thoroughly the merits of the case and the implications of the law. The Court wanted to know the efficacy of the drug as required under Section (3) of the Indian Patents Act, 1970. On Monday, April 1, 2013 the Supreme Court, in its landmark decision, rejected Novartis AG's request for the grant of a patent. for an updated version of a cancer drug.

VIII. Comments on the judgment of the Supreme Court

The Judgment has been appreciated by the health activists stating that the judgment ensures poor patients around the world to get continued access to cheap versions of lifesaving medicines. They have expressed their appreciation on the ground that the drug for which Novartis was claiming the Patent did not merit intellectual property protection in India because it was not a new medicine. What the Court said was that a patent could only be given to a new drug and not to those which are only slightly different from the original. The court's decision has global significance since India's $ 26 billion generic drug industry, which supplies much of the cheap medicine used in the developing world, could be stunted if Indian law allowed global drug companies to extend the life span of patents by making minor changes to medicines.[10] The judgment has been criticized by the dealers of drugs and the manufacturers as one affecting the concept of Research and Development in Science and Technology..

10- Associated Press, April 1, 2013.

member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

Referring to the Debate that took place in the Union Parliament with regard to the amendments to be made to the Patents Act, the Judgment of the Supreme Court has quote the following discussion :

«82. It is interesting to note that in the Parliamentary debate, the names of the appellant company (Novartis) and the drug (Gleevec) being the subject matter of this case were repeatedly mentioned, and the excessively high price fixed for the drug after the grant of «exclusive marketing rights» to the appellant was expressly cited as the likely result of bringing in the product patent regime in pharmaceuticals. One of the members said: «Sir, a company which obtains a patent by changing their chemicals, before the expiry of the patent, they will again apply for a patent and again get a patent. So, in this way, they will continue to get a patent for the same medicine. For example, the drug called ‹Glevic› (sic Gleevec/Glivec), is used for the treatment of Leukaemia. It is patented by Novartis. This was originally patented in 1993. The cost of the drug for the treatment of this disease comes to about Rs.1,20,000 per month[21] in India. At the same time, the generic versions are available in the country which cost only Rs.8,000 to Rs.10,000.

«83. As the deliberations were going on in Parliament, negotiations were also held between the ruling party and some of the opposition parties, in course of which certain amendments were suggested in the Bill. And in order to allay the apprehensions and fears voiced by the Opposition, one of the members from the Government said: «Madam, I am concluding. I would only like to refer to the amendment which is being incorporated in Clause 3 which talks of the known inventions, the products which are not considered to be inventions and therefore cannot be covered by the patent and patents cannot be sought for them. A good amendment is being introduced to that effect in Clause 3 of the Bill which says: «The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance of (sic or) the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.» The explanation to that should completely allay the fears of our friends on the other side. I hope they would accept that.

«84. Speaking at the conclusion of the debate, the minister who had sponsored the Bill also referred to the amendment proposed in section 3(d).He said: «There are so many provisions here. In regard to ever greening, I just want to read out section 3(d) which says that a mere discovery of a new property or a new use for a known substance or the mere use of known process in a new product - these are exceptions, these will not be granted any patent - and substances obtained by a mere ad-mixture resulting only in aggregation of properties of the components thereof or, processes of producing such substances will not be given patents.

«85. Finally, after three days of debate (March 18, 21 and 22) the Bill, along with the amendments proposed by the minister, was passed by the Lok Sabha on March 22, 2005. Some of the very important amendments that were incorporated in the Bill related to section 2(1)(ja) and section 3(d), and the insertion of the provision for pre-grant opposition to grant of patent.

Guided by the established principles of interpretation and the previous decisions on related subjects the Supreme Court examined

entire act and by reference to what preceded the enactment and the reasons for it that the Court construed the expression 'Prize Chit' in Srinivasa and we find no reason to depart from the Court's construction."

After the legislation of 1970 and the amendments made in 1999 and 2002 at the national level there were certain developments at the international level in the form of the Doha Declaration, the Trips Agreement etc. which called for further Amendments to the Patents Act. The debate that took place in the Parliament on this subject, which has been quoted extensively, in the judgment of the Supreme Court is a very crucial aspect of the controversy, particularly with regard to the interpretation of the relevant provisions of the Patents Act..

