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DEPARTMENT OF COMMERCE
Patent and Trademark Office
[Docket No. 941259-4359]

Request for Comments on Proposed Utility Examination Guidelines

AGENCY: Patent and Trademark Office, Commerce

ACTION: Notice and request for public comments.

SUMMARY: The Patent and Trademark Office (PTO) requests comments from any interested member of the public on proposed internal guidelines that will be used by patent examiners in their review of patent applications for compliance with 35 U.S.C. § 101. Because these guidelines govern internal practices, they are exempt from notice and comment rulemaking under 5 U.S.C. § 553(b)(A).

DATES: Written comments on the proposed guidelines will be accepted by the PTO until February 24, 1995.

ADDRESSES: Written comments should be addressed to the Commissioner of Patents and Trademarks, marked to the attention of Jeff Kushan. Comments submitted by mail should be sent to Commissioner of Patents and Trademarks, Box 4, Patent and Trademark Office, Washington, DC 20231. Comments may also be submitted by telefax at (703) 305-8885 and by electronic mail through the Internet to "comments-biotech@uspto.gov." Written comments should include the following information:

- name and affiliation of the individual responding;
- an indication of whether comments offered represent views of the respondent's organization or are the respondent's personal views; and
- if applicable, information on the respondent's organization, including the type of organization (e.g., business, trade group, university, non-profit organization) and general areas of interest.

Parties presenting written comments are requested, where possible, to provide their comments in machine readable format. Such submissions may be provided by electronic mail messages sent over the Internet, or on a 3.5" floppy disk formatted for use in either a Macintosh or MS-DOS based computer. Machine-readable submissions should be provided as unformatted text (e.g., ASCII or plain text).

Written comments will be available for public inspection on or about March 1, 1995, in Room 902 of Crystal Park Two, 2121 Crystal Drive, Arlington, Virginia. In addition, comments provided in machine readable format will be available on or around March 1, 1995, through anonymous file transfer protocol (ftp) via the Internet (address: comments.uspto.gov) and through the World Wide Web (address: www.uspto.gov).

FOR FURTHER INFORMATION CONTACT: Jeff Kushan by telephone at (703) 305-9300, by fax at (703) 305-8885, by electronic mail at kushan@uspto.gov, or by mail marked to his attention addressed to the Commissioner of Patents and Trademarks, Box 4, Washington, DC 20231.

SUPPLEMENTARY INFORMATION

I. Guidelines for Examination of Applications for Compliance with the Utility Requirement

A. Introduction

The following guidelines establish the policies and procedures to be followed by Examiners when examining applications for compliance with the utility requirement of 35 U.S.C. § 101. The guidelines also address issues that may arise during examination of applications claiming protection for inventions in the field of biotechnology and human therapy. The guidelines are accompanied by an overview of applicable legal precedent governing the utility requirement.

B. Guidelines for Examination of Applications for Compliance With 35 U.S.C. § 101

Examiners must adhere to the following procedures when examining applications for compliance with 35 U.S.C. § 101.

1. Determine what the applicant has claimed as his or her invention. This is done to:

   a) ensure that the applicant has claimed statutory subject matter (e.g., a process, a machine, a composition or a manufacture); and

   b) ascertain what the invention is for purposes of determining whether it is "useful."

2. Review the specification and claims to determine if the applicant has disclosed or asserted any credible utility for the claimed invention.

   a) If the applicant has asserted that the claimed invention is useful for any particular purpose and that assertion would be considered credible by a person of ordinary skill in the art, the Examiner should not impose a rejection based on § 101. Credibility is to be assessed from the perspective of one of ordinary skill in the art in view of any evidence of record (e.g., data, statements, opinions, references, etc.) that is relevant to the applicant's assertions.

   b) If the applicant has not asserted that the claimed invention is useful for a particular purpose but such a use would be readily apparent to a person of ordinary skill in the art, the Examiner should not impose a rejection under § 101.

3. If the applicant has not asserted any credible utility for the claimed invention or a utility would not be readily apparent to one of ordinary skill in the art, reject the claims under § 101. To be considered appropriate by the Office, a rejection under § 101 must include the following elements:

   a) A prima facie showing that the claimed invention has no utility. A prima facie showing of no utility must establish that it is more likely than not that a person of ordinary skill in the art would not consider credible any utility for the claimed invention that has been asserted by the applicant. Where no utility has been asserted in the disclosure, the prima facie showing must support a finding that a person of ordinary skill would not be able to ascertain any use for the claimed invention. A prima facie showing must contain:

      i) a well-reasoned statement by the Examiner that clearly sets forth the reasoning used in reaching his or her conclusions;

ii) support for factual findings relied upon by the Examiner in reaching his or her conclusions; and

iii) support for conclusions of the Examiner that evidence provided by the applicant to support an asserted utility would not be considered persuasive to a person of ordinary skill in the art.

b) Evidence that supports any factual assertions relied upon by the Examiner in establishing the prima facie showing. Whenever possible, the Examiner must provide documentary evidence that supports the factual basis of a prima facie showing of no utility (e.g., scientific or technical journals, excerpts from treatises or books, or U.S. or foreign patents). If documentary evidence is not available, the Examiner should note this fact and specifically explain the scientific basis for his or her conclusions.

4. A rejection under § 101 should not be maintained if an asserted utility for the claimed invention would be considered credible by a person of ordinary skill in the art in view of all evidence of record.

Once a prima facie showing of no utility has been properly established, the applicant bears the burden of rebutting it. The applicant can do this by amending the claims, by providing reasoning or arguments, or by providing evidence in the form of a declaration under 37 CFR § 1.132 or a printed publication, that rebuts the prima facie showing. Once a response has been received by the Examiner, he or she should review the original disclosure, any evidence relied upon in establishing the prima facie showing, any claim amendments and any new reasoning or evidence provided by the applicant in support of an asserted utility. It is essential that the Examiner recognize, fully consider and respond to each substantive element of any response to a rejection under § 101.

Examiners are reminded that they must treat as true credible statements made by an applicant or a declarant in the specification or in a declaration provided under 37 CFR § 1.132, unless they can show that one of ordinary skill in the art would have a rational basis to doubt the truth of such statements. Thus, not accepting the opinion of a qualified expert that is based on an appropriate factual record would clearly be improper.

II. Additional Information

The PTO has prepared an analysis of the law governing 35 U.S.C. § 101 to support the guidelines outlined above. Interested members of the public are invited to comment on the legal analysis as well as the guidelines. Copies of the legal analysis can be obtained from Jeff Kushan, who can be reached using the information indicated above.

Bruce A. Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks

Date

Overview of Legal Precedent Governing the Utility Requirement

I. General Principles Governing Utility Rejections

The Office must examine each application to ensure compliance with the utility requirement of 35 U.S.C. § 101. In discharging this obligation, however, Examiners must keep in mind several general principles that control application of the utility requirement.

As interpreted by the Federal courts, the utility requirement has two purposes.[1] First, § 101 defines which categories of inventions are eligible for patent protection. An invention that is not a machine, an article of manufacture, a composition or a process cannot be patented.[2] Second, § 101 serves to ensure that patents are granted on only those inventions which are "useful." This second purpose has a Constitutional footing--Article I, Section 8 of the Constitution authorizes Congress to provide exclusive rights to inventors to promote the "useful arts."[3] Thus, to satisfy the requirements of § 101, an applicant must claim an invention that is statutory subject matter and must show that the claimed invention is "useful" for some purpose, either explicitly or implicitly. Application of this latter element of the utility requirement is the focus of these guidelines.

A. The Utility Requirement Requires that the Claimed Invention Have "Real World Value"

To satisfy § 101, an invention must be "useful."[4] The Court of Customs and Patent Appeals (CCPA) and other courts have used the term "practical utility" as one measure of this concept. As the court stated in Nelson v. Bowler:

> "Practical utility" is a shorthand way of attributing "real-world" value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public.[5]

Examiners must be careful not to interpret the phrase "immediate benefit to the public" or similar formulations in other cases[6] to mean that products or services based on the claimed invention must be "currently available" to the public in order to satisfy § 101. Rather, the Examiner should accept as sufficient any reasonable use that an applicant has identified for the invention that can be viewed as providing a public benefit.

B. Wholly Inoperative Inventions Are Not "Useful" Inventions under 35 U.S.C. § 101; "Incredible" Utility

An invention that is inoperative (e.g., the invention does not operate to produce the results claimed by the patent applicant) is not a "useful" invention in the meaning of the patent law.[7] However, as the Federal Circuit has stated, "[t]o violate § 101 the claimed device must be totally incapable of achieving a useful result."[8] If an invention is only partially successful in achieving a useful result, a rejection of the claimed invention as a whole under § 101 is not appropriate.[9]

Cases decided by a Federal court in which a claimed invention was held to lack utility under § 101 because it was "inoperative" have been rare. Uniformly, in these cases the utility asserted by the applicant was "incredible in the light of knowledge of the art, or factually misleading"[10] when initially considered by the Examiner.

for the claimed invention to satisfy § 101.[24] If one asserted utility is credible, utility for the claimed invention as a whole is established.[25]

Examiners should be especially careful not to read into a claim unclaimed results, limitations or embodiments of an invention.[26] Doing so can inappropriately change the relationship of an asserted utility to the claimed invention and raise issues not relevant to examination of that claim.

B. Is There an Asserted or Readily Apparent Utility for the Claimed Invention?

After identifying what the claimed invention is, the Examiner should review the specification to ascertain if there are any statements asserting that the claimed invention is useful for any particular purpose. A complete disclosure should include a statement which identifies a specific utility for the invention. Such statements can be detailed statements of why an invention is believed to be useful by the applicant. They can also take the form of more general assertions of useful applications of the invention.

Some degree of specificity is needed in identifying utility. For example, a statement that a composition has an unspecified "biological activity" without any explanation of why the composition with that activity would be considered useful should not be viewed as a specific assertion of utility.[27]

If the Examiner cannot find any statements asserting utility for the claimed invention in the specification, he or she should then query whether a utility would be readily apparent to a person of ordinary skill from either the disclosure or from the characteristics of the invention. The result of this initial evaluation determines the next step for the Examiner in the review for compliance with utility.

1. An Asserted Utility Creates a Presumption of Utility

An applicant's assertion of utility creates a presumption of utility that will be sufficient, in most cases, to satisfy the utility requirement of 35 U.S.C. § 101.[28] As the CCPA stated in In re Langer:

> As a matter of Patent Office practice, a specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented must be taken as sufficient to satisfy the utility requirement of § 101 for the entire claimed subject matter unless there is a reason for one skilled in the art to question the objective truth of the statement of utility or its scope.[29]

To overcome this presumption, the Examiner must establish that it is more likely than not that one of ordinary skill in the art would doubt the truth of the statement of utility.[30] In other words, the Examiner must show that the asserted utility is not credible.

2. When is an Asserted Utility Not "Credible"?

Compliance with § 101 is a question of fact.[31] Where an applicant has specifically asserted that an invention has a particular utility, that assertion cannot simply be dismissed by an Examiner as being "wrong," even when the Examiner may believe the assertion is not accurate beyond a reasonable doubt. Rather, the Examiner

must determine if the assertion of utility is credible. If it is, the Examiner should not reject the claimed invention under § 101.

To assess credibility, the Examiner should determine if one of ordinary skill in the art would consider the assertions of the applicant to have any reasonable scientific basis. If they do, they should not be challenged as not being credible. Only where they do not (e.g., if the assertion is "incredible in view of contemporary knowledge"), should the Examiner challenge the statement as not being credible. In making credibility determinations, the Examiner must consider the full record of evidence related to the asserted utility, including any data and reasoning provided by the applicant in the specification and any references cited by the applicant to support utility. The Examiner must also consider information that is generally known in the art regarding the asserted utility.

As noted above, rejections under § 101 have been rarely sustained by Federal courts. Generally speaking, in these rare cases, the § 101 rejection was sustained because the applicant asserted a utility that could only be true if it violated a scientific principle, such as the second law of thermodynamics, or a law of nature, or was wholly inconsistent with contemporary knowledge in the art.[32] The phrase "incredible utility" has come to be associated with such cases. "Incredible utility," however, is a conclusion, not a starting point for analysis under § 101. A conclusion that an asserted utility is "incredible" thus can be reached only after the Examiner has evaluated both the assertions of the applicant regarding utility and any evidentiary basis for those assertions. An Examiner should be particularly careful not to start with the presumption that an asserted utility is per se "incredible" and then proceed to base a rejection under § 101 on that presumption.

Special care should be taken when assessing the credibility of an asserted therapeutic utility for a claimed invention. In such cases, a previous lack of success in treating a disease or condition, or the absence of a proven animal model for testing the effectiveness of drugs for treating a disorder in humans, should not, standing alone, serve as a basis for challenging the asserted utility under § 101.

3. No Statement of Utility for the Claimed Invention in the Specification Does Not Negate Utility

Occasionally, an applicant will not explicitly state in the specification or otherwise assert a specific utility for the claimed invention. In such cases, if a person of ordinary skill would recognize a utility for the claimed invention if provided with the specification at the time of its filing, no rejection under § 101 should be imposed.[33] For example, if an application teaches the cloning and characterization of the nucleotide sequence of a well-known protein such as insulin, and those skilled in the art at the time of filing knew that insulin had a well-established use, it would be improper to reject the claimed invention as lacking utility under § 101.

C. Initial Burden is on the Examiner to Establish Prima Facie Case and Provide Evidentiary Support Thereof

To properly reject a claimed invention under 35 U.S.C. § 101, the Examiner must (a) make a prima facie showing that the claimed invention lacks utility, and (b) provide a sufficient evidentiary basis for factual assumptions relied upon in establishing the

prima facie showing.[34] If the Examiner cannot develop a proper prima facie case and provide evidentiary support for a rejection under § 101, a rejection on this ground should not be imposed.[35]

The prima facie showing must be set forth in a well-reasoned statement. In the statement, the Examiner must articulate sound reasons why a person of ordinary skill in the art would conclude that it is more likely than not that an asserted utility is not credible or that one of ordinary skill would not recognize utility for the claimed invention if unstated. The statement should specifically identify the scientific basis of the Examiner's conclusions. The statement must also explain why any evidence of record that supports the asserted utility would not be persuasive to one of ordinary skill.

In addition to the statement setting forth the prima facie showing, the Examiner must provide evidentiary support for the prima facie case. In most cases, the Examiner can and should provide documentary evidence (e.g., articles in scientific journals, or excerpts from patents or scientific treatises) that supports his or her factual conclusions. Only when documentary evidence is not readily available should the Examiner attempt to satisfy the Office's requirement for evidentiary support for the factual basis of the prima facie showing solely through an explanation of relevant scientific principles.

It is imperative that Examiners use specificity in setting forth an initial rejection under § 101 and support their factual conclusions. For example, the Examiner should explain why any in vitro or in vivo data supplied by the applicant would not be reasonably predictive of an asserted therapeutic utility from the perspective of a person of ordinary skill in the art. By using specificity, the applicant will be able to identify the assumptions made by the Examiner in setting forth rejection and will be able to address those assumptions properly.

D. Evidentiary Requests by an Examiner to Support an Asserted Utility

As the courts have recognized, in appropriate situations the Office may require an applicant to substantiate an asserted utility for a claimed invention.[36] However, requests for additional evidence should be imposed rarely, and only if necessary to support the scientific credibility of the asserted utility (e.g., if the asserted utility is not consistent with the evidence of record and current scientific knowledge). As the CCPA stated in In re Isaacs, "it is clearly improper for the Examiner to make a demand for further test data, which as evidence would be essentially redundant and would seem to serve for nothing except perhaps to unduly burden the applicant."[37] Whenever possible, Examiners should identify the nature of evidence which, if provided, would be persuasive in establishing the credibility of an asserted utility.

E. Consideration of a Response to a Prima Facie Rejection for Lack of Utility

If an Examiner has properly rejected a claimed invention under § 101, the burden shifts to the applicant to rebut the prima facie showing.[38] An applicant can do this using any combination of the following: amendments to the claims, arguments or reasoning, or new evidence[39] submitted in an declaration under 37 CFR § 1.132, or in a printed publication.

Once a response has been provided, the Examiner must review the complete record, including the claims, to determine if it is appropriate to maintain the rejection under § 101. If the record as a whole would make it more likely than not that the asserted utility for the claimed invention would be considered credible by a person of ordinary skill in the art, the Examiner should not maintain the rejection.[40] If the Examiner concludes otherwise, he or she should maintain the rejection under § 101.

F. Evaluation of Evidence Related to Utility

There is no predetermined amount or character of evidence that must be provided by an applicant to support an asserted utility, therapeutic or otherwise. Rather, the character and amount of evidence needed to support an asserted utility will vary depending on what is claimed,[41] and whether the asserted utility appears to contravene established scientific principles and beliefs.[42] Furthermore, the applicant does not have to provide evidence sufficient to establish that an asserted utility is true "beyond a reasonable doubt."[43] Nor must an applicant provide evidence such that it establishes an asserted utility as a matter of statistical certainty.[44] Instead, evidence will be sufficient if, considered as a whole, it leads a person of ordinary skill in the art to conclude that the asserted utility is more likely than not true.

III. Special Considerations for Asserted Therapeutic or Pharmacological Utilities

The Federal courts have consistently reversed rejections by the Office asserting a lack of utility under § 101 for inventions claiming a pharmacological or therapeutic utility where an applicant has provided evidence supporting such a utility. In view of this, Examiners should be particularly careful in their review of evidence provided in support of an asserted therapeutic or pharmacological utility.

