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Judul ; Social cost and benefits of patent protection for medicines: Case of Indonesian seaweeds hard capsule invention

Penulis : Mas Rahmah (Penulis mandiri)

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Social cost and benefits of patent protection for medicines: Case of Indonesian seaweeds hard capsule invention

Costo social y beneficios de la protección de patentes para medicamentos: Caso invención de la cápsula dura de algas indonesas

M RAHMAH

<https://orcid.org/0000-0002-9881-498X>

rahmah.arifin@gmail.com

University of Airlangga, Surabaya, Indonesia

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ABSTRACT

Seaweeds become natural medicinal sources. This essay aims at discussing the patent protection of seaweeds for medication. To achieve the goal, this essay will firstly describe the importance of seaweeds for medication and their prospects, before analyzing the patenting of seaweeds for medicines. It also reviews substantial social costs and benefits of seaweeds patent protection for medicines and suspects that patent on the innovation of medicines might turn a miracle into a social tragedy. The paper recommends the effective balance between the public interest and the legitimate private interest of patent holders and averts the perception of prioritization of private rights over public health.

Keywords: Medicines, seaweeds, social benefit, social cost.

RESUMEN

Las algas se convierten en fuentes medicinales naturales. Este artículo tiene como objetivo discutir la protección de patentes de algas marinas para medicamentos. Se describirá la importancia de las algas marinas para la medicación y sus perspectivas, antes de analizar la patente de las algas marinas para los medicamentos. También revisa los costos y beneficios sociales sustanciales de la protección de patentes de algas marinas para medicamentos. El artículo recomienda el equilibrio efectivo entre el interés público y el interés privado legítimo de los titulares de patentes, y evita la percepción de priorización de los derechos privados sobre la salud pública.

Palabras clave: Algas marinas, beneficio social, costo social, medicamentos

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INTRODUCTION

The growth in the use of marine biological resources represents a fundamental change in the way humans derive benefits from the oceans (Duarte et al.: 2007, pp. 382-383). Seaweed products are used in our daily lives for multi-functional properties in the form of food, energy, and medicine because of their unique structure and biochemical composition. As a rich source of valuable chemical components, seaweeds are used in various other industries like cosmetics, fuel, water treatment, etc.

Along with biotechnology development, the diversification of the use of seaweed in increasingly sophisticated products, including medicines, is accelerating the domestication of seaweeds and the emerging patent market of seaweed biotechnology.

With a unique structure and biochemical composition, seaweeds could be used for multi-functional properties in the form of food, energy, cosmetics, and medicines. Despite their wide applications in the food and feed industries, they become natural medicinal sources because of their high healing, antimicrobial and antioxidative properties by offering a wide range of therapeutic possibilities both internally and externally for medication. As natural medicine sources, scientists and the pharmaceutical industry have developed seaweeds for new drugs as natural products that are also increasingly being used in medical and biochemical research, and have patented them.

This review focuses on patent protection of seaweeds based medicines by firstly describing the seaweeds for medication and their prospects, before analyzing the patenting of seaweeds for medicines. The substantial social costs and benefits of seaweeds patent protection for medicines will be further analyzed. The patent system provides social benefits such as induces more innovations, spillovers of knowledge, enhanced productivity, and higher economic growth, etc. Hence, this paper recognizes some social costs due to the exercise of the exclusive right of patent holders, such as the high cost of medicines, lower output, less competition, etc. Patent on the innovation of medicines might turn a miracle into a social tragedy by stifling public health and access to affordable medicines. To address public health concerns, patent systems need to meet the public health challenge and put the public interest and public welfare at their main focus. The effective balance between the public interest and the legitimate private interest of patent holders should be developed by nourishing the incentive structure of the patent system with other mechanisms for fostering inventive activity and the generation of life-saving medicines and ensuring public access to essential medicines.

