JUXTAPOSITION OF PATENT AND BIOTECH INVENTIONS: AWAITS ANSWER ON NEW TRENDS

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ABSTRACT

"I think biomarkers are patentable, depending on how they're claimed."

— Rochelle k. Seide

How will today's biotechnological inventions withstand the sea of change in intellectual property law? Most likely, the answer will vary from one invention to the next – according to which side of the litigation it falls on. Repercussions from recent patent cases in the different jurisdictions continue to be felt in a variety of ways. But for biotech patents, the movement has yet to crystallise into definitive guidelines issued by the courts. The concern is that changes in patent law may ultimately come at the expense of innovation within the industry. Thus, the paper aims at the proper understanding of the latest trends in biotech patents.

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I. INTRODUCTION

The technology has generally been associated more with chemistry and physics and less with the biology. The Organisation for Economic Corporation and Development ("OECD"**)** defined biotechnology as "the application of science and technology to living organisms, as well as parts, products and models thereof to alter living and non-living materials for the production of knowledge goods and services".[1]

The existing intellectual property laws struggle to cope up with the challenges posed by the technological advances as they were framed in an age when these advances were not foreseen by the framers. The traditional doctrines of intellectual property laws have been extended to new subject matters such as genes, proteins, and other unicellular and multi-cellular living organisms, which previously remained outside the grab of intellectual property law. Moreover, rapid advances in genomics have raised the intellectual property protection debate for scientific information. Intellectual property rights ("IPR") developers and holders claim that new technologies such as biotechnology fall within the existing bundle of the IPR, while end-users assert that technological change is so significant that contemporary intellectual property laws do not apply.

II. BIOTECHNOLOGY AND PATENTS: FRENEMY RELATION

One of the most contentious issues in biotechnology-IPR is the disclosure in the patentability of biotechnology. The traditional patent doctrine, patentable subject matter, novelty, non-obviousness (inventive step), utility (industrial applicability) and written description, struggle while dealing with the biotechnology inventions, especially genetic inventions. Human genes have become one of the most controversial subject matter of patent law because of its diverse nature.

One of the common objections against the gene patents is that genes are naturally occurring entities that are there to be discovered but not invented. In the context of gene patents, the line between discovery and invention is very thin and sometimes even discoveries are patentable through a broad interpretation of patent laws. With the development of genomics and the success of the human genome project, a gene becomes more important because of its informational content rather than its material qualities. Here the question arises, whether a gene as information is a patent-eligible subject matter or not. Some critics see it as a departure from the traditional patent doctrine which is based on an agreement to disclose information in

[1]Organisation for Economic Co-operation and Development [OECD], Glossary of Statistical Terms (May 2001*),* https://stats.oecd.org/glossary/detail.asp?ID=219.

exchange for giving the inventor right over material invention.[2]

They also argue that a gene being patentable subject-matter as information would not only challenge the traditional patent system, but also pose a great challenge to those who need access to information.[3] Further owning or treating genetic material as a property is a concern which could lead to monopolies exhibiting unethical behavior in healthcare and other industries.

On the legal end, genetic patents are currently on the hot seat in the courtrooms with some patents being upheld, others not. Many academics feel that the legal patent requirements of "utility," "non-obviousness" and "sufficiently isolated or transformed" are not being appropriately met and that there should be a higher standard for patent acceptance.

The evolving jurisprudence of gene patent stems from the biotech patent practices of different countries. The scope and coverage of biotechnology patents vary from country to country. Even in the countries having similar patent laws, such as the United States of America and Canada, the judicial interpretation of the courts differ significantly, and it is the judicial decisions rather than the legislative efforts that have shaped the fate of biotechnology patents in both the countries.

In Europe and India, significant legislative efforts have provided elaborate legislative provisions regarding biotechnology patents. Both Europe and India have a list of patentable and non-patentable subject matter in their respective legislations. These jurisdictions contain the *ordre public* and *morality* clauses to check the patentability of biotechnological inventions whereas the USA and Canada lack such provisions in their patent laws.

