-----Original Message-----
From: Jan Hasak
Sent: Friday, September 08, 2006 8:58 PM
To: AB95 Comments
Subject: Comments on Changes to Information Disclosure Statement Requirements

Dear Mr. Bernstein:

Attached is Genentech's paper on the above subject.

Sincerely,

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September 8, 2006

By electronic mail – AB95Comments@uspto.gov

Attn.: Hiram H. Bernstein
Commissioner for Patents
U.S. Patent and Trademark Office
Alexandria, Virginia

Re: *Changes to Information Disclosure Statement Requirements and Other Related Matters*, 71 Fed. Reg. 38808 (July 10, 2006)

Sir:

Genentech, Inc. ("Genentech") offers the following comments in response to the Office's Notice of proposed rule making.

Genentech has been delivering on the promise of biotechnology for almost 30 years, using human genetic information to discover, develop, manufacture, and commercialize biotherapeutics that address significant unmet medical needs. Today, Genentech is among the world's leading biotech companies, with multiple products on the market for serious or life-threatening medical conditions and over 40 projects in the pipeline. We are the leading provider of anti-tumor therapeutics in the United States. Of course, Genentech is not alone in its efforts to develop new biotherapeutics. Recent data from the Biotechnology Industry Organization indicate that there are currently more than 300 biotechnology-based products in clinical trials targeting more than 200 diseases, including various cancers, Alzheimer's disease, heart disease, diabetes, multiple sclerosis, AIDS, and arthritis.

Genentech invests over a billion dollars annually in its research and development programs. Strong patent protection is essential in recouping that investment, encouraging innovation, and sustaining future research and development. Genentech attaches great importance to its ability to procure patents efficiently. Of equal importance, however, is the ability of Genentech to obtain patents based on a thorough consideration of a complete record of evidence that may potentially be relevant to the claims of the patent.

Overview

Genentech supports the goals of facilitating efficient consideration of the most relevant evidence by patent examiners and encouraging discussion of such evidence on the record of patent applications. We appreciate that current practices often lead to the citation of numerous publications, patents and other information in individual cases, and that this places a strain on the Office's limited examination resources. However, the approach reflected in the proposed rules is neither realistic given the nature of most biotechnology applications, nor will it promote the goals of meaningful, comprehensive and efficient examination of applications.

The examination of applications in unpredictable fields, such as biotechnology, often requires examiners to consider a diverse array of information. Complex scientific questions often arise in these applications, necessitating the consideration of numerous scientific publications, including publications that are not prior art to an application.

Compounding the problem is the tension between what the proposed rules would require and what is prudent for an applicant to disclose to avoid later being accused of inequitable conduct. A patent applicant desiring to limit its risks under this doctrine (i.e., the risk of the patent being held unenforceable) must cite all potentially relevant information to the Office, without condition. The proposed rules would place applicants in the unenviable position of being prohibited by rule from taking the actions that courts seem to be demanding of them to ensure the enforceability of their patents.

We set forth our broader concerns in the general comments immediately below.

Notwithstanding these concerns, we agree that the Office and the public will benefit from standards and practices that will assist examiners in navigating extensive or complicated records. At the same time, it is not practical – nor is it good policy – to place unreasonable burdens on biotechnology patent applicants to gain efficiencies in other sectors of the patent applicant community. Accordingly, following our general comments we offer our views on the proposed rules, as well as alternatives to these rules that may prove more effective in achieving the Office's objectives while respecting the realistic constraints facing biotechnology applicants.

A. General Comments

1. The only effective "solution" to large and complex Information Disclosure Statements is a fundamental reform of the law governing inequitable conduct.

The practice of citing large and complex information disclosure statements is a direct result of the exaggerated risk of unenforceability created by the current law governing inequitable conduct. A regulatory solution cannot completely resolve this problem. To achieve meaningful reform, the Office and the Administration must support a change to the legal standards that govern this doctrine. Until this occurs, the root cause of the problems the Office faces cannot be effectively addressed without increasing the risks to patent owners. Genentech notes that several opportunities now exist to achieve this necessary reform of the law governing inequitable conduct. One opportunity is for the Administration to strongly support legislative

reform in the area (e.g., by supporting current legislation pending before Congress, including H.R. 2785 and S. 3818). This legislation might substantially modify not only the inequitable conduct standards, but also impose post-grant oppositions that would impact any IDS rules. Post-grant opposition procedure would make transparent all relevant art in an *inter partes* setting, Voluntary characterizations of the references would still be permitted at applicants' discretion, but not required. Similar systems have worked in Europe and Japan, and *inter partes* opposition in the trademark division of the Office provides another model.