METHODS

This paper is legal research aimed at analyzing the social cost and benefit of patenting seaweeds for medicines. To achieve the goal, this paper uses both the primary legal materials (all applicable legislation), and the secondary legal sources which are in the form of literature and related materials. The method of this research includes conceptual and statute approaches to affirm the conclusion that although social costs of patenting medicines exceed social benefits, the balance should be central to patent protection. Benefits deriving from any induced higher level of medication innovation must offset at least the costs at a societal level due to the grant of monopoly privileges (Akhmetkarimov: 2019, pp. 180-197).

RESULTS

A. Seaweeds: Emerging Plants

The term of Seaweeds, in this case, refers only to macrophytic marine algae, both wild and cultivated, growing in saltwater. Botanically, about 6 000 species of seaweeds have been identified and are grouped into three different classes green (Chlorophyceae), brown (Phaeophyceae), and red (Rhodophyceae) (Devi et al.:

2011, pp. 205-211). Seaweeds or marine algae are primitive non-flowering plants without true root, stem, and leaves. Seaweeds constitute one of the commercially important marines living renewable resources.

The commercial value of seaweed for human consumption is increasing year-over-year, and some countries harvest several million tons annually. Seaweed aquaculture, growing at 7.5% per year (Duarte et al.: 2009, pp. 967-976), is becoming an important component of marine aquaculture, propelled by a diversification of the demand for seaweed products from traditional uses to bio-energy (Kraan: 2013, pp. 27-46), cosmetics (Kijjoa & Pinchan: 2004, pp. 73-82) and biomedicine applications (Smith: 2004, pp. 245-262).

As marine biological resources, seaweed provides an opportunity, particularly for Indonesia, to access this emerging market. Indonesia is rich in seaweed, so it has great potential in this field. With more than 61.000 km of coastline spread over 17 000 islands, Indonesia has emerged as the second-largest producer of cultured seaweed in the world following China. Recorded by FAO, Indonesia contributed almost 38% (11.3 million tonnes) compared to China's 47 percent (14 million tonnes)- (Fleurence & Levine: 2016).

B. Seaweed for Medicines

Seaweeds are the main sources of food, fuel, cosmetics, and medicines. Food products like jelly, payasam, jam, chocolate, salad, soup, curry, etc. can be prepared from seaweeds. Despite their wide applications in the food and feed industries, they have gained importance as medicinal sources because of their high healing, antimicrobial and antioxidative properties (Shelar et al.: 2012, pp. 1-22). Seaweed may not only benefit the nutritional value of a food product but may also benefit the product in terms of improving the shelf-life and, in some cases improving the sensorial properties (Brownlee et al.: 2012; Fayzullina: 2019, pp. 87-98). Seaweeds offer a wide range of therapeutic possibilities, both internally and externally. Seaweeds are taxonomically diverse, largely productive, biologically active, and chemically unique offering great scope for the discovery of new medicines (Pooja: 2014, p. 33).

For medicines, seaweeds are the only source for the production of phytochemicals such as agar, agarose, carrageenan, and algin which are widely used in various industries as gelling, stabilizing and thickening agents in food, pharmaceuticals, confectionery, dairy, textile, paper, paint, and varnish industry, etc. They contain different vitamins, minerals, trace elements, protein, iodine, bromine, and bioactive substances (Kaliaperumal: 2003, pp. 33-42). Many bioactive compounds can be extracted from seaweeds. Seaweeds are used as raw materials for the production of other chemicals such as mannitol, iodine, bromine, laminarin, and fucoidan. There are several medicinal properties in seaweeds, and many bioactive compounds can be extracted from seaweeds (Chennubhotla: 1996, pp. 108-109; Kaladharan et al.: 1998, pp. 1-9).

In recent years pharmaceutical companies have started looking towards seaweeds for new drugs as natural products that are also increasingly being used in medical and biochemical research, including patenting them. Before the 1950s, the medicinal properties of seaweeds were restricted to traditional and folk medicines (Lincoln et al.: 1991, pp. 97-183). The discovery of new products from seaweeds has decreased since 1995, and attention has now shifted to marine micro-organisms. They have attained commercial significance through their use in various industries that exploit their physical properties such as gelling, water-retention, and their ability to emulsify (Kelecom: 2002, pp. 151-170).

