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Threats of Biotechnology and Protection of Law

Abbreviations

Aug. :August
Dec.: December
EC: European Commission
Edn : Edition
Feb.: February
GM: Genetically Modified
GMO: Genetically Modified Organisms
Ibid : Latin, short form Ibidem, meaning "same place".
Inc.: Incorporation
No.: Number
Oct.: October
OJ: Official Jurnal
U.S.: United States
TRIP: Trade-Related Aspects of Intellectual Property Rights
v. : versus
Vol. : volume
W.H.O. : World Health Organization

Introduction

Technology is at every part of human lives. To supporters, it is powerful to improve the quality of life but to opponents it can be an evil. Biotechnology is related to health and health is a fundamental right and without health people cannot live. Therefore health is a very fragile topic and it should be protected. Both of opponents and supporters agree that biotechnology raises some concerns and human health is protected these concerns by health law. To use the biotechnology, this area should be protected by law because people should feel safe when they cure. Moreover, this topic should not be thought individual level because biotechnology also affects public health. Then, governments have the role on this biotechnology and health law issue.

This paper will argue that there are two main issues in terms of biotechnology and health law cooperation: Patent issue and genetically modified foods. Firstly, this paper makes a clear explanation in terms of the patent law that genes are not patentable and also, gene patents carry to risk to damage right to life and right to effective remedy because gene patents affect the availability and affordability of health care. Secondly, genetically modified food might pose significant risks to human health and the paper supports that in order to protection both public and individual health labelling and educating the public about GM foods are necessary.

Technically Patent Law and Biotechnology

Before discussing the issue in terms of health care law, it should be discussed in terms of patent law. On the technical patenting side, it should be enlightened that human genes and life forms which are found in nature are at the class of discovery or they are at the class of invention. This discovery and invention issue is essential because Article 52 (1) of the European Patent Convention contains that inventions are patentable while Article 52 (2) of the European Patent Convention provides that discoveries, scientific theories and mathematical methods are not patentable. Therefore, if genes are patentable, they should be inventions rather than discoveries.[1] However, according to Dworkin, "if something is simply found in nature, for example a new plant with medicinal properties, in that state it is simply a discovery."[2] Actually, Dworkin is right, because genes are not created by human, in other words genes are independent of human rationality because definitely mother and father decide to make a baby but they are not ownership of this baby. They are just parents. For instance, there must be a marked difference between inventing an engine and finding the sequence of the DNA. Inventing a car is artificial but genes are natural, they are not patentable. As a result, gene patents are not patentable in terms of patent law because gene sequences or travels on genes are discoveries.

[1] European Patent Office (1973), *European Patent Convention*, 14th edn (Printed in Germany) (revised August 2010).

[2] Gerald Dworkin, "Should There Be Property Rights in Genes", *Philosophical Transactions: Biological Sciences, Vol. 352, No. 1357, Human Genetics: Uncertainties and the Financial Implications Ahead (Aug. 29,1997)*: p. 1080, JSTOR Database.

The Curse of Scientific Research which is against to Right to life and Right to effective remedy

Health law is related to right to life and right to effective remedy which are provided by Article 3 and Article 8 of Universal Declaration of Human Rights.[3] Health law is also meaningful when patients can easily reach effective remedy and when they rescue from situations which their lives are in danger. However, the results of research in genetics jeopardize the right to life and right to effective remedy in terms of the health law. Not surprisingly, ownership of gene patents tend to see this property right as a tool which helps them to make money and this relationship harms people because, health is a fundamental right and everybody should reach health-care. However, gene patents affect availability and affordability of health care which are very essential.[4] To the Constitution of WHO, health as a fundamental right and every human being is entitled to the enjoyment of the highest attainable standard of health conducive to living life in dignity.[5] Unfortunately, gene patents hinder available and affordable health care, therefore gene patents damage health law principles.

Available Health Care and Gene Patents

According to TRIPS Agreement, Article 27 provides that "Members may also exclude from patentability: plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof."[6] This means that patent issue is national and members decide what they do and there is no restriction. Although, Article 27 suggests that patent issue is national, it becomes global because ownership of a patent can claim one of the following four applications of DNA sequences: diagnostic testing; research tools; gene therapy; or the production of therapeutic proteins to be used as medicines.[7] Taken these four applications into consideration, it is clear that research on genetics become global because this four applications interest all patients. Moreover, global character of gene patents affects the availability of health care especially in developing countries. Research on genetics makes health care available; however, companies do not trust the patent system of developing countries. They tend to escape from invest money for a patented invention in developing countries. Companies do not want to risk their money. On the other hand, the majority of developing countries are unable to develop diagnostic tests and research on genetics themselves, they must rely on imports from the developed countries.[8] Therefore, developing countries become dependent on developed countries even companies in terms of health care. This situation affects availability of health care and human dignity because human who live in developing countries suffer from illnesses and

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[3] United Nations, *Universal Declaration of Human Rights*, (10 Dec. 1948).

