



## Question Q238

**National Group:** United States

**Title:** **Second medical use or indication claims**

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### Questions

#### I. Current law and practice

Groups are invited to answer the following questions under their national laws. If those national and regional laws apply to a set of questions, please answer the questions separately for each set of laws.

Please number your answers with the same numbers used for the corresponding questions.

- 1) Does your country permit patents covering any aspect of new uses of known pharmaceutical compounds (hereafter referred to as second medical use claims)?

**RESPONSE:** Under U.S. law, patent protection is available for new uses of previously known pharmaceutical compounds. Instead of being available in “second medical use” format, proper U.S. format relates to “methods of treatment” of the new use.

If yes, please answer Questions 2) to 7) inclusive before proceeding to the questions in Parts I and II. If no, please proceed directly to the questions in Parts II and III.

- 2) If the answer to Question 1) is yes, please answer the following sub questions.
  - a) What is the basis for patent protection?

**RESPONSE:** The basis for all patent protection in the U.S. can be found in 35 U.S.C. § 101, which states:

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.

With respect to a new use of an old compound specifically, further basis can be found in 35 U.S.C. § 100(b), which states that the “term ‘process’ means process, art, or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.”

- b) What types of second medical use are patentable? See, for example, paragraphs 14) - 17) above/WGLs.

RESPONSE: Under U.S. law, second medical use patent protection should be available for all of “classic” second medical use (later research shows an old drug is useful for a new purpose), for a new use of a known compound that was not previously successful for its initial purpose, and for new uses of known compounds previously discovered for non-medical uses.

A new dosage regime of a known drug to treat a known illness may be patentable under U.S. law, depending on what sort of unexpected results may be available to support an assertion of non-obviousness over that which was previously known.

- c) Are any types of second medical use impermissible subject matter? See, for example, paragraphs 14) - 17) above/WGLs.

RESPONSE: No types of second medical use are impermissible subject matter under U.S. law. The only issues are whether such second medical use would be novel and non-obvious in view of the teachings in the art.

- d) What forms of second medical use claims are permissible? See, for example, paragraphs 26) - 33) above/WGLs.

RESPONSE: As mentioned above, second medical use claims in the U.S. take a “method of treatment” format. Such claims would be directed to a method of treating a patient suffering from new disease Y by administering an effective amount of old compound X to the patient.

- e) What forms of second medical use claims are not permissible? See, for example, paragraphs 26) - 33) above/WGLs.

RESPONSE: No other format is available to protect second medical uses in the U.S. For example, use claims, Swiss-type claims, pharmaceutical formulation for use claims, and claims to the compound when used to treat a specific disease are all not permissible under U.S. law.

- f) Has any guidance been provided by courts or the national patent office in relation to the meaning, scope and/or effect of 'treatment', 'treating' or 'use to treat' integers in second medical use claims? See, for example, paragraphs 34) - 39) above WGLs.

RESPONSE: Medical method claims are much more straightforward in their meaning than other claim formats. Based on prior court decisions, the USPTO requires that patent-eligible method of medical treatment must include specific treatment steps. See, M.P.E.P. 2173.05(q). The meaning of specific treatment steps in such claims should be no different than what is recited in the claim.

3) If your country permits second medical use claims:

RESPONSE: **BRIEF OVERVIEW**

First, second medical use claims can be enforceable on the basis of either direct or indirect infringement, depending on the circumstances of the case. Second, parties that may be liable for infringing second medical use claims include a party marketing the drug with label instructions that describe the patented use, the physician prescribing the drug for such use; the pharmacist dispensing a drug for such purpose; and the patient using the drug for such purpose. Third, none of the above listed parties are exempt from infringement or liability for infringement. However, patients and physicians are rarely the targets of a lawsuit.

- a) Who may be liable for infringement of such claims? For example:
- i) the party marketing the drug with label instructions which describe the patented use;
  - ii) the physician prescribing the drug for such use;
  - iii) the pharmacist dispensing a drug for such purpose;
  - iv) the patient using the drug for such purpose?

