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From: Merrill, Deb - LAW **On Behalf Of** Watt, Stuart - LAW
Sent: Friday, September 08, 2006 7:53 PM
To: AB95 Comments
Subject: Comments to Proposed Rulemaking Entitled: Changes to Information Disclosure Requirements and Other Related Matters (Fed. Reg. Vol. 71, No. 131, page 38808, July 10, 2006)

Please see the attached letter from Stuart L. Watt, Vice President, Law and Intellectual Property Officer, Amgen Inc.

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September 8, 2006

BY ELECTRONIC MAIL to AB95.COMMENTS@USPTO.GOV

Mail Stop Comments – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attention: Hiram H. Bernstein

Re: Comments to Proposed Rulemaking Entitled: *Changes to Information Disclosure Requirements and Other Related Matters* (Fed. Reg. Vol. 71, No. 131, page 38808, July 10, 2006)

Dear Mr. Bernstein:

Amgen appreciates the opportunity to provide comments regarding the PTO's proposed rules involving information disclosure statements (IDS) and related matters (Fed. Reg. Vol. 71, No. 131, page 38808, July 10, 2006). The PTO asserts that these proposed rules are intended to improve the quality and efficiency of the examination process by limiting information submissions to relevant, non-cumulative information and requiring IDS submissions prior to the first office action.

Amgen supports the PTO's desire to improve the quality and efficiency of the examination process. We believe that it benefits all users of the patent system to increase the information and focus brought to bear on patent examination. Amgen is a research intensive biotechnology company that spends billions of dollars each year in developing breakthrough therapeutic products. What we need in order to protect our investment in our R&D are valid and enforceable patents with claims of appropriate scope. We agree that proper disclosure of relevant references in a timely way benefits the examination process. The examiner should have the benefit of the applicant's disclosure of relevant information when formulating the first Office Action on the merits. Amgen agrees with the PTO's desire to discourage the practice of submitting documents that have not been reviewed by the applicant, applicant's representative, another examiner or foreign patent office and irrelevant documents that were not cited by another examiner or foreign patent office.

While we applaud the PTO's initiative, we believe that adopting the proposed rules on IDS's without significant reforms to the law on inequitable conduct would be a serious mistake and only increase the challenges brought to patents in later litigation. As discussed below, the proposed rules will have a disparate impact on biotechnology companies whose patent

applications are more complex and involved than most other applications. Finally, we submit that alternative paths exist for accomplishing much of what the Office desires without adopting the proposed rules.

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. We believe that disclosing relevant information to a patent examiner in a timely manner furthers these goals.

The Proposed IDS Rules Disproportionately Impact The Biotechnology Industry

The Office asserts that only about 20% of IDS include more than 20 documents suggesting that the proposed changes will impact only a relatively small number of patent applicants. Conversely, it also suggests that the benefit to the Office of the proposed rules will be small. However, patent applications related to biotechnology inventions frequently involve IDS submissions of substantially more than 20 references and the proposed new rules would significantly increase the burden and expense of filing biotech patent applications.

The Office recognizes that biotechnology patent applications often involve a large number of references by giving examiners in the Biotech arts additional time to prosecute such cases. Further, by way of illustration, on average about 70% of US patents issued over the last five years to each of several US Biotechnology companies involved submissions of IDSs of substantially more than 20 references. We surveyed over a hundred of our recently filed patent applications and found that 67% of IDS filed in the applications listed more than 20 references. The reason for this is that biotechnology inventions encompass a variety of subject matters, such as nucleotides, peptides, vectors, plasmids, host cells, methods of use, compositions, etc. Each

of art in these areas may contain relevant references for the examiner to consider. For example, a method of treating a disease or disorder, such as inflammation or cancer, can involve a large number of indications or specific diseases that can be treated by the claimed agent(s) or through modulation of a specific pathway. A single reference involving each such indication will inevitably result in an IDS of substantially more than 20 references. Add to this the art involving related nucleotides, peptides, etc. and the number of relevant references can be rather large. Thus, Amgen respectfully submits that it is unlikely that the new rules will cause a significant reduction in the number of references submitted with respect to a biotech patent application and yet the cost and burden on an applicant to provide all that the rules require will be significant.

