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From: Elizabeth Barnhard [mailto:BARNHAE@wyeth.com]
Sent: Wednesday, May 03, 2006 4:12 PM
To: AB93Comments
Cc: John W. Hogan
Subject: Wyeth's Comments on 71 Fed. Reg. 48

To: Robert A. Clarke
Deputy Director
Office of Patent Legal Adminstration
Office of the Deputy Commissioner for Patent Examination Policy

Re: Comments on Proposed Rules Published in 71 Fed. Reg. 48 (January 3, 2006)

Dear Mr. Clarke:

Attached is a pdf file containing the comments of Wyeth on the proposed rule changes to "Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims".

Wyeth appreciates the opportunity to offer its comments and would appreciate confirmation that its comments have been received by the U.S. Patent and Trademark Office.

Very truly yours,

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May 3, 2006

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Mail Stop Comments
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Alexandria, VA 22313-1450

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

Re: Comments on Proposed Rules: "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 Under Secretary Dudas:

Wyeth appreciates the opportunity to provide comments on the U.S. Patent and Trademark Office ("PTO") proposed rules directed to changes to practice for continuing applications, requests for continued examination practice, and applications containing patentably indistinct claims published at 71 Fed. Reg. 48 (January 3, 2006).

Wyeth is one of the world's largest research based pharmaceutical and health care products companies. It is a leader in the discovery, development, manufacturing and marketing of pharmaceuticals, biotechnology products, vaccines and non-prescription medicines that improve the quality of life for people worldwide. Wyeth's major divisions include Wyeth Pharmaceuticals, Wyeth Consumer Healthcare and Fort Dodge Animal Health.

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Wyeth understands the critical importance of discovering and developing valuable new therapies and vaccines to help millions of people around the world. Cutting-edge pharmaceutical research and development is more challenging, more complex and more critical than ever. At the same time, the need for treatments for unmet medical needs is expanding greatly, even as regulatory hurdles increase and costs grow. Novel candidates and new mechanisms of action are central to Wyeth's pipeline, which pipeline includes small molecules, biopharmaceuticals and vaccines. The cost of developing a new drug is more than $800 million, on average, and can take up to 15 years. The patents granted on Wyeth's inventions enable Wyeth to continue to invest in developing the therapies and vaccines of the future to improve the lives of people and lead the way to a healthier world.

The PTO has proposed major, complex changes to the continued examination practice and, in a separate concurrent rulemaking notice, to the claim examination process (discussed by Wyeth in a separate letter). The stated rationale of the PTO is to reduce pendency and backlog, improve efficiency, promote innovation and improve the quality of issued patents. Wyeth supports the PTO's goals of improving both the efficiency of the examination process and the quality of issued patents. However, Wyeth believes that the changes being proposed will not improve efficiency, will not reduce the pendency of patent applications or the backlog, will stifle innovation and will not improve the quality of issued patents. Indeed, if the proposed rules are enacted in their present form, all of these problems will likely be exacerbated.

The PTO Does Not Have Sufficient Authority To Implement The Proposed Rules

Under established law, the proposed rule is contrary to statute and thus exceeds the statutory authority of the PTO. The sole authority for the proposed rule cited in the preamble is 35 U.S.C. § 2(b)(2), a subsection providing that, in certain circumstances, the PTO "may establish regulations, *not inconsistent with law.*" (Emphasis added). Neither this general grant of rulemaking authority nor any other statutory provision speaks directly to the PTO's authority to regulate or limit the use of continued examination filings. The proposed rule does not comply with the substantive elements of the patent laws set forth by Congress and, accordingly, exceeds the PTO's authority under § 2(b)(2).
Continued examination filings are a longtime practice approved by the Supreme Court for more than 140 years. In *Godfrey v. Eames*, 68 U.S. (1 Wall) (1864), the Supreme Court held that a patent applicant who filed a revised version of his

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application the same day he withdrew the original application was entitled to the original filing date. Congress ultimately enshrined this court-developed practice in the federal code in 1952. 35 U.S.C. § 120. *See* Chisum, *Patents* § 13.02. As amended in 1984, § 120 provides:

> An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, or as provided by section 363 of this title, which is filed by an inventor or inventors named in the previously filed application 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 similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application. No application shall be entitled to the benefit of an earlier filed application under this section unless an amendment containing the specific reference to the earlier filed application is submitted at such time during the pendency of the application as required by the Director. The Director may consider the failure to submit such an amendment within that time period as a waiver of any benefit under this section. The Director may establish procedures, including the payment of a surcharge, to accept an unintentionally delayed submission of an amendment under this section.

