-----Original Message-----

From: Wegner, Harold C.
Sent: Tuesday, March 14, 2006 5:57 PM
To: 'AB93Comments@uspto.gov'
Subject: Testimony on New Rules - Continuation Rules

Attached in pdf format is my –

Testimony

responsive to the proposed rulemaking

Changes To Practice for Continuing Applications,

Requests for Continued Examination Practice, and

Applications Containing Patentably Indistinct Claims

71 Federal Register 48 (January 3, 2006)

electronically submitted as **continuingAB93wegner** via AB93Comments@uspto.gov

Respectfully submitted,
Harold C. Wegner

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Testimony of

Harold C. Wegner

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Thank you for permitting me to testify concerning the captioned rule-making. The Office quite correctly focuses upon one of the several chronic problems that faces the Office and which requires prompt action.

The most important reform to meet the objectives of the proposed rulemaking is to immediately remove any production or "disposal" credits for examiners based upon continuing applications: This would instantly provide a motive force to reach the earliest conclusion of proceedings without continuing applications.

Insofar as the elimination of continuing applications, a *statutory* solution is suggested to bar *any* continuing application after thirty months from filing. This is a better solution to meet the precise objectives of the proposed rulemaking. A rules-based change would also raise a test case on the basis that the Office lacks statutory authority for the change.

Numerous ills are implicated by multiple continuation filings, particularly long net pendency and resultant late presentation of claims tailored to capture intervening third party innovations. But, *long pendency is still possible even with the elimination of continuing application*: This is a *different* problem better addressed by statutory reforms that would create *legal* intervening rights for anyone who commercializes a product before a broadening amendment.

[**hwegner@foley.com**]

PRO BONO PRESENTATION OF THIS TESTIMONY

I acknowledge my positions as former Director of the Intellectual Property Law Program and Professor of Law at the George Washington University Law School with which I remain affiliated and also as a partner in Foley & Lardner LLP. The testimony here is *pro bono* and does not necessarily reflect the view of any organization nor colleague nor client thereof. This testimony substantially follows the text of a letter dated February 15, 2006, to the Hon. Jonathan W. Dudas, Under Secretary of Commerce for Intellectual Property, captioned *A Preliminary Response to the Proposed Rules*:

PATENT WORKSHARING AS A PRIMARY GOAL

Before *any* of the changes in the proposed rulemaking can be seriously considered for implementation, they must be weighed in the context of the one true procedural reform of immediate necessity, patent worksharing which are the most important route to quality enhancement and a sharp curtailment of the backlog. There must be immediate implementation of realistic patent worksharing to permit American examiners to examine American patent applications while applications from Asia and Europe and elsewhere are first fully examined in each "home country" of the applicants. If the nearly half of all patent applications that are filed today of foreign origin were first examined abroad, then there would be more than ample time for both a quality and timely examination.

Patent worksharing has been considered in various fora for more than a decade, yet it obviously has not been taken into account as part of the proposed rulemaking. The reason that it is imperative that patent worksharing be considered *first*, prior to any of the proposed reforms, is that the proposed reforms will create more work for American examiners and do nothing to facilitate patent worksharing. This will only exacerbate the problems that already exist.

I. SUMMARY OF PROPOSED SOLUTIONS

First, to achieve the goals of the current proposal, there needs to be an *immediate* statutory reform, one that can be supported by all – whether it is the independent inventor community or the now-polarized industry groups, and this set of changes must be *prospective* in their application. Only with a solution that applies to everyone will it be possible to gain the necessary legislative consensus.

One of the root causes for prolonged pendency, whether through continuing applications or otherwise, is the inability of the system to handle simple mistakes that impact claim scope at any time after grant but particularly more than two years after grant. If a simple statutory fix is provided to remedy the problem, then much of the necessity for prolonged pendency will evaporate. *See* § II-A, *Simple Corrections at any Time via Reexamination.* One of the valid complaints about the present practice is the late stage amendment that broadens claim coverage to the detriment of industry that in the interval between the filing date and the amendment has made new technologies that are mirrored by subsequently presented claims. The proposed statutory reform, while permitting broadening amendments at any time, would also provide a *legal* intervening right to the public that would be keyed to developments made prior to the date of a broadening amendment. The *absolute* – as opposed to equitable – defense of intervening rights will better safeguard industry and eliminate any incentive for delayed prosecution. See § II-B**,** *Legal (as Opposed to Equitable) Intervening Rights.* All continuing applications of any kind should be barred thirty months after filing. *See* § II-C, *Elimination of All Continuing Applications after 30 Months.*