A. A Reasonable Correlation Between Evidence and Asserted Utility is Sufficient

As a general matter, evidence of pharmacological or other biological activity of a compound will be relevant to an asserted therapeutic use if there is a reasonable correlation between the activity in question and the asserted utility.[45] The applicant does not have to prove that there is a statistically proven correlation between characteristics of a compound and the asserted use, nor does he or she have to provide actual evidence of success in treating humans where such a utility is asserted.

B. Structural Similarity to Useful Products

The courts have on several occasions found evidence of structural similarity to known compounds with particular therapeutic or pharmacological uses as supporting therapeutic utility of a newly claimed compound.[46] Such evidence, when provided by an applicant in support of an assertion of utility, should be given appropriate weight in determining whether one skilled in the art would find the asserted utility credible.

C. Data from In Vitro and Animal Testing is Generally Sufficient to Support Therapeutic Utility

Data generated using in vitro assays and testing in animals almost invariably will be sufficient to support an asserted therapeutic or pharmacological utility.[47] In no case has a Federal court required an applicant to support an asserted utility with data from human clinical trials.

If an applicant provides data from in vitro and animal tests to support an asserted utility, the Examiner should determine if the tests, including the test parameters and choice of animal, would be viewed by one skilled in the art as being reasonably predictive of the asserted utility.[48] If so, and the data supplied is consistent with the asserted utility, the Examiner should not maintain a rejection under § 101. This approach is to be followed not only in cases where there are art-recognized animal models for assessing utility in human disease and treatment, but also where no such validation of a specific test has been performed. Thus, if one skilled in the art would accept the animal tests as being reasonably predictive of utility in humans, they should be considered sufficient to support the credibility of the asserted utility.[49] Examiners should be careful not to find evidence unpersuasive simply because no animal model for the human disease condition had been established prior to the filing of the application.[50]

D. Human Clinical data

There is no decisional law that requires an applicant to provide data from human clinical trials to establish utility for an invention related to treatment of human disorders,[51] even with respect to situations where no art-recognized animal models existed for the human disease encompassed by the claims.[52] Examiners should not impose on applicants the unnecessary burden of providing evidence from human clinical trials. Examiners should note that before a drug can enter human clinical trials, the sponsor (e.g., often the applicant) must establish a sufficient basis to those especially skilled in the art (e.g., the Food and Drug Administration) that the drug will be effective to some degree in treating the stated disorder. Thus, as a general rule, if an applicant has initiated human clinical trials for a product or process used for treating an indication, the subject of that trial has met the burden of being reasonably predictive of utility.

E. Safety and Efficacy Considerations

The Examiner must confine his or her examination, for purposes of utility, to compliance with the statutory requirements of the patent law. Other agencies of the government have been assigned the responsibility of ensuring conformance to standards established by statute for the advertisement, use, sale or distribution of drugs.[53] Thus, while an applicant may on occasion need to provide evidence to show that an invention will work as claimed, it is improper for an Examiner to request evidence of safety in the treatment of humans, or regarding the degree of effectiveness.[54]

F. Treatment of Specific Disease Conditions

Claims directed to a method of treating or curing a disease for which there have been no previously successful treatments or cures warrant careful review for

compliance with § 101.[55] The mere fact that there is no known cure for a disease, however, should not serve as the basis of an Examiner's conclusion that such an invention lacks utility. Rather, the Examiner should only reject the claims under § 101 if he or she can establish a prima facie case that the asserted utility is not credible.

In such cases, the Examiner should carefully review what is being claimed by the applicant. An assertion that the claimed invention is useful in treating a symptom of an incurable disease may be considered scientifically credible by a person of ordinary skill in the art on the basis of a fairly modest amount of evidence or support. In constrast, an assertion that the claimed invention will be useful in "curing" the disease may require a significantly greater amount of evidentiary support to be considered scientifically credible by a person of ordinary skill in the art.[56]

In these cases, it is important to note that the Food and Drug Administration has promulgated regulations that enable a party to conduct clinical trials for drugs used to treat life threatening and severely-debilitating illnesses, even where no alternative therapy exists.[57] Implicit in these regulations is the recognition that experts qualified to evaluate the effectiveness of therapeutics can and often do find a sufficient basis to conduct clinical trials of drugs for "incurable" or previously untreatable illnesses. Thus, affidavit evidence from experts in the art indicating that there is a reasonable expectation of success, supported by sound reasoning, usually should be sufficient to establish that such a utility is credible.

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1 The utility requirement is found in section 101 of title 35, United States Code, which reads:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2 See Diamond v. Chakrabarty, 447 U.S. 303, 206 USPQ 193 (1980); Diamond v. Diehr, 450 U.S. 175, 209 USPQ 1 (1981).

3 See Carl Zeiss Stiftung v. Renishaw PLC, 945 F.2d 1173, 20 USPQ2d 1094 (Fed. Cir. 1991).

4 Courts have recognized that the term "useful" used with reference to the utility requirement can be a difficult term to define. Brenner v. Manson, 383 U.S. 519, 529, 148 USPQ 689, 693 (1966) (simple everyday word like "useful" can be "pregnant with ambiguity when applied to the facts of life."). Despite this, courts readily find inventions "useful." For example, in Nelson v. Bowler, 626 F.2d 853, 206 USPQ 881 (CCPA 1980), the CCPA held that a composition was "useful" because it had been shown to possess a particular pharmacological activity.

5 Nelson v. Bowler, 626 F.2d 853, 856, 206 USPQ 881, 883 (CCPA 1980).

6 See, e.g., Brenner v. Manson, 383 U.S. at 534-535, 148 USPQ at 695.

7 See, e.g., Newman v. Quigg, 877 F.2d 1575, 1581, 11 USPQ2d 1340, 1345 (Fed. Cir. 1989); In re Harwood, 390 F.2d 985, 989, 156 USPQ 673, 676 (CCPA 1968) ("An inoperative invention, of course, does not satisfy the requirement of 35 U.S.C. 101 that an invention be useful.").

8 Brooktree Corp. v. Advanced Micro Devices, Inc., 977 F.2d 1555, 24 USPQ2d 1401, 1412 (Fed. Cir. 1992) (emphasis added). See also, E.I. du Pont De Nemours and Co. v. Berkley and Co., 620 F.2d 1247, 1260 n.17, 205 USPQ 1, 10 n.17 (8th Cir. 1980) ("A small degree of utility is sufficient . . . The claimed invention must only be capable of performing some beneficial function . . . An invention

does not lack utility merely because the particular embodiment disclosed in the patent lacks perfection or performs crudely . . . A commercially successful product is not required . . . Nor is it essential that the invention accomplish all its intended functions . . . or operate under all conditions . . . partial success being sufficient to demonstrate patentable utility . . . In short, the defense of non-utility cannot be sustained without proof of total incapacity" [citations omitted].).

[9] In such cases, a rejection under 35 U.S.C. § 112 may be appropriate. See, In re Gardner, 475 F.2d 1389, 177 USPQ 396 (CCPA), reh'g denied, 480 F.2d 879 (CCPA 1973); In re Marzocchi, 439 F.2d 220, 169 USPQ 367 (CCPA 1971).

[10] In re Citron, 325 F.2d 248, 253, 139 USPQ 516, 520 (CCPA 1963).

[11] Fregeau v. Mossinghoff, 776 F.2d 1034, 227 USPQ 848 (Fed. Cir. 1985).

[12] Newman v. Quigg, 877 F.2d at 1581, 11 USPQ2d at 1340.

[13] In re Ruskin, 354 F.2d 395, 148 USPQ 221 (CCPA 1966).

[14] In re Citron, 325 F.2d 248, 139 USPQ 516 (CCPA 1963).

[15] In re Ferens, 417 F.2d 1072, 163 USPQ 609 (CCPA 1969).

[16] The CCPA in Nelson used the term "pharmacological" utility. Examiners should rely on the guidance of Nelson and other cases in evaluating therapeutic, prophylactic, or pharmacological utility.

[17] In re Chilowsky, 229 F.2d 457, 461-2, 108 USPQ 321, 325 (CCPA 1956) ("There appears to be no basis in the statutes or decisions for requiring any more conclusive evidence of operativeness in one type of case than another. The character and amount of evidence needed may vary, depending on whether the alleged operation described in the application appears to accord with or to contravene established scientific principles or to depend upon principles alleged but not generally recognized, but the degree of certainty as to the ultimate fact of operativeness or inoperativeness should be the same in all cases"); In re Gazave, 379 F.2d 973, 978, 154 USPQ 92, 96 (CCPA 1967) ("Thus, in the usual case where the mode of operation alleged can be readily understood and conforms to the known laws of physics and chemistry, operativeness is not questioned, and no further evidence is required.").

[18] In Nelson v. Bowler, the CCPA addressed the practical utility requirement in the context of an interference proceeding. Bowler challenged the patentability of the invention claimed by Nelson on the basis that Nelson had failed to sufficiently and persuasively disclose in his application a practical utility for the invention. Nelson had developed and claimed a class of synthetic prostaglandins modeled on naturally occurring prostaglandins. Naturally occurring prostaglandins are bioactive compounds that, at the time of Nelson's application, had a recognized value in pharmacology (e.g., the stimulation of uterine smooth muscle which resulted in labor induction or abortion, the ability to raise or lower blood pressure, etc.). To support the utility he identified in his disclosure, Nelson included in his application the results of tests demonstrating the bioactivity of his new substituted prostaglandins relative to the bioactivity of naturally occurring prostaglandins. The Court concluded that Nelson had satisfied the practical utility requirement in identifying the synthetic prostaglandins as pharmacologically active compounds. In reaching this conclusion, the court considered and rejected arguments advanced by Bowler that attacked the evidentiary basis for Nelson's assertions that the compounds were pharmacologically active.

In In re Jolles, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980), an inventor claimed protection for pharmaceutical compositions for treating leukemia. The active ingredient in the compositions was a structural analog to a known anti-cancer agent. The applicant provided evidence showing that the claimed analogs had the same general pharmaceutical activity as the known anti-cancer agents. The Court reversed the Board's finding that the asserted pharmaceutical utility was "incredible," pointing to the evidence that showed the relevant pharmocological activity.

In Cross v. Iizuka, 753 F.2d 1040, 224 USPQ 739 (Fed.Cir. 1985), the Federal Circuit affirmed a finding by the Board of Patent Appeals and Interferences that a pharmacological utility had been disclosed in the application of one party to an interference proceeding. The invention that was the subject of the interference count was a chemical compound used for treating blood disorders. Cross had challenged the evidence in Iizuka's specification that supported the claimed utility. However, the Federal Circuit relied extensively on Nelson v. Bowler in finding that Iizuka's application had sufficiently disclosed a pharmacological utility for the compounds. It distinguished the case from cases where an only a generalized "nebulous" expression, such as "biological properties," had been disclosed in a specification. Such statements, the court held, "convey little explicit indication regarding the utility of a compound," 753 F.2d at 1048, 224 USPQ 745 (citing In re Kirk, 376 F.2d 936, 941, 153 USPQ 48, 52 (1967)).

19 Nelson v. Bowler, 626 F.2d at 856, 206 USPQ at 883.

20 The Federal Circuit, in Cross v. Iizuka, 753 F.2d 1040, 1051, 224 USPQ 739, 747-748 (Fed. Cir. 1985), commented on the significance of data from in vitro testing that showed pharmacological activity:

> We perceive no insurmountable difficulty, under appropriate circumstances, in finding that the first link in the screening chain, in vitro testing, may establish a practical utility for the compound in question. Successful in vitro testing will marshal resources and direct the expenditure of effort to further in vivo testing of the most potent compounds, thereby providing an immediate benefit to the public, analogous to the benefit provided by the showing of an in vivo utility

21 See, e.g., In re Sichert, 566 F.2d 1154, 196 USPQ 209 (CCPA 1977); In re Hartop, 311 F.2d 249, 135 USPQ 419 (CCPA 1962); In re Anthony, 414 F.2d 1383, 162 USPQ 594 (CCPA 1969); In re Watson, 517 F.2d 465, 186 USPQ 11 (CCPA 1975).

22 See section II.B. regarding evaluation of an asserted utility.

23 See, e.g., Raytheon v. Roper, 724 F.2d 951, 958, 220 USPQ 592 (Fed. Cir. 1983), cert. denied, 469 U.S. 835 (1984) ("When a properly claimed invention meets at least one stated objective, utility under § 101 is clearly shown."); Tol-O-Matic, Inc. v. Proma Produkt-Und Mktg. Gesellschaft m.b.h., 945 F.2d 1546, 1553, 20 USPQ2d 1332, 1338 (Fed. Cir. 1991) ("It is not required that a particular characteristic set forth in the prosecution history be achieved in order to satisfy § 101.").

24 See, e.g., In re Gottlieb, 328 F.2d 1016, 1019, 140 USPQ 665, 668 (CCPA 1964) ("Having found that the antibiotic is useful for some purpose, it becomes unnecessary to decide whether it is in fact useful for the other purposes 'indicated' in the specification as possibly useful").

25 See, e.g., Gottleib, 328 F.2d at 1019; 140 USPQ at 668, In re Malachowski, 530 F.2d 1402, 189 USPQ 432 (CCPA 1976); Hoffman v. Klaus, 9 USPQ2d 1657 (Bd. Pat. App. & Inter. 1988).

26 See, In re Krimmel, 292 F.2d 948, 130 USPQ 215 (CCPA 1961).

27 In re Kirk, 376 F.2d 936, 153 USPQ 48 (CCPA 1967); In re Joly, 376 F.2d 906, 153 USPQ 45 (CCPA 1967).

28 See, e.g., In re Jolles, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980); In re Irons, 340 F.2d 974, 144 USPQ 351 (1965); In re Langer, 503 F.2d 1380, 183 USPQ 288 (CCPA 1974); In re Sichert, 566 F.2d 1154, 1159, 196 USPQ 209, 212-13 (CCPA 1977).

29 In re Langer, 503 F.2d 1380, 1391, 183 USPQ 288, 297 (CCPA 1974) (Emphasis in original).

30 The evidentiary standard used throughout ex parte examination is a preponderance of the evidence. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992) ("After evidence or argument is submitted by the applicant in response, patentability is determined on the

totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument."); In re Corkill, 771 F.2d 1496, 1500, 226 USPQ 1005, 1008 (Fed. Cir. 1985). A preponderance of the evidence exists when it suggests that it is more likely than not that the assertion in question is true. Herman v. Huddleston, 459 U.S. 375, 390 (1983).

[31] Raytheon v. Roper, 724 F.2d at 956, 220 UPQ at 596.

[32] In re Gazave, 379 F.2d 973, 978, 154 USPQ 92, 96 (CCPA 1967), provides a good perspective on rejections for lack of utility. In reversing the Board's rejection for lack of utility where the applicant had asserted a specific utility, the CCPA held:

> Appellant's discovery here does not appear to us to be of such a "speculative," abstruse or esoteric nature that it must inherently be considered unbelievable, "incredible," or "factually misleading." Nor does operativeness appear "unlikely" or an assertion thereof appear to run counter "to what would be believed would happen by the ordinary person" in the art. Nor does appellant's field of endeavor appear to be one where "little of a successful nature has been developed" or one which "from common knowledge has long been the subject matter of much humbuggery and fraud." Nor has the examiner presented evidence inconsistent with the assertions and evidence of operativeness presented by appellant.

[33] In re Folkers, 344 F.2d 970, 145 USPQ 390 (CCPA 1965).

[34] In re Gaubert, 524 F.2d 1222, 1224, 187 USPQ 664, 666 (CCPA 1975) ("Accordingly, the PTO must do more than merely question operability - it must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability.").

[35] See, e.g., In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992) ("[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a prima facie case of unpatentability. If that burden is met, the burden of coming forward with evidence or argument shifts to the applicant... If examination at the initial stage does not produce a prima facie case of unpatentability, then without more the applicant is entitled to grant of the patent"). See also, Fregeau v. Mossinghoff, 776 F.2d 1034, 227 USPQ 848 (Fed. Cir. 1985) (applying prima facie case law to section 101); In re Piasecki, 745 F.2d 1468, 223 USPQ 785 (Fed. Cir. 1984).

[36] See In re Pottier, 376 F.2d 328, 330, 153 USPQ 407, 408 (CCPA 1967) ("When the operativeness of any process would be deemed unlikely by one of ordinary skill in the art, it is not improper for the examiner to call for evidence of operativeness"). See also In re Jolles, 628 F.2d at 1327, 206 USPQ at 890; In re Citron, 325 F.2d 248, 139 USPQ 516 (CCPA 1963); In re Novak, 306 F.2d 924, 928, 134 USPQ 335, 337 (CCPA 1962).

[37] In re Isaacs, 347 F.2d 887, 890, 146 USPQ 193, 196 (CCPA 1965).

[38] In re Oetiker, 977 F.2d at 1445, 24 USPQ2d at 1444 ("the examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a prima facie case of unpatentability. If that burden is met, the burden of coming forward with evidence or argument shifts to the applicant. . . After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument.").

[39] New evidence provided by an applicant must be relevant to the issues raised in the rejection. For example, declarations in which conclusions are set forth without establishing a nexus between those conclusions and the supporting evidence, or which merely express opinions, may be of limited probative value with regard to rebutting a prima facie case. In re Grunwell, 609 F.2d 486, 203 USPQ 1055 (CCPA 1979); In re Buchner, 929 F.2d 660, 18 USPQ2d 1331 (Fed. Cir. 1991). See also, Manual of Patent Examining Procedure, § 716 (Rev.16, 1994).