Thus, under Section 120, an applicant is entitled to the filing date of a prior application if the applicant meets certain conditions enumerated in the statute itself. Specifically, "[i]f the continuation application meets the requirements of continuity of disclosure, copendency, cross-referencing, and identity of inventorship, it will gain the benefit of the filing date of the prior application in determining patentability and priority." Chisum, § 13.01.[1]

Over the years, despite some concerns about continuation practice and resulting delays in the examination of patent applications, the courts have consistently ruled that Congress alone can change the requirements and framework of continuation

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[1] Under the Uruguay Round Agreements Act, effective since June 8, 1995, a continuation application merely preserves, rather than extends the original exclusivity period. This is because the Act provides that a patent term is twenty years from the date of *filing*, with limited exceptions. Uruguay Round Agreements Act, Pub. L. No. 103-465, 1994 U.S.C.C.A.N. (108 Stat.) 4809-5053.

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practice by limiting continuation applications. *In re Ernst Johan Jens Henriksen*, 399 F.2d 253 (C.C.P.A. 1968), presented the question whether § 120 could be read to "limit an applicant to the benefit of the filing date of the second preceding application in a chain of copending applications." *Id.* at 254. The Patent Office Board of Appeals had so held. The Court of Customs and Patent Appeals, the predecessor to the Federal Circuit, reversed:

> [U]nder [§ 120], in view of its longstanding interpretation by the Patent Office and the patent bar, there is no statutory basis for fixing an arbitrary limit to the number of prior applications through which a chain of copendency may be traced to obtain the benefit of the filing date of the earliest in a chain of copending applications, provided the applicant meets all the other conditions of the statute.

Id. In reaching this conclusion, the court conducted a thorough examination of all possible support for the contrary view.

The court rejected the argument that the text of § 120 itself required the reading advanced by the Board, and found nothing in the legislative history to support the limits the Board sought to impose. Turning to practical considerations, the court found that in "practice prior to" the enactment of § 120, "an applicant was not limited to a chain of three copending applications for the purpose of claiming an early effective filing date." *Id.* at 259. As further support, the court cited relevant treatises that reflected no limits on the number of continuation applications under § 120. *See id.* at 260 n.17 (citing 2 Robinson, *The Law of Patents* 204 (1890) ("It is immaterial how many of these substituted applications may be filed or for how long a period such efforts to obtain a patent may be continued."); 1 Rogers, The Law of Patents 21 (1914) (". . . and that no number of successive applications indicates an intention to abandon; but that, in reference to the question of abandonment, all such may be regarded as one application, the ones subsequent to the first being known as 'continuing' applications.")). And it remarked upon the absence of case law to the contrary prior to the statute. Indeed, from early decisions, the Supreme Court "has not seemed to question the right of the later-filed application to rely on an earlier-filed application, nor has it questioned—although the point does not seem to have arisen – the right to rely on more than two successively preceding applications." *Id.* at 260. It also found that no case since the enactment of the statute supports the position adopted by the Board of Appeals.

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Critically, the court agreed with the dissenters in the Patent Office Board of Appeals that only Congress has the power to address any policy problems occasioned by this set of statutory provisions, specifically holding that neither the Board of Appeals nor the federal courts can modify what Congress has set forth. "It is our view, as the judiciary, that it is for the Congress to decide, with the usual opportunity for public hearing and debate, whether such a restriction as sought by the board is to be imposed." *Id.* at 262; *see also id.* ("[T]he cure . . . rests with Congress, not with us. If a restriction is to be imposed, it must be based upon law, legislatively or judicially expressed.") This holding, including specifically the determination that any change must come from Congress, was reiterated a decade later in *In re Hogan,* 559 F.2d 595, 604 n.13 (C.C.P.A. 1977) ("The 24 years of pendency herein may be decried, but a limit upon continuing applications is a matter of policy for the Congress, not for us.").

