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From: Merrill, Deb - LAW [mailto:debram@amgen.com] **On Behalf Of** Watt, Stuart - LAW
Sent: Wednesday, May 03, 2006 7:23 PM
To: AB94Comments; AB93Comments
Subject: Office of the Deputy Commissioner for Patent Examination Policy
Importance: High

Stuart L. Watt
Vice President, Law and
Intellectual Property Officer
Intellectual Property & Litigation

AMGEN

Amgen
One Amgen Center Drive
28-2-C
Thousand Oaks, CA 91320-1799
Direct Dial: 805.447.2154
Fax: 805.499.8011
E-mail: swatt@amgen.com
www.Amgen.com

VIA EMAIL – AB93Comments@uspto.gov
AB94Comments@uspto.gov

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Office of the Deputy Commissioner for Patent Examination Policy
Mail Stop Comments – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attention: Robert W. Bahr, Esq.
Senior Patent Attorney

Robert A. Clarke, Deputy Director
Office of Patent Legal Administration

Re: Comments on Proposed Rules -- *Changes to Practice for the Examination of Claims In Patent Applications* (Fed. Reg. Vol. 71 No. 1 page 61, Jan. 3, 2006), and *Changes to Practice for Continuing Applications, Request for Continued Examination Practice, and Applications Claiming Patentably Indistinct Claims,* (Fed. Reg. Vol. 71 No. 1 Page 48, Jan. 3, 2006)

Gentlemen:

Amgen appreciates the opportunity to provide comments on the PTO's proposed rules on examination of claims in patent applications and continuation application practice published in the Federal Register on January 3, 2006. According to the PTO, these proposals are intended to alleviate a backlog of applications, address abuse in repeated filings and narrow the focus of the claims to be examined so that the examiners can perform a more thorough and reliable examination.

While we share the PTO's desires to achieve better quality in the examination of patent applications and reduce the backlog of pending applications, Amgen is concerned that the proposed rules will not help resolve the problems they are designed to address. Rather, we believe that the proposed rules will significantly curtail the rights of true innovators to seek legitimate patent protection for their inventions. We also share the PTO's desire to prevent abuse of the system by a few who repeatedly file continuation applications just to keep a case alive in the PTO in hopes of obtaining allowance not by the merits of their positions but by relentless perseverance. However, we believe the level of such abuse to be low, and we would rather see these wrongly issued patents weeded out by the courts than to impose artificial limitations on patent prosecution and the statutory rights of innovators.

Based upon our experience, we have many concerns about the proposed rules and the impact they would have, if adopted, on Amgen's ability to obtain meaningful patent protection for its

inventions. We further suggest alternative ways to address the stated goals of reducing the backlog of applications and achieving a more focused examination that are more likely to achieve these goals without impeding the pursuit of legitimate patent rights.

About Amgen

Amgen discovers, develops and delivers innovative human therapeutics. A biotechnology pioneer since 1980, Amgen was one of the first companies to realize the new science's promise by bringing safe and effective medicines from lab, to manufacturing plant, to patient. Amgen's therapeutics have changed the practice of medicine, helping millions of people around the world in the fight against cancer, kidney disease, rheumatoid arthritis, and other serious illnesses. With a broad and deep pipeline of potential new medicines, Amgen remains committed to advancing science to dramatically improve people's lives. In 2005, Amgen spent over $2.3 billion on research and development in order to bring these new innovative therapies to the patients who need them. Much of the hope for future breakthroughs in treating grievous illnesses rests on the research done at biotechnology companies like Amgen.

Valid and enforceable patent rights have been critical to Amgen's past success and will continue to be critical to its future. In biotechnology, patent rights are often described as the "crown jewels" of a company as they provide the basis for large investments of time and money in the pursuit of clinically meaningful products. Amgen's business operations and the decision to pursue development of a potential therapeutic product depend upon the ability to secure meaningful patent protection for our innovations. To be meaningful, patent rights must be sufficiently broad to protect the various aspects of the invention disclosed in the application and they must be secured in a timely manner. If we could obtain appropriate claims by prosecuting a single application our concerns over the proposed rules would diminish, but in our experience, it usually takes more than a single continuation application to obtain allowance of claims that provide appropriate protection for the disclosed inventions.

