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July 21, 2003

By electronic mail – unity.comments@uspto.gov

Mail Stop Comments – Patents
Commissioner for Patents
Attention: Robert A. Clarke
P.O. Box 1450
Alexandria, Virginia 22313-1450

RE: REQUEST FOR COMMENTS ON THE STUDY OF THE CHANGES NEEDED TO IMPLEMENT A UNITY OF INVENTION STANDARD IN THE UNITED STATES, 68 FED. REG. 27536 (MAY 20, 2003).

Dear Mr. Clarke:

Genentech hereby submits comments in response to the above-cited notice.

Genentech is a biotechnology company based on South San Francisco, California. Our 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.

Genentech supports the views expressed in the submission of the Biotechnology Industry Organization (BIO) in response to the above-cited notice. Our comments below build upon the views expressed in the BIO response.

General Observations

As the Office notes in its Request for Comments, the purpose of restriction practice is to "balance the interest of granting an applicant reasonable breadth of protection in a single patent against the burden on the USPTO of examining multiple inventions in a single application." Genentech supports use of an appropriate mechanism for determining and collecting the costs of

examining all related features of a single inventive concept in a single application. Current restriction standards and practices, both as defined in the statute and as applied by the Office, are not up to the task. The current practice does not serving the interests of applicants, the Office or the public. For this reason, Genentech supports both changing the statutory authority governing restriction practice and implementing new practices to be followed by the PTO under such authority.

Before addressing the specific questions presented for comment, Genentech notes that any new standard designed to revise current restriction practice should support, rather than attempt to change, prevailing U.S. standards for patentability and patent enforcement. Genentech also believes that new standards and practices should ensure that a thorough examination is made of each claim presented in an application. Standards that fail to encourage examiners to conduct a thorough and complete examination of each presented claim must be avoided. This is particularly important in the biotechnology field, where prior art issues frequently are not the primary issue governing patentability of a particular invention.

As we address more fully below, Genentech believes that restriction practice must be changed to allow applicants, rather than the Patent and Trademark Office (PTO), to determine which embodiments of an invention will be examined in a single application. We believe many benefits for applicants, the Office, and the public will stem from the use of a standard that provides for a single, contemporaneous examination of all critical claims relating to an invention. This is one of the primary benefits of "unity" practice practiced in most other patent offices and under the Patent Cooperation Treaty (PCT). Use of a "consolidated examination" approach avoids the needless duplication of effort that results from repeating essentially the same tasks in a series of related divisional applications.

While we support adoption of standards that will provide for consolidated examination of applications, we do not believe such standards should be based exclusively on the PCT standard of "unity of invention." That standard relies on evaluation of a "special technical feature" that distinguishes the presented claims from the prior art. This standard works well within the international phase of examination in the PCT, which is concerned almost exclusively with identifying relevant prior art and applying it to the claims. It also works well in disciplines where the prior art represents the only significant constraint on patentability.

In biotechnology, however, prior art is often not the only issue – or even the most significant issue – addressed during examination. Instead, the utility requirement of 35 U.S.C. § 101 and the description and enablement requirements of § 112 frequently dominate examination. As an example, when a novel polypeptide is patentable, "generic" claims to the corresponding antibodies are usually patentable for the same reasons.[1] However, certain

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[1] If a polypeptide is unrelated in structure to previously known polypeptides, there are usually not prior art issues that would bar claims to the antibodies. (There are exceptions to the general rule, as when prior art antibodies raised against whole-cell antigens happen to bind to the newly isolated protein.) The utility for a "generic" antibody is coupled to the utility of the antigen it recognizes. Thus, if a protein is useful, an antibody that binds specifically to that protein will likewise be useful.

limitations in dependent claims (*e.g.*, requiring the antibody to function as an antagonist of a particular activity, or to have therapeutic efficacy) can raise pivotal questions regarding enablement and description. Thus, even dependent product claims can raise patentability issues that would consume significant examination resources relative to the corresponding independent claim. When it reasonably appears likely that they will, the Office should recover fees that reflect the additional work. As such, any new restriction standard used by the PTO should assess the likely workload implicated by a complete examination of the claims presented, including work associated with the examination of non-prior art related issues.

