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From: Chris Walsh

Sent: Tuesday, October 09, 2007 3:12 PM

To: Markush.Comments

Subject: Comments on the NPRM: Examination of Patent Applications That Include Claims Containing Alternative Language

Sirs:

Attached please find comments from Genentech, Inc. for the NPRM entitled **Examination of Patent Applications That Include Claims Containing Alternative Language.**

Respectfully submitted,

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October 9, 2007

Mail Stop **Comments–Patents**
Commissioner for Patents
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Alexandria, Virginia 22313-1450

Re: *Examination of Patent Applications That Include Claims Containing Alternative Language*, 72 Fed. Reg. 44992 (August 10, 2007) – Docket No. PTO-P-2006-0004

Sir:

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

I. Genentech Relies On Strong Patent Protection To Bring Novel, Life-Saving Therapies To The Market

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

Genentech invests over a billion dollars annually in research and development, in both “biotech” and “small molecule” programs. Strong patent protection is essential in recouping that investment, encouraging innovation, and sustaining future research and development. Procuring issued patents in a timely manner is important, but it is also essential to the biotechnology and pharmaceutical industries to secure claims that fairly cover the full scope of inventions examined and granted.

II. The Proposed Rules Will Increase The Number Of Applications Needed To Protect Broad Small-Molecule Pharmaceutical Inventions And Will Substantially Increase Total Pendency for These Inventions.

In the search for cures to complex diseases, modern drug discovery employs advanced technology. Many novel and diverse chemical entities are rapidly prepared and screened using advanced technology. The patent system must allow for simple and efficient means of protecting these potential life-saving medicines.

Genentech supports the Office's efforts to make patent examination efficient and effective. Strong patent protection facilitates drug discovery, and ultimately, facilitates cures for diseases that previously could not be treated effectively.

The Office faces difficult administrative challenges including an unprecedented number of patent application filings. We acknowledge that efficient examination is challenging when applicants present complex Markush claims covering diverse chemical species. Administrative rule changes may be an appropriate response to these challenges.

Regrettably, the rule changes as proposed will only disperse related subject matter of a single invention over a larger number of divisional applications. Each application will be directed to a narrow aspect of the invention. In addition, the recently promulgated rules regarding numbers of claims actively discourage applicants from maintaining restricted, "rejoinable" subject matter (*e.g.*, a patentable product and a method of using the product) in a single application, since fewer claims would be available for properly covering each aspect of the invention.

The new examination model reflected in this and other recent rule packages will substantially increase the total effective pendency – the time from filing an original application until claims covering the full scope of the invention have been patented – for biopharmaceutical applicants. This new model may shorten the average pendency for any single application. However, effective pendency is a better measure of the Office's efficiency, for entities that depend on patent protection for their business, than is the pendency of any individual application.

The dispersal of claims across an increased number of divisional applications will also multiply the costs of patent procurement in a way that will become unreasonably burdensome, particularly for smaller innovators in the biotechnology industry.

III. The Proposed Rules Cannot Be Supported Because They Emphasize a Species-Based Examination Strategy at The Expense of Thorough Examination of Generic Inventions.

The focus on examining species embraced by a true generic claim, as reflected in proposed § 1.146, is not sound examination policy. As a matter of law and longstanding Office policy, the Office is obliged to examine the invention as the applicant claims it. A species-based examination diverts attention from the generic limitations that the applicant considers as defining a patentable advance. Importantly, the patentability of a generic claim does not depend exclusively on the patentability of any species that it may cover.

The diversion of focus that results from a species-based examination is not merely inefficient. Instead, it deprives the applicant, the public, and the Office of a fully developed record that treats the invention as claimed. Ultimately, the values of generic claims, and their underlying inventions, are diminished. In this regard, we find proposed § 1.146(b) particularly ill-advised because it has the potential to preclude an applicant from *ever* having the full scope of a generic claim fully examined.

