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Sent: Wednesday, May 03, 2006 6:34 PM
To: AB93Comments; AB94Comments
Subject: Medarex's Comments

The attached letter addresses both AB93 and AB94; therefore, it is being submitted to both addresses.

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VIA E-MAIL ONLY

May 3, 2006

Jon W. Dudas, Director
John J. Doll, Commissioner for Patents
Robert W. Bahr, Senior Patent Attorney

U.S. Patent and Trademark Office
AB93Comments@uspto.gov
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Re: Comments of Medarex, Inc., on Proposed Rules:
Changes to Practice for the Examination of Claims In Patent Applications
(Fed. Reg. Vol. 71 No. 1, Page 61, Jan. 3, 2006), and
Changes to Practice for Continuing Applications, Request for Continued Examination Practice, and Applications Claiming Patentably Indistinct Claims,
(Fed. Reg. Vol. 71 No. 1, Page 48, Jan. 3, 2006)

Director Dudas, Commissioner Doll and Attorney Bahr:

The United States Patent and Trademark Office (hereinafter "the Office") is to be commended for seeking creative approaches to reducing the backlog of unexamined patent applications and improving the quality of patents. However, the changes proposed by the Office in connection with continuation practice[1] and examination of claims[2] are ill-conceived. If implemented, the proposed new rules will weaken the patent system and result in insufficient protection for new and valuable inventions. The biotechnology industry in particular will be burdened by increased prosecution costs and reduced protection. These detrimental effects will be unaccompanied by any proportionate reduction in the burden on the Office.

Medarex is a biopharmaceutical company located in New Jersey and California focused on the discovery, development, and potential commercialization of fully human antibody-based therapeutics to treat life- threatening and debilitating diseases, including cancer, inflammation, autoimmune and infectious diseases. Medarex applies its UltiMAb® technology and product development and clinical manufacturing experience to generate, support and potentially commercialize a broad range of fully human antibody products for itself and its partners. Medarex is committed to building value by developing a diverse pipeline of antibody products to address the world's unmet healthcare needs.

[1] 71 Fed. Reg. 48 (January 3, 2006)
[2] 71 Fed. Reg. 61 (January 3, 2006)

As of December 31, 2005, Medarex held an ownership interest in 58 issued U.S. patents, and 75 pending U.S. patent applications.

Medarex's ability to fund the long-term research and development as well as clinical trials and commercialization of its biopharmaceutical inventions is critically linked to its ability to secure and enforce adequate patent protection of those inventions, and thus to provide security to its investors that their investments will be protected and ultimately rewarded by a period of exclusivity. This is the fundamental purpose of the patent system, developed over hundreds of years.

The Office's proposed rule changes will adversely impact innovation, especially in the biotechnology sector, by inhibiting innovators' ability to obtain adequate coverage on their inventions and to attract financing for products that often take a relatively long time to reach the marketplace. The Office's proposed rules are intended to address application pendency and backlog. The Office also indicates the proposed rules are intended to address the issue of delayed public notice of intellectual property rights. [3] Instead of addressing these concerns however, Medarex believes these rules if adopted will increase both the backlog and pendency and create unintended consequences for the U.S. patent system.

Because both of the proposed rules are related, Medarex will address concerns with both of them in this document.

First, Medarex wishes to acknowledge the superb efforts of a number of patent commentators who have made their comments publicly available for use of other members of the public in formulating their own responses to the Proposed New Rules. In fact, much of what follows is directly supported by those papers and the references cited therein. In order to avoid repetitious submissions, therefore, Medarex will in most cases summarize and cite to these documents rather than repeat them in their entirety herein.

In particular, in creating this document, Medarex has made significant use of the following excellent submissions to AB93Comments@uspto.gov, AB94Comments@uspto.gov and other documents, which will be cited as noted:

1. Submission by Ted Apple, Partner at Townsend and Townsend and Crew LLP, dated April 18, 2006
2. Testimony of Harold C. Wegner, electronically submitted March 14, 2006
3. Submissions by the American Intellectual Property Law Association, dated April 24, 2006, commenting respectively on Proposed Rules on Continuation Applications (71 Fed. Reg. 48 (January 3, 2006)) and Proposed Rules on Examination of Claims (71 Fed. Reg. 61 (January 3, 2006))
4. Comments of the Biotechnology Industry Organization, dated May 2, 2006

[3] See for example, Fed. Reg., vol. 71, no. 1, at page 48 (right column) and page 49 (center column).

