FROM BIRTH TO DEATH AND BENCH TO CLINIC

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CHAPTER 20

Intellectual Property and Biomedicine

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by Josephine Johnston

Framing the Issue

On April 12, 1955, after eight years of research and testing, Jonas Salk's polio vaccine was pronounced safe and effective. In the last century polio was a feared killer: an outbreak in 1916 left 6,000 American children dead and another 27,000 paralyzed. Two years following release of the vaccine, polio cases in the United States dropped by 90%, and since 1979 no cases of polio from the wild virus have been reported in this country.

Despite its enormous success, the polio vaccine was not patented. When asked who owned the patent on it, Salk famously responded, "Well, the people, I would say. There is no patent. Could you patent the sun?"

Although half a century old, Salk's argument is relevant today. The number of patents on materials and processes used in biomedical research is increasing. They are being sought and awarded not only for drugs and other medical products, but also for human cell lines, stem cells, human proteins, and genes (see chapter 15, "Gene Patents"). From 1990 to 2003 the number of U.S. patents more than doubled from about 80,000 to 169,000 per year. This increase has been particularly significant in the biological sciences, and, within that field, in genetics.

Biomedical patents are hotly debated. Is it acceptable to assert ownership over material derived from the human body? Do all these patents meet the legal criteria for patenting? What are the consequences for research—could patents slow the pace of innovation by restricting access to biological materials and processes? What are the consequences for lifesaving tests and treatments—could patents limit access to them?

HIGHLIGHTS

- The number of patents is increasing on biomedical materials and processes, such as cell lines, and methods of replicating them, such as cloning.
- These patents have advantages, such as providing the funds needed to develop and distribute needed therapies.
- They also have disadvantages, including driving up the cost of therapies and making them unaffordable to the poor.
- Ethical questions include the morality of "commodifying" the human body and the concern that patents could slow or prevent innovation by restricting access to important materials and processes.
- Many of the concerns about biomedical patents could be addressed by changing patenting and licensing practices.

The History of Biomedicine and Patents

Patents are intellectual property, which refers to "creations of the mind." Intellectual property includes inventions, literary and artistic works, symbols, names, images, designs, and trade secrets. Under U.S. patent law, any person who "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." In biomedicine, patentable inventions include materials, such as new drugs or new cell lines, and methods for deriving or growing them, such as extraction or

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cloning techniques.

Intellectual property shares many of the legal characteristics of tangible property—it can be bought, sold, licensed, exchanged, or given away. Patents are granted by national patent offices for a limited time, usually 20 years, depending on national law. When a patent expires (goes "off-patent"), anyone can make, use, or sell the material or method, subject to legal restrictions such as those covering the manufacture and sale of drugs. Copies of formerly patented drugs are called "generics."

Historically, patents have been considered a bargain between the individual inventor and society as a whole: in exchange for disclosing the invention to the public the person is given a time-limited right to control who makes use of it. (In patent terms, "invention" encompasses discoveries such as genes.) To obtain a patent from the U.S. Patent and Trademark Office, an individual must describe the invention clearly and show that it is useful (serves a purpose), nonobvious (it cannot merely be an improvement of an existing invention), and novel. A patent holder has the legal right to prevent others from making, using, or selling the invention without his or her permission, in the form of a license. Because patents are issued by national offices, people who wish to control the use of their intellectual property internationally need to apply for patents in different countries.

In some cases, patents issued in one jurisdiction will be rejected in another. For example, although Canada and the United States have very similar patent laws, Canada refused to grant a patent previously issued in the United States on a mouse genetically engineered to be susceptible to cancer. The Supreme Court of Canada decided that a transgenic mammal is not a "manufacture or composition of matter." The European Patent Office, which grants patents for up to 38 European countries, will not patent uses of human embryos for industrial or commercial purposes and has therefore refused patents involving human embryonic stem cells. The European Patent Convention allows individual nations to make laws prohibiting the patenting of inventions that are contrary to their public interest; France prohibits patents on "the human body, its elements, and its products, as well as knowledge of the total or partial structure of a human gene."

Patents and Access to Treatments

One of the greatest advantages of patents is that they generate revenue to develop new treatments and distribute them to people who need them. But a patent is no guarantee either that important drugs will be created or that they will be widely available. Despite the proliferation of patents, one-third of the world's population lacks access to essential drugs. In some cases, a patent can hinder access and, in other cases, have no effect on it.

Many treatments are unaffordable. Drugs, vaccines, and other treatments that are covered by patents are almost always more expensive than their off-patent counterparts. High prices can limit the access that people in need have to patented treatments. But even unpatented ones are not free, and they may be unaffordable to many people—it costs money to manufacture, distribute, and administer drugs. There usually needs to be the possibility of some profit for manufacturers and distributors to enter the market. All of these factors can drive up drug prices.

Appropriate treatments often do not exist. There is a lack of new treatments and vaccines for diseases that primarily affect people living in poor countries. The research and development pipelines for new drugs for diseases like tuberculosis are virtually empty. Market forces are, in part, to blame: poor countries seldom represent profitable markets. The same can be true for treatments for unusual diseases and conditions for which the market is too small to attract investors.

Some nations lack the infrastructure to distribute treatments. Even when treatments exist and are affordable—or free—access problems can persist. Poor countries often have poor health systems; they may lack the infrastructure for delivering treatments and the political will to make improvements. Against these obstacles, patents can do little to improve access to medicine.

