Научная статья
УДК 347.771
DOI: 10.17323/tis.2024.22300

Original article

ИНТЕЛЛЕКТУАЛЬНАЯ СОБСТВЕННОСТЬ В СФЕРЕ МЕДИЦИНЫ: ВОПРОСЫ ЖИЗНИ И СМЕРТИ

MEDICAL INTELLECTUAL PROPERTY: QUESTIONS OF LIFE AND DEATH

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Аннотация. Медицинская интеллектуальная собственность стимулирует разработку и производство лекарств и устройств, которые спасают и продлевают жизни. Однако найти баланс между поощрением изобретательства путем предоставления монопольных прав и ограничением доступа к изобретениям теми же монопольными правами очень сложно. Недавно в Соединенных Штатах было принято законодательство, призывающее к важному эксперименту по нахождению этого баланса, фактически вынуждающее фармацевтических производителей и других новаторов заключать контракты с государственной системой страхования пожилых людей по ценам, которые были бы ниже после истечения значительной части срока действия патента.

Ключевые слова: патент, срок патента, страховка, здоровье, старение

Для цитирования: *Мэггс П.Б.* Интеллектуальная собственность в сфере медицины: вопросы жизни и смерти // Труды по интеллектуальной собственности (Works on Intellectual Property). 2024. Т. 50, № 3. С. 70–73; DOI: 10.17323/tis.2024.22300

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Abstract. Medical intellectual property encourages the development and production of drugs and devices that save and prolong lives. However, finding a balance between encouraging invention by granting monopoly rights and restricting access to inventions by the same monopoly rights is very difficult. Recently, the United States has adopted legislation calling for an important experiment in finding this balance, by effectively forcing pharmaceutical manufacturers and other innovators to contract with the public insurance system for older people at prices that would be lower after a substantial part of the patent term had expired.

Keywords: patents, patent term, insurance, health, aging

For citation: *Maggs Peter B.* Medical Intellectual Property: Questions of Life and Death // Trudi po Intellectualnoy Sobstvennosti (Works on Intellectual Property). 2024. Vol. 50 (3). P. 70–73; DOI: 10.17323/tis.2024.22300

In market economies, the main roles of intellectual property protection are simple. Patent, copyright, and trade secrecy encourage innovation. Trademarks encourage the production of goods and services of consistent high quality. In the case of patents and copyright, this encouragement comes from a government guaranty of a monopoly for a limited time, allowing rightholders to charge more for their products. However, economic theory teaches that every monopoly comes at a cost. Those that cannot afford to pay the monopolistic price cannot enjoy the goods or services.

Medical intellectual property encourages the development and production of drugs and devices that save and prolong lives. Such intellectual property raises two questions of life or death: (1) without adequate incentives, businesses will not invest the huge sums needed to discover new drugs (or new software-based medical devices) and to meet legal requirements of proof of safety and effectiveness and (2) to the extent that the incentives are provided by allowing monopoly pricing, some people may be excluded from the benefits of innovation or impoverished by its cost.

In economically-advanced countries government-subsidized insurance programs generally pay most of the cost of newly-developed drugs and medical devices. Such programs are highly popular with the public. The insurance programs have considerable bargaining power because of the large scale of their purchases. If two or more pharmaceutical companies have patented new drugs with similar health effects, as in the case of recent medicines for diabetes and obesity, an insurance program may bargain a low price with a company willing to supply the drug for all the beneficiaries of the program. However, where there is one new drug that is better than all others, as in the case of blood thinner, government insurance programs are faced with a difficult financial and political choice. Paying the price demanded by the intellectual property holder will have serious budgetary consequences. Not paying the price may have serious political repercussions amid disappointed public insurance beneficiaries.

The pharmaceutical companies maximize returns from their word-wide patent portfolios by engaging in price discrimination. In bargaining with public insurance programs, they settle for lower prices with the national insurance systems of poorer countries but demand higher prices from the insurance systems of richer companies. The United States has been an exception to this policy. A high percentage of United States government payments for expensive drugs are made by the Medicare program, which provides comprehensive protection to Americans 65 years old and older. Because of their advanced age, the program recipients have much more need for expensive patented drugs than younger citizens. The pharmaceutical companies years ago successfully lobbied for a prohibition banning the Medicare system from bargaining on price with makers of patented drugs. As a result, the United States has long paid much more for patented drugs than other economically advanced countries such as the United Kingdom and Germany.

Legislation adopted in the United States in 2022 (but scheduled to go into effect gradually, beginning in 2025), entitled the "Inflation Reduction Act" [1] will radically change this situation. Key provisions of this legislation provide for gradual elimination of the restriction on bargaining and its replacement with prices that are purportedly negotiated, but are in fact imposed. As is well-known, the United States, as a leading exporter of goods protected by intellectual property is an international leader in pressing for ever higher international legal protection for intellectual property. However, the new law moves away from the centuries-old tradition of equal terms of patent protection for inventions in different areas. Earlier United States legislation had allowed patent term adjustment for unusually long administrative delays in the Patent Office and for the delays necessary to meet the stringent regulatory standards for proving safety and effectiveness before a drug could be marketed. However, these extensions were designed to equate the effective term of protection of pharmaceutical patents with the effective term of ordinary mechanical patents for which patent office delays were shorter and approval by health authorities was not required. Thus, these exceptions really continued the tradition of a uniform term during which a patentee could recoup its investment.