A second opportunity is for the Administration to support reforms that will constrain the scope of the doctrine in filings before the Supreme Court and the Federal Circuit. The Administration, for example, could support a petition for *certiorari* in the upcoming case of *Ferring B.V. v. Barr Labs, Inc*., 437 F.3d 1181 (Fed. Cir. 2006). Finally, the Office could consider reforms to its definition of materiality in 37 C.F.R. § 1.56, as suggested below.

Unfortunately, the Office is proposing rules that could actually exacerbate the current risks for patent applicants. For example, the proposed rules would require applicants that cite more than a small number of references to provide a characterization of each reference being provided in the IDS, and would prevent applicants from citing references in certain situations. The rule package assumes the determinations underlying these actions, such as a finding that a reference is "cumulative," or how a reference relates to a particular claim element, involve objective and straightforward analyses. They do not. Instead, these determinations inherently require some degree of subjective analysis by an applicant. In litigation, these subjective determinations (often made more than a decade before the time the patent is litigated) will be the target of intense scrutiny. Discovery will probe the distant memories of individuals, and decisions will be based on a distorted and incomplete record.

The "safe harbor" being proposed via Rule 56(f) will not remedy the underlying problems. Moreover, it will not limit the new risks created by the additional disclosure obligations that would be imposed by the proposed rules. For example, proposed Rule 56(f) does not address any of the factors that are pertinent to the current standards of inequitable conduct. Rather, the proposed rule applies only to the Office's requirements as to the duties of an applicant to supply information in addition to references that are provided in an IDS. Whether this "safe harbor" will prove to be safe in reality will not be known for many years (i.e., until patents issued under the rules are litigated). Unfortunately, the capacity of the Office to constrain the law of inequitable conduct is extremely limited. See, e.g., *Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1314-15 (Fed. Cir. 2006).

Because more effective and comprehensive solutions are at hand, we urge the Office in the strongest terms to withdraw the proposed rulemaking at this time. We encourage the Office instead to support a legislative solution to the problem of inequitable conduct claims in patent litigation.

2. The proposed rules are tailored to a simplified examination process that does not relate to patent applications in biotechnology.

The proposed rules appear to be based on the assumption that the patentability of every claim can be determined by simply comparing disclosures to individual claim elements, and that

references are cumulative unless they provide qualitatively unique teachings in respect of a claim. These assumptions may be correct for inventions that are simple combinations of predictable "old" elements. They are not correct, however, for most biotechnology inventions. Instead, the patentability of a biotechnology claim rarely depends on a single claim element, or whether that claim element has been disclosed in the prior art. Moreover, the most accurate perspective on the "state of the art" in the biotechnology field can often be found only by comparing several publications, not by inspecting a "most relevant" reference. Unrealistically simplistic assumptions such as these will lead to incorrect patentability determinations for biotechnology claims.

The proposed rules also seem to ignore the fact that in most biotechnology applications, the most significant questions affecting patentability determinations are those involving compliance with the utility requirement of 35 U.S.C. § 101, and the enablement and description requirements of § 112. For a typical therapeutic biotechnology invention, post-filing test data that further characterizes the biological or pharmacological activities of a claimed product, or references that describe therapeutic uses of different products with similar activities, may be pertinent to patentability determinations made by an examiner. When such references meet the standards for materiality, applicants have a duty to disclose them to the Office. Yet it would be virtually impossible to provide "a correlation of the specific feature(s), showing(s), or teaching(s) … corresponding to specific claim language, or to a specific portion(s) of the specification," as would be required under proposed § 1.98(a)(3)(iv)(B), for a reference that is material, *e.g.*, to assessing one of the *Wands* factors.

In addition, patentability assessments depend on numerous factual determinations. For example, compliance with the description requirement of § 112 and the utility requirement of § 101 are questions of fact. A proper legal determination of a factual issue requires an evaluation and balancing of evidence, both supportive and contrary to the particular issue of fact. Assessing the weight of the evidence as a whole, not determining whether a single item of evidence favors one finding or the other, is the legal task that examiners are required to perform. Relevant evidence for any question of fact might be found in several references that could be characterized as having qualitatively similar teachings. The proposed rules would exclude all but one such reference from consideration with respect to each factual point. Yet it would be legal error to resolve any legal question by weighing only some, but not all of the relevant evidence that bears on the question. *See, e.g.*, M.P.E.P. § 2141, section III (obviousness determination must take account of all objective evidence of record).

