IJPSR (2011), Vol. 2, Issue 6 (Review Article)

INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES AND RESEARCH

Received on 21 February, 2011; received in revised form 16 April, 2011; accepted 30 May, 2011

PATENTING OF BIOTECHNOLOGICAL PRODUCTS ISSUES PERSPECTIVE TO US, EUROPE AND INDIA

Pankaj Musyuni*

Brawn Laboratories Ltd., New Delhi, India

Keywords:
Biotechnology,
IPR,
Microorganism,
TRIPS,
Patents,
Invention,
Prior art,
Know how,
Socio-economic issues

Correspondence to Author:

Pankaj Musyuni

Regulatory Affairs Executive, Brawn Laboratories Ltd., New Delhi, India

ABSTRACT

This paper focuses on a favor in order to examine the implications of patents on innovation in the view of biotechnological developments and the utilization and associated efficacy of present patent system in promoting biotechnological innovations and the related issues and challenges therein. This article deals with patent related area in field of biotechnology. It discusses the various issues in biotechnology patenting.

INTRODUCTION: A biotechnological invention would commonly include products, compositions and processes or methods. Biotechnological products [1] would generally consist of a body of microorganisms as bacteria and fungi, part of microorganisms, plasmids and allied products as antibiotics and enzymes derived from recombinant DNA, antigens, monoclonal antibodies, hybridoma, artificial organs and novel microorganisms obtained as a result of discovery.

Biotechnology have a great impact and potential in field of agricultural techniques, plant varieties development, pharmaceutical issues, health and environment widely recognized as one of the frontier technologies and witnessed a new explosion area of new technologies in this area drawing the attention of the IPRs claims across the globe [2]. Biotechnology is a new area which has become the subject matter of worldwide attention about its patentability, especially with respect to genetically modified organisms.

It includes techniques that uses living organisms, or parts of organisms, to make or modify products, to improve plants or animals, or to develop microorganisms for specific uses. Recent innovations in the science of biotechnology, have led to a great revolution in multifunctional human activities, which in turn requires a re-look into the legal systems, particularly, the IPRs regime, in order to make them sustainable for the human development and prosperity [3].

Due to the large discrepancy in granting the patents in the area of biotechnology and variations in the different national patent laws, it was felt that there must be a harmonized method of patents & related issues in different countries the globe.

Patenting of Biotechnological Products:

Trips Scenario: TRIPS agreement covers the various aspects of present international intellectual property rights regime which provides the minimum standards of patent protection and its utilization that require mandatory compliance by all member countries [4].

In the context, Indian law of patents 'Indian Patent Act 1970', like many other member countries of WTO introduced modifications to the existing laws to make them substantially equivalent in conformity with the TRIPS agreement.

The TRIPS agreement, under Article 27, which is relevant to the field of innovations, provides details for patentable subject matter in the field of biotechnology. It includes products or processes, in all fields of technology, provided, that they are new, having an inventive step and are capable of industrial application. According to Article 27(3) of the TRIPS Agreement, it is mandatory for members to permit patenting of microorganisms, micro-biological and non-biological processes for the production of plants and animals. This provision initiates towards patenting of life forms as microorganisms are very useful in various aspects of agriculture, health and environment. Various processes and product development can be approached through biotech route [5].

However, the TRIPS agreement also provides for exclusion from patentability inventions, which is necessary in order to protect public order or morality, including human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by domestic law.

Thus, as per the TRIPS Agreement, it is essential for the member counties to provide protection for microorganisms as such [6].

Legal Framework of TRIPS: TRIPS oblige to provide patents to all products and processes that are new, involve an incentive step and are capable of industrial application. However, governments are allowed to exclude from patentability plants, animals and essentially biological process for their production. In the case of plant varieties, however, governments are obliged to protect them by patenting 'an effective sui generis system', or a combination thereof. Microorganisms and microbiological process are explicitly not allowed for exclusion from patentability. Nevertheless the lack of definitions leaves the interpretation of terms used in this article to national legislation [7].

TRIPS Controlling Patent Regime Of Member Countries: TRIPS significantly legalize domestic laws of its member's participant countries. It emphasize on criteria's that countries should have an effective patent system for practically all areas of technology which is subject matter to two exceptions given in second and third clauses of the provision [8].

