Medical Patents and How New Instruments or Medications Might Be Patented

by Denise L. Mayfield, MS

Introduction

A patent is a legal instrument that conveys to the patentee (the patent holder) the right to exclude others from making, using, selling, or offering to sell the subject matter of the patent “claims.” Medical patents, for purposes of the present article, will be defined broadly to include patents that relate to pharmaceuticals; methods of making and using them; medical treatment regimens; surgical procedures; medical devices; health care information technology for hospital and health care management systems (including software for managing hospital bed utilization, care distribution, medical staff allocation, and cost containment), and combinations of these (e.g., an “app” that includes the use of a “medical device” like an attachment that interacts with an iPhone for preforming a medically related function/measurement, such as blood pressure measurement, insulin level monitoring, etc.).

A patent provides the patentee a unique marketing advantage for his/her invention, as others may be prevented from utilizing any aspect of the patented subject matter unless a license, or other “right to use” is conveyed. Thus, a patentee may effectively preclude potential competitors from making, using or selling the patented item or process, while providing the patentee a mechanism (e.g., licensing) for capturing the value of the invention and incurred development costs.

In the United States, the main categories of patents are utility patents (machines, processes/methods and manufactured objects), design patents (ornamentation), and plant patents (under the Plant Variety Protection (PVP) Act, not to be confused with a plant utility patent). The present article will focus on medical “utility” patents.

Biotech companies, universities and physicians use patents to protect their patented inventions against competition for a finite number of years. Sophisticated patent and/or technology licensing strategies and other arrangements (e.g., collaborative research agreements), with one or more other parties, are vehicles that the patentee may use to generate revenue. Financial rewards are available to patentees who create new products in the form of higher product sale prices. However, critics of this system argue that the extraordinarily high prices of new drugs/new medical products protected by a patent seriously limit access of the best forms of health care to poorer populations, and are therefore unethical.

The Food and Drug Administration (FDA), upon approval of a New Drug Application (NDA), provides medical product applicants perhaps the most important element needed to bring the product to the public. The FDA is responsible for assuring that a new drug or new product is safe and effective. The FDA approval process requires compliance with rigorous testing programs (clinical trials) and compliance with a lengthy administrative approval process, and is most times very costly. The FDA approval process oftentimes runs concurrently with the patent application procurement process before the United States Patent and Trademark Office (USPTO). Because of the occasionally lengthy time frame involved in obtaining FDA approval, the period during which a patented drug or device may be commercialized under the effective patent term may be shortened. To correct for this delay, the patent term restoration provision was created under the Drug Price Competition and Patent Restoration Act, also known as the Hatch-Waxman Act, under 35 U.S.C. § 156. This provision grants patent term extensions for patents.

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MEDICAL | LEGAL

on human drug products, medical devices, food and color additives, and processes for making or using such products. This provision serves to restore a part of the patent term to the patentee for the period over which the patentee was unable to sell or market a product while awaiting FDA approval. The Hatch-Waxman Act also provides a “safe harbor” provision for patentees under 35 U.S.C. § 271(e)(1), and serves to shield a party from a charge of patent infringement for making, using, offering to sell or selling another’s patented product/process where these activities are conducted for the purpose of developing and submitting information related to obtaining FDA approval for a product.

Many types of biotechnology patents (e.g. regenerative medicine, human manipulation, embryonic stem cells) are extremely controversial. The cost of developing products related to these kinds of medical patents is often extremely high, and years are typically required before the product is ready to be sold to the public. However, because of the profound impact this class of inventions has on diseases historically considered untreatable and/ or fatal, and the immense improvement many of these products make to our quality of life, the choice of pursuing these kinds of medical patents continues to be made by companies and individuals involved in the health care industry around the world.

Obtaining a Patent

The first step towards obtaining a patent is to file a patent application with the USPTO. With the implementation of the America Invents Act (AIA), the first inventor to file a patent application has priority over another person who gets a patent application filed after that initial date, but who nonetheless may assert he/she was the first to “invent” the technology covered in the patent application. With this change in the law (prior to AIA, the race to get a patent application on file was not paramount to establishing right of priority), it is important for the potential patentee to expedite the filing of his/her patent application on the earliest date possible.

1. Requirements of “patentability”—“Patentable subject matter,” “novelty,” “non-obviousness,” and “enablement.”

In drafting the patent application, one of the first questions to ask, especially in the field of medical patents, is does the invention qualify as “patentable subject matter”, as that term is defined (and interpreted) under the patent statute. If the answer is yes, then the potential patentee must determine if the invention is “novel” (e.g., it was never disclosed to another before the patentee was able to get a patent application filed). A patent search should be done by a registered patent professional to determine of the invention is “novel.”

