The Honorable Susan E. Dudley
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
Washington, DC 20503

October 17, 2007

RE: RIN 0651-AB95

Changes to Information Disclosure Statement Requirements and Other Related Matters, 71 Fed. Reg. 38808 (Jul 10, 2006) ("Proposed IDS Rule")

Dear Ms. Dudley,

We are writing to express our concerns about the draft final regulation, "Changes to Information Disclosure Statement Requirements and Other Related Matters," submitted by the U.S. Patent and Trademark Office (USPTO) to OMB for review under Executive Order 12,866 (as amended). This draft rule was submitted on July 27, 2007.

Previously, we and others raised concerns to you about USPTO's disregard for basic Executive branch procedures with respect to two other draft final rules submitted for review.[1] In its notices of proposed rulemaking for those draft rules, USPTO failed to adhere to the regulatory philosophy and principles of Executive Order 12,866; violated the Information Quality Act and OMB's implementing guidelines thereof with regard to the limited supporting information it disclosed; and claimed *savings* in paperwork burden when in fact its actions significantly increased those burdens. We noted that these rules were obviously a package despite USPTO's efforts to disaggregate them to keep each below the threshold for economically significant rulemaking, and we asked you to exercise your authority to and return them for further consideration, designate the package as economically significant (because there was no question that they imposed private sector costs exceeding $100 million in any one year), and direct USPTO to perform a proper Regulatory Impact Analysis.

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[1] See the letter from David Boundy (Cantor Fitzgerald) and 24 others dated June 15, 2007 concerning RIN: 0651-AB93 [Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims ("Continuations Rule") and RIN 0651-AB94 ["Changes to Practice for the Examination of Claims in Patent Applications ("Limits on Claims Rule")], http://www.whitehouse.gov/omb/oira/0651/meetings/619-1.pdf, and related attachments.

The final rules, which were published in a single combined rulemaking action on August 21, 2007,[2] fully confirm our concerns. If they stand up under legal challenge, their practical effect will be to dramatically increase the cost of obtaining patent protection, make it much more difficult for inventors and innovators to protect their legitimate intellectual property rights, and "adversely affect in a material way the economy, a sector of the economy, productivity, [and] competition" (EO 12,866 Section 3(f)(1).

In the proposed IDS Rule, USPTO has again misrepresented to OMB the breadth and depth of the effects likely to result. The proposed IDS Rule is clearly "economically significant." If finalized, it will impose billions of dollars of burden on patent applicants and owners. The preamble asserts that the rule will generate savings to USPTO, but these savings are neither quantified nor reflected in USPTO's FY 2008 budget submission. In support of these radical changes, USPTO has disclosed no supporting evidence or analysis in the NPRM or the rulemaking docket.

The proposed IDS Rule has another fatal defect: it is fundamentally inconsistent with case law governing the conduct of patent applicants and their agents under federal patent law. The courts require applicants and agents to fully disclose all potentially relevant information to USPTO, and they will take away the property rights of patentees who fail to do so. Through the IDS Rule, USPTO is demanding that patent applicants break the law just to ease USPTO's workload.[3] It is worth remembering that patent applicants pay fees to USPTO that fully cover the cost of patent examination, and USPTO has specific authority to charge fees specific to the service at issue in this Rule, and currently does so.[4] USPTO now wants to refuse to consider the prior art and eliminate the fee.

I. WHAT WOULD THE IDS RULE DO?

We begin by reviewing the doctrine of "inequitable conduct" and current practice for complying with this law, and then discuss the implications of the USPTO's proposal to destroy applicants' ability to comply.

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[2] USPTO, "Changes To Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications," 72 Fed. Reg. 46765-46814 (RIN 0651-AB93 and RIN 0651-AB94 combined).

[3] *See* USPTO, "Changes To Information Disclosure Statement Requirements and Other Related Matters," 71 Fed. Reg. 38808-38823 ("The proposed changes will enable the examiner to focus on the relevant portions of submitted information at the very beginning of the examination process, give higher quality first actions, and minimize wasted steps," at 38808; "The proposed changes provide an incentive to the applicant to cite only the most relevant documents, and are designed to provide the examiner with useful and relevant information early in the examination process," at 38810).

[4] 35 U.S.C. § 41(d)(2); 37 C.F.R. § 1.97(c)(2), (d)(2), and § 1.17(p).

I.A. What is the Law of "Inequitable Conduct?"

The law of inequitable conduct arises under long-standing Supreme Court precedent, which USPTO lacks authority to change.[5] A patent applicant (*i.e.*, any inventor, attorney, or other person substantively involved with the patent application) has a "duty of candor and good faith" to fully reveal to USPTO all information that may be "material to patentability." What constitutes "material" is always judged after the fact.

There are two general kinds of "inequitable conduct": (a) failure to disclose material information to USPTO, and (b) making misleading statements to USPTO. Both result in the "death penalty" of unenforceability for all claims of any affected patent and, in some cases, all related patents. "There is no reprieve from the duty of square dealing and full disclosure that rests on the patent practitioner in dealings with USPTO."[6]

While this duty might seem extreme, it is a well-recognized element of patent practice that everyone understands and knows how to follow. The courts and (until the IDS rulemaking) USPTO have each made clear that it is better to give the Office everything that might be argued to be relevant by future infringer's counsel, than to neglect to report potentially material information.[7] The law is extreme in part because the costs of full disclosure are quite low, while the costs to the public of wrongfully issued patents are very high. Furthermore, full disclosure enables competitors to cost-effectively ensure that they do not infringe, by using information in the patent's file history as a template to design around the patent.

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[5] *E.g.*, *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240, 245-46 (1933).

[6] *Kangaroos U.S.A. Inc. v. Caldor Inc.*, 778 F.2d 1571, 1576, 228 USPQ 32, 35 (Fed. Cir. 1985).

[7] "Close cases should be resolved by disclosure, not unilaterally by applicant." *LaBounty Mfg., Inc. v. U.S. Int'l Trade Comm'n*, 958 F.2d 1066, 1076, 22 USPQ2d 1025, 1033 (Fed. Cir. 1992); "The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual … has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability…. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability … [is] submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98." 37 C.F.R. § 1.56 (to which no amendment is proposed, emphasis supplied); *see also* Notice of Final Rulemaking, Duty of Disclosure, 57 Fed. Reg. 2021, *passim* (Jan. 17, 1992), repeatedly stressing the importance of disclosing "all" material information; "The Office believes that most applicants will wish to submit the information, however, even though they may not be required to do so, to strengthen the patent and avoid the risks of an incorrect judgment on their part on materiality or that it may be held that there was an intent to deceive the Office." 57 Fed. Reg. at 2023, reply to Comment 3.

I.B. Under Current Practice, How Do Applicants Comply with the Law of Inequitable Conduct?

Patent applicants strive to submit to USPTO all "prior art"[8] documents that an examiner might possibly find useful, or more importantly, what a court might subsequently decide, with 20/20 hindsight, that the patent owner *should have* submitted.

About three-fourths of patent applications are "routine" and relatively low-value at the time they are filed. None of the factors discussed below come into play, fewer than 20 prior art references come to the knowledge of the inventors or attorneys, and the proposed IDS Rule would not be triggered.

1. Full disclosure

However, when an applicant seeks a high-value patent on an important invention, things change. Prior art is collected so that the invention can be more accurately assessed for patentability, and the attorney can determine precisely how to describe the invention so that the value of the patent application will be maximized. This prior art comes from several sources:

- The applicant will often obtain a prior art search of patent documents and relevant technical literature.
  - A prior art search typically turns up between 10 and 30 documents, sometimes many more.
- Pursuant to the legal duty of candor and good faith, the attorney requests all documents that the inventor possesses, and stresses the importance of *complete* disclosure. This can result in anything from a small handful to dozens of documents.
  - In the normal course of business, this information comes to the inventor's attention over time. Through the proposed IDS Rule, USPTO ignores these real-world conditions and demands that inventors know virtually everything they will ever know before they apply for a patent.
- An applicant may file patent applications in foreign countries.
  - As each foreign examiner examines the application, that examiner will report prior art to the applicant, and that prior art must be forwarded to USPTO.[9]
- The inventor may file several applications on related facets of the invention, each of which could be assigned to a different examiner.

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[8] "Prior art" includes all information that has been made available to the public before a given date in a form that affects a patent's claim of novelty. "Prior art" is formally defined in 35 U.S.C. § 102.

[9] Of the various categories of prior art that arise, this is the only one for which USPTO proposes a workable accommodation.

- With very narrow exceptions, the prior art developed in each application must be given to all examiners of other, potentially quite numerous applications in the same family.[10]

Little of this information will be available to the applicant during the so-called "first time period" during which an IDS would have to be submitted.

Once an applicant has information collected from these disparate sources, federal patent law gives almost no flexibility: the information must be disclosed to USPTO. For the most valuable applications, it is not uncommon for an applicant to be required by law to give an examiner 100 or more prior art references.[11]

There is no question that this results in the submission of more information (and more information of marginal value) to the examiner, and this results in some inefficiency in the examination phase. But there also is no question that erring on behalf of over-disclosure has substantial, and possibly greater, efficiencies for the patent system as a whole, particularly for competitors, which we discuss in § II.C of this letter.

2. Avoid misleading statements

On the flip side, to avoid the "misstatement" prong of inequitable conduct, patent attorneys strive to keep their letters to USPTO as short and focused as possible, to minimize the risk of saying anything that could be construed as "misleading." USPTO has expressly recognized this concern. Prior to 1992, USPTO rules required applicants to provide discussions of prior art references that were of much lower burden and posed far lower legal risk than the proposed IDS Rule. In a 1992 regulation, USPTO abandoned a weaker version of the proposed IDS Rule because, based on actual experience, it found that the rule was inefficient to the patent system considered as a whole.[12]

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[10] *PerSeptive Biosystems Inc. v. Pharmacia Biotech Inc.*, 225 F.3d 1315, 1321-22, 1331, 56 USPQ2d 1001, 1005-06, 1013 (Fed. Cir. 2000) (finding a daughter patent unenforceable, even though the information had been disclosed in the parent and the examiner found on the record that the information raised no issue of patentability); *Elk Corp. of Dallas v. GAF Building Materials Corp.*, 168 F.3d 28, 31, 49 USPQ2d 1853, 1856 (Fed. Cir. 1999) (rendering a patent unenforceable when prior art developed in a daughter application was not disclosed to the examiner of the parent application).

[11] David Boundy, the signatory of this letter, prosecuted one family of applications where these types of interactions among applications led to over 300 references being cited in each of 25 applications. Under current law, there really is no shortcut available at an acceptable level of malpractice or unenforceability risk.

[12] "[W]e became convinced that the potential harm that might be experienced by patentees during litigation due to inadvertent errors in such explanations outweighed the benefit to the PTO." Commissioner Harry F. Manbeck, Jr., *The Evolution and Issue of New Rule 56*, 20 AIPLA Q.J. 136, 143 n.17 (1992). Commissioner Manbeck, who led this reform, had decades of experience as a patent attorney on which to base this judgment.

I.C. The Proposed IDS Rule

The proposed IDS Rule turns this long-standing policy on its head. In cases where an applicant is aware of more than 20 prior art references, it would direct applicants to do one of the following:

- Deliberately withhold information from USPTO because the Rule forces applicants to submit only the "most" material information[13]; or
- Submit a "patentability justification document" describing each prior art reference in detail.

Choosing the first option unambiguously violates the failure-to-disclose prong of the law of inequitable conduct, and raises a very high risk of losing the property right conveyed by the patent if he dares to try to enforce these rights against infringers. Call this the Infringers' Free Ride Option.

