16 The "Novelty" Requirements for Gene and Genetically-Modified Organisms Inventions and the Potential Benefits of a Peer-to-Patent System (*)

Invited Researcher: Thomas Margoni (**)

The paper focuses on the patentability requirements applicable to the case of biotechnological inventions (gene patents and other genetically modified organisms). The paper takes a comparative standpoint and analyzes North-american, European, and Japanese landscapes. Attention will be also paid to the internal guidelines followed by the relevant Patent Offices, and their examiners. Particular attention will be paid to the "novelty" requirement, and it will be analyzed also under the more pragmatic aspect of the prior art searches that relies on public and community participation. The Peer-to-Patent system will be presented in its fundamental traits in order to identify its potentially beneficial outcomes in terms of quality and efficiency of the patent granting system.

Ⅰ Introduction

The paper focuses on the patentability requirements applicable to the case of biotechnological inventions (gene patents and other genetically modified organisms). The paper takes a comparative standpoint and analyzes North-american, European, and Japanese landscapes. Attention will be also paid to the internal guidelines followed by the relevant Patent Offices, and their examiners. Particular attention will be paid to the "novelty" requirement, and it will be analyzed also under the more pragmatic aspect of the prior art searches that relies on public and community participation. The Peer-to-Patent system will be presented in its fundamental traits in order to identify its potentially beneficial outcomes in terms of quality and efficiency of the patent granting system.

Given the technical features of genes, the objective of this study is to understand what "novelty" in the biotechnological patent system means: If researcher A isolates the DNA fragment ACTCCATTGA, is research B entitled to file a patent for its complementary strand? Under a pure chemical point of view, the complementary strand is made of a different molecular sequence, making it potentially a different invention. On the other side, it could be argued that regardless of the different chemical structures, the substances above mentioned are two sides of the same coin, as both segments carry the same set of genetic information. Of course such an example oversimplifies a very complex situation, and any given solution will stem from an analysis of all the patent requirements, and of the specific claims present in the application. Nevertheless, through the analysis of legislation, case law and Patent Offices guidelines of relevant jurisdictions, the present paper aims at finding analytical answers to the reported questions, and offer the base for the development of guidelines and best practices.

Ⅱ Gene Patents

In the field of biotechnological inventions – such as gene patents and other Genetically Modified Organisms (GMOs) – the novelty requirement is often analyzed (and sometimes confused) with the subject-matter one. The "product (or law) of nature" doctrine creates an important hurdle to the patentability of such types of inventions, in all those cases where biotechnological products and processes may be derived from the duplication of compounds found in living organisms or produced by naturally occurring animals or plants. If it is accepted that transgenic plants and animals, modified micro-organisms and isolated and purified DNA sequences are the results of human intervention and therefore patentable subject-matter, they are "new" in the sense of having no previous existence in the state of the art. However, at the same time, in a different chemical composition,

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(**) Post-Doctoral Fellow, Assistant professor, Faculty of Law, University of Western Ontario, Canada

exactly the same genetic and functional information may already exist in nature.

Patents are legal monopolies used in modern societies to protect and foster inventive activities[1]. The rationale behind such tools is to compensate a specific individual (the inventor) with a legal (not a natural) time-limited monopoly for her making public a new, useful and industrially applicable invention[2].

Patents can be seen as a form of retribution that the State grants to a specific category of workers: the inventors. Patents represent just one of the form a given societal organization can choose to use. Depending on the time and place, inventors have been retributed in other forms, not necessarily indexed to the success of their inventions. Let's only think at medieval societies where inventors were usual figures in royal courts, and where their survival depended from such form of patronage. This model has lasted for centuries, and certainly we cannot affirm that science and technology have not been developed by minds such as those of Archimedes or Al-Jazari. However, a first major issue with such model is the scientific and technological independence from the constituted power. Another problem that emerges clearly, is how to remunerate the inventor only for its successful inventions, those which could bring technological or militar advantage, aspects that sometime concretize with some year of discrepancy from when the knowledge has been produced. Such a form of patronage was proper of medieval societies, based mostly on local trade and rural production. It already looked not appropriate to bigger commercial empires[3], let alone to industrial form of organization[4].