The work of the many people who contributed these thoughtful and well-reasoned comments is hereby acknowledged, and in some specific instances mentioned below, is expressly incorporated by reference.

I. Summary

- In proposing rules that fundamentally change the patent system, the Office should provide reasoning and evidence the rules are needed and that implementing them will have the intended results. The Office has not done this. Instead, the arguments made by the Office in support of the new rules are characterized by unsupported conclusions, flawed reasoning, unwarranted assumptions, and misleading statistics.
- The problems the proposed new rules are intended to solve can be more effectively addressed through changes in Office practice and implementation of new rules that alter both Applicant and Office obligations. Several such changes are proposed by a number of commentators and the Office must, as promised in their many Roundtable discussions held over the past several months, fully and fairly consider them before the Office implements any material changes to US patent practice.
- It is submitted that the Office may not have authority to implement the proposed rules. In particular, as drafted, the rules limiting continuation applications are inconsistent with statute (35 USC § 120 and possibly 5 USC § 553) and case law (*In re Henriksen,* CCPA 1968). Furthermore, patent experts have questioned whether a limit placed on voluntary divisional applications may violate U.S. obligations under the Paris Convention Article 4G2. Similarly, a question has been raised regarding whether the limit of examination of only 10 claims additionally might violate U.S. obligations under the World Trade Organization TRIPS agreement, as it pertains to the Patent Cooperation Treaty (PCT), and as applied to international or national stage applications. These various concerns are likely to leave the validity of the new rules uncertain for years to come, as lawsuits challenging them work their way through the federal courts.
- In addition, the retroactivity of the proposed rules is particularly disturbing. This retroactivity would result in the highly unfair situation in which, if a continuing application is already pending before the Office when the rules go into effect, a second continuing application would be prohibited without the granting of a petition. Additionally, the proposed claim limits would be applied to any unexamined application pending at the Office at the time the Rules changes are adopted. This situation would deprive applicants of notice of these requirements when the applications were filed. Applicants would be denied the option of choosing a different patent strategy.
- Still further, because these proposed rules apply to patent applications which are already pending, their retroactivity is in effect an unauthorized "taking" of

applicants' property rights in their inventions, as discussed by Professor Polly Price:

- "[A]lthough Congress is not required to create intellectual property rights at all, once it has done so, there may be some constitutional constraint upon retroactive modification to those rights ... The U.S. Supreme Court has long recognized that the federal government, as well as the states, ought not to change expectations retroactively, particularly to impair previously conferred benefits supported by investment-backed expectations.[4]"

- If the Office is determined to implement the proposed changes to continuation and RCE practice, as well as the proposed claims limitations, the rules should be modified and clarified, as well as limited in scope by a pilot program until the actual results of these changes can be identified and measured.

Medarex further directs the Office's attention to a fact which several of the commentators have noted, and with which Medarex agrees, that these proposed rules will have an inordinate and negative effect on the biotechnology industry, which by itself indicates that the proposed rules are inapt and unfair, in that they are in effect applied to one industry more punitively than another. This is an inherent problem with the rules, and they should not, therefore, be implemented in their current form.

II. Specific Problems Created by the Proposed Rules

The following points are discussed fully, including supporting citations, in the documents cited with each issue mentioned. Rather than repeat these cogent arguments and explanations here, in most cases, the Office is directed to those cited documents as filed (or to be filed) for a full and complete exposition of the rationale supporting the identification of these problems.