A. *The Current Rules are Better Suited Than the Proposed Rules for Providing Quality Examination of Markush Claims*

The Office's current practice for examining generic claims is governed by existing § 1.146. Under that rule, the examiner may require an applicant to elect a species "to which his or her invention will be restricted if *no claim to the genus is found to be allowable*" (emphasis added). Accordingly, if a generic claim is found to be overbroad in some respect, the PTO will examine an amended generic claim and will limit the applicant to species claims only if "no claim to the genus" can be allowed. *See also* the language of current § 1.141(a) which the Office proposes to delete ("more than one species of an invention, not to exceed a reasonable number, may be specifically claimed in different claims in one national application, provided the application also includes an allowable claim generic to all the claimed species ...").

In contrast, proposed § 1.146(b) – which would apply to both true genus claims and claims reciting specific alternatives, such as Markush-type claims – would provide that the examiner could "require the applicant to restrict any claim that was subject to an election [of species] requirement ... to the one or more species that were searched and examined if *any species encompassed by the claim is not patentable*" (emphasis added). Thus, the Office proposes to dispense with examining any generic claim if it is able to identify any species within the scope of the claim that does not independently meet all of the requirements for patentability.¹

The Office's proposal to truncate the examination of generic claims upon the identification of any "unpatentable" species they encompass is simply bad policy. The public benefits when inventors secure patent protection that fairly corresponds to the full scope of patentable subject matter they invent and describe in their patent applications. Experience teaches that this scope of protection does not always correspond to the broadest original claims. The public interest, as well as the interests of applicants, is best served by maintaining an examination paradigm that allows the Office to ascertain the appropriate scope of generic protection for a generic invention.

Often, a generic claim will incidentally cover subject matter that was known in the prior art, but of which the applicant was unaware. In that situation, it is appropriate and fair for the

¹ Proposed § 1.146(a), relating to requirements for an election of species, states that the applicant may be required to elect "one *disclosed* species" for initial examination (emphasis added). Proposed § 1.146(b), concerning the restriction of claims to elected species based on the occurrence of unpatentable species covered by the generic claim, is not limited to species that are disclosed in the application. Thus, the proposed rule would allow the Office to decline to examine a generic claim based on an alleged failure to enable or describe any single species embraced by the claim.

applicant to excise such subject matter from the claims, permitting the Office to allow appropriately narrowed claims to issue. Alternatively, in some cases the Office is able to establish that initial claims are overbroad, as for example when the claims are not commensurate in scope with the enabling disclosure or the written description. In these instances, if the Office articulates the basis for a properly grounded rejection in a first Office action, the applicant can amend the claims to appropriately respond to the asserted patentability defect.

In either of the cases discussed above, the Office's current practice provides reasonable and practical limits on the resources that the examination of the claim will consume. In the typical scenario of a first nonfinal action and a second final action, at most the Office will have to examine the full scope of the original generic claim, and following amendment, the full scope of a narrowed generic claim. The applicant is entitled to these two examinations as a matter of right. 35 U.S.C. § 132(a).

B. The Proposed Rules Will Not Provide Thorough Examination of Generic Claims Under All the Statutory Requirements of Title 35

The practice of requiring an applicant to elect a species for initial examination makes sense, but only in the context of assessing patentability over the prior art. A determination that a species is not patentable compels a determination that a genus that includes the species is also not patentable. However, the reasoning does not hold up with respect to other substantive patentability requirements. For example, a generic claim may comply with the requirements of § 112 without necessarily enabling any particular species it encompasses. *See Capon v. Eshhar*, 418 F.3d 1349, 1359, 76 USPQ2d 1078, 105 (Fed. Cir. 2005) (citing *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 218 (C.C.P.A. 1976)). Thus, assessing, *e.g.*, enablement, utility, or written description on a species-by-species basis will not necessarily address the patentability of a generic claim as a whole.

For these reasons, the Office should continue to require an election of species with respect to generic claims for search purposes in appropriate circumstances. However, in accord with the objective of compact prosecution, the Office should examine the full scope of a generic claim with respect to all of the non-prior art requirements of Title 35 as part of a first action on the merits. This practice will allow the Office to conduct a systematic and efficient search of the prior art; apprise the applicant at an early stage of the inventions that may be pursued in divisional applications; and develop the best record in a patent on the appropriate extent of patent protection for a generic invention.

