PATENTQUARTERS[™]

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Are Patents Good or Bad for Medicine?

We have great respect for the medical profession, but some of its professionals do not understand or appreciate patents. Yet, our patent system can help create improved medical treatments.



According to the American Medical Association (AMA), a basic tenet of medical ethics is that discoveries and advances in medical care should be freely shared and openly disseminated. This ethical principle has served to make discoveries readily available, at minimal cost, for use in the diagnosis and treatment of patients.

The patent system, in fact, encourages the professional duty of doctors to publish and disseminate medical advances. Patents exist to promote the progress of science, *including medicine*. Patent publications relating to medical innovation can help future researchers understand the prior art, then experiment to develop better medicines and devices. The resulting innovation can be protected by patents, which create economic value. The prospect of high economic value gives the incentive to innovate in the first place. As much as medical companies might seek to improve the welfare of humans across the globe, the reality is that medical R&D is extremely expensive; without the possibility of financial reward, the R&D may never be justified in the first place.

The scope of patentable subject matter should not extend to a physician's consideration of a scientific fact. For example, a patient's elevated levels of a certain metabolite may indicate a vitamin deficiency. Suppose that a patent was issued for the method of correlating the metabolite level with vitamin deficiency. In this case, a physician could be torn between the ethical requirement to properly diagnose and treat a patient, on the one hand, and the legal case of patent infringement, on the other. A good argument can be made that such a patent is legally invalid.

But what about something like medical devices? Medical devices certainly are patentable, right? Using the specific example of surgical devices, the AMA in their Opinion 9.09 states, "A physician may patent a surgical or diagnostic instrument he or she has discovered or developed." If a patent is obtained, then that physician can theoretically prevent other physicians from using the improved surgical device, even when their ethics suggest they should actually infringe the patent.

In *Pallin v. Singer* (1993), a doctor patented a sutureless cataract treatment and sought to develop a licensing business via royalties of \$4 per procedure. There was outcry and litigation, because other doctors believed that the improvement should vest with the profession and be *free*. The inventor-physician was clearly not trying to gouge the industry by asking for thousands or even hundreds of dollars in royalties per procedure. Rather, the asking price was a virtually negligible four bucks, an amount that a doctor might charge for a few seconds of his/her time!

In the coming years, in view of rapidly advancing development of new medicines and treatments, there could be more ethical/legal dilemmas involving patents. It would not be surprising if insurance companies even tried to stipulate maximum patent royalty rates. The U.S. government may attempt to step in where conflicts may otherwise be irreconcilable, or perhaps in the context of health-care reform.

We absolutely want to see improvements to medicine! We believe that patents can help bring about revolutionary changes that improve human health and quality of life. **PQ**

Recovery Act Provides Big Money for Innovation



The American Recovery and Reinvestment Act of 2009 was enacted by the 111th United States Congress and signed into law by President Barack Obama on February 17, 2009. This Act is providing a great deal of money that can help innovators conduct R&D.

If you are interested in funds available from the Recovery Act, you need to be aware that funding opportunities are being posted constantly and often do not give very much time before an application is due. Check out www.FedBizOpps.gov for all federal government contracting opportunities that exceed \$25,000. The site lists all major solicitations, contract awards, subcontracting opportunities, and foreign business opportunities. For actions related to funds made available by the Recovery Act, go to www.fbo.gov/index?s=opportunity&mode=list&tab=search and click "Yes" under the advanced-search options for Recovery Act.

Certain industries are able to significantly benefit from money available. For example, loans and investments into green-energy technology are a significant part of the bill.

Want to find out about federal grants? Search and apply for grants from 26 different federal agencies through the www.Grants.gov site. If you are interested in finding loans or benefits that you might be eligible for, visit www.GovLoans.gov. The site will help you determine the loans that may be right for you, and where to find more information about them.

A large portion of the Recovery Act funding is going to states, which in turn are distributing funds through grants, contracts, subsidies, and loan programs. Be sure to check Recovery Act funding available through your state and its programs. PQ

Do You Live in an Innovative City?

The methods of measuring the "innovativeness" of a region take many forms, including metrics which gauge the concentration of those inventing new ideas though patents. From data made available through the Office of the University Economist at Arizona State University, one can track over time the number of patent inventors per capita by metro area. A proprietary patent dataset was supported by the Harvard Business School.

