[FR Doc. 96–6015 Filed 3–12–96; 8:45 am]
BILLING CODE 3510–22–P

Patent and Trademark Office

Notice of Hearings and Request for Comments on Issues Relating to Patent Protection for Therapeutic and Diagnostic Methods

AGENCY: Patent and Trademark Office, Commerce.

ACTION: Notice of Hearings and Request for Comments.

SUMMARY: The Patent and Trademark Office (PTO) will hold public hearings, and it requests comments, on issues relating to patent protection for therapeutic and diagnostic methods. Interested members of the public are invited to testify at public hearings and to present written comments on any of the topics outlined in the supplementary information section of this notice.

DATES: A public hearing will be held on Thursday, May 2, 1996, starting at 9:00 a.m. and ending no later than 5:00 p.m.

Those wishing to present oral testimony at the hearing must request an opportunity to do so no later than Friday, April 26, 1996.

Written comments on the topics presented in the supplementary information section of this notice will be accepted by the PTO until Friday, May 17, 1996.

Written comments and transcripts of the hearing will be available for public inspection on or about June 14, 1996. They will be maintained for public inspection in Room 902 of Crystal Park Two, 2121 Crystal Drive, Arlington, Virginia.

ADDRESSES: The hearing will be held from 9:00 a.m. to 5:00 p.m. in Suite 912, Commissioner's Conference Room, Crystal Park Two, 2121 Crystal Drive, Arlington, Virginia.

Requests to testify should be sent to Richard Wilder by telephone at (703) 305–9300, by facsimile transmission at (703) 305–8885, or by mail marked to his attention addressed to the U.S. Patent and Trademark Office, Office of Legislative and International Affairs, Box 4, Washington, D.C. 20231.

Written comments should be addressed to Richard Wilder, U.S. patent and Trademark Office, of Legislative and International Affairs, Box 4, Washington, D.C. 20231. Comments may also be submitted by facsimile transmission at (703) 305–8885, with a confirmation copy mailed to the above address.

FOR FURTHER INFORMATION CONTACT: Richard Wilder by telephone at (703) 305–9300, by facsimile transmission to (703) 305–8885, or by mail marked to his attention addressed to the Office of Legislative and International Affairs, Box 4, Washington, D.C. 20231.

SUPPLEMENTARY INFORMATION:

I. Background

On March 3, 1995, H.R. 1127, the ''Medical Procedures Innovation and Affordability Act,'' was introduced. H.R. 1127 would exclude from patentability any technique, method, or process for performing a surgical or medical procedure, administering a surgical or medical therapy, or making a medical diagnosis. In this notice, the foregoing subject matter is referred to collectively as ''therapeutic and diagnostic methods.'' The bill would, however, allow claims to such techniques, methods, or processes that are performed by or as a necessary component of a machine, manufacture, or composition of matter that is otherwise patentable. On October 19, 1995, the Subcommittee on Courts and Intellectual Property, Committee on the Judiciary, U.S. House of Representatives (''Congressional Hearing'') held a hearing on H.R. 1127.

On October 18, 1995, S. 1334, the ''Medical Procedures Innovation and Affordability Act'', was introduced. While S. 1334 would not exclude subject matter from patentability, as would H.R. 1127, it would grant limited immunity from patent infringement to certain persons. S. 1334 provides that a patient, physician, or other licensed health care practitioner, or a health care entity with which a physician or licensed health care practitioner is professionally affiliated, would be free to use or induce others to use a patented technique, method, or process for performing a surgical or medical procedure, administering a surgical or medical therapy, or making a medical diagnosis. This immunity would not extend, however, to the ''use of, or inducement to use, such a patented technique, method, or process by any person engaged in the commercial manufacture, sale, or offer for sale of a drug, medical device, process, or other product that is subject to regulation under the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act.''

The critics of the patenting and/or enforcement of surgical and medical procedure patents believe that ''it is unethical for physicians to seek, secure or enforce patents on medical procedures.'' ''Report 1 of the Council on Ethical and Judicial Affairs (A–95), Patenting of Medical Procedures,'' p. 9, the American Medical Association (1995) (''AMA Report''). The bases for this belief are that such patents restrict access to patented procedures, increase costs of medical care, and interfere with patient confidentiality. See, AMA Report, pp. 3–6.