Immediate regulatory reforms are needed that go beyond the current rulemaking proposal. *See* § III, *Immediate Regulatory Reforms.* Among other reforms, generalist examiners should be hired as opposed to ultra-specialized advanced degree scientists and engineers who may fill a void for the short term but will be unsuited to be transferred into a different art area when the needs arise. One of the paramount needs is the flexibility of the generalists so that manpower can be shifted to newly emerging backlog problem areas. It is imperative that the high technology areas be given a *priority* treatment, if there is to be a disparity, and not thrown into the back room of backlogged cases because the examiners are not able to deal with

[**hwegner@foley.com**]

the particular technology. *See* § III-A, *Equal Examination Backlogs in All Technologies.*

As part of the equal treatment of all applicants in all technologies, the Office should not permit "dipping" into newer cases that are easier to examine to gain short range production goals. More importantly, there should be an Office-wide announcement, once a month, that projects when cases will be taken up for action so that no case will be taken up within six months of a projection (unless previously slated for such action). In this way, applicants can better manage their preliminary filings and file just *one* preliminary filing just prior to examination, instead of the often piecemeal and rushed filings that take place today out of a concern that the first action will arrive "at any time". *See* § III-B, *Creation of a Realistic Schedule for First Actions.* Yet, any person at any time, applicant or third party, should be able to request – for a substantial fee – an accelerated examination; *inter partes* participation should also be considered, taking into account the era of all electronic filings or, now, at least electronic file wrappers open to the public. *See* § III-C, *Accelerated Examinations at Anyone's Request.*

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

The proof of the pudding lies in the greatly increased number of continuing application filings that one witnesses in recent years and which is a key driver of the rulemaking proposal. An immediate reform to eliminate continuation filing credits *must* be implemented or all the proposed changes will be for naught as the home team referees will continue to call the plays. *See* § III-D, *Elimination of Continuing Application Credits.*

[**hwegner@foley.com**]

Double patenting! Reminiscent of counting deckchairs on the Titanic, the rules have a focus upon double patenting issues in related patent applications. This is an entirely misguided focus. The proposed rules will only complicate matters further. First, at least insofar as the post-GATT post-1995 filings are concerned, there is no substantial problem with extension of patent term. The only other "concern" relates to the elimination of the possibility that different owners may have patents to overlapping subject matter. But, this problem *already* exists because the current regulations can be totally circumvented by maintaining a common title owner of the patents but with an exclusive licensing mechanism to split the actual ownership rights.

If the proposed reform is implemented, then applicants will no longer file multiple applications with related subject matter on the same date: Instead, they will simply file a "jumbo" patent application lumping everything together and then await a restriction requirement, after which a series of divisional applications will be filed – reaching the same result by a circuitous route that entails yet another layer of continuing or divisional filings. *See* § IV, *Faux Double Patenting Considerations.*

There are several public policy considerations that need to be given greater consideration. *See* § V, *Public Policy Considerations.* First, the one-size-fits-all regulations that are proposed discriminate heavily and unfairly against the biotechnology industry, particularly the high biotechnology cases that only comprise a fraction of the "biotechnology" of Technical Center 1600. While the Office is correct that the overall rate of continuing applications is very small, for high biotechnology the rate is approximately 250 % that of some traditional "muffler" arts. See § V-A, *Fairness for Biotechnology Applicants.*

Even worse is an outright xenophobia; it stands behind the rulemaking process and even permeates the official explanation of the proposed rulemaking in the otherwise carefully edited and thought out passages of the *Federal Register.* Overseas regimes learn from what we do in the United States, as graphically illustrated in a slightly different context as a Chinese court has held Pfizer's Viagra patent to be invalid (although there is an appeal pending). To be sure, foreign and particularly Japanese and Korean patent applicants will be the short term losers of any implementation of the current rulemaking package. Yet, like a boomerang, the proposed rulemaking will become a blueprint for foreign patent offices

to create anti-American regulations throughout Asia that will make it next to impossible for Americans to gain meaningful rights abroad. *See* § V-B, *Protecting American Rights Abroad.*

II. STATUTORY REFORM

A. Simple Corrections at *Any* Time via Reexamination

The first reform that is absolutely needed is that the patentee should be able to correct his mistakes in patent drafting *at any time* during the lifetime of the patent, particularly to cure the obvious drafting mistakes that become obvious only in the bright light of hindsight when a product is about to be commercialized. To make the reform as simple as possible, an amendment should be made to the reexamination statute that permits a *broadening* of claims at any time.