> …Statutory provision regarding the public order or morality exclusion under the Indian Patents law states that "*an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment*".[4]

> … Statutory provision regarding the public order or morality exclusion under the European Patent Convention states that patents '*shall not be granted in respect of inventions the commercial exploitation of which would be contrary to "ordre public" or morality and that 'such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting states*.[5]

Kailash Choudhary states that "United States of America never had an exception of morality or

[2]Kshitij Kumar Singh, Biotechnology and Intellectual Property Rights: Legal and Social Implications (2015).
[3]*Id.*
[4]The Indian Patent Act, 1970, No. 39, Acts of Parliament, 1970, § 3 (India).
[5]Convention on the Grant of European Patents, art 53, Oct. 5, 1973, 1065 U.N.T.S. 199.

ordre public in their patent laws however, such requirement was fixed by the courts but the same was rarely used. The United States Patents and Trademark Office ("USPTO") in the late nineties invoked the Moral Utility Doctrine in order to check the controversial applications related to biotechnology inventions However the courts criticised this because according to them, it is the legislature and not the executive which can define the boundaries of the law. Hence there are very a few examples where the morality exception was raised by the USPTO."[6]

Patenting of genetically engineered mouse called Harvard Oncomouse received different responses in the USA, Canada and Europe which demonstrates diverse patent approaches towards higher life forms.

> "In the case of OncoMouse, the exclusion under Article 53(a) of the EPC was argued for the first time. In this case, the subject matter of patent application was a mouse which has been genetically modified to carry an oncogene in order to make them more vulnerable to cancer. The object of the invention is to use these modified mice in cancer research. Upon examination of the application, the EPO rejected the application stating that the animal varieties are not patentable. However, on appeal the Technical Board of Appeal applies the morality clause under Article 53(a). The technical board is of view that genetically modifying a mammal and that to ensure that it will develop cancer was very problematic as the same cause suffering to the animal. However, the Board of Appeal forwarded the application back to the examination division stating that while considering morality, the Office should balance inventions utility to mankind with the suffering caused to the animals. The Board accordingly held the genetically modified mouse to be patentable on the grounds that the same was for the benefit of humanity."[7]

The Supreme Court of America in, *Association for Molecular Pathology et al vs. Myriad Genetics, Inc., et al*[8]*,* had made no mention of "human" v/s "non-human" DNA in their decision and simply ruled that naturally occurring DNA sequencings are ineligible to be patented. The court also held that complementary DNA (C-DNA) can be patented because it does not occur in nature. It is the transcript of natural protein encoding DNA sequence from which non-coding sequences called intron have been removed.

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[6]Kailash Choudhary, Ordre Public and Morality Exclusions from Patentability (2012).

[7]Harvard College v. Canada (Commissioner of Patent), 2002 SCC 76 (Can.). *See also,* Board of Appeal of the European Patent Office, (July 6 2004), *available at* http://www.jurisdiction.com/harvardvcanada.html.

[8]Association for Molecular Pathology et al. v. Myriad Genetics Inc., 569 U.S. 576 (2013).

> "…The Supreme Court held that naturally occurring gene sequences, and their natural derivative products, are not patent eligible. Under S. 101 of the Patent Act, the discovery of natural products does not warrant a patent. However, the Court also held that the creation of a new product in a lab exempts that product from being a product of nature. Therefore, gene sequences refined by synthetic processes to create molecules that do not occur naturally are patent eligible."[9]

In 1980, the Supreme Court decided in the famous, *Diamond vs. Chakraborthy*[10], that a new strain of bacteria produced artificially (by bacterial recombination, not genetic engineering) was a patentable invention. Although Chakroborthy's bacteria did not produce a useful product, they had the useful property that they could feed on and so disperse, oil slicks. Since the product which could be sold would be the bacterial strain itself, it was important to have a per se claim to the micro-organism.

