From: Chris Walsh
Sent: Wednesday, April 09, 2008 7:44 PM
To: Markush-irfa.comments; Markush.Comments
Subject: Comments on proposed rule and IRFA for Examination of Patent Applications That Include Claims Containing Alternative Language

Sir or Madam:

Attached please find comments from Genentech, Inc. and Curis, Inc. on the IRFA and NPRM entitled "Examination of Patent Applications That Include Claims Containing Alternative Language."

Respectfully submitted,

Genentech, Inc.

Christopher J. Walsh, Ph.D., J.D.
Patent Counsel
Genentech, Inc.
1 DNA Way, MS#49
South San Francisco, CA 94080-4990

Phone: (650) 467-3417
Fax: (650) 952-9881
Email: walsh.christopher@gene.com

Joan Mazzeo, Patent Assistant
(650) 467-0442

Genentech
IN BUSINESS FOR LIFE

1 DNA Way
South San Francisco, CA 94080-4990
(650) 225-1000
www.gene.com

CURIS

45 Moulton Street
Cambridge, MA 2138
(617) 503-6500
www.curis.com

April 9, 2008

By electronic mail – markush-irfa.comments@uspto.gov

Attn: Kathleen Kahler Fonda
U.S. Patent and Trademark Office

Re: Initial Regulatory Flexibility Analysis for Proposed Rules Entitled "*Examination of Patent Applications That Include Claims Containing Alternative Language*," 73 Fed. Reg. 12679 (March 10, 2008)

Dear Ms. Fonda:

Genentech and Curis welcome the opportunity to comment jointly on the above-captioned Initial Regulatory Flexibility Analysis ("IRFA"). We also update earlier filed comments on the above-captioned Notice for the proposed rules.

The Genentech-Curis collaboration brings life-saving cancer medicines to patients and would not be possible without strong, affordable patent protection. Genentech is a leading biotechnology company that seeks strategic relationships with innovative small entities.[1] Curis is a highly innovative company seeking to leverage its drug discovery efforts through strategic partnerships.[2] The Genentech-Curis collaboration was formed by licensing strategic patent rights covering potential medicines for treating life-threatening cancers.[3] The collaboration has resulted in clinical trials of a potential first- and best-in-class drug for the treatment of patients suffering from a variety of cancers.[4] The Genentech-Curis collaboration is a leading example of a collaboration that is founded upon affordable patent protection for innovative small molecule medicines.

---

[1] Genentech is among the world's leading biotechnology companies and invests over 20% of operating revenues in research and development, with over 100 programs in the pipeline. *See* http://www.gene.com/gene/pipeline/status/.

[2] Curis focuses its innovative drug development program on important medical fields with substantial unmet therapeutic needs. *See* http://www.curis.com/our_science.php.

[3] Daniel S. Levine, *Genentech, Curis team up on cancer drugs*, SAN FRANCISCO BUS. TIMES, Apr. 4, 2005, *available at* http://www.bizjournals.com/sanfrancisco/stories/2005/04/04/daily5.html.

[4] *Genentech, Curis move cancer drug toward Phase 2 trials*, EAST BAY BUS. TIMES, Mar. 14, 2008, *available at* http://www.bizjournals.com/eastbay/stories/2008/03/10/daily80.html?ana=from_rss.

Genentech and Curis urge the Office to refrain from implementing the proposed rules for at least the following three reasons:

- The proposed rules restrict substantive rights of applicants, which under Federal Circuit precedent, the Office cannot legally do by regulation.[5]

- The initial cost analysis ignores the broad applicability of these rules to chemical cases and thereby underestimates the additional cost burden associated with the proposed rules. The Office should perform another analysis with the appropriate methodology.

- The Office states that alternative claim language exacerbates problems with pendency. However, Technology Center 1620 (Organic Chemistry), where alternative language pervades nearly every case, has one of the lowest pendency and inventories of the Office.[6]

I. The Proposed Rules Affect an Applicant's Substantive Rights and the Office Has No Authority to Promulgate Such Rules Under *Tafas v. Dudas*

The proposed rules improperly seek to regulate an applicant's substantive right to determine claim form. The *Tafas* court defined a "substantive rule" as any rule that "affect[s] individual rights and obligations."[7] Courts have recognized that applicants have a substantive right to present claims using any language that best describes their invention.

