Lawsuits over laser patents raise serious issues for physicians, patients

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A patent-infringement lawsuit filed against several Canadian physicians who perform refractive eye surgery continues to send shivers through the ranks of Canada’s ophthalmologists. Other physicians should be worried too, because this is an emerging trend.

The 1995 suit by an American company, Visx, alleges that the physicians and 3 equipment manufacturers have infringed its Canadian patents for eye-laser technology, which date to 1988. Before the suit was filed, Visx asked for licence fees from physicians using the excimer-laser system. However, in its initial statement of claim the company demanded that the physicians stop using the technology and pay damages for unlicensed use.

The physicians responded that they cannot be held accountable for patent infringement because they had purchased the laser technology from other manufacturers “freely thinking it could be used in good faith.” The lawsuit comes in the wake of growing popularity of laser surgery across the country. For example, at special clinics in Alberta and Saskatchewan approximately 4000 patients are treated annually.

The surgery, known as photorefractive keratectomy, reshapes the cornea to reduce or eliminate myopia and end the need for eyeglasses or contact lenses. Canadian physicians were performing the procedure for 5 years before the US Food and Drug Administration gave its nod of approval in October 1995. The procedure, which is not covered by medicares, costs about $2200 per eye.

Because the matter is currently before the court, it is not possible to discuss either the merits or the likely outcome of Visx’s case against Canadian physicians. However, there are issues surrounding the use of patented technologies that are of interest to physicians, as well as policy concerns that suggest legislative changes may be needed to clarify the law.

The current court action draws attention to 2 contentious areas of patent law:

• the general issue of granting patents for developments in medical technology; and
• the availability of certain kinds of legal remedies when a patent has been infringed.

Although it is generally understood that medical procedures and treatments cannot be patented in Canada, Canadian law remains unsettled. Methods for carrying out medical or surgical treatments are not specifically addressed in the definition of an inventive process that can be patented. Only through case law has it been determined that if the process is a “medical” treatment it cannot be patented. However, the technology or instruments used to provide a treatment can be patented.

In the US, it is possible to patent both procedures and treatments and to require payment of royalties to the patent holder for alterations to procedures made during the evolution of medical knowledge. These patents grant a 20-year monopoly over the use and teaching of medical and surgical procedures, techniques and processes, including methods of diagnosis, therapy and treatment. This has led to a proliferation of medical-procedures patents in the US, a trend that some observers think will undermine the long-standing tradition of open and critical exchange of scientific information.

The patent issue has raised concerns in the US as well as Canada. A patent-infringement lawsuit in the US, which contributed to the controversy there and to physicians’ growing concern, may shed some light on the situation facing Canadian doctors because of the Visx lawsuit. The US case, which involved 2 New England ophthalmologists, was filed by Dr. Samuel Pallin against a colleague, Dr.

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In Canada, the CMA's Committee of Affiliated Societies recently asked the CMA Board of Directors to look into the enforcement of licence fees sought from physicians using a variety of procedures and technologies. A survey of all affiliated and other specialty societies was conducted to review potential biotechnology and other patent-related concerns. Six percent of respondents stated that there were medical devices, processes or technologies currently in use that might be subject to licensing fees in the future.

Respondents also identified some areas that might be subject to licensing fees in the future, including in-office "mini" arthroscopic procedures that require special equipment, ultrasonograms taken to determine bone density, computer software, patented microorganisms and polymerase-chain-reaction products. (In the latter case, firms have reportedly been requesting licensing fees from hospitals, which have ignored them; fees have also been sought over the use of nephrology research techniques.)

When patent-infringement cases are brought against physicians or hospitals, patent holders can seek several remedies, including an action to recoup the "infringing" user's profits, damages for past infringement (although generally the plaintiff will not be awarded both lost profits and damages), legal costs and injunctions to stop performing the procedure. In all of these cases, defendants would face significant costs.

Developments in the patenting of medical procedures in the US will inevitably have an impact on Canadian law and, more importantly, on the practice of medicine and quality of care. Physicians can make some positive contributions in this area by helping to clarify where the line should be drawn between patentable technology and unpatentable medical procedures or treatments.

Keeping in mind the ultimate best interests of the patient and the importance of maintaining opportunities to exchange medical and scientific information, physicians can argue for clear and limited guidelines on the following basis (Portman RM. Patenting medical and surgical procedures is threatening medical progress. Policy Options; May 1996:31-5):

- patents on medical procedures have a chilling effect on the medical profession's tradition of open communication of ideas;
- they may interfere with quality of care;
- the commercialization of medical procedures will inevitably increase health care costs, to the obvious disadvantage of patients; and
- these developments may interfere with the patient-physician relationship.

A number of these issues require action by physicians and hospitals, not only to offset potential problems at the practice level but also to provide the impetus for the federal government to consider a legislated solution for the long-term benefit of physicians and patients.

In the meantime, physicians should protect themselves as much as possible by ensuring that licensing agreements accompanying medical technology used in their practices contain indemnification for the user from a lawsuit by the patent holder. ☞