Finally, we urge the PTO to take action in the short term to remedy what we believe to be an improper use of restriction requirements in biotechnology applications. Existing practices followed by Group 1600 fail to conform to even a generous interpretation of the PTO's statutory authority under 35 U.S.C. 121. Restrictions are routinely imposed in situations where consideration of patentability issues associated with the restricted claims do not impose substantial additional work on the Office. The impact of these practices is introducing an unnecessary degree of complexity into the examination of many of our applications and leading to outcomes that adversely affect our commercial interests.

Responses to Questions

Issue 1

Should the USPTO study ways to adopt EPO claim treatment practice, including normally allowing only one independent claim per category of invention, when considering ways to adopt a Unity of Invention standard, and why?

No. The basic logic of a unity-like examination model is that claims raising similar significant issues will be examined together. Properly applied, it is that standard, and not the number of claims, that will limit the issues placed before the examiner. Artificial limitations on the number and types of claims will not conserve examination resources.

We are particularly troubled by the suggestion that the PTO would consider statutory changes that would be necessary to adopt central claiming practice in the United States. Modern U.S. patent law is based on peripheral claim construction. Any change in that basic methodology, even if supported by extensive statutory and regulatory provisions, would introduce an element of profound uncertainty into the procurement and enforcement of patents. Because the biotechnology industry is so critically dependent on patent protection, we place high value on obtaining predictable and enforceable patent rights. We see no need to so drastically change the rules of the game.

Moreover, restriction practice – whether conducted under the "independent and distinct" standard or a unity of invention standard – is a fundamentally procedural tool. Its purpose is to allow the examining office to regulate the use of its resources, not to modulate the substantive criteria for patentability or the way they are applied to the claims. Thus, adopting a new restriction standard should not require any fundamental changes to the way claims are drafted, examined, or construed. We do not agree with the premise that implementing unity of invention

or any similar restriction standard would compel adopting the same procedural or substantive practices employed by the EPO or any other examination authority.

Should the USPTO emphasize the examination of independent claims and modify the examination of dependent claims in the same fashion as the EPO? If so, would there be any reason to consider changes to the presumption of validity under 35 U.S.C. 282 of those dependent claims?

The PTO should not restructure examination to focus on independent claims at the expense of thoroughly and properly examining dependent claims. The presumption of validity must apply fully to every granted claim, not to only some claims. As a consequence, each claim must be thoroughly and completely examined for compliance with all statutory requirements of patentability, particularly compliance with 35 U.S.C. §§ 101 and 112.

The framing of the Office's question appears to assume that a unity standard would further burden its examination resources. This may account for exploring the assumption that a dependent claim will be patentable because the corresponding base claim is patentable. Such an assumption does not square with our experience obtaining, evaluating, and enforcing patent claims. We believe this is not a legitimate premise. Instead, we believe that on balance, the PTO will realize significant productivity gains from adopting a fundamentally more efficient examination practice (*i.e.*, one that provides for contemporaneous examination of all significant claims).

A consolidated examination practice also must not lead to predicating the patentability of a dependent claim upon the patentability of the independent claim from which the claim depends. In most cases, critically important limitations or features of an invention are reflected in dependent claims. The PTO should not adopt a practice of ignoring the significance (whether favorable or unfavorable to patentability) of the dependent limitations.

Issue 2

If the USPTO adopts a Unity of Invention standard, should the USPTO provide applicants the option of a PCT style Unity of Invention practice to pay for additional inventions that lack Unity of Invention in the same application?

Yes. Allowing applicants to elect a first invention and one or more "related" inventions for concurrent examination will make the best use of the Office's resources *and* best serve the business needs of our industry and, we suspect, other industries.

