

September 14, 2005

By electronic mail – robert.clarke@uspto.gov

Mail Stop Comments-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Re: *Notice ... and Request for Comments on Green Paper Concerning Restriction Practice*, 70 Fed. Reg. 45370 (August 5, 2005)

Dear Mr. Clarke:

Genentech, Inc. (“Genentech”) offers the following comments in response to the Office’s Request for Comments.

Genentech is a biotechnology company based in South San Francisco, California. Genentech’s mission is to be the leading biotechnology company, using human genetic information to discover, develop, manufacture and commercialize biotherapeutics that address significant unmet medical needs. Genentech commits itself to high standards of integrity in contributing to the best interests of patients, the medical profession, our employees and our communities, and to seeking significant return to our stockholders based on the continued pursuit of excellent science.

Patents are a fundamental aspect of Genentech’s business. Since it was founded more than 25 years ago, Genentech has filed thousands of patent applications to protect its inventions, and we continue to file new applications on a regular basis. At any given time, we typically have dozens or hundreds of applications pending before the Office. The Office’s restriction practices directly affect Genentech’s allocation of its patent procurement resources and its strategies for protecting its inventions. Because innovation is central to our business, restriction practices have a tangible impact on our ability to develop new products.

General comments

Genentech appreciates the systematic and sustained efforts the Office has directed to studying and considering potential reforms to its restriction practices. Genentech also applauds the modest but discernable gains in the consistency of restriction practice that have resulted from efforts such as the TC 1600 restriction action plan. But consistency by itself does not achieve efficiency.

The Green Paper reflects considerable and thoughtful effort. Its analytical approach is, we think, essential to structuring new standards that “work” for the Office. Yet we have concerns with the perspective, evidently adopted at the outset, that framed the questions that the analysis was designed to answer. Most notably, the standard for comparing different scenarios in every instance is a model based on current restriction practice. This approach allows for a relatively high degree of certainty for understanding how various process metrics – disposals per fiscal year, for example – might change using different sets of assumptions. We recognize that such comparisons are a necessary part of charting a way forward.

Taken in isolation, however, a series of comparisons to the *status quo* lacks an aspirational quality. We believe that the best outcome for restriction reform, in terms of both public policy and the efficiency of the Office’s operations, will result only if the Office continuously asks how restriction practices *should* be structured.

The proper objective of any reform is not to minimize disruptions to familiar workflow patterns, but to make the best use of the Office’s resources in the service of the innovation economy. Thus, we encourage the Office to take the view that the Green Paper is but one part of a larger equation – one in which experimentation and flexibility can also play valuable roles.

Detailed comments

As for any procedural aspect of patent examination, the restriction process used by the PTO should be transparent, predictable, and fair. It should be structured to support the proper and efficient application of substantive patentability standards to the claimed inventions. Also, it is in the interests of both the Office and patent applicants that any new system should be easy (or at a minimum, less burdensome than the current system) to administer.

We do not think that restriction practice is impossibly broken. We acknowledge the essential role that it plays in fairly regulating the Office’s allocation of examination resources. To be sure, we get our share of restriction requirements that mistake limitations for “species” and alternative embodiments for “distinct inventions.” At their worst, such requirements constrain claims artificially and impair the substantive rights of innovators. They are always frustrating.

The more prevalent and serious problem, in our view, involves restrictions that disperse the examination of claims to related features of an invention to several different examiners in a series of divisional and continuing applications. The effect of inconsistent examination in related applications – particularly for claims that raise essentially identical patentability issues – unreasonably complicates both the procurement and enforcement of patent rights.

We continue to hold the view that a consolidated examination model is the appropriate solution to this problem. According to such a model, claims that raise similar patentability issues should be examined together as a matter of course. Both a “unity of invention” formulation (Option 2 in the Green Paper) and the “three-tier structure” (Option 3) take this approach. We believe that in addition to providing significant advantages for patent applicants, a rationally designed consolidated examination scheme would benefit the Office enormously. Each major patentability issue arising from an original application would need to be examined only once, instead of repeatedly.

Genentech strongly agrees with the Director that the Office must be able to recover fees that fairly and fully reflect the resources that are actually expended on examining each application. Full fee recovery is essential for maintaining the quality of patent examination and minimizing application pendency. A restriction scheme that offers “consolidated” examination, relative to current restriction practice, would by definition require the Office to do more work in a single application than it does now. Thus, we would support a fee structure that provides, in effect, for increases in fees paid for a single application that correlates to the additional work implicated by examining additional embodiments, features or aspects of the invention in the single application.