One of the most striking inventions of the industrial revolution, together with the steam engine, has certainly been the limited liability for incorporations[5]. Another fundamental step in our modern societies has been the idea to render inventors participants of their success, or failure. The creation of a legal title stating that a given invention belongs *exclusively* to its inventor, and that everybody interested in its use should obtain permission, is but another model (more in line with the capitalistic and proto-democratic societies emerging during that century) to compensate a specific task believed to be fundamental for the social welfare of a given human organization. Under this point of view, a patent could be well idealized as a share in one owns invention's fate.

Nowadays, the situation might look, and actually is, extremely different, and the idea of the particularly gifted who invents something in its workshop is far away in time and space from the current market situation. However the legal framework stratified over the past few centuries, is in large parts still the same[6]. Requirements such as novelty, utility and non-obviousness have been filled up with specific content by courts and patent offices, and the eligibility of new products (software), new discoveries (genes), or new processes (business methods) has been largely discussed by international assemblies and national parliaments. However, the Patent Acts around the world have to a considerable extent looked almost the same during the past 100 years, and growing[7]. In light of such an apparent contradiction, we will proceed to an analysis of the patentability requirements for gene-related inventions in selected jurisdictions.

Inventions, to be patentable, needs to refer to fields such as art, process, machine, manufacture, and composition of matter, categories also known as patentable subject matter[8]. Gene patents usually take the form of composition of matter, such as in the case of isolated natural sequences of genes, or altered natural sequences that result in a more useful compound thanks to the alteration. A second type, and more recent, structure that gene-related patent usually take is that of a process, or method, such as in the cases of obtaining a natural sequence for diagnostic or testing purposes[9].

However, the trail that brought courts and patent offices to accept such type of claims is very steep and bumpy. Among the first patents regarding isolated forms of natural occurring substances there are U.S. Patent No. 730,176 and 753,177, both challenged in the case *Parke-Davis v. H.K. Mulford*[10]. What is really important about this case, is the view expressed by J. Hand regarding the patentability of an isolated form of adrenaline with regard to the novelty requirement. In his opinion in fact, such isolated form, is a new substance and not just a compound with a higher degree of purity, case in which there would be no novelty[11]. J. Hand goes further explaining that the patent at stake regards a new substance, in fact the claimed invention regards a composition of matter that *does not include a salt*, and no one ever isolated a substance which *was not in salt form before*[12]. Relevant at our purposes, is that the distinction between the natural occurring substance and the isolated one – from a chemical point of view – is not in degree but in kind[13]

The step following patentability's recognition of isolated natural occurring substances, would be

to recognize patentability of life forms. For such a decision we have to move forward in time of about seventy years. The landmark U.S. Supreme Court case discussing extensively such issue is certainly *Diamond v. Chakrabarty*[14]. In 1972 Chakrabarty applied for a patent regarding a bacterium of a known genus containing at least two stable energy-generating plasmids, which could provide separate hydrocarbon degradative pathways. Such characteristic of breaking-down crude oil was unknown – at least to the obtained level of effectiveness – in any natural occurring substance, and especially the bacterium did not have such ability, in its naturally occurring version.

Nevertheless, the Supreme Court in *Chakrabarty* tell us that its holding is not to suggest that § 101 has no limits, or that it embraces every discovery. Therefore, for example, the laws of nature, physical phenomena, and abstract ideas have been already held not patentable[15]. In these decisions, for instance, a "new mineral discovered in the earth or a new plant found in the wild are not patentable subject matter. Likewise, Einstein could not patent his celebrated law that E=mc2; nor could Newton have patented the law of gravity. Such discoveries are "manifestations of . . . nature, free to all men and reserved exclusively to none"[16].

However the present case is different, the Court points out, as the claim under judgment is not to an unknown natural phenomenon, but to something (manufacture or composition of matter) that does not occur naturally, a man-made product which has a "distinctive name, character [and] use.[17]" In light of these considerations, the Court concludes that the respondent's micro-organism plainly qualifies as patentable subject matter.