Biotechnology companies have a legitimate need to obtain comprehensive coverage for all related embodiments of an invention. For example, if a company determines and characterizes a medically relevant gene and determines the function of the protein it encodes, it should be entitled to obtain claims that cover all relevant product and method embodiments that are related to the functions it has identified and characterized. From a business perspective, all of these inventions relate to the same commercial asset. Thus, the ability to obtain timely patent

coverage for all of these related inventions without duplicative application expenses will provide substantial and tangible benefits to the biotechnology industry.

Genentech supports the approach reflected in the BIO submission that permits examination of all "related" inventions in a single application (i.e., "related" inventions are those that involve the same basic search). Examining all related inventions at once allows the PTO to leverage the search and the examiner's familiarity with the relevant art to dispose of several sets of claims at once. We thus support adopting a procedure that will permit applicants to elect to prosecute inventions according to their business needs and their resources.

Additional fees required for examining "related" inventions in one application must fairly reflect all of the resources that the Office will need to expend to conduct a complete and thorough examination of all the claims examined in the application. These resources include not only the examiner's search and consideration of the prior art, but also the examination for compliance with 35 U.S.C. 101 and 112. We strongly support maintaining the full capabilities of all Office resources to enable a thorough review of every claim presented for examination.

If so, should the USPTO consider any changes to patent term adjustment under 35 U.S.C. 154(b) for applications which have more inventions examined in a single application under a Unity of Invention standard than are permitted under current practice?

In view of the fact that examining multiple inventions in a single application could cause examination delay in other applications, what other revisions to patent term adjustment provisions under 35 U.S.C. 154(b) should be considered by the USPTO, or should the USPTO also consider revising the order that cases are taken up for examination?

No. The Office should defer any effort to consider changes to the patent term extension authority until it has fully evaluated the effects of changing to a more efficient examination system. We believe the new standards should enable the Office to better utilize its existing examining resources, thus leading to an overall decrease in pendency.

Instead of focusing on the patent term extension authority of title 35, we encourage the PTO to evaluate other statutory changes that would address what appears to be the basis of its concern. Specifically, the PTO has noted that the continued examination of one set of claims after a first invention has been found patentable could unnecessarily delay the grant of the patent on the first invention. One option to deal with this scenario more directly would be to explore the possibility of issuing patentable claims within an application when they are found patentable, while allowing continued prosecution of the claims that have not yet been found patentable. The primary difference between this approach and current restriction practices would be that all the related claimed embodiments of the invention will be examined concurrently, giving applicants a clearer picture of what rights can be obtained.

Issue 3

Should the USPTO adopt, for national applications, the practice currently used under the PCT of examining the first claimed invention where there is a holding of lack of Unity of Invention? Optionally, where Unity of Invention is lacking: (1) Should the USPTO examine the first claimed product, or the first claimed invention if there are no product claims; or (2) should applicant be given the opportunity to elect an invention to be examined?

The PTO should not adopt an "automatic" restriction practice. Under the current restriction standard, an applicant cannot always predict how any given examiner will choose to restrict a claim set. Also, the applicant's perspective on the relative commercial value of the different inventions in an application often changes in the interval between a first filing and the time the application is taken up for restriction. Thus, the applicant's ability to elect the invention to be prosecuted is an important element of current practice. It allows patents to be procured efficiently and in a cost-effective manner.

We do not believe that these fundamental uncertainties will be resolved simply by implementing a new restriction standard. We therefore strongly support maintaining the current practice of allowing the applicant the opportunity to elect in response to a restriction requirement. However, as we have discussed, the applicant's choice should be which one or more related inventions should be examined.

We note that the current practice of allowing applicants up to six months to reply to a restriction requirement substantially interferes with the Office's ability to effectively manage its examination resources. An unduly protracted restriction cycle is not advantageous for the PTO or applicants in the modern examination environment. We support amending the current authority to allow the PTO to commence examination of a first-claimed invention if the applicant does not respond within one or two months of the mailing of a restriction requirement.