> An applicant is given, by the statute, the right to claim his invention with the limitations he regards as necessary to circumscribe that invention, with the proviso that the application comply with requirements of § 112. We have decided that § 112, second paragraph, … allows the inventor to claim the invention as he contemplates it.[8]

"The right of applicants to freedom of choice in selecting phraseology which truly points out and defines their inventions should not be abridged."[9] This right of applicants extends to alternative claim language format.[10]

---

[5] *Merck & Co., Inc. v. Kessler*, 80 F.3d 1543 (Fed. Cir. 1996); *see also Animal Legal Defense Fund v. Quigg*, 932 F.2d 920 (Fed. Cir. 1991); *Tafas v. Dudas* 2008 WL 859467, Case No. 1:07-cv-00846-JCC-TRJ, at *4 (Apr. 1, 2008 E.D. Va.) ("Under Federal Circuit precedent, however, Section 2(b)(2) does not vest the USPTO with any general substantive rulemaking power.")

[6] Commissioner John Doll, Chicago Town Hall Meeting, slides 12-14, Feb. 1, 2006, *available at* http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/focuspp.html.

[7] *Tafas,* 2008 WL 859467 at *17 (quoting *Chrysler Corp. v. Brown*, 441 U.S. 281 (1979)).

[8] *In re Weber*, 580 F.2d 455, 458 (C.C.P.A. 1978) (*citing In re Wolfrum*, 486 F.2d 588, 179 USPQ 620 (C.C.P.A. 1973)).

[9] *In re Chandler*, 319 F.2d 211, 225 (C.C.P.A. 1963).

[10] *Ex parte Markush*, 1925 C.D. 126 (Comm'r Pat. 1925); *see also In re Harnisch*, 631 F.2d 716 (C.C.P.A. 1980).

The proposed rules improperly seek to restrict an applicant's right to select the appropriate format of claims with alternative language. The Notice states that "the Office proposes to require a simplified format for the presentation of such claims *to set forth conditions that must be met by any claim that uses alternative language*."[11] For example, "the Office proposes to specify that no alternative may itself be defined as a set of further alternatives."[12]

The Office cites "the administrative difficulties that arise during the search and examination of claims that present species using alternative language" as justification for the proposed rules.[13] However, the court in *Weber* decided that "in drawing priorities between the Commissioner as administrator and the applicant as beneficiary of his statutory rights, we conclude that the statutory rights are paramount."[14]

The proposed rules affect applicant's substantive right to describe the invention succinctly by prohibiting nested-alternative language. As the *Tafas* court held, "any rules that may be deemed substantive will be declared null and void."[15]

II. The Office's Analysis Lacks Transparency and Underestimates the Costs to Small Entities, Particularly, Those Small Entities In the Pharmaceutical and Chemical Arts

A. The biotech (large molecule) and chemical (small molecule) arts rely differently on complex alternative claim language and should not be grouped together

Nearly every small molecule (chemical) case with compound claims is affected by the proposed rules and the Office's analysis does not reflect this fact. Advancements in rapid small molecule design, synthesis and combinatorial screening have generated prolific, complex small molecule inventions. Nested alternative claim language succinctly describes these complex inventions. In contrast, many large molecule (biotech) cases covering nucleic acids, polypeptides and cell types use simple alternative claim language. Nested alternative claim language is often not needed to succinctly describe large molecule (biotech) inventions.

The Office likely underestimates the cost impact of the proposed rules by grouping together the biotech and chemical arts. The Office sampled 102 cases from the combined biotech/chemical arts.[16] The Office calculated that only 18 % of the combined bio/chem cases would incur costs under the proposed rules.[17] This number grossly underestimates the cost impact of the proposed rules in the chemical arts because it includes biotech cases.

---

[11] 72 Fed. Reg. 44996 (Aug. 10, 2007) (emphasis added).
[12] *Id.*
[13] *Id.*
[14] *Weber*, 580 F.2d at 458.
[15] *Tafas*, 2008 WL 859467 at *6.
[16] 73 Fed. Reg. 12682 (March 10, 2008).
[17] *Id.*

We performed an analysis of 50 recently issued U.S. patents in the chemical arts that use alternative claim language.[18] Our analysis showed that 64 % of those patents contain claims in which alternatives are defined as a set of further alternatives or else employ overlapping alternatives in violation of the proposed rules.[19] Importantly, 78 % of the patents covering new chemical entities would have run afoul of the proposed rules and therefore would have incurred additional costs during prosecution in order to bring them into compliance.