3. The proposed rules will divert significant examination resources away from core examining activities.

The Office has determined that its examination resources are strained, and that this strain is caused, in part, by the administrative requirements placed on examiners in considering excessive numbers of non-pertinent references cited in IDS filings. Unfortunately, the proposed rules, particularly §§ 1.97 and 1.98, will demand more, rather than fewer, examiner resources to administer. This is because these provisions invite and require a subjective evaluation of the form of IDS submissions by examiners.

For example, Proposed § 1.98(a)(3) sets forth several standards for compliance that are essentially subjective. At 71 Fed. Reg. 38814, col. 3, the Office suggests that an assertion that all or substantially all of a document is relevant would be assessed for compliance on the basis of examples of passages in the document, and that "[s]ufficiency of recitation of examples will vary on a case-by-case basis." Similarly, *id.* at 38815, col. 2, the Office suggests that where an "attempted correlation of a specific feature, showing or teaching … may not … be readily recognizable as actually correlating identified claim language," the applicant should amplify the explanation "to avoid a possible finding of noncompliance by the examiner with the correlation requirement." Each of these examples envisions that an examiner will evaluate the substance of an IDS, then make a determination whether the information provided meets the subjective standard set forth in the Rules. If the IDS does not, the examiner will refuse to accept the IDS, and the remedy for an applicant is to revise and resubmit the IDS.

Subjective standards that invite examiners to expend examination resources analyzing whether or not a citation complies with proposed § 1.98(a)(3), rather than assessing how a cited document is relevant to the claimed invention, will waste limited examiner resources and create more complicated examination practices. Disputes will inevitably arise between examiners and applicants as to the sufficiency or uniqueness of explanations. Resolving such procedural disputes does not contribute to any patentability determination. Moreover, many such disputes will give rise to petitions, to which the Office will be obliged to devote resources.

Unless the proposed rules are restructured to state objective and simple standards for compliance, it is likely that at least as much examining time as is "saved" by the additional disclosure requirements of proposed § 1.98(a)(3) will be lost to unproductive administrative and procedural exercises.

4. Assessing evidence and its relevance to the claims is an integral part of the patentability determination that must be performed by examiners, not applicants.

The assessment of how evidence relates to a claim involves construing the claim as a whole – a legal determination – and weighing the available evidence to resolve factual issues. This assessment is an essential aspect of the examination function performed by the Office. To the extent that the proposed rules call on applicants to analyze and cite evidence against their own claims, they improperly attempt to shift to the applicant the examination functions that the Office is statutorily obliged to conduct.

The proposed rules, and in particular the enhanced commentary requirements of proposed § 1.98(a)(3), could undermine the presumption of validity that patented claims are provided under 35 U.S.C. § 282. That presumption is based on the understanding that patent examiners make independent assessments of all evidence relevant to patentability of the claims of an application. The requirement that applicants characterize the cited art – and the possibility that examiners will rely on these characterizations instead of the actual evidence – could lead to criticisms, founded or otherwise, that the Office is not conducting its own comprehensive and independent assessment of relevant evidence. Moreover, this approach also invites the criticism that the Office may be relying on potentially biased perspectives on relevant evidence in the

examination of applications. All of these considerations could operate to weaken the strength of the presumption of validity that attaches to each patent under 35 U.S.C. § 282.

We also note that any description or characterization of references that applicants provide under § 1.98 is likely to be of little practical value to the Office. Applicants are aware that any minor anomaly between the actual disclosure of a reference and their characterization of that reference would be exploited by an opponent in litigation. Thus, applicants will strive to say as little of substance as possible about each reference, either by simply regurgitating the entire contents of every publication, or by providing overly general characterizations that cannot be portrayed as incomplete or misleading. As is clear from a review of any pre-1992 Information Disclosure Statement, such descriptions and characterizations are not helpful to examiners.

A simple indication of those references cited that have particular relevance would be far more useful to the Office than uninformative narratives. Moreover, it would place a far more reasonable burden on patent applicants to simply indicate, following a review of the reference, that the reference is among the more relevant references cited. Such indication could be accomplished, for example, by a separate listing on a PTO-1449-type form, or by a checkmark in an appropriate column. This approach would also have the desirable effect of significantly reducing the risk that an applicant's characterization of a reference could support a later claim for inequitable conduct.