Referring to the Doha Declaration it is quoted in the Judgment of the Supreme Court that The TRIPS Agreement also provides for a built-in mechanism for review through the biennial Ministerial Conference (vide Article 71). The Ministerial Conference is the highest decision-making body of the WTO and it can make decisions on all matters under any of the WTO agreements, including the TRIPS Agreement. The fourth WTO Ministerial Conference in Doha on November 14, 2001, adopted the Doha Declaration on the TRIPS and Public Health.

The Doha Declaration is as follows:

«1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

4. We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members› right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:
a. In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.
b. Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.
c. Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
d. The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each

i) Any process for the medicinal, surgical, curative, prophylactic or other treatment of human beings or any process for a similar treatment of animals or plants to render them free of disease or to increase their economic value or that of their products.

The term 'invention' was re-defined by the Amendment Act of 2002 as under :

Section 2 (1(j) 'invention' means a new product or process involving an inventive step and capable of industrial application.

VII. Interpretation of the relevant provision of law :

In Para 26 of the Judgment the learned Judges have given a lucid rationale of the method they adopted for the interpretation of the law. They say, "It is easy to know why section 5 was deleted but to understand the import of the amendments in clauses (j) and (ja) of Section 2(1) and the amendments in section it is necessary to find out the concerns of Parliament based on the history of the patent law in the country, when it made such basic changes in the Patents Act. What were the issues the legislature was trying to address? What was the mischief Parliament wanted to check and what were the objects it intended to achieve through the same amendments?

Proceeding further the Court referred to certain earlier decisions of the Supreme Court and emphasized the method which they considered to be appropriate. Reference was made to the case of Utkal Contractors and Joinery Pvt. Ltd and others v. State of Orissa and others[8] Justice Chinnappa Reddy, speaking for the Court said,

"A statute is best understood if we know the reason for it. The reason for a statute is the safest guide to its interpretation. The words of a statute take their colour from the reason for it. How do we discover the reason for a statute? There are external and internal aids. The external aids are statement of Objects and Reasons when the Bill is presented to Parliament, the reports of committees which receded the Bill and the reports of Parliamentary Committees. Occasional excursions into the debates of Parliament are permitted. Internal aids are the preamble, the scheme and the provisions of the Act. Having discovered the reason for the statute and so having set the sail to the wind, the interpreter may proceed ahead."

Again in Reserve Bank of India v. Peerless General Finance and Investment Co. Ltd and others [9] Justice Reddy said,

"Interpretation must depend on the text and the context. They are the bases of interpretation. One may well say if the text is the texture, context is what gives the colour. Neither can be ignored. Both are important. That interpretation is best which makes the textual interpretation match the contextual. A Statute is best interpreted when we know why it was enacted. With this knowledge the statute must be read, first as a whole and then section by section, clause by clause, phrase by phrase and word by word. If a statute is looked at, in the context of its enactment, with the glasses of the statute-maker, provided by such context, its scheme, the sections, clauses, phrases and words may take colour and appear different than when the statute is looked at without the glasses provided by the context. With these glasses we must look at the act as a whole and discover what each section, each clauses, each phrase and each word is meant and designed to say as to fit into the scheme of the entire Act. No part of a statute and no word of a statute can be construed in isolation. Statutes have to be construed so that every word has a place and everything is in its place. It is by looking at the definition as a whole in the setting of the

8- (1987) 3 SCC 279

9- (1987) 1 SCC 424

The IPAB also referred to the judgment of the Madras High Court, dismissing the appellant's writ petitions challenging the constitutional validity of section 3(d) where the High Court had observed: "We have borne in mind the object which the amending Act wanted to achieve namely, to prevent ever greening; to provide easy access to the citizens of the country to life saving drugs and to discharge their constitutional obligation of providing good health care to its citizens.

Against the order of the IPAB the appellant went directly to the Supreme Court in a petition under Article 136 of the Constitution.

VI. Matters that had arisen for the consideration of the Court

The Supreme Court had to examine thoroughly the provisions of the Patent Act 1970 which had replaced the Patents & Designs Act, 1911 defining the terms 'invention' and 'medicine' in clauses (j) and (l) respectively as under :

Section 2 (1) (j) 'invention' means any new and useful''

i) Art, process, method or manner of manufacture;
ii) Machine, apparatus or other article;
iii) Substance produced by manufacture and includes any new and useful improvement of any of them, and an alleged invention.