A. The proposed rules affect biotechnology inventions disproportionately

Perhaps no other industry is as dependent upon patents as is the biotechnology industry. It is not uncommon for a biotechnology company to expend hundreds of millions of dollars and work for more than a decade before it reaps its first dollar of product revenue. This is due to the huge investments in time and money required to bring a product through the discovery and lead optimization phase and, in the case of healthcare products, preclinical testing, and then clinical trials required to gain market approval. Both pharmaceutical and agricultural products are subject to extensive regulatory approval before commercialization.

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[4] Polly J. Price, PROPERTY RIGHTS ch. 4, at 8 (ABC-CLIO, 2003); see, e.g., *Connolly v. Pension Benefit Guaranty Corp.*, 475 U.S. 211 (1986): "In identifying a 'taking' forbidden by the Taking Clause, three factors should be considered: (1) 'the economic impact of the regulation on the claimant'; (2) 'the extent to which the regulation has interfered with distinct investment-backed expectations'; and (3) 'the character of the governmental action.' *Penn Central Transportation Co. v. New York City*, 438 U.S. 104, 124."

The early stages of biotechnology product development are most vulnerable to perturbations in the capital markets. At these early stages a patented idea can and must generate the interest of investors, entrepreneurs, and corporate partners. Among other factors, investors in the biotechnology sector look to a robust patent portfolio before funding the development of a particular technology. Piece-meal patent protection on risky biotechnology inventions such as that likely to result from implementation of the PTO's proposed rules will discourage investors from investing in such inventions. Without capital investment, biotechnology R&D will lessen and promising technologies will not be developed. The certainty that comes from knowing an invention discovered 10-15 years prior to coming to market can be protected provides the incentive for investors to fund high risk biotechnology products. And the strength and scope of biotechnology patents provides investors the assurance that their investments may some day be recouped.

Because of intense competition for capital investments, biotechnology companies such as Medarex are pressured to file patent applications early and often to protect both the initial concepts of their discoveries and additional supported practical embodiments. Many of these companies begin as spin-offs from initial discoveries made within an academic setting. The early years of new biotechnology companies are unstable and uncertain. Attracting investors to these high-risk ventures is difficult. However, investors are continually drawn to such companies because of the potential for high returns realized upon the discovery, development and successful marketing and/or licensing of an effective treatment or valuable product. This competitive pressure drives smaller biotechnology companies to file patent applications on inventions early in the development stage so that they may obtain that first patent to generate investor interest and to meet milestone markers established by investors. Consequently, biotechnology companies file patent applications years before a product or technology has been fully developed or commercialized. During this time, they may agree to initial narrow patents and continue to perform "proof of concept" experiments to further support their initial discovery. With the initial patent in hand, patent owners can point to other pending applications (continuations) which are broader and more comprehensive to secure further investor interest. While, biotechnology patent applicants expect broader claim coverage without additional information, they may not expend the resources to obtain a broader claim unless the area becomes an area of commercial focus.

As an example, while Medarex may have contemplated and claimed a product for human use and a method of treatment in humans, we may not have human clinical data at the time of filing. In general, we file patent applications based on promising animal and/or *in vitro* data. It is not uncommon for biotechnology arts patent applicants in general, and applicants claiming compositions and methods for treating humans in particular, to have to submit additional empirical evidence during prosecution. The PTO generally requires correlative if not corroborative evidence for patent claims to human use. Sometimes this evidence can only come in the form of clinical data which can take years to obtain. The time required to conduct such experiments often requires applicants to file continuation

applications. Further, obtaining substantive consideration of such experiments by patent examiners often requires the filing of continuations because of the PTO's restrictive "after final practice." Absent the opportunity to file continuation applications, a biotechnology company may be forced to accept protection on less than it had a right to protect, i.e., the invention in its entirety. In such a case, frequently, the only way a company will be able to protect the entire invention is by filing multiple stand-alone applications and by paying significantly more in filing and prosecution costs. As described above, biotechnology patent applications are often filed very early in the discovery process. During the time period between initial filing and first examination on the merits, experimentation to confirm the value of the disclosed invention continues, and investor relations are in flux.