RESPONSE: **Any of the Named Parties May Be Liable for Infringement of Second Medical Use Claims**

Under the plain interpretation of the statute, any of the parties in question, including the physician prescribing the drug, the pharmacist dispensing the drug, the party marketing the drug with label instructions that describe the patented use, and the patient using the drug, may be liable for infringement of any second medical use claims. 35 U.S.C. § 271(a) (“...whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States, or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.”). Furthermore, anyone who “actively induces infringement of a patent shall [also] be liable as an infringer.” 35 U.S.C. § 271(b).

- b) Are any parties exempt from infringement or liability for infringement of such claims. If so, what classes of party?

RESPONSE: **None of the Parties in Question Are Exempt from Infringement or Liability for Infringement Except under Certain Circumstances**

“Medical practitioners” are exempt for liability for “performance of a medical activity” that constitutes an infringement under 35 U.S.C. § 271(a) or (b). 35 U.S.C. § 287(c)(1). However, the term “medical activity” is limited to “the performance of a medical or surgical procedure on a body,” and specifically does 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.” 35 U.S.C. § 287(c)(2)(A). Thus, under the plain meaning of the language of the statute, medical practitioners are not exempt for liability for the use of a patented drug or the practice of a patented use of a drug. Furthermore, the legislative history

indicates that the statute was meant to protect medical practitioners from liability for infringement of medical treatment method patents, but specifically not to include an exemption for liability for the use of drugs. See *generally*, § 616 of the Conference Report to accompany H.R. 3610, 104<sup>th</sup> Cong. (1996).

- c) Are such claims enforceable on the basis of direct or indirect infringement? Please provide details.

**RESPONSE: Second Medical Use Claims Could Be Enforceable on the Basis of Either Direct or Indirect Infringement**

Whether second medical use claims could be enforceable on the basis of direct or indirect infringement depends entirely upon the circumstances of the case. For example, a party marketing the drug with label instructions that describe the patented use may be liable for inducing either the direct infringement of the doctor administering the drug according to the patented use, or the direct infringement of a patient using the drug. A doctor may be liable for directly infringing a patented method of use of a drug in the course of treatment, or for inducing the direct infringement of a patient who takes the drug at the physician's direction. Likewise, a pharmacist may be liable for either direct or indirect infringement depending on the facts of a specific case.

- 4) If a drug is approved for more than one indication, one or more of which (but not all) falls within the claims of a patent, is it an infringement if a party makes, supplies or uses a generic version of the drug for any use?

RESPONSE: It is possible that such acts would be an infringement. If a party has a patent covering a method of using a drug for a second medical use, then infringement would generally be proven under a theory of induced infringement and/or contributory infringement.

As set forth in 35 U.S.C. § 271(c), contributory infringement would require that the drug not be a "commodity of commerce suitable for substantial noninfringing use." Since the question presupposes the existence of substantial noninfringing uses, contributory infringement would not be applicable. Thus, infringement would need to be proven under a theory of induced infringement. Induced infringement might be found if the party sells the drug with advertising or instructions to carry out the infringing use. Case law also establishes that the party must know of the existence of the patent, and also know that his or her activities would lead to infringement of the patent.

Through a process colloquially termed "skinny labeling," the United States Food and Drug Administration (FDA) may permit "carve out" of infringing uses from a copyist's drug product labelling. This may reduce the chance of infringement liability under 35 USC 287(b). See, 21 U.S.C. § 355(j)(2)(A)(viii).

- 5) If the answer to Question 4) is yes, please answer the following sub questions in that context.
- a) Is each of the acts of making, supplying and using a form of infringement? If not, please specify which (or any other) acts which constitute infringement.

RESPONSE: The infringing acts would generally be the inducement of others to infringe. Thus, merely making, supplying, and using would not be infringement by the party offering the generic drug. While the use of the drug by the patient or the physician prescribing it may be considered acts of infringement, as mentioned above,

they are rarely the targets of a lawsuit. Nevertheless, the acts of direct infringement by these parties are considered a necessary component of the induced infringement by the party making and supplying the drug.

- b) Is it necessary for a finding of infringement that the party making, supplying or using the generic version of the drug does so in connection with the infringing use?