The subject matter of the invention must also be “non-obvious.” The interpretation of what is “non-obvious” follows a strict legal definition that differs from what might be considered “non-obvious” from only a scientific point of view.

The subject matter described in the patent application must also be “fully enabled” and meet the “written description” requirement for the invention that is described and claimed in the patent. Section 112 of the patent statute requires that a patent application include a detailed description of the invention, including the process of making and using it, such that this description is written in a manner that a layperson would be able to understand and practice the invention.

Once the patent application is filed and the formal examination process (called “patent prosecution”) begins, these statutory legal requirements for a patent will be assessed by a patent examiner.

2. The Provisional Patent Application (PPA) and the Non-Provisional Patent Application (NPA)

An initial patent application filing may take the form of a provisional patent application (PPA) or a non-provisional patent (NPA) application. Both the PPA and the NPA will provide the applicant with a “filing date.”

However, the PPA will not be examined (i.e., will not begin the “patent prosecution” process). A PPA will expire at the end of one (1) year, but the “priority” of the filing date obtained for the PPA may be preserved by filing a NPA if the NPA is filed before the expiration date of the PPA. The less expensive PPA alternative to filing a NPA is used by many entrepreneurs and/or academic institutions, giving them time to gauge commercial interest in the invention, among other things.

The PPA filing includes a USPTO form, termed a “cover sheet” (identifying information, the names of all inventors), a written description of the invention and drawings (as described above), and is submitted along with a relatively modest filing fee. The filing of a PPA alone will not result in the issuance of a patent.

The NPA must include a written description of the invention and drawings (as described above), and
must include at least one “claim.” A patent “claim” is a highly stylized sentence that defines the subject matter the inventor regards as the invention (the “novel” and “non-obvious” elements). The features/advantages of the invention as defined in the “claim” should be readily discernable in the detailed description (i.e., the “specification”) of the patent application. The NPA filing also requires an oath or declaration of the inventors to be filed, the payment of additional fees (“search” and “examination” fees), drawings (if needed for an understanding/full disclosure of the invention), and in some cases, a “sequence listing” (in the case where the invention relates to or includes a novel nucleic acid or novel amino acid sequence, or includes either of these; e.g., a genetic molecular construct used to make a new pharmaceutical).

3. The NPA USPTO Patent Prosecution Process

Once the NPA is filed, an examination, or “prosecution” process before the USPTO will begin. This process can take anywhere from one to six, or more years, and is a series of “office actions” from the USPTO examiner, and responses and amendments from the patent practitioner, ultimately identifying a patentable set of “claims.” A potential patentee is not guaranteed that a patent will ever be granted to the invention sought to be protected, and on occasion, a potential patentee will decide to abandon the process because of time and financial constraints.

In the event patentable claims are identified through the patent prosecution process, a Notice of Allowance will issue from the USPTO, identifying the subject claims that are to be allowed, and identifying a date on which an “Issue Fee” must be paid. Soon after the Issue Fee is paid, the patent will officially “publish” on a specific date. The patent becomes enforceable for a term that begins on the date the patent is issued, and ends on the date that is 20 years from the earliest priority date (filing date). The beginning date for measuring this 20-year span does not begin on the filing date of the PPA, but instead begins on the filing date of the earliest filed NPA to which priority is claimed.

Preparing and “prosecuting” a proper patent application may be accomplished by working with a registered patent professional (patent attorney or patent agent). A patent professional is one who has a Registration Number issued by the USPTO, which evidences that he/she has taken and passed a USPTO Examination. This examination tests the person’s knowledge of the patent laws and procedures, and establishes the person possesses at least the core knowledge of the patent laws. Attorneys who are not registered patent attorneys cannot represent a client before the USPTO. A patentee can check to see if the person the patentee is working with is a registered patent attorney or agent on the USPTO website, at no cost.

To make the process as efficient as possible, a patentee may prepare and provide to the patent professional some written form describing the invention, such as an “Invention Disclosure” document. In this way, both the inventor and the patent professional may develop a patent application more quickly, and the application may be filed more quickly to obtain the earliest filing date possible. The patent application preparation process is most effective when the patent professional has a technical background or experience with subject matter similar to the subject matter of the invention. Here, due diligence in the selection process of the patent professional should be done to assure he/she has the appropriate technical background needed to understand and draft the potential patentees patent application.

