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Controversies over the moral justification for patent protection in biotechnology^{*}

Abstract

This paper discusses the controversies over the moral justification for patent protection in biotechnology. Special emphasis has been put on the controversy over the moral justification for patent protection of stem cells. By referring to arguments for (1) human dignity and (2) patentability criteria, the moral justifiability of patent protection of stem cells is in serious doubt. A whole section of the paper is devoted to the moral issues linked to patent protection in biotechnology and their political and economic significance. An attempt is made to solve some of the discussed problems, i.e., the introduction of decision criteria based on the system of values shared by the members of a given society.

Keywords: moral justification, patents, biotechnology

JEL Classification: K11

1. Introduction

Patent laws have been broadly discussed since at least the 1750s (Karbowski & Prokop, 2013; Machlup, 1958). Many arguments in favour of and against patents presented at that time are still used today. In the 18th century it was believed

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that the inventor had the right to a patent because of moral reasons founded in natural law (Sterckx, 2006, pp. 249–265), or because of practical reasons, for the sake of their society (Machlup, 1958). Considering the directions that the discussion has taken until the present day, we can distinguish four fundamental stances regarding the inventor’s right to patent protection (Machlup, 1958):¹

- (1) natural law,
- (2) a reward in the form of a monopoly,
- (3) stimuli coming from extraordinary gains,
- (4) remuneration for revealing a secret.

Within natural law, it was argued that each human being is a natural owner of their ideas. Using others’ ideas without consent should be considered theft and we should be legally protected against it (Karbowski & Prokop, 2013). Monopolising the market as a reward assumed that in the name of social justice each man should receive payment for their services, proportional to the benefits that their society received. It was argued that the best way to realise this duty was to grant the entrepreneur a temporary monopoly in the form of exclusive rights to their invention. Another position was based on the assumption that economic progress is socially desirable and inventions and their industrial applications are at the core of this process. Thus, understood progress, however, cannot be effectively achieved if inventors and investors do not have a prospect of (stimuli in the form of) gaining extraordinary profits. Furthermore, it was argued that the easiest and the cheapest (most effective) way for the society to provide a proper system of economic stimuli for inventors and investors would be to grant them a temporary monopoly in the form of exclusive rights to their invention. The approach based on remunerating anybody who would reveal a secret assumed that the inventor and the society engage in a form of a transaction, in which the inventor reveals their arcane knowledge in exchange for temporary protection in the form of exclusiveness of its application. It was believed that if such a transaction does not take place, economic progress would slow down because we would have to wait longer for new technologies to spread. Quite often technological secrets would be lost on the death of their keepers. So, the society should care about negotiating a proper price for which the inventor would agree to reveal their secret for the sake of the whole society. The best way to achieve this would be to offer the inventor exclusive rights (a patent) in exchange for publicising their invention (Karbowski & Prokop, 2013).

We should note that the issue of patenting inventions is not ethically neutral and many scholars in this field directly base their argumentation on moral grounds. According to Peter Drahos (1999), all regulations can be considered ethically neutral if (1) they do not affect the realisation of subject A’s interest or (2a) do not hinder or (2b) do not facilitate the realisation of subject A’s interest (a) to the benefit of/ (b) at the expense of subject B. Because the essence of patent-

¹ It is worth noting that all these positions are harshly criticised by some participants of the international debate on patent laws. Specific arguments are presented by, e.g. Sigrid Sterckx (2006), Michele Boldrin and David Knudsen Levine (2013).

ing is to (temporarily) exclude others from using² the patented invention, it is difficult to argue that patenting does not affect the realisation of specific subjects' interests. As a consequence, it is also difficult to treat the matter of patent laws as a question devoid of moral qualities. This claim, despite not sounding very revolutionary, surprisingly causes adverse reactions among many participants of discussions about patenting or (at least) surprises them. Quite a few participants of this debate (held within and between the fields of, among others, economy, law, and technology) are convinced that (or so they declare) patenting an invention is a morally neutral act (Devaiah, 2010, pp. 14–17; Drahos, 1999; Grubb, 2004; Sterckx, 2006).