RESPONSE: The general rule is that an act of direct infringement is required to find liability under induced infringement. Thus, any acts found to be infringing would need to be done in connection with the infringing use.

The “single entity rule,” requiring that to find indirect infringement, direct infringement by a single entity must be found first has been the rule heretofore. *BMC Resources v Paymentech*, 498 F.3d 1373 (Fed. Cir. 2007). This rule was overturned by the Federal Circuit (*Akamai Technologies, Inc. et al v. Limelight Networks, Inc., McKesson Technologies, Inc. v. Epic Systems Corp.*, 692 F.1301, Fed. Cir. Aug. 30, 2012). Overturning the single entity rule broadens the scope of parties who may found to be infringers. However, certiorari was granted by the U.S. Supreme Court in *Akamai Technologies*, and oral arguments were heard on April 30, 2014.

- c) If yes to b), is it necessary that the party knows that their actions are in connection with the infringing use?

RESPONSE: Yes, as discussed above, induced infringement requires intent to cause others to carry out the infringing acts.

- d) If yes to c), what standard of knowledge is required? See, for example, paragraphs 38) and 47) above.

RESPONSE: Circumstantial proof that the person accused of inducing infringement knew of the patent, and knew that his or her activities would lead to infringement of the patent is generally sufficient to establish the requisite intent. See *DSU Med. Corp. v. JMS Co., Ltd.*, 471 F.3d 1293 (Fed. Cir. 2006).

- 6) How do the courts determine infringement of a second medical use claim? What are the legal tests and evidentiary requirements?

RESPONSE: Infringement of method of use claims in the United States is established by proving either direct infringement or indirect infringement, usually based on the proposed product label. The relevant portions of the United States statute states as follows:

- (a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.
- (b) Whoever actively induces infringement of a patent shall be liable as an infringer.
- (c) Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

35 U.S.C. § 271(a) pertains to direct infringement, where, for example, a single party performs all of the steps of a patented method claim. Indirect infringement arises when the defendant does not himself perform all of the steps of the method claim, but instead actively induces another to infringe under 35 U.S.C. § 271(b) or contributes to another's infringement under 35 U.S.C. § 271(c).

The likely target of a patent infringement lawsuit is the medical manufacturer, and infringement is determined based on proving indirect infringement under 35 U.S.C. § 271(b) or (c). However, liability for active inducement of infringement or contributory infringement is still dependent upon the existence of direct infringement. The patent holder in a patent litigation lawsuit must still prove that all of the steps of the patented method are performed, e.g., by the medical device practitioner or the patient himself. Recent case law in the United States has further held that "all the steps of a claimed method must be performed in order to find induced infringement, but that it is not necessary to prove that all the steps were committed by a single entity." *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301, 1306 (Fed. Cir. 2012) (en banc). cert. was granted by the U.S. Supreme Court, and oral arguments were heard on April 30, 2014.

Beyond proving direct infringement, a patent holder alleging inducement of infringement must prove not just that the defendant intended to cause the acts that produced direct infringement, but that the defendant had an affirmative intent to cause direct infringement. *DSU Medical Corp. V. JMS Co.*, 471 F.3d 1293, (Fed. Cir. 2006). Typically this will require actual knowledge of the patent, though the U.S. Supreme Court in *Global-Tech Appliances, Inc. v. SEB S.A.* has also held that willful blindness to a known patent will also satisfy the intent requirement. 563 U.S. \_\_\_\_; 131 S. Ct. 2060 (2011) "[A] willfully blind defendant is one who takes deliberate actions to avoid confirming a high probability of wrongdoing and who can almost be said to have actually known the critical facts." *Global-Tech*, slip opin. at 14.

Similarly, contributory infringement under 35 U.S.C. § 271(c) also requires proof of knowledge. In the context of a medical method claim, the defendant must know that the material or apparatus he is providing is especially made or especially adapted for use in an infringement of a patent. The U.S. courts have interpreted this to require actual knowledge of the patent.