Choosing the second option creates a high risk of violating the misrepresentation prong of the law of inequitable conduct.[14] Counsel to a future infringer can (and will) pore over the patentability justification document in search of any misstatement of fact. The more statements of fact the applicant must make about prior art, the greater is the likelihood that infringer's counsel will find an error. Call this the Infringer's Bounty Hunter Option.

The second option is also immensely burdensome even if future infringers' counsel never find errors. Each patentability justification document would cost tens of thousands of dollars to research and prepare. Furthermore, there no way to indemnify the patent owner against the value of lost patents if a future court declines to accept the quality of the work. The accompanying letter of Philip Steiner, a patent attorney with experience in preparing analogous documents, estimates the aggregate cost of preparing minimum-case documents at $1.9 billion per year (Attachment A). Inexplicably, USPTO says that being deluged with patentability justification documents will make its job easier.

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[13] "The proposed changes provide an incentive to the applicant to cite only the most relevant documents…" (71 Fed. Reg. at 38810, col. 3).

[14] A patent was rendered unenforceable because of a mischaracterization of the prior art in a similar fashion in *C.R. Bard Inc. v. Advanced Cardiovascular Systems, Inc.*, 28 USPQ2d 1852, 1856 (Fed. Cir. 1993) (unpublished).

II. The Proposed IDS Rule Violates the Principles of Executive Order 12,866

II.A. USPTO's Proposed Refusal to Consider Prior Art Conflicts With Its Statutory Duty under Federal Patent Law

Under the proposed rule, USPTO says prior art submitted that is unaccompanied by a patentability justification document will not be considered.[15] But USPTO lacks the statutory authority to choose not to review information it receives. USPTO's *primary statutory duty* is to evaluate information to determine patentability.[16] Indeed, USPTO has represented to courts that this substantive duty is so paramount that it is obligated to revoke allowances of applications up to the day of issuance if necessary to reconsider patentability. Courts have reluctantly confirmed USPTO's obligation to fully examine, even if the Office must resort to unspecified "suspicious procedures" to carry it out.[17]

USPTO now says it no longer wants to fulfill its primary statutory duty.

II.B. The Proposed Rule Offers No Effective Remedy to the Conflict It Would Create with Existing Law

In Section I.A we showed that the proposed IDS Rule conflicts with the law of inequitable conduct. USPTO is fully aware of this conflict, and so the proposed rule contains language purporting to create a "safe harbor." To gain shelter there, applicants must take "reasonable steps, "in good faith and to the best of [their] knowledge, information and belief, formed after a reasonable inquiry under the circumstances" "to comply with [these] additional disclosure requirements."[18]

As safe harbors go, this one has submerged hazards throughout. USPTO does not provide a clue as to what constitutes "reasonable," "good faith," or "best" knowledge. While it could have provided clear statements on this point, it did not do so. USPTO could have offered to provide patentees a certification that it was completely satisfied that the applicant had secured mooring in the safe harbor. It did not do that, either. In short, USPTO left patentees at the mercy of future infringers' counsel.

USPTO's offer of mercy on behalf of adversaries is welcome, but implausible and beyond the reach of regulations USPTO might issue. In the preamble USPTO expresses only wan hope that the courts might give deference to its proposed safe harbor:

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[15] 71 Fed. Reg. 38813-14.

[16] *Blacklight Power Inc. v. Dickinson*, 109 F.Supp.2d 44, 48, 55 USPQ2d 1812, 1815 (D.D.C. 2000), *aff'd Blacklight Power Inc. v. Godici*, 295 F.3d 1269, 1273, 63 USPQ2d 1534, 1537 (Fed. Cir. 2002).

[17] *Blacklight v. Dickinson*, 109 F.Supp.2d at 54 n.10, 55 USPQ2d at 1820 n.10.

[18] Proposed IDS Rule at 38811.

> While the proposed amendment … may not act as a complete defense in all situations, particularly as the court is not bound by any one duty of disclosure standard established by the Office, *the Office is hopeful that a court in deciding a duty of disclosure issue will take the proposed safe harbor into account*.[19]

But it is unlikely that the courts will give deference to USPTO's proposed safe harbor. First, the proposed language is ambiguous, unstructured, and fundamentally uninterpretable. Second, statements of "good faith" have repeatedly been held insufficient to protect a patent, if the court considers the error sufficiently egregious.[20] Third, the courts have struck down previous USPTO efforts to enact safe harbors by regulation.[21] One celebrated case,[22] decided only four months before this proposed rule was published for notice and comment, expressly rebuffed USPTO's attempt to narrow the scope of "material" prior art that must be disclosed. While this case has been the subject of widespread commentary in the patent profession, USPTO did not even discuss it in the preamble, nor did it explain why this latest "safe harbor" would survive challenge when its previous efforts had not.

For these reasons, all responsible patent lawyers will be exceedingly wary submitting a patentability justification documents. Some may advise applicants to keep their applications below the threshold that triggers the requirement. Billions of dollars worth of intellectual property would go unprotected, resulting in an immeasurable decline in research and development expenditures.[23] In any case where attorneys agree to file a

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[19] Proposed IDS Rule at 38811-38812, emphasis added.

[20] *Agfa Corp. v. Creo Products Inc.*, 451 F.3d 1366, 1378, 79 USPQ2d 1385, 1394 (Fed. Cir. 2006) (court rejects patent agents' assertions of good faith belief in non-materiality of references); *LaBounty Mfg., Inc. v. U.S. Int'l Trade Comm'n*, 958 F.2d 1066, 1076, 22 USPQ2d 1025, 1033 (Fed. Cir. 1992) (rejecting inventor's and attorney's testimony of lack of intent when they decided not to submit a marginal reference).

[21] *See Digital Control Inc. v. Charles Machine Works*, 437 F.3d 1309, 1316, 77 USPQ2d 1823, 1829 (Fed. Cir. 2006) (declining to accept PTO's narrowed definition of "material" prior art); *Dayco Products Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1365, 66 USPQ2d 1801, 1806 (Fed. Cir. 2003) (refusing to recognize a "safe harbor" stated in the agency's guidance document, MPEP 2001.06(b)); *PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315, 1322, 56 USPQ2d 1001, 1006 (Fed. Cir. 2000) (declining to honor a "safe harbor" for cancelled claims articulated in 37 C.F.R. § 1.56).

[22] *Digital Control Inc. v. Charles Machine Works*, 437 F.3d 1309, 1316, 77 USPQ2d 1823, 1829 (Fed. Cir. 2006).

[23] There is one other plausible market response to the proposed IDS Rule: innovators and inventors may abandon the U.S. patent system. For inventions, the best alternative is trade secret, which only works for inventions that cannot be readily reverse engineered, such as methods of manufacturing. Trade secrets can be protected only by purposefully restricting public knowledge of inventions, and thus sacrificing the value of the positive externality which disclosure provides. It is the height of folly to destroy the U.S. patent system just to secure a minor reduction in USPTO workload.

patentability justification document, they will take extraordinary precautions to avoid triggering the law of inequitable conduct, which means each such document will be very expensive to prepare.

Even if it could be imagined that USPTO's proposed "safe harbor" protected against misstatement allegations, nothing in the proposed Rule offers protection against allegations that applicants intentionally withheld information from USPTO, which appears to be USPTO's preferred response from applicants.[24]

There is a simple reason for the disconnect between this draft rule and substantive patent law. USPTO has no authority in areas of substantive law, and does not participate in patent litigation or licensing. Thus, it has no experience in the area of inequitable conduct (which applies only after a patent issues) and has developed no agency expertise in any area that would enable it to understand the consequences of its proposed regulation. The entire rule package is based on an illusory *quid pro quo*, in which USPTO has neither authority nor means to deliver on its half of the bargain.

II.C. The Proposed Rule Would Destroy Public Goods that Existing Practices Produce

The patent system offers a tradeoff between exclusivity (which is needed to motivate innovation) and use (which is needed to maximize value). A patent grants time-limited exclusivity in return for the public good of disclosure.[25] The proposed IDS rule would destroy this public good.

When a competitor seeks to avoid infringing a valid patent, the first strategy is to look at the prior art in the prosecution file and use that prior art as a template to design non-infringing alternatives. That is, current law and practice generate huge social benefits from the public assembly and disclosure of private information. This significantly reduces investments in redundant R&D, and the burdens competitors face complying with the patent rights of others.

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[24] Historically, when an applicant learned of new relevant prior art from a related application or foreign counterpart application, the usual course was to file a continuation application to open the opportunity to meet the duty of candor. However, in its August 21, 2007 Notice of Final Rulemaking on the Continuations Rule, USPTO essentially closed this door, too. USPTO has clearly said that it will not grant such petitions to enable applicants to disclose newly-discovered prior art, thereby putting all applicants in the untenable position of risking the ultimate loss of their patent rights because the USPTO simply refuses applicants all opportunity to comply with the court-mandated duty of candor. See 72 Fed. Reg. at 46773, col. 3 ("The Office will likely not grant such a petition for submitting an information disclosure statement (IDS) or an amendment necessitated by (or in view of) newly discovered prior art.").

[25] W. Kip Viscusi, John M. Vernon, and Joseph E. Harrington, Jr. 1997. *Economics of Regulation and Antitrust (2d ed)* at 831-833.

The proposed IDS Rule will curtail public disclosure, so the production of public goods will be reduced. For every innovation, invention and disclosure that the rule prevents, these public goods will simply vanish.

As USPTO itself stated last time it revised these rules, "The public interest is best served, and the most effective examination occurs when, at the time the application is being examined, the Office is aware of and evaluates all information material to patentability."[26] The rationale was stated in 1992, somewhat euphemistically: "The rules as adopted strike a balance between the need of the Office to obtain and consider all known relevant information pertaining to patentability before a patent is granted and the desire to avoid or minimize unnecessary complications in the enforcement of patents."[27] In 1992, USPTO itself recognized that inequitable conduct allegations were the primary "unnecessary complication."[28]

II.D. The Costs of the IDS Rules Will Fall Selectively and Discriminatorily on Innovation, Small Entities and the Most Valuable Patent Applications

Under Executive Order 12,866, agencies are supposed to tailor their regulations to impose the least burden and "consider incentives for innovation," taking particular account of small entities. The proposed IDS Rule is tailored in an unusual way – to impose the *greatest* burden on innovators and small entities.

The most innovative applications tend to have the most prior art references[29], so they are disproportionately affected by the proposed Rule. When an R&D-intensive entity invests in a patent, the entity hopes to build a business around that invention, and therefore fully vets it. This vetting includes a thorough search of the prior art, and disclosure to USPTO. The IDS Rule directly penalizes this socially-useful activity.

Small entities are also disproportionately affected. With few exceptions, small entities cannot afford to litigate their patents. Small entities and invent-to-license businesses want to ensure that patentability is thoroughly vetted during proceedings before USPTO, This enables them to offer strong patent protection to their licensees. The proposed rule would penalize these businesses by creating doubt about license value.

Biotechnology and life-sciences industries are disproportionately affected. USPTO only presented statistics averaged over all industries, and did no breakdown by

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[26] 37 C.F.R. § 1.56, emphasis added, as amended by Notice of final rulemaking, Duty of Disclosure, 57 Fed.Reg. 2021 (Jan. 17, 1992). The Notice states the importance to USPTO of the examiner having "all material information" or the like at least 10 times.

[27] Notice of Final Rulemaking, Duty of Disclosure, 57 Fed. Reg. at 2021 (Jan. 17, 1992).

[28] See footnote 12.