> "… Alive, man-made microorganism is a non-naturally occurring composition and therefore may be patented. Resolution of this issue is, regardless of its philosophical implications, strictly a matter of statutory construction. The relevant statute here, 35 U.S.C. § 101, defines as patentable any new and useful "manufacture" or "composition of matter," among other things. It is a basic rule of construction that words are given their natural, ordinary meanings. There can be little doubt that microorganisms produced by recombinant DNA technology may be said to be manufactured and to be compositions of matter. For purposes of patent law, the fact they are alive is not relevant. Although it is true that naturally-occurring products may not be patented, a genetically-engineered microorganism is not naturally occurring. While this Court recognises that recombinant DNA technology is a controversial field, it is ill-equipped to balance the competing values and interests manifested therein; this is a task for Congress. Since the patent laws clearly include materials such as are at issue here within their scope, and no specific law exists to exclude it, the only appropriate holding is that recombinant DNA-produced microorganisms are patentable."[11]

III. HUMAN GENETIC PATENTS: A NEW CHALLENGE TO BIOTECHNOLOGY PATENTS

There are groups, which see the patenting of life forms such as the human gene plainly wrong and some others who do not consider it necessarily wrong but in terms of its consequences.

[9] *Id.*

[10] Diamond v. Chakraborty, 447 U.S. 303 (1980).

[11] *Id.*

Sometimes the problem does not lie in the availability of the patents, but the way that granted patents are being asserted by the ruthless corporations to the detriment of the public and especially vulnerable people such as the patients.[12] The opposition was driven by a variety of concerns including the effects of such patenting on the environment, animal welfare, sustainable development, public health and patient's rights. One of the most fundamental objections regarding gene patents is based on religious conviction—the notion that humans are 'playing God'.[13]

As regards to patenting of a gene, it is always contended that a gene occurs naturally, hence it is the product of nature and is not new/novel. With the rapid advancement in the field of molecular biology and genetics, gene sequencing once considered as a laborious manual task has become a highly automated and routine part of laboratory practice.

This presents a great challenge to the inventive step/non-obviousness criterion. There is a significant challenge to the utility criterion as patents are being granted on gene fragments of unknown functions and gene sequences of limited or questionable utility. Since great uncertainty is involved in genetic technology, sometimes the description of an invention is not full. Many patents claimed are far more than what the inventor actually discovered (e.g. claiming the sequence of a protein within the patent and then also asserting rights over all the DNA sequences that encode that protein without describing those DNA sequences).[14] The unique nature of the science of genetics is the main reason for this failure.

Since a gene comprises a number of elements, therefore, it is possible that a number of patents could be granted in relation to one gene. For instance, in relation to a particular gene, patents could be sought for the full sequence of the gene, an expressed sequence tag ("EST"), a single nucleotide polymorphism ("SNP") or other variations of the gene, its promoter or enhancer, its individual exons or some other combination of the sequence.[15] Furthermore, a gene may be the subject of a product patent, process patent and use patent. For example, a product patent would cover the sequence itself which may be a product sold as a diagnostic tool to determine whether a particular gene is present or not.[16] There could also be a product patent asserting rights over a gene and its product protein. The scope of the product patent is relatively wide as it asserts rights

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[12]Timothy A. Caufliled & Bryan Wlliam Jones, The Commercialization of Genetic Research: Ethical, Legal, and Policy Issues (1999).

[13]ALAIN POTTAGE, *THE INSCRIPTION OF LIFE IN LAW: GENES, PATENTS, AND BIO-POLITICS,* 61 mod. l. rev. 740 (1998).

[14]*Id.*

[15]Pottage, *supra note 13.*

[16]*Id.*

over all the uses of that product.[17]

A process patent may apply to some method of isolation and purification of a gene. As compared to a product patent, a process patent is unlikely to assert rights over the sequence of the gene itself. However, if the gene or protein is an element of a process or method that is used to produce some other product, the process patent may assert rights over the sequence of the gene.[18]

The use patent relates to a specific use of a gene. It could take the form of the use of a gene or part of its sequence in the manufacture of medicine. It could also be framed in terms of the use of a gene for the diagnosis of a disease. The use patents in relation to gene and genetic components are very controversial due to their broad scope.[19] Commenting on the use patent practice of Myriad over BRCA 1, the Nuffield Council of Bioethics observed:

> "A broad use patent for a diagnostic test for BRCA1 that referred specifically to breast cancer would give the owner rights over all testing for that genetic susceptibility to breast cancer but not for other diseases. However, the effect of the patent owner having broad property rights over the diagnostic use of the gene for just one disease, would be that the patent owner has the monopoly over all ways of testing for that disease. This is because, even though the use patent does not include the sequence itself in the patent claims, in practice any other diagnostic test for the disease specified in a use patent would infringe that patent."[20]

So, the actual scope of gene patents depends upon the extent of the analysis carried out by the examiner at the relevant patent office. In addition to this, with the recent advancement in the field of genomics, gene has become more important as information rather than as a tangible entity. This transformation raises the issue of patent eligibility of information, which has been excluded from patenting as 'scientific truths and abstract ideas'.[21] Patenting gene as information has been viewed as a departure from the long-established patent practice.[22]

IV. DESCRIPTION AND DEPOSITION REQUIREMENT

As per Article 27(3)(b), of Trade Related Aspects of Intellectual Property Rights Agreement

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[17]See Timothy R. Holbrook & Mark D. Janis, *Patent-Eligible Processes: An Audience Perspective*, 17 VAND. J. ENT. & TECH. L. 349 (2015).

[18]Dan L. Burk, *Are Human Genes Patentable?*, 44 iic int'l rev. intellectual prop. & competition l. 747 (2013).

[19]*Id.*

[20]Dan L. Burk, *The Curious Incident of the Supreme Court in Myriad Genetics*, 90 NOTRE DAME L. REV. 505 (2014).

[21]James D.Watson et al., Molecular Biology of the Gene, (4th ED. 1974).

[22]Dan L. Burk & Mark A. Lemley, *Inherency*, 47 WM. & MARY L. REV. 371 (2005).

("TRIPS"), microorganisms, non-biological and microbiological processes can be patented.[23] It is only given to those inventions that include genetic modification and inserts valuable characters in microorganisms that were initially not present in the natural form of that organism. This can be attenuation of bacterial strain, making it less infective which is required during vaccine preparation (such as the tuberculosis vaccine)[24], or genetically modified oil-eating bacteria[25]etc. One of the mandatory obligations for the grant of a patent for an invention is its repeatability by a person who has knowledge in that field, with work related to non-biological in nature, testing of the invention is an easy process as most of the ingredients of work are stable in nature. However, working with microorganisms is a very different phenomenon as bacteria always change their character in native environment due to selective pressure making it difficult to repeat the experiment that was previously performed/claimed by the inventor. The approach developed to meet this problem is that of a deposition of the strain in a recognised culture and collection, which will maintain the strain in viable conditions and make samples of it available to the public. Under the US Patent law, the disposition had to be made on or before the U.S. filing date, but no access to the deposited strain need to be allowed until the patent was granted, whereupon it had to be made available unconditionally to the public. In 1985, in *Ex Parte* Lundak[26], the Court of Appeal for the Federal Circuit held that it was not essential that the deposit be made by the date of filing of the application, so long as the applicant had the strain and could make it available to the USPTO upon request. Deposit could be made at any time during the pendency of the application, and the addition to the specification of information about the deposit did not constitute a new matter. The requirement that as on date of the grant, the strain must be publicly available from a recognised depository remained unchanged.

The majority of developed countries have now decided that the inventor must deposit microorganisms in pure and viable form for its patent purpose in a depository house also known as bacterial depository bank or International Depository Authority ("IDA") as per the rules and regulations set by the international body in the form Budapest Treaty.[27] Further, single deposition of sample will be sufficient for its recognition for patent purposes by other countries that are part of this treaty.

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[23]K.D. Raju, *WTO and TRIPS Obligations and Patent Amendments in India: A Critical Stocktaking*, 9 JIPR 242 (2004).

[24]Sarman Singh et al., *Evolution of M. Bovis BCG Vaccine: Is Niacin Production Still a Valid Biomarker?*, 1 TUBERCULOSIS RESEARCH AND TREATMENT 1(2015).

[25]H.S. Chawla, *Patenting of Biological Material and Biotechnology*, 10 JIPR 44–51 (2005).

[26]*In Re* Robert L. Lundak, 773 F.2d 1216, (Fed. Cir. 1985).