Advantages and Disadvantages of Patenting

In some respects, the story of Salk's polio vaccine is unusual. The vaccine was developed in the laboratory of the university where he worked and was funded by the National Foundation for Infantile Paralysis, a charitable organization. Whatever his personal motives, Salk did not need the promise of a patent as an incentive to do the research that led to the invention of the polio vaccine. Neither did his university.

Today, developers of many drugs and treatments rely on patents to secure the commercial investment needed to bring these therapies from bench to bedside. Patents involving, for example,

methods of deriving cell lines are the products of numerous biotechnology companies, which license these inventions to generate the funds to conduct further research. Patents sometimes help biomedical research and development to move forward, but at other times they do nothing to enhance it or can even risk slowing research down. Weighing the pros and cons can be difficult.

Advantages of patents are that they can:

- Act as an incentive for biomedical research
- Secure funds to turn early discoveries into medical products
- Ensure that knowledge is disclosed to the public; unlike a trade secret, a patented invention is described in the public record
- Increase the chance that people will have access to the drugs and other medical products they need

Disadvantages of patents are that they can:

- Inhibit biomedical research by restricting access to materials and methods that are key to developing new treatments. Patents can also impede research if they create a cumbersome or expensive "tollbooth" through which researchers must pass
- Provide no incentive for biomedical research if there is no profitable market for eventual treatments, as is the case with some rare diseases or diseases affecting people in the developing world
- Drive up the cost of health care if patent holders charge excessive prices for patented diagnostic tests and treatments

Policy to Address Patent Problems

The recent increase in biomedical patents has fueled concerns about the legality and morality of patenting certain kinds of inventions. Critics argue that naturally occurring substances such as cell lines and genes do not meet the patentability criterion of novelty because their useful properties are neither new nor invented, but are inherent. In addition, now that DNA sequencing has become relatively quick and easy to do, some have argued that isolating a portion of DNA no longer meets the patentability criterion of nonobviousness—anyone skilled in genetics could do it.

Regardless of the legal criteria, some people believe that human biological substances should

Resources

Web sites

- www.who.int/intellectualproperty/en/ – Commission on Intellectual Property Rights, Innovation and Public Health, convened by the World Health Assembly in 2003. Includes the Commission's 2006 report, commentaries by the commissioners and others, and FAQs.
- www.wto.org – World Trade Organization. Gateway page for the trade-related aspects of intellectual property rights (TRIPS) agreement; includes WTO information on intellectual property, news and official records of TRIPS Council activities, and details of the WTO's work with other international organizations in the field.

Recent news

- John M. Maraganore, "Good for iPods, but Bad for Patients," *Boston Globe*, March 22, 2008.
- Bruce Japsen, "Bush Plan Would Allow Generic Biotech Drugs," *Chicago Tribune*, February 14, 2008.
- Todd Wallack, "Patent Awards Dip in State, U.S.," *Chicago Tribune*, January 2, 2008.
- "Patent Fight: Why a Bill on Reforming Protection of Inventions Is Worth Watching" (editorial), *Washington Post*, October 8, 2007.
- Barnaby J. Feder, "Keeping Arteries Cleared and the Courts Clogged," *New York Times*, October 4, 2007.

Further reading

- Erika Check Hayden, "Stem-Cell Patents Confirmed," *Nature*, March 17, 2008.
- Josephine Johnston and Angela Wasunna, "Patents, Biomedical Research, and Treatments: Examining Concerns, Canvassing Solutions," *Hastings Center Report* Special Report, January-February 2007.
- Josephine Johnston, "Health-Related Academic Technology Transfer: Rethinking Patenting and Licensing Practices," *International Journal of Biotechnology*, issue no. 2, 2007.
- Amanda L. Brewster, Audrey R. Chapman, and Stephen A. Hansen, "Facilitating Humanitarian Access to Pharmaceutical and Agricultural Innovation," *Innovation Strategy Today*, issue no. 3, 2005.
- Rachel Glennerster and Michael Kremer, "A Better Way to Spur Medical Research and Development," *Regulation*, Summer 2000.


See legislation appendix.


See online-only campaign appendix at www.thehastingscenter.org/briefingbook

not be patented because they already belong to humanity; they are "our common heritage." Another objection is that patenting parts of the human body inappropriately commodifies it, and that turning the body into a thing that can be owned is disrespectful to all humans. Finally, there is significant concern about injustice: that patented treatments will be unaffordable—and, therefore, unavailable—to some of the world's neediest citizens.

The patent system as applied to biomedical matter and processes is certainly not perfect. But some concerns, particularly those related to access to treatments, can be at least partially addressed with laws, policies, and practices designed to ease these problems and to offer additional incentives to innovate where patents alone do not suffice.

A number of measures have been implemented and others proposed. International treaties allow nations to override patents in health emergencies. Some national laws require that the results of publicly funded research be made widely available. Governments and other organizations can encourage research on needed therapies, such as a malaria vaccine, by setting up prizes for innovation related to them or by promising to purchase the therapies once they are developed. Other measures rely on voluntary action. Patented drugs can be sold at little or no mark-up in poor countries. Scientists and their employers can decide not to patent an invention that might prove useful to other researchers, or they might patent it but license it strategically to maximize its impact on future research and its availability to people in need.

This smorgasbord of policies and practices is necessary because different situations require different actions. Throwing out the patent system would almost certainly be harmful to biomedical research, but we cannot rely on it alone to stimulate needed innovation. New policies and practices will be needed periodically, aimed at easing any access problems and promoting important research.