It is too easy to say that simple drafting mistakes should be the responsibility of the patentee and should be caught before the patent issues. Experience proves that the garden variety patent practitioner is not able to spend sufficient time to make certain that all errors in claim preparation have been weeded out by the time the patent has been granted. Only years later, as a new product is commercialized, *then* and only then does the patentee spend the tens of thousands of dollars for a detailed study of the patent situation, and learn – often in horror – that the claims are not perfect and that there is a loophole that makes the patent commercially worthless. The mistake may be as simple as using the word "to" instead of "at", as happened in the *Chef America* baking process where the patentee's examples showed flash heating *at* near incineration temperatures, but the claim set forth heating the dough "to" such temperatures that results in the nonsensical interpretation of the patent as producing charcoal dust. *See Chef America, Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1372 (Fed. Cir. 2004)(Schall, J.). Here, if the patentee learns of the mistake even years later, he should be able to make a correction of a *Chef America* situation, but if the patent is more than two years old, the present law proscribing a post-grant broadening would bar correction.

As a consequence of the *Chef America* situation, many patentees find themselves with worthless intellectual property. Prudent patentees, however, file "Vogel trailers" just before grant – continuing patent applications that often remain pending for many years in order to permit the

creation of new claims without constraints imposed by the two year bar on broadening. "Vogel trailers" were considered in more detail in my testimony a few years ago in testimony before the United States House of Representatives Committee on the Judiciary Subcommittee on Courts and Intellectual Property, *Hearing on the "21st Century Patent System Improvement Act", H.R. 400*, February 26, 1997, § I-2-4, *Vogel Trailers, A Much Larger Problem* [http://judiciary.house.gov/legacy/4130.htm] (Under *In re Vogel*, 422 F.2d 438 (CCPA 1970), a patentee who seeks to protect a method of treating "pork" is able to gain a *second* patent to a method of treating "meat", which is considered not to be the "same invention".)

B. Legal (as Opposed to Equitable) Intervening Rights

While patentees need the right to broaden their claims at any time to deal with *Chef America* situations, it is at least as important that industry have certainty as to the scope of protection of a competitor's patent *as soon as possible.* Constructive suggestions to achieve this goal have been made, for example, by Micron's David Westergard, *Remedying the Growing Abuse of the Patent System Through Targeted Legislation*, p.2, Thirteenth Annual Conference on International Intellectual Property Law and Policy, Fordham University Law School, New York, March 31-April 1, 2005.

It is proposed that three statutory changes be made for intervening rights:

First, any broadening that occurs more than eighteen months from the first filing date (exclusive of Paris Convention or provisional application priority) be subject to *legal* intervening rights. Thus, intervening rights under the current statutory scheme, alone, leave great uncertainties for the public because they are *equitable* in nature.

Second, intervening rights would be keyed to the *date of amendment* as opposed to the date that a reexamination or reissue is concluded. Thus, if a *Chef America* type of mistake is discovered at the onset of commercialization by the pioneer inventor, it will be possible to freely use the proposed system. But, where intervening rights are keyed to the conclusion of reexamination or reissue, then third parties are able to delay the proceedings and develop intervening rights in the interval. This is a great discouragement to the use of the current system by the patentee. There also is no public notice problem for the public to determine the existence of

intervening rights before the conclusion of reexamination because all file wrappers in reexamination and reissue proceedings are electronically available from the Office.

Third, the same intervening rights after eighteen months would be applicable to patent *applications* as well as patents. This would put an end to the submarine patent situation once and for all.

C. Elimination of *All* Continuing Applications after 30 Months

1. The Correct Statutory Route

No continuing application of *any* type (other than a divisional) should be permitted to claim priority of any kind dating back more than thirty months from the effective filing date nor should a request for continued prosecution be permitted more than thirty months from the priority date.

Where a restriction requirement is made by the Office, the deadline for filing a divisional application should be the later of (a) thirty months from the filing date, (b) three months after a restriction requirement or (c) one month after the final denial of a request for reconsideration of a petition against a restriction requirement (including any administrative or judicial appeal).