The Inflation Reduction Act of 2022, on the contrary, has the effect of reducing the term of effective patent exploitation for many pharmaceuticals. Thus, the Act challenges the long-standing principle of equal terms of

protection for all inventions. Certainly, in view of the life-and-death and high-cost characteristics of pharmaceutical patent it can be argued that "one size fits all" protection is inappropriate. But the long tradition of equal-term protection has prevented the accumulation of economic data on the effect of the length of protection on incentives for development of new drugs. There is an immense amount of published information, for instance, on the optimum period of taking particular antibiotics for particular illnesses. But, in contrast, there is no data on the optimum period of patent protection for incentivizing the development of new antibiotics. Thus, the new law moves the United States into uncharted territory in that it effectively shortens the effective term of patent protection of the drugs for which publicly-financed insurance programs pay the most money.

The new law provides for a gradual transition, starting with a few drugs in 2025 to a maximum of 100 drugs subject to the law's price provisions. The drugs will be selected from those that have the highest total cost to the Medicare program. Obviously Medicare has exact accounting figures, so identifying the most costly drugs will be extremely simple.

There are a number of drugs that are exempted by the law even if they fall into the most costly category. There is an exemption for small-molecule drugs that are less than 9 years and for biological products that are less than 13 years from their approval for marketing. Put in plainer language, this means that the pharmaceutical companies will lose much of the benefit of patent protection between the 9 and 13 year cutoffs and the expiration of their patents. There is an exemption for drugs for which a biosimilar or a bona-fide generic is available. This exemption makes since, since if there is competitive market there may be no need for government price setting. There are a number of other reasonable exceptions, such as one for "orphan" drugs (drugs approved only for rare illnesses).

The law establishes what it calls a "maximum fair price." While the law presents this as an upper limit for negotiation, it is in fact a government-imposed price. The "maximum fair price" varies with the number of years beyond approval, reaching a low of 40% of the prior average sale price for drugs more than 16 years beyond approval. This is in essence another way of shortening the effective term of patent protection.

When negotiating the "maximum fair price" for a drug, the United States Department of Health and Human Services is required to consider the following factors:

> (A) Research and development costs of the manufacturer for the drug and the extent to which the manufacturer has recouped research and development costs.
> (B) Current unit costs of production and distribution of the drug.
> (C) Prior Federal financial support for novel therapeutic discovery and development with respect to the drug.
> (D) Data on pending and approved patent applications

The government is also required to consider the following types of evidence about alternative treatments:

> (A) The extent to which such drug represents a therapeutic advance as compared to existing therapeutic alternatives and the costs of such existing therapeutic alternatives.
> (B) Prescribing information approved by the Food and Drug Administration for such drug and therapeutic alternatives to such drug.
> (C) Comparative effectiveness of such drug and therapeutic alternatives to such drug, taking into consideration the effects of such drug and therapeutic alternatives to such drug on specific populations, such as individuals with disabilities, the elderly, the terminally ill, children, and other patient populations.
> (D) The extent to which such drug and therapeutic alternatives to such drug address unmet medical needs for a condition for which treatment or diagnosis is not addressed adequately by available therapy.

Because prior draft legislation had been wrongly attacked as creating "death panels" to deny health benefits to elderly patients, the law also provided:

> In using evidence described in subparagraph (C), the Secretary [of Health and Human Services] shall not use evidence from comparative clinical effectiveness research in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.

Not surprisingly, leading pharmaceutical companies have filed lawsuits alleging that the new legislation is unconstitutional [2]. To date, they have presented two main arguments: (1) that the effective shortening of the period of patent protection amounts to a taking of private property without adequate compensation and (2) that the requirement that the patent-holders sign a document designating a negotiated "fair price" violates constitutional guarantees of freedom of speech since it requires the companies to sign a false statement of fact to which they do not agree, since in their opinion the price is not negotiated but imposed and is not fair but unfair.

Assuming the law is held to be Constitutional, further litigation is inevitable over whether or not the government has properly interpreted and properly considered the factors listed in the law. The listed factors all incorporate very difficult issues of human judgment.

There are important unanswered international legal questions. First, does the new law violate the international intellectual property and investment protection treaty obligations of the United States? Second, if there are no treaty violations are other countries likely to respond with similar legislation?

And there are even more important unanswered economic, moral, and political issues. First, what is the effect of shortening the patent term on research on pharmaceuticals? Second, what reduction of research efforts dues to lessened intellectual property incentives would be an acceptable tradeoff for lower pharmaceutical prices?

REFERENCES

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