Comments On The Proposed Rules Regarding Continuation Practice

Amgen believes that the proposed reforms of continuation practice are unlikely to significantly reduce the backlog of applications, will actually increase the workload of the PTO in the near term, and will increase the burden on applicants by requiring them to file and prosecute all divisional applications simultaneously. More importantly, however, we believe that the proposed rules will unnecessarily restrict the legitimate pursuit of valid patent protection for significant inventions and thereby discourage the investment and incentive needed to spurn on truly breakthrough innovation.

The proposed rules seemed directed at the actions of a few, but the negative impact of these rules will be felt by the large majority of patent applicants. The problem of so-called "submarine patents" that remained hidden for years while the patent holder lay in wait for developments in the market in order to claim infringement are largely a thing of the past due to the adoption of the 20-year patent term and the 18-month mandatory publication for most applications. In order to eliminate the lack of notice of pending applications, Amgen would support the mandatory publication of all applications. While a few outliers have misused continuation practice, by the PTO's own estimates, this is a very small portion of the overall patent pool. Only about 3.4% of

applications filed in 2005 were second or subsequent continuation applications and only about 20% of requests for continuation filed in 2005 were second or subsequent requests for continuation. 71 Fed. Reg. 50 (January 3, 2006). Thus, the numbers alone do not validate this rule as a means to effectively address the work backlog.

Moreover, the clear implication of the proposed rules is that the PTO believes that continuation practice is illegitimate and that second and subsequent continuation applications are typically filed to pursue claims to which applicants are not entitled. PTO representatives have presented this position in several presentations given to industry groups in the past few months in support of the proposed rules. First, continuation practice has a statutory basis and it is unclear how the PTO believes that it can curtail a statutory right by administrative rulemaking. Second, by its owns rules, practices and the examiner quota system the PTO actually encourages, and in some cases compels, applicants to file continuation applications in order to pursue claims of appropriate scope. It seems odd that the PTO would take aim at a statutory right that its own practices encourage without first addressing those practices.

Continuation Practice Is Important In Order to Protect Biotechnology Inventions

Amgen is concerned that the actions of a small minority of patent applicants is prompting a change that would have a dramatic impact on all innovators and may deprive innovators of legitimate patent rights. The proposed rules will disproportionately affect industries, such as the biotechnology industry, that rely heavily on the patent system to reward and incentivize innovation. The technology is complex and the research and development pathway for biotechnology products is extremely long due to the significant amount of experimentation involved and the regulatory requirements these innovations must meet. As such, products are often not commercialized for 10-15 years after the initial discovery.

Continuation practice affords both the applicant and the examiner the opportunity to fully understand and appropriately claim the invention described and disclosed in the original patent application. The challenge in biotechnology patent prosecution is for the examiner and the applicant to reach a common understanding of the scope and attributes of the invention. Until that common understanding is reached, the applicant and examiner cannot agree on the format and wording used to claim the invention and prosecution of the application stalls. Like all patent applications, biotech patent applications must meet the disclosure requirements of written description and enablement imposed by 35 USC §112, and in fact, the requirements imposed on biotech patent applications are in many ways more stringent than in other technologies. The stringent disclosure requirements guard against abuse of continuation applications for "submarine-like" activities. In our practice, continuation applications are used to gain this agreement with the examiner to obtain valid claims of appropriate scope in view of the disclosure and the prior art and not as an attempt to avoid the requirements of §112. In many cases, this requires more than one continuation application top achieve.

In addition, other legitimate uses of continuation applications exist. Often in the prosecution of biotechnology applications, the examiners allow narrower claims, and it is important commercially for the applicant company to have those narrow claims issued to attract outside investments. The applicant may still be entitled to broader claims commensurate with the disclosure and should be allowed to pursue them in a continuation application. Conversely,

pursuit of species claims within an allowed genus is also a legitimate use of continuation applications. Of course, the need for filing a CIP may arise in order to insert additional disclosure to the application. If adopted, the proposed rules would restrain all of these legitimate practices.

Proposed Rules For Divisional Applications Would Yield More, Not Fewer, Applications

The proposed rules require that all divisional applications claim priority only to one application (the parent application in which a restriction requirement was issued). The practical effect of this proposal is that all divisional applications will be filed and examined simultaneously, rather than serially as they are typically prosecuted under the current rules. Amgen believes this change will disproportionately affect the biotechnology industry, to its detriment. Often, the PTO requires biotechnology inventions to be divided into numerous applications. Restriction requirements dividing an application into more than 10 groups are not uncommon in biotechnology practice.