It is not the purpose of the PTO hearing to discuss the ethics of patenting therapeutic and diagnostic method patents. Nor is it the purpose of the hearing to consider economic analyses of patenting therapeutic and diagnostic method patents. Rather, the purpose of the hearing is to consider whether the problems identified by the proponents of H.R. 1127 and S. 1334, some of which are discussed above, can be solved administratively, rather than legislatively. In this regard, the AMA Report draws a distinction between inventions in the field of therapeutic and diagnostic methods that are ''worthy'' of patent protection and those that are not. The Report states, at p. 8, that

> rigorous application of the standard [of obviousness] would not only remove the procedures which are currently causing an uproar in the medical community from patent protection but would ensure that procedures worthy of patent protection could come into existence. It seems reasonable to assert that generally the producers which were non-obvious would be the ones that required additional incentives and economic investment.

The requirement of non-obviousness, along with novelty, is one of the basic requirements to be met prior to a patent being granted. The novelty requirement ensures that a patent is not granted when the claimed invention is identical to an invention found in the ''prior art.'' The purpose of the obviousness standard is to ensure that an invention, even though novel, is not granted patent protection if it would have been obvious at the time the invention was made to a person of ordinary skill in the art or technology to which the invention pertains.

Accordingly, at the Congressional Hearing, the Administration offered to hold hearings at the PTO to determine the extent to which and how the problems presented by the patenting of therapeutic and diagnostic methods can be solved by changes in standards and practices within the PTO. In a letter from The Honorable Carlos J. Moorhead, Chairman of the Subcommittee on Courts and Intellectual Property, House Committee on the Judiciary, to PTO Commissioner Bruce Lehman, Chairman Moorhead requested the PTO to convene hearings ''to determine

whether the problems identified by the proponents of H.R. 1127 could be solved administratively, rather than legislatively.'' Chairman Moorhead suggested several areas of inquiry for such PTO hearings and those areas of inquiry are identified in the following section.

II. Issues for Public Comment

Interested members of the public are invited to testify and/or present written comments on issues they believe to be relevant to the discussion topics outlined below. Questions following each topic are included to identify specific issues upon which the PTO is interested in obtaining public input.

Information that is provided pursuant to this notice will be made part of a public record. In view of this, parties should not provide information that they do not wish to be publicly disclosed. Parties who would like to rely on confidential information to illustrate a point being made are requested to summarize or otherwise provide the information in a way that will permit its public disclosure. Individuals with questions regarding submission of such information may contact Richard Wilder at the numbers listed above for further information.

A. Application of the Standards of Patentability, PTO Resources, and Reexamination

Chairman Moorhead, in his letter to Commissioner Lehman, stated the following:

(At the Congressional Hearing) there appeared to be a great deal of concern that the PTO has issued patents in the field of therapeutic and diagnostic methods that fail to meet current patentability standards. This concern implies a need to inquire into the standards applied by the PTO, including obviousness, in determining whether or not to issue a patent. It also implies a need to examine the resources available to the PTO to be used in the examination process, including the prior art available to examiners. It may also be worthwhile to consider whether changes to the patent reexamination process may be useful.

1. Application of Patentability Standards by the PTO

In the field of therapeutic and diagnostic methods, as in any other technical field, the PTO applies the statutory standards for patentability, which include novelty, 35 U.S.C. 102, and non-obviousness, 35 U.S.C. 103. To receive a patent, an invention for which patent protection is sought must comply with all statutory requirements of patentability. The PTO examines each patent application on its own merits and does not apply per se rules regarding novelty, obviousness, or any other statutory requirement of patentability. Furthermore, the PTO strives to ensure that its examining practices reflect appropriate scientific and technological standards. The PTO thus seeks public input to help ensure that it is properly construing and applying the statutory requirements of patentability in the field of surgical and medical methods.

Are you aware of any problems related to the manner in which the requirements under 35 U.S.C. 102 and 103 are administered by the PTO for claims drawn to a therapeutic and diagnostic method? If so, please identify those problems with particularity, citing, if appropriate, specific situations or examples and providing steps that may be taken to solve the problems.

In responding to this question, you may wish to draw a distinction between problems caused by a lack of clarity of the legal standards governing 35 U.S.C. 102 and 103, as developed and interpreted by the Federal courts, and those caused by how those legal standards are applied by the PTO.

2. PTO Resources for the Search and Examination of Applications Directed to Therapeutic and Diagnostic Methods

In making a determination as to patentability under 35 U.S.C. 102 and 103, the examiner must compare the claimed invention with the prior art. The prior art can, inter alia, comprise knowledge, use, offer for sale, or a sale in the United States or U.S. or foreign patents or publications. Proponents of H.R. 1127 and S. 1334 argue that the PTO does not have access to all materials that comprise the prior art in the field of therapeutic and diagnostic methods. This is particularly so, they argue, in the case of prior uses of inventions that are not reported in journals, patents, or other publications. In this regard, testimony is solicited on the following points:

Do you believe that the prior art collection relating to therapeutic and diagnostic methods to which examiners in the PTO have access is deficient? If so, please suggest ways in which the prior art collection may be improved.