At this juncture, we do not think it is necessary to precisely define a metric for counting the “units” for determining fees in an application. We note that because it is familiar, the current “independent and distinct” standard, or some variation of it, may be a practical tool for identifying suitable fee multipliers. In any case, we expect that the Office will conduct an appropriate consultative process with the various technology sectors that file applications, once a basic restriction model has been selected. We believe this consultative process will enable the PTO to tune its new restriction standard to reflect the examination burdens implicated by distinct technologies, which we acknowledge do exist.

Our comments on the four options identified in the Green Paper follow.

Option 1 – Applicants may purchase examination of up to three “independent or distinct” inventions in a single application on an *a la carte* basis.

We do not favor this option. While it may provide a good solution for applications with relatively uncomplicated claim sets, it does not begin to address the needs of a typical biotechnology application. The fundamental problem of the dispersed examination of closely related claims would remain.

The more serious deficiency of this model is that it would not give the Office the benefit of rationally consolidating examination issues. Instead, it would allow an applicant to choose three essentially unrelated inventions for concurrent examination. We believe that this model has the potential seriously to erode the efficient use of examination resources. There is no logic, from the perspective of resource allocation, to examining unrelated inventions in a single application.

Option 2 differs critically from Option 1 in that it requires a degree of relatedness between inventions that may be chosen for examination in a single application. A modification of Option 1 requiring some relationship between the elected inventions – where that relationship is directly relevant to some aspect of the examination process – would be a more appropriate and useful restriction model than Option 1 as set forth in the Green Paper.

We do not favor the proposal in Option 1 to allow examination of up to 10 species of an elected invention only on payment of additional fees. Our concern is especially motivated by a recent trend in restriction requirements toward requiring species elections for every aspect of a claimed invention, whether or not all such aspects are novel in themselves. We think the current practice for handling species of a generic invention strikes the right balance: if the generic invention is patentable, the applicant should be entitled to claim a reasonable number of species. There is no reasonable basis for multiplying fees for species if the corresponding generic invention has been found patentable in its own right.

Option 2 – Modified unity of invention.

Genentech would support adopting a modified unity of invention standard, generally as proposed in the Green Paper.

The “traditional” (*i.e.*, European/PCT) formulation of a unity of invention standard is eminently sensible in an environment where patentability over the prior art is the only substantial issue that arises in patent examination. The requirement for a shared “special technical feature” – a common feature of a group of claims that defines a contribution over the prior art – means that all of the claims in an application that are patentable for the same reason will be examined together. The examination of the “special technical feature” relative to the prior art is performed only once.

Under current U.S. law, the prior art is not usually the most prominent issue raised in the examination of biotechnology applications. Instead, the description and enablement requirements of 35 U.S.C. § 112 and the utility requirement of § 101 (which is predicate to compliance with the enablement requirement as a matter of law) serve as the primary focus of examination. Thus, we believe it is appropriate, as the Green Paper proposes, to modify the unity of invention standard to take account of the practical consequences associated with examination of biotechnology applications for compliance with §§ 101 and 112.

We believe there is significant value in having the USPTO develop and put in practice a contemporary unity of invention standard. It appears likely that, at some point in the future, the United States will adopt “best practices” in legal standards and examination practices that will enable harmonization with global standards, either through amendment of the Patent Act or through bilateral and multilateral agreements with other examining offices. It seems plausible that such harmonization would eventually compel the Office to move toward unity of invention in some form. In our view, the USPTO should be a leader now in developing a unity standard that takes full account of all of the legal issues that arise in contemporary patent practice and that realistically addresses the resource-allocation concerns of major examining offices.

Although we support the broad outlines of the proposal, we do not agree with certain approaches that the Green Paper suggests for implementing a modified unity of invention standard.

First, it appears to us that the contemplated examination model calls for an affirmative “§ 112 challenge” by the examiner to define restrictable subject matter. The examiner would make such a challenge by demonstrating that some common “technical feature” does not comply with § 112. *See* Green Paper at Appendix III.

