

LIMITATIONS ON PATENTS CLAIMING
MEDICAL OR SURGICAL PROCEDURES

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Recent legislation has established new limitations on the remedies available for infringement of a patented "medical activity". A brief discussion of the new legislation (which does not apply to U.S. patents issued before the 30 September 1996 date of enactment) is provided herein.

The Legislation:

Appropriations legislation (HR 3610) signed into law on 30 September 1996 adds a new subsection to 35 U.S.C. 287, which establishes limitations on damages for patent infringement. This new subsection has been referred to as the "*medical procedures reform*" provision, and states:

(c)(1) With respect to a medical practitioner's performance of a medical activity that constitutes an infringement under section 271(a) or (b) of this title, the provisions of section 281, 283, 284, and 285 of this title shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.

'Medical activities' are defined in 35 USC 287(c)(2)(A) as:

"the performance of a medical or surgical procedure on a body, but shall not include (i) the use of a patented machine, manufacture, or composition of matter in violation of such patent, (ii) the practice of a patented use of a composition of matter in violation of such patent, or (iii) the practice of a process in violation of a biotechnology patent" (underlining added).

The following definitions are provided:

35 USC 287(c)(2)(B):

". . . 'medical practitioner' means any natural person who is licensed by a State to provide the medical activity described in subsection (c)(1) or who is acting under the direction of such person in the performance of the medical activity."

35 USC 287(c)(2)(C):

". . . 'related health care entity' shall mean an entity with which a medical practitioner has a professional affiliation under which the medical practitioner performs the medical activity, including but not limited to nursing home, hospital, university, medical school, health maintenance organization, group medical practice or a medical clinic."

35 USC 287(c)(2)(E):

". . . 'body' shall mean a human body, organ or cadaver, or a nonhuman animal used in medical research or instruction directly relating to the treatment of humans."

Thus, a physician practicing in a health maintenance organization (HMO) may

perform a patented 'medical activity' on a patient, and neither the physician or the HMO can be held liable for infringement.

Claims which are not affected by 287(c):

Key to the interpretation of the new legislation are the exclusions provided in 35 USC 287(c)(2)(A). A medical practitioner who uses a patented machine, manufacture, or composition of matter in violation of a patent is still liable for infringement. Thus patents claiming machines, medical devices, and new drugs are not affected by 35 USC 287(c)(2)(A). Additionally, a medical practitioner who performs a patented *method*, where that method *requires* the use of a composition of matter (such as a drug) to achieve its objectives, is also still liable for infringement. Further, a medical practitioner who practices a "process in violation of a biotechnology patent" is also still liable for infringement.

The term 'biotechnology patent' is not defined in the new legislation, but is explained in the record of the House and Senate action on the measure:

. . . the term 'biotechnology patent' includes a patent on a 'biotechnological process' as defined in 35 USC 103(b), as well as a patent on a process of making or using biological materials, including treatment using those materials, where those materials have been manipulated *ex vivo* at the cellular or molecular level.

Biological materials which may be manipulated *ex vivo* at the cellular or molecular level include a variety of cellular, intracellular, extracellular, and acellular substances. Cellular substances include (but are not limited to) cultured microbial and mammalian cells. Intracellular substances include (but are not limited to) genetic materials, such as DNA and RNA that is obtained from within the cell. Extracellular substances include (but are not limited to) proteins and other molecules that are secreted or excreted by cells. Acellular substances include (but are not limited to) viruses and other vectors for transmitting genetic material.

Ex vivo manipulation includes propagation, expansion, selection, purification, pharmaceutical treatment, or alteration of the biological characteristics of these substances outside of a human body.

Thus, for patents claiming "pure" medical, diagnostic or surgical methods -- those which do not encompass the novel uses of drugs, chemicals or biological reagents -- no remedies are available against a medical practitioner who directly infringes the patent, or against a medical practitioner who induces others to infringe.

Remedies for infringement are still available for patented *methods* which utilize a composition of matter to achieve the method's objective -- e.g., a novel method of treating a disease by administering a known drug. As explained in the summary provided in the Congressional Record of 28 September 1996 (H11865), such methods include "novel uses of drugs, novel uses of chemical or biological reagents for diagnostic purposes, novel methods for scheduling or timing administration of drugs, novel methods of combining drug therapies, and novel methods for providing genetic or other biological materials to a patient (including gene therapies)."