In responding to this question you may wish to draw a distinction between prior art that may not be included in a printed publication (including, for example, prior uses, including procedures performed in operating rooms and physicians' offices, prior knowledge, and prior sales) and prior art that is embodied in a printed publication. You may wish to comment on how the PTO can obtain access to obscure papers and other hard-to-obtain technical publications.

3. Reexamination of Patents in the Field of Therapeutic and Diagnostic Methods

A person may conclude that a patent is invalid and want to challenge its validity on the basis of a ''prior art'' reference that was not considered by the PTO during the original examination. Proponents of H.R. 1127 and S. 1334 argue that it can be costly to challenge the validity of a patent in court. An alternative to challenging such a patent in court is to request that the patent be reexamined in the PTO on the basis of that newly discovered reference. 35 U.S.C. 301. The bases upon which reexamination may be sought and the degree of participation of a person seeking reexamination are currently quite limited. Proponents of H.R. 1127 and S. 1334 cite these limitations as dissuading third parties from seeking reexamination and relying on litigation instead when a patent they consider invalid is asserted against them.

Another bill before Congress, H.R. 1732, would provide a more effective reexamination procedure by permitting greater participation by reexamination requestors throughout a reexamination proceeding, with a right of appeal for the requester. The bill would also allow the PTO to consider matters under 35 U.S.C. 112, first paragraph, except for best mode affecting patent validity, in addition to those based on the prior art. Some persons practicing in the field of therapeutic and diagnostic methods suggest that the changes contemplated in H.R. 1732 are not sufficient. In particular, they suggest that the basis upon which reexamination may be requested should be expanded to include prior art consisting of unpublished prior use, including medical procedures performed in operating rooms and physicians' offices. This gives rise to the following question:

Do you think the current reexamination statute requires modification to solve the concerns of persons practicing in the field of therapeutic and diagnostic methods beyond those contemplated in H.R. 1732? If so,

(a) please identify with specificity the modifications deemed necessary to solve the concerns; and

(b) explain the implications of such modifications, not only for patent owners, but for the PTO.

B. Publication of Patent Information

Chairman Moorhead, in his letter to Commissioner Lehman, stated the following:

We also heard from witnesses that patent protection in the field of therapeutic and diagnostic methods exercises a chilling effect on the publication or dissemination of knowledge in the field. I believe it would be worthwhile at the hearings you have

proposed to look into ways in which information contained in patent documents could be made more easily and widely available to the medical community. Perhaps a discussion on the role of early publication of patent applications would be useful here.

Proponents of H.R. 1127 and S. 1334 contend that patenting therapeutic and diagnostic methods may have a chilling effect on the development of new medical knowledge by creating an atmosphere of secrecy among physicians to protect their proprietary interests. One of the basic requirements of the patent law is that an applicant must disclose his or her invention in a manner sufficiently clear so that others skilled in the art are taught how to make and use it. Once issued, a patent is published, and thus, the public can read the information and learn from it. Another bill before Congress, H.R. 1733, would improve the information-dissemination function of patent documents. H.R. 1733 would require the PTO to publish patent applications no later than 18 months after the earliest effective filing date claimed by the patent applicant.

1. Does the medical community use information in granted U.S. patents or published foreign applications or patents, in particular such information concerning therapeutic and diagnostic methods?

(a) if not why not? if so, in what way is that information used?

(b) In either case, are there ways in which the dissemination of such information can be improved, both in terms of the form in which it is presented and its channels of distribution? For example, would the publication of patent applications as contemplated by H.R. 1733 improve the information-dissemination function of patent documents?

2. Would the absence of patent protection for inventions of therapeutic and diagnostic methods lead to a reduction in the dissemination of information in that field due to a desire to protect such inventions as trade secrets?

3. Does the availability of patent protection for inventions in the field of therapeutic and diagnostic methods inhibit the publication or dissemination of knowledge in the field? If so, in what way and to what extent?

C. Experimental Use

Chairman Moorhead, in his letter to Commissioner Lehman, stated the following:

The medical community has expressed concern that patent protection for therapeutic and diagnostic methods will have a chilling effect on the ''peer review'' of such procedures. Some of the proponents of H.R. 1127 have suggested that this concern may be overcome through a more expansive application of the ''experimental use doctrine.'' An inquiry into this matter may be useful at the hearings that the Administration has proposed.