[29] John Allison, Mark Lemley, Kimberly Moore, and Robert Trunkey, *Valuable Patents*, 92 Georgetown L.R. 435, 453-55 (2004); Kimberley Moore, *Worthless Patents*, 20 Berkeley Tech. L.J. 1521, 1532 (2005).

technological art sector, even USPTO as ready access to such statistics. Attachment C is a statistical analysis of patents issued to the top ten biotechnological companies for 2005. USPTO asserted that "a threshold of twenty documents" supports USPTO's [expectation] that more than 85% of IDSs … would not require any explanation." However, in 2005 in the biotechnology arts, the "20 document" threshold ensnare 73% of biotech patents, and the "25 page" threshold would ensnare 94% of biotech patents. Because of the disparate impact on a single, highly-innovative industry, the proposed IDS rule should not be adopted without a careful regulatory impact analysis.

In its proposal, USPTO claimed that the rule is exempt from the Administrative Procedure Act and, by inference, the Regulatory Flexibility Act.[30] It is our view that the proposed IDS Rule is clearly a substantive rule of general applicability and effect. Ultimately, the courts will have to decide whether the Patent Office even has the authority to promulgate it. Irrespective of that legal outcome, however, there should be no question that the proposal, if finalized, represents a huge imposition on small entities and innovators.

II.E. The Proposed Rule Contained No Supporting Data or Analysis

According to the NPRM:

> [T]he Office has determined that for IDSs submitted prior to a first Office action on the merits, a threshold of twenty documents best balances the interests of the Office and of the applicants.[31]

No analysis is provided to justify this determination. USPTO says threshold does not affect 85% of applications and asserts that the burdens it imposes on the other 15% are reasonable. USPTO has waved its hands; thus it must be so.

We doubt that only 15% of applicants would be affected, but we cannot test USPTO's claim because it has failed to disclose enough information to determine whether the estimate is unbiased. Even if USPTO is right, however, that means about 70,000 applications each year would be covered. The proposed IDS Rule would have impacts exceeding the $100 million threshold for an economically significant regulation if the average burden was just $100 million / 70,000 applications = $1,429 each. This is a fraction of the Rule's *minimum* cost of preparing a single patentability justification document, which has been independently estimated by a practicing patent attorney at $27,000 (Attachment A). It does not cover the costs of determining which alternative of the rule to choose (forced withholding of material information, or the patentability justification document), the cost of preparing the document, or ensuring its accuracy. If USPTO has a competing cost estimate, it has kept it under wraps.

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[30] 71 Fed. Reg. 38818-38819.

[31] 71 Fed. Reg. 38810, col. 1.

III. AN OPTIMAL REGULATION MINIMIZES ERROR

III.A. Type I and Type II Errors in Patent Application

Putting the problem in analytic terms, patent applicants are faced with the task of minimizing the sum of losses associated with two types of error. Type I error (often termed a "false positive") consists in this case of over-reporting potentially relevant information to USPTO. Type II error (often called a "false negative") consists of being judged after the fact to have under-reported. For patent applicants, the cost of Type I errors is small but the cost of Type II errors can be devastating. So, patent applicants do everything possible to avoid *any* Type II error in application, and that necessarily means committing *a lot* of Type I errors.

Type I errors in patent application may be minimally costly to applicants, but they are burdensome to USPTO. Examiners must sift through all the information provided to discern the most important data. Sometimes, applicants can help them manage this burden by informally pointing out the highlights. This is both a professional courtesy and a helpful way to expedite patent examination. As long as communications between applicant and examiner are unfettered, we think the process works reasonably well to balance applicants' duty to fully disclose and examiners' need to use their limited time cost-effectively. Whatever the burden of Type I error, however, it is applicants who actually bear its incidence. Applicants pay fees to USPTO that, by law, were set to fully cover "the average cost of processing" the prior art references that are subject to the proposed IDS Rule.[32]

The proposed IDS Rule would upset this delicate balance, all for the stated purpose of improving USPTO's internal efficiency. But USPTO merely asserts that this is true and provides no supporting evidence:

> One goal of the changes proposed in this notice is to enable an examiner to identify the most relevant prior art in an efficient and expeditious manner, even when an IDS containing a large number of documents is submitted. The changes proposed in this notice accomplish this by requiring in certain circumstances additional disclosure about documents cited in an IDS.[33]

Potential workload savings consist only of the difference in examination time. If the proposed IDS Rule reduced examination time by 10% for the 15% of applications USPTO says would be affected – a generous estimate of the average cost of considering IDS documents affected by the Rule – the potential reduction in total workload is only 1.5% (10% x 15%).

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[32] 35 U.S.C. § 41(d)(2); 65 Fed. Reg. 54604, 54630 col. 3 (Sept. 8, 2000); 37 C.F.R. § 1.97(c)(2), (d)(2), and § 1.17(p).

[33] The preamble (71 Fed. Reg. at 38809).mentions the goal of reducing Type I errors in application not as a virtue in its own right, but only insofar as it helps USPTO reduce Type I errors *in examination*. We discuss errors in examination in the following subsection.

III.B. Type I and Type II Errors in Patent Examination

Patent examination has its own species of Type I and Type II errors. Type I error (false positive) consists of issuing legally invalid patents. Type II error (false negative) consists of rejecting applications for legally valid patents.

USPTO says the IDS Rule will improve the quality of patents that USPTO issues.[34] This definition of "quality" necessarily takes account only of Type I errors in examination. The asymmetry reflects USPTO's bureaucratic incentives. USPTO is *sometimes* held accountable for Type I error, but *never* held accountable for Type II error. Under current practice, the social cost of Type II errors in examination probably exceeds the social cost of Type I errors for the simple reason that USPTO ignores Type II errors.

The proposed IDS Rule would make this bad situation worse. If successful, the rule would reduce Type I error in examination slightly and increase Type II error by an unknown (but potentially massive) amount. USPTO's strategy for reducing Type I error in examination involves penalizing Type I errors in application (applicants submitting "too much" information) at any cost in increased Type II errors in application (applicants submitting "too little" information). These additional Type II errors in application result in valid patents being subsequently destroyed through inequitable conduct allegations. That increases Type II error in examination, but USPTO has no bureaucratic reason to care about that.

III.C. Socially Optimal Error Minimization

Executive Order 12,866 directs agencies to maximize net social benefits. An approximation of that objective is to minimize errors in the patent system. Because "information, like other goods, is costly to produce and disseminate, the absence of perfect information is not per se evidence of market failure."[35] That is, there will always be both Type I and Type II errors in both patent application and patent examination. The policy challenge is how to minimize error, taking into account that different types of error have different social costs.

In the model below we show how Type I and Type II errors are defined for both applicants and examiners, and what would be required to minimize error. In our model we assume only that patent applicants and the USPTO each seek to minimize the value of

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[34] "The United States Patent and Trademark Office (Office) is proposing changes to information disclosure statement (IDS) requirements and other related matters to improve the quality and efficiency of the examination process" (71 Fed. Reg. 38808, col. 2, emphasis added); "The proposed changes will enable the examiner to focus on the relevant portions of submitted information at the very beginning of the examination process, give higher quality first actions, and minimize wasted steps" (71 Fed. Reg. 38819, col. 1, emphasis added).

[35] OMB, *Circular A-4: Regulatory Analysis* at 5.

Type I and Type II errors within their own domains, but each places very different weights on error.[36]

Patent applicants ("PA") care almost entirely about minimizing the sum of losses from Type II errors in application ($\sum PA_\beta$) but not the summed value of Type I errors ($\sum PA_\alpha$), because the former are very costly and the latter are not. The result is that applicants are, for all practical purposes, minimizing the sum of their Type II errors:

$$\text{Min } (\sum PA_\alpha + \sum PA_\beta) \approx \min \sum PA_\beta.$$

USPTO's incentives are opposite. To the extent that USPTO cares at all about error, it is the summed value of Type I errors in examination ($\sum USPTO_\alpha$) but not the summed value of Type II errors ($\sum USPTO_\beta$). Type I error has some cost to USPTO but Type II error never does. So at best USPTO has an incentive to minimize Type I errors in examination:

$$\text{Min } (\sum USPTO_\alpha + \sum USPTO_\beta) \approx \sum USPTO_\alpha.$$

Neither objective function mimics the social optimum, which is minimizing the summed value of *all* error:

$$\text{Min } (\sum PA_\alpha + \sum PA_\beta + \sum USPTO_\alpha + \sum USPTO_\beta).$$

What the proposed IDS Rule proposes to do is clearly not an improvement toward optimality. For a small (and speculative) reduction in the value of Type I errors in examination ($\sum USPTO_\alpha$), USPTO would tolerate any increase in Type II errors in application ($\sum PA_\beta$) and examination ($\sum USPTO_\beta$). To be a net improvement, the benefits from reduced Type I errors must exceed the increase in Type II errors, net of the cost to applicants of submitting patentability justification documents:

$$|\Delta \sum USPTO_\alpha| > |\Delta \sum PA_\beta| + |\Delta \sum USPTO_\beta| + \$1.9 \text{ billion.}[37]$$

Therefore:

$$|\Delta \sum USPTO_\alpha| - |\Delta \sum PA_\beta| - |\Delta \sum USPTO_\beta| > \$1.9 \text{ billion.}$$

USPTO has disclosed no evidence at all concerning the magnitude of internal efficiency gains it expects. However, these gains would have to exceed the Office's $1.7 billion total budget.[38]

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[36] Our model is simplified two ways. First, we have assumed that the value of error is proportional to their number. This assumption is surely not correct. All Type II errors in application do not lead to allegations of inequitable conduct. Second, we have assumed that USPTO, like a patent applicant, cares about the value of errors and not just their number. This assumption also is evidently false because USPTO's measure of quality concerns the number of invalid patents granted and not their value. These assumptions could be avoided with a more sophisticated model, but the added complexity is not necessary to illustrate the point and it would make the proposed IDS Rule even more inefficient.

[37] The *minimum* cost estimate from Mr. Steiner's letter, see page 6 of this letter, and Attachment A.

IV. RELIEF SOUGHT: RETURN FOR CONSIDERATION OF REGULATORY ALTERNATIVES

IV.A. Better Alignment of Fees and Examination Resources to Demand and Outcomes

By law, USPTO is obligated to make a bona fide effort to measure the costs associated with certain services provided by USPTO, including consideration of prior art references submitted to it, and set its fee levels accordingly: "The Director shall establish fees for all other processing, services, or materials relating to patents ... to recover the average cost to the Office of such processing, services or materials..."[39] USPTO's rulemaking authority is bounded by "cost effectiveness."[40]

USPTO appears to be collecting total fees that cover total cost, but it has not rationalized these fees at the margin. USPTO should align its fees so that applications that take more (or more specialized) examination time are charged proportionally higher fees. Ironically, in this rule, USPTO proposes to *eliminate* fees for the processing and services that USPTO states to be most burdensome for it to perform.[41]

In addition, USPTO should rationalize its internal workload assignment to take account of relative burden. Examiners should be allotted examination time that accords with the demands placed on them. For example, examination time could be made proportional to the fees paid by applicants (which are calibrated to complexity), including the fee paid for consideration of IDS references. Currently, examination time is set at a "flat rate" that disregards both application size and complexity. Examiners should have more time to examine complex applications. The examiner's union has been asking for this for some years (see Attachment B); it is unclear why USPTO management refuses to take an action that both applicants and the examination corps support.

Efficiency also requires tasks be assigned to the party that can perform them at least cost. Examiners are the lowest-cost provider of examination services, and the USPTO should not try to outsource this work onto higher-cost providers, especially when that outsourcing takes the form of creating new work and new burdens that do not exist today.

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[38] In the President's FY 2008 budget, USPTO requested $1,701,402,000 and expected to collect fees of $1,701,402,000. See Fiscal Year 2008 President's Budget, U.S. Patent and Trademark Office (February 2007) (http://www.uspto.gov/web/offices/ac/comp/budg/fy08pbr.pdf) at 15, col. 1.

[39] 35 U.S.C. § 41(d)(2).