Hybrid Patent Claims:

Less clear is the treatment of so-called "hybrid" claims -- those claims which recite at least one step requiring the use of a composition of matter and at least one

'pure' surgical or medical step (not requiring a composition of matter). Some 'hybrid' claims will not be affected by 287(c), as explained in 287(c)(2)(F):

(T)he term "patented use of a composition of matter" does not include a claim for a method of performing a medical or surgical procedure on a body that recites the use of a composition of matter where the use of that composition of matter does not directly contribute to achievement of the objective of the claimed method.

The discussion provided in the Congressional Record attempts to clarify:

For a "hybrid" claim, . . . the test established by subsection (c)(2)(F) must be applied to determine whether the claim as a whole is exempted from the definition of a "medical activity" because it is a patented use of a composition of matter. The first step in this test is to determine the objective of the claimed method taking into account all of the process steps set forth in the claim. The second part of this test is to determine whether the steps involving the use of one or more compositions of matter . . . contribute directly to the achievement of the objective of the claimed method. . . . (T)his part of the test will have been met if the uses of the compositions of matter, either individually or collectively, represents novel subject matter, or if one or more of these steps contributes to or are necessary to establish the non-obviousness of the claim as a whole. Thus, even where the steps involving the uses of one or more compositions of matter are not novel individually or in combination with each other, these uses may still directly contribute to the achievement of the objective of the claimed method if, in combination with the steps that involve collectively obvious medical or surgical techniques, they produce a novel and non-obvious method.

Congressional Record 28 September 1996, H11865. The example of heart transplantation is provided as an illustration. Where a patent claim recites a novel 'purely' surgical method of transplanting a heart, including in the claim the step of providing conventional anesthesia would not cause the claim to be treated as a 'patented use of a composition of matter' The anesthetic is not viewed as contributing to "the objective of the claimed method." A medical practitioner would not be liable, under 287(c), for infringement of such a claim. However, where the anesthetic was novel, or a novel dosing schedule or route of administration was used, the claim should be considered a 'patented use of a composition of matter', and exempted from the provisions of 287(c).

Proponents of 287(c) suggest that whether a 'hybrid' claim meets the requirements of subparagraph (F) can be decided during the initial stages of litigation (e.g., decided by a motion to dismiss or summary judgment). However, we note that such determinations may be highly fact intensive and not readily determined.

Additionally, it is not clear how claims reciting the novel use of known medical *devices* will be treated. 35 USC 287(c)(2)(A) states that the following are not considered 'medical activities' exempt from liability:

"(i) the use of a *patented machine, manufacture, or composition of matter* in violation of such patent, (ii) the practice of a *patented use of a composition of matter* in violation of such patent" (italics added).

Thus where the device itself is patented, the claims may be infringed. Not explicitly addressed in section (ii) is the patented use of a nonpatented device, such as a

novel method of delivering electrical impulses to stimulate heart activity using a known device. Comments by Senator Frist suggest that such methods should not be affected by 287(c): "(This legislation) would in no way . . . change patent law with respect to biotechnology, medical devices, drugs, or their methods of use"; "My legislation is very narrow in scope. It would simply prevent the enforcement of patents against health professionals or their affiliated facilities for pure procedure patents It does not impact in any way the patentability of medical devices, drugs, or their methods of use." (Congressional Record, 30 September 1996, S12023).

Inducing Infringement and Contributory Infringement:

The patent laws establish three different types of infringement which are actionable: direct infringement, inducement of infringement, and contributory infringement. The latter two acts often provide the most attractive basis for enforcement, as they may provide means to reach commercial entities rather than individual end users.

Section 287(c) provides that no remedies are available for direct infringement by a medical practitioner of a patented medical activity, or where a medical practitioner induces another to infringe a patented medical activity. Non-medical practitioners who directly infringe a patented medical activity are clearly not protected by 287(c); further, non-medical practitioners who *induce* infringement *by medical practitioners* may also fall outside the protection of 287(c).

