from claims in each of such other pending applications or patents" or file a terminal disclaimer. It is common in the biotechnology arts to have pending or patented nonprovisional applications or patents on separate but related proteins that share the same filing date and name at least one inventor in common; moreover, the inclusion of common disclosure (e.g., routine methods) in such applications may be automatically considered "substantial overlapping disclosure". In these instances, even where the claimed inventions are completely unique, applicant will be forced to justify the patentability of each claim prior to examination by the PTO to avoid a final double-patenting rejection. The Proposed Rule effectively transfers examination duty to the applicant by forcing the applicant to present arguments or evidence on the record as to the merits of an invention prior to PTO examination.

Not only is this examination duty transfer contrary to both statute and case law, the use of the combination of "substantially overlapping disclosure" and common inventorship factors as a basis in determining double patenting is arbitrary, since such factors are completely unrelated to double patenting. The doctrine of double patenting seeks to avoid unjustly extending patent rights at the expense of the public, thus the focus of any double patenting analysis necessarily is *on the claims* in the patents or applications, not on their disclosures (MPEP 804). Since the disclosure is not the basis for double patenting, the burden placed on applicants by the Proposed Rule is unjustified. Furthermore, proposed 37 C.F.R. §1.78(f)(2) is unconstitutional as a violation of an applicant's right to procedural due process because it recites another vague standard ("substantial overlapping disclosure") that must be applied by applicant when examining his or her own application.

Both the transfer of examination duty to the applicant and the basis for the double patenting presumption are not only against the public interest, but the Proposed Rule has no statutory basis and exceeds PTO's rulemaking powers.

F. Proposed Rule §1.78(d)(ii) Conflicts with Statute

Proposed 37 C.F.R. §1.78(d)(ii) would limit divisional applications to claiming the benefit of only a single prior-filed application. This proposal is in conflict with 35 U.S.C. §§120 and 121. Section 120 has been discussed above in regards to proposed 37 C.F.R. §1.78(d)(1), and those comments are equally applicable to proposed 1.78(d)(ii). In addition, 35 U.S.C. §121 provides that a divisional application is entitled to claim benefit of an earlier application as provided in §120: "If the other invention is made the subject of a divisional application which complies with the requirements of section 120 of this title it shall be entitled to the benefit of the filing date of the original application.". Consequently, the limitation in the rules for a divisional to claim the benefit of only a "single-prior filed" application has no basis in law and is in fact contradictory to established law.

Moreover, the effect of this rule is particularly detrimental in the Biotechnology arts where inventions are complicated and are already encumbered by extensive restriction practice. With restriction practice so common in the biotechnological arts, a single original application usually leads to a multiplicity of divisional applications. Under proposed 37 C.F.R. §1.78(d)(ii), a divisional application can claim the benefit of only a single prior-filed application. In our experience an average of 6- to 20-way restrictions for an application on a new protein is not uncommon and we have encountered 50- to 60-way restriction requirements in some of our cases.

As a result of this rule change, applicants will necessarily file all divisionals during the pendency of the initial application in order to obtain the priority of the original application. This could result in the filing of 6-50 divisionals per patent family prior to the issuance of the initial parent case. The need to file divisionals during the pendency of the original application will compel applicants to file on all originally claimed inventions, some of which may later be found to be of no commercial interest. To avoid weakening our portfolio of over 190 patent families, which are each divided by the PTO into 5 to 50 or more applications, we will need to file many continuing applications before the proposed rules go into effect. This year we would have to file at least 881 applications costing at least $1.762 million in filing fees alone. This cost does not include the cost of personnel resources at ZymoGenetics needed for their preparation.

Not only is this cost-prohibitive for a biotech company like ZymoGenetics, but would increase, rather than reduce, the PTO's examination burden.

While the PTO states that "[t]his proposed rule change does not affect a substantial number of small entities" (71 F.R. 48-61, 57 (January 3, 2006)), the changes *will* have a significant economic impact on *every* small or mid-sized biotechnology entity who desires to claim the full scope of its broad invention.