With the virtually automatic publication of all applications eighteen months from the priority date, any new application that is filed to claim new matter more than thirty months from the priority date will generally be barred under 35 USC § 102(b) based upon the publication of the underlying application. This makes the use of a continuation-in-part application to add evolutionary inventions in a common application an often misguided venture.

2. A Rules-Based Solution Clearly Violates the Law

The clear advantage of the solution proposed here is that it is a statutory solution, whereas the proposed rulemaking will be open to challenge for many years. 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.

Before the 1952 Patent Act and the creation of 35 USC § 120 there was no limit to the number of continuing applications that could be filed. As explained by the late Judge Rich, "[s]ection 120 appeared in the statutes for the first time in the Patent Act of 1952. Prior to 1952, continuing application practice was a creature of patent office practice and case law, and section 120 merely codified the procedural rights of an applicant with respect to this practice. *Transco Products Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 556-57 (Fed. Cir. 1994)(citing *Racing Strollers, Inc. v. TRI Indus., Inc.*, 878 F.2d 1418, 1421 (Fed.Cir.1989); *In re Hogan*, 559 F.2d 595, 603, 194 USPQ 527, 535 (CCPA 1977); *Henriksen*, 399 F.2d at 258-260). Furthermore, "[b]efore section 120 was enacted, the Supreme Court noted that a continuing application and the application on which it is based are considered part of the same transaction constituting one continuous application. *Transco,* 38 F.3d at 556-67, citing *Godfrey v. Eames,* 68 U.S. (1 Wall) 317, 325-26(1864)(footnote omitted).

One of the management leaders of the Office in his explanation of the proposed rules to the Bar Association of the District of Columbia stated in effect that Congress could not possibly contemplate patent application filings that would extend for twenty years. Yet, whether *today's* Congress would repudiate *Henriksen* or not is a question that is left for *today's* Congress to determine: *Yesterday's* Congress clearly did not have this viewpoint, as seen from the legislative history.

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)).

Thus, "[t]he deletion of this provision indicates that Congress did not intend limitations such as patent expiration date with that of the patent issued on the parent application to be imposed on the patent issuing on the continuation application." *Bauman,* 683 F.2d at 410 n.12. 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).

Placing limits on the number of continuing applications will work undue hardships on applicants who face the clearly arbitrary or "stubborn" examiner who refuses to play by the rules. The Office has itself *acknowledged* the problem of the "stubborn" examiner and suggests that for this situation the applicant should file an appeal instead of continuing prosecution before the Examiner! This is actually stated in the proposed rulemaking. *Continuing Application Rulemaking*, 71 Fed. Reg. at 51 ("[F]or an applicant faced with a rejection that he or she feels is improper from a seemingly *stubborn examiner*, the appeal process offers a more effective resolution than seeking further examination before the examiner.")(emphasis added).

There are also other, legitimate reasons to file a continuing application that have not been considered in the proposed rulemaking. For example, in the case of an evolutionary invention in the pharmaceutical field, numerous entities are produced over months and many years. It may be advisable to file a continuing application each time there is a significant new entity in order to add an example to that new entity. The claim to the new entity, alone, has a priority date only as of the actual filing date. But, in addition to whatever claim is presented, by inclusion of an example to a further new entity, a patent-defeating right is created that will bar a third party with a junior claim from dominating or otherwise claiming the new entity. Numerous continuing applications can be envisioned under this scenario.

III. IMMEDIATE REGULATORY REFORMS

A. Equal Examination Backlogs in All Technologies

The Office should *immediately* implement a policy that the *oldest* applications should be taken up for examination *immediately*. There is no valid public policy consideration for favoritism of certain cases because they represent "easy" disposals or because of the technology differences amongst the applications. With a pool of roughly 4000 examiners, it should be possible for the Office to reassign examiners to make certain that there are no glaring discrepancies in the time for examination.

Thanks to the high turnover rate, no examiner need be fired or replaced to achieve an ongoing balance. The high attrition rate will take care of any problems. This means that *immediately* there must be a focus on high backlog areas such as biotechnology, which in any event is one of the crown jewels of American intellectual property successes.

B. Creation of a Realistic Schedule for First Actions

The Office should maintain a current projection of precisely *when* new patent applications are to be taken up for a first Office Action. *No* application should be taken out of turn to disrupt this schedule. The projection should be on an Office-wide basis and not technology by technology.