Biotechnology companies such as Medarex would be disproportionately impacted by these proposed rules, as they would be forced to choose between filing additional applications and funding R&D. Some resource-limited biotechnology companies may be forced to put their inventions into the public domain or turn to trade secrets as an option to protect their intellectual property. Without protection on commercially useful technologies, investors would not invest into the further development of such technologies. Consequently, promising technologies would simply languish on the laboratory shelves and gather dust.[5]

Given the extraordinary scope of the proposed new rules, it is incumbent on the Office to justify them with clear reasoning and clear evidence. The Office has not done so. Applicants, especially in the biotechnology community, believe that if the proposed changes to continuation and RCE practice are implemented, meaningful patent protection will not be available for many inventions, and the cost of obtaining those patent rights that remain available will increase significantly. Even though the Office does not now share this view, respect for the rights and views of patent applicants demands that the Office should at least support the proposed rules with clear reasoning and evidence showing the rules are necessary and would accomplish the goals intended by the Office. Instead the Office relies on murky reasoning, unsupported conclusions, and artificial categories to justify the proposed changes.

The Office asserts the proposed rules changing continuation and RCE practice are needed because:

i. Current continuation and RCE practice are not good uses of Office resources;
ii. Implementation of the proposed rules is required to reduce the backlog of pending applications at the PTO;
iii. Implementation of the proposed rules will reduce attorney incompetence or inattention, and will combat abuse of the patent system;

[5] The previous five paragraphs were substantially taken from BIO's draft comments on the proposed rules, circulated in advance of submission to the USPTO.

iv. Under the new rules the public will have earlier and better notice about which inventions disclosed in a patent application may be removed from the public domain as granted claims;
v. Implementation of the rules will result in better patents.

Sections 1-5 of Ted Apple's Comments (Submission 1. mentioned above) explain how the arguments made by the Office are unsupported and incorrect and/or the rules offered by the Office do not solve, or are not appropriately tailored to, genuine problems of the patent system.[6] In addition, Mr. Apple's comments specifically address how the proposed rules disproportionately affect biotechnology patent applicants.

Moreover, as discussed at some length and with supporting citations, Professor Wegner has further noted that these proposed rules are particularly unfair to biotechnology applicants[7]:

> The Office says that its proposed rules "will not have an effect on the vast majority of patent applications." 71 Fed. Reg. at 50. However, the flaw, here, is that a one-size-fits-all mentality is used and individual art areas are not considered. The proposal notes that "[o]f the roughly 63,000 continuing applications filed in ... 2005, about 44,500 were designated as continuation/continuation-in-part (CIP) applications, and about 18,500 were designated as divisional applications. About 11,800 of the continuation/CIP applications were second or subsequent continuation/CIP applications. Of the over 52,000 requests for continued examination filed in fiscal year 2005, just under 10,000 were second or subsequent requests for continued examination." *Id.*
>
> Yet, quite clearly, this will not be true in the high biotechnology area where there is a necessarily inordinate number of continuing applications that are filed to permit Examiners to tread water with artificially high disposal requirements. The 250% greater frequency of continuing application filing in certain high biotechnology areas versus conventional arts such as "mufflers" speaks for itself, as per the *Survey: High Biotechnology Versus "Mufflers"*, which follows as an appendix.***[see Wegner's submission]***
>
> High biotechnology has been the red-headed stepchild of the patent system where the Office has attempted to extract disposals from Patent Examiners at roughly the same rate as in more traditional arts, despite the manifestly greater complexity of the patent applications inherent in high biotechnology.

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[6] The previous three paragraphs were substantially taken from Ted Apple's comments on the proposed rules, submitted April 18, 2006, to AB93Comments@uspto.gov, and kindly provided to other patent practitioners as a guide to prepare additional comments.

[7] The following quote is taken from Professor Wegner's submission to AB93Commnets@uspto.gov.

There is no area where the pressure on disposals is greater than biotechnology, and no area where there is a greater abuse of the continuation system to obtain disposals, whether through overly formalistic rejections, coercion of Vogel trailers or arbitrary and unreasonable restriction requirements.

If there is to be reform of the continuation abuse, this must start with a reform of the quota system that unreasonably pressures biotechnology examiners. *A fortiori*, to impose limits on continuing applications would be greatly to the disadvantage of applicants in biotechnology.

