-----Original Message-----
From: Elizabeth Barnhard [mailto:BARNHAE@wyeth.com]
Sent: Wednesday, May 03, 2006 4:13 PM
To: AB94Comments
Cc: John W. Hogan
Subject: Wyeth's Comments on 71 Fed. Reg. 61

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. 61 (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 the Examination of Claims in Patent Applications".

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 the Examination of Claims in Patent Applications"
71 Fed. Reg. 61 (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 the examination of claims in patent applications published at 71 Fed. Reg. 61 (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.

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

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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 claim examination process and, in a separate concurrent rulemaking notice, to the continued examination practice (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.

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.[1] For pending applications, applicants have already paid their fees for the number of claims present in their pending applications with the expectation that these claims will be searched and examined in accordance with the current laws and rules. Decisions have been made and strategies developed 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 claims to only ten claims will be highly prejudicial to those applicants who will be forced to conduct reviews of all their pending applications at considerable expense to select ten claims. Those applicants will lose the fees already paid, lose any benefit of examination to date, and incur new filing fees for new continuation

[1] 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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applications that must be filed to obtain examination of the claims exceeding the selected ten. Even for a large corporation like Wyeth, this will be a huge expense and an administrative nightmare.

Limitation of Initial Examination to Ten Claims is Unreasonable

The PTO proposes amending 37 CFR § 1.75 to limit the total number of claims that will be initially examined to only ten independent claims or ten total independent and dependent claims. Dependent claims not designated for initial examination will not be considered until the application is in condition for allowance. The PTO states that it will examine every claim in an application before issuing a patent on the application. Rather than search and examine all the claims at one time, the proposed rules will create an inefficient search and examination process with multiple searches and examinations that will necessarily increase pendency of the application. Worse yet, the overburdened examiners may not have sufficient time to properly do these multiple searches and examinations, resulting in significantly decreased quality of the searches and examinations for the dependent claims.

The PTO states the effort to do an initial patentability examination is wasted when the patentability of the dependent claims stand or fall together with the independent claim from which they directly or indirectly depend. The PTO does not provide any support for its assumption that dependent claims routinely stand or fall together with the independent claim from which they depend. To the contrary, many times an independent claim will be rejected, but one or more dependent claims are found to be allowable. Thus, when dependent claims do not stand or fall together with their independent claim, a separate search and/or examination must still be made. And, if any of the representative claims were found allowable, all of the dependent claims (whether dependent on the allowed claims or not) would still need to be examined, thereby adding an additional examination step and undoubtedly increasing the pendency time of the application. In fact, the Examiner may need to revisit art or other types of rejections that had previously been considered and dealt with in order to properly examine the remaining claims. This would seem to be the real "re-work" that the PTO complains of with respect to continuing applications, but instead of lessening it, this rule would increase it.

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In those situations where dependent claims do appear to stand or fall with their parent independent claim, it has been Wyeth's experience that examiners efficiently consider all the claims in one group. To delay examination of these dependent claims until a later stage will be less efficient, because the examiners may have to revisit essentially the same issues previously considered. Furthermore, the examiners' ability to efficiently group claims that they are examining undercuts the necessity for the proposed rule.

The PTO compares this proposed practice to the representative claim practice before the Board of Patent Appeals and Interferences and before the courts. This is not an appropriate comparison. Both the Board of Patent Appeals and Interferences and the courts are reviewing claims that have already been examined and are supported by a developed record. The choice of whether to rely on a representative claim is made by the applicant/patentee after the record is developed, be it in prosecution or litigation. At that time, an applicant is in a position to determine if certain claims should stand or fall together, a choice that depends on numerous factors. That is not the case at the start of prosecution.

With respect to limiting the total number of claims that will be initially examined, Wyeth agrees with the comments of the American Intellectual Property Law Association submitted on April 24, 2006, that it is questionable that the PTO has the statutory authority to ignore claims for which search and examination fees have been paid. *See*, 35 U.S.C. §§ 2(B)(2), 41(d)(1)(A), 111,112, 131, In re Wakefield, 422 F.2d 897, 164 USPQ 636 (CCPA 1970). Under the statutes, an applicant filing an application and paying the fee is entitled to have the application and the invention examined, rather than part of the application or part of the invention.

