

How Changes in Patent Law May Affect Doctor Inventors

Aylin Z. Kim

Invention is central to American jobs, competitiveness, and prosperity. After the Cold War, nations adopted market practices that produced a global economy more interconnected than we have ever known. In today's world, many nations compete very well on the basis of cost or quality. It is the ability to innovate—to create new high-value, high-margin goods and services—that sets a country, state, region, or industry apart (3).

Because the acquisition of new technologies and information is the driving force of innovation and economic growth worldwide, Intellectual Property (IP) rights are becoming central to the modern economy. This is particularly true in the context of current global challenges that include economic recession, the challenges of climate change, and public policy issues such as health and food security. In all of these cases, human creativity and inventiveness will be essential to finding solutions for a sustainable future, and IP rights are an important tool for stimulating and rewarding that creativity (7). Neurosurgery is inherently tied to technology development and IP; hence changes in the IP space may have profound effects on future inventions and thus the future of the field.

The National Summit on Competitiveness, Statement of the National Summit on Competitiveness: Investing in U.S. Innovation, from December 2005, has one fundamental and urgent message: if trends in U.S. research and education continue, the nation will squander its economic leadership, and the result will be a lower standard of living for the American people. The actions recommended in the document are as follows:

- Revitalize fundamental research.
- Expand the innovation talent pool in the United States.
- Lead the world in the development and deployment of advanced technologies.

Of all the patents granted over the past 20 years around the world, 6.3 million remained in force in 2007. Residents of Japan and the United States own approximately 47% of this total, showing that there is a strong relationship between the volume of patent filings and the level of GDP and investment in research and development. In 2007, filings at the EPO (European Patent Office) numbered 131,000, USPTO received 234,000, and Japan's Patent Office had the largest number at 321,000 (8).

Preliminary figures for 2008 indicate that growth rates in the number of applications for new IP rights are tending toward zero, or declining, as the recession takes full effect. History has shown, however, that companies and countries that continue to invest in new products and innovation during times of economic recession will be those that will be best positioned to take advantage of the recovery, when it arrives (7). Based on the trends, it is more

important now than ever that the United States continue to innovate.

Data on international patent applications submitted through the Patent Cooperation Treaty (PCT) provides clarity on where the United States currently stands. For 2007, the United States applied for more than 126,000 patents whereas Japan (no. 2) had 67,000 of the total worldwide pool of 430,000. However, the Republic of Korea and Japan are each filing more than 2600 resident patents per million of population, whereas the United States is ranking third at 800 (7). Therefore, when the effects of country size are eliminated, it becomes clearer that the United States is lagging.

When we look specifically at medical technology patents filed through the PCT (2006), we see that 46,000 of 123,000 (35%) originated in the United States, which far outnumbers any other country. In 2008, the United States also led the world in the number of published Medical Technology PCT applications (6067 vs. 1324 in Japan, which was the second highest) (7). In 2009, more than 3169 utility patents related to surgery (6) alone were filed in the United States.

Historically, the United States' ability to innovate stems from its "soft infrastructure"—laws, capital markets, and culture. According to the Small Business Association, small firms "produce 13 times more patents per employee than large patenting firms; these patents are twice as likely as large firm patents to be among the one percent most cited." Individuals are incentivized to think independently, outside the box, as leaders in their industry, and by the users who demand new products and embrace innovation. Every day, neurosurgeons and physicians in general are challenged with a health problem that they first must diagnose and then seek to solve. They play a key role in helping medicine advance by finding ways of improving existing products or determining an unmet market need. Their ideas become inventions when they are diligently worked on to bring the invention from concept to practice. In fact, physicians contribute to medical device innovation, accounting for almost 20% of approximately 26,000 medical device patents filed in the United States during 1990–1996. Moreover, two measures indicate that physician patents had more influence on subsequent inventive activity than nonphysician patents (1). Famous physician-led inventions include the Fogarty balloon catheter, Robert Jarvick's permanently implantable artificial heart, and Damadian's magnetic resonance imaging scanner.

However, oftentimes physicians are too busy to pursue their invention, so the idea gets noted in a lab notebook and then put on the shelf, waiting for a larger entity to proceed with its development. Under current U.S. Patent Law, as long as the invention is novel and of nonobvious subject matter, the physician is deemed an inventor and is entitled to a patent. Should another entity file a patent on the same invention, it is the first inventor, not the first to file the invention, who receives patent priority. This definition encourages innovation without requiring a major commitment (time and cost) to patent and commercialize.