IV. The Proposed Rules Contravene Settled Law Regarding Markush Claim Drafting

A. The Proposed Rules Lack Basis in Law for Limiting the Number of Species a Markush Claim May Cover

As a justification for the rules it proposes, the Office cites the difficulty of examining Markush-format claims that encompass large numbers of species. We cannot agree either with the premise that broad Markush claims are somehow illegitimate, or with the assertion that the Office cannot reasonably search and examine any but the most simplistic claims.

At the outset, we note that the Office's concern with the number of species that a claim may encompass is irrelevant to questions of proper claim format and restriction practice. The caselaw makes clear that the test of whether a Markush claim is "proper" for examination is whether the members of the group bear an appropriate relationship to each other in the context of the invention, not the reach of the claim. As Judge Rich wrote, concurring in *In re Weber*, 580 F.2d 455, 561, 198 USPQ 328, 334 (C.C.P.A. 1978):

It is elementary patent law that the number of "species" "covered" by a patent having a generic claim is virtually without limit [T]he discretionary power to limit one application to one invention is no excuse at all for refusing to examine a broad generic claim no matter how broad, which means no matter how many independently patentable inventions may fall within it.

Nor does the number of species embraced by a Markush claim bear on whether the claim can be searched with a reasonable expenditure of examination resources. The rule package appears to be framed around the assumption that a search is always conducted using a species-by-species approach. But no chemical searcher would rationally take such an approach, and indeed it is not the way the Office currently searches claims defined by a structural genus.

Modern chemical databases – which comprehensively cover U.S. and foreign patent publications, as well as the full scope of the research literature – can be queried with reference to structural fragments, or combinations of structural fragments. If desired, result sets can be cross-referenced against keyword searches that are useful to identify, *e.g.*, uses or properties of the compounds described. Using such tools, an experienced patent searcher can quickly and efficiently search even an expansive chemical genus.² Certainly chemical claims that involve structurally dissimilar alternatives in a "core" structure become more cumbersome to search. But the Office already has an effective tool to address this concern in the form of the criterion noted with approval in the *Harnisch* decision, that a "single structural similarity" that should unify the subject matter of a claim. *See In re Harnisch*, 631 F.2d 716, 722, 206 USPQ 300, 305 (C.C.P.A. 1980).

B. The Justification Presented by the Office for the Proposed Rules was Soundly Rejected by the Harnisch Court

Harnisch provides illustrative criteria for determining whether a group of claimed compounds have "a community of properties justifying their grouping which [is] not repugnant to the principles of scientific classification." *Id.* at 722, 206 USPQ at 305. In the case of the

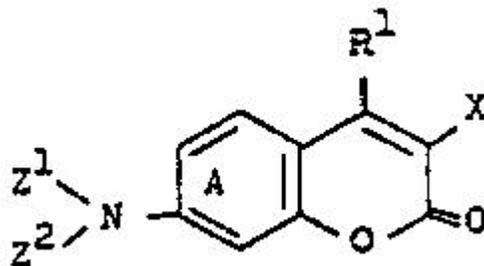
² An experienced patent examiner in any art will design a search to take account of the "components" of a claim that might be found in separate references, and which might be fairly combined to make a case that a claim reads on obvious subject matter. To be sure, a simple search for the novelty of any single species requires no such insight. We take no position here as to whether the Office can or should compartmentalize "search" and "examination" functions. However, we note that the current standard of Office practice is defined by the searches conducted by its examiners and the professional searchers in its library (STIC).

claims on appeal, the claimed coumarin compounds were held to exhibit a “single structural similarity” and the shared property of being dyes.

The Office proposes to provide by rule that a claim reciting species in the alternative will be limited to a “single invention” if (1) the species share a substantial feature essential for a common utility, or (2) the species are *prima facie* obvious over each other. See proposed § 1.140(a). The Office suggests that the first of these criteria is “based on the guidance provided ... in *In re Harnisch*.” 72 Fed. Reg. at 44996. This criterion, however, is nowhere to be found in the cited decision.