On June 29, 2016, the USPTO announced a new “fast-track” review process for patent applications related to cancer treatments, in support of President Obama’s “cancer moonshot” program to combat cancer. More than 1.6 million Americans are estimated to be diagnosed with some form of cancer in 2016, and the “fast-tracking” of medical patents related to cancer is anticipated to spur faster commercial development of new cancer drugs/therapies.

Types of Medical Patents

While not intended as an exhaustive list, the main categories of “medical patents” described here are medical devices, chemical/pharmaceuticals, health care information technology, surgical methods, and regenerative medicine technologies.

1. Medical Devices

This category of medical patents includes physical devices used by physicians, hospitals, and an other providers, and includes such items as diagnostic instruments, stents, implantable devices (prostheses), surgical tools, surgical suite equipment (sterilization hoods, patient lifts, patient or monitoring devices), drug and food delivery devices and systems (IV bags, tubing,
patient feeding apparatus, assisted breathing equipment, etc.), heart/breathing monitoring equipment, artificial heart valves, heart pacemakers, and many others.

Patented products in this category generally have smaller profit margins (compared to new pharmaceutical drug products, discussed below), but tend to be “commercializable” much sooner that other types of products under the “medical patent” umbrella.13

2. Chemical Products and Pharmaceutical Drugs

Inventions under this category include chemical compounds (vitamins, compounds used to manufacture drugs, tissue sterilization and cleaning materials) and the more complicated group of products categorized here as pharmaceuticals. Pharmaceuticals include materials that will be used to treat infectious disease (e.g., antimicrobials, vaccines, antibiotics), or a physical condition (such as conditions related to aging, chemical/hormonal imbalance, e.g., insulin/diabetes, high blood pressure, dementia, Alzheimer’s, Parkinson’s disease).

Patents that relate to pharmaceutical drugs and methods of using pharmaceutical drugs form an important part in the economic success of a pharmaceutical company, and of the pharmaceutical industry as a whole. Among other things, medical patents in these and related categories permit businesses to recoup the huge costs associated with research/development, clinical trials, patent associated expenses and regulatory approval process costs, by providing a finite period during which the patent protected products may be commercialized free of competition from other products in the same space as the patentee’s patented product.

3. Health care Information Technology

Patents that focus on streamlining the flow of medical history information through electronic medical records, patient data picture archiving, health information exchange systems within or among hospital systems and/ or physicians, web-based medical software applications, computerized physician order entry and digital imaging, are some examples of healthcare information technology related patents. This category of medical patents has been the fastest growing category of medical patents in recent years, and the number of medical patents in this area is expected to continue to grow.

The exponential growth of medical patents in this category stems partially out of a need to find new methods and systems designed to contain and manage medical costs more efficiently.14 Medical patents in this category function to reduce the administrative costs of providing health care, while at the same time increasing the ease of access to medical services for greater numbers of patients.

4. Medical and Surgical Methods

This category includes, for example, methods and techniques for providing and performing medical and surgical procedures, as well as streamlined procedures for administering care or diagnosing a medical condition, whether or not the condition is medically categorized as a disease.15 Surgical methods for repairing a rotator cuff, as well as methods for performing spine surgery to avoid contact with nerves, are some specific examples that fall within this category of medical patents.

While the United States allows the patenting of medical procedures and treatment methods, more than 80 countries exclude medical procedures from patentability.16 In these situations, a “second medical use” patent claim format may be used as an alternative for obtaining roughly equivalent patent protection in these countries.

5. Regenerative Medicine

This category includes stem cell therapeutics, as well as tissue transplant technologies, including knee cartilage replacement rejuvenation and cosmetic reconstructive procedures. Stem cell therapeutics is considered to be the next best and biggest medical frontier in human health care. As with any new medical treatment modality, these technologies are not only confronted with existing regulatory and legal requirements, but in many cases face additional, newly implemented requirements (by the FDA and USPTO, for example). Unfortunately, this results in even greater expense and time delays in bringing these innovative technologies to the public.