5. The Office considered and rejected imposing similar characterization requirements on patent applicants less than 10 years ago.

The problem of whether, or how, to alleviate the examination burdens on the Office is not new. Since Rule 56 was promulgated in 1977, the Office has attempted to define standards that balance competing objectives:

- procuring the most relevant art from applicants for consideration by the examiner;

- procuring statements from applicants that would aid the Office's understanding of the cited art; and

- minimizing the litigation risks for patentees that could result from the overinclusion or underinclusion of cited art, or from an inadvertent error or omission in the characterization of a reference.

See generally H. Manbeck, "The Evolution and Issue of New Rule 56," 20 AIPLA Q.J. 136 (1992).

As first proposed, Rule 56 would have required applicants to provide a patentability brief explaining how each claim distinguished over the cited prior art. That provision was not included in the final rule. *Id.* at 138. Nonetheless, the original version of Rule 56 required applicants to provide a concise statement of relevance for each cited reference.

When Rule 56 was reformulated in 1992, the requirement for concise summaries of the cited art was excised from Rule 98. Many in the patent bar at the time argued strongly for the removal of the requirement. *Id.* at 143. Whether the requirement should have been maintained was apparently a close question within the Office, but serious concerns about the resulting risks for patentees carried the day. As Commissioner Manbeck recalled:

> [Concise explanations are] helpful to the examiner and may save him recognizable time … . However, we became convinced that the potential harm [to] patentees during litigation due to inadvertent errors in such explanations outweighed the benefit to the PTO.

Id. (Footnote 17).

The Office revisited the question of procuring statements from applicants in 1998. *See* "Changes to Implement the Patent Business Goals" (Advance notice of proposed rulemaking), 63 Fed. Reg. 53498 (October 5, 1998). In particular, the Office proposed that applicants be required to provide a "unique description of each citation's importance to each independent claim." *Id.* at 53512. The informational content of the "unique descriptions" proposed in the 1998 rule package was substantially the same as that of the "non-cumulative" descriptions that the Office now proposes to require.

The next year, after reviewing "numerous and varied" comments submitted in opposition to the proposal in the Advance Notice for a "unique description" requirement, the Office withdrew the proposal.[1]

We find it puzzling that the Office now proposes to implement requirements that are substantially similar to those it expressly rejected only seven years ago, and without any reference in the present Notice to the earlier rulemaking process. The Office procured and considered an extensive docket of comments from the public, and it took note of and specifically identified the reasons why it would have been undesirable in 1999 to require patent applicants to provide "unique descriptions" to distinguish independent claims over references cited in a disclosure statement. The Office has provided no rationale for imposing burdens on applicants now that were found to be unwarranted in 1999.

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[1] The Office specifically stated:

> The overwhelming majority of the comments expressed opposition to the unique description proposal of the Advance Notice. The Office has taken note of the large burden that would be imposed on applicants and attorneys by the description proposal of the Advance Notice, the potential for future adverse consequences stemming from doing the description or the choice not to describe, and the applicant's role reversal [*i.e.*, performing functions that should be performed by the examiner] that would be imposed by the description proposal. Accordingly, a decision has been made to not go forward with the unique description proposal at this time.

"Changes To Implement the Patent Business Goals" (Notice of proposed rulemaking), 64 Fed. Reg. 53722, 53798 (October 4, 1999).

B. Comments on Specific Proposed Rules

Should the Office elect to proceed with the present rulemaking, we provide the following suggestions for mitigating the adverse impacts of the proposed rules.

1. If the Office believes that only certain kinds of relevant information are material to patentability, it should revise the § 1.56(b) standard of materiality to correspond to the scope of information it considers appropriate for review.

The Office has traditionally encouraged the liberal citation of information for examiners' consideration. M.P.E.P. § 609, for example, suggests that applicants "may want the Office to consider information for a variety of reasons, e.g., to make sure that the examiner has an opportunity to consider the same information that was considered by [§ 1.56(c)] individuals, or by another patent office … ." Courts have cited guidance such as this in articulating the standard of materiality to which they hold patentees accountable when they consider questions of compliance with the duty of candor and good faith.