[40] 35 U.S.C. § 2(b)(2)(F).

[41] 71 Fed. Reg. at 38809, col. 3.

IV.B. If the Rule Is Intended to Curb Abuse, It Should be Targeted at Abuse

The preamble to the proposed IDS Rule implies that USPTO management believes that applications with more than 20 references are associated with abuse. USPTO discloses no evidence in support of this inference, but even if it could be validated, the proposed rule would be a blunt instrument for addressing it. USPTO has sufficient adjudicatory powers to deal with abuse, under its attorney disciplinary authority.[42] Applicants who are making a *bona fide* effort to secure strong patent protection for an important invention should pay the costs of that examination, but should not face collective punishment for the sins of a few.

IV.C. Examination on Request

Another alternative is to allow applicants to signal when they want their applications examined. Most other major jurisdictions allow applicants to file applications and allow them to lay fallow for several years, and then request examination. In Europe, Japan and Canada, this results in about 20% of applications simply being abandoned, with no expenditure of examination resources.[43] "Examination on Request" would enable USPTO to focus its resources where it provides the most value, and simply ignore those applications in which applicants have lost interest. Also, if patent pendency were measured from the date examination was requested, and if applications not designated for immediate review were excluded from the denominator, this would immediately reduce pendency by a large amount and help USPTO achieve its management objectives.

Ironically, USPTO proposed that such a system be devised in its FY 2008 budget proposal:

> **Need for an Alternative Examination System**
> A critical challenge for the USPTO in achieving the most important objectives of patent examination quality and application pendency lies in addressing the constraints imposed by the very nature of the examination process. The current patent examination system in the United States is basically a one-size fits all process that culminates in the grant of letters patent (with a statutory presumption of validity for all such granted patents 35 USC 282) or the abandonment of the application. Although almost 450,000 UPR applications will be filed in 2007, not all will mature into products that are ultimately brought into the market place, be licensed for use by others, or have ownership transferred to others for possible future

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[42] 37 C.F.R. § 10.23(c), forbidding "giving false or misleading information ... to ... The Office"; § 10.23(c)(5), disbarment for violation of Rule 56 duty of disclosure.

[43] Letter of R.D. Katznelson to Susan Dudley, June 29, 2007 re "Continuations" Rule, http://www.whitehouse.gov/omb/oira/0651/comments/460.pdf at pages 20-22.

> exploitation. The current examination process imposes high demands for resources on the part of both the applicant and the USPTO. Further, the high demand for examination under this traditional process has exceeded the current abilities of the USPTO to examine applications as they are filed, resulting in an increasing backlog of unexamined applications. With the limited options for determining when examination is desired or advancing applicants position's in the examination queue, some applicants are forced to pursue the examination process before they are ready to capitalize upon a successful result from the process, while others in need of a rapid determination of their rights languish in the queue. As a result, the USPTO intends to explore the development of alternative approaches to examination in collaboration with stakeholders.[44]

We are inclined to agree with USPTO that such an alternative system is very much worth considering. Unfortunately, the proposed IDS Rule sets us back even further from where we would all like to be.

IV.D. Expand Peer-to-Patent

A joint public-private sector initiative that would address these issues, peertopatent.org, is currently in a pilot phase. Applicants can put their patent applications up for public comment during pendency, and interested parties are permitted to submit prior art and comment on the art that exists.

USPTO could offer applicants a *quid pro quo* based on Peer-to-Patent: an applicant would submit a patent application, with all potentially material prior art, for public comment, in much the form that they are submitted to USPTO today (that is, by simply listing the relevant prior art, without comment). The public would anonymously comment, and direct the examiner's attention to the most relevant prior art references. The applicant himself would provide this information anonymously, in order to assist the examiner in giving the best-possible examination, but without going on the record with binding statements that could lead to inequitable conduct allegations.

While no one is proposing peer-to-patent as a panacea for all of USPTO's ills, this approach has at least preliminary support of USPTO and a wide range of patent applicants, including those on both sides of litigation over valuable patents. It has a number of virtues including a high level of transparency and an inherently market-oriented, rather than command-and-control, approach to patent application and examination. At the same time, it preserves the unique role of USPTO as the authority for issuing U.S. patents. Combined with other reforms, it could be a valuable innovation.

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[44] Fiscal Year 2008 President's Budget, U.S. Patent and Trademark Office (February 2007) (http://www.uspto.gov/web/offices/ac/comp/budg/fy08pbr.pdf) at 18, emphasis added.

IV.E. The IDS Rule Should Be Returned for Further Consideration

Each of these ideas has merit, and indeed, they are not mutually exclusive. The proper way for USPTO to proceed is to follow the procedures set forth in Executive Order 12,866 for economically significant regulations. A Regulatory Impact Analysis performed in compliance with OMB Circular A-4 would enable USPTO to examine a range of options and for the public to contribute to and comment on its analysis.

What is obvious is that the proposed IDS Rule has no merit whatsoever, and it would cost patent applicants billions of dollars each year just to comply with onerous new paperwork burdens. We respectfully request that OMB put an end to USPTO's flagrant disregard for proper procedure and the exorbitant costs it imposes on its customers, and return this draft rule to USPTO for further consideration.

Sincerely,

/s/ David E. Boundy

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Attachments:

A. Letter of Philip Steiner

B. Testimony of Ronald J. Stern, President of Patent Office Professional Association, to House Subcommittee on Courts, the Internet, and Intellectual Property

C. Letter of ZymoGenetics with statistical appendix showing disparate impact on biotechnology and life sciences industries

Attachment A

Letter of Philip Steiner

L A W O F F I C E O F P H I L I P A S T E I N E R

Honorable Susan E. Dudley
Administrator
Office of Information and Regulatory Affairs
United States Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

October 8, 2007

RE: RIN 0651-AB95, Changes to Information Disclosure Statement Requirements and Other Related Matters, 71 Fed. Reg. 38808 (Jul 10, 2006) ("IDS Rule")

Dear Administrator Dudley,

I am writing you to provide my estimate of costs to be imposed on the public by the PTO's IDS Rule. I have been a patent attorney for 8 years, and have experience preparing patent applications, Information Disclosure Statements, patent infringement opinions, clearance opinions, and validity opinions. These kinds of work are similar enough to the incremental burden on applicants proposed under the IDS rule that I believe that my professional experience gives me a valid basis to opine on these costs.

Background – What is an IDS, and Why is it Needed?

37 C.F.R. § 1.56 is the intra-agency expression of the "duty of candor and good faith" created by courts. Both require an applicant to provide a patent examiner with all the information known to the applicant believed material to the patentability of his or her submitted patent application. The courts' common-law doctrine, which the PTO lacks authority to modify by rule, defines "materiality" somewhat more broadly than PTO's Rule 56. An "Information Disclosure Statement," or "IDS," is the conventional form by which an applicant provides this information to the PTO.

It's crucial to understand that an IDS is *mandatory*, even though it is not provided by statute. If an applicant knows of material information and fails to disclose it to the PTO, the patent – and potentially all related patents in the same family – is rendered unenforceable. The PTO has no authority to narrow this duty, or the scope of "material"

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information that must be disclosed. The PTO appears to recognize this, because the scope of the "safe harbor" in proposed 37 C.F.R. § 1.56(f) would not shelter non-disclosure of documents. Under the current law, which the PTO cannot change by rule, attorneys have very little latitude to submit fewer documents to the Patent Office than they do today, without incurring large risks of unenforceability for inequitable conduct, and risks of loss of their licenses to practice. Therefore, there is very little latitude to reduce the number of documents submitted. Because almost all attorneys (with only a tiny number of exceptions) recognize that "burying" material prior art in a mountain of non-material information would itself create a risk of "inequitable conduct," very nearly all documents that are cited to the PTO today will continue to be cited to the PTO under the IDS Rule.

Estimate of Costs Per Affected Application and For the Economy as A Whole

I estimate that on average comparing each prior art reference to the first independent claim of each application will cost about $1,500 each, increasing with the technical complexity of the claimed subject matter. Applications with multiple independent claims provide some economies of scale, so the cost will rise less than proportionally with the number of claims. For an application with three independent claims, I would expect the total cost to be 1.2 to 1.5 times the cost for a single independent claim. However, the cost will increase proportionally with the number of prior art references. For 21 references, I would expect the total cost to be at least 18 times the cost of a single prior art reference. Thus, for a minimum application that would trigger the requirement for a patentability justification document, I estimate that the cost of the document would be – conservatively –

$$\$1{,}500 \times 1.2 \times 15 = \$27{,}000$$

The cost will be somewhat lower for some applications, but not a significantly lower. This is because claims in simple technological fields tend to be more complex than claims in complex technological fields, and thus will require more complex discussion, even though the subject matter is simpler. On the other

hand, the distribution of far more complex and costly patentability justification documents is likely to be fairly large, but I cannot estimate the extent today.

This is purely an incremental cost, relative to the way applications are typically prosecuted today. For example, the discussion of each reference is not required under today's law, so the "patentability justification" document is pure incremental cost.

Because applicants have very little latitude to change behavior in response to this increased cost (except to totally abandon the patent system for a given invention that is likely to be subject to the IDS Rule), the cost of the IDS rule can be estimated quite accurately based on today's numbers.

The Notice of Proposed Rulemaking notes that about 15% of applications cite more than 20 references. Even assuming, very conservatively, that the average is 21 references, the total cost for preparing patentability justification documents is

480,000 applications/year × 0.15 × $27,000 = $1,944,000,000

Note that this is a minimum cost for only one requirement of the Rule; it does not consider the cost of preparing patentability justifications for prior art references that exceed 25 pages but that are not in excess of 20 documents total, it does not consider costs for the 22nd and further items of material information, and it does not consider increased litigation costs.

It is Far More Costly for Applicants to Prepare this Analysis than for the PTO

There are several reasons that this shift of task from the PTO to applicants is not a zero-sum shift, it is several orders of magnitude more expensive.

First, an examiner only skims most references, and typically only writes up one comparison of the prior art to the claims (typically based on one primary reference and a

few secondary references). In contrast, the IDS Rule proposes to compel applicants to write up at least 21 comparisons. That is simply a waste.

Second, examiners are allowed to be wrong, but applicants are absolutely bound by what they write. Examiners are often wrong, the system provides means to correct their errors, no one is bound by the error, and the cost of error is low. On the other hand, the law creates a near-inescapable presumption that anything that an applicant says is binding. Thus, each word that an applicant would provide in a patentability justification document, no matter how immaterial, would have to be prepared with great care, and considerable cost.

Third, when a patentability justification document is prepared by an attorney, the attorney must assume the liability risk of mischaracterizing (by either overstatement or understatement) every reference in the patentability justification document. This business risk cost was apparently not considered by the PTO. Realistically, the business risk of preparing and filing a patentability justification document based on inequitable conduct considerations alone, places an patentability justification document in the same risk categories as patent infringement and patent validity opinions which range anywhere from $20,000 to over a $100,000. I understand that several firms have decided that "examination support documents" ("ESD's," provided under the "Continuations" rule that OMB evaluated in April-July 2007, which in turn are very similar to patentability justification documents in this IDS rule) are "opinions" that must be reviewed by two partners of the firm, adding considerable billable cost to preparing such a document.

In this day and age of highly complex inventions, limiting the submission of relevant documents to avoid the draconian effects of preparing and filing a patentability justification document is almost certain to invoke the same level of scrutiny for inequitable conduct issues as actually filing an patentability justification document. The end result dramatically increases the cost of patenting and unfairly favors only those who can afford to seek patent protection.

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The new malpractice risk will add at least $4,000 to the cost of preparing a patentability justification document, a cost that was not considered by the PTO.