The court argues that the invention in *Funk* is of a different nature. In *Funk*, the patentee discovered something that already existed in nature (i.e. that some bacteria do not exert mutually inhibitive effect on each other), and he used such discovery to produce a mixed culture capable of producing a useful result. In such case the court held that the patentee discovered only some of the handiwork of nature, and this was not patentable[18].

In *Chakrabarty*, however, the courts believe that the patentee has produced a "new bacterium with markedly different characteristics from any found in nature, and one having the potential for significant utility"[19]. Such invention does not correspond to something nature has already, but to something that the patentee has newly invented, thus it is patentable subject matter under § 101.

1 The Myriad Genetic Saga

The Myriad case is a long and complex, yet still actual one. The last stone in this saga has been layed down by the Court of Appeal for the Federal Circuit, which with an order of September 13 2011 no. 2010-1406 has denied rehearing of the Myriad case. The next step will then be up to the Supreme Court.

Such motion for rehearing was filed by both parties as a consequence of the Court of Appeal for the Federal Circuit decision of July 29, 2011, which partially reversed the district court summary judgment of March 29, 2010[20] that had invalidated most of Myriad patents.

During the obvious appeal, the holdings of the District court were reversed in large parts, although with dissenting opinions on different points.

Regarding isolated genes, cDNAs and partial isolated gene sequences, the Court of Appeal for the Federal Circuit (in a 2 to 1 decision) decided that such products are § 101 compliant, thus patentable subject matter. For the CAFC "cleaving" DNA out of chromosomes, is a process that produces something that does not exists as such in nature. Isolating is different (after all the precedent of Park-Davis regarded a new substance, not just an isolated one, which was believed to be patentable by J. Hand in its obiter[21]).

It is possible to note how weak certain passages of the court are, almost sounding as an ex-post justification of an already taken decision in the sense of not creating excessive financial harm to a sector, while maintaining some of the prerogatives of the District Court. Such an implicit tension is evident in the dissenting opinion, where it is writes that there is no magic to a chemical bond which requires the Court to recognize a new product when such a chemical bond is altered or broken. What is claimed in the BRCA genes is the genetic coding material, and *that material is the same*, structurally and functionally, in both the native gene and the isolated form of the gene[22]. The dissenting opinion goes further and adds that patent thickets are significant obstacle to the next generation of innovation in genetic medicine, multiplex tests and whole-genomic sequencing, contesting the position of the majority of the Court on the fact that there are already more than 2,500 gene patents, and invalidating them would create economic losses. Finally, the dissenting opinion clarifies that cDNA and DNA sequences as short as 15 nucleotides should not be patentable.

2 Myriad Patents in EU

The Myriad saga is an interesting one as it allows us to draw a comparison with the EU, as the patents have been granted to Myriads also by the European Patent Office. However, as we will see the European part of the story is much different, as it will focus on a series of decisions withing the very same European Patent Office, and not on court of justice decisions. At this regard is relevant the different political and administrative organization of the EU with regard to the USA, and of the fact that the European Patent Office is no part in the EU organization, but a different and separate international body. This is not the place for an analysis of the role of the European Patent Office in the EU, therefore we will only incidentally clarify those aspect that could ingenerate confusion.

The European Patent Office has granted mainly 4 patents regarding the BRCA genes, although not before a long and painful way[23]. In fact, after a period of almost 6 years between filing and issuance of the patents, between 2002 and 2003 all of them have been opposed following the specific third party opposition procedures set forth by art. 99 – 105c of the European Patent Convention (EPC)[24]. Following this procedure a specific panel of patent examiners at the European Patent Office, the Opposition Division (OD), decides on the oppositions filed by the concerned third parties on the base of the compliance of the opposed patent to the European Patent Office rules and to EU legislation. Following this procedures, one of the patent has been entirely revoked (EP699754) while the other three have been maintained in narrowed versions. It must be observed how, apart the variety in the reasons why these four patents have been either revoked or amended, there are many inconsistencies connected with the inadequacies in the gene sequence, in the prohibitions of extensive amendments, in relation to the satisfaction of patent requirements (such as novelty, inventive step and industrial application), in addition to the prohibition of granting patent protection to discoveries, scientific theories and mathematical methods, diagnostic methods performed on the human body, and inventions contrary to public morality[25].