[40] As the CCPA stated in reference to review of an applicant's response to a prima facie showing of obviousness in In re Rinehart, 531 F.2d 1048, 1052, 189 USPQ 143, 147 (CCPA 1976):

> When prima facie obviousness is established and evidence is submitted in rebuttal, the decision-maker must start over. . . An earlier decision should not, as it was here, be considered as set in concrete, and applicant's rebuttal evidence then be evaluated only on its knockdown ability. Analytical fixation on an earlier decision can tend to provide that decision with an undeservedly broadened umbrella effect. Prima facie obviousness is a legal conclusion, not a fact. Facts established by rebuttal evidence must be evaluated along with the facts on which the earlier conclusion was reached, not against the conclusion itself. . . [S]uch finding will rest upon evaluation of all facts in evidence, uninfluenced by any earlier conclusion reached by an earlier board upon a different record.

[41] In Ex parte Ferguson, 117 USPQ 229 (Bd. App. 1957), the applicant asserted that a drug would provide relief from the pain of ulcers. The Examiner rejected the claims on the basis that the applicant had not shown that the drug was effective in curing ulcers. The Board reversed the Examiner and indicated that the evidence necessary to support the asserted utility merely had to demonstrate that the subjects felt better after using the drug.

[42] In re Gazave, 379 F.2d at 978, 154 USPQ at 96 (CCPA 1967); In re Chilowsky, 229 F.2d at 462, 108 USPQ at 325.

[43] In re Irons 340 F.2d at 978, 144 USPQ at 354.

[44] Nelson v. Bowler, 626 F.2d 853, 856-857, 206 USPQ 881, 883-84 (CCPA 1980) (reversing the Board and rejecting Bowler's arguments that the evidence of utility was statistically insignificant. The court pointed out that a rigorous correlation is not necessary when the test is reasonably predictive of the response).

[45] Cross v. Iizuka, 753 F.2d 1040, 224 USPQ 739 (Fed. Cir. 1985); In re Jolles, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980); Nelson v. Bowler, 626 F.2d 853, 206 USPQ 881 (CCPA 1980).

[46] In In re Jolles, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980), the claimed compounds were found to have utility based on a close structural relationship to daunorubicin and doxorubicin, both of which were known to be useful in cancer chemotherapy. The evidence of close structural similarity with the known compounds was presented in conjunction with evidence demonstrating substantial activity of the claimed compounds in animals customarily employed for screening anti-cancer agents.

[47] The CCPA has sustained rejections under § 101 for a claimed therapeutic utility in only two instances. In re Citron, 325 F.2d at 253, 139 USPQ at 520 (therapeutic utility for an uncharacterized biological extract not supported or scientifically credible); In re Buting, 418 F.2d 540, 543, 163 USPQ 689, 690 (CCPA 1969) (confusing lack of enablement under § 112 for range of species claimed for lack of utility of claimed invention as a whole under § 101 because record did not establish a credible basis for the assertion that the single class of compounds in question would be useful in treating disparate types of cancers). In contrast, in the vast majority of cases where § 101 was the basis of a rejection, the courts have relied on a varying combination of data from in vitro and animal testing, and from structural similarities to known compounds to find credible an asserted utility. See, e.g., Cross v. Iizuka, 753 F.2d 1040, 224 USPQ 739 (Fed. Cir. 1985); In re Jolles, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980); Nelson v. Bowlar, 626 F.2d 853, 856, 206 USPQ 881, 883 (CCPA 1980); In re Gazave, 379 F.2d 973, 154 USPQ 92 (CCPA 1967); In re Hartop, 311 F.2d 249, 135 USPQ 419 (CCPA 1962); In re Krimmel, 292 F.2d 948, 130 USPQ 215 (CCPA 1961).

[48] See, e.g., Ex parte Maas, 9 USPQ2d 1746 (Bd. Pat. App. & Inter. 1987); Ex parte Balzarini, 21 USPQ2d 1892 (Bd. Pat. App. & Inter. 1991).

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[49] A number of decisions have addressed the question of whether animal data provide sufficient evidence of utility.

In In re Hartop, 311 F.2d 249, 135 USPQ 419 (CCPA 1962), the applicant submitted affidavit evidence that the compound tested successfully for therapeutic effectiveness and acute toxicity in the "standard experimental animal". The court held that "inherent in the concept of the 'standard experimental animal' is the ability of one skilled in the art to make the appropriate correlation between the results actually observed with the animal experiments and the probable results in human therapy". Therefore, the court concluded that appellants' claimed solutions were useful within the meaning of 35 U.S.C. § 101".

In In re Krimmel, 292 F.2d 948, 130 USPQ 215 (CCPA 1961), the court held that when the specification teaches the use of the claimed compound for the treatment of any animal, and is not limited to the treatment of humans, and when statistically significant tests with "standard experimental animals" establish that the compound exhibits a useful pharmaceutical property, sufficient statutory utility for the compound has been presented. The court defined "standard experimental animals" as "whatever animal is usually used by those skilled in the art to establish the particular pharmaceutical application in question." 292 F.2d at 953, 130 USPQ at 219.

In Ex parte Krepelka, 231 USPQ 746 (Bd. Pat. App. & Inter. 1986), the Board reversed the Examiner's rejection under 35 U.S.C. § 101 that claims drawn to compounds asserted to be useful in treating human cancer were "incredible" and thus lacked patentable utility. The Examiner did not support the assertions with any evidence to controvert evidence in the applicant's disclosure. The evidence in the disclosure included test results derived from acceptable experimental animals, i.e., results from animals which were known to correlate with pharmacological effects observed in humans, were sufficient to demonstrate the utility of the claimed compounds.

[50] Lack of an appropriate animal model to assess effectiveness of a drug or a treatment modality should not itself preclude a finding that an invention has utility. See, In re Chilowsky, 229 F.2d at 461, 108 USPQ at 325 ("The mere fact that something has not previously been done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it."); In re Wooddy, 331 F.2d 636, 639, 141 USPQ 518, 520 (CCPA 1964) ("It appears that no one on earth is certain as of the present whether the process claimed will operate in the manner claimed. Yet absolute certainty is not required by the law. The mere fact that something has not previously been done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it").

[51] Indeed, in In re Isaacs, 347 F.2d 889, 146 USPQ 193 (1963), the CCPA stated:

> No authority has been cited and we have been able to find none which requires that in order to secure a patent, utility of a pharmacologically active substance must be proved by in vivo testing. The mere fact that the claimed invention may have possible utility in vivo does not warrant disregard of in vitro activity where the claims are not limited to in vivo use [347 F.2d at 889, 146 USPQ at 195].

Similarly, in In re Langer, 503 F.2d at 1393-94, the CCPA, after considering the evidence relied upon by the Office in imposing a § 101 rejection stated:

> It is not proper for the Patent Office to require clinical testing in humans to rebut a prima facie case for lack of utility when the pertinent references which establish the prima facie case show in vitro tests and when they do not show in vivo tests employing standard experimental animals.

[52] In Ex parte Balzarini, 21 USPQ2d 1892 (Bd. Pat. App. & Inter. 1991) (human clinical data is not required to demonstrate the utility of the claimed invention, even though those skilled in the art might not accept other evidence to establish the efficacy of the claimed therapeutic compositions and the operativeness of the claimed methods of treating humans).

[53] Congress has created a special agency to determine both the safety, and the effectiveness, of new drugs. That agency is the Food and Drug Administration (FDA). According to 21 U.S.C. § 355(a), in order to introduce any new drug, an individual must obtain approval of an application filed with the FDA. The statute defines "drug" extremely broadly and defines "new drug" as any drug not generally recognized as both safe and effective for the use suggested. See 35 U.S.C. §§ 321(g) and (p). Under the FDA, the clinical investigation of a new drug is divided into three distinct phases. The general principles of new drug investigations require the agency to assess the likelihood that the drug will meet the statutory standards for marketing approval before granting approval of these phases. 21 CFR § 312.22(a). Part of these statutory standards include the requirement that the drug prove effective, a higher standard than the utility requirement. 21 U.S.C. § 355(a), 21 CFR § 314.105. Cf. In re Irons, 340 F.2d 974, 978, 144 USPQ 351, 354 (CCPA 1965) (reversing the Board of Appeals' utility rejection and pointing out that proof with a double blind test—even where the art recognized a very significant placebo effect—amounted to proof beyond a reasonable doubt, which was not required to comply with 35 U.S.C. § 101). Indeed, the simple request to begin testing the drug requires submission of an explanation of the rationale for the research, as well as information relating to the effectiveness of the drug. 21 CFR §§ 312.23 (a) (3) (iv), (5) (iv), (8) (i), and (9) (i). Thus, the FDA pursues a two-prong test to provide approval for testing. Under that test, an applicant must show the drug is not injurious to health and that there is a reasoned expectation to think the drug will actually work. As a review matter, there must be a rational reason to think that the compound will actually be effective.

If the use approved by the FDA is not set forth in the specification, FDA approval may not satisfy 35 U.S.C. § 101. However, if the approved use is one set forth in the specification, the Examiner must be extremely hesitant to challenge utility. In such a situation, the inventor has signed an oath stating a utility (i.e., the application) and experts at the FDA have assessed the likelihood that the drug will be effective for the utility indicated and found it satisfactory. Thus, in challenging utility, the examiner is at odds with those experts designated by Congress to decide the issue and who have assessed the likelihood that the drug will meet the statutory standards of efficacy.

[54] See In re Sichert, 566 F.2d 1154, 196 USPQ 209 (1977); In re Hartop, 311 F.2d 249, 135 USPQ 419 (CCPA 1962); In re Anthony, 414 F.2d 1383, 162 USPQ 594 (CCPA 1969); In re Watson, 517 F.2d 465, 186 USPQ 11 (CCPA 1975); In re Krimmel, 292 F.2d 948, 130 USPQ 215 (CCPA 1961); Ex parte Jovanovics, 211 USPQ 907 (Bd. Pat. App. & Inter. 1981).

[55] The credibility of an asserted utility for treating a human disorder may be more difficult to establish where current scientific understanding suggests that the such a task would be impossible. Such a determination has always required a good understanding of the state of the art at the time of the invention. For example, in the 1960s, there were a number of cases where an asserted use in treating cancer in humans was viewed as "incredible." In re Jolles, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980); In re Buting, 418 F.2d 540, 163 USPQ 689 (CCPA 1969); Ex parte Stevens, 16 USPQ2d 1379 (Bd. Pat. App. & Inter. 1990); Ex parte Busse, 1 USPQ2d 1908 (Bd. Pat. App. & Inter. 1986); Ex parte Krepelka, 231 USPQ 746 (Bd. Pat. App. & Inter. 1986); Ex parte Jovanovics, 211 USPQ 907 (Bd. Pat. App. & Inter. 1981).

[56] In re Sichert, 566 F.2d 1154, 196 USPQ 209 (CCPA 1977); In re Jolles, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980). See also, Ex parte Ferguson, 117 USPQ 229 (Bd. Pat. App. & Inter. 1957).

[57] See 21 CFR §§ 312.80-88.

Press Embargo until 10:00 a.m., December 22, 1994

Remarks of Bruce A. Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks

Announcement of Draft Examining Guidelines for Utility

A little over two months ago, we traveled to San Diego, California, to hear from one of our most important user communities; the biotechnology industry. What we heard was that patents are absolutely critical to this industry. We also heard that we were creating problems for the biotechnology industry through our current approach to examining applications, particularly for compliance with the "utility" requirement. Today, I am pleased to announce that we are taking aggressive steps to address these concerns.

At the heart of our response are new guidelines for examiners to follow when reviewing applications for compliance with the utility requirement. The guidelines emphasize that any credible statement of utility consistent with the scope of the claimed invention that is made by an applicant will satisfy section 101. In other words, if an applicant presents a scientifically plausible use for the claimed invention, it will be sufficient to satisfy the utility requirement. And, once implemented, the guidelines will ensure that if a utility rejection is appropriate, it will be made and reviewed according to consistent and correct legal standards. We have worked hard to ensure that these guidelines are fully consistent with the law, so that our changes in examining practice will not in any way affect perceptions about the presumption of validity of patents issued by our Office.

We developed the guidelines because we believe they will address the root of the problems identified by the biotechnology industry -- an absence of adequate guidance to the examiners on how to evaluate compliance of applications with the utility requirement. The guidelines will articulate for the first time in a comprehensive way the guidance they need. As I stated in San Diego, we have been extraordinarily successful in our efforts to recruit and retain technically skilled Examiners in the biotechnology group. I am extremely proud of our biotechnology Examiners and am confident that they are up to the task before them.

We believe the guidelines will also address several specific concerns that were raised during our hearing. The most serious of these was a "catch-22" many companies described of being required by the PTO to provide human clinical data to support an asserted therapeutic utility while at the same time being unable to raise funds to perform those trials because their patent situation was unclear. The guidelines, consistent with present law, provide that if an applicant can show that an asserted utility is credible using any kind of evidence, it will be sufficient to satisfy section 101. We will not impose unrealistic and unattainable evidentiary requirements, like successful human clinical trials, on patent applicants.

The guidelines also reestablish the proper level of deference that must be given to expert opinions. We heard, for example, many people say that some examiners routinely challenge the sound scientific conclusions of

recognized experts in the field. This practice will not be condoned under the new guidelines.

And, in response to the requests of many in the patent bar, we are publishing the guidelines for public comment. This will help "open up" the process of how we train our examiners. We invite any interested member of the public to comment on the guidelines and offer constructive suggestions. We'll accept comments on the interim guidelines through February 24, 1995, and will finalize them sometime in early March.

Now, I recognize that effective implementation of a new operating approach requires more than simply issuing guidelines. This is why we are taking several additional steps to change the practices that our customers, particularly biotechnology patent applicants, found so troubling.

First, we will effectively train the examining corps on how to use the new guidelines. We realize that examiners must have a sound legal foundation to apply the law correctly. Our training will provide them this training. It will also be tailored to address unique fact patterns that arise in each examining group. And we will also incorporate the guidelines into the initial training of examiners--this will cultivate a proper perspective on utility from day one in an examiner's career.

We will also be making some changes in how we manage examiners. Supervisors will be trained so that they fully understand the guidelines

and can review examiner actions properly. This will enable them to correctly train examiners during their day to day review of examiner actions, and enable them to correct errors before they cause problems for applicants. Our supervisors will thus be able to instill into Examiners the proper approach to take during the review of applications for compliance with the utility requirement. And, if necessary, we will not hesitate to change management practices or personnel where they have proven ineffective in carrying out Office policies.

Finally, we will be creating two, and possibly more if needed, biotechnology practice specialists to review applications in Group 1800. Together with the quality assurance expert that we already have assigned to the Group 1800, and like their counterparts in the Computer Applications Examining Group, these experts ensure that office actions are consistent with the guidelines. These individuals will have the authority to revise any Office action that they believe is inconsistent with the guidelines before it is mailed to an applicant. Putting this quality team in place will give me the ability to quickly pinpoint problems and correct them.

Our actions today are only one of many steps we will be taking to serve our customers better, especially the independent inventors who have been so instrumental in our Nation's history. We are committed to working with the new Congress to implement legislative reform that will make the patent system work better and provide more effective rights. For example, we will continue our support for reexamination reform and pre-grant publication, as well as effective legislative solutions to

problems related to the patenting of biotechnology processes. We will also be open to studying other proposals, such as reform of the patent term extension authority for regulated products, if they can be shown to be needed and useful changes. And we will also continue our efforts to make to the patent application process more user-friendly, including by making it possible to file regular and provisional applications electronically.

We also realize that with the passage of the Uruguay Round implementing legislation, a rapid and complete examination of patent applications is imperative. As such, we will reform those aspects of our operating procedures, administrative and substantive, that prove to be burdensome, inefficient or outmoded. And as we have demonstrated over the past year by holding public hearings all over the country, we will actively seek input from our customers on how we can improve the patent examination process. Doing so will enable us to provide innovative American businesses with one of the most important the competitive tools they need to compete in today's markets -- reliable patent rights that provide an effective term of protection.

REMARKS OF DAVID BEIER[1]

ON BEHALF OF

BIOTECHNOLOGY INDUSTRY ORGANIZATION

December 22, 1994

The Biotechnology Industry Organization today announces its support for steps taken by the United States Patent and Trademark Commissioner to improve the strength and timeliness of biotechnology patents. This breakthrough in the fair and prompt treatment of biotechnology patent applications should help remove some of the uncertainty surrounding the ability of our scientists to obtain rapid patent protection for our inventions.

Today's announcement represents the culmination of months of work between the executive branch and the private sector. Beginning earlier in 1994, the biotechnology industry began a series of meetings to focus the attention of the Patent Office on the unique problems of the industry. This process included an extraordinary public hearing in October of 1994 in San Diego, California. At that hearing, the Patent Commissioner heard first hand about the concerns of the industry from more than 50 individual witnesses, including chief executive officers, investment bankers, venture capitalists, scientists and patent lawyers. Today's announcement by the Patent Office is a strong and vigorous down payment on a comprehensive response by the Patent Commissioner to that hearing.

The vitality of our intellectual property system depends on the **certainty** of the rules for obtaining and enforcing patents, **celerity** of the patent application and prosecution process, patents of adequate **scope**, and patents whose validity is **strong**. All of the four elements that are key to strong intellectual property protection for biotechnology inventions are all addressed comprehensively in this major regulatory initiative.

Commissioner Bruce Lehman's announcement today of new guidelines for patent examiners makes clear the rules that should be applied in determining whether a patent application should be approved. The specific reform is to clarify that human clinical trials are not necessarily required to meet the so-called "utility" standards of patentability. This change – once fully implemented – should make biotechnology patent prosecutions more rapid. Moreover, this rule change will assure the continued division of responsibility between the Patent Office and the FDA. Under this approach,

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[1] Vice President, Public Policy, Genentech, Inc.

the Patent Office will test the invention's usefulness in a general sense early in the R&D cycle which should help clarify the patent status of a given invention. The absence of delay and uncertainty at this stage in the process will increase the likelihood of early seed capital. Nothing in the announcement, however, alters the traditional role of the FDA to determine that a drug is both safe and effective. This change merely instructs examiners that the "efficacy" determinations are not theirs, but rather they belong to the FDA.