First, article 27(2) provides that members may exclude inventions from patentability where preventing the commercial exploitation of the invention is necessary to protect public order or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment.

Secondary, article 27(3) provides that members may exclude diagnostic, therapeutic and surgical methods for the treatment of humans or animal and plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However members must provide protection of plant varieties either by patents or sui generis system [9].

It would be pertinent to mention that Article 30 of TRIPS ensures that enforcement of such exceptions does not interfere with normal exploitation of patent and legitimate interest of the patent holder.

Indian Patent Law:

Perspective for Grant of Patents: Indian Patent Act, 1970, which is considered as model law in the history of the Patent regimes, provides for a simple definition of the term, 'invention', which is the foundation in determining the steps for the grant of patents. Section 2(1) (j) of the Act defines an 'invention as follows:

"Invention means a new product or process involving an inventive step which is capable of industrial application"

A detailed approach can be taken from above definition which reveals that, the criteria for patentability of an invention are novelty, non-obviousness and industrial application or utility.

Novelty, as first essential criteria means that the invention must be new and it must be different from 'prior art'. 'Prior art' suggests that it should not have been published anywhere in the world or in public domain before the date of filing of patent application [10].

An inventive step or non-obviousness implies that an invention should not be obvious to a person skilled in the art. Person skilled in art is presumed to an ordinary practitioner aware of what was common general knowledge in the art before the date of filing. Such person needs not posses any inventive capability and he would never go against the established scientific principles nor try to neither enter in an unpredictable area nor take incalculable risk. The skilled person can be expected to look for suggestions in neighboring field, if the same or similar problems arise in such fields, he would perform a transfer of technology from a neighboring field to his specific field of interest, if this transfer involves routine experimental work.

Thus, for an invention to be patentable, the Indian patent law requires the invention to be new, to have inventive step (non-obvious) and to be industrially applicable (utility). Additionally, the invention must be repeatable. The question whether the substances such as microorganisms or other biological materials, which are present in nature, can be treated as new, is to be decided by applying the above criteria. The requirements of inventive step constitute one of the most complex questions in the field of biotechnology. It is mandatory requirement of the patent law to provide detailed information of the invention to be protected.

This is commonly referred to as 'sufficiency of disclosure'. In the field of biotechnology the requirement of the condition of sufficient disclosure poses specific problems due to the fact that the inventions in this field involve living entities (biological material). Such materials are not easy to explain in words. It is significant to note that, in order to meet the test of 'sufficiency of disclosure', so far as the biological inventions are concerned, practice has been developed now, wherein, the inventor has to deposit the sample of the living entity involved in the invention with an authorized depository authority [11].

However, though section 10(4) of the Act stipulates the requirement of sufficiency of description, as regards inventions involving biological materials the Act is silent on how to meet the requirement' Certain biotechnological inventions are barred from patenting under Indian Patent Act such as living and non living substances occurring in nature. This includes any microorganism available or found in nature but does not include any microorganism which is modified in its character or isolated. However, where such microorganisms which are modified in its character, and the resultant product or process is contrary to public order or morality which causes serious prejudice to human, animal or plant life or health or to the environment.

Apart from these, according to the Act, any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their product is also not allowed to be patentable. Further, the Act also excludes from patenting the plants and animals in whole or any part thereof including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals [12].

It is significant to note that, in spite of such limitations on the patentable inventions, the inventions in the field of biotechnology have been growing particularly from classical biotechnology such as fermentation, east etc.,

However, the inventions relating to processes or methods of production of tangible and non-living substances by bioconversion or using such microorganisms or by utilizing the above referred

biologically active substances were considered and held patentable. Although, there was no specific mention in the Act of 1970, regarding patentability of live forms such as microorganisms, gene-cell lines etc., the spirit of patent law was to exclude them from patentability.

US Perspective for Grant of Patent: The US has adopted the most liberal approach in the areas of patents relating to biotechnology It is admissible to patent animals and plant varieties in the US In the US, the Patent Act does not contain any exclusionary provisions and has proven to be the country with the most liberal approach towards patenting inventions in the field of biotechnology [13].