Historical connections between patent laws and morality have been seen for many years. Even historical regulations of patent issues (e.g. the Australian *Statute of Monopolies* from 1623, the British *Patents Act* from 1883) included clauses according to which a special state institution could refuse to grant a patent if using it would violate social moral norms (Drahos, 1999). Nowadays, similar clauses—rules accepting the possibility of not granting a patent for an invention if it violates norms of the so-called public morality (Warrington, 1964, p. 1326)—are present in the legal codes of the EU, USA, Australia, New Zealand and India (Devaiah, 2010). The relationship between patent laws and morality can be very clearly seen in biotechnology. Although the human body and its tissues cannot fall under patent regulations due to moral and legal reasons,³ it does not protect biotechnology from moral dilemmas. And so it seems more and more controversial (Devaiah, 2010) to patent biological materials of human origin that are not human organs or tissues, such as stem cells, isolated genes, or DNA. The debate on the moral and legal justifications of patenting such “incomplete” human biological materials has been gaining momentum in recent years, somewhat commensurately to the rapid development of biotechnology (Khachiauri, 2012; Resnik, 2007).

The goal of this paper is to present and discuss the controversies related to the moral justification of patent protection in biotechnology. Special emphasis was put on controversies over moral justification of patenting stem cells. Research on stem cells (Inoue, Nagata, Kurokawa & Yamanaka, 2014; Puri & Nagy, 2012, pp. 10–14; Yamanaka, 2012) is currently viewed as one of the most promising areas of progress in medicine and biotechnology.⁴ It is worth noting that in 2012 John Bertrand Gurdon and Shinya Yamanaka were awarded a Noble prize (Physiology or Medicine) for their research on stem cells.

² Using understood legally, with all legal limitations of patent protection. Cf. e.g. the bill from 30 June 2000 r. (*Prawo własności przemysłowej*).

³ Entire human tissues and organs do not fall under the so-called *patentability criteria*), according to which the subject of the patent is new (is not a part of technology—*novelty criterion*), does not stem from current technology in any obvious way (*non-obviousness criterion*) and can be industrially applied (*utility criterion*) (cf. Devaiah, 2010; Looney, 1994; Oman, 1995, p. C42; Resnik, 2004).

⁴ Research on stem cells lie at the foundation of the so-called regenerative medicine, which is supposed to offer non-pharmacological treatments to many diseases. For details on the role of biotechnology in regenerative medicine cf., e.g. Kamieniarz et al. (2006).

The following part of the paper presents moral dilemmas related to patenting stem cells. Then, in part 3, we discuss moral problems connected with patent laws in biotechnology in a wider economic and political context. That part also includes a proposal of a solution (or moving towards a solution) to certain moral issues discussed here. The paper ends with a summary and conclusions.

2. Moral problems related to patenting stem cells

Stem cells are cells that are capable of division—self-renewal over a long period of time, sometimes throughout the entire lifespan of the organism (Sikora & Olszewski, 2004). Stem cells, when exposed to certain stimuli, can differentiate and give rise to many types of cells that compose our bodies. A stem cell is (1) multipotent when it can differentiate into more than one type of derivative cells, (2) pluripotent when it differentiates into all types of mature cells coming from three germ layers (Alison, Poulson, Forbes & Wright, 2002; Blau, Brazelton & Weissman, 2001; Sikora & Olszewski, 2004), (3) totipotent when it is capable of giving rise to a whole organism and the placenta (Cogle et al., 2003; Sikora & Olszewski, 2004).

Most likely, the most morally dubious is research on and patenting pluripotent stem cells because they are special due to their origin—some of them are embryonic stem cells, originating from the earliest stage of the embryo, i.e. the blastocyst. These cells can differentiate into all three germ layers and the tissues originating from them (Bishop, Lee & Polak, 2002; Sikora & Olszewski, 2004).

According to Salome Khachiauri (2012), the sources of moral controversies related to patenting stem cells are rooted primarily in the belief that the human embryo has special cultural significance. The proponents of such a stance argue that granting somebody/something (a subject, a company) exclusive rights (in the form of a patent) to stem cells means in fact objectifying the human embryo, lowering its status from a person to a thing, or rather to an economic resource, which is subject to market exchange and instrumental treatment.

It may seem morally dubious to provide certain subjects with property rights to living matter, especially coming from human beings (Khachiauri, 2012). Granting property rights to the human body has been explicitly banned and these prohibitions were clearly stated in many legal systems (Bahadar & Morrison, 2010) as contradicting the concept of human dignity (Resnik, 2007).

Many critics of stem cell patent protection also quote this argument “from human dignity”. According to Khachiauri, human dignity in the context of the aforementioned debate should be understood after Immanuel Kant (Senser, 2009) as an “absolute inner value all human beings possess.” Kant assigned the following attributes (qualities) to this value: absolute character, inherence (in the human being) and unconditionality, which, when taken together, made the value of the human being in

this concept independent from anything else (Khachiauri, 2012). Kant clearly stated that human dignity is an immanent quality of human beings from the moment of conception (Rothhaar, 2010).