Excluded from the protection of 287(c) are the activities of any person "engaged in the commercial development, manufacture, sale, importation, or distribution" of compositions, apparatus or machines, where the activities in question are "directly related" to the commercial development, sale, importation or distribution of the item, and the activities are regulated by the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Clinical Laboratories Improvement Act. Thus, remedies for direct infringement or inducement of infringement should remain available, for example, against a medical equipment manufacturer who induces medical practitioners to perform a patented process using a medical device regulated by the FDA -- even though remedies would not be available against the medical practitioners who actually carried out the patented process.

The new legislation specifically states in 287(c)(1) that it covers both direct infringement (271(a)) and inducement of infringement (271(b)), but does not mention contributory infringement under 35 USC 271(c). Section 271(c) provides that whoever offers to sell, sells, or imports into the United States a material or apparatus for use in practicing a patented *process*, where that material or apparatus constitutes a material part of the invention and does not have substantial non-infringing uses, is liable for infringement. Thus, both medical practitioners and non-medical practitioners remain liable for contributory infringement under 271(c).

Examples:

A patented process of relieving back pain by performing a series of chiropractic manipulations would be defined as a "medical activity" under 287(c), as the process:

does not require the use of a patented machine, manufacture or composition of matter;

does not require the use of a composition of matter to achieve the

objective of the method;

is not a 'biotechnology patent'.

No remedies for infringement would be available where a medical practitioner performed the patented process, or if a medical practitioner actively induced others to perform the patented process. However, remedies should be available against a non-medical practitioner who actively induced others to perform the patented process.

A patented method of diagnosing a disease using a known composition in a novel way would not be a "medical activity" under 287(c), as the claim recites the use of a composition of matter which directly contributes to achieving the method's objective. For example, a monoclonal antibody known to bind to a specific protein might unexpectedly be found useful in diagnosing certain types of tumors; a method of diagnosing tumors using such monoclonal antibodies could be claimed. Remedies would be available against a medical practitioner who infringed the patented diagnostic method, or against one who actively induced infringement.

As noted above, an example of a "hybrid claim" is provided in the Congressional Record discussion of 287(c):

(I)n the case of a surgical method for transplanting a . . . heart, the inclusion of the step administering a conventional anaesthetic in a claim reciting a novel and non-obvious surgical transplantation procedure would not cause the surgical procedure to be treated as a patented use of a composition of matter within the meaning of subsection (c)(2)(A)(ii). Therefore, assuming none of the other exceptions in subsection (c)(2)(A) apply, the claimed surgical method would necessarily qualify as a medical activity.

Because the administration of anaesthesia is not viewed as contributing directly to achieving the objective of the claimed method, the claim is considered a medical activity and the protection of 287 applies to medical practitioners conducting the patented procedure.

History of the Legislation:

The presently enacted legislation is a compromise. An original proposal (H.R. 1127, the "Medical Procedures Innovation and Affordability Act") would have excluded medical and surgical procedures from *patentability*, and the Patent Office would have been prohibited from issuing such patents. The present legislation defines the affected procedures more narrowly and, while patents on medical processes will still issue, affected patents are unenforceable in most situations -- the effective equivalent of no patent at all.

Opposition to and Support for 287(c):

Serious concerns have been expressed about whether the present legislation is consistent with Trade-Related Intellectual Property agreement of the General Agreement on Tariffs and Trade (GATT-TRIPs), and whether a precedent has been established which other countries could invoke to deny or weaken patent protection provided to U.S. industries under the TRIPs. (See Congressional Record, 30 September 1996, S11843; Senate Floor Proceedings on HR 3610).

Opposition to the present provision has been voiced by the Clinton Administration, the American Intellectual Property Law Association, the Intellectual Property Owners, and the Intellectual Property Law Section of the American Bar Association.

Such organizations have questioned the need for the present provision, and have questioned the wisdom of exempting a certain section of industry from the protection of patent laws.

The American Medical Association supports the present legislation. Senator Frist states that "(p)ermitting innovative doctors to charge a fee every time their new technique was used would be a windfall for the doctor but a huge and costly burden for the patient community. Because these innovations would occur anyway, these additional costs would be wholly unnecessary." Congressional Record, 30 September 1996, S12024.

Conclusion:

The above is a general introduction to what will undoubtedly be an evolving area of law. Because newly introduced 287(c) applies only to patents issued after the date of enactment, it may be some time before the nuances of this legislation are addressed in court.

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