Ⅲ Japan

We do not have any record of similar BRCA patents, either filed or issued, in Japan.

However, this does not exempt us from trying to answer the question of whether isolated DNA sequences or methods of comparison can be considered "highly advanced creation of technical ideas by which a law of nature is utilized"[26]. The point is obviously a bit speculative, and the answer of course would strongly depend on the specific drafting of any given claim. At this regard the Japanese Patent Office guidelines reveals particularly helpful.

1 Novelty in Gene Patents

Most of the case law we have observed – thus mostly U.S. – argue the patentability of genes in terms of subject matter. However, as the analysis in Bergy 1979, the decisions of the EPO, and with even more clarity JPO guidelines indicate, maybe the correct way to decide about the patentability of gene related inventions needs to revolve around the other requirements, especially novelty and non-obviousness.

At this regard it will be very interesting to see what the Supreme Court will decided in the Myriad case, and some similar cases that regard diagnosis methods.

2 Novelty in Japan

Regarding the novelty requirement in biotechnological invention, the Japanese Patent Office Guidelines are once more very clear, and offer a series of cases and examples to clarify the situation. So for example if a protein as an isolated and purified single substance is known, a recombinant protein specified by a process of production is not novel if it results identical as a chemical substance to the former[27]. However, in case where a "recombinant process inevitably leads to a different product, for example in its sugar chain or the like, due to the difference of the host cells, even though the recombinant protein has the same amino acid sequence as the publicly known one, a claimed invention concerning the recombinant protein specified by a process of production is novel"[28].

The clarity of the Patent Office Guidelines guidelines is admirable, and is functional to an efficient system. However Patent Offices guidelines are but one part of the more general patent system, together to, at least, Courts and Parliaments. Therefore, even in the less problematic jurisdiction here analyzed, the ultimate question cannot be avoided. Can genes be

protected as chemical compounds?

Ⅳ How to Reconcile Opposing Positions

A possible way to recompose such dichotomy is called purpose-bound patents. There is no magic behind such concept, which resembles under many aspects the original protection offered by patents. Inventions regarding a specific gene covering a specific claimed use, do not protect for a third party using the invention in a manner not covered by the function claimed, or in a way different from that used by the claimed invention. At this regard of particular interest is decision C-428/08Monsanto Tech LLC of the European Court of Justice. In such decision the European Court of Justice had the opportunity to clarify in particular the meaning of art. 9 Directive 98/44EC[29].

Ⅴ Novelty and the Role of Community: Peer-to-Patent

Peer-to-Patent is a project aiming at a significant increase in the quality, accountability and public participation of the patent system. It implements a methodology that is paradigmatic of our times and technological evolution: the participation of experts on a volunteer basis, who offer their help and expertise to improve the overall effectiveness of a fundamental public function, through web-based technologies. As we have seen at the beginning of this paper, such is in fact the goal of a patent system: Inventors file a detailed description of the fruit of their inventiveness, completely disclosing it publicly, so as the whole society can benefit from the knowledge produced. The trade-off for such a public disclosure (in contrast of keeping it secret), is the legal sanctioned monopoly that the society recognizes to the make, sell, and use of such technology for 20 years. This bargain, that has represented for decades a well balanced trade-off between chocking interests (private benefit *versus* public access), allowed for a terrific evolution of the technological sector in the past centuries, granting scientific and economic independence to inventors, and a fast and widespread diffusion of the latest scientific discoveries.

Ⅵ Final Remarks

In this report, focusing on patentability requirements applicable to biotechnological inventions, North America, Europe and the Japanese landscapes are analyzed.

Particular attention is paid to "novelty" requirement which is considered by keeping watch on the Examination Guidelines.