In order to get a patent in US, an invention has to satisfy the following requirements;

- Patentable subject matter
- Utility
- Novelty
- Non-obviousness
- Specification

Patentable subject matter: The first and the most basic requirement for patentability is that the invention should fall within the scope of patentable subject matter as defined by the patent statue. The scope and extent of patentable subject matter is very broad and open in US. Only laws of natural world, substantial phenomena, conceptual and abstract ideas fall outside the extent of patentable subject material.

Utility: Section 101 of the US patent Act provides that an invention or discovery should be useful in order to be eligible for a patent grant. Usefulness is a very subjective enquiry and is not considered strictly by the USPTO while dealing with biotech inventions to satisfy this requirement, an invention should have some practical utility in the form of immediate benefit to the public.

A biotech invention would be eligible for patent protection if some; substantial and credible utility judged from the perspective of a person with ordinary skill in the art could be shown.

Novelty: Novelty means originality or innovation. An invention categorize to be patentable must be new in the light of the prior art search (existing data and knowledge at the time of conception of the invention in the public domain).The novelty under section 102 is not diverse from the newness mandatory under section 101. The threshold of novelty to be cleared in the field of biotechnology inventions is very petite whilst compared to other inventions.

Non-obviousness: An invention in order to be patentable should be non-obvious in the light of the prior art. The invention would not be patentable if the differences between the subject matter sought to be patented and the prior art are such that in the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Under US patent law, DNA sequences are considered chemical compounds by US Patent office and are patentable as compositions of matter. Thus US grant patents on all plants of a particular species in to which a specific new gene is inserted by biotechnological means. In this way, a gene can be patented along with legal claims over the isolated gene and DNA sequences, the genetic engineering tools that use the sequences and over the plants derived from these tools [14].

Europe Scenario for Grant of Patent: In Europe, the national, European (European Patent Convention 1973- EPC) and international (Patent Convention Treaty 1970- PCT) patents rights exist in consistently. Knowing the be deficient in of standardization, especially in the patentability of biotechnological inventions, the European Parliament and the Council enacted the Directive 98/44/EC on the legal protection of biotechnological inventions to require the Member States to protect these inventions by means of their national patent law in order to prevent smash up to the unity of the internal market which might result from the Member States' deciding unilaterally to grant or refuse such protection. The Directive has also been incorporated into the EPC by amendment of the Implementing Regulations to the Convention. In

principle, biotechnological inventions may be patentable under the EPC. For European patent applications and patents concerning biotechnological inventions, the relevant provisions of the Convention are to be applied and interpreted in accordance with the provisions of Rules 23b-e. The Directive 98/44/EC is to be used as a supplementary means of interpretation [15].

In fact, Europe adopts a more vigilant approach towards granting biotechnological patents. A non-exclusive list of unpatentable processes is listed, for example, cloning, germ-line modifications, embryo processes, transgenic processes, etc. The discovery/invention distinction also referred to as “attack of obviousness” has been one which has featured strongly in biotechnological patents in Europe.

Inventive Step in Patentability of Biotechnological Inventions: One of the three prerequisites to render a biotechnological invention patentable is inventive step (non-obviousness according to US patent law 35 U.S.C §103), everything that falls within the scope of the claim must be inventive. An invention shall be considered to involve an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art (Art. 56 EPC). The state of the art for the purposes of considering inventive step is as defined in Art. 54(2)

Thus, according to EPO the question to consider, in relation to any claim defining the invention in general and biotechnological invention in particular, is whether at the priority date of that claim, having regard to the art known at the time, it would have been obvious to the person skilled in the art to arrive at something falling within the terms of the claim. If so, the claim is bad for lack of imaginative step. The term "obvious" means that which does not go further than the normal progress of technology but purely follows evidently or rationally from the prior art, that is something which does not involve the implement of any skill or ability beyond that to be predictable of the person skilled in the art. In considering inventive step, as distinct from novelty, it is fair to interpret any published document in the light of succeeding knowledge and to have considered to all the knowledge usually obtainable to the person skilled in the art at the priority date of the claim [16]. However, biotechnology is a field in which matters that are new and inventive today are frequently routine and obvious in only a few year time. Therefore, determining the inventive step for biotechnological inventions is not often easy.