Looking at the most recent 2005 data that averages values over the 2001 to 2005 timeframe, the metro region of Santa Fe, NM—home to many employees from Los Alamos National Laboratory—led the country with 4.44 inventors per 1,000 residents.

The top ten U.S. metros using this metric are as follows. PQ

Metro Area	Inventors per 1,000 Residents
Santa Fe, NM	4.44
Corvalis, OR	3.27
Boulder, CO	2.53
Burlington, VT	2.18
Fort Collins, CO	1.96
Blacksburg, VA	1.95
Rochester, MN	1.90
Ann Arbor, MI	1.83
Boise, ID	1.73
Charlottesville, VA	1.46



Supreme Court to Decide on Patentable Subject Matter

Bilski v. Doll is heading to the U.S. Supreme Court and will probably be heard later this year. The issue in the case is patentable subject matter—that is, what types of inventions even qualify for patent protection, regardless of novelty or non-obviousness. The Supreme Court has not decided a case involving patent-eligible subject matter since the early 1980s, when biotechnology innovation began to quickly emerge. The Bilski case involves business methods.

Bilski's invention relates to a method practiced by a commodity provider for managing (hedging) the consumption risks associated with a commodity sold at a fixed price. It is disclosed that energy consumers face two kinds of risk: price risk and consumption risk. The proliferation of price risk-management tools allows easy management of price risk. However, consumption risk (e.g., the need to use more or less energy than planned due to weather) is said to be not currently managed in energy markets. Consumption risk is the problem addressed by the invention, as summarized in the following figure from the patent application.

Bilski's claimed process essentially comprises these steps:

- (a) initiating a series of sales or options transactions between a broker and purchaser-users by which the purchaser-users buy the commodity at a first fixed rate based on historical price levels;
- (b) identifying producer-sellers of the commodity; and
- (c) initiating a series of sales or options transactions between the broker and producer-sellers, at a second fixed rate, such that the purchasers' and sellers' respective risk positions balance out.

The Examiner stated, during patent examination in the USPTO, that the invention according to claims 1-11 is not implemented in a specific apparatus, merely manipulates an abstract idea, and solves a purely mathematical problem. The Examiner rejected Bilski's claims pursuant to 35 U.S.C. §101, saying that the invention does not fall within the technological arts and therefore is disqualified from possible patent protection. The Examiner did not care whether the process is actually novel and non-obvious over prior art.

Bilski appealed the rejection to the Board of Patent Appeals and Interferences, which is essentially the U.S. administrative patent court. The Board agreed with the rejection. The case then went to the U.S. Court of Appeals for the Federal Circuit, which also agreed with the USPTO.

The U.S. Court of Appeals for the Federal Circuit did more than just agree with the prior decision. They also came up with a new test to determine patent eligibility for inventions. The test is that, to be patentable, a process must be tied to a particular machine or apparatus, or transform a particular article into a different state or thing (the "machine-or-transformation" test).

The Supreme Court decided to hear this case because there is legal precedent declining to limit patent eligibility in this manner. The Federal Circuit's machine-or-transformation test for patent eligibility could effectively foreclose meaningful patent protection to many business methods, including previously issued patents.

On the other hand, patent applications can be drafted with the machine-or-transformation test in mind, in case the Supreme Court does not reverse. To the extent possible, business methods, software concepts, web-based processes, and so on should always be tied to a particular computer rather than generically tied to a local server or the Internet. Stay tuned... **PQ**

Money Problems at the Patent Office

The problems within the U.S. economy this year have now reached the USPTO itself. Fewer new patent applications are being filed, and fewer discretionary fees are being paid (e.g., maintenance fees). We may see a temporary or permanent increase in certain fees for patent prosecution.

The U.S. Senate passed the House-passed version H.R. 3114, a bill that allows the USPTO to borrow up to \$70 million from 2009 trademark fees to avoid furloughs and layoffs in patent operations. President Obama is expected to sign it into law.

The bill authorizes the USPTO to establish a temporary surcharge on patent fees, to take effect no later than September 2011, to enable the agency to collect up to \$70 million in extra patent fees in order to pay back the borrowed trademark fees. The percentage increase in patent fees resulting from a surcharge apparently would be small, because patent fee income is much larger than trademark fee income at the USPTO. The bulk of the USPTO's \$1.9 billion annual budget is supported by patent fees.

Given the significant backlog of patent applications at the USPTO, and fairly recent efforts to hire more Examiners and try to retain existing staff, layoffs would be very unfortunate. **PQ**

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