Under this backdrop, the proposed rules regarding divisional practice would only exacerbate the backlog problem at the PTO. Applicants will be filing multiple divisional applications upon allowance rather than one application, as is the current practice. Moreover, the decision to file divisional applications will be moved to a much earlier time in the development process, when there is much less information about the commercial embodiments. As a result, applicants may be inclined to file more, not fewer, applications than are filed currently. Thus, the effect of the proposed rules would only make the application backlog problem more severe.

The proposed rules are particularly onerous on smaller, less capitalized companies, as financial constraints will make filing and prosecuting multiple divisional applications impracticable. Amgen shares the concerns of less capitalized biotechnology companies and relies on the value that is created by their innovations, including developing patent portfolios, through joint development agreements or other business relationships. Thus, less capitalized companies will be forced to pick and choose aspects of inventions to pursue in divisional applications, typically at an early stage in product development, long before commercial embodiments are known. One of the many benefits of the current system is that it fosters innovation by allowing small companies to file divisional applications serially, thus providing an opportunity to defer significant fees until a time when the invention is better defined and/or more resources are available. Amgen is concerned that because the proposed rules will force applicants to either pay significant fees at one time or forgo filing divisional applications, the proposed rules will result in a loss of legitimate patent rights for innovators. This effect is only exacerbated for biotechnology inventions due to their complex nature.

PTO Reforms Should Be Implemented To Encourage A Productive Dialog Between Examiners And Inventors

In lieu of the proposed continuation application reform, Amgen believes reform of internal PTO practice that encourages communication between examiners and applicants would greatly help reduce the backlog of pending patent applications. For example, the PTO examiner credit system is currently designed such that examiners rely on the filing of continuation applications to

adequately review complex applications. Frequently, because there is no incentive for examiners to consider after-final amendments and arguments, these submissions are summarily rejected and applicants must file a continuation application or an RCE to have their responses considered, even though the first submission was fully responsive to the original rejection. The examiner credit system should be revised to encourage examiners to consider after-final submissions. To this end, after-final interviews should be allowed as of right. Similarly, examiners should be encouraged to issue second non-final rejections if, in their opinion, the applicant is making a legitimate attempt to advance prosecution.

Given the increased importance that first office actions on the merits may have under the proposed rules, the examination system should also be reformed to encourage examiners to thoroughly review an application before issuing a first office action. Accordingly, Amgen recommends that the PTO allow pre-examination interviews as of right. These opportunities allow applicants to explain their technology and the scope of the invention to the examiner, thus making the examiner's subsequent search and examination more productive. Through the credit system, examiners should also be encouraged to spend a sufficient amount of time to acquaint themselves with the invention prior to conducting a search, thereby improving the quality of the first office action. Finally, Amgen recommends that the PTO institute a review process prior to issuing a final rejection. Amgen notes the success of the PTO's pilot pre-appeal conference program. *See* 1303 Off. Gaz. Pat. Office 21. A similar program instituted earlier in prosecution could serve the goals of advancing prosecution and obviating unnecessary appeals. Such a review process could also include the option of appealing to an ombudsperson, designated to hear issues regarding errors in examination.

The Rebuttable Presumption Of Double Patenting Proposed By The Rules Shifts The Burden Of Prosecution To The Applicant

Amgen is also concerned that the rebuttable presumption of double patenting for applications filed on the same day unfairly shifts the examiner's burden of initial examination to applicants. Even if a terminal disclaimer is filed, the proposed rules require applicants to either explain how the claims in one application are patentably distinct from the claims in every other application filed on the same day or to file a terminal disclaimer. The proposed rules also require applicants to explain, to the satisfaction of the Director, why it is necessary to file multiple applications containing patentably indistinct claims. The proposed rules do not provide a standard for meeting these requirements "to the satisfaction of the Director." Given the dire consequences of having claims eliminated if the showing is insufficient, Amgen encourages the PTO to at least provide illustrative examples of showings that would be sufficient to meet this requirement.