However, EPO has specific criteria to assess inventive step. The Boards of Appeal of EPO usually concern the "problem and solution approach”. This consists fundamentally in: (1) identifying the "closest prior art", (2) assessing the technological results (or effects) achieved by the claimed invention when compared with the "closest state of the art" conventional, (3) significant the technical dilemma to be solved as the purpose of the invention to achieve these results, and (4) investigative whether or not a skilled person, having regard to the state of the art in the sense of Art. 54(2) would have recommended the claimed technical features for obtaining the results achieved by the claimed invention. The problem and solution approach was primarily residential to ensure objective estimation of inventive step and avoid ex position facto examination of the prior art. Thus, the most important issue to determine the inventive step in biotechnological field is the determining of the person skilled in the art and expectation of success in question.

The person skilled in the art in the biotechnological field: The person skilled in the art should be presumed to be an ordinary practitioner aware of what was common general knowledge in the art at the relevant date. He should also be supposed to have had access to everything in the "state of the art", in exacting the credentials cited in the search report, and to have had at his clearance the normal means and capacity for routine work and conducting tests. The person skilled in the art in the biotechnological field is well defined by the case law of the boards of appeal of EPO.

The skilled person in genetic engineering could not be defined as a Nobel Prize laureate. Rather he should be assumed to be a scientist or team of scientists working as a teacher or researcher in the laboratories which made the transition from molecular genetics to genetic

engineering at the time in question. From the notional skilled person nothing more can be expected than the carrying out of experimental work by routine means within the framework of the normal practice of filling gaps in knowledge by the application of existing knowledge [17].

It had to be assumed that the average skilled person would not engage in creative thinking. Yet he (she) could be expected to react in a way common to all skilled persons at any time, namely that an assumption or hypothesis about a possible obstacle to the successful realization of a project must always be based on facts. Thus, an absence of evidence that a given feature might be an obstacle to carrying out an invention would not be taken as an indication that this invention could not be achieved, nor that it could. The knowledge of the notional person skilled in the art had to be considered as that of a team of appropriate specialists who knew all the difficulties still to be expected when considering the cloning of a new gene. However, the skilled person had to be assumed to lack the inventive imagination to solve problems for which routine methods of solution did not already exist.

Patenting of Biotechnological Products:

Various Issues:

Economic and Social Implications: Although biotechnology was known since fermentation was used to produce beer and make bread, the economic interest in biotechnology has increased extraordinarily since modern biotechnology emerged in the as a result of the development of monoclonal antibody technology and techniques of molecular biology and recombinant DNA. Biotechnology based pharmaceuticals as recombinant erythropoietin, growth hormone, genetic engineering to plants, animals as transgenic varieties resistant development [18].

Medicinal plants are valuable sources for agriculture and industrial aspects. However, there cultivation and collection is still an issue governing various regulatory laws. Protection of certain traits as higher yield, higher content yet is a debatable issues.

Recombinant DNA technology makes it possible to selectively modify the genetic material of higher organisms. Genes can be transferred between different species of organisms and between organisms that are not even closely related, for example, bacteria and mice. Existing genes can be cut and spliced to form new gene combinations with new and improved functions.

By comparison with selective breeding methods, the ability to combine genetic material from different organisms by recombinant DNA technology provides a more rapid and reliable way to produce organisms with desired traits. The “transgenic” animals that are produced are used in medical research, in pharming2 and as farm animals with improved nutritional value, reproductive efficiency and growth rate and disease resistance. Transgenic know-how can also potentially be used to conserve animal species [19].

The ability to produce and patent transgenic animals has led many questions as whether creation and patenting of invention that are alive should be permitted. Modern biotechnology creates an unprecedented challenge to the patent system which essentially relies on the discovery, use and transformation of materials found in nature including living materials.

The patenting of biotechnological inventions remains a controversial issue. There are multiple factors responsible for the controversial further biotechnological patents. Some of the key issues and challenges before the patenting regime in relation to the field of biotechnology need to be addressed at the earliest. These steps include:

Criteria of Patentability: In the case of biotechnology the patentability criteria-novelty, utility and non obviousness for granting a patent, has been throwing open new challenges in the form of identifying the novelty in the living matters, which is a very difficult task, if not impossible. This is because, the living things like, animals and gene sequences exist naturally, and as some rightly argue it is impossible for such living matter to be novel.

Non-obviousness: Obviousness has been a sticky subject in the realm of biotechnology because scientists use similar techniques to isolate different gene sequences, been through the gene sequences may be new. Non-obviousness precludes patentability, if given the prior available technology 'prior art', the invention would have been obvious to someone of ordinary skill in the art [20].