Proving infringement is a question of fact that is decided by a trier of fact. The plaintiff must prove the infringement by a preponderance of the evidence. Thus, if a plaintiff is seeking to prove that a manufacturer actively induces (or will induce) patent infringement of a patented method, the plaintiff must prove that direct infringement occurred by a preponderance of the evidence, and that the defendant actively induced the infringement by a preponderance of the evidence.

In the large majority of cases involving second medical uses, infringement is proved based on the proposed label applied to a product used for the second medical use

- 7) What relief is available for infringement of a second medical use claim:
- a) at a preliminary / interim / interlocutory level?

RESPONSE: A preliminary injunction is available if the patentee can prove that it is (1) likely to succeed on the merits; (2) likely to suffer irreparable harm in the absence of preliminary relief; (3) the balance of equities tips in its favor; and (4) an injunction is in the public interest. *Apple, Inc. v. Samsung Elecs. Co.*, 678 F.3d 1314, 1323 (Fed.

Cir. 2012). A preliminary injunction may properly be denied where a movant fails to establish any one of these four factors. See *Apple*, 678 F.3d at 133.

A temporary restraining order (TRO) may also be sought by the patent holder. The legal standard for obtaining a temporary restraining order is the same as a preliminary injunction. The main differences are that a preliminary injunction requires the adverse party to have adequate notice (unlike a TRO which may be entered without notice), and a preliminary injunction is of indefinite duration while a TRO is of a short, limited duration (e.g., 14 days).

Quite distinct from injunctive relief, and in some ways more powerful because of the heightened certainty is the 30-month stay available to a party who timely files an infringement action in federal district court on an Orange Book listed patent claiming an approved drug against a filer of a generic application seeking approval to market that drug, The FDA is prohibited from approving the generic application for a period of 30 months from the filing of the infringement action. Without an approval, the generic filer can not market the drug. Second Medical Use patents can and have been used to obtain such 30-month stays.

b) by way of final relief?

RESPONSE: A plaintiff who successfully proves infringement of a medical method of use claim may be entitled to injunctive relief (35 U.S.C. § 283) and/or damages (35 U.S.C. § 284, 285). Injunctive relief is often the only relief available when a generic drug manufacturer is sued based on its challenge to a patent in the Orange Book. Nevertheless, in cases of an “at risk” launch by a generic drug manufacturer, damages could also be awarded.

Injunctive relief is most commonly sought as most relevant cases occur before the launch of a product into the market. However, damages can be awarded under circumstances in an amount “adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court.” 35 U.S.C. § 284. Enhanced damages of up to three times the amount found or assessed may also be awarded to the plaintiff if the plaintiff can prove that the defendant willfully infringed the patented method. 35 U.S.C. § 285.

8) In respect of Question 7)a), can a preliminary / interim / interlocutory injunction be granted solely upon the statements provided in the product packaging or based on the writing of a prescription? If not, what is the basis for relief?

RESPONSE: Statements used in product packaging may be used as evidence that a medical manufacturer actively induced the infringement of a patent. However, proof of direct infringement and proof of intent to cause the infringement would still be required. Moreover, all of the four factors mentioned above must be considered in deciding whether to grant a preliminary injunction or a temporary restraining order.

The writing of a prescription may be used as evidence to prove direct infringement, e.g., to prove that a patient actually took a particular medication as covered by a patented method. To successfully prove induced infringement by a medical manufacturer, additional evidence may be needed to prove that the physician was instructed by the manufacturer to prescribe the medical for a particular patented purpose. This may be difficult if the prescription does not indicate for what purpose a drug is being prescribed.

9) In respect of Question 7)b), what level of proof is required to obtain a final injunction?

RESPONSE: Permanent injunctions in U.S. patent cases are not automatic. After a plaintiff proves direct infringement and indirect infringement, if alleged, to obtain a permanent injunction, the plaintiff will usually also need to prove by a preponderance of the evidence:

- (1) that it has suffered an irreparable injury;
- (2) that remedies available at law are inadequate to compensate for that injury;
- (3) that considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and
- (4) that the public interest would not be disserved by a permanent injunction.

*eBay, Inc. v. MercExchange, LLC*, 547 U.S. 388 (2006).

## II. Policy considerations and proposals for improvements to your current law

10) If your country permits second medical use claims, please answer the following sub questions.

a) What are the policy reasons behind permitting such claims?