The Duty to Disclose Material Information is Paramount Because the Ramifications of not doing it are Severe

For over 20 years, the courts and the PTO have required patent applicants to disclose all information in their possession that may be material to the examination of a patent application. A breach of this duty may constitute inequitable conduct, which can arise from an affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive or mislead the PTO. The result of a finding of inequitable conduct can be the forfeiture of all patent rights and not just those claims involving the inequitable conduct.

In the proposed rules, the Office recognizes this imbalance and seeks to reduce the risk to an applicant by creating a safe harbor in rule 56. However, the Office acknowledges in its discussion of the proposed safe harbor amendment that this amendment is simply a "hope" and may not be effective in protecting an applicant from a good faith error in judgment. Even if a good faith review is made, the courts may continue to view the failure to disclose material information as in equitable conduct. Compounding this is the obligation to identify the pertinent portions of a document relevant to the claims or specification if the document is more than 25 pages (e.g., most published patent applications) or there are more than 20 references. By identifying or only providing those portions of the document that applicant perceives as pertinent, an applicant runs the risk of being accused of misleading or misdirecting the Office away from other information in the document. Because it is often difficult to assess when or which portions of the information is material, relevant, marginally relevant or cumulative, the proposed rules put the applicant is in a very precarious position.

The Proposed Rules Will Lead to More Uncertainty and More Litigation

Amgen respectfully submits that the new rules will open the door to a substantial increase in not only the frequency of inequitable conduct allegations in litigation but in the scope and number of different arguments available to be raised by an accused infringer. Each time an applicant submits only a portion of a reference, a skilled attorney will imply in litigation that something significant was omitted. Each explanation provided by an applicant as required under the proposed rules will be challenged as being inadequate or in error. Amgen respectfully submits that the resulting outcome will likely be weaker patents with questionable reliability. Such an

outcome will have a chilling effect on the biotechnology sector. Consequently, without significant reform of the law on inequitable conduct, it is our view that the proposed rules will only cause further damage to the patent system.

No Avenue for Disclosing Newly Discovered Documents Without Penalty

During the prosecution of a patent application, as relevant documents become known to persons associated with the patent application, this information should be promptly communicated to the Office with the appropriate certification. The proposed rules do not permit such submissions without significant explanation burdens. Amgen respectfully submits that newly discovered information, supported by the appropriate certification petition, should be treated in the same manner as timely filed IDS information prior to the first Office Action on the merits.

Alternative Proposals

By disclosing all information that reasonably appears to be relevant, the Office has the opportunity to review that information and make its own assessment. The Office historically recognizes that to make a patent stronger and reduce the risks of an incorrect judgment regarding materiality of a reference, an applicant will submit references that they may reasonably believe they are not required to submit (MPEP 2001.05). Balancing this, an applicant must be judicious in deciding which references to submit or risk later being accused of misleading the Office by burying key references in a large number of less important references. Amgen respectfully submits that improving the ease and efficiency of reviewing submitted information will more likely lead to reduced workload and prosecution time without the concomitant loss of the strength of the resulting patent or the significant increase in risk of forfeiture. Thus Amgen respectfully suggests the Office adopt a requirement that applicants submit text searchable electronic copies of information provided in an IDS. Text searchable electronic copies would permit the Office to more efficiently search, review and evaluate the information disclosed.

A rule requiring applicant's IDS be filed within three months of the filing date of a national application would give the Office the opportunity to review and use disclosed information in the first Office Action on the merits. Failure to provide the IDS in that timeframe could result in a heavy fine and loss of any prosecution related term extension benefit.

Finally, the references disclosed in an IDS could be given designations by the applicant to indicate which references the applicant believes are the most relevant. This happens in a European search report. The Office could adopt rules requesting the applicant to list as "A" references the ten (or some other number) references that the applicant believes are most relevant to the claimed inventions and then list as "B" references those other references that the applicant believes should be made of record. This would be done as purely an aid to the examiner, and the Office would not rely on such designations and would not relieve the examiner from reviewing the "B" references. A listing of a reference as a "B" reference instead of an "A" therefore would

not be a basis for a later allegation of inequitable conduct. We believe that such a framework would assist the examiner and not expose the applicant to allegations of improper conduct.

In sum, we submit that adoption of the proposed rules without significant inequitable conduct reform would do damage to the patent system and we propose alternatives that would achieve much of the goals of the Office. Thank you in advance for your consideration of our comments and suggestions.

Respectfully submitted,

Stuart L. Watt

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