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From: JENJ (Jennifer Johnson)

Sent: Friday, September 08, 2006 2:22 PM

To: AB95 Comments

Cc: JENJ (Jennifer Johnson)

Subject: ZymoGenetic's Comments to Propose Rules on IDS practice

Importance: High

Attn: Hiram H. Bernstein

Senior Legal Advisor

Office of Patent Legal Administration

Office of the Deputy Commissioner for Patent Examination Policy

Dear Mr. Bernstein,

Please post the attached .pdf on the Comments Regarding Proposed Rules for "Changes to Information Disclosure Statements Requirements and other Related Matters" [71 *Fed. Reg.* 38808] (July 10, 2006).

Sincerely,

Jennifer K. Johnson

<<ZGEN IDS Comments to PTO 09-08-06.pdf>>

Jennifer K. Johnson

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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

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/11/515mkt.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	T Separate-clstron contracts for secretion of aglycosylated antibodies from prokaryotes	95	Y	Y
2	6,974,798	T Treatment of balance impairments	118	Y	Y
3	6,974,696	T PRO853 nucleic acids	24	Y	Y
4	6,974,689	T Nucleic acid encoding PRO211 polypeptides	50	Y	Y
5	6,972,325	T PRO273 polypeptides	6	N	Y
6	6,972,186	T Nucleic acid encoding pro 1410 polypeptides	28	Y	Y
7	6,972,185	T Nucleic acids encoding PRO844 polypeptides	7	N	Y
8	6,969,758	T Secreted and transmembrane polypeptides and nucleic acids encoding the same	39	Y	Y
9	6,967,245	T UCP5	70	Y	Y
10	6,967,241	T Process for protein extraction	12	N	Y
11	6,965,015	T Secreted and transmembrane polypeptides and nucleic acids encoding the same	21	Y	Y
12	6,965,011	T Secreted and transmembrane polypeptides and nucleic acids encoding the same	18	N	Y

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

58	6,878,807	T Secreted and transmembrane polypeptides and nucleic acids encoding the same	9	N	Y
59	6,875,567	T Method of detecting cardiac hypertrophy through probe hybridization and gene expression analysis	102	Y	Y
60	6,875,432	T Reduced-viscosity concentrated protein formulations	14	N	Y
61	6,872,735	T LFA-1 antagonist compounds	8	N	Y
62	6,872,704	T Acidic mammalian proteins and polynucleotides encoding the same	64	Y	Y
63	6,870,034	T Protein purification	29	Y	Y
64	6,870,033	T Antibody fragment-polymer conjugates and humanized anti-IL-8 monoclonal antibodies	111	Y	Y
65	6,867,213	T (2S)-2-(adamantan-1-ylmethoxycarbonylamino)-3-(4-(2-(1,4,5,6-tetrahydropyrimidin-2-ylcarbamoyl)ethyl)benzoylamino)propionic acid isopropyl ester, its preparation and its use	2	N	Y
66	6,867,208	T Vitronectin receptor antagonists, their preparation and their use	9	N	Y
67	6,858,427	T Sphingosine kinases	25	Y	Y
68	6,855,508	T ELISA for VEGF	77	Y	Y
69	6,852,848	T Secreted and transmembrane polypeptides and nucleic acids encoding the same	81	Y	Y
70	6,838,479	T 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	T Polyol/oil suspensions for the sustained release of proteins	56	Y	Y
2	6,977,264	T Substituted piperidines and methods of use	13	N	Y
3	6,974,672	T Gene amplification in cancer	140	Y	Y
4	6,967,254	T Substituted heterocyclic compounds and methods of use	18	N	Y
5	6,967,029	T Method for increasing hematopoietic progenitor cells by stem cell factor	120	Y	Y
6	6,964,967	T Substituted pyrido[2,3-d]pyrimidines and methods for their use	30	Y	Y
7	6,964,765	T Inhibitors of apoptosis	18	N	Y
8	6,956,105	T Chandra: a Th1-specific protein	22	Y	Y
9	6,956,027	T N-terminally chemically modified protein compositions and methods	129	Y	Y
10	6,949,366	T Cytokines that bind the cell surface receptor hek	30	Y	Y
11	6,946,264	T Metalloproteinase inhibitor	105	Y	Y
12	6,943,238	T Antibodies to cyclin E2 protein	84	Y	Y
13	6,939,874	T Substituted pyrimidinyl derivatives and methods of use	54	Y	Y
14	6,936,439	T OB fusion protein compositions and methods	96	Y	Y
15	6,921,762	T Substituted indolizine-like compounds and methods of use	19	N	Y
16	6,919,426	T Peptides and related molecules that modulate nerve growth factor activity	6	N	Y
17	6,919,176	T Polypeptides and nucleic acids associated with cancer	32	Y	Y
18	6,908,935	T Calcium receptor modulating agents	52	Y	Y
19	6,906,069	T LXR modulators	27	Y	Y
20	6,904,369	T 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	T Phosphatases which activate map kinase pathways	265	Y	Y
22	6,884,782	T STAT modulators	57	Y	Y