Moreover, the statement requirements in conjunction with the proposed rules puts applicants in a position of having to make statements against interest long before the scope of their invention is realized. These statements will likely cloud the enforceability of a patent that is ultimately issued.

Alternative Examination Reforms Will Alleviate The Backlog Of Applications

Amgen recommends that the PTO consider a deferred examination program, similar to that in place in many foreign countries, to help alleviate the backlog of pending applications. Along

with such a program, the PTO should also consider an accelerated examination process, which will help prioritize examination of inventions deemed critical. Such an accelerated examination process could take advantage of search results from other jurisdictions, such as PCT search results.

Rather than setting an arbitrary limit on the number of continuation applications that can be filed, Amgen recommends that the PTO consider a fee-based incentive strategy to reduce the number of continuation applications filed. For example, a graduated fee structure whereby filing and examination fees for second and subsequent continuation applications and requests for continuation are increased will force applicants to consider the value of the underlying invention before filing a patent application. For inventions of great value, however, such a program will not put inventors in the position of forsaking legitimate patent rights. A similar strategy has been successful in reducing the number of claims per application.

In summary, Amgen opposes the proposed rules limiting continuation practice. The proposed rules likely will not address the backlog concerns of the PTO. Given the prospect of continuation applications being disallowed, applicants will undoubtedly be inclined to file more applications of increasingly narrow scope. Such a narrow scope will make these applications more difficult to examine because applicants will be prevented the opportunity to fully explain their inventions in a single coherent document. In addition, Amgen believes the number of patent filings will actually increase as a result of inventors filing all of their divisional applications at one time. This creates an additional backlog in some of the art units that are already among the busiest at the PTO. The proposed rules will further hamper examination by potentially spreading "related" applications (narrow applications filed on the same day) among different examiners, thereby diluting the knowledge each examiner has regarding a particular invention. Finally, the result of the proposed rules will undoubtedly be a rise in the number of appeals filed, a great concern to inventors particularly considering that the Board only recently successfully reduced its own backlog of pending cases.

Proposed Rules Regarding Claim Examination

Amgen is also concerned that the PTO's proposed rules regarding claim examination will not further the agency's goals of reducing backlog and improving patent pendency. First and foremost, there is no assurance that an arbitrary limit on the number of claims in an application will meet the PTO's goals. In industries with complex technology like biotechnology, claim strategy helps to inform the examiner of the scope of the invention. Often, such a strategy is necessary to clearly set forth the metes and bounds of the invention. In biotechnology related applications that contain a multiplicity of separately patentable inventions, ten claims are clearly not enough to capture all the described inventions. If these proposed rules were adopted, it would be critical for the examiners to issue restriction requirements first before the claim limitation was imposed.

The Proposed Rules Raise Questions Regarding The Presumption Of Validity Of Patent Claims

The PTO proposes that only the independent claims and dependent claims designated by the applicant (limited to a total of 10 claims) will be examined against the prior art. The remaining dependent claims will only be examined for compliance with 35 U.S.C. §§ 101 and 112. These

proposed rules raise significant questions about the presumption of validity of patent claims. This change will likely result in an increase in the litigation surrounding these claims, ultimately undermining their value to the patent holder.

The Proposed Examination Support Document Exposes Inventors To A High Degree Of Risk

The examination support document provided for in the proposed rules is also an invitation to a plethora of pitfalls for inventors and will not be used. The proposed rules provide that more than 10 representative claims may be examined only with the concurrent filing of an examination support document. The examination support document requires inventors to perform a pre-examination search and to report the results of that search to the PTO.

The requirement for an examination support document improperly shifts the burden of examination to the applicants. In addition, the requirement places applicants at an unfair risk of inequitable conduct allegations once they attempt to enforce the patent. For example, litigants will likely claim that the search was inadequate, that certain limitations were omitted or improperly searched, or that the search was performed too early in an effort to avoid certain art. Finally, the requirement that the search encompass any disclosed features that may be later claimed is nearly impossible for an applicant to successfully fulfill, as it is difficult to know all the claims and claim limitations that may ultimately issue.

In sum, we submit that the limitation on the number of claims is artificial and will expand rather than simplify the examination of complex applications.

Respectfully submitted,

Stuart L. Watt

Stuart L. Watt
Vice President, Law and
Intellectual Property Officer