The PTO's Effort to Reduce Submission of Prior Art Adds Further Costs, Both on Applicants and on Competitors Seeking to Avoid Infringement

Attempting to cull the most relevant information to "fit" within the 20-reference limit arbitrarily proposed by the PTO could be misleading as only the examiner is in the position to determine what is really material and non-cumulative for examination purposes.

The Notice of Proposed Rulemaking discloses no data relied on by the PTO to determine the cutoff of 20 – the PTO says this limit was merely "deemed." Technically complex inventions usually require multiple references of varying page numbers to fully and completely disclose the prior art to an examiner. Moreover, in many cases, the additionally provided information assists the examiner in understanding the various nuances of a specific technology area in which a patent is sought.

Thus, limiting the inflow of information to the examiner is actually detrimental to patent examination quality.

The PTO's "Certification Analysis" for ESD's Far Underestimated the True Cost

In my view, the cost estimates in the "Certification Analysis Under the Regulatory Flexibility Act" that the PTO prepared in June 2007 for ESD's under the Continuations rule are far below any reasonable estimate. On page 15, the Certification states "Activities [were estimated based on] discussions with USPTO staff." I note that there was no discussion with any knowledgeable person about the actual time that would be required by applicants. The time estimates in the Certification Analysis appear to be based on the time taken by a typical examiner to perform the cursory review and first-impression write-up typically generated by the Patent Office in a first Office Action. I described the differences in care, time and cost above – these were not considered by the

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PTO. Patent attorneys and applicants simply cannot obtain viable patents if they produce work product at the quality level typical of Patent Office first Actions. Thus, the cost estimates in the Certification are woefully understated. In particular, the estimates for elements (3), (4) and (6) are completely out of any reasonable estimation range, off by factors of four to twenty.

I understand that it is PTO's obligation to explain to you why it made such poor assumptions and used such faulty data analysis, so I will avoid speculating here. Once the PTO provides this to you, I would be delighted to review it, to help you avoid relying on work of quality similar to the work the PTO submitted to you in June. I can identify some of the false assumptions in the June 2007 Certification Analysis, but would need an analysis that comports with normal standards of analytical rigor to fully comment and wring out all the errors.

Conclusion

I currently represent small entities and individual inventors; none of which will be able to afford the added cost imposed if this rule package is actually promulgated.

If you have any questions regarding my concerns, please feel free to call me at the number provided below.

Sincerely,

Philip A Steiner, MS MBA
Registered Patent Attorney

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Attachment B

Testimony of Ronald J. Stern, President of Patent Office Professional Association, to House Subcommittee on Courts, the Internet, and Intellectual Property

REVIEW OF U.S. PATENT AND TRADEMARK OFFICE OPERATIONS, INCLUDING ANALYSIS OF GOVERNMENT ACCOUNTABILITY OFFICE, INSPECTOR GENERAL, AND NATIONAL ACADEMY OF PUBLIC ADMINISTRATION REPORTS

HEARING

BEFORE THE

SUBCOMMITTEE ON COURTS, THE INTERNET, AND INTELLECTUAL PROPERTY

OF THE

COMMITTEE ON THE JUDICIARY
HOUSE OF REPRESENTATIVES

ONE HUNDRED NINTH CONGRESS

FIRST SESSION

SEPTEMBER 8, 2005

Serial No. 109–48

Printed for the use of the Committee on the Judiciary

Available via the World Wide Web: http://judiciary.house.gov

U.S. GOVERNMENT PRINTING OFFICE

23–324 PDF WASHINGTON : 2005

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Mr. SMITH. Mr. Stern.

TESTIMONY OF RONALD J. STERN, PRESIDENT, PATENT OFFICE PROFESSIONAL ASSOCIATION (POPA)

Mr. STERN. Thank you, Mr. Chairman, Ranking Member Berman and Members of the Subcommittee. As many of you know, POPA represents the engineers, scientists and attorneys who, as patent examiners, determine the patentability of hundreds of thousands of patent applications each year.

The agency has come under serious criticism lately. The principal problems deal with quality and timeliness. In addition, there is a problem with hiring and retaining our workforce.

The agency manufactures patents, but it does so in the high-stress environment of a legal sweatshop. When it comes to patent examination, you can take steps to get the job done faster or cheaper, but those steps will inevitably decrease the quality of the work.

You cannot increase the quality of examination without providing examiners the time necessary to do the job. Examiner quotas, measured in 6-minute increments, currently provide as little as 11.2 hours to primary examiners in low-complexity arts, and only 22.1 hours in the most complex arts.

Quotas established in 1976 are still in use today. In the meantime, technology is more complex, specifications are bigger, applications have more claims, and the amount of literature to be searched has ballooned. Electronic file wrappers cost examiners 1 to 3 hours of extra work per case. Examiners need a 20 percent increase in time per case.

Applicants pay substantial fees for excess claims, large specifications and information disclosure statements. Examiners must be given time proportional to these fees to ensure that applicants will get what they have paid for.

The most common criticism is that examiners do not find the best prior art. Text searching works in some arts, but not for all. Speedy searches require updating the U.S. Classification system regularly, which has not happened.

In the automated databases the wisdom and experience of prior examiners is lost. Old paper search files were regularly augmented by examiners' explanatory notes and by "feeding the shoes" newly discovered references.

There is no problem hiring examiners. The problem is keeping them. Approximately half leave within their first 3 years on the job. More important are the midcareer employees who leave the agency. In fiscal 2005, approximately 40 percent of all of those expected to leave will be employees with between 3 and 15 years of experience. Some of these employees are leaving without even having another job to go to.

The USPTO has implemented employee benefits such as special pay rates, flexible work schedules, family-friendly policies and transit subsidies. Benefits, however, are not by themselves sufficient to overcome many employees' dissatisfaction with the production-oriented nature of patent examining. The appeal of the USPTO's benefits is in constant opposition with the stress of the day-to-day legal sweatshop environment.

Attachment C

Letter of ZymoGenetics with statistical appendix showing disparate impact on biotechnology and life sciences industries

ZYMOGENETICS

September 8, 2006

The Honorable Jon W. Dudas
Under Secretary of Commerce for Intellectual Property
and Director of the U.S. Patent & Trademark Office
Mail Stop Comments
P.O. Box 1450
Alexandria, VA 22313-1450

Attn: Hiram H. Bernstein
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner for Patent Examination Policy

RE: Comments Regarding Proposed Rules for "Changes to Information Disclosure Statements Requirements and other Related Matters" [71 *Fed. Reg.* 38808] (July 10, 2006).

Dear Under Secretary Dudas,

ZymoGenetics, Inc. appreciates the opportunity to offer comments concerning the U.S.P.T.O. Proposed Rules for "Changes to Information Disclosure Statements Requirements and other Related Matters" [71 *Fed. Reg.* 38808] (July 10, 2006). We respectfully request consideration of the following comments.

A. Proposed Changes to Information Disclosure Statement Requirements Would Disparately Impact the Biotechnological Arts

The U.S.P.T.O. (the "Office") has stated that the proposed changes to Information Disclosure Statements (IDS) would not trigger any additional disclosure requirements during the first time period (see proposed §1.97(b)). However, an "explanation" is required to accompany an IDS whenever a document over twenty-five (25) pages is submitted to the Office (§1.98(a)(3)(i)(B)), or for all documents when their cumulative number exceeds twenty (20) references, in all IDSs filed in this first time period (§1.98(a)(3)(i)(C)). The Office has set these limitations on the number of references cited, and page limitations based on a survey of patents across a wide variety of industries with the belief that 85% of applicants would not be affected. Unfortunately, for biotechnology industry, as described below, in over 90% of biotechnology applications, applicants will be required to submit such "explanations" which are time consuming and costly to the biotechnology business. This disparate impact on a single industry is simply unfair.

The practice of biotechnology, and hence biotechnological inventions, is generally considered an "unpredictable art" for the purposes of patent law. The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art (M.P.E.P §2164.03 citing In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970)). If little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling (M.P.E.P. §2164.03). Because of the unpredictability of biotechnology inventions, Applicants are required to provide more extensive disclosure of an invention in order to teach a person of ordinary skill in the art

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how to make and use the invention. Thus, biotechnology-related patent applications are generally greater than twenty-five (25) pages in length. Accordingly, an applicant citing a U.S. Patent document or Foreign Patent document in the biotechnological arts is almost assured of having to submit an explanation with the IDS. This conclusion is supported by data on biotechnology filings shown in the Appendix, and further described below.

The results of the Office's all-industry wide survey do not accurately represent the biotechnology industry, and in fact the proposed rule disparately impacts the industry. The Appendix shows a statistical analysis of the top ten biotechnological companies, by market cap, for 2005. The Office noted that "a threshold of twenty documents for IDSs submitted prior to a first Office action on the merits would not require a change in practice for most applications. The Office expects that more than 85% of IDSs filed prior to first Office action on the merits would not require any explanation." In other words, the Office expects that less than 15% of IDSs will require any explanation. However, in 2005 in the biotechnology arts, in 73% of the patents granted to these companies more than twenty (20) documents were submitted to the Office, and in 94% of the patents granted there was a submission of at least one document with greater than 25 pages. Thus, for the average biotechnological arts patent application, the Office's assertion that the proposed changes would require the submission of an "explanation" for only about 15% of the IDSs filed during the first time period is false. An "explanation" would in fact be required in over 90% of typical biotechnical arts applications for one reason or another, with over 70% requiring extensive explanations for *all documents* within the IDS (because of the "over 20 references" rule). Moreover, it is highly likely that 100% of biotechnology businesses that file and prosecute patent applications would be affected, as all of the companies surveyed had issued patents in 2005 that would have triggered the heightened disclosure requirements under the proposed rules. Because of the disparate impact on a single industry these rules changes should not be adopted as proposed.

The proposed limitation on the threshold number of documents at 20 is arbitrary, and does not reflect the reality of prior art that must be cited for the average biotechnology patent application. The Office provides no evidence in regards to the reasoning for this 20-reference limit. As discussed below, the 20-reference rule fails to be related to the actual goal of enhancing the quality of patent examination and resulting patents.

Moreover, the proposed definition of a "large document" as any document over 25 pages (not including sequence and computer listings) is arbitrary in that page count is not an accurate measure of content. The actual amount of information contained in a document is also a function of such factors as page layout, font size, and other formatting parameters. For example, a U.S. patent is printed in a two-column format with a font size approximately equal to 10-point Times New Roman and single line spacing. In contrast, published PCT applications are printed as filed, commonly with 12-point type and at least 1.5 line spacing. As a result, a PCT publication will have approximately twice the page count of the counterpart U.S. patent, even though the content may be identical. Hence the page limitation is inherently arbitrary and fails to consider the actual content of a prior art document that would be before the Examiner. As discussed below, the 25 page limitation fails to be related to the actual goal of enhancing the quality of patent examination and resulting patents.

If the goal of these proposed rule changes is to encourage Applicants to submit an IDS to the Examiner within the first time period thus enabling the Examiner to identify the most relevant prior art and perform a more efficient and effective examination, then any potential penalty at all for a good-faith submission of an IDS in the first time period is unnecessary and excessive. It appears that the intent of the Office was to enhance patent examination by allowing a first time period as a grace period to ensure the timely submission of the relevant prior art before the examiner to ensure quality examination and to enable a patentee to submit prior art in good faith. It is unclear how the proposed 20 reference and 25 page limitations benefits the examination process for biotechnology applicants. A patentee has a duty to disclose all prior art related to patentability of an invention, but has no control over the number of references in the prior art nor the number of pages of those references. However, the arbitrary limitations set forth in the proposed rule do not reflect the typical patent application in the biotechnological arts. The requirement for an "explanation" of any document over 25 pages or for every reference in an IDS of over 20 references, effectively penalizes applicants for circumstances over which they have no control. The size of any prior art document is determined by the author of that document, not by the applicant who must cite it. Statistically speaking, because over 90% of typical biotechnical arts applications would require the "explanation" for one reason or another, for all practical purposes this grace period will be simply ablated for most biotechnology applicants. To make a level playing field for all patentees, we would propose that the page limitations and reference number limitations of the proposed rule be struck so that no industry is disparately impacted and can take advantage of the first time period grace period.