For instance, hard shell capsules for drug delivery can be made from seaweed extracts (Pujiastuti et al.: 2017, pp. 1140-1144). In general, hard shell capsules are made from natural gelatin of animal bones and non-animal natural polymers such as starch, chitosan, alginate, and carrageenan.

C. Patent of Seaweeds Based Medicines

A patent is a legal document granted by a specific country to an inventor that provides the commercially valuable ability to exclude others from the patented invention within the boundaries of the patent-granting country. The patent rights will be granted by the government in response to a patent application as a basis for legal protection. Patents protect any inventions that meet patentability requirements (novelty, inventive steps, and industrially applicable) in twenty years, including innovation on seaweeds.

The combined effect of rapidly increasing seaweeds domestication and production with increasing demand for natural medicines promote innovation on seaweed medical biotechnology. Patents for processes and applications of seaweed for pharmaceutical grow rapidly. The examination of patents for seaweed aquaculture and seaweed-derived products registered between 1980 and 2009 (Smith: 2004, pp. 245-262). Patents propelling seaweed biotechnology is co-opted by a small number of Asian nations (Japan, China, and South Korea hold 84% of all registered seaweed patents), in contrast to the dominance of marine gene patents by Western nations (Arnaud-Haond et al.: 2011, pp. 1521-1522).

Arguably, patenting seaweed for medicines should not be accepted unless it satisfies the patent requirement. To identify the patentability of pharmaceuticals derived from seaweeds, it is important to notify the prevailing legal standard for patents in the *Trade-Related Aspect of Intellectual Property Rights (TRIPs)*. *TRIPs* protects inventions that are "new, involve an inventive step, and are capable of industrial application." Since Article 27 of *TRIPs* does not provide any definition of the invention, member states can define it in any matter (Basheer: 2005). As a result, there is no international consensus and global standards on what constitutes the invention, and it leads to the nonuniformity of invention definition.

D. Patenting Medicines: the Dilemma

In the lens of *TRIPs*, any innovations, including seaweeds innovation for medicines or pharmaceutical ingredients, can be protected under the patent system. However, patenting medicines are still contentious issues because medicine is one of the most basic factors in the public health service system. In the socio-economic aspect, medicine is the public goods incorporating extensively rapid, innovative technological development, and moral goods. More specifically, medicine is non-rivalrous in consumption. Thus, it should be made available to the general public at a low cost.

Many essential medicines have not made available to the public at accessible cost because the pharmaceutical industry holds market exclusivity, endowed by the patent system. This exclusive position creates a very long period of monopoly market by conferring market power and controlling high price over new pharmaceutical products. As a result, in developing and least developed countries, a large number of patients cannot access to the essential patented medicines due to unaffordable high price that causes public health crisis. This public health crisis, including unaffordable access to medicines, has raised the concern on the dilemma of patented medicine.

Pharmaceutical companies argue that removing drugs from patentability is controversial as it negates the principle of nondiscrimination in patented fields of technology in Article 27.1 of *TRIPs*. They also argue that removing pharmaceuticals from patentability will deter the invention of the new drugs and will damage the pharmaceutical industry. However, it is also not clear that the patent-free medicines will damage the pharmaceutical companies as most developing countries have no complicated capability to manufacture even for patent fee medicines. Also, pharmaceuticals are not totally a field of technology, although some pharmaceuticals may be addressed with products originating from indifferent technological fields, such as equipment, software, diagnostic kits, and a variety of devices used for medical treatment. According to Adelman (Adelman: 2016), there is also evidence that innovation and patent systems can exist alongside the delivery of medicines and health services to people in need.

The global concern about questionable patent practices of pharmaceutical companies raises substantial discussion and debate concerning the benefit and cost of patent medicines. Some believe that the patent system is defined as one where social benefits exceed social costs, and the system, therefore, improves a nation's economic well-being. However, on the other hand, some have already overlooked concern on the social cost of a patent that has suppressed public health, including blocked access to affordable medicines. Different tensions and imbalanced perspectives on medicines patients are likely to be exacerbated. To balance the perspective on patenting medicines, the following subsections of this article review the benefit and the cost of patent medicines.