Furthermore, the PTO has not provided any analysis of the impact of the large increase in application claim fees that went into effect on December 8, 2004. These fees are now $200 each for every independent claim over 3, and $50 each for every claim over 20. The PTO's own statistics state that only a small minority of applications has more than ten independent claims. It is reasonable to assume that the very significant fee increase has further reduced the number of applications with excessive claims or that those applicants who retain a significant number of claims have made the business decision to pay the increased fees with the expectation that those claims will be searched and examined as the PTO is obligated to do. In either event, the proposed limit of ten claims unfairly penalizes all applicants for the actions of a few and imposes complex

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administrative burdens on both applicants and PTO examiners that can only lead to longer pendency of applications and lower quality examinations. The net effect of this ten-claim limitation rule is a major disservice to applicants who will not be able to submit claims covering the full scope of what applicants regard as their invention in one application and to have those claims examined. Moreover, since, according to the PTO, this rule will only affect a small percentage of the total number of applications, it will not significantly further the stated goals of the PTO. This rule also prejudices certain industries, such as the pharmaceutical and biotechnology industries, more than others because of the nature of those industries and the inventions made in them. Such discrimination could violate TRIPS Article 27.1, which requires all member states to make patents available for any inventions, whether products or processes, in all fields of technology without discrimination, subject to the normal tests of novelty, inventiveness and industrial applicability. Pioneering inventions, those that may be most precious to the applicant and most significant to the public at large, may be among those most likely to be adversely impacted by this proposed rule since those inventions may require more than an average number of claims to protect the full scope of what has been invented.

It must also be noted that **after** an applicant initially selects ten claims to be examined, the applicant may receive a restriction requirement. If traversal is unsuccessful, applicant must cancel non-elected claims and, if there are less than ten claims remaining, applicant may add claims to bring the total up to ten. The rules as proposed force applicants to guess at how their claims may be grouped as inventions for examination purposes by an Examiner. Together with the proposed changes to continuation practice, the rules will likely result in applicants being barred from pursuing non-elected claims or, applicants will be forced to file numerous divisional applications simultaneously to preserve their rights. The impact of this rule change to continuation practice is discussed more fully in Wyeth's concurrently submitted letter of comments on the proposed rules: "Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims", 71 Fed. Reg. 48.

It is unclear how the proposed rules will be implemented in practice. For example, according to proposed § 1.75(b) and § 1.104(b), the examination of all dependent claims not designated for initial examination may be held in abeyance until the application is otherwise in condition for allowance. Will those claims actually be examined in a second round examination, or will they be subject to

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belated restriction requirements thereby delaying divisional filing opportunities? Under proposed § 1.75(d)(1)(i), no divisional application can be filed before a restriction requirement is issued by the PTO. Yet under proposed new rule § 1.78(a)(3), it appears that an applicant could be precluded from filing a divisional application for claims that are dependent from claims that were elected for examination and not restricted in a first office action.

In another scenario, after the first or a second non-final office action is received, if the applicant cancels, for example, three of the ten claims, may the applicant add either three more originally filed dependent claims or three new claims by amendment and will these three new claims be examined? Under proposed § 1.75(b)(3), if by filing *or amending*, the applicant has more than 10 independent claims, or attempts to elect more than 10 total claims for examination without filing the onerous "examination support document" of proposed § 1.261, the applicant must respectively cancel and rescind the claims or submit a suggested restriction requirement accompanied by an election without traverse, or face a rejection and abandonment. Another round of examination will be added that will create more work for the examiner. This can only increase pendency and add to the backlog of pending applications . The PTO's stated goals to reduce pendency and backlog and improve efficiency will not be accomplished.

Claims Containing Markush Groups

The PTO has requested comments on the treatment of Markush claims containing Markush groups for the purpose of counting the number of claims under proposed § 1.75(b). The answer is simple. A claim containing a Markush group should be counted as a single claim. A Markush group enables an applicant to present a claim with an element, step or ingredient identified in the alternative where a generic term that covers all the alternative embodiments does not exist. Such a claim is no different that a generic claim that covers an equal number of embodiments using a generic term, which generic claim would be counted as one claim under the existing and the proposed rule. No legal basis or rationale has been presented by the PTO for creating an artificial distinction between claims that claim alternative embodiments where one claim uses generic terms and a second uses a Markush group. Neither of the alternatives suggested by the PTO will work. The ambiguity inherent in both of these alternatives and the lack of clear guidance on their application prevents Wyeth from offering specific comments on these two alternatives.