The Office, patent applicants, and the public as a whole will be best served if all material art is disclosed before substantive examination of an application begins. This should be the goal of any revisions to the rules of practice, and the revised rules should not penalize applicants who make a good-faith effort to comply.

B. The Proposed Rule Would Adversely Impact Small and Mid-sized Biotechnology Companies Financially.

Because of the disparate impact on the biotechnological arts, the proposed rule adds further cost to the already expensive prosecution of biotechnology-related patent applications. Financial costs are both direct (e.g., for foreign document translations) and indirect in terms of patent practitioners' time in not only "identifying" specific features in the prior art documents, but in "correlating" such art to specific claim language, and reviewing and potentially revising each "explanation" with each subsequent claim amendment. In addition, if an outside firm were to prosecute a patent under these rules, the level of involvement and potential liability risk for an outside firm (based on inequitable conduct concerns discussed herein) could make compilation of "explanations" surrounding IDS submissions and claim amendments comparable to full-blown legal opinions which typically run between $50,000 and $100,000 each. For an innovative small- to mid-sized biotechnology company, such as ZymoGenetics Inc., the costs related to such "explanations" could quickly escalate into several hundred thousand dollars or more per year. This is a cost that we simply cannot afford to have on a regular basis.

In addition, and more daunting financially, will be the predicted resulting litigation created in the form of inequitable conduct claims based on statements provided by applicants in the "explanation" about prior art and how it correlates to claim language, the requirement for non-cumulative description, and updates on the "explanation" with every subsequent claim amendment. Requiring disclosure of a "correlation" of prior art to claim language or non-cumulative description, and further commentary with each claim amendment will further broaden the already increasing inequitable conduct claims against patentees and increase litigation costs. In addition, under the present rules, a patentee's duty to disclose prior art references causes the applicant to err on the side of being inclusive in an IDS of a reference that may be considered cumulative by the Office, but non-cumulative by an applicant. Under the new proposed rules an applicant may err on the side of not submitting such a reference in an IDS. Again, the non-inclusion of a reference which is later considered "material" by a court will predictably result in increased inequitable conduct claims and an overall increased financial burden to the biotechnology industry. As discussed above, the biotechnology industry will not be able to avoid such "explanations" even in the first time period, opening up the industry as a whole to potential increase in litigation. That is, even good-faith practices and an effort to simply comply with the rule will predictably be used against patentees in the form of inequitable conduct claims when they try to enforce their patents.

Unless the law surrounding inequitable conduct is modified, the proposed rule will create a conflict between the practitioner's duty to disclose the relevant prior art and the potential for inequitable conduct liability down the road.

C. The Proposed Changes Add a Further Means of Finding a Patent Unenforceable, Thus Undermining the Value of Biotechnology Patents as a Whole

The proposed rules will likely increase the cost of prosecuting patent applications and render the enforceability of issued patents less certain. Notably, these negative consequences of the proposed rules will disproportionately impact the biotechnology industry. By raising the standard of what Applicants must provide to meet the minimum duty of disclosure, the Office is providing yet another means for patent litigators to attack and invalidate issued patents, and potentially impact any other patent in the "invalidated" patent family. Under the guise of an inequitable conduct assertion, litigators will pick apart every sentence of all references cited for any relationship to the claims of the patent at issue about which the prosecuting practitioner failed to include a statement. Furthermore, litigators will scrutinize all explanatory statements made about a reference and their relationship to the claims for even the slightest arguable hint of misrepresentation of content. Additionally, litigators will re-read each statement in light of claim amendments during subsequent prosecution to try to show examples where the practitioner has arguably breached this newly broadened duty of disclosure.

Despite good faith efforts on the part of practitioners to comply with the additional proposed disclosure requirements, courts will likely find more cases of inequitable conduct based on explanatory statements not made, explanatory statements not amended, and explanatory statements not made as straightforwardly as the court would see fit. It is far from clear whether these added requirements will aid the examination of the claims in a manner proportional to these new areas of vulnerability.

The task of initially interpreting the art and its impact on the claims falls squarely within the function of the examiner, and that is where this responsibility should remain in order to keep issued patents enforceable. The suggested disclosure rules add a broad method of attack for litigators and have a predictable negative effect on patents – it renders the enforceability of patents even more uncertain and thus reduces the value of all patents issued after the rule change. This has an even more insidious effect on business as a whole, as patents that are more easily attacked are less valuable in licensing, in the start up or purchase of a business, and other means of profiting from intellectual property.

The resulting weakening of patents by the proposed rules will greatly affect the biotechnology industry, a segment of business that relies heavily on the presumed validity, value, and alienation of patents to do business. In order to maintain the value patents now enjoyed in the United States, particularly within the biotechnology industry, it is urged that the Office not adopt the suggested heightened disclosure requirements, at least as they apply in the first period.

D. Considerations Regarding Disclosures Made During the Third and Fourth Time Periods

With respect to the Office's proposal requiring a "patentability justification" in the third and fourth time periods for documents identified in a foreign search or examination report, again, the applicant has no control over when a foreign search report or examination report citing references will be received. Given that foreign patent prosecution generally lags behind U.S. patent prosecution, there is a strong possibility that such foreign search or examination reports will need to be submitted to the Office during the third and maybe the fourth time periods under the proposed rules. It seems unjust to require a "patentability justification" for such documents at all, since they are submitted by a foreign patent office and hence are by their nature considered material to patentability by an official world patent office. Consequently, we urge the Office to eliminate the requirement in the third and fourth time periods for a "patentability justification" under proposed rule 1.98(a)(3)(vi)(A) and (B) for documents identified in a foreign search or examination report.

Depending upon how the Office administers these and other proposed rules (e.g., re: continuation practice, if enacted), applicants may be prevented from submitting material information that is first identified after payment of the issue fee. Under proposed §1.98, submission of art during the 4th period requires, *inter alia*, an unequivocal statement that one or more claims are "unpatentable" in view of the cited information. This standard is, however, substantially higher than the materiality standard set forth in 37 C.F.R. 1.56(b). As a result, newly discovered art that is *material* without making one or more claims *unpatentable* (e.g., art that is not cumulative and is inconsistent with a position taken by the applicant earlier in prosecution; 37 C.F.R. 1.56(b)(2)) cannot be disclosed to the Office during the 4th period.

In order to fulfill the duty of disclosure under the above scenario, an applicant will be required to file either a continuation or a request for continued examination (RCE). Under the proposed rule revisions for continuing applications [71 *Fed. Reg.* 48], the applicant may either have to use up its single continuing application to submit the newly discovered material information in an IDS, or potentially be barred from filing the continuation or RCE, since it is not clear if this scenario meets the proposed requirement for filing a second or later

continuation or RCE; that is, if the new information is "evidence that could not have been submitted prior to the close of prosecution in the application." For example, the Office could find that the applicant *could have* submitted the information earlier if a more comprehensive search had been performed. Barring the filing of a continuation or RCE, the applicant's only recourse will be reexamination of the issued patent. The Office is therefore urged to amend the proposed rules to explicitly permit the filing of a further continuation application or RCE for the purpose of submitting newly discovered, material (as defined in Rule 56) information.

E. Proposed Recommendation to the Proposed Rules for "Changes to Information Disclosure Statement Requirements and Other Related Matters"

(1) Eliminate proposed rule §1.98(a)(3)(i) and rely on proposed rules §1.98(a)(3)(ii) and (iii) to encourage Applicants to submit an IDS to the Examiner within the first time period.

(2) If the first suggestion is impossible, then amend the proposed rules to enable biotechnology applicants to submit a reasonable or typical IDS (regarding number of references and content of references) in the first time period without requiring heightened disclosure or "explanation," so that biotechnology applicants are treated like all other applicants.

(3) Amend proposed rules to explicitly permit the submission of newly discovered, material (as defined in Rule 56) information without penalty to the applicant.

(4) Eliminate the requirement in the third and fourth time periods for a "patentability justification" under proposed rule 1.98(a)(3)(vi)(A) and (B) for documents identified in a foreign search or examination report, to enable submission of documents identified in such reports during any of the time periods without penalty to the applicant.

(5) Amend proposed rules to explicitly permit the filing of a further continuation application or RCE for the purpose of submitting newly discovered, material (as defined in Rule 56) information.

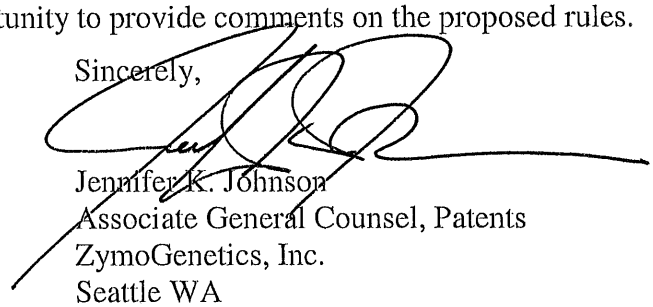
(6) In the event applicants are requested to "identify" relevant portions of references, remove the "correlation" step.

(7) Eliminate the requirement for non-cumulative description and updates on the "explanation" with every subsequent claim amendment.

(8) The Office should clarify that any disclosure requirements or "explanations" provided under the new IDS rules shall not be construed as an admission of materiality or lack thereof by the applicant.

Again, we appreciate the opportunity to provide comments on the proposed rules.

Sincerely,



Jennifer K. Johnson
Associate General Counsel, Patents
ZymoGenetics, Inc.
Seattle WA

APPENDIX

IDS STATISTICS FOR THE TOP TEN BIOTECHNOLOGY COMPANIES FOR 2005

The Top Ten Biotechnology Companies surveyed below were determined by reference to Yahoo Finance, "Leaders in Market Capitalization" (Mkt Cap). See Biotechnology Industry Leaders & Laggards: Industry Center - Yahoo Finance, http://biz.yahoo.com/ic/ll/515mkt.html (8/30/2006, 12:31 PM).

The Top Ten Biotechnology Companies include: Genentech, Amgen, Gilead Sciences, Genzyme Corporation, Biogen, Celgene CP, Serono SA, Medimmune Inc., Amylin Pharma Inc., Invitrogen Corp.

The Information Disclosure Statement data contained in this survey was determined by reference to the U.S. Patent Collection Database. See US Patent Full - Text Database Boolean Search, http://patft.uspto.gov/netahtml/PTO/search-bool.html (8/30/2006, 1:04 PM). Each entry shows the search terms used.

All averages are simple averages, not weighted.

General Summary (Including all Top Ten Companies):	
No. of Drug Patents:	194
Average No. of disclosures Per Patent:	53.4
Median No. of disclosures Per Patent:	44
Percentage of Patents with >20 disclosures:	72.68%
Percentage of Patents with at least 1 disclosure with > 25 pgs:	93.81%

(1) Genentech (Mkt Cap = $85.4 Billion)

Results of Search in US Patent Collection db for:
AN/"Genentech Inc" AND ISD/1/1/2005->12/31/2005: 70 patents.