E. The Benefit of Patenting Medicines

Richard Nelson (Nelson: 1997) identify four broad theories about the principal benefit of patents, i.e., invention-inducement theory, disclosure theory, development and commercialization theory, prospect development theory. In summary, invention-inducement theory presumes that patents motivate useful inventions. While disclosure theory views that patents facilitate wide knowledge about and use of inventions by inducing inventors to disclose their inventions when otherwise, they would rely on secrecy. Under the development and commercialization theory, patents induce the investment needed to develop and commercialize inventions. According to the prospect development theory, patents enable the orderly exploration of broad prospects for derivative inventions. Meng (Meng: 2019, pp. 1204-1229) considers the height of a patent that can extend to which the patent controls later improvements and variations in the initial invention. Strong patents would then also serve the purpose of providing incentives to invent for parties who are limited in the extent to which they can use the invention themselves, by facilitating the sale of rights to an invention. Possession of a patent gives the original patent holder an incentive to push its inventions out to firms that can develop and commercialize them, thus without a strong initial patent, and a firm will not undertake the development work necessary to lead to a profitable product or process innovation.

In general, without a patent system, incentives for the invention will be too weak to reflect the public interest because if there is no patent protection, there will be no invention. In particular, the stronger patent protection on medicines will increase the number of drug inventions. The pharmaceutical industry reported that without patent protection, 60% of their new pharmaceuticals would not have been developed.

F. The Cost of Patenting Medicines

The effect of patent protection is minimum in developing countries with weak technological abilities, based on evidence concerning trade, foreign investment, and growth. In the foreseeable future, the benefit of patent protection in developing countries will not be higher than the costs. Gimenez (Gimenez: 2018) argue that: "although there are strong economic reasons the support property rights to inventions, there are also tremendous social costs."

There is a fundamental legal principle that private property rights can be curbed if doing so serves a greater public purpose (Kennedy: 1997, pp. 375). A patent should be a better solution to public health rather than a barrier to affordable access to essential drugs. A patent should become a panacea for the pains of the public health crisis and access to life-saving drugs for numerous diseases, such as HIV/AIDS, malaria, and tuberculosis, which are an epidemic in developing countries.

The stronger position of patent holders sustains monopoly prices. The cost of patent protection will most likely raise drug prices and are depriving the world's poor of essential medications. Society loses because part of the loss to consumers is transferred as monopoly profits to the patent holders. Access to drug innovations is also likely to be socially very costly. Prices of patented medicine will increase and patients suffering from a disease. Patent on the innovation of medicines might turn a miracle into a social tragedy (Adelman: 2016).

DISCUSSION

Patents promote knowledge sharing by requiring the details of the patented invention to be placed in the public domain in return for the exclusive right to exploit the invention. The disclosure requirements of the patent system are based on the idea that 'scientific and technical openness benefits the progress of society more than doing confidentiality and secrecy.' By encouraging knowledge sharing, patents reduce the duplication of research effort and encourage researchers to build on existing inventions. Researchers may study a patented product and find ways to improve upon it. Access to patented inventions may also facilitate research that would not otherwise be possible.

Possessing a patent may help a company to grow by capitalizing on the market potential of its inventions. Patents stimulate the growth of the national industry because local companies that hold patents can attract

overseas investment and develop products for export. Profits generated by patent exploitation can be invested in further research and development, which may stimulate commercial and industrial growth.

Patents provide a system for trading knowledge through license agreements. The grant of licenses to international companies to exploit locally developed inventions provides returns to inventors and access to foreign markets. The grant of licenses to national companies to manufacture inventions developed overseas can improve the skill and know-how within the community.

Also, Indonesian local pharmaceutical companies still rely heavily on imported ingredients. About 90 percent of the pharmaceutical industry still uses imported materials, particularly the active pharmaceutical ingredients, because it is not easy to produce those materials, and the industry was unable to carry out sufficient research on developing such materials (Jakarta Post: 2018). Many ingredients were patented by pharmaceutical companies in Germany, France, and Japan, while Indonesia lacked appropriate laboratory facilities for researching the development of pure chemicals as an initial step toward processing and producing active pharmaceutical ingredients because of the exorbitant costs of establishing such a facility, including the high cost of clinical tests.