The Patent Reform Act, first proposed in 2005, would make the patenting process more costly and difficult. One component of the act is aimed at switching U.S. patent priority from the “first to invent” system to the “first to file” system that is used in most other countries. The objective is to bring better harmony between U.S. and non-U.S. patent law, thereby making American inventors more competitive in the global IP landscape. It would theoretically also put a greater emphasis on commercialization rather than innovation alone by rewarding those who file first with market exclusivity.

The 2010 Act currently under review includes this provision, so it is worth knowing potential repercussions for U.S. inventors. Some argue that the change would negatively impact the small business/individual inventor most because corporations would more frequently win the race to develop an idea to practice so that it can be aptly filed for patenting. If we examine the number of foreign inventors seeking U.S. patents to get an indication of what would happen under the reform, we see that foreign corporations applied for 17,980 patents in 2008, whereas foreign individuals applied for only 2190. For the same year, U.S. resident statistics were 16,401 and 5845 respectively (5). Assuming that foreign individuals have less incentive to apply for U.S. patent protection than foreign corporations, this variation is partly accounted for. However, data on the percentage of patent applications that are actually granted is more foreboding on what the change in patent law would translate into. Although foreign and U.S. corporations have similar statistics (38.2% and 37.7%, respectively), foreign individuals attained only 4.9% of their applications versus the 18.6% of U.S. resident individuals. Clearly, the quality of their proposed inventions is not the same. Their “soft infrastructure” is different, and this is what is propelling U.S. individuals to eventually build the next large corporation.

Furthermore, along with the proposed change to U.S. law in priority is a change in the definition of novelty. Under current U.S. law, there is a 1 year grace period to file a patent application ensuing publication of the

invention. A change to the absolute novelty system to mimic non-U.S. law would immediately disqualify any invention that has been publicly disclosed prior to filing a patent application (2). Public disclosure includes all public uses, sales, offers for sale, publications, and other disclosures available to the public as of the filing date, other than publications by the inventor within 1 year of filing. The current patent system allows the inventor to gauge market interest prior to patenting and still balances inventor and society interest by providing exclusivity to the inventor (up to 20 years) in exchange for disclosure of the invention to the public.

Current patent law encourages altruistic innovation. The proposed change incorporates a new administrative proceeding—called a “derivation” proceeding—to ensure that the first person to file the application is actually a true inventor and that the application was not derived from another inventor. Any such proceeding request may only be made within 12 months after the date of first publication of an application containing a claim that is the same or is substantially the same as the claimed invention (4). Furthermore, not only is this procedure very costly but physician inventors would still need to take extra precautions when disclosing their idea to potential investors/collaborators because the threshold to inventorship would be much further along the process than it is currently. Essentially, the individual generating ideas may no longer be the patent holder because there would be less certainty that ideas can be protected on the path to commercialization.

Medical device technology and the sector as a whole are leading industries within the United States, providing lots of jobs and superior patient care. Adequate IP protection is critical for the sustained viability of the medical device industry, patient care, and fundamental innovations in general. Neurosurgeons are integral to the invention process and have the responsibility to continue to keep the United States on the forefront of medical technology innovation. As a result, inventors and innovators will need to keep close watch on these developments in patent law.

REFERENCES

1. Chatterji AK, Fabrizio KR, Mitchell W, Schulman KA: Physician-industry cooperation in the medical device industry. *Health Aff* 27:1532-1543, 2008.
2. Radack DV: Patent harmonization: creating uniform patent laws. *JOM* 49:66, 1997.
3. Task Force on American Innovation, 2010. <http://www.innovationtaskforce.org/>.
4. The Patent Reform Bill, S-515.
5. U.S. Patent and Trademark Office. <http://www.uspto.gov/web/offices/ac/ido/oeip/taf/stmech.htm>.
6. U.S. Patent and Trademark Office Patent Technology Monitoring Team (PTMT) Patenting By Geographic Region (State and Country), Breakout by Technology Class, Count of 2005-2009 Utility Patent Grants.
7. World International Property Indicators, 2009 edition WIPO Publication No. 941(E)
8. WIPO Statistics Database and World Bank (World Development Indicators), June 2009.

1878-8750/\$ - see front matter © 2010 Elsevier Inc.
All rights reserved.
DOI: 10.1016/j.wneu.2010.09.023

Abcc8 Suppression Reduces Secondary Injury After Experimental SCI

Harshpal Singh and Michael Y. Wang

With an annual worldwide incidence range of 10 to 83 per million people per year, spinal cord injury (SCI) exacts a devastating medical, social, and economic impact. To date, much research has been directed

at limiting secondary injury patterns occurring after the initial injury, with numerous targets already identified. However, the search for new potential targets for therapeutic intervention continues.