RESPONSE: The United States has a policy that includes patenting novel, nonobvious, useful inventions directed to patent-eligible subject matter. According to U.S. law, second medical uses are patent-eligible subject matter. Generally, the U.S. patent policy promotes the progress of science and useful arts (U.S. Constitution, Article I, Section 8). Second medical use claims accomplish this policy by providing incentives to companies and inventors that invest resources discovering new medical uses for existing products.

b) Are such claims as are currently permissible in your country considered to strike the right balance between the interests of relevant stakeholders?

RESPONSE: In the United States, the interests of the relevant stakeholders related to second medical use claims are closely tied to regulations governing the use of such products. Specifically, the balance of interests is affected by the medical uses that can be approved for marketing by the United States Food and Drug Administration ("FDA"). The interplay between patent law and regulatory law is governed by a complicated statutory scheme commonly referred to as the "Hatch-Waxman Act." The practical effect of these regulations and whether they strike a proper balance depends on the perspective of the various stakeholders, i.e., whether the company seeks to protect a second medical use or seeks to market a generic product for such use.

Generally, proving infringement of second medical use claims requires showing that the generic company plans to market the existing product for the second medical use. In many circumstances, the generic label is used to demonstrate infringement of medical use claims. Because, under certain circumstances, the Hatch-Waxman Act allows generic companies to remove second medical uses from their proposed labels, the patentee may have difficulty proving infringement of the second medical use claims. In this situation, the patent provides less protection or reward for the patentee. Similarly, in this situation, the policy of allowing second medical use claims provides questionable benefit to the patentee.

- c) Is it considered that such claims better serve the interests of some stakeholders and/or are detrimental to other stakeholders?

RESPONSE: See above: this is highly dependent on the perspective of the stakeholder.

- d) If there is any empirical or anecdotal data available, please address the following.

- i) What is the prevalence of second medical use claims in your country?

RESPONSE: Second medical use claims are prevalent in the United States.

- ii) What is the profile of patentees for second medical use claims in your country?

RESPONSE: The typical patentee of second medical use claims is an innovator pharmaceutical company seeking to identify additional indications for a marketed drug product.

- 11) If your country does not permit second medical use claims, please answer the following sub questions.

- a) What are the policy reasons behind not permitting such claims?

- b) Would such claims serve the interests of relevant stakeholders?

- c) Would such claims be considered to better serve the interests of some stakeholders and/or be detrimental to other stakeholders?

- 12) To what extent does your country's law in relation to second medical use claims affect the pharmaceutical industry (originator and generic) in your country?

RESPONSE: Second medical use claims provide an important incentive for the pharmaceutical industry to invest in research and development of new uses for known pharmaceuticals. Originator companies may list patents with second medical use claims in the "Approved Drug Products with Therapeutic Equivalence Evaluations", also known as the Orange Book. Generic companies wishing to market a therapeutically equivalent pharmaceutical must make a certification against any patents listed in the Orange Book. If the listed second medical use claim covers the only approved indication of the pharmaceutical, the generic would either need to challenge the validity of the second medical use patent or wait until the patent expires or a non-patented use is approved to market the drug.

### III. Proposals for Harmonisation

The Groups are invited to put forward proposals for the adoption of harmonised laws in relation to second medical use claims. More specifically, the Groups are invited to answer the following questions without regard to their existing national laws.

- 13) Is it desirable to permit second medical use claims?

RESPONSE: Yes, in order to promote innovation in the medical field as discussed above, patent protection of new beneficial uses of known compounds is an appropriate incentive to

innovator companies. Such incentive is necessary to balance the time and monetary investment, as well as significant risk, undertaken by such companies.

14) Is harmonisation of laws relating to second medical use claims desirable?

RESPONSE: Yes, consistency in these laws on an international scale would provide further incentives to innovator companies. Harmonization would further reduce waste involved in preparing different claims sets for different countries. An international consensus on this issue would also lead to greater understanding of patent claims across borders.

15) Please provide a standard that you consider to be best in each of the following areas relating to second medical use claims.

a) Types of second medical use constituting permissible subject matter. See, for example, paragraphs 14) - 17) above/WGLs.