Harnisch contains no suggestion that a “substantial feature” that is common the members of a genus must be “essential” to a shared utility as a precondition of finding that the members of a Markush group share “unity of invention.” Indeed, the genus of the claims appealed in *Harnisch* itself appear not to meet the standards of the Office’s proposed § 1.140, as well as proposed § 1.75(j)(2) and (3). Appealed claim 1 was directed to:

Coumarin compounds which in one of their mesomeric limiting structures correspond to the general formula



wherein

X represents aldehyde, azomethine, or hydrazone,

R¹ represents hydrogen or alkyl,

Z¹ represents hydrogen, alkyl, cycloalkyl, aralkyl, aryl or a 2- or 3-membered alkylene radical connected to the 6-position of the coumarin ring and

Z² represents hydrogen, alkyl, cycloalkyl, aralkyl or a 2- or 3-membered alkylene radical connected to the 8-position of the coumarin ring

and wherein

Z¹ and Z² conjointly with the N atom by which they are bonded can represent the remaining members of an optionally benz-fused heterocyclic ring which, like the ring A and the alkyl, aralkyl, cycloalkyl and aryl radicals mentioned, can carry further radicals customary in dyestuff chemistry.

This claim would not satisfy proposed § 1.140 because there is no evidence that the shared structural feature – the coumarin nucleus – is by itself “essential” to the shared utility of use as a dye. As noted by the *Harnisch* court, “in determining the propriety of a Markush grouping the compounds must be considered as wholes and not broken down into elements or other components.” *Id.* at 722, 206 USPQ at 305. An underivatized coumarin nucleus would not

be useful as a dye because it would have no reactive groups. In other words, the parts of the claimed species that *differ* are “essential” to the shared utility.

Additionally, Harnisch’s claim would not meet proposed § 1.75(j)(2) (no alternative defined as a set of further alternatives) at least because Z^1 and Z^2 are defined with reference to further optional derivitization. The claim would also fail the standard of proposed § 1.75(j)(3) (no alternative encompassed by another alternative) at least because alkyl is generic to cycloalkyl and aralkyl.

As the Office notes, it has not received any guidance concerning Markush practice from its reviewing courts since the *Harnisch* decision. 72 Fed. Reg. at 44993. It therefore has no warrant to implement rules that would prohibit presentation of the very claims that the *Harnisch* court held to recite proper Markush groups.

The Office expresses its concern that applicants may turn to Markush-format claims to avoid the restrictions imposed by the recently promulgated limitations on the total numbers of claims presented for examination. So they may. But the concepts that actually correspond to the holding of *Harnisch* provide reasonable limits that would allow the Office to appropriately regulate the consumption of its examination resources.

C. The Proposed Rules Will Harm The Pharmaceutical Industry By Requiring Claims Narrower in Scope Than The Contributions Made To The Art

The Office asserts that its proposed rules are necessitated by a “volume and complexity of patent applications [that] continue to outpace the examining corps’ current capacity to examine them.” 78 Fed. Reg. at 44994. The reason that patent applications – particularly those in the biotechnology and pharmaceutical sectors – are growing in “volume and complexity” is that the rate and complexity of invention in the industry are likewise growing. If innovators are to obtain adequate and effective intellectual property rights to protect their inventions within the framework of the proposed rules, they will need to file larger numbers of less “complex” applications to seek appropriate claim coverage. The net effect of such a practice would be an even greater backlog of new patent applications.

The statute gives patent applicants an affirmative right to present claims in terms that correspond to their inventions:

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.

Weber, supra, 580 F.2d at 458, 198 USPQ at 332 (C.C.P.A. 1978) (citing *In re Wolfrum*, 486 F.2d 588, 179 USPQ 620 (C.C.P.A. 1973)).

The regulatory objective the Office pursues in the proposed rules is contrary to law, and it is bad public policy. The Office points to *Weber, id.*, for the recognition by the courts that it

“must have some means for controlling such administrative matters as examiners’ caseloads and the amount of searching done per filing fee.” 78 Fed. Reg. at 44993. But the Office overlooks the injunction that appears in the very next sentence of the *Weber* opinion:

But, 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.

Id.

Broad structural genus claims are appropriate to protect inventions in the pharmaceutical and biotechnology arts. Perhaps the Office supposes that because marketed drug products typically correspond to single chemical species covered by patent claims, an applicant need only limit his claims to the species that will cover an eventual product. But at the time a genus of compounds is invented – when the genus is identified with respect to a common “substantial feature,” such as a core structure, and a shared generic utility – it is often not possible for an inventor to know which particular species may become viable clinical candidate compounds. Only through characterization of pharmacology, toxicity, pharmacokinetics, potential for interaction with other drugs, and a host of other factors can an appropriate candidate be selected and tested.