[27]Budapest Treaty On The International Recognition Of The Deposit Of Microorganisms For The Purposes Of Patent Procedure, Apr. 28, 1977, [Hereinafter, "Budapest Treaty"],.

> "… In 1974, the Director General of WIPO convened a Committee of Experts to discuss the possibilities of international cooperation over the deposit of microorganisms for patent purposes. The essence of the solution prepared in discussions of this Committee was that certain culture collections should be recognized as depositary authorities and that a deposit made with any one of them should be recognized as valid for patent purposes by all the countries in which protection for the relevant invention was sought. The Committee of Experts also found that the conclusion of a treaty would be necessary to put this proposed solution into effect. …The Diplomatic Conference, which was attended by representatives of 29 States members of the Paris Union for the Protection of Industrial Property and observers from two non-member States of the Paris Union, the Interim Committee of the European Patent Organisation, and non-governmental international organizations, adopted a treaty with the title "Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure," together with Regulations under the Treaty."[28]

It establishes a list of IDAs, a single deposit made at any of the signatory states will suffice for all.[29]

> "… Under the Treaty, certain culture collections are recognized as "international depositary authorities" (IDA's). Any Contracting State which allows or requires the deposit of microorganisms for the purposes of patent procedure must recognize, for those purposes, a deposit made in any IDA, wherever that IDA may be. Similarly, if any intergovernmental industrial property organization (e.g., the European Patent Office) files a formal declaration with the Director General of WIPO to the effect that, for its own patent purposes, it accepts the provisions of the Treaty and the Regulations, then it too must recognize a deposit made in any IDA."[30]
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> "..Any culture collection can become an IDA provided that it has been formally nominated by the Contracting State on whose territory it is located and that that Contracting State has furnished solemn assurances that the collection complies

[28]*Id.*

[29]World Intellectual Property Organization ["WIPO"], International Depository Authority, *available at* http://www.wipo.int/budapest/en/idadb/.

[30]*Id.*

> and will continue to comply with the requirements of the Treaty and the Regulations. The most important of these are that the IDA will be available on the same terms to any depositor, that it will accept and store microorganisms deposited with it for the full period specified by the Treaty, and that it will furnish samples of deposited microorganisms only to those entitled to receive them. An intergovernmental industrial property organization which has filed the declaration referred to in paragraph 6 similarly may furnish assurances in respect of a culture collection located on the territory of one of its member States."

Budapest Treaty has given clear rules and regulations of creation and maintenance of an IDA, daily working protocol of an IDA and guidelines to the depositor. It was decided that each member country will make an IDA for microorganism's deposition with the full infrastructural facility and that IDA will accept microorganisms from depositors of the native country as well as outside from country. One of the burning issues that were solved in this treaty was to stop multiple deposition of sample in more than one IDA for patent purpose. The treaty says that a single deposition of sample for patent purpose in an IDA will be enough to give recognition by other member countries of the Budapest treaty.[31]

Since India acceded and ratified the Budapest Treaty on December 17 2001, therefore biological material which is not available to the public, access to that material is available in the depository institution only after the date of the application of patent. The Controller General of Patents, Designs and Trademarks had issued a notification regarding the aforesaid, on July 2nd, 2014, which states as follows:

> "According to the provisions of the Act, the deposition of such material in an International Depository Authority (IDA) under the Budapest Treaty shall not be later than the date of filing of patent application in India. However, the reference of deposition of biological material in the patent application shall be made within three months from the date of filing of such application as per Rule 13(8) of the Patents Rules, 2003."[32]

In view of the above and according to the provision of Section 10 of Indian Patent Act, the

[31]WIPO, Introduction to the Budapest treaty,
http://www.wipo.int/export/sites/www/treaties/en/registration/budapest/guide/pdf/introduction.pdf.