At this point, it is worth noting that Kant distinguished between *inherent human dignities* possessed by each individual from the moment of conception *moral human dignity*. While the former characterises to the same extent each human being, the latter can be different in different individuals, depending on their moral choices (Andorno, 2009; Khachiauri, 2012). In the light of Kant's ethical philosophy, we can try arguing that the human embryo does not possess moral dignity, but we cannot legitimately say that the human embryo is not characterised by human dignity.

Some bioethicists, based on Kant's work (2014), reach for one of the formulations of his categorical imperative, that is—act in such a way that you treat humanity, whether in your own person or in the person of any other, never merely as a means to an end, but always at the same time as an end. Next, on the basis of Kantian understanding of human dignity and the presented above formulation of the categorical imperative, they argue that the status of any human being, regardless of their circumstances, cannot be reduced to a means to an end, and this is what they believe happens in research on and patenting embryonic pluripotent stem cells (Khachiauri, 2012). It is difficult to imagine that (1) an end of an embryo is to devote itself or a part of itself to creating a novel biotechnology treatment within the so-called regenerative medicine, and it is even more difficult to imagine that (2) this embryo would want its own cells to be patented. One thing appears to be certain—the embryo is defenceless against any and all potential abuses (Holland, Lebacqz & Zoloth, 2001).

The presented above argumentation is relatively complex, uses philosophical concepts from Kantian and, possibly, Christian doctrine (Resnik, 2007). We should note, however, that the lack of justification (moral and legal) for patenting stem cells can be shown in a much simpler way. The structure of patent protections systems is based on a fundamental principle that a patent can be granted only for an invention, and not a discovery. The advocates of patenting stem cells argue that stem cells when properly harvested (from a human being) and properly prepared (isolated, purified) become inventions because in such a “processed” they do not exist in nature. Consequently, the advocates believe that the “processed” stem cells can be patented. We should note, however, how weak an argument this is. Following this line of thought, we can claim that a piece of rock (created by nature) found by a river, after its removal and cleaning (according to geological recommendations), becomes an invention and the person who removed and cleaned it is its inventor. Such a reasoning clearly contradicts the criteria of patentability, i.e. this piece of rock, even if it is covered with a unique natural pattern (and perhaps meets the condition of novelty), underwent *obvious* preparation (removal, cleaning, etc.) and, therefore, cannot be defined as an invention.

We can argue in a similar fashion when it comes to stem cells. They were created by nature, they are naturally unique, but subjecting them to standard “biotechnological processing” does not make them inventions and, therefore, they

cannot be patented in the light of the currently functioning world of legal regulations. Taking advantage of inadequacies of patent law (and patent offices) by patent applicants in some countries in order to gain exclusive rights to stem a cell is, economically speaking, an example of rent-seeking behaviour (Krueger, 1974) and a seriously dubious moral behaviour from the perspective of ethics.

3. Ethical problems related to patent protection in biotechnology in a broader political and economic perspective

Drahos discusses two distinct long-term (at least several decades in duration) global tendencies within patent laws: (1) systematic broadening of the scope of the so-called patentability (extending the boundaries delineating the set of things that can be patented) and (2) systematic narrowing of the role or morality as a decisive criterion in granting patent laws. According to Drahos, the employees of patent office consequently present pro-patent attitudes, i.e. in unequivocal, problematic situations it is easier to convince them to grant a patent than to reject the application. In psychological terms, it can be assumed that Drahos describes a certain motivational asymmetry of patent office employees. To achieve the same effect in terms of magnitude but with an opposite vector (“+” for granting the patent, “-” for rejecting the application), weaker arguments can be used to justify granting the patent than to justify the rejection of the application.

According to Drahos, the reasons for such a bias (see tendencies 1 and 2 in the previous paragraph) in patent regulations can be found in the structure of the global competition of national economies. Drahos calls this special structure of international competition a *structural problem*. What is this problem about, then?

Well, the influx of foreign investments is an important factor in the development of national economies (Wiśniewska, 2008). Foreign investments are an important source of *know-how*. However, foreign investors expect their own technologies to be protected against their unauthorised use by domestic competitors. Therefore, high standards in patent protection are considered to be a competitive advantage of a given national economy. Drahos sees the USA, the EU, and Japan as three main actors in global technological competition, arguing that these three political entities control most important patent systems—the American, European, and Japanese. Certainly, these political entities compete with each other (politically and economically); also using the quality of the industrial property protection systems they are in control of. Weakening the patent protection of inventions would be to their disadvantage because lowering the standard of industrial property protection in any one of these economies would significantly decrease the amount of foreign investment in that economy. Such a structure of global technological competition between these three main actors creates strong stimuli only for increasing the standards of patent protection, not for lowering them. As a result,

over time, patent systems expand in these economies, which at least partially explain the occurrence of the aforementioned two tendencies and their negative consequences.