B. The proposed rules changes will not remedy the backlog in patent applications, in particular biotechnology patent applications

Every commentator has addressed this issue in exquisite detail; therefore, only an outline of those arguments will be listed here, with reference to the detailed arguments in the originals.

i. The Office's assertion that current continuation and RCE practice are inferior uses of Office resources is unsupported by any evidence or meaningful analysis, and is incorrect in at least the biotechnology arts.[8]

ii. The assertion that implementation of the proposed rules is necessary to reduce workload is based on bundling Rule 53 continuation applications and RCEs. By not distinguishing between an application and a request for continued examination, the Office presents misleading statistics, and misconstrues the problem to be solved. Having mischaracterized the problem, the Office provides an inappropriate "solution."[9]

iii. The proposed rules are an inappropriate mechanism for combating attorney incompetence and misfeasance or for combating abuse of the patent system.[10]

a. In particular, Mr. Apple's following comment is commended to the Office for careful consideration:

1. This "gaming" of the patent system appears to be an issue primarily in the computer and high tech arenas. Without intending to minimize what some believe is a significant issue, the proposed new rules are not the best way to address this problem. First, it makes no sense to make a major change to the entire patent system to address a practice by "a small minority of applicants" and largely limited in a particular technology. Second, a better tailored modification of the patent system would be to limit the types of claims that can be filed in a continuation application (for example, to limit broadening claims in continuations) or to limit the time-frame in which claims can be presented or prosecuted. Finally, rare abuses of the patent system may be have been and are properly addressed by the Courts and Congress (e.g., through the doctrine of prosecution laches or creation of prior

[8] Ted Apple's Comments, page 3
[9] Ted Apple's Comments, page 5
[10] Ted Apple's Comments, page 7

use rights for parties developing technology covered by a claim broadened in a late-filed continuation application).[11]

iv. In fact, the Office's proposed rules will likely result in an increase in the Office's workload, as noted in the BIO comments (reproduced herein):
   a. Although the PTO views these proposals as the means to reduce its backlog, exactly the opposite will occur. Indeed, the PTO's own figures show that the proposed changes in continuation and claim practices will not reduce backlog, but simply maintain it at projected levels.[12] Moreover, the PTO will likely experience a spike in application filings similar to that experienced in 1995 as a result of compliance with GATT requirements. Because of the restrictive nature of the proposals, biotechnology applicants with the necessary resources will be forced to file related applications in bulk. Currently, the steady stream of divisional applications allows the PTO to adjust and respond to needs in manpower and resources. However, the proposed rules will result in biotechnology companies being required to file large numbers of related applications in order to preserve their ability to retain the filing date of their invention.
   b. Additionally, the PTO's proposals are likely to increase the number of appeals and petitions. Applicants unable to make their case to the examiner will likely appeal to the Board of Patent Appeals and Interferences (Board). After several years of backlog, the Board has reduced its backlog and is deciding appeals in a timely manner. An increase of appeals propagated by the PTO's proposals will dramatically increase the Board's work load. In addition, Congress is currently considering legislation that would implement a new post-grant opposition procedure to be handled by the Board of Patent Appeals and Interferences. It is unclear how the PTO intends to address the increase the Board's workload.

v. One of the primary causes of the "problem" sought to be solved by these proposals is the Office's own internal problems, which are a particular problem in some biotechnology art units, and which should be addressed first. For example, as Professor Wegner notes:
   a. One of the greatest abuses that has spawned the proliferation of continuing applications is not the fault of the applicant community: A substantial minority of examiners have found that coerced continuing or divisional filings will boost their production figures and gain them promotions and bonuses. Furthermore, since lower and middle management performance ratings are dependent upon the gross production of examiners within their sphere or authority, there is an incentive to encourage or at least not discourage what has become a grossly abused practice within the PTO.