23	6,881,737	T Substituted triazinyl acrylamide derivatives and methods of use	18	N	Y
24	6,881,542	T Serine threonine kinase member, h2520-59	12	N	Y
25	6,878,714	T Substituted alkylamine derivatives and methods of use	39	Y	Y
26	6,869,925	T Inhibition of retrovirus infection	113	Y	Y
27	6,864,255	T Substituted triazinyl amide derivatives and methods of use	30	Y	Y
28	6,858,619	T Fused heterocyclic compounds	48	Y	Y
29	6,858,409	T Nucleic acids encoding interleukin-1 inhibitors and processes for preparing interleukin-1 inhibitors	158	Y	Y
30	6,855,815	T Inhibitors of apoptosis	17	N	Y
31	6,852,839	T Fhm, a novel member of the TNF ligand supergene family	77	Y	Y
32	6,852,313	T Method of stimulating growth of melanocyte cells by administering stem cell factor	129	Y	Y
33	6,849,639	T Integrin inhibitors and their methods of use	76	Y	Y
34	6,849,450	T Antibodies to the metalloproteinase inhibitor	112	Y	Y
35	6,849,260	T Methods and compositions for treating IgE-related disease using NNT-1 inhibitors	19	N	Y
36	6,846,834	T Antiinflammation agents	25	Y	Y
37	6,841,147	T Stem cell factor compositions	56	Y	Y
38	6,838,454	T 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	T Non-homogeneous systems for the resolution of enantiomeric mixtures	77	Y	Y
2	6,962,784	T Vascular endothelial growth factor (VEGF) nucleic acid ligand complexes	48	Y	Y
3	6,939,965	T Process of manufacture of 1,3-oxathiolane nucleosides using titanium trichloride mono-isopropoxide	53	Y	Y
4	6,933,116	T Nucleic acid ligand binding site identification	57	Y	Y
5	6,933,114	T Nucleic acid ligands to the prostate specific membrane antigen	32	Y	Y
6	6,914,138	T Urea nucleosides as therapeutic and diagnostic agents	66	Y	Y
7	6,855,496	T Truncation SELEX method	27	Y	Y
8	6,846,918	T 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	Any Refs > 25 pgs (Y/N)
				Disclosures (Y/N)	
1	6,972,176	T KVLQT1--a long QT syndrome gene	49	Y	Y
2	6,969,728	T Modulators of TNF-.alpha. signalling	34	Y	Y
3	6,955,806	T Ionene polymers and their use as antimicrobial agents	86	Y	Y
4	6,943,154	T Water insoluble derivatives of polyanionic polysaccharides	42	Y	Y
5	6,923,986	T Multiblock biodegradable hydrogels for drug delivery and tissue treatment	79	Y	Y
6	6,916,802	T Amino ceramide-like compounds and therapeutic methods of use	59	Y	Y
7	6,911,216	T Targeted delivery via biodegradable polymers	83	Y	Y
8	6,903,220	T Synthesis of chiral 2-alkyl amino acids	49	Y	Y
9	6,890,523	T Anionic polymers as toxin binders and antibacterial agents	71	Y	Y
10	6,878,828	T Synthesis of 2-alkylcysteine via substituted thiazoline ester	47	Y	Y
11	6,875,883	T Synthesis of benzonitriles from substituted benzaldehyde	45	Y	Y
12	6,875,882	T Synthesis of benzonitriles from substituted benzoic acid	47	Y	Y
13	6,875,428	T Lipase inhibiting polymers	63	Y	N
14	6,867,288	T Polycystic kidney disease gene	5	N	N
15	6,861,532	T Synthesis of 2-alkylcysteine	47	Y	Y
16	6,861,408	T Therapeutic anti-melanoma compounds	114	Y	Y
17	6,858,592	T Aryl boronic acids for treating obesity	81	Y	Y
18	6,858,425	T Human acid alpha glucosidase gene and bovine alpha-S1 casein gene sequences	7	N	Y
19	6,858,203	T Method of making phosphate-binding polymers for oral administration	73	Y	Y
20	6,855,830	T Synthesis of UDP-glucose: N-acylsphingosine glucosyltransferase inhibitors	22	Y	Y
21	6,846,958	T Synthesis of benzimidate from benzoic acid	43	Y	Y
22	6,841,153	T 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	Any Refs > 25 pgs (Y/N)
				Disclosures (Y/N)	
1	6,962,978	T Polymer conjugates of interferon beta-1a and uses	41	Y	Y
2	6,955,810	T Method for the treatment of inflammatory disorders	9	N	N
3	6,949,534	T Cell adhesion inhibitors	62	Y	Y
4	6,943,146	T Method for promoting neovascularization	78	Y	Y
5	6,897,297	T Hydrophobically-modified protein compositions and methods	25	Y	Y
6	6,897,044	T Production of tetravalent antibodies	44	Y	Y
7	6,896,885	T Combined use of anti-cytokine antibodies or antagonists and anti-CD20 for treatment of B cell lymphoma	64	Y	Y
8	6,893,636	T Gamma-1 and gamma-3 anti-human CD23 monoclonal antibodies and use thereof as therapeutics	153	Y	Y
9	6,875,846	T Heterologous polypeptide of the TNF family	40	Y	Y
10	6,875,743	T Cell adhesion inhibitors	85	Y	Y
11	6,869,605	T BAFF, inhibitors thereof and their use in the modulation of B-cell response	63	Y	Y
12	6,861,509	T 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	T Process and intermediates for resolving piperidyl acetamide stereoisomers	36	Y	Y
2	6,962,940	T (+)-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	T Compositions and methods for the treatment of colorectal cancer	53	Y	Y
4	6,911,464	T N-alkyl-hydroxamic acid-isoindolyl compounds and their pharmaceutical uses	1	N	N
5	6,908,432	T 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	T 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	T 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	T Method for carrying out a biochemical protocol in continuous flow in a microreactor	27	Y	Y
2	6,960,441	T Assays for the detection of human defensin polypeptide (Def-X)	19	N	Y
3	6,955,902	T 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	T IN 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	T Methods of priming the immunogenic activity of vaccines useful for eliciting a protective immune response	11	N	Y
3	6,955,717	T Crystals and structure of Synagis Fab	9	N	Y
4	6,913,750	T Therapeutic compounds structurally-linked to bacterial polypeptides	31	Y	Y
5	6,908,613	T Chimeric human papillomavirus (HPV) L1 molecules and uses therefor	7	N	Y
6	6,887,480	T Streptococcus pneumoniae proteins and vaccines	10	N	Y
7	6,863,893	T Derivatives of choline binding proteins for vaccines	31	Y	Y
8	6,858,706	T Polypeptide 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	T Methods 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	T Use of exendins for the reduction of food intake	62	Y	Y
2	6,936,584	T Mixed amylin activity compounds	67	Y	Y
3	6,924,264	T Modified exendins and exendin agonists	54	Y	Y
4	6,902,744	T Exendin agonist formulations and methods of administration thereof	44	Y	Y
5	6,894,024	T Treatment of hibernating myocardium and diabetic cardiomyopathy with a GLP-1 peptide	8	N	Y
6	6,884,579	T GLP-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	T Methods for glucagon suppression	52	Y	Y
8	6,858,576	T Methods for regulating gastrointestinal motility	52	Y	Y