Note: The PTO has solicited written comments on the experimental use defense to patent infringement. See, Public Hearings and Request for Comments on Economic Aspects of the U.S. Patent System, 58 FR 68394 (December 27, 1993); Cancellation of Public Hearings on Economic Aspects of the U.S. Patent System, 59 FR 1935 (January 12, 1994); and Notice of Public Hearings and Request for Comments on Patent Protection for Biotechnological Inventions, 59 FR 45267, (September 1, 1994).

A concern among medical professionals is that the existence of patents on therapeutic and diagnostic methods has a chilling effect on the study of such procedures. In particular, there is concern that the need to seek and obtain a license to practice a patented procedure will restrict ''peer review'' whereby experimentation and testing of such procedures are carried out to assess their quality and safety. It has been suggested that some of these concerns could be avoided by expansion of the ''experimental use doctrine.'' See, AMA Report, p. 5. This doctrine would exempt from infringement certain acts considered purely experimental, unrelated to any commercial use of the patented invention. Yet, other than limited provisions allowing for testing of patented pharmaceutical products for purposes of regulatory approval (e.g., section 271 (e)(1) of title 35, United States Code), existing law does not provide a general, statutory defense against a charge of infringement for experimental use of patented technology.

Despite this, the Federal courts have recognized a limited defense to a charge of patent infringement based on use of the patented technology for experimental purposes. This defense, referred to as the experimental use defense, has been raised infrequently, and when considered has been construed very narrowly. There are few cases elaborating the nature of the defense, primarily because patent rights are not frequently enforced against members of the public that use the patented technology for purely experimental purposes. In these cases, the courts have not recognized the defense where the accused infringer has engaged in use of the patented invention for purposes of commercially exploiting the invention, rather than for increasing his or her understanding of the invention. In cases in which the defense has been raised successfully, the experimental use in question was to ascertain how the invention functioned or for purely philosophical or academic reasons.

Proponents of H.R. 1127 and S. 1334 contend that the need for an experimental use exception in the field of therapeutic and diagnostic methods is greater than in other fields of technology, including the fields of pharmaceuticals or medical devices. They argue first that, while the Food and Drug Administration has responsibility for regulating pharmaceuticals or medical devices, peer review serves as the primary regulatory mechanism for therapeutic and diagnostic methods. Second, they argue that a patent on a surgical or medical procedure acts as a barrier to peer review that could lead to a decrease in the quality and safety of such procedures. Given these two postulates, proponents of H.R. 1127 and 1334 conclude that an expanded form of the experimental use doctrine is needed.

The foregoing discussion raises the following questions:

1. Does the grant of patent protection for therapeutic and diagnostic methods impose a ''chilling'' effect on the peer review of such procedures?

2. If the answer to question 1 is ''yes,'' explain how such patents have such a ''chilling'' effect.

3. If the answer to question 1 is ''yes,'' do you think modification of the present experimental use exception would reduce or eliminate such a ''chilling'' effect?

4. If the answer to question 3 is ''yes,'' how should the experimental use exception be modified to reduce or eliminate such a ''chilling'' effect? In particular,

(a) What activities involving a patented invention should be exempted from infringement under the experimental use exception?

(b) Which entities should be able to take advantage of such an experimental use exception? That is, should it be limited to physicians or health care providers or should it extend to legal entities with which physicians or health care providers are affiliated?

(c) What gains or losses to levels of basic research, inventive activity, and investment in research-intensive industries, if any, would you expect to occur if the nature of the present experimental use defense to infringement was modified as you suggest?

D. Foreign and International Experience

Chairman Moorhead, in his letter to Commissioner Lehman, stated the following:

As you know, many countries, including developed industrialized countries, exclude therapeutic and diagnostic methods from patentability. I think it would be useful to invite testimony on the way in which exceptions from patentability of therapeutic and diagnostic methods are provided for in the laws of other countries, the ways in which those exclusions are implemented,

and the effect such exclusions have on the medical community and industry.