Section 2 (1) (l) 'medicine or drug' includes—

i) All medicines for internal or external use of human beings or animals;
ii) All substances intended to be used for or in the diagnosis, treatment, mitigation or prevention or diseases in human beings or animals;
iii) All substances intended to be used for or in the maintenance of public health, or the prevention or control of any epidemic disease among human beings or animals;
iv) Insecticides, germicides, fungicides, weedicides and all other substances intended to be used for the protection or preservation of plants;
v) All chemical substances which are ordinarily used as intermediates in the preparation or manufacture of any of the medicines or substances above referred to."

Section 3 What are not inventions:

The following are not inventions within the meaning of this Act-

a) An invention which is frivolous or which claims anything obviously contrary to well established natural laws;
b) An invention the primary or intended use of which would be contrary to law or morality or injurious to public health;
c) The mere discovery of a scientific principle or the formulation of an abstract theory;
d) The mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless known process results in a new product or employs at least one new reactant;
e) A substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance;
f) The mere arrangement or re-arrangement or a duplication of known devices each functioning independently of one another in a known way;
g) A method or process of testing applicable during the process of manufacture for rendering the machine, apparatus or other equipment more efficient or for the improvement or restoration of the existing machine, apparatus or other equipment or for the improvement or control of manufacture;
h) A method of agriculture or horticulture;

term of protection of 20 years counted from the date of filing.

The WIPO treaty and several related international agreements are premised on the notion that the protection of intellectual property rights are essential to maintaining economic growth. The WIP Intellectual Property Handbook gives two reasons for intellectual property laws: One is to give statutory expression to the moral and economic rights of creators in their creations and the rights of the public in access to those creations. The second is to promote, as a deliberate act of Government policy, creativity and the dissemination and application of its results and to encourage fair trading which would contribute to economic and social development.

V. The dispute between Novartis and the Drug authorities of India

Novartis International AG is a Swiss multinational pharmaceutical company based in Basel, Switzerland, ranking number two in sales among the world wide industry. Novartis manufactures such drugs as Glozapine, diclofenac, carbamazepine, and Imatinib mesylate (Gleevec).

In 1997, Novartis had filed its application before the Drug Authority for a patent. A patent for an invention protects the technical aspects and/or characteristics of a new technical achievement, a new machine, a new chemical product, a new process or method.

The Assistant Controller of Patents and Designs heard the parties to the dispute as per rules. The Assistant Controller held that the invention claimed by the appellant was anticipated by prior publication, i.e., the Zimmermann patent; that the invention claimed by the appellant was obvious to a person skilled in the art in view of the disclosure provided in the Zimmermann patent specifications; and further that the patentability of the alleged invention was disallowed by section3 (d) of the Patent Act of India.

Novartis challenged the orders passed by the Assistant Controller in writ petitions filed directly before the Madras High Court. Apart from challenging the orders of the Assistant Controller, the appellant also filed two writ petitions (one by the appellant and the other by its Indian power of attorney holder) seeking a declaration that section 3(d) of the Act is unconstitutional because it not only violates Article 14 of the Constitution of India but is also not in compliance with "TRIPS" Agreement. After the formation of the Intellectual Property Appellate Board, five writ petitions challenging the five orders of the Assistant Controller were transferred from the High Court to IPAB by order dated April 4, 2007, where these cases were registered as appeals and were numbered. The other two writ petitions assailing section 3(d) of the Act were finally heard by a Division Bench of the High Court and dismissed by the judgment and order dated August 6, 2007..

The appellant's appeals against the orders passed by the Assistant Controller were finally heard and dismissed by the IPAB by a long and detailed judgment dated June 26, 2009. Though the IPAB reversed the findings of the Assistant Controller on the issues of anticipation and obviousness it held that the patentability of the subject product was hit by section 3(d) of the Act. Referring to section 3(d) the IPAB observed: "Since India is having a requirement of higher standard of inventive step by introducing the amended section 3(d) of the Act, what is patentable in other countries will not be patentable in India. As we see, the object of amended section 3(d) of the Act is nothing but a requirement of higher standard of inventive step in the law particularly for the drug/pharmaceutical substances.

of confining the patentability of inventions relating to chemical products or substances to process claims. The law was then followed in many other countries in the world, for instance Austria, Brazil, Czechoslovakia, Holland, Hungary, Japan, Mexico, Norway, Poland and the U.S.S.R. Products produced by chemical process were not patentable though processes for making such products were patentable, if, of course, they satisfied the other tests of patentability, e.g. novelty, subject matter, etc. In light of the experience of the other countries, Justice Ayyangar recommended: "I have considered the matter with the utmost care and have reached the conclusion that the chemical and pharmaceutical industry of this country would be advanced and the tempo of research in that field would be promoted if the German system of permitting only process claims were adopted.