Issue 4

When adopting the Unity of Invention standard, should the USPTO follow the practice of performing only a "partial search" if the examination of the entire scope of the claims is unduly burdensome due to non-prior art issues?

No. As implemented by the EPO, a partial search corresponds to an essentially arbitrary determination by the examiner of a scope of subject matter that will be "reasonable."[2] An arbitrarily chosen subgenus of the applicant's claimed invention may or may not be something

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[2] We note that an essentially equivalent practice is also sometimes employed by the PTO under the guise of "independent and distinct" restriction, particularly for Markush claims in chemical practice.

that the applicant actually invented.[3] Instead of adopting a practice by which the Office *sua sponte* constrains the scope of examination by limiting the search, we support devising standards that will permit the Office to restrict an application in accord with the nature of the invention and the patentability issues that are likely to arise in examination.

We support adopting standards to allow a determination of the "relatedness" or "unrelatedness" of inventions without regard to the manner in which the invention is claimed. Thus, if a single claim embraces several unrelated inventions, the Office should have the authority to require the applicant to restrict the claim to a single invention or pay appropriate surcharges. Similarly, if a claim embraces a plurality of related inventions that would raise divergent patentability issues, the Office should have the authority to recover fees that reflect the resources used to fully consider those issues. We do not, however, believe that every subgenus of an invention *necessarily* raises significantly distinct patentability issues that will justify treatment as a separate "related" invention for which a surcharge should be required. Restriction practices should take account of the complexity of the issues and the extent to which they should be considered with respect to the full scope of the claimed invention.[4]

It is essential that every granted claim be examined fully. The presumption of validity requires no less. Even with the best tools to appropriately limit the scope of examination, some claims will nonetheless be "burdensome" to examine. The Office should seek restriction standards that allow the resources consumed *on average* in an application to match those that are available.

Alternatively, should the USPTO assess adequacy of the disclosure and industrial applicability in addition to the prior art when determining whether the claims' common feature makes a contribution over the prior art?

The Office should consider all patentability issues in determining whether restriction is appropriate. The combination of restriction practices and surcharges must allow the Office to match the resources consumed to the fees received for examination. It is essential that the PTO devote the full measure of resources to evaluating significant non-prior art patentability issues when they arise. This is particularly so in view of the inability of third parties to challenge the validity of granted claims with respect to such issues except through costly and protracted litigation.

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[3] Claiming a subgenus of an invention that was not described as such in the application as filed raises questions of compliance with the written description requirement. *See Fujikawa v. Wattanasin*, 93 F.3d 1559 (Fed. Cir. 1996).

[4] For example, the fact that the applicant has not enabled a particular dependent method limitation may or may not reasonably justify regarding the dependent claim as a separate "related" invention. If the same *issue* concerning enablement is properly considered in examining the independent claim, regardless of whether the *conclusion* regarding satisfaction of a particular patentability requirement is the same for all the claims, then restriction or the imposition of surcharges would not be appropriate.

We are wary of framing the inquiry as to whether certain features of the claims "make a contribution over the prior art." Approaching the analysis from this perspective invites improper consideration of single limitations, rather than the invention as a whole. It also calls for cursory determinations by the examiner regarding important patentability criteria at the restriction stage. Such determinations, once made, can be difficult to rebut or resolve. The proper approach, we believe, is for the Office to restrict in light of the issues that are raised, and to resolve those issues in the course of examination once the applicant has elected to pursue a given invention.

Issue 5

Which of the above approaches [(1) all filing fees; (2) all filing fees and an additional fee for examination of claims that lack Unity of Invention with an elected invention; (3) increased issue and/or maintenance fees of all applications; (4) increased issue and/or maintenance fees for applications paying the additional invention fee; or (5) a combination of two or more of (1) through (4) above] should the USPTO propose in regard to any fee increases?