The proposed rules appear to reflect a substantially narrower scope of information that the Office considers to be "material" to the examination of applications. Despite this, the Office has not proposed amending § 1.56(b) to conform the rules to this new perspective of "material" information. Proposed § 1.56(f), as noted above, does not concern the standards for materiality. The only meaningful regulatory protection that the Office could provide applicants would be to revise § 1.56(b) to conform it to the narrower standard of materiality defined by limitations that would be imposed by proposed § 1.98.

Although amendments to § 1.56(b) are not binding on the courts, they carry some influence. *See generally Dayco Prod., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1363-64 (Fed. Cir. 2003). An amendment of the materiality standard of § 1.56(b) would carry far more weight with a court than the Office's stated "hope[ ]," 71 Fed. Reg. at 38812, that the courts might take some note of proposed § 1.56(f).

We note that the standard for "cumulative" disclosures impacts both the standard of materiality under § 1.56(b) and the scope of permissible disclosures under § 1.98(a)(3)(v). The term has been used for years in judicial opinions, as well as in the rules and the M.P.E.P. However, a precise definition is elusive. The Office should articulate an explicit regulatory definition of "cumulative" information as part of its proposed reforms to 37 C.F.R. § 1.56.

2. The "update" requirement of proposed § 1.98(a)(3)(ix) would be excessively burdensome for applicants and would rarely provide useful information for the Office.

Proposed §1.98(a)(3)(ix) would require applicants to provide an updated characterization of every cited reference each time claims are amended. This rule is enormously wasteful of applicants' prosecution resources, and it would yield essentially no additional benefit for examiners in most applications. Indeed, it will be an exceptional case where an examiner, having already reviewed the claims of an application and considered the cited references, would

be unable to appreciate how a claim amendment changed the manner in which the references could be considered relevant.

We also note that the Office has authority under § 1.105 to require additional specific information from applicants when warranted. We believe that the selective use of such authority is a more appropriate mechanism than the automatic requirement of proposed § 1.98(a)(3)(ix) for obtaining additional characterization of cited references that the Office may desire.

3. The requirement of proposed § 1.98(a)(3)(v) for non-cumulative descriptions will burden applicants unreasonably and deprive examiners of useful and relevant information for evaluating patentability.

Genentech believes strongly that the public interest is best served if applicants are permitted to cite any information that they believe could be relevant for consideration by the examiner of a patent application. This is particularly so for biotechnology, where an accurate appreciation of the teachings in the art comes more often from consideration of a collection of several references than from the disclosure of any single reference. We strongly urge the Office to allow the citation of plural references, even if such references relate to the same point, if the applicant determines in good faith that the record will be improved by the consideration of such references. In this regard, "grouped" explanations of references would be appropriate and efficient.

The specific requirement for non-cumulative descriptions of individual references creates considerable risks for applicants of later claims of inequitable conduct in litigation. Any statement that an applicant places on the record of a patent application will be subjected to intense scrutiny by potential opponents for opportunities to question the applicant's good faith during prosecution. In our view, such risks outweigh any benefit that the Office would realize from detailed statements provided by patent applicants.

An intermediate standard for characterization could provide useful guidance to the Office without exposing patent applicants to undue litigation risks. In this regard, we suggest that the Office permit applicants to provide generic classifications of various collections of references that the patent applicant, in good faith, considers relevant to the claims presented for examination.

4. The Office should consider contracting for international-type search reports, at applicants' expense, to evaluate large collections of cited art.

The Office has begun to contract with other search authorities to provide search reports in certain PCT applications, and it has explored contracting search functions in certain national applications. The Office could consider using private contractors as intermediaries for classifying and summarizing large IDS filings, as an alternative to the approach reflected in the proposed rules. Such contractors could "search" a defined set of references cited by the applicant, and characterize the relevance of the cited references in the format of an international-type search report or another form useful for examiners. Such an arrangement would –

- alleviate the burdens on the Office's internal resources;

- minimize the potential litigation risks that would arise from applicants' characterizations of the documents they cite;

- provide a straightforward mechanism for the Office to recover the costs associated with considering larger numbers of references, in proportion to the number of references cited;

- make efficient use of external examining resources (e.g., foreign patent examiners) already trained to effectively identify relevant teachings in references; and

- provide an initial evaluation of references in a uniform and succinct format that is already familiar to Office personnel.

Genentech has consistently advocated the concept that patent applicants should bear the reasonable and proportionate costs associated with their applications. In this regard, we note the Office could impose additional fees for large IDS filings that would cover the costs associated with employing private contractors to perform this function.