As an ancillary benefit to creation of a schedule of this nature, then applicants facing, say, an eighteen month further pendency before a first action could take most of this period to update prior art status with foreign counterparts and otherwise file an Information Disclosure Statement just before the expiration of the expected time for the first action. No penalty should be imposed upon an applicant who files an IDS prior to the scheduled first action date.

C. Accelerated Examinations at *Anyone's* Request

To be sure, there will be some applications that *should* be accelerated for examination, whether due to the interest of the applicant or a third party. Here, conditions should be placed upon the applicant who makes such a request that would include, for example, the following:

1. *Inter partes* Presentation of a Concise Prior Art Statement

The public should be able to present no more than one or two or so pieces of prior art and an at most one (1) page statement of relevance to the Examiner that can be considered in the prosecution of an accelerated case.

2. Prior Art Search Results from the Applicant

The applicant should present an Examiner's first action on the merits from either the European or Japan Patent Office from a counterpart *or* the applicant should authorize for a high fee a special search that the Office could conduct on its own or outsource.

D. Elimination of Continuing Application Credits

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

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.

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:

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.

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" where the broad claims will eventually be granted, if not promptly, then by an appeal.

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)).

According to a reliable report concerning a 2005 meeting of the patent community with leaders of Technology Centers 1600, 1700 and 2800 in 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. *FAUX* DOUBLE PATENTING CONSIDERATIONS

Double patenting rejections should be eliminated insofar as different inventions are claimed in related patents or applications. Two or more applications will always be to different "inventions" in the sense of double patenting absent the rare situation with claims of identical scope. As explained earlier in connection with Vogel trailers, one application may claim a method of treating "pork", yet a second application may claim a method of treating "meat" and be deemed to be to a different invention.

The ostensible harm to the public with the grant of related patents to patentably indistinct subject matter *was* the extension of patent term, a problem that has largely evaporated since the implementation of the GATT. The second "evil" is that the public should not be faced with the need to license from or otherwise deal with two or more parties. The premise that there is a difficulty with dealing with plural parties is a concern that appears to be largely of the making of the Office, itself. Yet, even assuming, *arguendo*, that this is a valid concern, the present regulatory scheme is totally deficient as providing any meaningful protection to the public: Because the patentably indistinct subject matter cannot be *assigned* to different parties, a common assignee simply grants an exclusive license to divide the effective ownership of the several patents. Even worse, the public is unable to determine the different ownership of rights from the records of the Office because there is recordation of assignments but not licenses at the Office.

Therefore, the Office should forthwith *eliminate* double patenting rejections insofar as two or more applications and/or patents deal with claims to different – even if patentably indistinct – inventions. There is essentially no harm at all to the public through the grant of plural applications having the same or roughly the same filing dates, while the technical traps for the unwary and the unnecessary examination burdens established by double patenting rejections unduly complicates procurement, creating a burden also on the Office. The burden on the Office is manifested by the proposed rulemaking, which seeks to put new burdens on the applicants who file applications to related subject matter.

The proposed rulemaking, to the extent that it imposes new burdens on patent applicants and creates a presumption of double patenting, goes 180 degrees in the wrong direction. Instead of *eliminating* double patenting rejections it *complicates* filings and places new burdens on patent applicants.

To the extent that the proposed rulemaking suggests that there should be a double patenting rejection against an applicant unless the applicant can establish a lack of double patenting, this flips the burden from the Examiner to the applicant and for this reason alone should be reconsidered. This is akin to saying that if the applicant cites prior art, there is a presumption of obviousness unless the applicant establishes that the invention is nonobvious over the prior art.

[**hwegner@foley.com**]

From a practical standpoint, the rules create only more problems for the Office than they solve. If, today, the applicant has three distinct but related inventions, he may file three applications in parallel. If the new policy is created, then the applicant will instead file a *single* application but with three sets of claims, each starting on a new sheet, permitting the Examiner the opportunity to readily see that a restriction requirement is made. Then, the applicant will elect one of the inventions, and file two divisionals, perhaps serially, to achieve the same net effect.

V. PUBLIC POLICY CONSIDERATIONS

A. Fairness for Biotechnology Applicants

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.

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.

