Physicians are rightly worried about the high-profile laws, regulations, and issues that threaten to disrupt their practices (e.g., The Health Insurance Portability and Accountability Act of 1996, medical malpractice, and the Resource-Based Relative Value Scale). However, physicians also should be aware of a more subtle, but potentially more significant, change. The past 5 years has seen a sea change in the types of intellectual property that can be patented. The US Patent and Trademark Office is increasingly granting patents for business processes—that is, the methods of doing business. If this trend continues unabated, it also could have a major impact on how physicians practice medicine.

**A BRIEF BACKGROUND ON PATENT PROTECTION**

The legal protection of new products has existed since the founding of the United States. Article 1, Section 8 of the Constitution gave Congress the power “to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” Patents encourage innovation and creativity by allowing the inventor to profit from his or her initiative, free of imitation or competition for a fixed period of time. On the other hand, as economists have noted, this legal monopoly has the potential to limit dissemination of the invention and to raise its price above its value in a competitive market.

Congress has since created laws that declare, “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 therefore.”

A patentable invention or discovery must be novel and contain “non-obvious subject matter” (subject matter is obvious if “the difference between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains”).

**PATENT PROTECTION IN THE AGE OF INFORMATION**

The Supreme Court has in the past acknowledged that “Congress intended statutory subject matter to ‘include anything under the sun that is made by man,’” but that “the laws of nature, physical phenomenon, and abstract ideas” are not patentable. Likewise, “an algorithm, or mathematical formula, is like a law of nature, which cannot be the subject of a patent.” On the other hand, “while a scientific truth, or the mathematical expression of it, is not a patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be.”

The US economy has evolved from an industrial and manufacturing base to one that is services and e-commerce oriented. Concern has arisen about protecting the intellectual capital that is the foundation of those businesses: computer software, optimal pricing algorithms, and innovative ways of addressing customer needs. This issue has come to a head as these companies have sought patent protection for their “business processes”—that is, their methods of doing business.

Historically, business processes were considered to be abstract ideas, and thus not patentable. However, in July 1998 the US Court of Appeals for the Federal Circuit ruled that business processes could be patented if they were novel, non-obvious, and created a “useful, concrete and tangible result.” (The US Supreme Court let the decision stand, so it now has national precedence.)

This decision released an explosion of business process patent applications and awards: Amazon.com for its “1-click” method of shopping; Priceline.com for its reverse-auction process of selling airline tickets; Netflix for the way its customers rent DVDs. The broad nature of these and other business process patents has generated controversy in both the trade and popular press. Proponents argue that these processes are the essence of the companies’ legitimate competitive advantage, while opponents argue that most...
business processes are, in fact, not novel and obvious and that such patents confer undue market power.

**Implications to Medicine**

Why is this issue of interest to physicians? After all, the culture of the medical profession is to share openly any new techniques that improve patient care. The mantra of “See one, do one, teach one” is deeply rooted in medical history and practice. In addition, the widespread availability of patents for medical devices, pharmaceuticals, and other medical products has not corrupted physicians’ ethic of sharing medical expertise without recompense.

In fact, the extent to which medical and surgical techniques are patentable has long been contested. The famous “ether case” in 1862 held that “one of the great discoveries of modern times” (ie, that inhalation of ether produces insensitivity to pain) was not patentable. In 1995, the American Medical Association’s Council on Ethical and Judicial Affairs declared that “it is unethical for physicians to seek, secure, or enforce patents on medical procedures.” In 1996, Congress exempted medical practitioners from patent infringement in the performance of a medical activity.

Nevertheless, in an environment with an increasingly liberal interpretation of patentability, it is not a stretch to imagine that the concept of business process patents could be applied to a wide range of medical innovations: a new surgical technique that is less invasive than current procedures; a process for triaging patients in the emergency department that reduces waiting time; a staffing scheme for intensive care units that improves patient outcomes; a clinical pathway that reduces length of stay; practice guidelines that enable a hospital to gain contracts with Leapfrog Group members. Physicians seeking to replace the income lost to managed care contracts and Medicare/Medicaid might be tempted to capitalize on their process improvements. Indeed, institutions such as universities are already intensifying their efforts to commercialize the results of the research conducted by their faculty and employees, and the prospect of business process patents may become impossible to resist.

In effect, the mantra might become pay an admission fee to see one, pay a royalty to do one, and buy a franchise to teach one. The implications for the medical profession are immense:

- Many practicing physicians will face the dilemma of whether to pay a royalty to use a new procedure (likely with no higher reimbursement) or continue to use an old procedure that is less efficacious.
- Physicians will be less willing to share their innovations with their colleagues until they have secured a patent, thus slowing the diffusion of improvements in medical practice and adding another dimension that is turning colleagues into competitors.
- Hospitals and physicians will fight over who has to pay—the surgeon, the surgical team, or the hospital—if a physician on the medical staff uses a new patented surgical technique in the operating room.
- Physicians and their affiliated institutions will fight over who “owns” the new triaging processes used in the emergency department—the physicians and other clinicians who developed it, or the hospital in which it was created.
- The potential for conflicts of interest and of commitment will mushroom, especially if physician innovators link up with businesses that do not share medicine’s collegial ethic.

If business process patents become popular in healthcare, the law of unintended consequences will have prevailed, as legal decisions meant to promote the new economy will irretrievably damage the medical profession.

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**References**

13. 35 USC 287(c). United States Code. Title 35, Part III, Ch 29, Sec 287(c). Limitation on damages and other remedies; marking and notice.