Summary:	
No. of Drug Patents:	70
Average No. of disclosures Per Patent:	47.2
Percentage of Patents with >20 disclosures:	65.71%
Percentage of Patents with at least 1 disclosure with > 25 pgs:	92.86%

List No.	PAT. NO.	Title	No. of Disclosures	>20 Disclosures (Y/N)	Any Refs > 25 pgs (Y/N)
1	6,979,556	Separate-cistron contructs for secretion of aglycosylated antibodies from prokaryotes	95	Y	Y
2	6,974,798	Treatment of balance impairments	118	Y	Y
3	6,974,696	PRO853 nucleic acids	24	Y	Y
4	6,974,689	Nucleic acid encoding PRO211 polypeptides	50	Y	Y
5	6,972,325	PRO273 polypeptides	6	N	Y
6	6,972,186	Nucleic acid encoding pro 1410 polypeptides	28	Y	Y
7	6,972,185	Nucleic acids encoding PRO844 polypeptides	7	N	Y
8	6,969,758	Secreted and transmembrane polypeptides and nucleic acids encoding the same	39	Y	Y
9	6,967,245	UCP5	70	Y	Y
10	6,967,241	Process for protein extraction	12	N	Y
11	6,965,015	Secreted and transmembrane polypeptides and nucleic acids encoding the same	21	Y	Y
12	6,965,011	Secreted and transmembrane polypeptides and nucleic acids encoding the same	18	N	Y

13	6,964,947	Stabilizing formulation for NGF	24	Y	Y
14	6,962,797	Nucleic acids encoding PRO615	25	Y	Y
15	6,956,108	PRO1184 antibodies	6	N	N
16	6,953,844	Isolation of neurotrophins from a mixture containing neurotrophin variants using hydrophobic interaction chromatography	89	Y	Y
17	6,953,842	Antibodies to heregulin 2	59	Y	Y
18	6,953,841	Secreted and transmembrane polypeptides and nucleic acids encoding the same	24	Y	Y
19	6,953,836	PRO844 polypeptides	7	N	Y
20	6,951,921	Secreted and transmembrane polypeptides and nucleic acids encoding the same	4	N	Y
21	6,951,920	PRO1340 polypeptides	18	N	Y
22	6,951,737	Secreted and transmembrane polypeptides and nucleic acids encoding the same	5	N	Y
23	6,949,349	Insulin-like growth factor agonist molecules	191	Y	Y
24	6,949,245	Humanized anti-ErbB2 antibodies and treatment with anti-ErbB2 antibodies	345	Y	Y
25	6,946,263	Secreted and transmembrane polypeptides and nucleic acids encoding the same	3	N	Y
26	6,944,522	Chemical process machine programming system	25	Y	Y
27	6,936,697	Secreted and transmembrane polypeptides and nucleic acids encoding the same	3	N	Y
28	6,936,440	Selecting ligand agonists and antagonists	85	Y	Y
29	6,936,436	Secreted and transmembrane polypeptides and nucleic acids encoding the same	6	N	Y
30	6,936,254	Method of inducing fetal hemoglobin synthesis	25	Y	N
31	6,933,314	Integrin receptor inhibitors	30	Y	Y
32	6,932,965	Purified forms of DNase	53	Y	Y
33	6,930,172	Secreted and transmembrane polypeptides and nucleic acids encoding the same	38	Y	Y
34	6,930,170	PRO1184 polypeptides	1	N	N
35	6,929,947	Secreted and transmembrane polypeptides and nucleic acids encoding the same	3	N	Y
36	6,927,204	Treatment of inner ear hair cells	214	Y	Y
37	6,927,024	PCR assay	58	Y	Y
38	6,926,833	Tangential-flow filtration system	20	N	Y
39	6,924,355	PRO1343 polypeptides	32	Y	Y
40	6,921,659	Protease-deficient cells	32	Y	Y
41	6,919,369	Serine protease inhibitors	16	N	Y
42	6,916,916	Sialidase and recombinant cell lines	24	Y	Y
43	6,916,648	Secreted and transmembrane polypeptides and nucleic acids encoding the same	10	N	N
44	6,916,624	Antibodies that bind gamma-heregulin	76	Y	Y
45	6,914,130	Compositions and methods for the diagnosis and treatment of tumor	23	Y	Y
46	6,914,129	Anti-IgE antibodies	80	Y	Y
47	6,914,123	Hairpin peptides with a novel structural motif and methods relating thereto	80	Y	Y
48	6,913,767	Compositions for microencapsulation of antigens for use as vaccines	76	Y	Y
49	6,911,321	Non-human primate Fc receptors and methods of use	114	Y	Y
50	6,908,993	Secreted and transmembrane polypeptides and nucleic acids encoding the same	9	N	Y
51	6,906,034	Acid-labile subunit (ALS) of insulin-like growth factor binding protein complex	36	Y	Y
52	6,905,830	Tissue analysis and kits therefor	46	Y	Y
53	6,897,294	Inhibitors of vascular endothelial growth factor activity, their uses and processes for their production	52	Y	Y
54	6,894,148	Secreted and transmembrane polypeptides and nucleic acids encoding the same	3	N	N
55	6,891,022	NSP molecules	44	Y	Y
56	6,887,705	Tyrosine phosphorylated cleavage furrow-associated proteins (PSTPIPs)	54	Y	Y
57	6,884,879	Anti-VEGF antibodies	85	Y	Y

58	6,878,807	Secreted and transmembrane polypeptides and nucleic acids encoding the same	9	N	Y
59	6,875,567	Method of detecting cardiac hypertrophy through probe hybridization and gene expression analysis	102	Y	Y
60	6,875,432	Reduced-viscosity concentrated protein formulations	14	N	Y
61	6,872,735	LFA-1 antagonist compounds	8	N	Y
62	6,872,704	Acidic mammalian proteins and polynucleotides encoding the same	64	Y	Y
63	6,870,034	Protein purification	29	Y	Y
64	6,870,033	Antibody fragment-polymer conjugates and humanized anti-IL-8 monoclonal antibodies	111	Y	Y
65	6,867,213	(2S)-2-(adamantan-1-ylmethoxycarbonylamino)-3-(4-(2-(1,4,5,6-tetrhydropyrim idin-2-ylcarbamoyl)ethyl)benzoylamino)propionic acid isopropyl ester, its preparation and its use	2	N	Y
66	6,867,208	Vitronectin receptor antagonists, their preparation and their use	9	N	Y
67	6,858,427	Sphingosine kinases	25	Y	Y
68	6,855,508	ELISA for VEGF	77	Y	Y
69	6,852,848	Secreted and transmembrane polypeptides and nucleic acids encoding the same	81	Y	Y
70	6,838,479	Amidine inhibitors of serine proteases	32	Y	Y

(2) Amgen (Mkt Cap = $80.3 Billion)

Results of Search in US Patent Collection db for:
AN/Amgen AND ISD/1/1/2005->12/31/2005: 38 patents.

Summary:	
No. of Drug Patents:	38
Average No. of disclosures Per Patent:	61.2
Percentage of Patents with >20 disclosures:	71.05%
Percentage of Patents with at least 1 disclosure with > 25 pgs:	100.00%

List No.	PAT. NO.	Title	No. of Disclosures	>20 Disclosures (Y/N)	Any Refs > 25 pgs (Y/N)
1	6,979,674	Polyol/oil suspensions for the sustained release of proteins	56	Y	Y
2	6,977,264	Substituted piperidines and methods of use	13	N	Y
3	6,974,672	Gene amplification in cancer	140	Y	Y
4	6,967,254	Substituted heterocyclic compounds and methods of use	18	N	Y
5	6,967,029	Method for increasing hematopoietic progenitor cells by stem cell factor	120	Y	Y
6	6,964,967	Substituted pyrido[2,3-d]pyrimidines and methods for their use	30	Y	Y
7	6,964,765	Inhibitors of apoptosis	18	N	Y
8	6,956,105	Chandra: a Th1-specific protein	22	Y	Y
9	6,956,027	N-terminally chemically modified protein compositions and methods	129	Y	Y
10	6,949,366	Cytokines that bind the cell surface receptor hek	30	Y	Y
11	6,946,264	Metalloproteinase inhibitor	105	Y	Y
12	6,943,238	Antibodies to cyclin E2 protein	84	Y	Y
13	6,939,874	Substituted pyrimidinyl derivatives and methods of use	54	Y	Y
14	6,936,439	OB fusion protein compositions and methods	96	Y	Y
15	6,921,762	Substituted indolizine-like compounds and methods of use	19	N	Y
16	6,919,426	Peptides and related molecules that modulate nerve growth factor activity	6	N	Y
17	6,919,176	Polypeptides and nucleic acids associated with cancer	32	Y	Y
18	6,908,935	Calcium receptor modulating agents	52	Y	Y
19	6,906,069	LXR modulators	27	Y	Y
20	6,904,369	Conjugated ligands for the stimulation of blood cell proliferation by effecting dimerization of the receptor for stem cell factor	7	N	Y
21	6,900,043	Phosphatases which activate map kinase pathways	265	Y	Y
22	6,884,782	STAT modulators	57	Y	Y

23	6,881,737	Substituted triazinyl acrylamide derivatives and methods of use	18	N	Y
24	6,881,542	Serine threonine kinase member, h2520-59	12	N	Y
25	6,878,714	Substituted alkylamine derivatives and methods of use	39	Y	Y
26	6,869,925	Inhibition of retrovirus infection	113	Y	Y
27	6,864,255	Substituted triazinyl amide derivatives and methods of use	30	Y	Y
28	6,858,619	Fused heterocyclic compounds	48	Y	Y
29	6,858,409	Nucleic acids encoding interleukin-1 inhibitors and processes for preparing interleukin-1 inhibitors	158	Y	Y
30	6,855,815	Inhibitors of apoptosis	17	N	Y
31	6,852,839	Fhm, a novel member of the TNF ligand supergene family	77	Y	Y
32	6,852,313	Method of stimulating growth of melanocyte cells by administering stem cell factor	129	Y	Y
33	6,849,639	Integrin inhibitors and their methods of use	76	Y	Y
34	6,849,450	Antibodies to the metalloproteinase inhibitor	112	Y	Y
35	6,849,260	Methods and compositions for treating IgE-related disease using NNT-1 inhibitors	19	N	Y
36	6,846,834	Antiinflammation agents	25	Y	Y
37	6,841,147	Stem cell factor compositions	56	Y	Y
38	6,838,454	Carboxylic acid substituted heterocycles, derivatives thereof and methods of use	15	N	Y

(3) Gilead Sciences (Mkt Cap = $29.3 Billion)

Results of Search in US Patent Collection db for:
AN/"Gilead Sciences" AND ISD/1/1/2005->12/31/2005: 8 patents.

Summary:	
No. of Drug Patents:	8
Average No. of disclosures Per Patent:	51.6
Percentage of Patents with >20 disclosures:	100.00%
Percentage of Patents with at least 1 disclosure with > 25 pgs:	100.00%

List No.	PAT. NO.	Title	No. of Disclosures	>20 Disclosures (Y/N)	Any Refs > 25 pgs (Y/N)
1	6,979,561	Non-homogeneous systems for the resolution of enantiomeric mixtures	77	Y	Y
2	6,962,784	Vascular endothelial growth factor (VEGF) nucleic acid ligand complexes	48	Y	Y
3	6,939,965	Process of manufacture of 1,3-oxathiolane nucleosides using titanium trichloride mono-isopropoxide	53	Y	Y
4	6,933,116	Nucleic acid ligand binding site identification	57	Y	Y
5	6,933,114	Nucleic acid ligands to the prostate specific membrane antigen	32	Y	Y
6	6,914,138	Urea nucleosides as therapeutic and diagnostic agents	66	Y	Y
7	6,855,496	Truncation SELEX method	27	Y	Y
8	6,846,918	Nucleoside modifications by palladium catalyzed methods	53	Y	Y

(4) Genzyme Corporation (Mkt Cap = $17.4 Billion)

Results of Search in US Patent Collection db for:
AN/"Genzyme Corporation" AND ISD/1/1/2005->12/31/2005: 22 patents.