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. Protecting American Rights Abroad

The proposal represents an undisguised xenophobia against foreign patent applicants that, if enacted, will have their desired effect of hurting the protection by Japanese, European and other foreign applicants in the United States. 71 Fed. Reg. at 49 ("The Office … notes that not every applicant comes to the Office prepared to particularly point out and distinctly claim what the applicant regards as his invention, for example, where the applicant's attorney or agent has not adequately reviewed or revised the application documents (often a literal translation) received from the applicant."). Under the long-standing global patent procurement regime that goes back to the nineteenth century, an applicant seeking a global patent portfolio first focuses upon gaining full and proper protection in his "home country" patent office, while merely filing what is often a translation of the application in the foreign patent offices via the Paris Convention – now aided by the use of the PCT that defers translations for up to thirty months or more from the priority date.

After the applicant achieves a patent position in his home country, then there is an assessment made of whether it is worthwhile to gain strong patent protection on a global basis *or* to obtain minimal coverage *or* to abandon foreign rights. Under the first situation, then often massive efforts are expended to revise the claims and tailor the prosecution to meet the local foreign law conditions; under the second situation, the application as filed is simply procured to the end, with instructions to obtain whatever claims the examiner may permit; while, under the final situation, the case is permitted to lapse. What is key is that the triage that separates cases into the three categories takes place several years after the first filing, both after the conclusion of the "home country" proceedings and after the time needed to determine the relative importance of a particular case.

What the proposal will accomplish is that all foreign filings will be squeezed into a one-size-fits-all model and foreign applicants will be forced to perform their triage at a prematurely early stage. While this will have no impact on the Office, it *will* have a huge impact on domestic applicants who

are seeking protection in Europe, Japan and elsewhere: Clearly, if the United States on a unilateral basis implements the proposal, then the major, negative impact on applicants in Europe, Japan and elsewhere will result in retaliatory, reciprocal challenges that will make it far more difficult for corporate America to obtain meaningful foreign patent protection. As one concrete example of how foreign countries are "educated" by strict American practice, consider the situation where China has learned about the strict "written description" requirement of American law and has held Pfizer's Chinese Viagra patent invalid. (The case is on appeal.)

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APPENDIX –

SURVEY: HIGH BIOTECHNOLOGY VERSUS "MUFFLERS"

For more than a decade, small samples have been taken of certain high biotechnology areas versus "muffler" patents as a contrast between high tech and the more mature industries, and such studies have invariably shown a huge discrepancy between the two. In a recent study, a small biotechnology sampling showed 65 % of the patents were based upon at least one parent filing (domestic or foreign); of those having a at least one parent filing, the average number of parent filings was 2.8. The *net* pendency for biotechnology was found to be nearly seven (7) years, whereas pendency counted from the most recent filing was "only" four (4) years. 65 % of the patents were based upon at least one parent filing (domestic or foreign); of those having a at least one parent filing, the average number of parent filings was 2.8. (note 1) In contrast, the average *net* pendency from first filing for "mufflers" was less than three (3); or, just over two (2) years from *actual* filing (28 months); there was less than one parent per patent (0.8); for the 70 % of the patents that did have a parent, the average was just over one per patent (1.1) (note 2).

Note 1: The survey was carried out on Lexis on June 6, 2005, "claims(plasmid)", for U.S. utility patents granted in May 2005. "Plasmid" was used as a search term to find only or largely patents that would deal with "high tech" biotech. The twenty most recently granted patents were obtained as they were listed on Lexis when this search was run; all patents were granted in the time frame May 10-31, 2005. The dates were rounded off to the month without consideration of the specific day of the month.

(1) 6900368 ACTUAL FILING DATE: January 13, 2003 PATENT GRANT DATE: May 31, 2005; *Division of Ser. No. 10/340693, US 09/597771, June 19, 2000; Continuation-in-part of Ser. No. 09/597771 09/348675, July 6, 1999*; (2) 6900305 ACTUAL FILING DATE: August 2, 2001 PATENT GRANT DATE: May 31, 2005; *Continuation-in-part of Ser. No. 09/921944 09/632314, August 4, 2000*; (3) 6900042 ACTUAL FILING DATE: February 26, 2004 PATENT GRANT DATE: May 31, 2005; *Division of Ser. No. 10/786065, US 10/224562, 20040504 (20040504), August 21, 2002; Division of Ser. No. 10/224562, US 09/801861, 20021210 (20021210), March 9, 2001; Provisional Application Ser. No. 60/265151, January 31, 2001*; (4) 6900035 ACTUAL FILING DATE: November 7, 2002 PATENT GRANT DATE: May 31, 2005*; Continuation of Ser. No. 10/289760, US 09/498918, February 4, 2000; Continuation of Ser. No. 09/498918 PCT/CA98/00246, March 20, 1998; Provisional Application Ser. No. 60/054835, August 5, 1997;* (5) 6899890 ACTUAL FILING DATE: March 20, 2002 PATENT GRANT DATE: May 31, 2005; (6) 6897359 ACTUAL FILING DATE: January 13, 2003 PATENT GRANT DATE: May 24, 2005; *Division of Ser. No. 10/340583, US 09/597771, June*