UNITED STATES DEPARTMENT OF
COMMERCE
NEWS
WASHINGTON, D.C. 20230

PATENT AND
TRADEMARK
OFFICE

PAT 94-28

FOR IMMEDIATE RELEASE

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PTO Announces New Biotechnology Guidelines

The Commerce Department's Patent and Trademark Office today announced new interim guidelines for the examination of biotechnology patent applications, saying it now will rely on standard screening tests to assess potential usefulness of drugs in the treatment of incurable diseases.

The interim guidelines are being issued to improve the agency's current guidelines for examining patent applications for inventions for treating incurable human illnesses.

The guidelines outline the Office's new policies regarding compliance with the "utility" requirement. By law, a patent applicant must show that an invention is "useful" before a patent is granted. The new guidelines outline specific policies for Examiners to follow in reviewing these applications.

Assistant secretary of commerce and patent and trademark commissioner Bruce Lehman, in making today's announcement, noted that: "These guidelines will shift our approach in reviewing these applications from one which doubts whether an invention works to one where we assume it does unless there are sound reasons to suspect otherwise. Obviously, there will be rare cases where an applicant will have to provide persuasive evidence to show that a drug will work as the applicant claims. However, for most cases, standard screening tests that the industry relies on to assess a drug's potential will satisfy our requirements for utility."

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12/22/94

Changes To come 10-1-94
3% fee increase
new cover sheet & correction assignments
20 mos. from filing publication

VIRGINIA STATE BAR

Intellectual Property Law Section

Continuing Legal Education Seminar

April 28, 1994

NEW RULES AND NOTICES

Abraham Hershkovitz
Petitions Examiner
Office of the Assistant Commissioner for Patents

I. Rule Changes Implemented

A. **PCT Practice** (1147 OG 29 (February 9, 1993); 58 FR 4335) Effective date May 1, 1993.

B. **Revival of Patent Applications and Reinstatement of Patents** (1154 OG 35 (September 14, 1993); 58 FR 44277) Effective date September 20, 1993.

C. **Changes in Patent Drawing Standards** (1153 OG 33 (August 10, 1993); 58 FR 38719) Effective date October 1, 1993.

D. **Filing and Signature Requirements** (1156 OG 61 (November 16, 1993); 58 FR 54494) Effective date November 22, 1993.

E. **Miscellaneous Changes in Patent Practice** (1156 OG 54 (November 16, 1993); 58 FR 54504) Effective date January 3, 1994.

Guidelines re Donaldson: scope of claims means n step + function previously, if function in ref. was the same, reject now - Ex. will interpret scope of means + function limited to means description in spec. or equivalents thereof

II. Official Gazette Notices

A. Taking Action Before the PTO by the Assignee under 37 CFR 3.73 (1150 OG 27 (April 25, 1993))

B. Withdrawing the Holding of Abandonment When PTO Actions are not Received (1156 OG 53 (November 16, 1993))

C. IDS in PCT National Stage Applications (1156 OG 91 (November 23, 1993))

D. Procedures for Restarting Response Periods (1160 OG 14 (March 1, 1994))

E. U.S. Postal Service Interruption and Emergency in Los Angeles (1160 OG 39 (March 8, 1994))

F. Issuance of a Patent to an Assignee (1161 OG 293 (April 12, 1994))

G. Guidelines to Examiners - O.G. May 17, 1994
35 USC 112 ¶6 after Donaldson

I. Rule Changes Implemented

A. PCT Practice (1147 OG 29 (February 9, 1993)) Effective date May 1, 1993.

The PTO amended the rules of practice relating to applications filed under the Patent Cooperation Treaty (PCT): (1) to amend the rules in accordance with revised regulations under the PCT; (2) to bring the rules regarding applications entering the national stage under 35 U.S.C. 371 more in line with existing regulations applicable to national applications filed under 35 U.S.C. 111; and (3) to clarify existing practice under the PCT. The changes will result in more streamlined and simplified procedures for filing and prosecuting international and national stage applications under the PCT.

Thus, the new practice, which requires payment of the basic national fee on or before 20 or 30 months from the priority date, has several advantages: (1) it will enable the applicant to identify the U.S. attorney or agent for correspondence from the Office; (2) the Office, after a check of the national stage papers at 20 or 30 months, will mail a notice identifying any deficiencies and affording applicant a period for correction of those deficiencies; and (3) as in

national practice under 37 CFR 1.53, it will enable applicants to extend the period of time under 37 CFR 1.136 for submission of a proper oath, declaration or translation.

Those international applications entering the national stage under 37 CFR 1.494 where 20 months from the priority date expires on, or before, 30 April 1993 are under the previous rule and those international applications entering the national stage under 37 CFR 1.495 where 30 months from the priority date expires on, or before, 30 April 1993 are under the previous rule. Those international applications entering the national stage under 37 CFR 1.494 where 20 months from the priority date expires on, or after, 01 May 1993 are under the new rule (37 CFR 1.494 effective 01 May 1993) and those international applications entering the national stage under 37 CFR 1.495 where 30 months from the priority date expires on, or after, 01 May 1993 are under the new rule (37 CFR 1.495 effective 01 May 1993). No more extensions of time!

37 CFR 1.494(b) and 1.495(b) were amended to require that the basic national fee and a copy of the international application must be filed with the Office by 20 or 30 months, respectively, from the priority date to avoid abandonment. The 22 or 32 month period, respectively, for filing the basic national fee with a surcharge in previous 37 CFR 1.494(c) and 1.495(c) have been eliminated. The International Bureau normally provides the copy of the international application to the Office in accordance with PCT Article 20. At the same time, the International Bureau notifies the applicant of the communication to the Office. In accordance with PCT Rule 47.1, that notice shall be accepted by all designated offices as conclusive evidence that the communication has duly taken place. Thus, if the applicant desires to enter the national stage and applicant has received the notice from the International Bureau, applicant need only pay the basic national fee by 20 or 30 months, respectively, from the priority date. The 20 or 30 month time limit, respectively, for submission of the basic national fee and a copy of the international application is not extendable.

37 CFR 1.494(c) and 1.495(c) were amended to provide that applicants who have provided the basic national fee and a copy of the international application by 20 or 30 months, respectively, from the priority date but who omit a proper translation, oath or declaration will receive a notification setting a time period for submission of the omitted requirements. The time period set in the notice can be extended pursuant to 37 CFR 1.136. Filing of the oath or declaration later than 20 or 30 months, respectively, will require the payment of the surcharge set forth in 37 CFR 1.492(e). Filing of the translation later than 20 or 30 months, respectively, will require the payment of the processing fee set forth in section 1.492(f).

37 CFR 1.494(g) and 1.495(g) were amended to specify when an application that fails to enter the national stage becomes abandoned. Abandonment occurs at 20 or 30 months, respectively, from the priority date if the basic national fee and a copy of the international application have not been provided to the Office. If they have been provided to the Office within 20 or 30 months, respectively, and the translation and/or oath or declaration are not filed timely, abandonment occurs upon expiration of the time limit set in the notification pursuant to 37 CFR 1.494(c) or 1.495(c). Thus, in the latter situation, abandonment would occur at the expiration of the time period set in the notice to file the missing translation, and/or oath or declaration.

B. **Revival of Applications and Reinstatement of Patents** (1154 OG 35 (September 14, 1993)) Effective date September 20, 1993.

The PTO amended the rules of practice in patent cases to: (1) modify the petition requirements for reviving abandoned applications; (2) extend the provisions for revival under the unintentional standard to applications abandoned under 37 CFR 1.53(d); (3) modify the requirements for a petition to accept late payment of a maintenance fee filed more than six months after expiration of a patent; (4) modify the requirements for a petition to accept unavoidably delayed payment of a maintenance fee; and (5) provide for reinstatement of a patent where the delay in timely payment of a maintenance fee was unintentional. The Office established the amount of $1,500 for the surcharge for accepting a maintenance fee after expiration of a patent for non-timely payment of a maintenance fee where the delay in payment is shown to the satisfaction of the Commissioner to have been unintentional.

37 CFR 1.137(c), 1.155(d) and 1.316(d) were amended to reflect the current practice that a terminal disclaimer filed for the purpose of reviving an application also applies to a patent granted on any continuing application entitled to the benefit of the filing date of the subject application under 35 U.S.C. 120.

The above-noted sections were amended to specify a two-month period or such time as may be set in the dismissal as being the appropriate deadline for requesting reconsideration. In those situations where petitioners require more time to gather additional evidence or items needed for reconsideration, an extension of time of up to four months may be obtained under the provisions of 37 CFR 1.136(a). The filing of a renewed petition within the period specified in the decision or within the extended period permitted under 37 CFR 1.136 will satisfy the promptness requirement of petitions under the

unavoidable standard. Upon failure to timely file a renewed petition under the unavoidable standard, the Office will require a showing of unavoidable delay for the entire period of abandonment. To be entitled to relief under the unavoidable standard, petitioner must be able to show unavoidable delay from a time prior to abandonment to the filing of a grantable petition. *In re Application of Takeo*, 17 USPQ2d 1155 (Comm'r Pat. 1990). Upon failure to timely file a renewed petition under the unintentional standard (see 37 CFR 1.137(d), 1.155(e), 1.316(e) and 1.317(e)), petitioner may be subject to a loss of the right to proceed under the unintentional standard if more than one year lapsed between the date of abandonment and the date the renewed petition is filed.

The unintentional provisions specified in 37 CFR 1.137(b) will apply to applications abandoned under 37 CFR 1.53(d).

The Office amended 37 CFR 1.137(b) to clearly require applicant to state that the delay, rather than the abandonment, was unintentional. A person seeking revival should not make a statement that the delay was unintentional unless the entire delay, including the delay from the date it was discovered that the application was abandoned up until the petition to revive was actually filed, was unintentional. For example, a statement that the delay was unintentional would not be proper when applicant becomes aware of an abandonment and then intentionally delays filing a petition to revive the application under 37 CFR 1.137.

The Office had adopted a policy wherein, under certain strictly limited conditions, the one-year period for requesting revival of an unintentionally abandoned application could be waived. Accordingly, the prohibition against requests for waiver found in 37 CFR 1.137(b), 1.155(c), 1.316(c) and 1.317(c) was deleted. However, applicants are cautioned that waiver of the one-year deadline under the unintentional standard will be subject to strictly limited conditions.

Public Law 102-444 amended subsection 41(c)(1) of title 35, United States Code, to permit the Commissioner to accept late payment of any maintenance fee filed within twenty-four months after the six-month grace period, if the delay in payment is shown to the satisfaction of the Commissioner to have been unintentional. In order to implement Public Law 102-444, paragraphs (a) and (c) of 37 CFR 1.378 were amended to permit the filing of a petition to accept late payment of a maintenance fee, where the delay in payment was unintentional.

In addition to the timeliness deadline set forth in the preceding paragraph, a petition filed under the unintentional standard of § 1.378(c) would have to include the required maintenance fee set forth in 37 CFR 1.20 (e) through

(g), the surcharge for an unintentionally expired patent as set forth in § 1.20(i)(2), and a statement that the delay in payment of the maintenance fee was unintentional. A person seeking reinstatement of an expired patent should not make a statement that the delay in payment of the maintenance fee was unintentional unless the entire delay, including the delay from the date it was discovered that the maintenance fee was not paid timely up until the maintenance fee was actually paid, was unintentional. For example, a statement that the delay in payment of the maintenance fee was unintentional would not be proper when patentee becomes aware of an unintentional failure to timely pay the maintenance fee and then intentionally delays filing a petition for reinstatement of the patent under 37 CFR 1.378.

Petitions to accept delayed payment of a maintenance fee in an expired patent, prior to enactment of Public Law 102-444, required a showing of unavoidable delay. 37 CFR 1.378(b) was amended to provide that the unavoidable delay provisions are available at any time following expiration of a patent for failure to pay a maintenance fee. Furthermore, the practice of accepting the unavoidably delayed late payment of maintenance fees was modified to be more analogous to the practice of reviving abandoned applications and accepting late payment of issue fees. In addition to the maintenance fee and surcharge previously required, paragraph (b) was amended to require prompt filing of a petition after the patentee is notified, or otherwise becomes aware, of the expiration of the patent. The public interest is best served by prompt reinstatement of a patent in which there was an unavoidable or unintentional delay in the timely payment of the maintenance fee.

no time limit for "unavoidable" - show in matter analogous to reviving abandoned apps.

C. **Changes in Patent Drawing Standards** (1153 OG 33 (August 10, 1993)) Effective date October 1, 1993.

The PTO amended the rules of practice regarding patent drawings to adopt international standards and to eliminate unnecessary requirements. The Office amended the rules to provide clarification and adopt international standards; to delete the reference to changes by bonded draftsmen since the Office no longer releases drawings from patent applications; and to include the option of submitting black and white photographs in lieu of black ink drawings.

37 CFR 1.84(a) permits the acceptance of color drawings upon the granting of a petition explaining why the color drawings are necessary. On rare occasion, color drawings are necessary as the only practical medium by which to disclose the subject matter sought to be patented in a utility patent application or the subject matter of a statutory invention registration. The Office will accept

color drawings in utility patent applications and statutory invention registrations only after granting a petition filed under this paragraph explaining why the color drawings are necessary. Any such petition must include the following: (i) The appropriate petition fee set forth in 37 CFR 1.17(h); (ii) Three (3) sets of color drawings; and (iii) The specification must contain the prescribed language as the first paragraph in that portion of the specification relating to the brief description of the drawing. If the language is not in the specification, a proposed amendment to insert the language must accompany the petition.

37 CFR 1.84(b) permits the acceptance of photographs upon granting of an applicant's petition. The Office will accept black and white and color photographs or photomicrographs (not photolithographs or other reproductions of photographs made by using screens). The Office will accept photographs in utility and design patent applications only after granting a petition filed under this paragraph which requests that photographs be accepted. Any such petition must include the following: (i) The appropriate petition fee set forth in 37 CFR 1.17(h); and (ii) Three (3) sets of photographs. Photographs must either be developed on double weight photographic paper or be permanently mounted on bristol board. The photographs must be of sufficient quality so that all details in the drawing are reproducible in the printed patent.

37 CFR 1.84(f) was amended to permit one additional size of paper, i.e., 21.6 cm. by 27.9 cm. (8 1/2 by 11 inches) for drawings.

37 CFR 1.152 was amended to provide that photographs and ink drawings must not be combined in one design application. The reason for this requirement is to avoid inconsistencies between the photograph and the drawing, and further eliminate views that may distort the proportionate relationship between the corresponding elements on the drawing and the photograph. All design photographs are limited to the design for the article claimed and are not to include environmental structure. Color drawings and color photographs are not permissible in design patent applications.

D. **Filing and Signature Requirements** (1156 OG 61 (November 16, 1993)) Effective date November 22, 1993.

The PTO amended the rules of practice in patent and trademark cases to: specify the types of correspondence which will no longer require original signatures; provide for facsimile transmission of certain correspondence to the Office; discontinue use of the drop boxes at Crystal Plaza Building 3 and at the Department of Commerce Building in Washington, D.C.

The Office amended 37 CFR 1.4 to include a new paragraph (d) to specify that most correspondence filed in the Office, which requires a person's signature, may be an original, or a copy thereof.

The Office amended 37 CFR 1.4(e) to identify types of correspondence in which an original must be submitted to the Office.

The Office amended 37 CFR 1.4(f) to provide that when a document that is required by statute to be certified must be filed (such as a certified copy of a foreign patent application, pursuant to 35 U.S.C. 119; a certified copy of an international application, pursuant to 35 U.S.C. 365), a copy of the certification, including a photocopy or facsimile transmission, will not be acceptable.

The Office amended 37 CFR 1.6(d) to specify the types of correspondence which may be transmitted by facsimile. The situations where transmissions by facsimile remain prohibited are identified in the rule. Prohibitions cover situations where originals are required as specified in 37 CFR 1.4 (e) and (f), and situations where accepting a facsimile transmission would be unduly burdensome on the Office. As a courtesy, the Office will attempt to notify senders whenever correspondence is sent to the Office by facsimile transmission that falls within one of these prohibitions. Senders are cautioned against submitting correspondence by facsimile transmission which is not permitted under 37 CFR 1.6(d) since such correspondence will not be accorded a receipt date.

The following list itemize types of correspondence which the Office will not accept if filed by facsimile transmission, and, if submitted by facsimile, will not be accorded a date of receipt:

(1) A document that is required by statute to be certified;

(2) A national patent application specification and drawing or other correspondence for the purpose of obtaining an application filing date;

(3) Drawings submitted under 37 CFR 1.81, 1.83-1.85, 1.152, 1.165, 1.174, or 1.437; ("formal" drawings) Don't fax informal drawings until you have a filing date

(4) Correspondence in an interference which an examiner-in-chief orders to be filed by hand or "Express Mail";

(5) Agreements between parties to an interference under 35 U.S.C. 135(c);

(6) Correspondence to be filed in an interference proceeding which consists of a preliminary statement under 37 CFR 1.621; a transcript of a deposition under 37 CFR 1.676 or of interrogatories, cross-interrogatories, or recorded answers under 37 CFR 1.684(c); or an evidentiary record and exhibits under 37 CFR 1.653;

** Use Rule 1.8 - Certificate of transmission or submission. Use copy of this certificate of submission as evidence in lieu of receipt card.

If client faxes signed declaration, this can all be filed sans surcharge. Do not follow up c original signature!
If you file faxed appln. sans declaration, there will be a surcharge.