One solution to reduce the dependence on imported medicines, including the pharmaceutical chemical ingredients is by developing local medicinal plants such as seaweeds and other natural ingredients used in local herbal treatments across the archipelago of Indonesia. Seaweeds can be the alternative to substitute the imported drugs, including the ingredient and to reduce the dependence by developing their medicinal properties that could be used for antibodies, anesthetics, and other medicines. The development of seaweeds for medicines is expected to play a role in meeting the needs of national medicines. For instance, the need for national capsule shells reaches 6 billion per year, and it is met by capsules made from gelatin coming from domestic production worth 5 billion and imports worth 1 billion (QS WowNews: 2019). Thus, there is a great opportunity for seaweeds to be the substitute for imported drug and their ingredients because they will be more efficient and cheaper. The availability of abundant raw materials of seaweeds and guaranteed halal value is expected to encourage the development and market acceptance of seaweeds based medicines.

CONCLUSION

Patents on medicines are expected to give social benefits by inducing more innovations, generating increased consumer surplus, spillovers of knowledge, enhanced productivity, and higher economic growth. Some believe that the patent system is designed where social benefits exceed social costs. However, the unrestricted and exceedingly protected patents on medicines become a heavy burden on society. There are social costs of patenting medicines due to the exercise of exclusive rights and monopoly power of patent holders such as the high cost of medicines, lower output, less competition, reduced consumer surplus, etc. Patents on medicines have stifled public health and prevented access to affordable medicines, which affects extensive deadweight losses in third world nations. Patent on the innovation of medicines might turn a miracle into a social tragedy.

There is an unclear answer to the question of whether the benefits of patents on medicines have indeed exceeded costs. The patent system will benefit greatly and serve the technological and economic advantages, only after the negative impact of the patent system is properly assessed. The social cost of a patent on medicines is not avoidable but controllable. The high pharmaceutical prices make the government need to set the public policies to foster monopoly pricing in the patent law and subsidize purchasing in the Medicare prescription drug, including regulatory schemes that are designed to place upward limits on pharmaceutical prices. The government needs to allocate more funds to basic research, controlling price for key products such as pharmaceuticals, promoting education, and nurturing the idea of patent rights in public, etc. To address public health problems, including access to essential medicines, the government should take a more active role to employ the flexibility of TRIPS such compulsory license, government use, or parallel importation for ensuring the availability and accessibility of medicine. The state must participate in and affect the determination of social costs in social resources allocation and social benefits coordination positively, rather than rely solely on the spontaneous adjustment of the market (Lizhi: 2016, pp. 85-89) to balance the cost and benefit of a patent on medicines.

To reduce the dependence on imported medicines including the pharmaceutical chemical ingredients, Developing local medicinal plants such as seaweeds and other natural ingredients used in local herbal treatments across the archipelago of Indonesia will be an alternative solution. The development of seaweeds for medicines is expected to play a crucial role in fulfilling the demand for national medicines. Seaweeds can substitute the imported drugs, including the pharmaceutical ingredient, by developing their medicinal properties that could be used for antibodies, anesthetics, and other medicines. As the substitute for imported medicines or pharmaceutical ingredients, seaweeds will be more cost-efficient and cheaper because of the availability of abundant raw materials of seaweeds in Indonesia.

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BIODATA

M Rahmah: Mas Rahmah works as a full-time Associate Professor in the Department of Private Law, Faculty of Law Universitas Airlangga, Surabaya, Indonesia. Mas Rahmah obtained her Doctor of Law from Universitas Airlangga, Master of Law from Monash University, Melbourne, Australia, and Bachelor of Law from Universitas Airlangga. She is the chief of the Intellectual Property Centre of Universitas Airlangga and Vice Chief of Indonesian Intellectual Property Lecturers Association.