Summary:	
No. of Drug Patents:	22
Average No. of disclosures Per Patent:	52.8
Percentage of Patents with >20 disclosures:	86.36%
Percentage of Patents with at least 1 disclosure with > 25 pgs:	90.91%

List No.	PAT. NO.	Title	No. of Disclosures	>20 Disclosures (Y/N)	Any Refs > 25 pgs (Y/N)
1	6,972,176	KVLQT1--a long QT syndrome gene	49	Y	Y
2	6,969,728	Modulators of TNF-.alpha. signaling	34	Y	Y
3	6,955,806	Ionene polymers and their use as antimicrobial agents	86	Y	Y
4	6,943,154	Water insoluble derivatives of polyanionic polysaccharides	42	Y	Y
5	6,923,986	Multiblock biodegradable hydrogels for drug delivery and tissue treatment	79	Y	Y
6	6,916,802	Amino ceramide-like compounds and therapeutic methods of use	59	Y	Y
7	6,911,216	Targeted delivery via biodegradable polymers	83	Y	Y
8	6,903,220	Synthesis of chiral 2-alkyl amino acids	49	Y	Y
9	6,890,523	Anionic polymers as toxin binders and antibacterial agents	71	Y	Y
10	6,878,828	Synthesis of 2-alkylcysteine via substituted thiazoline ester	47	Y	Y
11	6,875,883	Synthesis of benzonitriles from substituted benzaldehyde	45	Y	Y
12	6,875,882	Synthesis of benzonitriles from substituted benzoic acid	47	Y	Y
13	6,875,428	Lipase inhibiting polymers	63	Y	N
14	6,867,288	Polycystic kidney disease gene	5	N	N
15	6,861,532	Synthesis of 2-alkylcysteine	47	Y	Y
16	6,861,408	Therapeutic anti-melanoma compounds	114	Y	Y
17	6,858,592	Aryl boronic acids for treating obesity	81	Y	Y
18	6,858,425	Human acid alpha glucosidase gene and bovine alpha-S1 casein gene sequences	7	N	Y
19	6,858,203	Method of making phosphate-binding polymers for oral administration	73	Y	Y
20	6,855,830	Synthesis of UDP-glucose: N-acylsphingosine glucosyltransferase inhibitors	22	Y	Y
21	6,846,958	Synthesis of benzimidate from benzoic acid	43	Y	Y
22	6,841,153	Prevention of adhesions	15	N	Y

(5) Biogen (Mkt Cap = $15.2 Billion)

Results of Search in US Patent Collection db for:
AN/Biogen AND ISD/1/1/2005->12/31/2005: 12 patents.

Summary:	
No. of Drug Patents:	12
Average No. of disclosures Per Patent:	62.3
Percentage of Patents with >20 disclosures:	91.67%
Percentage of Patents with at least 1 disclosure with > 25 pgs:	91.67%

List No.	PAT. NO.	Title	No. of Disclosures	>20 Disclosures (Y/N)	Any Refs > 25 pgs (Y/N)
1	6,962,978	Polymer conjugates of interferon beta-1a and uses	41	Y	Y
2	6,955,810	Method for the treatment of inflammatory disorders	9	N	N
3	6,949,534	Cell adhesion inhibitors	62	Y	Y
4	6,943,146	Method for promoting neovascularization	78	Y	Y
5	6,897,297	Hydrophobically-modified protein compositions and methods	25	Y	Y
6	6,897,044	Production of tetravalent antibodies	44	Y	Y
7	6,896,885	Combined use of anti-cytokine antibodies or antagonists and anti-CD20 for treatment of B cell lymphoma	64	Y	Y
8	6,893,636	Gamma-1 and gamma-3 anti-human CD23 monoclonal antibodies and use thereof as therapeutics	153	Y	Y
9	6,875,846	Heterologous polypeptide of the TNF family	40	Y	Y
10	6,875,743	Cell adhesion inhibitors	85	Y	Y
11	6,869,605	BAFF, inhibitors thereof and their use in the modulation of B-cell response	63	Y	Y
12	6,861,509	Antibodies to Ret and RetL3	84	Y	Y

(6) Celgene CP (Mkt Cap = $15.0 Billion)

Results of Search in US Patent Collection db for:
AN/Celgene AND ISD/1/1/2005->12/31/2005: 7 patents.

Summary:	
No. of Drug Patents:	7
Average No. of disclosures Per Patent:	36.9
Percentage of Patents with >20 disclosures:	42.86%
Percentage of Patents with at least 1 disclosure with > 25 pgs:	71.43%

List No.	PAT. NO.	Title	No. of Disclosures	>20 Disclosures (Y/N)	Any Refs > 25 pgs (Y/N)
1	6,962,997	Process and intermediates for resolving piperidyl acetamide steroisomers	36	Y	Y
2	6,962,940	(+)-2-[1-(3-Ethoxy-4-methoxyphenyl)-2-methylsulfonylethyl]-4-acetylaminoiso indoline-1,3-dione: methods of using and compositions thereof	117	Y	Y
3	6,914,067	Compositions and methods for the treatment of colorectal cancer	53	Y	Y
4	6,911,464	N-alkyl-hydroxamic acid-isoindolyl compounds and their pharmaceutical uses	1	N	N
5	6,908,432	Methods for delivering a drug to a patient while preventing the exposure of a foetus or other contraindicated individual to the drug	19	N	Y
6	6,869,399	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated	18	N	Y
7	6,844,359	Substituted imides	14	N	N

(7) Serono SA Ads (Mkt Cap = $12.6 Billion)

Results of Search in US Patent Collection db for:
AN/Serono AND ISD/1/1/2005->12/31/2005: 3 patents.

Summary:	
No. of Drug Patents:	3
Average No. of disclosures Per Patent:	24.0
Percentage of Patents with >20 disclosures:	66.67%
Percentage of Patents with at least 1 disclosure with > 25 pgs:	100.00%

List No.	PAT. NO.	Title	No. of Disclosures	>20 Disclosures (Y/N)	Any Refs > 25 pgs (Y/N)
1	6,977,145	Method for carrying out a biochemical protocol in continuous flow in a microreactor	27	Y	Y
2	6,960,441	Assays for the detection of human defensin polypeptide (Def-X)	19	N	Y
3	6,955,902	High throughput DNA sequencing vector	26	Y	Y

(8) Medimmune Inc. (Mkt Cap = $6.7 Billion)

Results of Search in US Patent Collection db for:
AN/"Medimmune Inc" AND ISD/1/1/2005->12/31/2005: 9 patents.

Summary:	
No. of Drug Patents:	9
Average No. of disclosures Per Patent:	33.6
Percentage of Patents with >20 disclosures:	44.44%
Percentage of Patents with at least 1 disclosure with > 25 pgs:	100.00%

List No.	PAT. NO.	Title	No. of Disclosures	>20 Disclosures (Y/N)	Any Refs > 25 pgs (Y/N)
1	6,962,777	TIN VITRO METHOD FOR DISASSEMBLY/REASSEMBLY OF PAPILLOMAVIRUS VIRUS-LIKE PARTICLES (VLPS), HOMOGENEOUS VLP AND CAPSOMERE COMPOSITIONS PRODUCED BY SAID METHODS; USE THEREOF AS VEHICLE FOR IMPROVED PURIFICATION, AND DELIVERY OF ACTIVE AGENTS	14	N	Y
2	6,962,701	TMethods of priming the immunogenic activity of vaccines useful for eliciting a protective immune response	11	N	Y
3	6,955,717	TCrystals and structure of Synagis Fab	9	N	Y
4	6,913,750	TTherapeutic compounds structurally-linked to bacterial polypeptides	31	Y	Y
5	6,908,613	TChimeric human papillomavirus (HPV) L1 molecules and uses therefor	7	N	Y
6	6,887,480	TStreptococcus pneumoniae proteins and vaccines	10	N	Y
7	6,863,893	TDerivatives of choline binding proteins for vaccines	31	Y	Y
8	6,858,706	TPolypeptide comprising the amino acid of an N-terminal choline binding protein a truncate, vaccine derived therefrom and uses thereof	46	Y	Y
9	6,855,493	TMethods of administering/dosing anti-RSV antibodies for prophylaxis and treatment	143	Y	Y

(9) Amylin Pharma Inc. (Mkt Cap = $5.7 Billion)

Results of Search in US Patent Collection db for:
AN/"Amylin Pharmaceuticals" AND ISD/1/1/2005->12/31/2005: 9 patents.

Summary:	
No. of Drug Patents:	9
Average No. of disclosures Per Patent:	44.6
Percentage of Patents with >20 disclosures:	77.78%
Percentage of Patents with at least 1 disclosure with > 25 pgs:	100.00%

List No.	PAT. NO.	Title	No. of Disclosures	>20 Disclosures (Y/N)	Any Refs > 25 pgs (Y/N)
1	6,956,026	TUse of exendins for the reduction of food intake	62	Y	Y
2	6,936,584	TMixed amylin activity compounds	67	Y	Y
3	6,924,264	TModified exendins and exendin agonists	54	Y	Y
4	6,902,744	TExendin agonist formulations and methods of administration thereof	44	Y	Y
5	6,894,024	TTreatment of hibernating myocardium and diabetic cardiomyopathy with a GLP-1 peptide	8	N	Y
6	6,884,579	TGLP-1 as a diagnostic test to determine .beta.-cell function and the presence of the condition of IGT and type-II diabetes	7	N	Y
7	6,872,700	TMethods for glucagon suppression	52	Y	Y
8	6,858,576	TMethods for regulating gastrointestinal motility	52	Y	Y

9	6,852,690	Method and composition for enhanced parenteral nutrition	55	Y	Y

(10) Invitrogen Corp. (Mkt Cap = $3.6 Billion)

Results of Search in US Patent Collection db for:
AN/Invitrogen AND ISD/1/1/2005->12/31/2005: 16 patents.

Summary:	
No. of Drug Patents:	16
Average No. of disclosures Per Patent:	85.6
Percentage of Patents with >20 disclosures:	87.50%
Percentage of Patents with at least 1 disclosure with > 25 pgs:	87.50%

List No.	PAT. NO.	Title	No. of Disclosures	>20 Disclosures (Y/N)	Any Refs > 25 pgs (Y/N)
1	6,977,295	Locked nucleic acid hybrids and methods of use	49	Y	Y
2	6,964,861	Enhanced in vitro recombinational cloning of using ribosomal proteins	471	Y	Y
3	6,960,464	Methods for lyophilizing competent cells	75	Y	Y
4	6,936,150	Methods and apparatus for electrophoresis of prior-cast, hydratable separation media	70	Y	Y
5	6,933,121	Use of predetermined nucleotides having altered base pairing characteristics in the amplification of nucleic acid molecules	27	Y	N
6	6,924,098	Nucleic acid ladders	46	Y	Y
7	6,916,632	Methods and reagents for molecular cloning	115	Y	Y
8	6,916,423	Device and methods for subdividing and filtering gel material and extracting molecules therefrom	18	N	Y
9	D506,554	Gel cassette opener	7	N	N
10	6,905,858	Nucleic acid-free thermostable enzymes and methods of production thereof	48	Y	Y
11	6,890,554	Genetic immunization with cationic lipids	97	Y	Y
12	6,878,551	Materials for enhancing staining of biopolymers in matrices	36	Y	Y
13	6,875,857	Reagent for the isolation of RNA	46	Y	Y
14	6,875,568	Method for isolating and recovering target DNA or RNA molecules having a desired nucleotide sequence	77	Y	Y
15	6,855,494	Method for increasing viability and transformation efficiency of bacteria during storage at low temperatures	114	Y	Y
16	6,838,238	Morphatides: novel shape and structure libraries	73	Y	Y