19, 2000; Continuation-in-part of Ser. No. 09/597771 09/348675, July 6, 1999; (7) 6897300 ACTUAL FILING DATE: February 19, 1998 PATENT GRANT DATE: May 24, 2005; *PRIORITY: February 21, 1997 - 9037499, Japan (JP)*; (8) 6897063 ACTUAL FILING DATE: June 19, 2002 PATENT GRANT DATE: May 24, 2005; *Division of Ser. No. 10/177871, US 09/406363, September 28, 1999; Continuation of Ser. No. 09/406363, US 08/745957, November 7, 1996; Provisional Application Ser. No. 60/006402, November 9, 1995*; (9) 6897055 ACTUAL FILING DATE: April 20, 2001 PATENT GRANT DATE: May 24, 2005; *PRIORITY: November 25, 1999 - 19956686, Germany (DE); Continuation-in-part of Ser. No. 09/838564 09/728498, November 27, 2000;* (10) 6897027 ACTUAL FILING DATE: March 27, 2002 PATENT GRANT DATE: May 24, 2005; (11) 6896905 ACTUAL FILING DATE: December 13, 2001 PATENT GRANT DATE: May 24, 2005; *Provisional Application Ser. No. 60/268832, February 15, 2001*; (12) 6893866 ACTUAL FILING DATE: May 26, 2000 PATENT GRANT DATE: May 17, 2005; *PRIORITY: November 28, 1997 - PP0627, Australia (AU); September 23, 1998 - PP6096, Australia (AU); Continuation of Ser. No. 09/580476 PCTAU98/00993, November 30, 1998;* (13) 6893861 ACTUAL FILING DATE: February 18, 1999 PATENT GRANT DATE: May 17, 2005; *PRIORITY: February 18, 1998 - 38898, Switzerland (CH); Continuation of Ser. No. 09/833799, US 08/427170, April 24, 1995; Continuation of Ser. No. 08/427170, US 07/926371, August 10, 1992; Continuation of Ser. No. 07/926371 07/536096, June 8, 1990*; (14) 6893843 ACTUAL FILING DATE: April 13, 2001 PATENT GRANT DATE: May 17, 2005; *Continuation of Ser. No. 09/833799, US 08/427170, April 24, 1995; Continuation of Ser. No. 08/427170, US 07/926371, August 10, 1992; Continuation of Ser. No. 07/926371 07/536096, June 8, 1990*; (15) 6893638 ACTUAL FILING DATE: April 7, 1998 PATENT GRANT DATE: May 17, 2005; (16) 6891084 ACTUAL FILING DATE: October 22, 1999 PATENT GRANT DATE: May 10, 2005*; PRIORITY: April 26, 1996 - 8107682, Japan (JP); July 26, 1996 - 8198079, Japan (JP); April 28, 1997 - 9111124, Japan (JP); Continuation of Ser. No. 09/425055 PCTJP97/03879, October 24, 1997; Continuation-in-part of Ser. No. PCTJP97/03879, US 08/846234, April 28, 1997*; (17) 6891028 ACTUAL FILING DATE: July 22, 1999 PATENT GRANT DATE: May 10, 2005; *Provisional Application Ser. No. 60/107502, November 6, 1998*; (18) 6890744 ACTUAL FILING DATE: August 30, 2001 PATENT GRANT DATE: May 10, 2005; *PRIORITY: September 2, 2000 - 10043331, Germany (DE);* (19) 6890740 ACTUAL FILING DATE: February 12, 2001 PATENT GRANT DATE: May 10, 2005; (20) 6890733 PCT- ACTUAL FILING DATE: July 21, 1999 PATENT GRANT DATE: May 10, 2005*; Provisional Application Ser. No. 60/093590, July 21, 1998.*

Note 2: The search followed the same methodology and was run for the same period but yielded only ten patents for claims with the term "muffler": 6899199**;** 6899198; 6899100; 6893487; 6893233; 6892855; 6892853; 6892852; 6889789; 6889499.