[4] Louise Bernier, Karen L. Durell, E. Richard Gold, "W.H.O. Literature Review On The İmpact OF Gene Patents On Access to Genetic Technologies and Services: View from Developing Countiries." *Centre For Intellectual Propert Policy (Jan. 15, 2004)*: p.11.

[5] World Health Organization , *Consitituiton of WHO*, 45th edn (Oct. 2006).

[6] World Trade Organization, *TRIP Agreement*, Morocco (15 Apr. 1994).

[7] *Ibid*, Bernier, Durell, and Gold, p.7.

[8] World Health Organization, "Genetics, genomics and the patenting of DNA". *WHO Library Cataloguing-in-Publication Data (2005):* p.50.

they cannot escape their fates. Developing countries do no interest research companies but developing countries also do not have enough money to invest money on health care industry so this vicious circle should be ruined because as mentioned before, health is fundamental right and global society is responsible to protect this right.

Affordable Health Care and Gene Patents

Gene patents not also complicate the availability of health care but also it complicates the affordability of health care. Chricton gave very specific example about this issue at his article, "they (gene patents) raise costs exorbitantly: a test for breast cancer that could be done for $1,000 now costs $3,000."[9] However, the ideal diagnostic test should be affordable because its assignment is to determine genetic conditions[10]. However, if a diagnostic test is not affordable, how do people benefit from it? Probably, they do not. Moreover, raising costs compulsorily leads to start of the debate on public good versus private good. If the ownership of genes is free to maximize their profits by raising costs of benefits of genetic research, the private good is chosen instead of public good. According to the directive of European Parliament and of the Council on the legal protection of biotechnological inventions, Article 6, "inventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality."[11] It seems clear that European Union chooses public good and actually, this is right because governments decide gene patents, on the other hand they have to protect their citizens. Therefore, public good always should take precedence over private good. As a result, affordable health care is essential to reach health care and taking public good into consideration, governments should not emphasize on private good, therefore governments should hinder raising costs of gene patents' benefits (such as diagnostic tests).

Diamond versus Chakrabarty Case and the Argument which provides gene patents

Unlike European Union, American Law System advocates patent system. In the case of Diamond versus Chakrabarty is suggested: "the productive effort thereby fostered will have a positive effect on society through the introduction of new products and processes of manufacture into the economy and the emanations by way of increased employment and better lives for our citizens."[12] Patent protection is seemed encouraging tool to companies because the productive effort can be provided by patent system. According to this case, patent laws promote the investments on gene discoveries and this fact helps to improve the health care. Since, companies tend to invest more money on genetic discoveries if there is a judicial protection. To public good versus private good perspective, court seems to decide on the behalf of public good but actually, it decided on the behalf of private good. Encouraging discoveries is necessary but government can try different ways to encourage companies. Since, giving permission to patent

[9] Micheal Crichton, "Patenting Life". *New York Times*. 13 Feb. 2007. Web. 21 Feb.2013.

[10] World Health Organization, "Genetics, genomics and the patenting of DNA". *WHO Library Cataloguing-in-Publication Data (2005):* p.4.

[11] Directive 98/44/EC of The European Parliament and of The Council of 6 July 1998 on the legal protection of biotechnological inventions [1998] OJ L 213/13

[12] Diamond, Commissioner Of Patents and Trademarks v. Chakrabarty, *Inc.,* 447 U.S. 303, 206 USPQ 193.

microorganisms carries some risks. As mentioned before, genes patents are against to available and affordable health care, even technically gene patents are against to patent law system. Therefore, for protecting public good against private good, governments can develop different strategies to improve gene industry because patent provides companies ample opportunities.

Genetically Modified Foods

Another biotechnological finding is genetically modified foods. Firstly, what are genetically modified (GM) foods? The term GM usually refers to special set of technologies that change the genetic makeup of plants, or animals or bacteria[13]. Genetically modified food is very controversial issue because some people support that these foods are useful and people should benefit them, some people support that whatever they are beneficial, people should not benefit from them because they might be risky. Some benefits of GM foods are: improved resistance to disease, pests, and herbicides, new products and growing techniques, improved animal health and diagnostic methods, better natural waste management, increased food security for growing population etc.[14] By contrast with these benefits, there are some concerns about GM foods. Most important concern in terms of health law issue is human health risks.