The PTO's attempt to impose similar limits in the proposed rule is likewise foreclosed. The proposed rule would limit a patent applicant's right to submit continued examination filings to one such filing, requiring approval of a petition by the applicant for any subsequent filings. The PTO cites no specific statutory authority supporting the power it asserts to impose this new burden on patent applicants. Section § 120, which lays out the requirements for such a filing, forecloses additional requirements; the statute states that filings meeting the requirements "*shall* have the same effect, as to such invention, as though filed on the date of the prior application." (emphasis added). Moreover, in practice, the new petition requirement under the proposed rule could well serve as far more than a procedural hurdle to subsequent filings. The proposed rule fails adequately to outline how the petition requirement is to be applied, leaving open the possibility that they serve to limit outright continued examination filings. As demonstrated by *Henriksen* and *Hogan,* it would violate Congress's affirmative command to deny the original filing date to an applicant who meets the statutory requirements on the ground that he failed to meet an additional, agency-created hurdle. To the extent the petition requirement fails to limit such filings it will serve only to increase the burdens of the application process without serving a legitimate purpose; to the extent it substantively curtails applications that would otherwise be entitled by statute to the original filing date, it is ultra vires.[2]

[2] Nor do the statutory defects of the proposed rule end with § 120. The very idea of a petition to accompany any subsequent continued examination filings appears to give the PTO an element of discretion in whether to review applications that the statute does not envision. *See, e.g.,* 35 U.S.C. § 131 ("The Director shall cause an examination to be made of the application and the alleged new invention; and if on such examination it appears that the applicant is entitled to a patent under the law, the Director shall issue a patent therefor.").

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In examining challenges to agency rules, courts must "hold unlawful and set aside agency action" that is arbitrary, capricious, an abuse of discretion or contrary to law. 5 U.S.C. § 706(2). The Supreme Court outlined the framework for judicial review in *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-43 (1984). Under the first step of *Chevron*, courts must consider "whether Congress has directly spoken to the precise question at issue." *Id.* at 842. If Congress has done so, "that is the end of the matter," and the question for the court is simply whether the regulation comports with congressional intent. *Id.* If, however, "the statute is silent or ambiguous with respect to the specific issue," then, under the second step of *Chevron*, "the question for the court is whether the agency's answer is based on a permissible construction of the statute." *Id.* at 843. Because Congress has spoken directly to the requirements for continuation applications, the analysis of the proposed rule here at issue stops at the first step of the *Chevron* analysis: The rulemaking authority of the PTO cannot be employed to fashion policy and correct perceived inadequacies in ways that violate the law. The proposed rule therefore is ultra vires, plainly exceeding the authority of the PTO under § 2(b)(2).

Retroactive Application of These Rule Changes is Prejudicial

If adopted, the proposed rules should only be applied to applications filed on or after the effective date of the final rule.[3] For pending applications, applicants have made their decisions and developed their strategies under the current rules. A retroactive change would defeat the decisions and strategies that were made in reliance on the current regime. For the PTO to change the rules midway during prosecution and limit the number of continuation and divisional applications will be highly prejudicial to those applicants who will be forced to conduct reviews of all their pending applications at considerable expense to identify those applications affected by the changes in the rules. Even for a large corporation like Wyeth, this will be a huge expense and an administrative nightmare.

[3] Ideally, the effective date of the rule should not be the same day as enacted, but instead should be several months after the final rule is announced to allow for an orderly transition.

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Public Notice and Delay

One of the justifications for the proposed rules limiting the number of continuation applications is that the possible issuance of multiple patents arising from such a process tends to defeat the public notice function of patent claims in the initial application. The proposed rules are designed to address a problem that is virtually extinct – that of submarine patents. There are very few remaining pre-GATT (pre June 8, 1995) applications that continue to be unpublished and confidential and which may issue as patents with 17-year terms from date of issuance.[4] Today, the overwhelming numbers of pending applications are published and have a term fixed at 20 years from the effective filing date. Filing successive continuation applications does not extend that 20-year term. Importantly, once a U.S. application has been published, any third party can access the application's file through public PAIR and monitor the prosecution, as well as the filing of any and all continuation and divisional applications based on that application. Even though the exact claims that will issue are not known, one can review the published application and determine the scope of the invention supported by the specification.