The problem with this approach is that it assigns the examiner the task of defining a “technical feature.” As the concept is understood in international unity of invention practice, however, there is not a one-to-one correspondence between a claim or an invention, on the one hand, and a single “special technical feature” on the other. A special technical feature is *any* common element that defines a contribution over the prior art. Thus, any single claim may be characterized by *several* special technical features, and it may share those special technical features with other claims in a variety of groupings.

Any attempt to assign “a” special technical feature to a claim is legal error to the extent that it overlooks other special technical feature(s) that may characterize the claim. The practical implication for restriction practice is that it would be improper for an examiner to impose a requirement for restriction between certain claims on the basis of a shared feature that does *not* comply with § 112 if other described, enabled, novel, and inventive features link those claims.

Second, we are concerned over the feasibility and fairness of a procedure that would require an applicant to identify a “reference” claim for defining relationships with other claims. *See* Green Paper at Appendix VII. If the invitation requires no more than identifying a reference claim by specifying its number, then we see no problems. However, we would vigorously oppose extending the concept to inviting the applicant to identify a common technical feature, or even simply to identify other claims that would share a feature with the reference claim. Such practice would essentially require applicants to define a phantom “inventive concept,” akin to a count in interference practice. The substantive implications of such a practice, particularly when patented claims are eventually enforced in litigation, would likely be substantial and detrimental.

Third, we oppose an absolute and arbitrary cap on the number of “additional” invention groups that should be examined in the same application under a unity of invention standard. The administrative elegance of a unity standard is that it affords genuine economies of scale in patent examination – the greater the number of claims that can be found patentable for the same reason, the greater the resources saved in not examining those claims in separate applications. If, however, the Office can make the business case that it would be burdened by having to examine more than a certain number of invention groups in one application, we would be open to supporting a progressive fee scale that, for example, charges more for a fifth invention group than a third invention group.

Option 3 – Three-tier structure

Genentech was one of the original advocates of the proposal that emerged as Option 3 in the Green Paper, and we continue to favor it. The proposal is similar in essence to a unity of invention approach, but it adds distinctions between “substantially similar,” “related,” and “unrelated” inventions. A three-tier structure would provide all the benefits of a unity standard. Moreover, incorporating the noted distinctions would allow the Office to recover fees that more accurately reflect the examination burdens likely to be encountered in examination of applications. We believe this type of system would also provide a tangible incentive to applicants to limit their applications to groups of substantially similar inventions.

The Green Paper expresses grave doubts about the manageability of a three-tier restriction regime. In particular, it suggests that standards for differentiating the three categories of inventions would be unclear and confusing. We do not foresee nearly the difficulties that the Green Paper envisions.

The Office has a long history of instructing examiners to parse relationships between inventions for determining the propriety of restrictions. A large part of Chapter 800 of the M.P.E.P. is devoted to explaining the methodologies for defining various relationships. The standards for identifying related inventions have been used with little confusion or unpredictability for decades. Under those procedures, one significant factor that supports imposition of a restriction is a finding that an additional search would be required for the additional inventions (relative to a first claimed invention). Using the additional, independent search distinction as the distinction that justifies a significant increase in fees (i.e., authorizing division of the application or payment of a complete additional application fee) is in line with current PTO practices.

The other criteria that would have to be established to justify additional fees (and additional time for examiners) would be that the additional embodiments being claimed present distinct legal questions for resolution. Thus, as previously exemplified, a case that presented claims to a second embodiment (e.g., an antibody that binds to a particular polypeptide) that required independent consideration of patentability (e.g., for written description) would justify the Office requiring payment of an additional fee and the provision of additional examining time credit.

Notwithstanding our preference for the three-tier model, we would strongly support pursuing either Option 2 or Option 3. In our view, moving toward any form of a consolidated examination model that allows claims that present similar examination issues to be examined in a single application would be a significant improvement over current practice.

Option 4 – Reformulated “independent and distinct” standard.

We do not favor this option because it depends on an administrative recharacterization of the statutory standard for restriction. Five decades of cases that attempted periodically to explain

what this standard means, or what it should mean, teach that this is not a practical approach for the future.

We also find this option wholly inadequate for addressing the critical issue of dispersed examination that results from current restriction practice.

Conclusion

We support the Office's efforts to explore and implement restriction standards that match the technological and commercial needs of contemporary innovation. We appreciate the opportunity to offer comments on the Green Paper, and we look forward to working with the Office to improve the examination process.

Sincerely yours,

/Janet E. Hasak/

Janet E. Hasak
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