The consequence for pharmaceutical innovators of limiting patent claims at the outset to the “wrong” species – the members of a genus that do not become viable clinical candidates – is not that drug products will come to market without basic patent protection, perhaps relying instead on patents for later-discovered uses for treating particular diseases. Instead, the result is that the drug products *will never be developed and commercialized*.

One of the realities of the pharmaceutical business is that companies must justify the risks they assume to their investors. Rarely, if ever, could a company justify risking the tens of millions of dollars necessary to undertake a preclinical testing program – let alone the hundreds of millions of dollars required for clinical trials – without an assurance that an eventual drug product will be fully protected by intellectual property rights when the product is launched, and for a reasonable number of years thereafter.

The proposed rules, by design and effect, are substantive in nature. The Office proposes to compel applicants to claim less than the subject matter they invent. This policy will directly and tangibly harm the ability of the pharmaceutical and biotechnology industries to bring new drug products to market.

Both the patent statute and sound patent policy require the Office to examine claims that correspond to what applicants invent. If the examination of patent claims in the pharmaceutical and biotechnology arts is disproportionately resource-intensive, the Office needs to explore different examination and revenue models to make appropriate use of its resources. A requirement that inventors conform the nature of their inventions to a “one-size-fits-all” model of examination resource allocation does not serve the interests of the public or of inventors.

V. *Comments Pertaining to Specific Proposed Rules*

In addition to the general concerns discussed above, Genentech has a number of concerns with various specific provisions of the proposed rules. These are discussed below with reference to particular proposed rules.

A. § 1.75(a) – “*Single invention*”

As a preliminary matter, we believe that the terminology the Office has chosen to identify concepts involving related inventions is likely to lead to confusion. More fundamentally, the statute does not confer authority on the Office to impose requirements for restriction according to the proposed rule.

Proposed § 1.75(a) states that “A claim must be limited to a single invention.” The courts have construed the meaning of the term “invention” as it relates to a claim – the “invention” *is* the claim. *See, e.g., Vas-Cath v. Mahurkar*, 935 F.2d 1555, 1564, 19 USPQ2d 1111, 1117 (“The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*” (emphasis in original)). *See also Weber*, 580 F.2d at 459, 198 USPQ at 333 (Rich, J. concurring):

Ever since *Ex parte Eagle*, 1870 C.D. 137 (Com’r Pats. 1870), at least, the expression used in § 121, “two or more ... inventions are claimed,” has connoted separate claims to separate inventions. It has no reference to generic or broad claims which “embrace” ... two or more inventions.

Thus, to say that a single claim must be limited to a “single invention” conveys nothing meaningful.

The *Harnisch* court used the term “unity of invention” to describe an appropriate criterion for the relatedness of different embodiments claimed in a Markush-style claim. *See In re Harnisch*, 631 F.2d 716, 721, 206 USPQ 300, 305 (C.C.P.A. 1980). In the years since that decision, the term has found widespread use in PCT practice. In that context, unity of invention is defined by PCT Rule 13.2 to be present when the claims share a special technical feature that defines over the prior art. This definition differs from the *Harnisch* definition, which in turn differs from the standard of proposed § 1.140(a). The use of “unity” to explain and illustrate the concept of “single invention” in the proposed rules is likely to lead to confusion and imprecise application.

If the Office adheres to its proposal to promulgate a “single invention” standard, we suggest that it adopt a new term to assimilate the concept of quasi- “unity of invention,” but differing sufficiently from “unity” to allow one to recognize readily that it does not refer to the concepts of PCT practice. Such a new term may also be defined to include the concept of mutual *prima facie* obviousness, so as to correspond to a “single invention” as it appears to be intended in proposed §§ 1.75 and 1.140(a). A suitable term might be, *e.g.*, “unitary invention.”