Impact on Divisional Applications

At present, divisional practice is orderly and rational. Applicants can monitor the progress of their technology and make informed decisions about the timing and number of divisional applications to be filed. The PTO has proposed in § 1.78(d)(1)(ii) that a nonprovisional application that is a divisional application may claim the benefit under 35 U.S.C. §§ 120, 121 or 365(c) of only a single prior-filed application. Under the proposed rules, applicants will have no choice but to file all divisional applications during the pendency of the original application (which, as a practical matter, means simultaneously) in order to protect their rights. This will exacerbate the backlog of unexamined applications because applicants will be forced to file and prosecute all divisional applications simultaneously, rather than seriatim. Currently, in the pharmaceutical and biotechnology practices, divisional applications covering many of the restricted groups are never filed. As projects proceed through research and development, the focus often narrows or shifts, and projects are dropped along the way. All of this means that the majority of restrictions under current practice never yield a

[4] Even as to those pre-GATT patents, courts have invalidated those which have issued as a result of abuse of continuation practice ("prosecution laches"). See *Symbol Technologies, Inc. v. Lemelson Foundation LP,* 69 USPQ2d 1738 (D. Nev. 2004), aff'd, 76 USPQ2d 1354 (Fed. Cir. 2005).

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filed divisional application. That will not be the case under the proposed rule. This problem with the proposed rule is not temporary and will continue to burden the PTO for as long as the proposed rule remains in effect.

For the time period of January 1, 2003 through April 26, 2006, Wyeth has reviewed the number of divisional applications filed by Wyeth, the number of restriction requirements received by Wyeth, and the total number of groups of restricted claims for which divisional applications could be filed.[5]

	Number of Nonprovisional Applications Filed[6]	Number of Restriction Requirements	Number of Restricted Groups	Number of Divisionals Filed	Total Number of Divisionals To Be Filed Under Proposed Rules
1/1/03-4/26/06	**588**	**386**	**3874**	**208**	**3488**

As the data shows, approximately two-thirds of Wyeth applications are subject to restriction requirements. The PTO's restriction practice, which is not being changed by these proposed rules, will result in the filing by Wyeth under the proposed regulations of hundreds of divisional applications every year that it would otherwise be unlikely to file over time. Based on our calculations, there could be an annual increase of over 1600 percent in the number of divisional applications filed as a result of these proposed rules. If the proposed rules are put into effect, the PTO should expect an enormous increase in the number of patent applications filed by the pharmaceutical and biotech companies - all as a direct result of the proposed regulations.

The PTO's proposed regulations, by forcing a tremendous increase in the number of patent application filings, will have additional societal costs. Because of the central importance of patent protection to the pharmaceutical and biotech industries, companies will be forced to simultaneously file and prosecute all of

[5] The determination of the total number of groups of restricted claims does not include election of species requirements, which could increase substantially the total number of applications that could be filed.

[6] PCT national stage applications are included in the number of nonprovisional applications filed; divisionals, continuations and continuation-in-part applications are excluded.

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their divisional applications, at a tremendous cost in terms of additional legal and filing fees. Money spent in this way will not be available to spend on research and development efforts, thereby delaying or perhaps even preventing the research and development that will produce tomorrow's medicines.

Impact on Continuation Practice

Even if one discounts the effects of the huge increase in divisional filings that the proposed rules will cause, the proposed rules will have little or no impact on the backlog of unexamined applications. By the PTO's own calculations, only about 3.7 percent (or 11,800 out of 317,000) of applications filed in fiscal year 2005 were a second or subsequent continuation or continuation-in-part application, and only about 3.1 percent (or 10,000 out of 317,000) were a second or subsequent request for continued examination. Targeting a decrease in a very small percentage of current applications will not significantly reduce the backlog. Instead, applicants will be prejudiced by the proposed rules because they will no longer be able to continue prosecution where progress toward allowance could be made. Many more cases will be appealed, at considerable expense in terms of both time and money. The expected increase in appeals will reverse the progress that the Board of Patent Appeals and Interferences has made through great effort and pendency times of appeals will surely be significantly lengthened. The number of appeals to the Federal Circuit will also increase, and appeal time there increased as well. And, of course, when the impact of thousands of additional divisional filings per year is added, any potential benefit brought by the proposed rules will be illusory. Indeed, the backlog will only worsen.

The PTO's comments to the proposed rules fail to give any details on how the proposed changes will have any favorable impact on ensuring patent quality. In particular, the PTO has not detailed any proposal to reevaluate the examiner quota system, standards governing the circumstances under which a final rejection can be made, or the standards for submission of an amendment, argument, or evidence in response to a final rejection. To truly increase PTO efficiency, there must be a sufficient nexus between the examiner quota system and the amount of work required to examine a continued application compared to an original application. Simply put, the incentives in the current system for examiners to issue a final rejection or otherwise necessitate a continued application filing must be changed if there is going to be an improvement in the efficiency of examination of applications.