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[11] Ted Apple's Comments, page 8
[12] Presentation by Commissioner Doll, February 1, 2006 at slides 52-54

This would be equivalent to having the home basketball team supply referees from amongst its own benchwarmers to call the fouls at a game.[13]

vi. Implementation of the rules in their current form would result in an unprecedented back-log of applications.[14]

a. The chief purported goal of the new rules is to reduce Office back-log. Notably, none of the materials provided by the Office provide any prediction of the extent of the expected reduction. I believe that, if the rules are implemented in their current form, prosecution burden in the Office will increase:

1. In the vast majority of cases in which the Director asserts an "amendment, argument, or evidence to be pursued in the continuation or RCE could not have been submitted prior to the close of prosecution in the application" the applicant will appeal the finding. This problem will be exacerbated by the vague (and therefore arbitrary) standard for determining whether an amendment "could have" been submitted earlier. Both the decision of the Director and the decision on appeal will require the attention and resources of the Office.
2. Applicants will have every incentive to appeal any final rejection, in part to maintain extended copendency for purposes of prosecution of divisional applications.
3. The number of divisional applications filed will rise due to the requirement that all divisional applications be filed during the pendency of the parent, possibly resulting in a net increase in Office burden.
4. The number of petitions for review of restriction requirements will rise substantially as the consequences of restriction change.

b. Although there might or might not be a change in the number of so-called "continued examination filings" upon implementation of the rule, it is predictable that the net result of implementation will be to clog the application process, increase the number of applications pending and under appeal, lengthen pendencies, and thereby increase uncertainty by the public as to what claims will ultimately issue.

c. Moreover, if implemented, the rules will be challenged in the courts. Such a challenge would likely succeed. The process then necessary to restore rights denied to applicants will be nightmarish for both the Office and applicants.

III. <u>There are more important reforms which the Office should attend to first and which may to a larger extent obviate the "problems" the Office cites.</u>

A. Modifications to restriction practice[15]

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[13] Professor Wegner's Comments, page 4
[14] Ted Apple's Comments, page 16, Section V, is reproduced in full.
[15] Substantially as discussed in BIO's Comments

i. One contributor to the Office's workload is the Office's current restriction practice. All too often the Office restricts a single discovery into multiple groups each requiring a separate filing. At times, it may be necessary for a biotechnology applicant to file 20 or more patent applications in order to fully protect his/her invention. The current problems with the present Office Restriction practice include the extreme complexity and demonstrated difficulty of the Office to apply consistent standards. In this regard the Office has not yet concluded its study on the practicality of a Unity of Invention Practice and Restriction Practice. Medarex urges the Office to consider the comments submitted by BIO September 14, 2005.

B. Changes in the Office examiner production system and after final practice[16]

i. The need for patent applicants to file continuation applications often arises because the present Office examiner production system discourages a dialogue between examiner and applicant. Such dialogue is necessary to efficiently resolve issues after the first office action. All too often the second action is made final without thorough consideration of applicant's arguments. Moreover, once the application is finally rejected there is little hope the Office will consider "after final" communications because the Office does not allot time or credit for such communications. The patent applicant is then "forced" by the circumstances to file a continuation in order to further advance prosecution. The result is inefficient examination and unnecessary expense by both the applicant and the Office.

ii. Medarex believes that a reevaluation of examiners' goals to provide more time for the initial examination and a graduated credit system where appropriate will ensure higher quality search and examination. A graduated credit system that takes into consideration time spent on subsequent Office Actions or "rework applications" such as continuations, RCEs and Continuations-in-Part (CIPs), will provide the appropriate incentive for the patent examiner to perform a proper and thorough examination in the first Office Action. It will also likely reduce "forced" continuations through the denial of amendments after final action. Medarex believes that a graduated credit system in conjunction with additional time per balanced disposal for consideration of amendments, evidence or prior art identified from another patent office, and after final amendments would go a long way to reducing continuation filings and lessening the backlog of applications.