RESPONSE: The permissible subject matter for second medical use claims should be broad and similar to that of first medical use and other method claims.

b) Types of any second medical use constituting impermissible subject matter. See, for example, paragraphs 14) - 17) above/WGLs.

RESPONSE: Exclusions should include generally impermissible subject matter such as laws of nature or abstract ideas.

c) Form of permissible claims. See, for example, paragraphs 26) - 33) above/WGLs.

RESPONSE: Many U.S. practitioners believe that "Method of treatment" claims represent the most desirable format. Such a format avoids the need to rely on the intended use recited in a claim as an exception to the general rule in the U.S. that product claims are not limited by their intended use.

In contrast to other claim formats, "method of treatment" claims are governed by the rules for claiming methods generally. Such claims must include at least one active step and are generally not limited by intentions recited in the preamble. Thus, method of treatment claims can be more clearly understood regarding what exactly is covered. Moreover, they can be applied to any second medical use without regard to any specific exemptions to other general rules. The concern that physicians and other medical personnel should be free to take whatever steps they believe to be most medically practical is addressed by exempting such personnel from infringement.

Some other U.S. practitioners feel that method of treatment claims might appear as undesirable to the public based on a belief that even with exemptions from liability for medical practitioners, the lay public may find it difficult to accept the patentability of claims directed to acts typically performed by a medical practitioner.

d) Form of impermissible claims. See, for example, paragraphs 26) - 33) above/WGLs.

RESPONSE: Claims reciting a product limited only by an intended use or that do not recite an active step are currently impermissible. However, if method of medical treatment claims are also made impermissible, the result would be that no claims would be available to cover second medical use inventions. In such a case, some alternate form of claims would need to be permitted to provide patent protection for second medical uses.

e) Who may be liable for infringement?

RESPONSE: All parties other than medical practitioners and related who infringe the claim of a patent should be liable.

f) Any parties/institutions that should be exempted from infringement or liability for infringement.

RESPONSE: Medical practitioners and related parties should be excluded from liability for infringement.

g) Where a drug is approved for more than one indication, one or more of which (but not all) falls within the claims of a patent, the acts that should constitute patent infringement, and in particular, the standard of knowledge of the alleged infringer.

RESPONSE: The acts that constitute patent infringement should be no different for second medical use claims than for other claims. The standard of knowledge of the alleged infringer should only be considered in connection with indirect infringement.

h) Relief available upon a finding of infringement:

- i) at a preliminary / interim / interlocutory level; and
- ii) by way of permanent relief.

RESPONSE: Relief for infringement of second medical use claims should be the same as for relief for all other infringement. The standards for grant of injunctive should include consideration of the public interest.

i) In each case for h)i) and h)ii), the level of proof for the granting of such relief.

RESPONSE: The level of proof for granting relief for infringement of second medical use claims should be the same as the level of proof required for all other acts of infringement.

## Summary:

Under United States law, patent protection for medical treatments is broadly available, covering both new uses of previously known pharmaceutical compounds and previously known medical devices. The proper format for such claims is a "method of treatment" reciting the active steps of the new use. Claims reciting a product limited only by an intended use or that do not recite an active step are currently impermissible. United States law provides that medical practitioners are exempt from liability for performance of a medical activity that constitutes an infringement. However, under current law, medical practitioners are not exempt for liability for the use of a patented drug or the practice of a patented use of a drug. Method of medical treatment claims can be enforced on the basis of either direct or indirect infringement. In order to prove indirect infringement, it generally must be shown that at least one party is a direct infringer. Thus, proof that a manufacturer of a medical product is indirectly infringing a claim directed to a method of medical treatment will often require proof that a medical practitioner is carrying out the steps of that claim, even if the medical practitioner is exempt from liability.

United States practitioners broadly agree that harmonization is desirable in this area. Many believe that "Method of treatment" claims represent the most desirable format, provided that

a broad exemption for liability of medical practitioners is adopted. Some other practitioners believe that such method claims may be perceived as inflammatory even with a broad exemption for medical practitioners.