In our view, the surcharges for "additional" examination should be borne by the applicants who elect it. At the same time, the savings that we believe will come about from adopting consolidated examination practices should accrue to the benefit of the parties who prosecute multiple inventions. We would not support a fee structure that *disproportionately* taxed applicants presenting a plurality of related inventions to subsidize the examination of other applications.

We support the current fee structure that permits relatively low filing fees by collecting revenue to support a substantial part of the Office's operations by way of issue and maintenance fees. Thus, we believe that all of the fees incurred after a restriction requirement has been imposed (*i.e.*, search, examination, issue, and maintenance fees) should be implicated. We do not see a need to "saddle" a patentee who had elected multiple inventions for examination with multiplied maintenance fees if only some of the inventions are commercially viable. Thus, we would support treating a "consolidated examination" patent as a bundle of single-invention patents for maintenance fee purposes. As under current practice, a patentee could then allow subsets of claims (defined according to the original restriction requirement) to expire by declining to pay maintenance fees for those claims.

Issue 6

How should work be assigned to ensure that examination quality would not suffer if examiners have to examine multiple inventions from different disciplines in a single application? Should the USPTO consider: (1) Using team examination, similar to the EPO where applications are examined using three-person teams called ''examination divisions'' (2) extending the use of patentability report procedures provided for in section 705 of the Manual of Patent Examining Procedure (8th ed. 2001) (Rev. 1, Feb. 2003); (3) maintaining the current process of a single examiner on an application; or (4) using some other option of how work is performed by examiners?

We strongly support the current practice of having one examiner retain responsibility for the examination of each application. In our experience, the need for cross-disciplinary consultations has been rare. Where the need does arise, however, it is critical for the examiner to appreciate the invention as a whole. In this regard, we discourage the Office from "subcontracting" the examination of certain claims to personnel in other examining units. We believe that the likely consequence of such a practice will be that each of the various examiners involved in examining the application may obtain a basic understanding of "his or her" technologies as they relate to aspects of the invention, but that none would develop a proper perspective of what the applicant has contributed to the art. Such perspective is essential for fairly and properly evaluating the patentability of an invention.

We support arrangements that will allow examiners to consult with specialists in other disciplines when needed. We leave the details of how such consultations should be structured to the PTO.

Issue 7

Should the USPTO consider this option [to permit applicants to pay an RCE fee and submit or rejoin claims to additional inventions after prosecution has been closed on a first invention, so long as the claims presented with the RCE fee either depend from or otherwise include the features of the allowed claims which make a contribution over the prior art]? Should this option be available only to applicants whose applications are published? If so, how should the new RCE fee be set relative to the current fee structure?

Issue 8

Should the USPTO consider this option [to permit requests under RCE authority that the USPTO continue examination of claims which were withdrawn from consideration]? If so, how should the loss in issue and maintenance fee collections be offset relative to the current structure?

We strongly oppose the proposals outlined in Issues 7 and 8. Each of these practices seeks to contort existing statutory authority to provide "relief" from an application of the Office's restriction authority that is improper at the outset. Neither proposal will improve the problems associated with the current approach taken by the Office in imposing restriction

requirements (*i.e.*, inefficient division of related aspects of a single inventive concept). Rather than attempting to devise "make-do" procedures to address the problems of the current standard, the Office should address the root of the problems.

Issue 9

Should the USPTO consider: (1) Seeking a change to 35 U.S.C. 121 to adopt a Unity of Invention standard (and if so, what would such statutory change be, including whether such a statute would provide for applicants to pay for additional inventions that lack Unity of Invention to be examined in the same application); (2) maintaining the current restriction practice in the USPTO; and/or (3) modifying the USPTO rules and procedures to adopt aspects of Unity of Invention practice without making any statutory changes (if so, in what manner should rule changes be made)?