(7) Correspondence to be filed in a patent application subject to a secrecy order under 37 CFR 5.1-5.8 of this chapter and directly related to the secrecy order content of the application;

(8) An international application for patent;

(9) A copy of the international application and the basic national fee necessary to enter the national stage, as specified in 37 CFR 1.494(b) or 37 CFR 1.495(b);

(10) A request for reexamination under 37 CFR 1.510.

The Office amended 37 CFR 1.8(a) to prescribe procedures for the use of a certificate of mailing or transmission to file papers or fees in the Office by first class mail or by facsimile transmission. A suggested format for a Certificate of Mailing and a Certificate of Transmission to be included with the correspondence, is reproduced below:

Certificate of Mailing

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to:

Commissioner of Patents and Trademarks
Washington, D.C. 20231

on _____
Date

(must be by U.S. Postal Service!)

_____
Signature

_____
Typed or printed name of person signing certificate

Certificate of Transmission

I hereby certify that this correspondence is being facsimile transmitted to the Patent and Trademark Office:

on _____
Date

_____
Signature

_____
Typed or printed name of person signing certificate

E. **Miscellaneous Changes in Patent Practice** (1156 OG 54 (November 16, 1993)) Effective date January 3, 1994.

The PTO amended the rules of practice in patent cases to: expand the authority to sign a terminal disclaimer in a patent application or a disclaimer in a patent; eliminate some formal requirements for an appeal brief for an appellant appearing without counsel; prohibit fee extensions of time to file reply briefs and requests for oral hearing; clarify the requirements for claiming foreign priority; specify the manner in which the fee deficiency is computed when applicants seek to correct an error in claiming small entity status; and correct errors in published regulations.

The Office amended 37 CFR 1.28(c) to reflect Office practice in calculating fee deficiencies when fees have been improperly paid as a small entity. The Office receives deficiency payments that differ based on varying interpretations of 37 CFR 1.28(c). Some simply double the small entity fee in effect when the fee was originally paid in error in the small entity amount, while others compute the difference between the fee already paid and the other than small entity fee level in effect at the time the deficiency is paid. The Office will require payments to be based on fee levels in effect at the time the other than small entity fee is paid.

The Office amended 37 CFR 1.136(a) by adding two additional situations in which applicants would no longer be able to use fee extensions. The new prohibitions will apply to situations where the request to extend the time is: (1) to permit filing reply briefs under 37 CFR 1.193(b); and (2) to permit filing requests for oral hearing under 37 CFR 1.194(b) before the Board of Patent Appeals and Interferences (Board). If Ex. Answer was mailed on or after 1-3-94, new Rules apply.

The Office amended 37 CFR 1.192(c) to eliminate some of the formal requirements for an appeal brief for a pro se appellant, that is, an appellant appearing without counsel. This section was amended to allow a pro se appellant's brief to be accepted provided it is at least in substantial compliance with the requirements of subparagraphs (1), (2), (6) and (7) of paragraph (c).

The Office amended 37 CFR 1.193(b) to clarify the consequence of failure to file a reply brief in response to an expressly stated new ground of rejection made in an examiner's answer. The failure to file a reply brief will result in dismissal of the appeal as to the claims made subject to the expressly stated new ground of rejection. If the dismissal of the appeal applies to all claims in the

do not need a new ground rejection for 2 mos. for new ground rejection.

application, the application will be abandoned. Additionally, this section was amended to change the period for filing a reply brief to two months from the date of the examiner's answer, regardless of whether the examiner's answer includes a new ground of rejection.

The Office amended 37 CFR 1.321 to permit the signing of a disclaimer in a patent by the patentee, or an attorney or agent of record, whereas, persons permitted to sign a disclaimer in a patent application will be any person specified in 37 CFR 1.33(a)(1)-(4). The person signing the disclaimer must state the present extent of the disclaiming party's (i.e., patentee's or assignee's) interest in the patent or patent application. MUST BE OF RECORD to sign TD.

II. Official Gazette Notices

A. Taking Action Before the PTO by the Assignee under 37 CFR 3.73 (1150 OG 27 (April 25, 1993))

When the assignee first seeks to take action in a matter before the PTO, the assignee must establish its ownership. Ownership is established by submitting copies of chain of title documents, or by referring to the reel and frame number where the evidence is recorded in the PTO. Additionally, certification is required, that title is in the assignee seeking to take action.

Examples of situations where ownership must be established, are where the assignee signs: a status request or power to inspect; an express abandonment; an appointment of attorney or agent; a terminal disclaimer; a consent to file a reissue application, an application under § 1.47(b) or 1.475, or to change inventorship; an issue fee transmittal form, or a response to a PTO action.

B. Withdrawing the Holding of Abandonment When PTO Actions are not Received (1156 OG 53 (November 16, 1993))

Practice in accordance with Delgar Inc. v. Schuyler, 172 USPQ 513 (D.D.C. 1971) to show non-receipt of a PTO action has been simplified. All PTO needs in most cases is a statement, from the practitioner, that the action was not received and attesting to the fact that a search of the file jacket and docket records indicates that the PTO action was not received. A copy of the docket record where the action would have been entered had it been received and docketed must be attache and referenced in the practitioner's statement.

C. **IDS in PCT National Stage Applications** (1156 OG 91 (November 23, 1993))

The practice regarding filing information disclosure statements in a national stage application has been modified where the same documents were cited in the international application. The examiner will consider the documents cited in the international search report, without any further action by applicant under §§ 1.97 and 1.98, when the international search report and copies of the documents are indicated to be present in the national stage file. Otherwise, compliance with §§ 1.97 and 1.98 is required in order to ensure that the examiner considers the documents cited in the international search report.

mail room now date stamps

D. **Procedures for Restarting Response Periods** (1160 OG 14 (March 1, 1994))

Revised procedures have been established to restart a previously set period for response when a PTO action is received late at the correspondence address. The PTO will grant a petition to restart the previously set period for response to run from the date of receipt of the PTO action, or in some cases, to run from the postmark date shown on the envelope which contained the PTO action. The criteria for granting the petition are set forth in the OG Notice.

E. **U.S. Postal Service Interruption and Emergency in Los Angeles** (1160 OG 39 (March 8, 1994))

The PTO designated the January 17, 1994, Los Angeles earthquake as a postal service interruption and an emergency within the meaning of 35 U.S.C. 21(a). Requests for acceptance of delayed submissions should be directed to Office of Petitions.

F. **Issuance of a Patent to an Assignee** (1161 OG 293 (April 12, 1994))

When the correct name of the assignee was not provided on the Issue Fee Transmittal form (PTOL-85b), a correction can be made by filing a petition under §1.183 requesting waiver of §3.81 (which states that the patent may issue in the name of the assignee). This procedure is applicable at any time after payment of the issue fee, including after issuance of the patent.

(94) **Department of Commerce**
Patent and Trademark Office
37 CFR Parts 1 and 10
[Docket No. 920539-2313]
RIN: 0651-AA51

Revision of Patent Cooperation Treaty Provisions

Agency: Patent and Trademark Office, Commerce
Action: Final Rule
Summary: The Patent and Trademark Office (Office) is amending the rules of practice relating to applications filed under the Patent Cooperation Treaty (PCT): (1) to amend the rules in accordance with revised regulations under the PCT; (2) to bring the rules regarding applications entering the national stage under 35 U.S.C. 371 more in line with existing regulations applicable to national applications filed under 35 U.S.C. 111; and (3) to clarify existing practice under the PCT. The changes will result in more streamlined and simplified procedures for filing and prosecuting international and national stage applications under the PCT.
Effective Date: May 1, 1993.
For Further Information Contact: Vincent Turner by telephone at (703) 305-9384 or by mail addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231 and marked to the attention of Vincent Turner (Crystal Park 2, room 919).
Supplementary Information: The Office published a notice of proposed rulemaking relating to revision of the Patent Cooperation Treaty provisions, in the *Federal Register*, 57 Fed. Reg. 29248 (July 1, 1992) and in the *Official Gazette*, 1140 Off. Gaz. Pat. Office 27 (July 14, 1992). No oral hearing was held. Eight individuals or organizations submitted written comments in response to the notice of proposed rulemaking. The eight written comments are available for public inspection in the Office of the Assistant Commissioner for Patents, room 919,Crystal Park II, 2121 Crystal Drive, Arlington, VA.

Familiarity with the notice of proposed rulemaking is assumed. Changes in the text of the rules published for comment in the notice of proposed rulemaking are discussed. Comments received in writing in response to the notice of proposed rulemaking are discussed.

This rule change will improve filing and processing procedures for applicants both in the filing of international applications and in the filing of national stage applications under 35 U.S.C. 371.

Background

During the first 14 years under the PCT, the annual volume of international patent applications filed in the U.S Receiving Office has increased from just under 100 to almost 10,000 in fiscal year 1991. The volume of U.S. national stage applications has shown similar growth to the point that the U.S. is now designated more than 10,000 times each year by applicants filing international applications under the PCT. Historically, approximately 60% of those applicants that designate the U.S. enter the national stage in the United States.

On July 8 to 12, 1991, representatives of the patent offices of the member countries, in a series of meetings held in Geneva, Switzerland, agreed upon several changes to the PCT regulations which are designed to make the PCT more user-friendly. These adopted changes require corresponding changes in Title 37, CFR.

The practice under the revised PCT regulations will permit an applicant to provide, in addition to at least one specified designation, a precautionary designation of all other PCT member countries and regions so that any intended designation which may have been overlooked on filing can be corrected within 15 months of the priority date byconfirmation of the designation. Applicants are cautioned, however, that in order for the confirmation of a designation of the U.S: to be valid, the inventor must have been named in the application papers as filed, 37 CFR 1.421(b).

International applications are searched and published prior to the 20-month deadline for entry into the national stage. If a demand for preliminary examination is filed before expiration of 19 months from the priority date the time for entry into the national stage is extended to 30 months from the priority date and the international application will be subject to preliminary examination under Chapter II of the PCT. The practice under the revised PCT regulations permits an applicant to indicate in the demand that preliminary examination is to be based on an accompanying PCT Article 34 amendment and, if the amendment is not received with the demand, the applicant will be notified and given a time period within which to file the missing amendment. This new procedure will ensure that examination will go forward based on the desired PCT Article 34 amendment.

Also, the Office is aware that certain applicants have had difficulty in properly filing national stage applications due to the different requirements in the rules for PCT and U.S. national applications. Some differences cannot be avoided due to different procedures required under the PCT from U.S. national practice. It is desirable, however, to minimize these differences and to simplify national stage filing procedures.

International applications have become abandoned for failure to timely provide an oath or declaration, a filing fee and/or an accurate translation. In national practice under 35 U.S.C. 111, if any of these items was not presented at the time of filing, a notice would be mailed to the applicant setting a period of time to provide the missing item(s) and to pay a fee. The amendments to the rules governing entering the national stage will establish a greater degree of uniformity of practice and requirements for filing an application under 35 U.S.C. 111 and entering the national stage in an international application under 35 U.S.C.371.

Amending sections 1.494 and 1.495 results in regulations much like the present section 1.53. The major exception is that a notification of any missing parts in sections 1.494 and 1.495 will only be mailed in those instances where the applicant has paid the basic national fee within 20 or 30 months from the priority date depending on whether election of the U.S. under Chapter II of the PCT has been made prior to 19 months. Applicants can no longer pay the basic national fee with a surcharge after the 20/30 months deadline. Failure to pay the basic national fee within 20/30 months from the priority date will result in abandonment of the application. Paying the fee gives a clear indication to the Office that the applicant desires to enter the national stage. If the required oath, declaration or translation has not been filed within 20/30 months from the priority date, as appropriate, the Office will send applicant a notice and provide a period of time to supply the deficiency. Upon paying the basic national fee within 20/30 months from the priority date, the applicant will have the opportunity to inform the Office of a U.S. correspondence address, if any. Thus, the Office will avoid unnecessary handling of approximately 40% of those applications that designate the U.S. but do not enter the national stage, and will be able to send a notice to a U.S. correspondence address in most cases.

Often at 20 or 30 months from the priority date, the only communication which has been received by the Office is a copy of the international application from the International Bureau with the address of the foreign attorney or agent who represented the applicant in the international stage. The foreign attorney or agent may not be conversant in English or knowledgeable about U.S. practice, factors which often contribute to complicating the processing of applications. Thus, the new practice, which requires payment of the basic national fee on or before 20 or 30 months from the priority date, has several advantages: (1) it will enable the applicant to identify the U.S. attorney or agent for correspondence from the Office; (2) the Office, after a check of the national stage papers at 20 or 30 months, will mail a notice identifying any deficiencies and affording applicant a period for correction of those deficiencies; and (3) as in national practice under section 1.53, it will enable applicants to extend the period of time under section 1.136 for submission of a proper oath, declaration or translation.

The changes to sections 1.494 and 1.495 address the problems which have been most frequently encountered in entering the national stage in the United States. The new practice of notifying applicants of the omission of a proper oath, declaration or translation and setting an extendable period of time for correction will allow applicants greater flexibility in the time for submission of these documents, thus avoiding the consequence of abandonment and potential loss of rights in the United States.

Implementation

The rule changes which reflect corresponding amendments in the PCT regulations were implemented on 01 July 1992 when the

(53) **Patent and Trademark Office**
37 CFR Part 1

Changes in Procedures for Revival of Patent Applications and Reinstatement of Patents

Agency: Patent and Trademark Office, Commerce
Action: Final Rule
Summary: The Patent and Trademark Office (Office) is amending the rules of practice in patent cases to: modify the petition requirements for reviving abandoned applications; extend the provisions for revival under the unintentional standard to applications abandoned under §1.53(d); modify the requirements for a petition to accept late payment of a maintenance fee filed more than six months after expiration of a patent; modify the requirements for a petition to accept unavoidably delayed payment of a maintenance fee; and provide for reinstatement of a patent where the delay in timely payment of a maintenance fee was unintentional. The Office is also establishing the amount for the surcharge for accepting a maintenance fee after expiration of a patent for non-timely payment of a maintenance fee where the delay in payment is shown to the satisfaction of the Commissioner to have been unintentional.
Effective Date: Sept. 20, 1993. These rules will be applicable to all papers filed with the Office on or after the effective date.
For Further Information Contact: Jeffrey V. Nase by telephone at (703) 305-9282 or by mail marked to his attention and addressed to Office of the Assistant Commissioner for Patents, Box DAC, Washington, D.C. 20231.
Supplementary Information: In a Notice of Proposed Rulemaking published in the Federal Register (57 FR 41899) on Sept. 14, 1992, and in the Patent and Trademark Office *Official Gazette* (1143 Off. Gaz. Pat. Office 8) on October 6, 1992, the Office proposed to amend §§1.17, 1.137, 1.155, 1.316, 1.317 and 1.378. In an Interim Rule published in the Federal Register (57 FR 56448 on November 30, 1992, and in the Patent and Trademark Office Official Gazette (1145 Off. Gaz. Pat. Office 339) on December 8, 1992, the Office, pursuant to Public Law 102-444 enacted October 23, 1992, established interim rules for reinstatement of a patent where the delay in timely payment of a maintenance fee was unintentional. The Office also established the amount for the surcharge for accepting a maintenance fee after expiration of a patent for non-timely payment of a maintenance fee where the delay in payment was shown to the satisfaction of the Commissioner to have been unintentional. No oral hearing was held.

DISCUSSION OF SPECIFIC SECTIONS TO BE CHANGED OR ADDED:

(1) Post issuance fees.(§1.20)

Section 1.20(i) is amended to add a $1,500 surcharge fee for accepting the unintentionally delayed payment of a maintenance fee.

(2) Unavoidable or unintentional abandonment of an application

Sections 1.137, 1.155, 1.316 and 1 317 each provide for petitions to the Commissioner for relief from failure to timely comply with a requirement of the Office. Section 1.137 provides for petitions to revive patent applications abandoned for failure to prosecute where the delay in prosecution was unavoidable (§1.137(a)) or the delay was unintentional (§1.137(b)). Section 1.155 provides for petitions for acceptance of late payment of issue fees in applications for design patents as though no abandonment had ever occurred where the delay in payment was unavoidable (§1.155(b)) or unintentional (§1.155(c)). Section 1.316 provides for petitions for acceptance of late payment of issue fees in applications for patent as though no abandonment had ever occurred where the delay in payment was unavoidable (§1.316(b)) or unintentional (§1.316(c)). Section 1.317 provides for acceptance of late payment of the balance of issue fees in patents as though no lapse had ever occurred where the delay in payment was unavoidable (§1.317(b)) or unintentional (§1.317(c)).

In order to obtain relief under the unavoidable standard in the above-noted sections, the regulations continue to require the filing of a terminal disclaimer if the petition is filed more than six months after the date of abandonment. See §§1.137(c), 1.155(d), 1.316(d) and 1.317(d). The terminal disclaimer must disclaim a period equivalent to the period of abandonment. The period of abandonment is considered to be the number of months lapsed from the date of abandonment until the date of filing of a grantable petition.

Sections 1.137(c), 1.155(d) and 1.316(d) are amended to reflect the current practice that a terminal disclaimer filed for the purpose of reviving an application also applies to a patent granted on any continuing application entitled to the benefit of the filing date of the subject application under 35 U.S.C. 120.

Applicants may petition under the provisions of §1.183 for a waiver of the requirement that a period equivalent to the period of abandonment be disclaimed if it can be shown that an extraordinary situation exists in which justice requires waiver of this requirement.