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A proposal worthy of consideration in Wyeth's view is to allow applicants an opportunity to amend the claims as of right after a final rejection and have such claims considered by the examiner. The current system encourages examiners to deny entry of such amendments and causes much of the problem of which the PTO now complains. This is especially true in those cases in which the Examiner has cited new art or any other new ground of rejection. If amendments and responses after a final rejection were entered and considered by the examiner, it would significantly reduce the number of RCEs and continuation applications that are filed.

The PTO also fails to acknowledge that in almost all cases, continued application practice is a *bona fide* attempt by an applicant to advance prosecution. As examples, the submission of newly identified prior art or comparative testing data, the addition of new matter in a continuation-in-part application, and the initial acceptance of narrow claims with the option to pursue broader claims are all *bona fide* attempts to advance prosecution that are regularly employed by legitimate patent stakeholders. The current exchange between examiner and applicant allows for a resolution of complex issues to the mutual satisfaction of both the examiner and the applicant, without being unduly limited by an arbitrary cutoff.

This is particularly true for the request for continued examination ("RCE"). RCEs are used to expedite prosecution by providing the applicant with an opportunity for further amendment and/or argument as a matter of right. There is no recognition by the PTO in the proposed rules that an RCE is typically required because under "compact prosecution" only a single amendment of a patent application is allowed to applicants in almost all current patent applications, even if the examiner substitutes completely new grounds of rejection in the second and final office action in response to an applicant's single amendment opportunity, as too often occurs. Examiners, unlike applicants, are not bound by "compact prosecution" rules. If they were, most RCEs would not be needed, because examiners would have to provide complete first actions containing all grounds of rejection and would not be able to issue "final" rejections containing a new ground of rejection; often the primary reason that applicants are forced to file RCEs.

The other major reason for RCEs is the now-typical examiner refusal to enter even the most minor of corrections, including corrections suggested by the examiners themselves in interviews, after second-action-final rejections, in order to force and obtain RCE disposal credits. Thus, a high percentage of RCEs result in an almost immediate allowance, with no extra examination effort, because they are filed just to obtain entry of Rule 116 amendments previously refused entry.

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It should be noted that examiners typically act quickly to process an RCE. RCE practice often advances prosecution to allowance, thus avoiding the requirement for appeals or continuation applications. No limitation is necessary to prevent abuse of the RCE process, both because the RCE filing requires a submission that necessarily demonstrates the applicant's *bona fide* attempt to advance prosecution, and because of the significant fees associated with the RCE filing.

Wyeth is also troubled by the PTO's proposed requirement that an applicant requesting a second or subsequent continuing application must petition the Office with a showing of why "the amendment, argument, or evidence presented in the continuation could not have been submitted in the earlier filed, parent application." The proposed petition process will introduce its own inefficiencies. For example, the PTO has not described how it intends to process these petitions. This uncertainty will discourage applicants from filing a petition and will further burden the appeals procedure. In addition, Wyeth is concerned that the proposed standard for approval of the petition is unclear, may be difficult to meet, and may require applicants to argue against their interests resulting in the *de facto* elimination of second or subsequent continuation practice. In its comments discussing the proposed rules, the PTO states "[T]hat an amendment, argument, or evidence is refused entry because prosecution in the prior-filed application is again closed (after the filing of a continuation or continuation-in-part application ... will not by itself be a sufficient reason to warrant the grant of a petition under § 1.78(d)(1)(iv)." There is no recognition by the PTO of those situations in which a second or subsequent continuation, particularly an RCE, is required in a patent application due to examiners generating new final rejections based on newly cited prior art or other new grounds of rejection. Furthermore, the PTO has not addressed the situation where a final rejection has been appealed and the Board remands the application to the examiner for further examination. In such circumstances, among many others, an applicant should be allowed to file a continuation application.