5. Proposed §§ 1.97 and 1.98 should apply only to original applications filed on or after the effective date of the rules.

It would be fundamentally unfair and unduly burdensome to impose the requirements of the proposed rules on applications that are already on file in the Office. The proposed rules call for the application of substantial analytical effort to evaluate and characterize the references cited in each patent application. Prudence calls for applicants to conduct such an evaluation in light of the potential risks for litigation. It is neither practical nor reasonable to impose such obligations on applications that were prepared and have been prosecuted under current practice.

The proposed rules would place particularly acute burdens on applicants if they were applied to continuing applications. Where references have been cited and considered according to existing practice in parent applications that have issued to patent, any characterizations of those references in a new continuing application inevitably create litigation risks for that issued patent. Such risks would present uncertainties regarding the enforcement of existing patents.

As a practical matter, we believe that the Office would not realize significant benefit from application of the proposed rules to existing or continuing applications. Where the Office has already considered references of record in parent applications, examiners are readily able to assess the relevance of such references to claims in continuing applications. Thus, the additional characterization that would be required under proposed § 1.98 would provide minimal and marginal assistance to examiners in such applications. On balance, the litigation risks to applicants of applying the proposed rules to existing or continuing applications outweigh any potential benefits to examiners.

We strongly encourage the Office to "phase in" any changes in practice by making the proposed rules effective only to newly filed original applications. In any event, no rules should

be implemented in a manner that would have retroactive effect as to any references already of record in any pending application.

6. The Office should always accept a foreign "international-type" search report as complying with the requirements of proposed § 1.98(a)(3)(iv).

The commentary that accompanies the proposed rules considers the possibility that foreign search reports might not always satisfy the disclosure requirements of proposed § 1.98(a)(3)(iv). *See* 71 Fed. Reg. at 38815, col. 3. This possibility would create unnecessary uncertainty regarding compliance with the rules, burden applicants with the need in some cases to obtain translations of foreign-language documents, and interfere with the prompt submission of relevant information to the Office.

The better approach is to provide expressly that a foreign search report prepared, *e.g.*, according to PCT or EPO standards, will be accepted as satisfying all of the disclosure and characterization requirements of the proposed rules. The Office retains authority under §105 to obtain additional information as it believes necessary and appropriate to a given situation.

7. The Office should always accept IDSes citing newly published US patent applications of which the applicant timely becomes aware and which the applicant believes in good faith are relevant to the claims.

The proposed rules under § 1.97(b) through (d) establish four time periods for submission of an IDS. For the first and second time periods under proposed § 1.97(b) and (c), applicants are exempt from filing an explanation and, for the second phase, a non-cumulative description of documents cited in a foreign counterpart application if accompanied by the search/examination report and, for the second phase, a timeliness certification. This is presumably because the citation of such documents (which are likely to be relevant) is out of the control of the applicant. However, under proposed § 1.97(d)(1) and (d)(2), even documents cited in a foreign search/examination report must be accompanied by patentability justifications.

Not only should documents cited in a foreign search/examination report in a counterpart application be exempt from all four periods if meeting the requirements of §1.97(b) or (c), since the timing for citation of these presumably relevant documents is totally out of applicants' control, but also newly published US patent publications under certain conditions. Such US patent applications, published on an ongoing basis, can be highly relevant prior art and may even contain interfering subject matter. The conditions under which such US publications would be exempt from the rules could include that they must be cited within three months from their publication date, and that the applicant must believe in good faith that such publications are relevant to the claims of the application of interest. An IDS citing these documents that meets these criteria would be accepted by the Office as satisfying all of the disclosure and characterization requirements of the proposed rules. The Office retains authority under §105 to obtain additional information as necessary and appropriate.

8. Proposed § 1.98(a)(3)(i) should be revised to exempt the first 40 documents, as well as documents of less than 15 pages in length, from the requirements for additional disclosure.

The limits on the length and number of cited references that would not trigger the enhanced characterization requirements of proposed § 1.98(a)(3) are unreasonably stringent in the context of biotechnology patent prosecution.

The Office arrived at the limit of 20 documents by conducting a survey of allowed applications across all technology sectors, a "one-size-fits-all" approach that is not appropriate for every industry. The Office has long recognized, however, that the level of complexity varies from art to art, both in terms of technical features and the level of detail in patent applications. Biotechnology is a complex art. The Office has accounted for this fact, *inter alia*, by providing examiners in most biotechnology disciplines a substantially higher than average number of hours per balanced disposal to examine the applications assigned to them.