If petitions under the above-noted sections were not grantable because of insufficient evidence or petitioner's failure to comply with certain requirements, the Office dismissed the petitions. The dismissal indicated any missing items and warned petitioners that any renewed petition seeking reconsideration must be filed promptly. While the promptness requirement was not precisely defined, §1.181(f) requires the filing of petitions within two months from an action complained of in order to avoid possible dismissal of the petition on the grounds that it was not timely filed. The above-noted sections are being amended to specify a two-month period or such time as may be set in the dismissal as being the appropriate deadline for requesting reconsideration. In those situations where petitioners require more time to gather additional evidence or items needed for reconsideration, an extension of time of up to four months may be obtained under the provisions of §1.136(a). The filing of a renewed petition within the period specified in the decision or within the extended period permitted under §1.136 will satisfy the promptness requirement of petitions under the unavoidable standard.

Upon failure to timely file a renewed petition under the unavoidable standard, the Office will require a showing of unavoidable delay for the entire period of abandonment. To be entitled to relief under the unavoidable standard, petitioner must be able to show unavoidable delay from a time prior to abandonment to the filing of a grantable petition. *In re Application of Takeo*, 17 USPQ2d 1155 (Comm'r Pat. 1990). Upon failure to timely file a renewed petition under the unintentional standard (see §§1.137(d), 1.155(e), 1.316(e) and 1.317(e)), petitioner may be subject to a loss of the right to proceed under the unintentional standard if more than one year lapsed between the date of abandonment and the date the renewed petition is filed.

The unintentional provisions specified in §1.137(b) will apply to applications abandoned under §1.53(d). Effective Nov. 5, 1990, the Commissioner waived, under §1.183, the exception specified in §1.137(b) as to applicability of petitions under the unintentional standards to applications abandoned under §1.53(d). See "Petitions to Revive Patent Applications Waiver of Provisions of 37 CFR §1.137(b)", 1121 Off. Gaz. Pat. Office 6 (Dec. 4, 1990). Section 1.137(b) is amended to incorporate this new practice into the regulations.

The Office is amending §1.137(b) to clearly require applicant to state that the delay was unintentional, rather than the abandonment was unintentional. The Office has withdrawn its proposal that would have amended the rules of practice to require a terminal disclaimer if a grantable petition to reinstate an abandoned application was not filed within six months from the date of abandonment. The terminal disclaimer proposal was withdrawn because of the burden that such a requirement would impose on applicants and the Office and because it is unnecessary to achieve its intended purpose. The Office had suggested the terminal disclaimer proposal to ensure that any petition to revive was promptly filed. However, the proposed terminal disclaimer requirement is unnecessary to ensure prompt filing of the petition to revive since the first sentence of §1.137(b) states that an application may be revived if the delay was unintentional. Accordingly, the specific requirements for the unintentional petition to revive have been amended to correspond to the existing rule provision that revival is available if the delay was unintentional, not just that the abandonment was unintentional. A person seeking revival should not make a statement that the delay was unintentional unless the entire delay, including the

(46) **Patent and Trademark Office**
37 CFR Part 1
Changes in Patent Drawing Standards

Agency: Patent and Trademark Office, Commerce
Action: Final Rule
Summary: The Patent and Trademark Office (Office) is amending the rules of practice regarding patent drawings to adopt international standards and to eliminate unnecessary requirements. The Office is amending the rules to provide clarification and adopt international standards; to delete the reference to changes by bonded draftsmen since the Office will no longer release drawings from patent applications and to include the option of submitting black and white photographs in lieu of black ink drawings.
Effective Date: October 1, 1993. These rules will be applicable to all drawings and papers filed with the Office on or after the effective date.
For Further Information Contact: Richard A. Bawcombe by telephone at (703) 305-8594, by mail marked to his attention addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231, or by facsimile transmission to his attention at (703) 305-4372.
Supplementary Information: In a Notice of Proposed Rulemaking published in the *Federal Register* (57 FR 42721) on September 16, 1992, and in the Patent and Trademark Office *Official Gazette* (1143 Off. Gaz. Pat Office 13) on Oct. 6, 1992, the Office proposed to amend the rules of practice in patent drawings. Drawings acceptable for patent applications filed outside of the United States are not always acceptable in a patent application filed in the United States. Therefore, the rules relating to drawing requirements are being amended to enable the Office, when appropriate, to accept drawings that are capable of clear reproduction for the printing of any resulting patent. Drawings in compliance with the old §1.84 will be in compliance with the new §1.84.

An oral hearing was not conducted. However, six written comments were submitted.

Response to Comments on the Rules

The comments received in response to the notice of proposed rulemaking have been given careful consideration and several of the suggested modifications have been adopted.

Another modification, since the "Notice of Proposed Rulemaking," is under §1.84 wherein five sets of drawings were required, but the total has been decreased to three sets due to a reassessment of the need for the additional copies for Office use. The comments and responses are discussed below.
Comment: Three comments were received regarding the proposed changes within §1.84(b). Three other comments were received regarding the proposed changes to §1.165. All six comments suggested that the Office continue to accept mounted photographs.
Response: The Office will adopt the suggestion and continue to accept mounted photographs for utility, design, and plant patent applications. The initial reason the Office sought to change the rule was to overcome the problem of mounted photographs becoming detached and separated from the file. The apparent burden to applicants associated with the Office not accepting mounted photographs is the reason the Office will continue to permit mounted photographs provided they are permanently affixed.

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The corrected Final Rulemaking incorporating the changes identified above is set forth below.

DEPARTMENT OF COMMERCE
Patent and Trademark Office
37 CFR Parts 1, 2 and 10
[Docket No. 90671-3225]
RIN 0651-AA55

Changes in Signature and Filing Requirements for Correspondence Filed in the Patent and Trademark Office

Agency: Patent and Trademark Office, Commerce.
Action: Final Rule.
Summary: The Patent and Trademark Office (Office) is amending the rules of practice in patent and trademark cases to: specify the types of correspondence which will no longer require original signatures; provide for facsimile transmission of certain correspondence to the Office; discontinue use of the drop boxes at Crystal Plaza Building 3 and at the Department of Commerce Building in Washington, D.C.; and clarify other provisions with respect to practice before the Office.
Effective Date: November 22, 1993. These rules will be applicable to all correspondence filed with the Office on or after the effective date.
For Further Information Contact: Abraham Hershkovitz by telephone at (703) 305-9282, by facsimile transmission at (703) 305-8825, or by mail marked to his attention and addressed to Office of the Assistant Commissioner for Patents, Box DAC, Washington, D.C. 20231.
Supplementary Information: In a Notice of Proposed Rulemaking published in the Federal Register at 57 FR 36034 (August 12, 1992) and in the Patent and Trademark Office Official Gazette at 1142 Off. Gaz. Pat. Office 8-13 (September 1, 1992), the Office proposed to amend the rules of practice in patent and trademark cases to simplify the manner in which correspondence may be transmitted to the Office and clarify other provisions with respect to practice before the Office. This rulemaking includes changes to expand those situations where a party can use the Certificate of Mailing or Transmission procedure, and minor technical modifications in Part 2 of Title 37 of the Code of Federal Regulations which were not part of the proposed rulemaking. This rule making also expands the acceptability of facsimile transmissions to certain trademark documents which were not part of the proposed rulemaking.
Written comments were submitted by twenty-two law firms, five individuals, nine corporations, two organizations and three agencies. An oral hearing was not conducted.
The following includes a discussion of the rules being changed and the reasons for those changes, and an analysis of the comments received in response to the notice of proposed rulemaking.

Discussion of Specific Sections to be Changed or Added:

(1) Types of Correspondence No longer Requiring Original Signatures (Section 1.4)

Section 1.4 is amended to include a new paragraph (d) to specify that most correspondence filed in the Office, which requires a person's signature, may be an original, or a copy thereof. See §§ 1.4 (e) and (f) for types of correspondence where the original must be filed in the Office. The word original, as used in this rulemaking, is defined as correspondence which is personally signed in permanent ink by the person whose signature appears thereon. Where copies of correspondence are acceptable, photocopies or facsimile transmissions may be filed. For example, a photocopy or facsimile transmission of an original of an amendment, declaration, petition, issue fee transmittal form, authorization to charge a deposit account, etc., may be submitted in a patent or trademark application. Furthermore, where copies are permitted, second and further generation copies (i.e., copy of a copy) are acceptable. The original, if not submitted to the Office, should be retained as evidence of proper execution in the event that questions arise as to the authenticity of the signature reproduced on the photocopy or facsimile-transmitted correspondence. If a question of authenticity arises, the Office may require submission of the original.

Section 1.4(e) identifies types of correspondence in which an original must be submitted to the Office. Where an original is required, copies are not acceptable and will not be accorded a receipt date. Correspondence, as referred to in this section, includes application forms for registration to practice before the Office and data sheets for the register of patent attorneys and agents.

Section 1.4(f) provides that when a document that is required by statute to be certified must be filed (such as a certified copy of a foreign patent application, pursuant to 35 U.S.C. 119; a certified copy of an international application, pursuant to 35 U.S.C. 365; a certified copy of a foreign trademark registration, pursuant to 15 U.S.C. 1126(e); a certified copy of a final court order, pursuant to 15 U.S.C. 1119; or a certified copy of a U.S. trademark registration), a copy of the certification, including a photocopy or facsimile transmission, will not be acceptable. The requirement for an original certification does not apply to certifications such as required under §§ 1.8, 1.10, 1.60, 1.97(e) and 3.73(b), since these certifications are not required by statute.

(2) Identification of Applications (Section 1.5) Section 1.5(a) is amended to make reference to the certificate procedure under § 1.8 consistent with the new title for § 1.8.

(3) Receipt of Correspondence (Section 1.6)

A descriptive heading is added to each paragraph of § 1.6 to identify the content of that paragraph.

The phrase "correspondence" is used in § 1.6 since the terms "papers", "letters" and "fees" all fall within the generic definition of "correspondence".

Section 1.6(a) is amended to clarify that correspondence transmitted by facsimile on weekends or Federal holidays within the District of Columbia, will be accorded the next business day as the date of receipt.

Sections 1.6 (b) and (c) are amended to clarify that weekdays refer to any day except a Saturday, Sunday, or Federal holiday within the District of Columbia.

Section 1.6(c) is amended to delete reference to the box locations in the lobby of Crystal Plaza Building 3, Arlington, Virginia, and at the Department of Commerce Building in Washington, D.C. The use of the drop boxes was discontinued on April 21, 1992, and the hours of operation for the attorney's window were extended to midnight, the same hours the drop boxes were available. The public can now deposit correspondence with the Office and obtain an acknowledgment of receipt after normal business hours. See "Changes in How Papers May Be Filed in the Patent and Trademark Office", 1137 Off. Gaz. Pat. Office 7 (April 7, 1992).

Use of the drop boxes at Crystal Plaza Building 3 and Department of Commerce Building locations had caused problems for both the public and the Office. Occasionally, it had been difficult to determine the dates of actual deposit of correspondence in the boxes. On occasion, Office employees and/or members of the public had been denied access to the drop box at the Department of Commerce by building security guards due to a special event taking place at the Department. Additionally, there were instances of correspondence being found outside of the drop boxes

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(70) **DEPARTMENT OF COMMERCE**
Patent and Trademark Office
37 CFR Part 1, Part 5 and Part 10
[Docket No. 920779-3226]
RIN 0651-AA34

Miscellaneous Changes in Patent Practice

Agency: Patent and Trademark Office, Commerce.
Action: Final Rule.
Summary: The Patent and Trademark Office (Office) is amending the rules of practice in patent cases to: expand the authority to sign a terminal disclaimer in a patent application or a disclaimer in a patent; eliminate some formal requirements for an appeal brief for an appellant appearing without counsel; prohibit fee extensions of time to file reply briefs and requests for oral hearing; clarify the requirements for claiming foreign priority; specify the manner in which the fee deficiency is computed when applicants seek to correct an error in claiming small entity status; and correct errors in published regulations.
Effective Date: Jan. 3, 1994. The time periods and extension of time provisions of §§ 1.193 and 1.194 for filing reply briefs and requests for oral hearing will be applicable where the examiner's answer was mailed on or after the effective date.
For Further Information Contact: Abraham Hershkovitz by telephone at (703) 305-9282, or by facsimile transmission at (703) 305-8825, or by mail marked to his attention and addressed to: Office of the Assistant Commissioner for Patents, Box DAC, Washington, D.C. 20231.
Supplementary Information: In a Notice of Proposed Rulemaking published in the Federal Register at 57 FR 43412 (September 21, 1992) and in the Patent and Trademark Office Official Gazette at 1143 Off. Gaz. Pat. Office 33-40 (October 13, 1992), the Office proposed to amend several rules of practice in patent and trademark cases. This rulemaking includes changes in § 1.9(d) which were not part of the proposed rules. The changes in § 1.9(d) were made in order to update the information pertaining to establishing small entity status as a small business. No substantive changes have been made in § 1.9(d). The proposed rule requiring that the specification of a design application describe the nature and intended use of the article being claimed has been withdrawn. Additionally, the proposed rule prohibiting a fee extension of time to file corrected drawings after allowance has been withdrawn.

Written comments were submitted by 13 firms, one association and one individual. An oral hearing was not conducted.

The following includes a discussion of the rules being changed and the reasons for those changes and an analysis of the comments received in response to the notice of proposed rulemaking.

Discussion of Specific Sections to be Changed or Added:

(1) Definitions (Section 1.9)

Section 1.9(d) is amended in order to update the information therein regarding the regulations of the Small Business Administration (SBA). The SBA's rule for defining a small business has been modified. Section 1.9(d) will no longer repeat the SBA rule in its entirety. Rather, § 1.9(d), as adopted, contains a short summary of the SBA definitions. The size limit of 500 employees (including those of its affiliates) for a small business concern has not been changed. Information on size standards for a small business concern may be obtained from the Small Business Administration by calling (202) 205-6618, or by writing to: Small Business Administration, Size Standards Staff, 409 Third Street, S.W., Washington, D.C. 20416.

(2) Copies of Papers (Section 1.13)

Section 1.13(a) is amended to clarify that the paragraph pertains to non-certified copies, and that copies of patents, trademark registrations and other papers within the jurisdiction of the Office, as opposed to being within the jurisdiction of another agency, may be obtained from the Office upon payment of the fee therefor.

Section 1.13(b) is amended to clarify that certified copies of the above items may be obtained from the Office upon payment of the fee for a certified copy.

(3) Patent Applications Preserved in Secrecy (Section 1.14)

Section 1.14(b) is amended to correct a typographical error in that the second and third sentences of this section were inadvertently deleted during an earlier revision of this section. See 50 Fed. Reg. 9378 (March 7, 1985) and 1053 Off. Gaz. Pat. Office 10-26 (April 2, 1985). Section 1.14(b) is amended by restoring the deleted sentences and by changing, in the first sentence, the plural "applicants" to the singular "applicant".

(4) Effect on Fees of Failure to Establish Status, or Change Status, as Small Entity (Section 1.28)

Section 1.28(c) is amended to reflect Office practice in calculating fee deficiencies when fees have been improperly paid as a small entity. The Office receives deficiency payments that differ based on varying interpretations of § 1.28(c). Some simply double the small entity fee in effect when the fee was originally paid in error in the small entity amount, while others compute the difference between the fee already paid and the other than small entity fee level in effect at the time the deficiency is paid. The Office requires payments to be based on fee levels in effect at the time the other than small entity fee is paid.

Since 1989, fee levels have been adjusted annually. In view of these adjustments, there are frequently situations where the fee amount has changed since it was originally paid erroneously at the small entity rate. Calculation of deficiency amounts based on fee levels in effect at the time the deficiency is paid conforms with the general concept that fees to be paid are those in effect at the time of receipt of the fees. Section 1.28(c) is amended to reflect this practice of calculating the amount of the deficiency based on the fee level in effect at the time of the deficiency payment.

(5) Claim for Foreign Priority (Section 1.55)

Section 1.55(a) is amended to incorporate the limitations of 35 U.S.C. 119, which provides that the claim for priority and the appropriate copy of the foreign application must be filed before the patent is granted. Additionally, some applicants did not realize that submission of priority papers after payment of the issue fee, but before the grant of the patent, required the filing of a petition to accept submission of priority papers after payment of the issue fee. After a patent is granted, applicants may still be able to establish priority benefits by filing a reissue application to correct the failure to perfect the claim for priority. *Brenner v.*

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(28) Taking Action in a Patent Matter Before the Office by the Assignee under 37 CFR 3.73.

When the assignee of the entire right, title and interest first seeks to take action in a matter before the Office with respect to a patent application, patent or reexamination proceeding, the assignee must establish its ownership of the property to the satisfaction of the Commissioner. 37 CFR 3.73(b). The assignee's ownership may be established either 1) by submitting to the Office copies of the documentary evidence of a chain of title from the original inventor to the assignee, or 2) by specifying, by reel and frame number, for example, where such documentary evidence is recorded in the Office. In addition to the establishment of ownership, there is further requirement that the assignee submit a statement specifying that the evidentiary documents have been reviewed and certifying that, to the best of the assignee's knowledge and belief, title is in the assignee seeking to take action. Once 37 CFR 3.73(b) is complied with by an assignee, that assignee may continue to take action in that application, patent or reexamination proceeding without filing a 37 CFR 3.73(b) statement each time, provided that ownership has not changed.

When an assignee files a continuation or divisional application (under 37 CFR 1.53, 1.60 or 1.62), reference may be made to a statement filed under 37 CFR 3.73(b) in the parent application or a copy of that statement may be filed. A newly executed statement under 37 CFR 3.73(b) must be filed when a continuation-in-part application is filed by an assignee.

The statement under 37 CFR 3.73(b) may be signed on behalf of the assignee in the following two manners if the assignee is an organization (e.g., corporation, partnership, university, government agency, etc.).