We would support statutory and related changes to implement a new standard to replace the current "independent and distinct" approach reflected in 35 U.S.C. § 121. The current standard has proven unworkable, and it has led to significant problems for applicants and the Office. We also recognize that adopting a different standard, permitting applicants to obtain examination of more claims than presently allowed in a single application, will have implications both for examination procedure and fees. We accordingly would support changes to other provisions of title 35 governing the authority of the PTO to conduct examination, grant patents on allowable claims, and collect additional fees to cover the added costs of examining more claims in a single application.

In this regard, we support the proposal of BIO to create a three-tiered "restriction" standard. In particular:

- Claims that raise no distinct issues of patentability and do not implicate a new search should be examined without the need for any additional fees.

- Sets of claims that present distinct patentability issues, but do not implicate a substantially different search (i.e. "related claims"), should be examined in the same application if the applicant pays an appropriate additional fee for each such additional set of claims.

- Sets of claims that require consideration of distinct patentability issues and the performance of a substantially different search (i.e., "unrelated claims") should either be restricted from the application or be examinable in the same application only if the applicant pays additional fees that are comparable to a new application.

Given the importance that we attach to the complete and thorough examination of all presented claims, we would support a fee schedule that charges an appropriate additional fee for each set of added related or unrelated claims.

We believe statutory changes must be made to fully address the problems of the current environment defined by the way the Office applies the restriction authority. However, we urge

the PTO to take steps immediately to restrain the inappropriate use of its restriction authority. We do not believe that doing so will require statutory or regulatory changes. Instead, such changes can be made by exercising more control over use of restriction by examiners.

Issue 10

Do you have other solutions to offer which are not addressed in this notice?

The PTO can immediately gain many of the advantages of consolidated examination practice by revising its internal procedures. In particular, the PTO's policy of rejoining claims that depend from, or other otherwise include, the limitations of allowed product claims[5] should be revised.

Under existing practice, *all* method claims having the limitations of corresponding product claims are rejoined with an elected product when the product claim is allowed. This practice has two aspects that make inefficient use of examination resources and prolong pendency. First, claims are rejoined without regard to the issues that their examination might raise. Second, treating new issues "late in the game" frustrates the objective of compact prosecution.

Often in biotechnology applications, rejoining claims in an application raises significant new issues involving utility, description, and enablement. Also, in some cases, the priority dates for the method claims are not the same as the priority dates for the products, and double patenting issues that do not pertain to the product claims can also come into play. When rejoinder raises such "new" issues, the examiner is obliged to issue a non-final Office action to address them. A thorough examination of intricate patentability questions will often require more than one action to properly define and resolve the issues. Thus, pendency may be extended for months or years.

Alternatively, some examiners will not be inclined to fully examine the rejoined claims, particularly since a nonfinal action will earn no count. The absence of production credit, in fact, provides an incentive for examiners to avoid focusing on complicated patentability issues specific to the methods, and simply allow all of the claims. Allowing claims under such circumstances works a tremendous disservice to both the patentee and the public. Even where the issues involving dependent claims are relatively straightforward (*e.g.*, matters of form or clarity), issuing a nonfinal Office action late in prosecution imposes at least a three-month delay in prosecution, assuming an applicant can respond promptly.[6]

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[5] M.P.E.P. § 821.04.

[6] The Office encourages resolving such issues by telephone, as it should. In a significant proportion of cases, however, the examiner cannot wait for an applicant to review a proposal and convey its response through its attorney.

All patent applicants, including Genentech, want their applications examined and issued promptly. However, it is just as important that they be able to rely on the soundness of the examination process. The presumption of validity – upon which patentees rely – requires that *every* significant patentability issue for *every* claim be treated and resolved before the claims are issued in a patent.

These problems can be addressed by amending the Office's treatment of rejoinder. Specifically:

- Examiners should be encouraged to rejoin dependent method claims (and claims that include equivalent limitations) with the corresponding product claims as soon as it is reasonably clear that the only *significant* patentability issues for the methods will be the same as the patentability issues for the products.