Far more than 20 references are cited in most biotechnology patent applications. Moreover, in our experience, examiners in the biotechnology group are fully capable of efficiently and effectively reviewing the larger numbers of references required for examination of applications in this art. We believe that 40 references would be a more appropriate number to exempt from the enhanced characterization requirements of § 1.98(a)(3). This number would be sufficient to exempt most biotechnology applications from the burdensome characterization requirements, but not so high that it would place disproportionate or unreasonable burdens on the Office personnel responsible for examining patent applications.

We also consider that 25 pages is an unreasonably low page limit for documents that will be exempt from enhanced characterization requirements. Most of the documents cited in biotechnology applications that exceed 25 pages in length are patent references. Even excluding sequence listings, biotechnology patents tend to be long. However, biotechnology examiners are experienced at identifying the portions of patent documents that do not concern background, general methodology, and so forth. Thus, the "effective length" of a patent reference is much less than its total number of pages. We suggest that 100 pages (not including sequence listings) would be a more appropriate limit, at least for U.S. and foreign patent documents, to incorporate into proposed § 1.98(a)(3)(i)(B).

As to the interaction between the lengths and numbers of cited documents, we note that by far the majority of references that are cited in most biotechnology patent applications are articles from research journals. Typically, such articles are less than 10 pages in length, and they include abstracts that summarize their technical disclosures. Thus, it is generally not difficult for biotechnology examiners to review efficiently a relatively large number of references for relevance. Research articles that warrant more thorough review are generally short enough that the appropriate review does not place an undue burden on the Office's resources. In light of these considerations, we believe the suggested limits of 40 references and 100 pages are reasonable in the context of biotechnology prosecution, and that documents of less than 15 pages always be exempt from the characterization requirements of § 1.98(a)(3).

9. All documents submitted to the Office during the prosecution of a patent should appear on the face of the patent document that issues.

The Office indicates that applicants may provide and discuss any evidence they consider appropriate as part of a response to an Office action. 71 Fed. Reg. at 38813-14. However, only documents cited in Information Disclosure Statements complying with §§ 1.97 and 1.98 would be listed on the face of an eventual patent. *Id.* This is in contrast to current practice, whereby applicants may, and most often do, formally cite all documents they place on the record.

The proposed departure from current practice will not serve the interests of patentees or the public. The listing of references of record on the face of the patent promotes the transparency of the examination record by providing clear notice and ready reference for the public of the documentary prior art considered by the Office. The effect of the proposed rules would be to obscure the actual examination record.

It is the case now that interested members of the public generally review the file history of a patent to evaluate the scope, validity, and enforceability of the patent claims. Such a review permits the reader to identify all of the evidence cited and discussed on the record. Even so, the listing of prior art on the face of the patent serves important and useful functions. The Office should specifically provide that any evidence cited and discussed by either the examiner or the applicant will be identified on the face of the patent.

10. The "first period" of proposed § 1.97(b) should extend to a reasonable time period following the mailing of a requirement for restriction.

Discoveries in biotechnology often translate into several aspects or embodiments linked by one or more common inventive concepts. Applicants, of course, draft applications that present claims to all of the linked aspects or embodiments. Under current U.S. practice, however, the Office often determines that such claims will support separate patents, and accordingly imposes a requirement for restriction. For example, examiners routinely require restriction between claims to novel proteins, recombinant systems and reagents for producing them, antibodies that bind to the proteins, and various methods of using these products. The prior art that is relevant for assessing the patentability of the restricted inventions may include different groups of references, depending on the particular subject matter of the claims.

In this regard, the timing requirements of proposed § 1.97(b) would impose unneeded inefficiencies on patent applicants. A reference concerning antibody technology, for example, may not be relevant for claims to DNA. Yet as proposed, § 1.97(b) would require the citation and (in all likelihood) the description of references that are relevant to every claim in the original application. The effort invested by applicants in the citation and characterization of references that are potentially relevant only for non-elected inventions would provide no benefit to the Office, and it would consumes the applicant's resources.

A more appropriate model for arts where restriction requirements are routine, including biotechnology, would extend the "first period" for filing Information Disclosure Statements to a reasonable period following a restriction requirement. We suggest that an appropriate deadline would be the date of a written response to a restriction requirement. Under such a model,

applicants would limit their Disclosure Statements (and the effort and expense associated with preparing such statements) to the references that are relevant to examining the elected invention. Similarly, the examiner would only be required to take the time to consider the cited relevant references.