Stem cell therapeutics have been described for the treatment of arthritis, loss of hearing, cancer, and other serious conditions for which existing medical science has poor treatment alternatives. In the United States, the world of accessible stem cell therapeutics continues to lag behind other countries for a number of reasons, one of which is the added burden of the path to market. The Center for Biologics Evaluation and Research (CBER), a specialized department within the FDA that regulates biological products including stem cell products, has approved some limited stem cell related products, and the number of these approved products is expected to grow as historical clinical data is made available. Growing societal
acceptance (among both doctors and patients) of these types of alternative therapeutic modalities has resulted in a wider acceptance of these alternative treatment modalities, with the delay to access of these modalities in the United States driving many to seek treatment elsewhere.\textsuperscript{17}

**Recent Trends in Medical Patents**

Between 2009 and 2014, there was a 170\% increase worldwide in medical device patents granted in the United States.\textsuperscript{18} The dramatic change in the number of patents granted started in 2010, which corresponds to a jump in the number of patent applications filed in 2007. This was in part influenced by the Affordable Care Act signed into law in 2010, and the medical device tax that became effective January 2013. Most patents granted during this period were of domestic (US) origin; 68\% coming from within the U.S. in 2014. California obtained the most medical device patents, followed by Minnesota, then Massachusetts.

A number of notable medical patent developments have recently made headlines. Some of these medical patents include:

- The superbug test: Australian patent received by Translational Genomics Research Institute (TGen) and Northern Arizona University (NAU).\textsuperscript{19}
- Reprogramming human skin cells: Converts human skin cells into engines of tissue regeneration (patent number 9,290,740).\textsuperscript{20}
- BioStack 4 Microplate Stacker: Unique technology associated with automatic microplate de-lidding and re-lidding (patent number 9,366,686).\textsuperscript{21}

A controversial Congressional bill recently introduced would shorten the exclusivity period for expensive biologic medications from 12 to 7 years.\textsuperscript{22} Rep. Janice Shakowsky (D-IL) introduced the bill on June 23, 2016 in an effort to allow manufacturers of drugs to market lower-cost versions of drugs more quickly to help reduce healthcare expenses. Biologic medications cost tens of thousands of dollars and are used to treat various forms of illnesses such as multiple sclerosis and cancer. Biosimilar versions of the drugs are predicted to cost between 10 to 30 percent less. Rep. Shakowsky cited data from the U.S. Department of Health and Human Services showing that reducing the exclusivity period for biologic medications would save taxpayers nearly $7 billion over the next ten-year period.

The 12-year exclusivity period was initially introduced as part of the Affordable Care Act, and the White House has routinely proposed shortening the period to 7 years to save federal health care dollars.

**Physicians and Medical Innovation—Patented Surgical Methods and Other Types**

Physicians continue to create new medical innovations that find their way into granted medical patents. In addition, the actions of physicians and surgeons have become implicated in establishing liability for patent infringement when disputes arise between companies involved in obtaining and commercializing surgical methods in a medical patent. Legal protections exist that shield physicians/surgeons from patent infringement liability and other types liability in some circumstances. For example, in Warsaw Orthopedic, Inc. v. NuVasive, Inc. (decided on June 2, 2016), a U.S. Court of Appeals explored whether NuVasive could be charged with infringement of Warsaw Orthopedics’ patent as a consequence of teaching physicians/surgeons how to perform the procedure protected in Warsaw’s existing patent.\textsuperscript{23} In this case, evidence that the surgeons were instructed by NuVasive on how to perform Warsaw’s patented surgical procedure was used to support a charge of patent infringement against NuVasive.

Medical practitioners are shielded from patent infringement liability for performing a medical/surgical procedure that infringes a patented medical procedure on a body under 35 U.S.C.A. § 287(c).\textsuperscript{24} However, medical practitioners are not shielded from liability when performing a medical activity using a patented machine or medical device, including a pharmaceutical device. Device manufacturers could be found guilty on an inducement to infringe under 35 U.S.C. § 271(b) if they direct or influence doctors to infringe on another company’s existing patent.\textsuperscript{25} Device manufacturers who provide physicians with tools/devices and instructions for using those tools/devices in a method that infringes another’s patent could be liable for inducing the infringing activities of those physicians. Thus, providing instructions on how to perform a patent-protected method may be considered infringement-inducing conduct.\textsuperscript{26} On a related note, caution should be taken when physicians become shareholders of pharmaceutical
companies and/or medical device manufacturers, so as to preserve the individual physician’s immunity to patent infringement under the statute, among other potential protections to liability.27

A Case Study on Insulin: From Patent-Protected Product to Non-Patent-Protected Product.

Significant medical patents expired in 2015. The top 10 patent expirations risked $44 billion in sales for holders of those patents, from the possibility of generics being released into the market and being consumed by the public instead of the patented drugs and devices.28 However, generics are expected to take a much smaller bite from the drugs losing exclusive access to their respective markets because several involve biotech drugs. Even if biosimilar drugs make it to market, their impact on sales will be limited because they may not be automatically substitutable for the brands they are seeking to replace.