- Method claims that raise *significant* patentability issues[7] that are not raised by the corresponding product claims should *not* be rejoined in the same application. Such claims should be prosecuted in a divisional application.

Where all of the significant issues for product and method claims are the same, prosecution will be most efficient if all of the claims are treated concurrently. We expect that a congruence of issues involving certain restricted claims should generally be apparent once the examiner has reviewed the disclosure and the prior art. Minor issues of form or clarity involving the method claims can then be treated in a first Office action without significantly burdening either the examiner or the applicant. As under current practice, dependent method claims that are not amended in parallel with product claims during prosecution should still be subject to restriction or withdrawal.

Discontinuing the practice of rejoining claims that would raise new sets of issues in an application will allow such issues to be fully and properly treated in later applications. Moreover, it will allow a patent to be granted promptly for allowed product claims, instead of deferring the patent for significant issues *unrelated to the patentability of the elected invention*.

The Office has the authority to implement such changes. The current policy was set forth in an *Official Gazette* notice[8] and is now incorporated in the M.P.E.P. at § 821.04. It was adopted in response to *In re Ochiai*,[9] *In re Brouwer*,[10] and the enactment of 35 U.S.C. § 103(b).[11]

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[7] We would encourage the Office to develop guidelines to assist examiners in differentiating between significant new issues (*e.g.*, those that would require the evaluation of substantial evidence or consideration of substantial legal questions) and those that are susceptible of relatively straightforward description and resolution.

[8] 1184 O.G. 86 (1996).

[9] *Supra.*

[10] *Supra.*

The rejoinder policy has not been codified in the C.F.R., and it was not implemented pursuant to any statutory requirement. The reasoning underlying the policy is that once claims are determined to be novel and non-obvious, as a matter of law, then no significant patentability issues remain that continue to justify restriction with respect to corresponding method claims. This reasoning is *not* compelled by either of the cited cases or by § 103(b).[12] Thus, the Office is free to amend its policy at any time.

More recent case law supports the view that the utility requirement under 35 U.S.C. § 101 and the description or enablement requirements under § 112, for example, are not merely subsidiary issues for assessing patentability. In its recent *Festo* decision,[13] the Supreme Court held expressly that such requirements are as much substantive requirements for patentability as are novelty under § 102 and nonobviousness under § 103.

The patent statute charges the Director with implementing procedures to ensure that each claim examined is reviewed for compliance with all of the statutory criteria for patentability. The current practice of rejoining dependent method claims with elected product claims often raises significant new patentability issues, leading either to protracted prosecution or cursory examination. Maintaining a restriction requirement in those circumstances would be fully consistent with the status that patentability issues under §§ 101 and 112 hold in the law, and it would allow the PTO to make more efficient use of its examination resources. We urge the Office to revisit its policies in this regard.

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[11] Section 103(b) was added to title 35 by Pub.L. 104-41, 109 Stat. 3511, which was enacted specifically to address the problem of determinations by the PTO that biotechnology processes that made or used patentable products were nonetheless obvious. Such determinations typically relied on *In re Durden*, 763 F.2d 1406 (Fed. Cir. 1985).

[12] 35 U.S.C. § 103(b) provides that on election by applicant, such a process of making or using a biotechnology product will be considered nonobvious if the product is found to be nonobvious under § 103(a). It further provides that pursuant to applicant's election, a patent to the *process* shall contain claims to the product, or be set to expire on the same day as a separate patent containing claims to the product. The statute does *not* require that a patent containing claims to the *product* also contain claims to a corresponding process. Thus, the current practice of rejoining dependent method claims with allowed product claims would not be mandated by an applicant's invocation of § 103(b).

[13] *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, –, 122 S.Ct. 1831, 1839-40 (2002).

Conclusion

We appreciate the opportunity to comment on this aspect of examination practice.

Sincerely yours,

Janet E. Hasak
Associate General Counsel - Patent Law