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Patenting genes: how do India and the US compare?

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India's position on patenting genes borrows heavily from that of the US, but will the status quo change? Swarup Kumar of Remfry & Sagar reports.

Patent laws for life forms, particularly genes, have been hit by numerous controversies despite thousands of patents already being granted in major patenting jurisdictions such as the US, Europe and Japan. The grant of patents on human genes has elicited serious

apprehension in view of associated legal, ethical, moral and political sensitivities. With courts, legislatures and patent offices the world over reacting to such developments, the only constant in gene patent jurisprudence is change.

The TRIPS Agreement sets minimum binding standards for protection of intellectual property in more than 171 World Trade Organization member states. While such minimum standards have resulted in a basic uniformity in patent laws, practically speaking, member nations often deviate from one another in terms of substantive law and practices.

Non-discrimination on the basis of place of invention or field of technology is one of the basic tenets of the TRIPS Agreement. However, article 27(3) allows plants, animals, etc—essentially biological processes—to be excluded from patentability. Interestingly, TRIPS does notforesee, and is silent on, such exclusion extending to patenting of genetic material including DNA sequences. Therefore, some observers argue that member nations compliant with TRIPS are not justified in forbidding gene patents.

The counterargument made by other interest groups is that there are significant flexibilities in the TRIPS Agreement, including article 8—which allows adoption of necessary measures by member states to protect public health and nutrition—that can be used to impede patenting of genetic material. Add to this, the *ordre public* and morality exception under TRIPS, which can be used by member nations to prohibit patenting of genes on account of proprietary, ethical and social concerns, and it boils down to the interpretation given by a member nation to the flexibilities envisioned under the broad legal framework of TRIPS.

The US view

What constitutes patentable subject matter in the US is statutorily governed by 35 USC §101, which states that “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof” may be patented. It is, therefore, evident that non-discrimination on the basis of subject matter is clearly enshrined in the US statute. This was affirmed by the US Supreme Court in *Diamond v Chakrabarty* (1980), when it held that Congress had intended patentable subject matter to “include anything under the sun that is made by man.”

Post *Chakrabarty*, the US Court of Appeals for the Federal Circuit in *Amgen v Chugai Pharmaceutical* (1991),while deciding the case on §102 and §112 issues, drew an important distinction between genomic DNA (gDNA) and complementary DNA (cDNA). Upholding thebroadest claim of the invention that related to “a purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin”, the court implicitly interpreted the expression “purified” as meaning “only the coding regions” and treated this as a claim to the cDNA version of the gene and not the gDNA. Until 2013,

this was the most noticeable, and perhaps the only, instance where the issue of gene patenting cropped up before the US courts.

The Supreme Court has since acknowledged that inventions in the field of biotechnology deserve consideration as applications of the laws of nature, despite the statutory limitation under §101. In *Mayo v Prometheus* (2012),it set forth an analysis that to qualify as patent-eligible subject matter under §101, a patent must do more than simply state the law of nature with the words “apply it”; rather, it must limit the scope of the patent to a particular, inventive application of the law. The highest court has, however, cautioned that the worthy nature of biotechnological inventions cannot overrule the principle that patent law should not inhibit future discovery by “improperly tying up the future use of laws of nature”.

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A year later came the Supreme Court’s decision in *Association for Molecular Pathology v Myriad Genetics*(2013),which involved a patent related to DNA sequences and screening methods for the BRCA genes, which are associated with a greater risk of developing breast and ovarian cancers. The claims in dispute asserted patent rights on the DNA code that signalled a cell to produce the string of BRCA amino acids as well as isolated segments of the corresponding cDNA code. The Supreme Court noted that, if held valid, these claims would give Myriad the exclusive right to isolate an individual’s BRCA genes and to synthetically create BRCA cDNA.