9 6,852,690 **T**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	T Locked nucleic acid hybrids and methods of use	49	Y	Y
2	6,964,861	T Enhanced in vitro recombinational cloning of using ribosomal proteins	471	Y	Y
3	6,960,464	T Methods for lyophilizing competent cells	75	Y	Y
4	6,936,150	T Methods and apparatus for electrophoresis of prior-cast, hydratable separation media	70	Y	Y
5	6,933,121	T Use of predetermined nucleotides having altered base pairing characteristics in the amplification of nucleic acid molecules	27	Y	N
6	6,924,098	T Nucleic acid ladders	46	Y	Y
7	6,916,632	T Methods and reagents for molecular cloning	115	Y	Y
8	6,916,423	T Device and methods for subdividing and filtering gel material and extracting molecules therefrom	18	N	Y
9	D506,554	T Gel cassette opener	7	N	N
10	6,905,858	T Nucleic acid-free thermostable enzymes and methods of production thereof	48	Y	Y
11	6,890,554	T Genetic immunization with cationic lipids	97	Y	Y
12	6,878,551	T Materials for enhancing staining of biopolymers in matrices	36	Y	Y
13	6,875,857	T Reagent for the isolation of RNA	46	Y	Y
14	6,875,568	T Method for isolating and recovering target DNA or RNA molecules having a desired nucleotide sequence	77	Y	Y
15	6,855,494	T Method for increasing viability and transformation efficiency of bacteria during storage at low temperatures	114	Y	Y
16	6,838,238	T Morphatides: novel shape and structure libraries	73	Y	Y