B. § 1.75(d)(2) – *Identification of support for claims in parent applications*

Proposed § 1.75(d)(2) would require applicants to represent which claims are “disclosed in the manner provided by the first paragraph of 35 U.S.C. § 112” in the parent(s) of a continuation-in-part application. Framed this way, the proposed requirement goes beyond the inherent authority of the Office to require information, and it would prejudice the substantive rights of patent applicants.

Certainly the Office may obtain factual information from an applicant to assist its examination. However, the representations that the Office proposes to require are not in the nature of objective facts. The language of proposed § 1.75(d)(2) implicates both the enablement requirement of § 112, a legal question resolved on the basis of factual information, and the written description requirement, a fact issue weighed by the fact-finder in light all of the relevant evidence. Assessing compliance with each of these requirements as to an asserted priority application is inherently a patent examination function. It is improper for the Office to require patent applicants to concede legal inquiries and factual determinations that the statute assigns to the Director in the first instance. *See* 35 U.S.C. § 131.

Apart from being improper, proposed § 1.75(d)(2) is impractical. An applicant having a reasonable good-faith basis for asserting that a claim for priority is effective as to particular application claims will properly represent to the Office that those claims have § 112 support in the parent application(s). The fact that the applicant may reasonably state such an assertion does not mean that the Office would reach the same conclusion in light of the same underlying evidence, and it certainly does not mean that the Office should rely on the applicant’s positions.

The public interest and the interests of applicants who seek properly examined patents require the Office to make an independent determination of the question of claim support in a series of continuation-in-part applications. This said, we acknowledge that applicants may be in a position to provide objective factual information that would assist the Office in assessing priority dates for particular claims. The Office could reasonably require, for example, that applicants summarize the textual differences between parent and continuation-in-part applications (*e.g.*, “examples 4 and 5 in the ’222 application are new, relative to the ’111 application”).

C. § 1.75(j) – *“Format” requirements for claims reciting alternatives*

The Office describes the mandatory standards of proposed § 1.75(j) as mere “simplified format” requirements. However, for the reasons discussed in the sections above, these “format” restrictions will impose substantive limitations on the rights of applicants to present claims that correspond to the subject matter they regard as their inventions. Moreover, these requirements, will not have the effect that the Office desires. Instead, they are likely to lead to more cumbersome claims and problematic application of the standards for compliance.

1. § 1.75(j)(1)

Proposed Rule 75(j)(1) would prohibit claims that are “difficult to construe” on account of the number or presentation of alternatives. The inspiration for this standard is Paragraph 5.18 of the PCT Guidelines. This paragraph is inapposite to the question of defining proper claim format in U.S. practice. It is rarely, if ever, invoked in PCT practice by the USPTO in its capacity as an International Search Authority or International Preliminary Examination Authority, let alone in the *ex parte* examination of U.S. national applications. The “difficult to construe” standard is fundamentally subjective, and it has no foundation in the experience of U.S. patent examiners or practitioners to provide a basis for consistent and transparent application.

Moreover, the “difficult to construe” standard of Paragraph 5.18 interprets the requirements for clarity and conciseness of PCT Article 6. To the extent that these requirements have an analog in U.S. practice, it is the requirement of 35 U.S.C. § 112, second paragraph, that the specification include claims that particularly point out and distinctly claim the invention. Indeed, the question of whether a claim can be readily construed goes directly to whether it reasonably apprises the skilled person of the subject matter claimed. This is a substantive patentability requirement subject to a right of appeal, not a procedural formality that the Office may administer by regulation.

2. § 1.75(j)(2)

Proposed Rule 1.75(j)(2) would prohibit alternatives defined with reference to further alternatives, *e.g.*, nested Markush groups. This requirement sets an arbitrary standard of form that is likely to make claims more difficult to write, understand, and examine.

Particularly in chemical practice, nested Markush groups provide a concise and efficient way to delimit an invention. A new class of compounds typically includes very many different possible substituents at different positions on a core nucleus, which may itself be tolerant of some structural variation. It is far more informative, for example, to write “wherein R¹ is a C₁-C₅ alkyl, C₁-C₅ alkenyl, C₁-C₅ alkanol, or C₁-C₅ aldehyde” than to enumerate each of the alternatives for R¹ that this group includes. Indeed, listing individually all of the possible alternatives for a typical multi-substituent chemical structure could render a claim unsuitable for presentation in a PCT application since it might violate the requirement of PCT Article 6 for conciseness. Yet, if that is the scope of subject matter that a U.S. applicant regards as his invention, he is not only permitted, but *required* to claim it. 35 U.S.C. § 112, second paragraph.