(1) The statement may be signed by a person in the organization having apparent authority to sign on behalf of the organization. An officer (president, vice-president, secretary, or treasurer) is presumed to have authority to sign on behalf of the organization. The signature of the chairman of the board of directors is acceptable, but not the signature of an individual director. A person having a title (manager, director, administrator, general counsel) that does not clearly set forth that person as an officer of the assignee is not presumed to be an officer of the assignee or to have authority to sign the statement on behalf of the assignee. A power of attorney from the inventors in an organization to a practitioner to prosecute a patent application does not make the practitioner an official of an assignee or empower the practitioner to sign the statement on behalf of the assignee.

(2) The statement may be signed by any person, if the statement includes an averment that the person is empowered to sign the statement on behalf of the assignee and, if not signed by a registered practitioner, the statement must be in oath or declaration form. Where a statement does not include such an averment, and the person signing does not hold a position in the organization that would give rise to a presumption that the person is empowered to sign the statement on behalf of the assignee, evidence of the person's authority to sign will be required.

Examples of situations where ownership must be established and the statement under 37 CFR 3.73(b) *must* be submitted are when the assignee: signs a request for status of an application or gives a power to inspect an application; acquiesces to express abandonment of an application; appoints its own legal representative; signs a terminal disclaimer; consents to the filing of a reissue application; consents to the correction of inventorship, files an application under 37 CFR 1.47(b) or 37 CFR 1.475, signs an Issue Fee Transmittal (PTOL-85B); or signs a response to an Office action.

Examples of situations where ownership need not be established and a statement under 37 CFR 3.73(b) *is not* required to be submitted are when the assignee: signs a small entity declaration; signs an affidavit or declaration of common ownership of two inventions; signs a NASA or DOE property rights statement; signs an affidavit under 37 CFR 1.131 where the inventor is unavailable; signs a Certificate of Mailing under 37 CFR 1.8; or files a request for reexamination of a patent under 37 CFR 1.510.

An acceptable certification under 37 CFR 3.73(b) is attached to this notice.

For further information related to actions taken by an assignee in patent matters, contact Jeffrey V. Nase at (703) 305-9282.

Apr. 30, 1993

CHARLES E. VAN HORN
Patent Policy and Projects Administrator
Office of the Assistant Commissioner
for Patents

II A

CERTIFICATE UNDER 37 CFR 3.73(b)

Applicant:_____

Application No.:_____ Filed:_____

For:_____

_____, a_____,

(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

certifies that it is the assignee of the entire right, title and interest in the patent application identified above by virtue of either:

A. [ ] An assignment from the inventor(s) of the patent application identified above. The assignment was recorded in the Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

OR

B. [ ] A chain of title from the inventor(s), of the patent application identified above, to the current assignee as shown below:

1. From:_____ To:_____
   The document was recorded in the Patent and Trademark Office at
   Reel _____, Frame _____, or for which a copy thereof is attached.

2. From:_____ To:_____
   The document was recorded in the Patent and Trademark Office at
   Reel _____, Frame _____, or for which a copy thereof is attached.

3. From:_____ To:_____
   The document was recorded in the Patent and Trademark Office at
   Reel _____, Frame _____, or for which a copy thereof is attached.

[ ] Additional documents in the chain of title are listed on a supplemental sheet.

[ ] Copies of assignments or other documents in the chain of title are attached.

The undersigned has reviewed all the documents in the chain of title of the patent application identified above and, to the best of undersigned's knowledge and belief, title is in the assignee identified above .

The undersigned (whose title is supplied below) is empowered to sign this certificate on behalf of the assignee.

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements, and the like so made, are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date : _____

Name :_____

Title :_____

Signature:_____

Withdrawing the Holding of Abandonment When Office Actions Are Not Received

The purpose of this notice is to announce a practice that will minimize costs and burdens to the practitioner and the Office when an application has become abandoned due to a failure to receive an Office action.

A petition to withdraw the holding of abandonment in accordance with *Delgar Inc. v. Schuyler*, 172 USPQ 513 (D.D.C. 1971) is burdensome to the practitioner since the practitioner must overcome a strong presumption that an Office action duly addressed and indicated as mailed was timely delivered to the addressee. To overcome this presumption, a practitioner is currently required to submit a persuasive showing that would permit the Office to conclude that the Office action was not received. Accordingly, evidence which is typically required includes: copies of records which would disclose the receipt of other correspondence mailed from the Patent and Trademark Office on or about the mail date of the non-received Office action, but fail to disclose receipt of the Office action mailed that date; copies of records on which the Office action would have been entered had it been received (e.g., a copy of the outside of the file jacket maintained by the practitioner); and verified statements from persons who would have handled the Office action (e.g., mail clerks, docket clerks, secretary, etc.).

In order to minimize costs and burdens to the practitioner and the Office when an application has become abandoned due to a failure to receive an Office action, the Office is modifying the showing required to make a petition to withdraw the holding of abandonment grantable. The showing required to establish the failure to receive an Office actio must consist of a statement from the practitioner stating that the Office action was not received by the practitioner and attesting to the fact that a search of the file jacket and docket records indicates that the Office action was not received. A copy of the docket record where the non-received Office action would have been entered had it been received and docketed must be attached to and referenced in practitioner's statement.

The showing outlined above may not be sufficient if there are circumstances that point to a conclusion that the Office action may have been lost after receipt rather than a conclusion that the Office action was lost in the mail, e.g., if the practitioner has a history of not receiving Office actions. Two additional procedures are available for reviving an application that has become abandoned due a failure to respond to an Office Action: (1) a petition based on unintentional abandonment or delay; and (2) a petition based on unavoidable delay. See Manual of Patent Examining Procedure §711.03(c).

Oct. 25, 1993

Charles E. Van Horn
Patent Policy and Projects Administrator
Office of the Assistant Commissioner
for Patents

II B

Information Disclosure Statements In PCT National Stage Applications

The purpose of this notice is to announce a change in practice with regard to the need for applicants in a national stage application to file an information disclosure statement with respect to documents cited in an international search report under certain circumstances.

When an international application is filed under the Patent Cooperation Treaty (PCT), prior art documents may be cited by the examiner in the international search report and/or the international preliminary examination report. When a national stage application is filed under 35 U.S.C. 371, or a national application is filed under 35 U.S.C. 111 claiming benefit of the filing date of the international application, it is often desirable to have the examiner consider the documents cited in the international application when examining the national application.

As a result of an agreement among the European Patent Office (EPO), Japanese Patent Office (JPO) and the United States Patent and Trademark Office (USPTO), copies of documents cited in the international search report issued by any one of these International Searching Authority Offices generally are being sent to the other Offices when designated in the international application. Accordingly, in many national stage applications where the international search was conducted by the EPO, JPO, or USPTO, copies of the documents cited in the international search report are made available to the examiner in the national stage application.

At this time, when all the requirements for a national stage application have been completed, applicant is notified (Form PCT/DO/EO/903) of the acceptance of the application under 35 U.S.C. 371, including an itemized list of the items received. The itemized list includes an indication of whether a copy of the international search report and copies of the references cited therein are present in the national stage file. The examiner will consider the documents cited in the international search report, without any further action by applicant under 37 CFR 1.97 and 1.98, when both the international search report and copies of the documents are indicated to be present in the national stage file. Otherwise, applicant must follow the procedures set forth in 37 CFR 1.97 and 1.98 in order to ensure that the examiner considers the documents cited in the international search report.

This notice applies only to documents cited in the international search report relative to a national stage application filed under 35 U.S.C. 371. It does not apply to documents cited in an international preliminary examination report that are not cited in the search report. It does not apply to applications filed under 35 U.S.C. 111 claiming the benefit of an international applicatoin filing date.

Practice relating to documents cited in a search report in an international application filed under the Patent Cooperation Treaty as set foth in § 609 of the Manual of Patent Examining Procedure will be modified in accordance with this notice.

Oct. 27, 1993

Charles E. Van Horn
Patent Policy and Projects Administrator
Office of the Assistant Commissioner for Patents

I I C

Official Gazette Notice

Procedures for Restarting Response Periods

The purpose of this notice is to announce revised procedures for restarting response periods set in patent related matters. Occasionally, mail from the Patent and Trademark Office (PTO) is received late at the correspondence address or the mail is delayed in leaving the PTO.

The following revised procedures are effective immediately and will be followed in processing a petition to reset a period for response due to late receipt of a PTO action or due to a postmark date which is later than the mail date printed on a PTO action. The authority to decide such petitions is delegated to the Group Director, where the PTO action involved in the petition was mailed by a patent examining group.

Petition to reset a period for response due to late receipt of a PTO action

The PTO will grant a petition to restart the previously set period for response to a PTO action to run from the date of receipt of the PTO action at the correspondence address when the following criteria are met: (1) the petition is filed within two weeks of the date of receipt of the PTO action at the correspondence address; (2) a substantial portion of the set response period had elapsed on the date of receipt (e.g., at least one month of a two or three month response period had elapsed); and (3) the petition includes (a) evidence showing the date of receipt of the PTO action at the correspondence address (e.g., a copy of the PTO action having the date of receipt of the PTO action at the correspondence address stamped thereon, a copy of the envelope (which contained the PTO action) having the date of receipt of the PTO action at the correspondence address stamped thereon, etc.), and (b) a statement (verified if made by other than a registered practitioner) setting forth the date of receipt of the PTO action at the correspondence address and explaining how the evidence being presented establishes the date of receipt of the PTO action at the correspondence address.

There is no statutory requirement that a shortened statutory period of longer than thirty days to respond to a PTO action be reset due to delay in the mail or in the PTO. However, when a substantial portion of the set response period had elapsed on the date of receipt at the correspondence address (e.g., at least one month of a two or three month response period had elapsed), the procedures set forth above for late receipt of a PTO action are available. Where a PTO action was received with less than two months remaining in a shortened statutory period of three months, the period may be restarted from the date of receipt. Where the period remaining is between two and three months, the period will be reset only in extraordinary situations - e.g., complex PTO action suggesting submission of comparative data.

Petitions to reset a period for response due to a postmark date later than the mail date printed on a PTO action

The PTO will grant a petition to restart the previously set period for response to a PTO action to run from the postmark date shown on the PTO mailing envelope which contained the PTO action when the following criteria are met: (1) the petition is filed within two weeks of the date of receipt of the PTO action at the correspondence address; (2) the response period was for payment of the issue fee[1]; or the response period set was one month or thirty days[2]; and (3) the petition includes (a) evidence showing the date of receipt of the PTO action at the correspondence address (e.g., a copy of the PTO action having the date of receipt of the PTO action at the correspondence address stamped thereon, etc.), (b) a copy of the envelope which contained the PTO action showing the postmark date, and (c) a statement (verified if made by other than a registered practitioner) setting forth the date of receipt of the PTO action at the correspondence address and stating that the PTO action was received in the post-marked envelope.

The provisions of 37 CFR 1.8 and 1.10 apply to the filing of the above-noted petitions with regard to the requirement that the petition be filed within two weeks of the date of receipt of the PTO action.

The showings outlined above may not be sufficient if there are circumstances that point to a conclusion that the PTO action may have been delayed after receipt rather than a conclusion that the PTO action was delayed in the mail or in the PTO.

C. E. Van Horn

Charles E. Van Horn
Patent Policy and Projects Administrator
Office of the Assistant Commissioner for Patents

03 Feb. 1994
(Date)

[1] 35 USC 151 permits payment of the issue fee within three months of the date that the Notice of Allowance is mailed to the applicant.

[2] 35 USC 133 does not permit a response period to be less than thirty days from the date the PTO action is given or mailed to the applicant.

IIE

United States Postal Service Interruption and Emergency In Los Angeles

The January 17, 1994, Los Angeles earthquake has caused a service interruption in United States Postal Service (USPS) in the greater Los Angeles area. Normal postal delivery and collection operations of the USPS were impacted by the earthquake throughout the greater Los Angeles area to varying degrees from January 17, 1994, through January 21, 1994.

The Patent and Trademark Office (PTO) is designating the interruption in the service of the greater Los Angeles area and the overall destruction caused by the earthquake as a postal service interruption and an emergancy within the meaning of 35 U.S.C. 21(a). Any request to accept a paper or fee delayed by the emergency should be directed to Jeffrey V. Nase, Director, Office of Petitions, (703) 305-9285, PK3-704, for patent-related matters, and to Lynne G. Beresford, Trademark Legal Administrator, (703) 305-9464, PK2-910, for trademark-related matters.

Feb. 9, 1994

BRUCE A. LEHMAN
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks

Issuance of a Patent to an Assignee

The purpose of this notice is to clarify the procedures to have a patent issue to an assignee. See 37 CFR 3.81 and Manual of Patent Examining Procedure § 307.

Section 3.81(a) permits a patent to issue an assignee, provided that at the time the issue is paid, the assignment has been submitted for recordation and the name of the assignee is provided. The name of the assignee is usually provided in item 5 of the Issue Fee Transmittal form (PTOL-85B).

Section 3.81(b) permits a patent to issue to an assignee when the assignment is submitted for recording after the date of payment of the issue fee, but prior to issuance of the patent, provided a petition and fee are filed requesting that the patent issue to the newly recorded assignee.

When the correct name of the assignee was not provided in accordance with either section 3.81(a) or (b) (i.e., either no name or an incorrect name was provided in item 5 of the Issue Fee Transmittal when the assignment had been recorded or submitted for recordation at the time the issue fee was paid, or an incorrect name was provided in the petition required by section 3.81(b) when the assignment is submitted for recording after the date of payment of the issue fee, but prior to issuance of the patent), a correction can be made by filing a petition under 37 CFR 1.183 requesting that the requirements of 37 CFR 3.81 be waived. This procedure is required at any time after the issue fee is paid, including after issuance of the patent. A petition under 37 CFR 1.183 should include: (1) the petition fee set forth in 37 CFR 1.17(h) (currently $130); (2) the correct name of the assignee; and (3) the reel and frame number where the assignment is recorded or proof of the date the assignment was submitted for recordation.

If the petition under 37 CFR 1.183 is filed and granted prior to issuance of the patent, the patent will either: (1) be printed with the correct assignee's name; or (2) be printed without the correct assignee's name. In the latter case, patentee would be entitled to a certificate of correction under 37 CFR 1.322 to correct an Office mistake in not correctly printing the assignee's name on the patent.

If the petition under 37 CFR 1.183 is filed and/or granted after issuance of the patent, the patent would be printed without the correct assignee's name. However, if the petition is granted, patentee would be entitled to a certificate of correction under 37 CFR 1.323 due to the mistake in not complying with 37 CFR 3.81.

~~March 16~~, 1994

CHARLES E. VAN HORN
Patent Policy and Project Administration
Office of the Assistant Commissioner
for Patents

IIF

C. Ardent, Owner of Record: *Inventor*, Attorney or Agent: James C. Weseman, Ex. Gp.: 323

4,835,852, Re. S. N. 07/625,045, Filed Dec. 10, 1990, Cl. 29/464, METHOD OF INSTALLATION OF HARDWARE, Timothy K. Asplund, et al., Owner of Record: *Inventor*, Attorney or Agent: William A. Bradock, Ex. Gp.: 326

4,913,770, Re. S. N. 07/629,837, Filed Dec. 19, 1990, Cl. 157/1.17, TIRE BEAD BREAKER, Douglas A. Sims, Owner of Record: *Freezone Pty. Ltd., South Perth, Australia*, Attorney or Agent: Harold W. Milton, Ex. Gp.: 323

REQUESTS FOR REEXAMINATION FILED

Notice under 37 CFR 1.11(c). The requests for reexamination listed below are open to inspection by the general public in the indicated Examining Groups. Copies of the requests and related papers may be obtained by paying the fee therefor established in the Rules (37 CFR 1.19(a).

In the event correspondence to the patent owner is not received, this notice will be considered to be constructive notice to the patent owner and reexamination will proceed (37 CFR 1.248(a)(5) and 1.525(b).

De. 286,524, Reexam. No. 90/002,236, Requested Dec. 18, 1990, Cl. D12/154, ANTI-SKID CHAIN UNIT FOR VEHICLE TIRE, Ragnar Hardmark, Owner of Record: *Onspot AB., Linkoping, Sweden*, Attorney or Agent: Burns, Doane, Swecker & Mathis, Alexandria, Va., Ex. Gp.: 291, Requester: Lynn G. Foster, Salt Lake City, Utah

4,307,320, Reexam. No. 90/002,238, Requested Dec. 21, 1990, Cl. 313/474, PIGMENT COATED PHOSPHOR AND HIGH CONTRAST COLOR TELEVISION CATHODE RAY TUBE USING SAME, Noboru Kotera, et al., Owner of Record: *Kasei Optonix, Ltd., Odawara, Japan*, Attorney or Agent: Charles E. Miller, Pennie & Edmonds, New York, N.Y., Ex. Gp.: 264, Requester: Owner

4,314,665, Reexam. No. 90/002,244, Requested Dec. 17, 1990, Cl. 236/046, ELECTRONIC THERMOSTAT, Michael R. Levine, Owner of Record: *Honeywell, Inc., Minneapolis, Minn.*, Attorney or Agent: D.C. Toedt, Arnold, White & Durkee, Houston, Tex., Ex. Gp.: 344, Requester: Owner

4,688,529, Reexam. No. 90/002,240, Requested Dec. 26, 1990, Cl. 123/196, LUBRICATING SYSTEM FOR HORIZONTAL CYLINDER OVERHEAD VALVE ENGINE, Takashi Mitadera, et al., Owner of Record: *Kawasaki Jukogyo Kabushiki Kaisha, Kobe, Japan*, Attorney or Agent: Leydig, Voit & Mayer, Washington, D.C., Ex. Gp.: 342, Requester: Owner

4,741,711, Reexam. No. 90/002,239, Requested Dec. 24, 1990, Cl. 439/620, MODULAR DISTRIBUTION FRAME INCLUDING PROTECTOR MODULES ADAPTED FOR BREAK ACCESS TESTING, Loren A. Singer, Jr., Owner of Record: *ADC Telecommunications, Inc., Minneapolis, Minn.*, Attorney or Agent: Merchant, Gould, Smith, Edell, Welter & Schmidt, Minneapolis, Minn., Ex. Gp.: 322, Requester: Krone AG, Berlin, Germany

4,828,399, Reexam. No. 90/002,241, Requested Dec. 31, 1990, Cl. 366/345, COMPOST HANDLING MACHINE, Thomas J. Pacentino, et al., Owner of Record: *International Process Systems, Inc., Glastonbury, Conn.*, Attorney or Agent: Scully, Scott, Murphy & Presser, Garden City, N.J., Ex. Gp.: 242, Requester: Owner

4,831,282, Reexam. No. 90/002,243, Requested Jan. 4, 1991, Cl. 307/443, CMOS INPUT CIRCUIT, Joseph H. Colles, Owner of Record: *Brooktree Corp., San Diego, Calif.*, Attorney or Agent: Ellsworth Roston, Roston & Schartz, Los Angeles, Calif., Ex. Gp.: 254, Requester: Martin C. Fliesler, Fliesler, Dubb, Meyer & Lovejoy, San Francisco, Calif.