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The Examination Support Document Requirement Should be Dropped

Proposed § 1.75(b)(1) provides that an applicant must submit an examination support document in compliance with § 1.261 for each representative claim if the application contains, or is amended to contain, more than ten independent claims, or the number of representative claims is greater than ten. Each such "examination support document" would require: (i) a statement that a search was conducted that must include publications and foreign art, and an explanation of the search, (ii) an information disclosure statement, (iii) an identification of all claim limitations that are disclosed by each reference, (iv) an explanation of how the claims are patentable over the references cited, (v) a statement of utility, and (vi) a showing of where each claim limitation is supported in the written description. This examination support document "option" is clearly so overly burdensome as to be illusory. PTO officials have acknowledged as much in their statements, made at various public meetings, that the requirements were deliberately made onerous to raise the bar and discourage applicants from filing them. Congress has not seen fit to limit applicants' opportunity to file more than ten independent claims; it is not within the authority of the PTO to do so by creating unreasonable obstacles for applicants.

Furthermore, the proposed examination support document is in reality an improper transfer of the PTO's statutory obligation to search and examine the patent application onto the applicant at applicant's expense on top of applicant's payment of the search and examination fees to the PTO. *See,* 35 U.S.C. §§ 41(d)(1)(A), 131. Rather than draft a rule that addresses a small, discrete group of applications with excess claims, the PTO has proposed a set of draconian rules that accomplishes nothing positive and will only worsen the backlog and pendency of applications before the PTO and prejudice applicants' rights to patent the full scope of their inventions.

Proposed Section 1.75(b)(4) on Multiple Applications Should be Dropped

Under proposed Section 1.75(b)(4), if there is at least one claim in one application that is patentably indistinct from at least one claim in one or more of the other applications owned by the same person or subject to an obligation of assignment to the same person, the PTO may (a) require elimination of patentably indistinct claims from all but one of the applications, or (b) only allow the designation of a total of ten claims for initial examination in all such related applications without triggering the requirement for an examination support document. Wyeth agrees with the comments of the American Intellectual Property Law Association submitted on April 24, 2006 concerning this proposed rule. As the AIPLA stated,

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in addition to increasing complexity and unnecessarily consuming PTO and applicant resources, this proposal provides new incentives for applicants to challenge double patenting rejections that are currently handled by filing terminal disclaimers. The AIPLA further states:

> This proposed practice could reduce the number of representative claims identified for initial examination in related applications to significantly less than ten, depending on the number of related applications which the PTO determines contain patentably indistinct claims. It is both unfair and unwise to further limit the number of claims examined in a single application because it would almost certainly lead to greater inefficiencies, and may lead to the search and initial examination of only a single claim (*e.g.*, where there are 6-10 related applications) in some applications, notwithstanding that a full search and examination fee has been paid in each of the applications.

Wyeth also wishes to point out that this proposed rule does not take into account the situation where an applicant is involved in a collaboration or alliance with another party. In the pharmaceutical and biotechnology industries, it is common practice to have formal research and development collaborations. Such collaborations foster the development of novel therapies and vaccines for the treatment of diseases around the world. Oftentimes, an invention is made that has applications both within the scope of the collaboration and outside the scope of the collaboration. In these situations, multiple applications that have the same or substantially identical specifications and different claim sets, having at least one owner in common, will be filed on the same day. For example, a first application is filed with claims relating to the subject matter of the collaboration that is co-owned by the collaboration partners. A second application owned by only one partner, is filed with claims relating to non-collaboration subject matter. Under the proposed rule, it is likely that the PTO would require merger of the two applications, thereby causing the loss of exclusive rights by one party, and the gain of undeserved rights by another. The substantive effects on ownership rights, such as these, are unintended consequences of these proposed rules.

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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 and the quality of issued patents is about the same as the likelihood of success of

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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 individual inventors and large corporations alike, the proposed rules will result in piecemeal examination of patent applications and patents with eroded presumptions 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.