Justice Ayyangar submitted a comprehensive Report on Patent Law Revision in September 1959 and the new law of patent, namely, the Patents Act, 1970, came to be enacted mainly based on the recommendations of the report of Justice Ayyangar, and came into force on April 20, 1972, replacing the Patents and Designs Act, 1911.

IV. International perspectives on Intellectual Property Rights

The Twentieth Century gave a new twist to the concept of intellectual property, in that certain international organizations like the United Nations considered intellectual property to be worthy of protection and introduced a few international agreements. The Universal Declaration of Human Rights, the General Agreement on Trade and Tariff, the Trips Agreement, the Doha Declaration etc. are instances of how the concept of intellectual property has captured the attention of international organizations. But such an international outlook has created a problem for the national governments as to how they should adopt the new regulations.

According to the Universal Declaration of Human Rights, "everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author".[7]

The World Trade Organization (WTO) has been established by an agreement which has since been ratified by India. This Agreement inter alia, contains an Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) which came into force from 1st January 1995. It lays down minimum standards for protection and enforcement of intellectual property rights in member countries which are required to promote effective and adequate protection of intellectual property rights with a view to reducing distortions and impediments to international trade. The obligations under the TRIPS Agreement relate to provision of minimum standard of protection within the member countries legal systems and practices.

The Agreement provides for norms and standards in respect of the areas of intellectual property such as Patents, Trade Marks, Copyrights etc. The basic obligation in the area of patents is that, invention in all branches of technology whether products or processes shall be patentable if they meet the three tests of being new involving an inventive step and being capable of industrial application. In addition to the general security exemption which applied to the entire TRIPS Agreement, specific exclusions are permissible from the scope of patentability of inventions, the prevention of whose commercial exploitation is necessary to protect public order or morality, human, animal, plant life or health or to avoid serious prejudice to the environment. The TRIPS Agreement provides for a minimum

7- Article 27 of the Universal Declaration of Human Rights, 1948

substance or any invention relating to surgical or curative devices. The committee's recommendation prompted the Government to introduce a bill[4] in Parliament, but the bill was not pressed and it was allowed to lapse.

In 1957, another committee came to be appointed under the chairmanship of Justice N. Rajagopala Ayyangar to take a fresh look at the law of patent and to completely revamp and recast it to best sub-serve the(contemporary) needs of the country.[5]

Justice Ayyangar painstakingly collected valuable data (taking the figures for the years 1930 to 1939 from the Bakshi Tek Chand report) and, compiling them into a number of tables,[6] showed the share of Indians in the field of patents. He analyzed the figures in the tables and pointed out that during the period 1930-37, the grant of patents to Indians and foreigners was roughly in the ratio of 1:9. Even after Independence, though a number of institutions for post-graduate training were set up and several national laboratories were established to encourage a rapid growth of scientific education, the proportion of Indian and the foreign patents remained substantially the same, at roughly 1:9. Justice Ayyangar further pointed out that this ratio does not take into account the economic or industrial or scientific importance of the inventions. If these factors are taken into account, Indians would appear to be lagging even further behind. Further, taking into reckoning the number of inventions for which renewal fees were paid beyond the 6th year, which would give a rough idea of the value attached to the invention by the patentee, the patents taken by Indians would appear to be of little wo§§ §rth as compared with patents held by foreign nationals.

Justice Ayyangar examined the nature of the patent right and considered the arguments advanced as justifications/rationalizations for grant of patents. He described the patent law, in his report, as an instrument for managing the political economy of the country. He observed: "It would not be an exaggeration to say that the industrial progress of a country is considerably stimulated or retarded by its patent system according as to whether the system is suited to it or not." (p. 9, para 16) He also quoted from Michel with approval as under: " Patent systems are not created in the interest of the inventor but in the interest of national economy. The rules and regulations of the patent systems are not governed by civil or common law but by political economy.

Observing that industrial countries and under-developed countries had different demands and requirements, Justice Ayyangar pointed out that the same patent law would operate differently in two countries at two different levels of technological and economic development, and hence the need to regulate the patent law in accordance with the need of the country.