The proponents of H.R. 1127 and S. 1334 have argued that many countries exclude therapeutic and diagnostic methods from patent protection and that the United States should follow their lead and ''harmonize'' our law with theirs. Testimony is invited in this regard in response to the following questions:

1. Identify countries that exclude therapeutic and diagnostic methods from patentability. As to such exclusions, identify:
(a) the way in which exceptions from patentability of therapeutic and diagnostic methods are provided for in the laws of other countries (for example, whether they are specifically excluded or defined as not being industrially applicable);
(b) the ways in which those exclusions are implemented (for example, whether they are strictly or liberally construed by offices in those countries that grant patents);
(c) the effect such exclusions have on the medical community and industry in countries that maintain them;
(d) any international obligations that would prevent such countries from continuing such exclusions; and
(e) the rationale for providing such exclusions.
2. Identify countries that grant limited immunity from patent infringement to certain persons that practice therapeutic and diagnostic methods. As to such limited immunity, identify:
(a) the way in which such limited immunity is provided for in the laws of other countries (for example, whether it is part of such countries' patent law or general tort law);
(b) the ways in which such limited immunity is implemented in practice;
(c) the effect such limited immunity has on the medical community and industry in countries that provide for such immunity;
(d) any international obligations that would prevent such countries from continuing such limited immunity; and
(e) the rationale for providing such limited immunity from patent infringement.

III. Guidelines for Oral Testimony

Individuals wishing to testify must adhere to the following guidelines:

1. Anyone wishing to testify at the hearings must request an opportunity to do so no later than Friday, April 26, 1996. Requests to testify may be accepted on the date of the hearing if sufficient time is available on the schedule. No one will be permitted to testify without prior approval.

2. Requests to testify must include the speaker's name, affiliation, and title, phone number, fax number, and mailing address.

3. Speakers will be provided between 5 and 15 minutes to present their remarks. The exact amount of time allocated per speaker will be determined after the final number of parties testifying has been determined. All efforts will be made to accommodate requests for additional time for testimony presented before the day of the hearing.

4. Speakers may provide a written copy of their testimony for inclusion in the record of the proceedings. These remarks should be provided no later than Friday, May 17, 1996.

5. Speakers must adhere to guidelines established for testimony. These guidelines will be provided to all speakers on or before Wednesday, May 1, 1996. A schedule providing approximate times for testimony will be provided to each speaker prior to the hearing. Speakers are advised that the schedule for testimony will be subject to change during the course of the hearings.

(Authority: 35 U.S.C. 6(a))

Dated: March 7, 1996.

Bruce Lehman,

Assistant Secretary of Commerce and Commissioner of Patents and Trademarks.

[FR Doc. 96–5895 Filed 3–12–96; 8:45 am]

BILLING CODE 3510–16–M

COMMODITY FUTURES TRADING COMMISSION

Coffee, Sugar and Cocoa Exchange: Proposed Amendments Relating to the Quality Standards, Delivery Ports, Packaging, Demurrage, and Trading Month Specifications for the White Sugar Futures Contract

AGENCY: Commodity Futures Trading Commission.

ACTION: Correction of Closing Date for Public Comment Period for Proposed Contract Rule Changes.

On March 7, 1996, the Division of Economic Analysis (''Division''), acting pursuant to Commission Regulation 140.96, published a notice in the Federal Register (61 FR 9147) on behalf of Commodity Futures Trading Commission requesting public comment on the referenced proposed amendments by the Coffee, Sugar and Cocoa Exchange (''CSCE''). In accordance with Section 5a(a)(12) of the Commodity Exchange Act, the public comment period for the CSCE's proposed amendments ends April 8, 1996.

Any person interested in submitting written data, views or arguments on the proposed amendments should send such comments to Jean A. Webb, Secretary, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, D.C. 20581 by the specified date.

Issued in Washington, DC, on March 8, 1996.

Blake Imel,

Acting Director.

[FR Doc. 96–6033 Filed 3–12–96; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF DEFENSE

Proposed Information Collection Available for Public Comment

ACTION: Notice.

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Under Secretary of Defense (Personnel and Readiness) announces the following proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

Written comments and recommendations on the proposed information collection should be sent to the Office of the Under Secretary of Defense (Personnel and Readiness) (Requirements and Resources), ATTN: Reports Clearance Officer, Room 3C980, 4000 Defense Pentagon, Washington, DC 20301–4000. Consideration will be given to all comments received within 60 days of the date of publication of this notice.

Title, Applicable, and OMB Control Number: DoD Loan Repayment Program (LRP); DD Form 2475; OMB Control Number 0704–0152.

Summary: Public Laws 99–145 and 100–180 authorize the Military Services to repay student loans for individuals who agree to enter the military in specific occupational areas for a specified services obligation period. The law provides for repayment for service performed on active duty or as a member of the Reserve Components in a military specialty determined by the Secretary of Defense. The legislation requires the Services to verify the status of the individual's loan prior to