In context with novelty, the fundamental traits of the Peer to Patent system is presented to identify its potentially beneficial outcomes in terms of quality and efficiency of the patent granting system.

It is hoped that the analysis of this report will offer the base for the development of examination guidelines and the best practices.

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1 For a history of patent and technological evolution see Pottage A., Sherman B., Figures of Invention: A History of Modern Patent Law, Oxford University Press, 2010.

2 The formal requirements for patent protections are different but somehow comparable across the world. This is connected to the many international agreements signed with the aim of harmonization of patent law, see *infra* fn. 9.

3 See for example the Venetian Statute on Industrial Brevets, Venice (1474) available at: http://www.copyrighthistory.org/cgi-bin/kleioc/0010/exec/showThumb/%22i_1474%22/start/%22yes%22# last visited Feb, 2012.

4 See *inter alia* Boldrin M., Levine D., Against Intellectual Monopoly, Cambridge University Press, 2008; Perry M., From Pasteur to Monsanto: Approaches to Patenting Life in Canada, in Gendreau Y., ed., An emerging intellectual property paradigm – Perspectives form Canada, Ch. 4, Edward Elgar, 2008.

5 See Margoni T., Perry M., Legal Consequences of Packet Inspection, in Berntzen L., ed, *Cyberlaws: The Second International Conference on Technical and Legal Aspects of the e-Society* (International Academy Research and Industry Association, 2011) 18-21.

6 The still in force Paris Convention for the Protection of Industrial Property was first signed in 1883.

7 In addition to the Paris Convention, the Patent Cooperation Treaty, the Patent Law Treaty, the The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), or the Convention on the Unification of Certain Points of Substantive Law on Patents for Invention have played a fundamental role in the harmonization of international patent law.

8 See for example *Canadian Patent Act,* RSC 1985, c P-4 s; and *U.S. Patent Law* 35 U.S.C. § 101 (2007).

9 See for example the Myriad patent that will be analyzed *infra* in this paper.

10 Parke-Davis & Co. v. H.K. Mulford & Co., 189 F. 95 (C.C.S.D.N.Y. 1911).

11 Ibid. at 103.

12 Ibid. at 103.

13 Ibid. at 104

14 Diamond v. Chakrabarty, 447 U.S. 303 (1980).

15 *See* Parker v. Flook, 437 U.S. 584 (1978); Gottschalk v. Benson, 409 U.S. 63, 67 (1972); Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948); O'Reilly v. Morse, 56 U.S. 62, 112-121 (1854); Le Roy

v. Tatham, 55 U.S. 156, 175 (1853).

[16] See. Chackrabarty 447 U. S. 303; See also *Funk Brothers Seed Co. v. Kalo Inoculant Co.,* 333 U.S. 127.

[17] See Chacrabarty at page 447 U. S. 310 (citing *Hartranft v. Wiegmann,* 121 U. S. 609, 121 U. S. 615 (1887)).

[18] Cfr. *Funk*.

[19] Cfr. *Chakrabarty.*

[20] See *Association for Molecular Pathology v. U.S. Patent and Trademark Office*, 94 USPQ2d 1683 (S.D.N.Y. March 29, 2010).

[21] See Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95 (C.C.S.D.N.Y. 1911).

[22] See Association for Molecular Pathology et al. v. Myriad Genetics, Inc et al. (Case No 2010-1406, Decided July 29, 2011).

[23] In particular EP699754, EP705902, EP705903 (the three filed in 1995 and issued in 2001), and EP0785216 (filed in 1996 and issued in 2003).

[24] Convention on the Grant of European Patents (European Patent Convention) of 5 October 1973 as revised by the Act revising Article 63 EPC of 17 December 1991 and the Act revising the EPC of 29 November 2000.

[25] See arts. 52 and 53 EPC.

[26] See art. 2(1) Japanese Patent Act (Act No. 121 of 1959).

[27] Ibid part. VII, chapter 2, paragraph 1.3.2 (Novelty).

[28] Ibid part. VII, chapter 2, paragraph 1.3.2 (Novelty).

[29] See Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, in L213, 30 July 1998, pp. 13–21.