C. Elimination of continuing application credits[17]

i. Examiners should be given disposal credits only for a first action on the merits of an initial application and for the grant of a patent – or the final abandonment of an application that does not have a daughter continuing

[16] Substantially as discussed in BIO's Comments
[17] Prof. Wegner, page 12-13, Section D, copied (though reformatted) in its entirety.

application, and no credits should be given for requests for continued examination.

ii. Today, the default is for an Examiner to create additional filings and thereby generate additional disposals. Flipping the equation by limiting disposal credits to exclude refilings would focus the Examiner's attention on resolving all prosecutions at the earliest date without any refiling.

iii. The problem is particularly severe in the high biotechnology area where the disposal pressures on examiners are totally unrealistic and are met only by coercion of refilings. This occurs in several ways:

   a. First, some examiners write inordinately long and complex formal rejections, often without a full search or full consideration of the prior art. By the creation of complex formal issues, it is not possible to satisfactorily conclude proceedings without at least one continuing application being filed.

   b. Second, many examiners will readily allow narrow claims but will stubbornly deny generic coverage without an appeal. This has led to the routine scenario of a narrow allowance followed by the above-described "Vogel trailer"[18] where the broad claims will eventually be granted, if not promptly, then by an appeal.

   c. Third, legally ridiculous restriction requirements are made (by a minority of examiners) that have the effect of multiplying the number of applications. If there is no credit given for further continuing applications based upon restriction requirements, then the default will shift to properly examining patent applications in the first instance. A great many of the restriction requirements are inconsistent with the Patent Cooperation Treaty (PCT). There is certainly to be expected a challenge at some point in time against restriction practice in contravention of the PCT. The first court challenge occurred twenty years ago, based upon the fact that the rules of that day were inconsistent with the treaty. *Caterpillar Tractor Co. v. Commissioner of Patents and Trademarks*, 650 F.Supp. 218 (E.D.Va. 1986). Some of the interpretations of the statute and the rules have been inconsistent with American treaty obligations, which runs contrary to Charming Betsy: As pointed out by Judge Dyk, "[i]n cases of ambiguity, we interpret a statute [that implements a treaty] as being consistent with international obligations." *In re Rath*, 402 F.3d 1207, 1211 (Fed. Cir. 2005)(Dyk, J.)(citing *Murray v. The Schooner Charming Betsy*, 6 U.S. (2 Cranch) 64, 118 (1804); *Allegheny Ludlum Corp. v. United States*, 367 F.3d 1339, 1348 (Fed.Cir.2004); *Luigi Bormioli Corp. v. United States*, 304 F.3d 1362, 1368 (Fed.Cir.2002)).

iv. According to a reliable report concerning a 2005 meeting of the patent community with leaders of Technology Centers 1600, 1700 and 2800 in

[18] A "Vogel trailer" as described by Prof. Wegner is a continuing patent application filed just before issuance of a parent application that often remains pending for many years, filed in order to permit the creation of new claims without constraints imposed by the two year bar on broadening.

connection with nanotechnology, the problem of gross violations of procedural rules on patent restriction by examiners was presented. It was flatly stated there is a considerable amount of restriction requirements or rejections of generic claims that is simply contrary to the procedures and the law, yet such gross misconduct continues today. Since the performance awards of both the line examiners and their immediate superiors are in part measured by production, these production-focused shortcuts by line examiners are being policed by middle management of the Office that has its performance measured – and bonuses awarded – to a great extent based upon production that includes the fruits of such gross misconduct.

IV. The Office's authority to make the proposed changes is questionable

A. A rules-based solution clearly violates the law[19]

i. There is a holding on all fours in *In re Henriksen*, 399 F.2d 253 (CCPA 1968), that there is no statutory limitation to the time or filing of unlimited numbers of continuing applications.

ii. It is up to Congress to make any change in the present statutory provision. Insofar as the Congress that enacted the 1952 Patent Act, it is utterly wrong to attribute a negative view toward continued filings. Indeed, Congress abandoned "[t]he preliminary draft of section 120 [which] stated: 'The term of the patent granted on said later application shall not extend beyond the date of expiration of the patent if any, which may be granted on the earlier application.'" *In re Bauman*, 683 F.2d 405, 410 n.12 (1982) (quoting *In re Henriksen*, 399 F.2d 253, 257 n.10 (1968)).

iii. In the Hogan case, the court acknowledged policy concerns with a prolonged pendency, "but a limit upon continuing applications is a matter of policy for the Congress, not for us." In *re Hogan*, 559 F.2d 595, 604 n.13 (1977) (citing *Henriksen*, 399 F.2d at 262).