G. The Proposed Rules Do Not Reduce The PTO's Examination Burden

(1) Because in many cases an applicant will not be able to obtain claims to the entire scope of his or her invention with a single continuing application, the burden on the PTO will shift. A likely outcome is an increase in appeals and reissues, particularly in cases where a continuing application is denied. An applicant will have no recourse but to appeal any denial of a continuing application, or to appeal prior to filing continuing applications. Moreover, the PTO has not considered the burden of increased reissue practice that may result. A reissue would enable the applicant to obtain claims that could have been presented in a continuing application, but such continuing application was denied. Because the basis for a reissue is claiming more or less than the patentee had a right to claim, both broadening and narrowing reissues could become more common. If an applicant could not get broader claims in a continuation, he or she could get another round of examination by filing for a broadening reissue. An applicant could also use reissue to get narrower claims (or claims of intermediate scope) that more clearly read on their own product, or a competitor's product. Again, this approach employs reissue for a purpose for which we now properly use continuations.

(2) The publication of applications already provides notice to the public of the entire scope of the inventions that may arise therefrom. All patentable claims resulting from those applications must be supported by the published disclosures. The proposed limitations on continuing application practice will not decrease public confusion where applicants choose to appeal any denial of a continuing application. Such appeals will create further delays in the issuance of patents rather than reduce the public's confusion or establish more certainty.

(3) As stated in Part B above, the PTO's own statistics show that the "problem" of multiple continuing applications (i.e., second or subsequent continuation/CIP or RCE) is limited to less than 4% (11,800 out of 317,000) of all applications and about 20% (10,000/52,000) of RCEs. 71 F.R. 48-61, 50 (January 3, 2006). So, one must question whether indeed continuing applications do pose a problem that justifies the promulgation of such draconian rules.

(4) As noted in Part E above, with Restriction practice so common in the biotechnological arts, it will be necessary to file all divisionals during the pendency of the initial application, rather than sequentially, in order to obtain the benefit of the original application. This will certainly increase examiner caseload rather than reduce it.

(5) As was seen prior to enactment of GATT rules (in particular to the change to a 20-years-from-filing patent term), these Proposed Rules will result in a foreseeable deluge of divisional and continuation filings in all art areas prior to the enactment date. Again, this will certainly increase Examiner caseload rather than reduce it. It will also place an economic burden on the PTO's customers, which could be particularly damaging to small and mid-sized biotechnology businesses.

H. Alternative Solutions That Could Reduce The PTO's Examination Burden

(1) The PTO cites *In re Bogese* as basis for its authority to limit continuations. That case dealt with unreasonable prosecution delay or prosecution laches (applicant filed a series of at least 11 continuations without any amendments). To deal with such situations, the PTO could require any continuation after the first to be accompanied by a good faith amendment, argument or evidence. This way the rules would target those applicants who abuse continuation practice rather than those applicants who are legitimately trying to advance prosecution of their claims in the Office.

(2) Adopt a request for examination requirement, whereby applicants must request examination within a certain time frame and pay an examination fee. This would reduce the number of applications that must be examined by placing the burden on applicants to decide what applications are of sufficient interest to warrant examination. Examination of applications of questionable value could be deferred; many of them would be allowed to go abandoned.

(3) The number of divisional applications could be spread out in time by allowing applicants their proper claim to priority to a parent application and enabling sequential filings of divisional cases.

(4) The number of divisional applications could be reduced by reforming restriction practice and adopting the PCT unity of invention standard based on a single general inventive concept. This would allow Examiners to examine the entire scope of an application at once and would reduce the number of applications that must be processed and examined.

(5) Although least favorable, instead of limiting the *number* of continuing applications, discourage excessive continuing application practice by increasing fees for applications that result in potential prosecution abuse, such as successive continuations and RCEs. For example, the PTO could devise a progressive, increasing fee schedule for continuations and RCEs. Such a fee structure, although costly to applicants, would discourage excessive filings.

Again, we appreciate the opportunity to provide comments on the proposed rules.

Sincerely,

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