Insulin was one of the more significant products that lost patent protection in 2015. Companies are racing to produce new forms (analogs) and formulations of non-native insulin to obtain new patents, and in this way, secure a new “exclusivity” market for the new insulin-like products.29 Due to the expiration of the patent, off-patent (generic) insulin will become much more affordable as the insulin product may be made freely by competitors at lower prices. From a public healthcare policy perspective, greater availability of insulin products will improve health care for a large population of diabetic persons previously unable to afford the cost of this medication. Pharmaceutical companies will now need to commit greater resources to research and development of new drug products, and to patent these new products, in order to maintain the level of profitability they had become accustomed to.30

Innovation vs. Culture and Societal Norms

The use of regenerative medicine/stem cell technologies in patents is an international source of heated controversy, and there is a stark division among countries on what is and is not protectable by patents related to this subject matter.

In the United States, three stem cell patents are held by the Wisconsin Alumni Research Foundation on primate and human embryonic stem cells (hESCs).31 Two patents dominate most of the anticipated commercial uses of hESCs in the U.S. While many scientists work with human embryonic stem cells in conducting non-profit, federally funded research, few have been able to reach agreements with providers and/or commercial partners to conduct the collaborative research needed for human treatment.

The landscape of intellectual property law related to hESCs differs between various countries. For instance, in Canada there is a complete ban on granting patents on hESCs.32 The United Kingdom bans patents directed to totipotent embryonic stem cells (i.e., those stem cells that could theoretically turn into humans), while Sweden allows patents on all kinds of stem cells. New guidelines for stem cell research were released by the International Society for Stem Cell Research in May 2016.33 These guidelines relate to defining embryo research oversight projects, as well as supporting research entailing gene editing of nuclear genomes of human sperm, egg, and embryos.

In an effort to seek health care procedures and/or therapies not available in the United States, patients and their families have been willing to travel to those areas where they can be provided. The CDC estimates approximately 750,000 U.S. residents travel abroad for medical care each year.34 Clinics worldwide, especially in China, India, the Caribbean, Latin America, and the former Soviet Union, provide stem cell treatments for conditions such as autism, brain damage, cerebral palsy, Chron’s disease, diabetes, genetic disorders, Huntington’s, lupus, muscular sclerosis, Parkinson’s disease, spinal cord injuries, stroke, and cancer, among others.35 While some cancers have been shown to respond to stem cell therapy, sparse literature exists documenting the effectiveness of this therapy in treating these cancers or other ailments. Additionally, the content and quality of stem cell-containing preparations used by these clinics is often unknown and unregulated. A Harvard panel concluded that the practice of stem cell tourism hurts the legitimacy of the entire field of stem cell science and medicine. Clinics providing these treatments are often accused of financially exploiting desperate people with grave illnesses, people who many times after treatment are ultimately left in the same medical condition or worse.

Within the United States, a form of national medical tourism has sprung up related to access to medical cannabis.36 Twenty-five states have passed laws allowing some degree of use of marijuana, and 14 states have acted to decriminalize the substance in some degree.37 Alaska,
Colorado, Oregon and Washington have legalized the sale and possession of cannabis for both medical and non-medical use. Washington, D.C. has legalized personal use, but not commercial sale.

As with the controversies surrounding stem cell/regenerative medicine, the medicinal marijuana in the United States continues to face challenges. However, these challenges do not preclude the issuance of U.S. patents to medicinal (and non-medicinal) marijuana products and methods for making them, as over 970 THC- and cannabis-related patents have issued to date.**

Conclusion

Medical patents and innovations in health care improve the quality and delivery of medical care and the quality of life for millions of people around the world, and especially in the United States. Challenges remain in finding the most effective manner for making these advances available to individuals in greatest need, primarily because of cost constraints. The United States system governing innovation and implementation of medical patents, in balance with commercial interests and safety/efficacy concerns, while time consuming and expensive, provides a measured framework within which societal health care benefit through products created through medical patents may be realized.

References


8. 35 USC § 102(a).


10. 35 USC § 112.


26. Moulton, Elizabeth, Note, Inducing Infringement: the Interplay of Section 287(c) and Section 271(b), 13 Colum. Sci. & Tech. L. Rev. 206 (2011).


38. Two patents related to marijuana were recently granted in the U.S. in June 2016: patent number 9,376,367 for cannabinoid carboxylic acids and salts of those acids, and patent number 9,375,417 for transdermal cannabinoid formulations (a cannabis patch).