It is also worth noting that the companies are interested in acquiring as many patents as possible. Such behaviour is primarily motivated not by their willingness to protect their technologies against potential imitators but rather to increase their price on the capital market. The number of patents in a company's portfolio is an important economic variable (Liberda, 2008), which is considered when evaluating the worth of the company by the capital market. It can be said that patents (an element of companies' assets) play the role of a signal for the participants of the market, a signal contributing to the increase of companies' value and, consequently, to increase their capacity to accumulate capital (Drahos, 1999). The latter is especially important for biotechnological companies, which usually exhibit a high rate of growth and a relatively high demand for capital (Chakma, Sammut & Agrawal, 2013).

Thus, companies only care about obtaining patents for its own sake, and to primarily to protect their inventions—can be of secondary or even marginal importance to them.⁵ Naturally, if companies are interested in acquiring the largest possible number of patents, their managers can indirectly (e.g. through speaking out at certain conferences or scientific seminars) or directly (through lobbying⁶) exert pressure on a patent office so that it adopts a “liberal” attitude when deciding over the patent laws.

The problems described above that are related to patent protection in biotechnology are not easy to solve. As we can see, these problems are often entangled in various political, economic, or legal issues. However, it seems socially beneficial to steer away from the narrowing of the role morality by the patent offices in their decision making. Obviously, the moral criterion for making patent decisions should be proposed (designed) in accordance with the dominant system of values in a given society. Those criticising the introduction of such a principle argue that imposing the duty to adhere to moral criteria on patent experts can make the whole process of patent rights evaluation extremely arbitrary, coincidental, and subjective (depending on the whims of the experts).⁷

Drahos does not believe these fears are grounded. A distinction between psychologically understood *attitudes* and *values* is needed. Attitudes are acquired evaluations of objects whereas values are standards for the assessment of goals, types of actions, events, and behaviours (Wojciszke, 2011). It seems that a general social agreement is more likely to be achieved in the domain of thus understood values than attitudes. Drahos argues further that by applying empirical methods we can quite effectively map the network of values shared by the members of a given society. Especially, we can map the network of social values related to the

⁵ For more details on companies using patents for strategic purposes cf. Karbowski & Prokop (2013).

⁶ Examples of successful lobbying of biotechnological companies can be found in Peter Drahos work (1999).

⁷ The term “subjectivism” is used here in its colloquial meaning (it does not describe a philosophical stance).

issue of patenting in biotechnology. Values, unlike attitudes, are much more robust and are subject to much slower changes (if they change at all). It is one of the reasons why introducing a criterion referring to and based on social values does not necessarily have to make the process of patent rights evaluation arbitrary and subjective.

Lastly, it seems that the (preferably well-coordinated) introduction of appropriate moral criteria into the systems of patent protection of all three major actors in the global technological competition (the USA, the EU, and Japan) could ameliorate the negative socio-economic consequences of the so-called structural problem (most of all the rising of industrial property protection standards, ongoing but unnecessary from the perspective of social well-being maximisation).

4. Summary

This paper analysed some of the controversies related to moral justification of patent protection in biotechnology. It concentrated on the controversies over moral justification of patenting stem cells. Using the arguments—(1) from “human dignity” and (2) “from patentability criteria”, the paper questioned the moral foundation for justifying patenting stem cells. Argument (1) comes from Kantian understanding of human dignity and the principle of promoting humanity, and states that the status of any human being, regardless of their circumstances and conditions, cannot be reduced to a means to an end, which is the case in research on and patenting of embryonic pluripotent stem cells. Argument (2) states that stem cells, even when “processed”, do not qualify as an invention and, therefore, cannot be patented. These cells are created by nature, are naturally unique and subjecting them to standard “biotechnological processing” does not make them inventions. Therefore they cannot be patented in light of current legal regulations.

It appears that a good solution would be to introduce a criterion for patent rights decision-making that would refer to and be designed on the basis of the axiology of a given society. Values are more durable than human attitudes and change much more slowly (if at all). Moreover, such an understanding of values functioning in a given society can be effectively mapped using empirical methods, which are able to ensure intersubjective falsifiability of the claims they produce. Of course, the presented above evaluative stance (proposed by Peter Drahos) is not complete. It would be reasonable to complement it in further research with, e.g. the ideas of Juergen Habermas (2003) and Thomas Lemke (2010).

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