One of the improvements suggested was to define, with precision, those inventions which should be patentable and clearly identify certain inventions, the grant of patents to which would retard research, or industrial progress, or be detrimental to the national health or well-being, and to make those inventions non-patentable. Justice Ayyangar's report specially discussed (a) patents for chemical inventions; and (b) patents for inventions relating to food and medicine.

In regard to patents for chemical substances, Justice Ayyangar examined the history of the law in other countries and pointed out that Germany was the first to adopt the system

4- Bill No. 59 of 1953.
5- Bakshi Tek Chand Committee's Report also called Patents Enquiry Committee Report.
6- Michell on Principal National Patent Systems, Vol.1, page 15.

has considerably widened, unfortunately none of the matters concerning them has been free from controversy. As in the case of other kinds of intellectual property in the case of patents also the nature of the rights guaranteed to the inventors and the scope of the regime established for the protection of the rights have raised the question of the recognition of the inventions and the extent to which the authorities could go to protect them. One such problem was noticed in the case of the recent controversy of a Patent against the drug authorities of India in which the drug manufacturer wanted a Patent to be recognized for his drug called Gleevec It is with this controversy that this article is concerned.

Before dealing with any particular aspect of the controversy of the Novartis case the presenter of this article considers it necessary to submit that the Legal systems at the national and International levels not only gave recognition to the interests of a man in his discoveries and inventions but also managed to establish a regime for the protection of the different components of intellectual property. The supporter of intellectual property law believe in the theory that intellectual property is desirable because it encourages innovation. By giving such a protection and full value they treat intellectual property as another type of 'real property'. The exclusive rights given to the inventor allow the owners of intellectual property to benefit from the property they have created, providing a financial incentive for the creation of an investment in intellectual property and in case of patents, pay associated research and development costs. As in the case of other forms of intellectual property in the case of Patent laws also the authorities believe that the creators will not have sufficient incentive to invent unless they are legally entitled to capture the full social value of their inventions.

It is on this theory that the law on the legal regime for the protection of Patents has developed at the national as well as the international levels.

III. Patent Law in India

Prior to Independence of the country India's patent regime was governed by the Patents and Designs Act, 1911, which had provisions both for product and process patents**.** It was, however, generally felt that the patent law had done little good to the people of the country. The way the Act was designed benefited foreigners far more than Indians. It did not help at all in the promotion of scientific research and industrialization in the country, and it curbed the innovativeness and inventiveness of Indians. Shortly after Independence, therefore, in 1949, a committee was constituted under the chairmanship of Justice (Dr.) Bakshi Tek Chand, a retired judge of the Lahore High Court, to undertake a comprehensive review of the working of the 1911 Act.

The Committee submitted its interim report on August 4, 1949 and the final report in 1950 making recommendations for prevention of misuse or abuse of patent rights in India. It also observed that the Patent Act should contain a clear indication that food and medicine and surgical and curative devices were to be made available to the public at the cheapest price commensurate with giving reasonable compensation to the patentee.

Based on the committee's recommendations, the 1911 Act was amended in 1950[2] in relation to working of inventions, including compulsory licensing and revocation of patents. In 1952, a further amendment was made by an Act[3] to provide for compulsory license in respect of food and medicines, insecticide, germicide or fungicide, and a process for producing

2- Act XXXII of 1950.
3- Act LXX of 1952.

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Legal Analysis of the Problems That Were Involved In the Recent Battle for a Patent Between Novartis, A.G. and The Union of India

Abdul Rayees Khan

I. General Introduction

Patent is concerned with the protection of invention which is the result of the mental capacities of a person. The protection is afforded to the inventor for his personal achievement and the work is treated by the modern systems of law as property of the inventor.

Ancient jurisprudence however used the term 'property' in respect of material objects only and the ownership of these objects was called corporeal ownership.[1] No ownership was conceded in respect of incorporeal objects. Further, the remedies in relation to material objects were under the rules of private law only; they were mostly in the form of writs of trespass which were issued under the Law of Torts. A peculiar feature of the regime in vogue for the protection of property earlier afforded no protection to things which were not material or physical objects.