We believe the estimated cost impact of the proposed rules lacks validity as evidenced by our analysis. Grouping biotech and chemical cases together grossly underestimates the number of affected cases. Many biotech inventions may not require complex alternative language, but nearly all chemical cases covering new compounds are impacted by the proposed rules. The Office should distinguish between biotech (large molecule) and chemical (small molecule) cases to achieve a more valid analysis.

B. The AIPLA cost estimates employed by the Office are not appropriate for estimating the cost of compliance with the proposed rules

In collecting cost data, AIPLA estimated the cost of a "typical case with no unusual complications."[20] First, complying with the proposed rules in existing cases would require unusually complicated amendments. Removing nested alternative language is expected to be extremely time consuming. All of the alternatives would have to be listed serially. There is no precedent for estimating the cost, but it is expected to be far higher than a "typical case with no unusual complications."

Likewise, filing divisional applications under the proposed rules will be more complicated than a "typical case" considered by the AIPLA estimates. Listing all of the alternatives serially will be required in both the specification and the claims. The time required for producing and proof-reading the exhaustive listings of alternatives is expected to be great. The exhaustive listings of alternatives will increase page counts and increase filing fees.

Additionally, the Office should estimate the cost impact of drafting new cases under the proposed rules. Again, there is no precedent for estimating these costs but experience suggests that the legal costs will be far higher than the Office estimates using the AIPLA numbers.

---

[18] We analyzed 50 U.S. patents, recently issued in sequence, from Class 514 that employ alternative claim language.

[19] Every case impacted by the proposed rules in our sample analysis of class 514, with one exception, employs nested alternative claim language. The one exception employs overlapping variables.

[20] AM. INTELLECTUAL PROPERTY LAW ASS'N, *Descriptions of Statistics and Formatting Conventions*, AIPLA REPORT OF THE ECONOMIC SURVEY 2 (2007).

III. The IRFA Should Include the Proposed IDS Rules In Estimating the Cost Impact of the Proposed Rules Covering Alternative Claim Language

The proposed IDS rules[21] are expected to impose a great economic impact on small entities.[22] The Office should estimate the cost of complying with the proposed Markush rules, in combination with the costs of the proposed IDS rules. These two rule packages are related and create a complex regulatory framework that greatly increases the cost of protecting new small molecule medicines. In combination, the proposed IDS and Markush rules are expected to make application filings prohibitively expensive for small entities. The Office should estimate the combined cost impact of these two rule packages.

IV. Restricting Markush Practice Will Not Reduce Office Backlog Because the Greatest Backlog Is In Technology Centers That Do Not Rely On Complex Alternative Claim Language

Different art areas rely differently on alternative claim language. Chemical cases rely on complex alternative claim language−the language the Office seeks to abolish−to the greatest extent. To the extent electrical and mechanical cases employ alternative claim language, simple alternative language is usually sufficient.

Of the 95,000 small entity applications analyzed by the Office, only 21,000 (22 %) are in the biotech and chemical arts, while the remaining 73,000 (78 %) are in the electrical and mechanical arts.[23] The Office's analysis shows that only 15 % of electrical and mechanical cases filed by small entities include alternative language.[24] But these are the art areas that have the greatest backlogs. Technology Center 2611 (Interactive Video) has one of the highest backlogs in the Office (over 50 months to first action), but the proposed rules do little to facilitate clearing this backlog. Interactive video cases do not rely on the complex alternative claim language the Office targets in the proposed rules.

In comparison, 43 % of all biotech and chemical cases, filed by small entities, include alternative claim language.[25] And it is in the chemical arts, particularly, where complex alternative claim language is absolutely necessary. But Technology Center 1620 (Organic Chemistry, Heterocycles, etc.), where complex alternative language is most prevalent, has one of the lowest pendency and inventories of the Office (17 months to first action).[26] The Office's numbers just don't add up. The biotech and chemical

---

[21] 71 Fed. Reg. 38808 (July 10, 2006).
[22] For a recent analysis, *see* Richard B. Belzer, *Cost of Complying with the Proposed IDS Rule*, *available at* http://www.whitehouse.gov/omb/oira/0651/meetings/663.pdf (last accessed Apr. 4, 2008).
[23] 71 Fed. Reg. 38808 (July 10, 2006).
[24] *Id.*
[25] The Office is again urged to separate out chemical cases from biotech cases in its final analysis. Our analysis of patents recently issued in Class 514 shows that the vast majority of these cases use alternative claim language. Chemical cases are uniquely affected by these rule packages, and the Office's cost analysis should reflect this fact.
[26] Commissioner John Doll, Chicago Town Hall Meeting, slides 12-14, February 1, 2006, *available at* http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/focuspp.html.

cases filed by small entities with complex alternative claim language are a fraction of the Office's caseload, and the Technology Centers examining these cases have the lowest backlog. We urge the Office to reconsider the proposed rules because they will not facilitate clearing the Office's backlog.