The best standard for evaluating the propriety and the tractability of claim alternatives is not the architecture of their presentation, but the relationship of the alternatives. If all of the “top-level” alternatives share “unity of invention” according to the *Harnisch* standard, and the members of each “sub-level” grouping are congruent, the claim will be clear, concise, and limited to a “single invention.” Some limitations on nested alternatives may be appropriate, such as a limitation on conditional alternatives that depend on the presence or absence of specified other alternatives in other parts of the same claim (*e.g.*, “provided that R⁴ is not a C₂ haloalkyl group when X⁵ is a chalcogen or R⁷ is methyl”). However, a categorical prohibition on nested

groups of alternatives would not promote the objectives of the Office or serve the needs of the public.

3. § 1.75(j)(3)

Proposed Rule 1.75(j)(3) would prohibit included or overlapping alternatives within a single group “unless there is no other practical way to define the invention.” Indeed, it is often the case that overlapping subgenera are properly listed as alternatives in the same grouping (*e.g.*, “wherein the antibody recognized a B cell antigen or a pre-B cell antigen”). Even where there is no compelling reason for including overlapping, or even wholly-included alternatives (“wherein the fabric is cotton, rayon, or synthetic”), such claims are generally not difficult to parse; at worst, they are inelegant. The effort that would be expended by both Office personnel and applicants to determine or demonstrate whether “there is no other practical way to define the invention” would likely outweigh any benefit that would result from imposing the requirement of proposed § 1.75(j)(3). The paragraph should be deleted.

4. § 1.75(j)(4)

Proposed Rule 1.75(j)(4) would require that a group of recited alternatives “be substitutable one for another.” We have some concern with the discussion that supports this language at 72 Fed. Reg. 44997, col. 2. The discussion states that a claim “would not be in proper format unless all of the alternatives are interchangeable, and substitution of one for another would result in the same invention.” If two claims were identical, except for the substitution of one alternative for another, by definition they would be directed to different inventions. Thus, it is not clear what the Office intends. The requirement of § 1.75(j)(4) may be reasonable if by “substitutable,” it is meant that two alternatives can serve the same function with respect to the mechanics of the claim structure, and that “unity of invention” is shared by embodiments that include the two alternatives. If that is the case, we request that the Office clarify the intent of this provision. If something more restrictive is intended, we believe such requirement is inappropriate and should be deleted.

D. § 1.75(k) – Incorporating other parts of the specification

Proposed § 1.75(k) would prohibit reference to elements of the specification other than the claims, “unless there is no other practical way to define the invention.” Particularly in biotechnology, it is frequently necessary for claims to refer to the figures or sequences set forth in the sequence listing. It would be helpful for the Office to provide illustrative examples of situations in which a reference to another part of the specification should not give rise to an objection.

E. § 1.140(a) – Standard for a “single invention”

Proposed § 1.140(a) sets forth the alternative standards (*i.e.*, quasi- “unity of invention” or mutual *prima facie* obviousness) for determining whether a claim is directed to a “single invention.” However, the first sentence of the rule states that “[t]wo or more independent and

distinct inventions may not be claimed in a single claim.” The “independent and distinct” standard governs whether pairs of inventions may be properly restricted. It is not coextensive with the “single invention” concept, which embraces linking claims and the otherwise-distinct claims that they link. Taken at face value, the first sentence of proposed § 1.140(a) prohibits any claim that recites patentably distinct species in the alternative. This is not the result that the Office expressly contemplates. *See* 72 Fed. Reg. at 44997. The reference to “independent and distinct” in the first sentence of proposed § 1.140(a) should be revised to refer to “single inventions” (or a successor designation for the concept).

VI. Conclusion

Genentech appreciates the opportunity to offer these comments. We would be pleased to provide any additional information to support the Office’s efforts to improve its examination practices.

Respectfully submitted,

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