For applications in which the Office determines that no requirement for restriction will be imposed, the Office could advise applicants of that determination by mail or telephone. Applicants would then be given a reasonable period, *e.g.*, three months, in which to file an Information Disclosure Statement covering all of the claims in the application. For divisional applications filed in response to a requirement for restriction in a parent application, it would be reasonable to require that applicants file a Disclosure Statement within three months of filing.

11. The Office should provide mechanisms for applicants to cite collections of references that are common to several related patent applications and for preliminary discussions of relevant references with patent examiners.

We continue to believe strongly that patents are examined most efficiently – and that patentability determinations are, as a rule, most often correct – if a full complement of relevant art is made available to the examiner. To that end, we provide the following suggestions to facilitate access to relevant evidence and to facilitate the efficient consideration of such evidence.

First, it is often the case in biotechnology that several applications will relate to a common body of prior art. Frequently, such applications are related as original and continuing applications, but just as often, applications that are not formally related nevertheless concern the same underlying technology. Where a substantial number of "core" references form the basis for understanding the art to which inventions in several applications pertain, it is wasteful of both applicants' resources and the Office's resources to provide duplicate copies of the "core" references in each of the applications. We propose that the Office should provide for the creation of applicant-generated electronic "digests" of references. Such digests, in analogy to the paper-copy digests once maintained by examiners in the shoes, would constitute collections of information that could be collectively cited or referred to by applicants without the need for re-submitting copies of the references. The existence of such digests would also provide a tool for the Office to cross-reference the prosecution of related applications before different examiners.

Second, we suggest that the Office should encourage preliminary interviews – before a first action – to discuss references cited in initial Information Disclosure Statement(s). Such interviews, conducted before any rejections have been placed on the record, would facilitate an open discussion that would allow applicants to orient examiners in the body of art and direct them to the more relevant references.

We encourage the Office to consider these options as alternatives or adjuncts to the approach reflected in the proposed rule package, as each will increase the flow of information between applicants and examiners.

12. The time limits for filing an IDS after receiving a foreign search report under §§ 1.97(e)(1) and 1.704(d) should be conformed.

Proposed § 1.97(e) retains the current provision that an IDS citing references first provided in a foreign patent office communication must be submitted within three months of the date the references were *cited* in the foreign communication. Section 1.704(d) continues to provide that submission of an IDS citing such references will not lead to a loss of patent term adjustment (PTA) if it is filed within thirty days of the date the communication was *received* by the applicant. The different timing requirements are a source of unnecessary confusion.

The Office should amend § 1.704(d) to conform to the timing requirement of § 1.97(e). The three-month period of § 1.97(e) is more appropriate than the thirty-day period of § 1.704(d) because of the variable delays associated with the translation and reporting of communications by local counsel. A deadline that runs three months from the date of a foreign patent office document is transparent, easily calculated, and uniformly sufficient to cover mailing and translation delays.

There is no benefit to the Office or the public in having two timing requirements for submitting the same document. The early submission of relevant information to the Office will be facilitated by conforming § 1.704(d) to § 1.97(e).

13. The time periods of proposed § 1.97 should not be applied to reexamination proceedings.

The proposed amendments to §§ 1.97 and 1.555 would extend the timing and content requirements developed for the prosecution of original applications to reexamination proceedings. The proposed rules take no account of the vastly different nature of both the proceedings and the way information is used in them, leading to requirements that would be burdensome and counterproductive in the context of reexamination.

We note in particular that it is unreasonable to set the "first period" for filing an information disclosure statement as the three months after the filing date of a reexamination proceeding. This interval corresponds identically to the period under 35 U.S.C. § 303 during which the Office is required to complete its evaluation of a request for reexamination and issue a decision on the request. It makes no sense to burden patentees with a requirement to prepare comprehensive information disclosure statements to support a reexamination before the Office even decides whether a reexamination will be initiated.

We suggest that the question of procedures for citing references in reexaminations be deferred to a separate rulemaking, should the Office consider new or additional procedures to be desirable.

Conclusion

Genentech appreciates the opportunity to comment on the proposed rules. We would be pleased to discuss any of our suggestions further with the Office.

Sincerely,

GENENTECH, INC.

/s/

Janet E. Hasak
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