Disagreeing with the Federal Circuit’s finding in *Amgen* that both isolated DNA and cDNA were patent-eligible under §101, the Supreme Court stated that Myriad’s DNA claim fell within the laws of nature exception, as the principal contribution was uncovering the precise location and genetic sequence of the BRCA genes. The court stressed that the company did not create or alter either the genetic information encoded in the BRCA genes or the genetic structure of the DNA. However, the court concluded that the claims for cDNA did not pose the same issue since they were not naturally occurring, and therefore were patentable.

Although *Myriad* did not directly affect the patentability of cDNA or sufficiently modified compounds, it is still not entirely clear how much modification is required to render a molecule sufficiently distinct from naturally occurring counterparts.

The Indian perspective

Indian patent practice and jurisprudence with respect to biological material is relatively new and thus not well settled and/or uniform. In fact, the expression “biological material” is not defined in the Indian Patents Act, 1970 or its rules. Guidance may, therefore, be sought

from the European Patent Convention, which defines biological material as “any material containing genetic information and capable of reproducing itself”.By this definition, genes qualify as biological material.

Until 2002 living organisms, or processes relating to the manufacture of a product containing living organisms, were not patentable in India. The Calcutta High Court broke new ground in the landmark case *Dimminaco v Controller of Patents Designs & Others* (2002),when for the first time in the history of the Indian patent system, the patenting of a process for manufacturing a product containing living organisms was considered lawful.

However, claims relating to living organisms *per se* were considered patentable only in 2003, when amendments brought to section 3(j) of the act provided for the patenting of, *inter alia*, microorganisms. Subsequently, the exclusion to patentability under the amended section 3(j) that extends to “plants or animals in whole or any part thereof”has been interpreted by the Indian Patent Office (IPO) to prohibit patenting of organs, tissues and even cells, but no *carte blanche* exclusion has been extended to proteins, genes or DNA.

The patentability of human genes *per se* has not yet been a subject for consideration by a court in India. However, the Delhi High Court’s observations in *Emergent Genetics India v Shailendra Shivam and Others* (2011) may be considered instructive because of its general approach to IP issues surrounding genes. Although the decision dealt with, *inter alia*, the copyright pertaining to a genetic sequence of hybrid seeds, it rejected the plaintiff’s claim for copyright infringement, and opined that the genetic sequence was “not an ‘original’ expression of ideas but mere reproduction of something found in nature”.

The decision also referred to section 3(j) of the act, with the court opining that the originality of a genetic sequence “has to be seen from the background that the process by which those gene sequences are created, or isolated, or an improved or unique variety is developed, does not receive any intellectual property protection, and is expressly denied patent protection by reason of section 3(j) of the Patents Act 1970”.

In conclusion, the judge warned of the dangers in the court’s acceptance of a *“*ritualistic enforcement of intellectual property” that could potentially “implicate access to vital material resources which is vastly detrimental to public and national interest”. This approach does, in part, appear to be in sync with the principles that governed the *Myriad* decision of the US Supreme Court.

Broadly speaking, just like any other field of invention, biological materials including genes are also *prima facie* patentable in India so long as they are (i) novel; (ii) inventive; and (iii) capable of industrial application. If, however, such biological materials are merely an isolated form, rather than a genetically or otherwise modified version, they will not be

considered to fulfil the patent eligibility criteria set by the IPO. Biotechnology guidelines published by the IPO in 2013 corroborate this stance. Crucially, while *Chakrabarty* and *Amgen* provided persuasive arguments for patenting of gDNA, post-*Myriad* the scope of citing these decisions in support of patent eligibility has diminished.

The similarity in the legal position of the US and India towards patentability of genes is unquestionable. This may be explained by the fact that India's patent practice in this domain has borrowed heavily from US jurisprudence. As a consequence, it now finds itself constrained by the *Myriad* decision, which has all but dissolved reliance on *Chakrabarty*. Only time will tell if the status quo changes and reveals the way forward for India on the subject of gene patenting.

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