Genetically Modified Foods and Risks to Human Health

According to World Health Organization, the three main issues which are related to GM foods and risks to human health are allergic reaction (allergenicity), gene transfer, and outcrossing.[15] These are very serious risks because they are life-threatening and they threaten human health. This issue is mainly related to public health law because government should take precautions of preventing public health and this is provided by law. According to Ogalthorpe, "public health law is the study of the legal powers and duties of the state to assure the conditions for people to be healthy (e.g., to identify, prevent and ameliorate risks to health in the population) and the limitations on the power of the state to constrain the autonomy, privacy, liberty, proprietary, or other legally protected interests of individuals for the protection or promotion of community health."[16] Therefore, this discussion also turns to distinction of public good pr private good and this paper suggests that public good is main issue which government have to protect. In order to protection, there are two main issues: Labelling and educating the public about GM foods.

Labelling of GM Foods

In order to labelling of GM foods most controversial issue is that labelling should be mandatory or not? Given the importance of labelling into consideration labelling of GM foods should be mandatory because people have to the right to know what they eat and also government can protect the public health and control GM contamination in non-GM products. First of all,

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[13] Human Genome Project Information, "Genetically Modified Foods and Organisms", *U.S. Department of Energy Genome Program's Biological and Environmental Research Information System (BERIS).*2012. Web. 21 Feb. 2013.
[14] *Ibid.*
[15] World Health Organization. "20 questions on genetically modified foods". *Biotechnology (GM foods) publications*.2013. Web. 21 Feb. 2013.
[16]Larry Ogalthorpe Gostin, *Public Health Law: Power, Duty, Restraint* (California: University of California Press, 2000), also available in Web. 21 Feb. 2013.

people have to right to learn what they eat and this condition is provided by labelling. If people know what they will eat, they may give up eating this food. Labelling is about transparency, transparency can save people some potential risks which are related to GM foods. However, big companies which are in food industry are fighting against labelling include Nestle, Coca-Cola, Kellogg, and General Mills.[17] Actually, this attitude of these big companies raises doubts in order to harm people's health. In that situation government have some responsibilities because in order to protect public health governments should take some precautions and furthermore, they should control GM contamination in non-GM products. European Union took precaution with a regulation on genetically modified food and feed. According to the article 12 of this regulation provides that "this section (Labelling) shall apply to foods which are to be delivered as such to the final consumer or mass caterers in the Community and which: contain or consist of genetically modified organisms (GMOs) or are produced from or contain ingredients produced from GMOs."[18] Thence, people can know what they eat and government fulfil their responsibilities by providing transparency. Moreover, in that way governments can control GM contamination in non-GM products because contamination is also dangerous and finding contamination is difficult without labelling. As a result, labelling should be mandatory because it is a right and it helps governments to protect the public health and control GM contamination in non-GM products.

Education the public about GM foods

Educating public about GM foods and GMOs is helpful to protect public. Education means that people should learn what GM food and GMOs means, GM food' and GMOs' harms, and how they read labels. Education is essential because unfortunately most people do not realize that they consume GM foods.[19] Therefore, if they are educated, they choose whether they eat GM foods or not by their own will. There is no consensus on GM foods are unhealthy or not, therefore, people should educate and they decide what they eat. Informed choices are essential because in that way people notice that possible effects. As a result, education the public about GM foods is necessary in terms of people's choices on food consumption.

Conclusion

Biotechnology should improve people's quality of life and technological devices should not be seemed as a commercial tool and governments should always remember that public good is more important that private good. In that case, health law cooperation is essential because law arrange the limits of technology. Therefore, genes are not patentable and genetically modified foods should be labelled. Since, on patent law perspective genes are discoveries and labelling can protect humans against the potential risks of GM food. Law can supervise government or institutions, then human's can reach health care services and they be protected. Heath is a fundamental right and authorities have to respect to protect this right.

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[17] Donnie Yence CN RH AHG. "Food Labelling: We Have the Right to Konow". *Mederi Foundation*. 30 Oct. 2012. Web. 18 Feb. 2012.

[18] Regulation (EC) No 1829/2003 of The European Parliament and of The Council of 22 September 2003 on genetically modified food and feed [2003] OJ L268/1.

[19] Donnie Yence CN RH AHG. "Food Labelling: We Have the Right to Know". *Mederi Foundation*. 30 Oct. 2012. Web. 18 Feb. 2012.

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