The proposed rules would also restrict the legitimate practice of drafting claims to cover a competitor's product, or to provoke an interference based on an allowed claim, in a pending continuation application. This long-standing practice was reaffirmed by the Federal Circuit in *Kingsdown Medical Consultants, Ltd. v. Hollister, Inc.*, 863 F. 2d 867, 874 (Fed. Cir. 1988), *cert. denied*, 490 U.S. 1067 (1989):

> [T]here is nothing improper, illegal or inequitable in filing a patent application for the purpose of

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> obtaining a right to exclude a known competitor's product from the market; nor is it in any manner improper to amend or insert claims intended to cover a competitor's product the applicant's attorney has learned about during the prosecution of a patent application.

For those few extreme cases where there is abuse and avoidance of advancement of prosecution, the PTO already has rules and mechanisms in place for dealing with such abuses. Placing limitations on continuation application filings on all applicants to curb the abuses of a very few will prevent good faith applicants from protecting what the Federal Circuit has held to be legitimately patentable subject matter. Wyeth submits that case-by case determinations are a much more appropriate mechanism to handle the admittedly small number of abuses of the system.

Wyeth is also concerned about the unintended consequences arising from the proposed rules. Any final rule should not have as its result new and unnecessarily draconian consequences. For example, under proposed § 1.114, an applicant who files a second RCE during an appeal will have that RCE request automatically "treated only as a request to withdraw the appeal," *i.e.*, there will be an automatic immediate abandonment of the application caused by an automatic immediate appeal withdrawal without any further prosecution, a result clearly unintended by the applicant who is seeking to continue prosecution. Draconian consequences such as these should not be permitted, even as a consequence of well meaning change.

Another likely consequence of the proposed rules will be an enormous increase in the number of appeals filed with the Board of Patent Appeals and Interferences. Given the choice, after a final rejection, of filing a continuation application (which will result in loss of the original priority date) or filing an appeal, the overwhelming majority of applicants will proceed with appeals. This avalanche of appeals may paralyze the Board, thereby delaying a final determination on the patentability of an application for many years. Such delays will prejudice applicants, and will also lengthen the period of uncertainty for third parties.

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Alternative Proposals

Wyeth believes that the PTO's goals are admirable, an efficient Patent Office that yields high quality patents. However, the proposed rule changes will not yield that result. Instead, Wyeth suggests that the PTO continue the public debate by considering alternative proposals, such as those previously mentioned, as well as those below.

One proposal that could help with the backlog of applications to be examined is voluntary deferred examination. By allowing deferred examination, the PTO would get an immediate benefit of time: time to hire and train new Examiners; time to work through the current backlog without adding to the backlog; and time to consider and adopt other proposals. Deferred examination could lessen the absolute number of applications that would need to be examined. Requests to examine an application may never occur in a certain percentage of cases. Experience with deferred examination in other countries indicates that if an application has not been examined before the company loses interest in pursuing the invention, an examination request is never filed. By allowing voluntary deferral of examination for "X" years, it would be expected that in those industries, such as biotech or pharmaceutical, where immediate grant is not always necessary because of time consuming trials, requests for examination may be delayed. The public and competitors alike would still have public notice of the invention because the application would be published at its normal eighteen-month publication date. In addition, deferred examination may lessen the need for a large number of continuation or divisional applications, further helping the backlog situation. Since the applicant would have more time to see, for example, the results of testing or the commercial viability of the invention, the applicant may decide not to file such continuations or divisionals that otherwise might have earlier been thought necessary or desirable.

Another proposal that bears investigation is a graduated fee structure for second and subsequent continuing applications. By increasing fees on a graduated scale, the PTO would ensure that applicants are wisely choosing when and how to file a continuing application. This will result in a decrease in the overall number of continuations filed.

* * * * *

In the final analysis, the likelihood of success of the PTO's proposed rules accomplishing the goals of improving the efficiency of the examination process

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and the quality of issued patents is about the same as the likelihood of success of killing a fly with a sledgehammer. The selected tool will miss its mark and will result in sowing havoc and destruction in its wake. For small inventors and large corporations alike, the proposed rules will result in piecemeal examination and patents with an eroded presumption of validity, with an attendant adverse impact on innovation and its commercial development.

Rather than adopting these proposed rules, Wyeth urges the PTO to hold public hearings to address the specific problems confronting the PTO. The combined creativity of the PTO and its customers can lead to more effective solutions than what is currently proposed.

Wyeth thanks the PTO for the opportunity to provide comments.

Very truly yours,

Elizabeth M. Barnhard

John W. Hogan, Jr.