V. The Office Has the Tools Necessary to Deal With Abusive Complex Alternative Claim Language And the Proposed Rules Detract From Substantive Examination

When faced with abusive complex alternative claim language, the Office should issue statutory-based rejections.

> If the language of the claim is such that a person of ordinary skill in the art could not interpret the metes and bounds of the claim so as to understand how to avoid infringement, a rejection of the claim under 35 U.S.C. 112, second paragraph, would be appropriate.[27]
>
> If the claim is too broad because it is not supported by the original description or by an enabling disclosure, a rejection under 35 U.S.C. 112, first paragraph, would be appropriate. If the claim is too broad because it reads on the prior art, a rejection under either 35 U.S.C. 102 or 103 would be appropriate.[28]

However, "a claim may not be rejected solely because of the *type of language* used to define the subject matter for which patent protection is sought."[29]

The complex regulatory framework of the proposed rules will detract from substantive examination under the Patent Statutes. Examination will focus on the *form* of claims, not the *scope* of claims. Public policy is not served by the new rules because they detract from substantive examination and put claim form before claim substance.

VI. The Office Should Reform Examiner Incentives and Allow Greater Time to Examine More Complex Patent Applications

More applications require more examiners not more regulations. The Office should reform the quota system to retain more of its best examiners. About two-thirds of examiners that leave list the quota system, not private sector opportunities, as the biggest reason for leaving.[30] The Government Accounting Office has concluded that "the root of this high level of attrition appears to be the stress resulting from the agency's outdated

---

[27] M.P.E.P. § 2173.02 (Aug. 2006), citing *Morton Int'l, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464 (Fed. Cir. 1993).
[28] M.P.E.P. § 2173.04 (Aug. 2006).
[29] *In re Swinehart*, 439 F.2d 210 (C.C.P.A. 1971) (emphasis added).
[30] Stephen Barr, *Backlog, Quotas Overwhelm Patent Examiner*, WASH. POST, Oct. 8, 2007, *available at* http://www.washingtonpost.com/wp-dyn/content/article/2007/10/07/AR2007100701199.html.

production goals."[31] Complex technology begets complex patent applications and examining greater numbers of complex applications requires more Office time and better employee incentives, not more government regulation.

VII. Conclusions

Genentech and Curis appreciate the opportunity to comment on the Office's IRFA analysis and proposed rules. We urge the Office not to finalize the proposed rules after the *Tafas v. Dudas* decision, as they improperly affect substantive rights of applicants. The proposed rules will not facilitate clearing the backlog and the Office has all the tools needed to deal with abusive alternative claim language. We urge the Office to consider focusing reform efforts on its human resources and not on complicated and elaborate rule making.

The Genentech-Curis collaboration is a leading example of collaborations in the drug discovery industry. Such collaborations are essential for bringing new treatments to patients. However, they rely on strong, affordable patent protection. The Office should not hinder these partnerships, or their discovery efforts, by increasing their costs with complex government regulations. The proposed rules would do just that, and the Office is urged not to implement them.

Sincerely,

Genentech, Inc.

/Christopher J. Walsh/
Christopher J. Walsh, Ph.D., J.D.
Patent Counsel
Reg. No. 55,709

/Timothy Schwartz/
Timothy Schwartz, Ph.D., J.D.
Associate General Counsel
Reg. No. 32,171

Curis, Inc.

/Daniel Passeri/
Daniel Passeri, M.Sc., J.D.
President & CEO
Reg. No. 39,325

/Mark Noel/
Mark Noel
Vice President - Technology Management
& Business Development
Reg. No. 32,162

[31] U. S. GOV'T ACCOUNTING OFFICE, GAO-07-1102, HIRING EFFORTS ARE NOT SUFFICIENT TO REDUCE THE PATENT APPLICATION BACKLOG (2007), *available at* http://www.gao.gov/new.items/d071102.pdf.