Patenting of Human Genome: Patenting of human genome demands great concern. The most common objection to this type of patent is that human genes occur, naturally, they are there to be discovered and not invented. Gene patenting raises two opposing questions [21]:

Is it ethically permissible to patent segments of the human genome when the segments represent part of humankind's 'natural' or universal heritage?

Is it unethical to deny patenting of human genome given the vast economic resources and human efforts expanded for identifying it?

Conflict over Patenting Issues in Biological Materials: Exclusive features of new technologies can result in complicated questions of explanation for patent law. In modern biotechnology, the characteristic between discovery and invention is becoming indistinguishable. Moreover, genetically modified organisms (GMOs) are distinctive as inventions. Not only are several of them alive, but also they are capable to reproduce on their own, and are not well consistent, effortlessly described and so on. If they are unrestricted into the environment, they will intermingle with it unpredictably [22].

It should be noted that, the least developed countries are rich in genetic resources, and many object to intellectual property laws and alleged 'biopiracy' on grounds of morality and social justice.

The TRIPS agreement has not clear micro-organisms and microbiological processes. This leads to doubts as to whether the micro-organisms existing freely are patentable or their mere isolation in pure form are patentable or human intervention in establishing a level of novelty in the discovered micro-organism is needed for patenting. It further leads to the question as to whether a product produced by a micro-organism which is known, can be patentable or the process is patentable. In absence of clear definition of micro-organism and micro-biological process in the TRIPS agreement, the country needs to draw a distinctive line between the product of human intervention leading to novelty and those freely occurring in nature [23].

In the vicinity of biotechnology, there are additional debates and issues on the right to patent living organisms, especially possessions and seeds that have been developed or accepted on as conventional and community knowledge. This condition on public knowledge often comes onto conflict with indigenous knowledge and the right of indigenous people, sustainability of local ecosystems, and even the ability of protection of the global environment.

The current patent system may not provide adequate property protection for biotechnological inventions. This is for the reasons, that genetically engineered inventions are too complex to be accurately described, making it difficult to determine whether the invention is patentable or infringing and that the complex of organisms inhibits disclosure of inventions that would enable the public to make and use the invention after the patent expires.

In the case of biotechnological patents there is a great possibility of granting benefit of patent to an undeserving patentee because sometime the interested parties involved in this technology make it possible to grant patens on gene fragments, genetic tests and proteins where the real functioning is not fully known[24]. The fears associated with the products of biotechnology are not so much because of the product but because of the emerging IPR regime and control of intellectual property by the MNCs.

Suggestions: In the context of biotechnological developments it requires rigorous research and collective studies in order to have a better and optimum understanding of the implications of biotechnological patents. Harmonization of the conflicting opinion of different countries should be the guiding spirit and the key for permitting innovations, in

the field of biotechnology for grant of patents. The international patent regime should be harmonized in such a way that the sovereignty over resources is maintained and simultaneously international collaboration for biotechnological research is carried on.

In order to maintain fair and adequacy of supply of the biotech based medicines and other health products, the countries should adopt a range of policies to ensure that the new patent regime will not hamper their human right to health. And need to ensure that their IP protection regimes do not run counter to their public health policies and that they are consistent with human rights protection.

So far as the utility criteria is concerned, for the grant of a patent, high standards need to be strictly implemented and only inventions that have clear substantial, credible and current utility should be allowed. Such an approach would avoid lot of patents, which might hamper research and also make the scientific advancements to remain within the public domain.

CONCLUSION: The international legal system pertaining specially to patent regime needs to be redefined with association of ongoing biotechnological development in developing countries. In present scenario, biotechnology has capability to serve the public in various ways by providing great advantages to health, food, medicine and environment. The approach, while dealing with the biotechnology should be practical and efficient. Patent is yet most viable tool for patent protection. Patent system provides optimum protection by encouraging inventors to concentrate on view of industrial applications also.

Human rights approaches to intellectual property rights always have a controversial issue between rights of inventors, creator and interests of society and public. Thus, there is also an imperative need for adopting a balanced human rights approach to IP regimes to facilitate and enhance growth of scientific attitude. In a broad way, it automatically have an advantageous impact on an individual, group level and also approach the benefits of source at both level.