4,905,189, Reexam. No. 90/002,242, Requested Jan. 4, 1991, Cl. 364/900, SYSTEM FOR READING AND WRITING INFORMATION, Michael J. Brunolli, Owner of Record: *Brooktree Corp., San Diego, Calif.*, Attorney or Agent: Ellsworth Roston, Roston & Schwartz, Los Angeles, Calif., Ex. Gp.: 232, Requester: Martin C. Fliesler, Fliesler, Dubb, Meyer & Lovejoy, San Franocisco, Calif.

Service by Publication

A petition to cancel each of the registrations identified below having been filed, and the notice of such proceeding sent by registered mail to registrant at the last known address having been returned by the Postal Service as undeliverable, notice is hereby given that unless the registrants listed herein, their assigns or legal representatives shall enter an appearance within thirty days from the date of this publication, the cancellation will be proceeded with as in the case of default.

Jaco Pants, Inc., Thomasville, Ga., Reg. No. 554,847, for the mark "FAIRCHILD", Canc. No. 19,216.

Centurion Import & Export, Inc., Studio City, Calif., Reg. No. 1,342,780, for the mark "WET PAINT", Canc. No. 19,108.

Raleigh Manufacturers, Inc., New York, N.Y., Reg. No. 299,714, for the mark "WALL STREET", Canc. No. 19,139.

JEAN BROWN
Administrator, Trademark Trial and Appeal Board
For JEFFREY M. SAMUELS
Assistant Commissioner for Trademarks

SURVEY OF REGISTERED PRACTITIONERS IN PATENT CASES

Pursuant to 37 CFR 10.11(b), a survey letter was mailed on Nov. 30, 1990 from the Office of Enrollment and Discipline (OED) to all practitioners in patent cases whose last names began with T through Z. Enclosed with the letter was a data sheet which should have been completed and returned to OED as soon as possible. Failure by a practitioner to submit a completed data sheet within the time period specified in the survey letter will result in the practitioner being removed from the register in accordance with 37 CFR 10.11(b).

If your last name begins with T through Z and you did not receive a data sheet or of you returned the data sheet to OED and you did not receive an acknowledgement within three (3) months after mailing the data sheet to OED, please contact Shirley B. Rasheed at (703) 557-1728.

Dec. 24, 1990 CAMERON WEIFFENBACH, *Director*
Office of Enrollment and Discipline

Filing of Certain Trademark Papers and Authorizations to Charge Deposit Accounts by Facsimile Tranmission

Effective Feb. 12, 1991, the Trademark Examining Operation (TMEO) and the Office if the Assistant Commissioner for Trademarks (A/C TM) will implement a pilot program to study the feasibility of accepting certain trademark documents by facsimile transmission (fax). The information gathered from this program and the pilot program currently in place for acceptance of certain patent documents by fax, *(See 1096 Official Gazette 30, November 15, 1989)*, will be evaluated for the purpose of drafting a rules package governing the fax procedure. The Trademark Trial and Appeal Board will not participate in the program at this time, but may consider accepting fax tranmissions at a later date.

Because this is a pilot program, only select documents will initially be accepted via facsimile transmission. These trademark documents include, but are not limited to: (1) Responses to Office Actions (but not those which include specimens of use and/or drawings; (2) Petitons to the Commissioner; (3) Letters of

Protest; (4) Deposit Accou
Reconsideration.

Documents Excl

Any document to be fi
Board, including the no
accepted by fax transmiss
Any documents which
fications or certified cop
orders, etc., will also *not* b
the following documents

Trademark Applications;
Responses to Office Actio
Include Specimens of U
Section 8 Affidavits or De
Renewal Applications;
Statements of Use;
Amendments to Allege U
Certifications or Certified
and renewals thereof;
Section 7 Requests to Am
Section 7 Applications for
Registration; and
Certified Copies of Court

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follows:

Location	*Fax N*
TMEO	(703)
A/C TM	(703)

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attached thereto, will be evid
of Facsimile Transmission s
appear on the paper or incl

Protest; (4) Deposit Account Authorization; and (5) Requests for Reconsideration.

Documents Excluded from Fax Transmission

Any document to be filed with Trademark Trial and Appeal Board, including the notice of ex parte appeal, will *not* be accepted by fax transmission.

Any documents which include specimens, drawings or certifications or certified copies of forgien registrations or court orders, etc., will also *not* be accepted by fax transmission. Thus, the following documents will not be accepted by fax:

Trademark Applications;
Responses to Office Actions and Other Submissions which Include Specimens of Use and/or Drawings;
Section 8 Affidavits or Declarations;
Renewal Applications;
Statements of Use;
Amendments to Allege Use;
Certifications or Certified Copies of Foreign Registrations, and renewals thereof;
Section 7 Requests to Amend the Mark in a Registration:
Section 7 Applications for Voluntary Surrender of a Registration; and
Certified Copies of Court Orders.

When any trademark document explicitly excluded from the fax transmission procedure is received in the PTO via fax transmission, the document will not be considered as having been filed. The sender will be notified that the paper was improperly tranmitted by fax. It is impermissible to file papers by fax and submit the supporting exhibits by mail.

The fax machines will be attended betweeen the business hours of 8:30 a.m. and 5:00 p.m., East Coast Time, Monday through Friday, excluding holidays. Although the fax machines may normally be accessed 24 hours a day, there may be times, even during business hours, when reception is not possible due to equipment failure or maintenamce requirements. Accordingly, persons transmitting documents by fax are cautioned against relying on the availability of this service near the end of response periods or other deadlines.

A fax machine has been installed in the TMEO and in the A/C TM. The corresponding fax and telephone numbers are as follows:

Location	*Fax No.*	*Phone No.*
TMEO	(703) 308-0429	(703) 308-0928
A/C TM	(703) 557-8263	(703) 557-3061

Submissions by facsimile transmission to the TMEO or A/C TM should be transmitted to the location for which they are intended. Fax transmissions regarding trademarks will not be deemed to have been filed in the PTO, and will not be considered, if transmitted to any fax machines other than those identified above.

The Office will not formally acknowlege receipt of documents transmitted by fax. The Office facsimile machine will usually confirm to the sending unit that the transmission is complete.

Effect of Filing by Fax

Certain trademark papers and fees required to be filed in the PTO will be considered filed if they are transmitted to one of the above fax numbers. The date of receipt is the date that the transmission is completed as indicated by the date shown on the Office's facsimile transmission activity report. If that date is a Saturday, Sunday or Federal holiday within the District of Columbia, the document will be considered to be have been filed on the next business day.

Papers transmitted by fax may include a certificate of facsimile transmission, certifying the date of transmission. In the event the facsimile transmitted paper is misplaced or lost in the PTO, a copy of the paper, with Certificate of Facsimile Transmission attached thereto, will be evidence of filing by fax. The Certificate of Facsimile Transmission should be labeled as such and should appear on the paper or include a reference to the registration number or application serial number, and must include the following:

The date of facsimile transmission; and
The signature of the person certifying that the document is being facsimile transmitted on a certain date.

The Certificate of Facsimile Transmission should also include the fax number to which the transmission is directed. The person signing the Certificate should have a reasonable basis to expect that the entire paper will be transmitted by fax on or before the date indicated.

When possible, the Certificate should appear on the paper being transmitted. An example of a preferred Certificate of Facsimile Transmission for use with the paper being transmitted is as follows:

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this paper for <reg. or ser. no.> is being facsimile transmitted to the Patent and Trademark Office fax number _____on the date shown below.

_____
Type or print name of person signing certificate

_____ _____
Signature Date

If the Certificate of Facsimile Transmission is presented on a separate paper, it *must* identify the application or registration to which it relates.

In the event that the facsimile transmission is misplaced or lost in the Trademark Office, the submission will be considered filed as of the date of the transmission, if the party who transmitted the paper:

1) Informs the PTO of the previous facsimile transmission promptly after becoming aware that the submission has been misplaced or lost;

2) Supplies another copy of the previously transmitted submission with the Certificate of Transmission; and

3) Supplies a copy of the sending unit's report confirming transmission of the submission in question.

Items one through three above must be supported by an affidavit or declaration under § 2.20. The required evidence should be directed to the area in the Office where the misplaced or lost document was intended to be filed, e.g., the Law Office or Post Registration.

If all criteria above cannot be met, the only remedy available is a petition to the Commissioner comprised of a verified statement which attests on a personal knowledge basis to the previously timely transmission.

The above procedures for establishing that a misplaced or lost submission was filed in the PTO are *not* available for those submissions enumerated as exceptions to the 37 CFR 1.8 Certificate of Mailing procedures.

Requirements for Filing by Fax

- Each facsimile transmitted document must be legible.
- Each transmission should have a cover sheet which includes: the number of pages, and the name, the address, the fax number and the telephone number of the transmitting party.
- The preferred size of the document being transmitted is 8 1/2 inches by 11 inches, letter size or A4 paper. However, in no event will the Office accept a document being transmitted that is larger than 8 1/2 inches by 14 inches.
- Each transmission must be limited to papers relating to a single trademark application or registration. The application serial number, if one has been assigned, or the registration number must be referenced on each page of the transmission. If a serial number has not yet been assigned to an application, each page of the transmission must bear the name of the applicant and an identifier of the mark. The Office strongly recommends that applicants wait, if possible, until a serial number is assigned before filing a related document by fax.
- The document that is used as the original for the facsimile transmission must have an original signature and should be retained by the sender as evidence of the content of the facsimile transmission.

PARTIES SHOULD NOT SUBMIT BY MAIL THE ORIGINAL OR ADDITIONAL COPIES OF THE DOCUMENT TRANSMITTED BY FAX, UNLESS SPECIFICALLY REQUESTED BY THE OFFICE.

Jan. 15, 1991 JEFFREY M. SAMUELS
Assistant Commissioner for Trademarks

U.S. DEPARTMENT OF COMMERCE
Office of the Assistant Secretary and Commissioner of Patents and Trademarks

PUBLIC ADVISORY COMMITTEE FOR TRADEMARK AFFAIRS

Agency: Patent and Trademark Office, Comerce
Action: Notice of Committee Charter Amendment
Summary: In accordance with the provisions of the Federal Advisory Committee Act, 5 U.S.C. App. (1976), and after consultation with GSA, it has been determined that an amendment of the charter of the Public Advisory Committee for Trademark Affairs is in the public interest in connection with the performance of duties imposed on the Department by law. The charter amendment was signed on December 3, 1990.

The charter has been amended as follows to: (1) broaden the topics that the Committee may address to include international trademark law, (2) allow the membership of the Committee to be drawn from a wider range of the trademark community rather than soley from the regular, associate and supplementary membership of the United States Trademark Association (USTA), (3) increase the number of members on the Committee fron 15 to 18, (4) provide for the direct selection of the members and appointment of the chairman of the Committee by the Assistant Secretary and Commissioner of Patents and Trademarks rather than by the president of the USTA, and (5) set the term of membership at two years.

For Further Information Contact: Lynne Beresford, Committee Control Officer, Office of the Assistant Commissioner for Trademarks, U.S. Patent and Trademark Office, Washington, D.C. 20231, telephone: (703) 557-7464, or Jan Jivatodi, Committee Management Analyst, U.S. Department of Commerce, Washington, D.C. 20230, telephone: (202) 377-4217.

Suuplementary Information: The Committee was first established in September 1970, and the latest charter renewal was signed on April 4, 1990. The charter amendment was approved on December 3, 1990, and provides for the following:

(1) The amendment broadens the objectives and duties of the Committee to specifically embrace international trademark law. The previous charter permitted the Committee to advise the Patent and Trademark Office only on the steps which could be taken to increase the efficiency and effectiveness of the administration of the Trademark Act and to provide a continuing source of knowledge from the private sector to the Government. Given the increased interest within the trademark community and the Patent and Trademark Office in international trademark law, especially in the Madrid Protocol and harmonization, it is desirable that the charter refer explicitly to international trademark law.

(2) Section 5(b)(2) of the Federal Advisory Committee Act requires that the membership of advisory committees be "fairly balanced in terms of the points of view represented...." The amendment furthers that goal by permitting the membership to be drawn from a wide range of the trademark community including users of the public search room, academia, members of the public at large, and the business community.

(3) The amendment increases the number of members on the Committee from 15 to 18. The increase was needed to permit additional members, from different sectors of the trademark community, to be added to the Committee without having to displace any of the current Committee members.

(4) Section 5(b)(2) of the Federal Advisory Committee Act requires that "the membership be fairly balanced in terms of the points of view represented..." The amendment futhers that goal by permitting the chairman to be appointed, and the members of the Committee to be selected by the Assistant Secretary and Commissioner of Patents and Trademarks.

(5) The charter of the Public Advisory Committee for Trademark Affairs did not set terms for members. In order to promote more orderly administration of the Committee, the amendment sets the terms of the members at two years. Members will serve at the discretion of the Assistant Secretary and Commissioner of Patents and Trademarks. Appointements, when vacancies occur, shall be for the remainder of the unexpired term.

Jan. 16, 1991 HARRY F. MANBECK, Jr.
Assistant Secretary and Commissioner of Patents and Trademarks

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PATENTS AVAILABLE FOR LICENSE OR SALE

4,702,704 TETRAHEDRAL CONDON STEREO TABLE, Leonard R. Svensson, Birch, Stewart, Kolasch & Birch, P.O. Box 747 Falls Church, Va. 22046

4,635,563 ADJUSTABLE SHELVING SYSTEM, James L. Young, Esq. Kinney & Lange, P.A. Suite 1500, 625 Fourth Ave., South, Minneapolis, Minn. 55415-1659

4,683,097 PROCESS OF MAKING A DUNNAGE RACK, James L. Young, Esq. Kinney & Lange, P.A. Suite 1500, 625 Fourth Ave., South, Minneapolis, Minn. 55415-1659

4,716,824 FOOD MARINATOR, James L. Young, Esq. Kinney & Lange, P.A. Suite 1500, 625 Fourth Ave., South, Minneapolis, Minn. 55415-1659

4,956,915 SANITARY NAIL CLIPPING DEVICE, Charles A. Anderson, 2402 108th N.E., Norman, Okla. 73071

07/000,131 HAIR PROTECTION SHIELD, Julius C. Lienhard, 10307 Tingewood Terr., Richmond, Va. 23233

DEPARTMENT OF COMMERCE
Patent and Trademark Office
37 CFR Part 5

PATENT LAW FOREIGN FILING AMENDMENTS

Agency: Patent and Trademark Office, Commerce
Action: Notice of Final Rulemaking
Summary: The Patent and Trademark Office (Office) is amending the rules of practice in patent cases to implement the Patent Law Foreign Filing Amendments Act of 1988, Subtitle B of Public Law 100-418. The rules reflect changes made to 35 U.S.C. 184 which specify that a license is not required to, file amendments, modifications, and supplements containing additional subject matter to a previously licensed foreign patent application if such amendments, modifications, and supplements do not change the general nature of the invention disclosed in the application in a manner which would require a corresponding United States patent application to be made available for national security inspection under 35 U.S.C. 181. These regulatory changes are applicable to most existing foreign filing license holders if their patent application did not undergo security inspection under 35 U.S.C 181. Also, under the rules, a retroactive foreign filing license may be granted in situations where a proscribed foreign filing occurred through error and without deceptive intent as opposed to the earlier standard of inadvertence.

Effective Date: Feb. 19, 1991.

Supplementary Information: A notice of proposed rulemaking was published in the *Federal Register* at 55 Fed. Reg. 24270-24275 (June 15, 1990) and at 1116 Official Gazette 21-25 (July 10, 1990). No oral hearing was held. Three written comments on the proposed rulemaking were received. The comments received and replies thereto are listed below.

The rules are intended to implement the Patent Law Foreign Filing Amendments Act of 1988, Subtitle B of Public Law 100-418 (hereinafter the Act), which amended §§ 184, 185 and 186 of Title 35, United States Code, in order to simplify the procedures for United States inventors filing and prosecuting patent applications in foreign countries. The Office has not made any rule changes to implement the amendments to 35 U.S.C. 185 or 186 since these changes affect matters outside its jurisdiction.

Section 184 of Title 35
national security interests
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unless the inventor receive
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license to the scope allowed
separate petition under § 5.

The present Act clarifies
Patent and Trademark Offic
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F.2d 238, 151 USPQ 1 (6th
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standard of "inadvertence."