

IF YOU HAVE QUESTIONS REGARDING
THIS MATTER, PLEASE CONTACT:



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PATENT INFRINGEMENT AND THE PRACTICE OF MEDICINE

According to current U.S. Patent law, anything which can be made by man (or woman) may be patented as long as it is novel, has utility and would not be obvious to one of ordinary skill in the art. If a patent is issued from the US Patent and Trademark office, the patent holder is given a grant to prevent others from making, using and selling his/her invention in the United States. In the instance where the patent is being infringed, the patent holder can file suit in federal court and i) prevent the infringer from further use of the patented invention, ii) receive money for damages caused by the infringement and iii) obtain attorney fees and treble damages from the infringer if the infringement was found to be willful. The relief available from the federal court provides a strong deterrent to infringement of an issued patent. In the case of a pharmaceutical product, damages for infringement can be astronomical. Thus, being accused of patent infringement is not a claim to be dismissed as trivial.

From the broad definition of what may be patentable, inventions comprising medical devices, pharmaceuticals, genetically engineered medicines and medical methods have provided the medical practitioner with many new weapons to treat and in some cases cure disease. Many of the medicines, devices and products used today to treat patients for their condition are protected by one or more patents. Clearly, when a practitioner or health care provider purchases a medical device, medicine or product from the manufacturer, the purchaser is not only receiving the product but is also receiving the express or implied permission of the patent holder to use the product.

However, owing to the broad definition of what is patentable, the U.S. Patent and Trademark Office has issued patents to inventors (usually physicians) for medical and surgical methods. For example, the inventor describes a novel surgical method for the removal of a tumor from a particular organ or describes a novel method for medical management of a particular condition. The medical or surgical method is published in a medical journal. Neither invention requires subsequent practitioners who want to use the method to purchase anything from the inventor in order to practice the invention. However, the inventor timely prepares a patent application describing the new medical or surgical method, submits the completed application to the U.S. Patent Office and a couple of years later is issued a patent for his/her medical or surgical method. The inventor now wants to enforce his patent and collect royalties from all who have used his/her invention. Are subsequent practitioners subject to being found liable for patent infringement for using the patented medical or surgical method? The answer to the question is maybe and depends on a number of factors, including when the patent application was filed.

On its face it appears that a health care provider who performs a patented medical or surgical method might be liable to the inventor for damages stemming from the infringement of the patent. However, some members of Congress recognized the problem and attached a rider to an appropriations bill that provides an exception to the statute authorizing patent infringement suits. This exemption is codified at 35U.S.C. 287 (c)(1). According to the exemption statute, it is not infringement for a medical practitioner to perform a medical or surgical procedure even though the procedure may be patented by another. The facility in which the

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procedure or treatment takes place may also fall within the umbrella of protection the amendment affords. For a medical method patent as described above, the statute exempts from infringement uses of the medical method which may be technically infringing upon another person's patent.

The exemption statute applies to medical practitioners and to health care entities in which the medical method is practiced. According to the exemption statute, this includes physicians licensed to practice medicine by a state and individuals working under the direction of a licensed physician. Hospitals are also included in the exemption if the physician has a professional relationship with the hospital such as membership on the hospital medical staff when the medical method patent is technically infringed. The exemption to infringement does not apply to veterinarians or to clinical laboratories since the statute pertains only to medical activities performed on a human body. Not surprisingly, the exemption also does not protect manufacturers of medical devices and products from patent infringement claims regarding a medical method, nor does it protect persons or entities from inducing another individual to infringe a valid medical method patent except as provided above. An example of this would involve a manufacturer who produces a medical product and then advertises the product's use for a particular medical method which is patented by another. Such a manufacturer may be subject to a claim that it induced others to infringe the medical method patent.

The statute applies to those medical or surgical procedures performed on a human body which do not involve the use of a patented machine or composition of matter in violation of the patent or the use of a biotechnology process in violation of the patent. Moreover, the exemption statute applies to all medical method patents filed after September 30, 1996. That means that there are probably a number of patents filed which are not covered by the statute and for which the exemption to infringement does not apply. Due to term limitations of an issued patent of about 17 years, most of the patents issued before 1990 are no longer valid. However, there are probably many patents issued after 1990 or filed prior to September 30, 1996 which are still valid and a potential hazard for infringement because they do not fall within the coverage provided by the exemption to infringement. Moreover, the exemption statute does not apply to those who induce infringement of an unexpired medical method patent by a medical practitioner even though the patent application was filed after the effective date of the statute.

This possibility of infringing upon a patented medical or surgical method places an ethical burden upon the medical practitioner. Should the medical practitioner risk infringing the medical method patent and possibly incur the expense of defending himself/herself in federal court or perform the medical/surgical method on the patient? The analysis can be further complicated if the performance of the contemplated medical/surgical method constitutes the accepted standard of care in treatment of the patient in question. Failure to adhere to the accepted standard of care resulting in injury to the patient could subject the medical practitioner to professional liability or malpractice for violation of his duty to his patient. It is likely that most physicians would opt to provide the best treatment possible to the patient even if it did raise the possibility that the medical practitioner might become the subject of a patent infringement claim. To the physician's benefit is the probability that most medical method patents would be very difficult to enforce against the medical practitioner. First, it would be quite a chore for an inventor to identify those physicians who had used the invention in violation of the patent. Medical information privacy laws such as HIPAA would likely prevent the inventor

from identifying those patients who had received the patented surgical method. Without that information it would be difficult to go forward with any patent infringement suit. Even if the patient voluntarily surrendered information regarding his medical care to the inventor, the subsequent trial would be held before a jury, which might side with the medical practitioner who did his utmost for the patient in comparison with some inventor who just wants money from the doctor. Nevertheless, it is important to recognize that for the next several years an inventor might make a claim for infringement of a medical/surgical patent. Eventually, all of those patents will expire and with them so too will expire the risk to the medical practitioner. The risk will then shift to those who induce or contribute to infringement of medical method patents which were filed after the effective date of the statute.