REFERENCES

1. G J Annas, “The Man on the Moon, Immortality and Other Millennal Myths: The Prospects and Perils of Human Genetic Engineering” (2000) 49 Emory Law Journal 753
2. J. Thomson, The Grey Penumbra of Interpretation Surrounding the Obvious Test for Biotech Patents, European Intellectual Property Review, EIPR 1996, 18(2), 90-96
3. C. Occoferri, , Patents - Patentability of Biotech Inventions, European Intellectual Property Review, Italy, EIPR 2000, 22(10), N142-144
4. R J Gutowski “The Marriage of Intellectual property and International Trade in the TRIPs Agreement: Strange Bedfellows or a Match made in Heaven” (1999) 47 Buff. L. Rev. 713
5. J H Reichman, “The TRIPs Agreement Comes of Age: Conflict or Cooperation with the Developing Countries (2000) 32 Case W. Res. J. Int'l L. 441
6. Y Ko, “An Economic Analysis of Biotechnology Patent Protection” (1992) 102 Yale L. J 777
7. Intellectual Property Reading Material, (World Intellectual Property Organization (WIPO)), Publication 476E, Sections 4.60 and 4.61, p .59.
8. Agreement on Trade-Related Aspects of Intellectual Property Rights Annex 1C, Art 70 §9 (entered into force 1994) http://www.wto.org/english/tratop_e/trips_e/t_agm2_e.html
9. Correa Carlos M., (2000) `Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options’, Zed Books Ltd, London and Third World Network, Malaysia.
10. Indian Patent office (http://www.ipindia.nic.in/)
11. TRIPS Agreement and Amendment of Patents Act in India, Economic and Political Weekly, 2005, Vol.37, No.32, P.3354-3360
12. Gupta, S. (2002), The Problems Raised by Biotechnological Inventions for Patent Scope Interpretation (http://www.inter-lawyer.com/articles/patent-scope.html)
13. Lemley, Mark The Patent System Today and Tomorrow Before Subcommittee on Intellectual Property of the Senate Committee on the Judiciary, 109th Cong. (2005) (statement of John W. Dudas, Under Secretary of Commerce for Intellectual Property and Direct of the U.S. Patent and Trademark Office); Rational Ignorance at the Patent Office, 95 Nw. U. L. Rev. 1495, 1495-96 (2001) (comments on the numerous criticisms of the PTO’s patent prosecution process).
14. L. Foster, et al. (2002), Patenting in Biopharmaceutical Industry-Comparison (http://www.derwent.com/ipmatters/features/biopharmaceutical.html)
15. D. Wood, European Patents for Biotechnological Inventions-Past, Present and Future, World Patent Information 23 (2001) 339-348
16. European Patent Office, Guideline for the Examination in the EPO, Rule 23 (http://www.european-patent-office. org/legal/ guidelines/e/c_iv_2a.html)
17. Muir, et al, European Patent Law: law and Procedure under the EPC and PTC, Oxford University Press, ISBN 0-19-826875-0, p.163
18. Gould, M. David and C Gruben William, “The Role of Intellectual Property Rights in Economic Growth,” Journal of Development Economics, 1996, 48, 323-350.

19. Mansfield, Edwin, 1994, Intellectual Property Protection, Foreign Direct Investment, and Technology Transfer, International Finance Corporation, Discussion Paper 19
20. R. Chapman Audrey, A human rights perspective on intellectual property, scientific Progress, and access to the benefits of science, Science and Human Rights, American Association for the Advancement of Science (Washington, D.C., United States of America)
21. Article 15.1 (b), International Covenant on Economic, Social and Cultural Rights, henceforth ICESCR, adopted 16 December 1966, 21 U.N. GAOR Supp. (No. 16), p. 49, U.N. Doc. A/6316 (1966)
22. Mcinrey, Biotechnology: Biogen v. Medeva in the House of Lords, [1998] EIPR 14 and Ko Yusing, An Economic Analysis of Biotechnology Patent Protection, 102 The Yale L. J., 777 (1992)
23. J. Barton, Research-tool patents: issues for health in the developing world. Bulletin of the World Health Organization, 2004, 80, 121-125.
24. R. Dahl, Pending resolution: the question of who owns DNA. Environmental Health Perspectives, 109 (1), 2007, A31-A33

****