B. The Office does not have authority to implement the proposed rules.

i. In particular, as drafted, the rules limiting continuation applications are inconsistent with statute (35 USC § 120) and case law (*In re Henriksen,* CCPA 1968). There are concerns about the limit placed on voluntary divisional applications possibly violating U.S. obligations under the Paris Convention Article 4G2, as well as the limitation of examination of only 10 claims violating U.S. obligations under the World Trade Organization TRIPS agreement, as it pertains to the Patent Cooperation Treaty (PCT), and as applied to international or national stage applications.

V. Other, alternative, changes to Office practice which may also obviate the asserted "problems"

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[19] Adapted from Prof. Wegner's Comments, page 8-9

A. From Ted Apple's suggestions (see his Comment for details)[20]:

i. Adopt optional Unity of Invention practice
ii. Prior to beginning examination of an application, ask the applicant to confirm intent to maintain the application
iii. Require the applicant to advance prosecution (in abusive cases)
iv. Change the format of claim amendments
v. Evaluate the effect of examiner's incentives on prosecution
vi. Implement or expand quality control procedures
vii. Optional expedited examination
viii. … The more important point is that the solution to the problem of application back-log, or the perceived problem of increasing numbers of RCEs filed, lies in improving the examination system, not on introducing rules that will deny applicants, particularly in the biotechnology arts, legitimate patent protection.

B. From the BIO Comments:

i. Improve cooperation with other patent offices to reduce "double work"
ii. Flexible examination: deferred/accelerated examination[21]
   a. At the request of either applicant or third party, with preference given to accelerated examination in case of conflict

VI. Specific comments regarding the proposed Changes to Practice for the Examination of Claims in Patent Applications

A. Medarex respectfully submits that the Comments submitted by the AIPLA[22] substantially set forth its objections to the proposed rules changes.

B. In addition, Medarex urges that the same objections cited above with regard to the frustration of purpose and waste of both applicants' and the Office's resources due to improper restriction practice be considered in considering the limitations on the number of claims examined.

C. In particular, Medarex urges that adoption of Unity of Invention standards and multiply dependent claims be considered to expedite and enhance efficient and compact prosecution.

VII. Conclusions

A. Medarex respectfully submits that the proposed rules changes are an inappropriate mechanism for correction of a problem which has not been

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[20] Ted Apple Comments, page 11-13
[21] See complete discussion in BIO's Comments
[22] Submission by the American Intellectual Property Law Association, dated April 24, 2006, commenting on Proposed Rules on Examination of Claims (71 Fed. Reg. 61 (January 3, 2006)

adequately demonstrated, with potentially disastrous consequences, both foreseeable and not yet appreciated, and should be withdrawn.

B. Medarex further submits that the proposed rules changes are in contravention of applicants' property rights under the Constitution, the Patent Statutes (notably 35 U.S.C. § 120), possibly also in contravention of the Administrative Procedures Act (5 U.S.C. Section V), as well as long-standing and well-settled case law (e.g., *In re Henriksen*), and that the Office is acting *ultra vires* in amending patent practices which can only properly be changed by an Act of Congress.

C. While Medarex appreciates that the Office perceives that problems exist that need to be addressed by drastic measures, Medarex nevertheless strongly urges that the Office look to addressing their own internal issues that are contributing to a larger extent to these problems, and "clean their own house" before they attempt to implement changes to patent practice that could have devastating impacts on the ability of companies in the United States, in particular to U.S. biotechnology companies, as well as innovators throughout the world, to obtain meaningful patent protection and thus their ability to attract investment capital, and to disturb the settled expectations of world investment markets.

Sincerely,

MEDAREX, INC.
Diana Hamlet-Cox, Ph.D., J.D.
Vice President and Chief Patent Counsel
USPTO Reg. No. 33,302

/dhc