[32]Office of the Controller General Patents, Designs and Trade Marks, Government of India, No. CG/F/ Public Notice / 2014/22, (July 2nd, 2014), www.ipindia.nic.in/writereaddata/Portal/News/159_1_115-public-notice 02july2014.pdf.

applicants should ensure that the deposition of the biological material to the IDA is made prior to the date of filing of patent application in India and the reference of such deposition in the specification is made within three months from the date of filing of such application, if the same is not already made. Further according to Section 10(4)(d)(ii), "if the applicant mentions a biological material in the specification which may not be described in such a way as to satisfy clauses (a) and (b), and if such material is not available to the public, the application shall be completed by depositing the material to an international depository authority under the Budapest Treaty and by fulfilling the following conditions, namely:-

> (A) the deposit of the material shall be made not later than the date of filing the patent application in India and a reference thereof shall be made in the specification within the prescribed period;
>
> (B) all the available characteristics of the material required for it to be correctly identified or indicated are included in the specification including the name, address of the depository institution and the date and number of the deposit of the material at the institution;
>
> (C) access to the material is available in the depository institution only after the date of the application of patent in India or if a priority is claimed after the date of the priority;
>
> (D) disclose the source and geographical origin of the biological material in the specification, when used in an invention."[33]

V. CONVENTION ON BIOLOGICAL DIVERSITY (CBD) AND IDA

CBD was signed by more than 150 countries during the Earth Summit at Rio de Janeiro, Brazil in 1992.[34] The agreement gives the right to nations to conserve their biodiversity. The aim includes conservation of biological resources, sustainable use of biological diversity and equal sharing of benefit among the people who are using the genetic resources of biodiversity. IDA, which is used for safe and long-term deposition of microorganisms, can work as a preservation house for microbial population.[35] In view of the above situation, two organisations; World Federation of Culture Collections ("WFCC") and World Data Centre for Microorganisms ("WDCM") were established. The WFCC is an institution that helps in establishment of culture collections centres. It gives different guidelines for establishment, authentication and maintenance of cultures in culture centres. Also, it creates a platform for online networking

[33]The Indian Patent Act, 1970, No. 39, Acts of Parliament, 1970, § 10.

[34]Convention on Biological Diversity, *History of the Convention*, https://www.cbd.int/history/.

[35] Abhishek Parashar, *International Depository Authority and its Role in Microorganism's Deposition*, 11(8) J. Clin, & Diagn. Res. DE01 (2017).

between culture centres for better communications. WFCC has created WDCM whose main role is to maintain statistical data of the culture collection centres which includes how many people are working, what kind of cultures are maintained in each culture centres, different facilities provided by culture centres etc.[36]

VI. CONCLUSION

It may be concluded that since the biotechnology based processes and products have now assumed an increasing importance in the global economy, there is a definite need to globally harmonise policies and procedures in respect of protection of intellectual property. Especially in view of the fact that enterprises engaged in research will make investment only if strong legal protection is available for the result of their research and therefore the TRIPS agreement is a step forward in this direction. The IDAs also play an important role in conservation of biotechnological inventions. A culture collection centre not only stores valuable microorganisms but also stores other useful biological materials which can be used in research, agriculture, industry, and pharmaceutical sector etc. Everyday new microorganisms are being discovered and the IDA provides a platform for storage of these bacterial strains in pure form thus preventing the loss of biodiversity. The stored bacterial strains can further be utilised for research and potential application. To convert a culture collection centre into an IDA requires huge financial support, infrastructure and manpower which itself is a big challenge. The Budapest Treaty gives provisions for interstate deposition of microorganisms in an IDA. Valuable bacterial strains found in countries where there is no IDA can be deposited in IDA of other countries. It is important to understand that the misuse of IDA should also be avoided. IDA stores both pathogenic and non-pathogenic bacteria; pathogenic bacteria could be used in making biological weapons. In upcoming years, more and more countries will ratify the Budapest Treaty and give emphasis on storage of valuable microorganisms at culture collection centres for their better utilisation.

Biotechnological inventions were earlier interpreted in different ways by different patent offices of the world but discussions and unification of ideas have emerged in some cases while differences, on various aspects of protection of biotechnological inventions through patents and the Budapest Treaty, still persist. However, it remains to be seen how the issue of protection of biotechnological inventions by patents is dealt with by the policymakers of countries. It is expected in the near future that these will also be solved and common ground will be laid down in the context of the present TRIPS regulations.

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[36]Singh, *supra* note 2.