But a change took place in the wake of changes in the economic philosophy and legal thinking of the people which brought about a change in the matter of protecting a thing even if it was not a physical object. The modern jurisprudence has therefore conceded the term 'property' even in respect of such objects which are not material or physical objects as such but are the result of abstract ideas. The kind of ownership in respect of such things is known as incorporeal ownership. In other words, the Law has come to recognize intangible interests besides the tangible interests as worthy of protection.

1- Dr.Avatar Singh: Introduction to Jurisprudence, Edition 2001, p. 216

II. Intellectual Property Law

Intangible interests have in course of time grown in number and together they form the subject matter of Intellectual Property Law. Patents, Trade marks, Copyrights, Goodwill in business, interests in artistic and literary works are all subject matters of the Intellectual Property Law.

Among the significant features of this new branch of law mention may be made of the fact that the rights of the owners of this kind of property are protected both under the Private Law and the Public Law. The availability of new remedies through the marriage of private and public law has in fact afforded a boost to the Intellectual Property Law.

The growth and development of intellectual property rights has been due mostly to the advance of Science and Technology. These feeder disciplines have been responsible for new inventions and have considerably widened the scope of Intellectual Property Law in various matters.

Recognition given by law to the invention of persons has resulted in various companies and organizations coming up in various fields including food and drug. Research has progressed a lot and a number of multinational companies pursing the course of research and working in the cause of development have come up. Some of the companies which have come up are the Pfizer, the Novartis, the Ciba, the Sandows etc.

Although the concept of intellectual property

التحليل القانوني

للمشاكل الناشئة عن النزاع الحديث بين منتج الدواء (نوفارتس) والسلطات الهندية المخولة بمنح البراءة

عبد الريس خان
تنزانيا – شرق أفريقيا

الملخص

يتعلق هذا البحث بالمشاكل التي ظهرت بين منتج الدواء نوفارتس أي ج والسلطات المخولة ببراءات الاختراع في الهند. فالدواء الذي طلب نوفارتس براءة الاختراع عنه كان نوعا جديدا (كليفس) ولكن أصل الدواء سبق أن منحت براءة الاختراع عنه لنوفارتس. ونازع نوفاترس بأن النوع الجديد للدواء كان ثمرة الجهود البحثية العلمية وأنه يمكن أن يفيد عددا كبيرا من المرضى الذين يعانون من مرض السرطان والأمراض الأخرى ذات الصلة في الهند وخارجها. وقد رفضت المحكمة العليا للمدارس التي رفعت القضية أمامها أن تستجيب لطلب نوفارتس. ومن ثم بحث نوفارتس عن معالجة إدارية للموضوع أمام المجلس الاستئنافي الذي ينظر في قضايا الدواء ولكنه لم ينجح أيضا. وهذا ما جعل المحكمة العليا تتجه إلى مقاربة قضائية خاصة.

ففي أبريل عام ٢٠١٣ أصدرت هذه المحكمة قرارها وصادقت بموجبه على قرار محكمة مادراس وبذلك رفضت منح براءة لنوفارتس عن النوع الجديد للدواء. ورأى البعض أن القرار هو تفسير متوازن لقانون براءات الاختراع الهندي عام ١٩٧٠ بينما انتقده بعض آخر، خاصة من يدعم العمل الصيدلي ووصف القرار بأنه يقوض البحوث العلمية والتطور في هذا المجال. والبحث يقدم تحليلا للمشكلة القانونية التي تتعلق بهذه القضية التي أصبحت محل جدل. إن براءة الاختراع هي من موضوعات الملكية الفكرية، والمعالجة في هذا البحث تبدأ ببيان مفهوم الملكية الفكرية وتبين كيف تظهر المصالح المختلفة لتكون جزءًا من الملكية الفكرية وما هو دور الشركات في هذا السياق. ويتتبع البحث تطور قانون براءات الاختراع على المستوى الوطني والدولي فيما يتعلق بالبراءات المتعلقة بالدواء. ويغطي التحليل في هذا البحث الطرائق التي تبنتها المحكمة العليا في تفسير النصوص ذات الصلة في القانون الهندي، مع ملاحظة أن المشرع الهندي أخذ بالاعتبار النصوص الدولية المتعلقة ببراءات الاختراع. ويأخذ البحث بعين الملاحظة حقيقة أن الجهات القانونية الهندية نظرت مسألة تشجيع البحث وتطوره في مجال العلم والتكنولوجيا، وحاولت المحافظة على مصالح شركات الأدوية إلى الحد الأدنى. وأخيرا فإن المعالجة في هذا البحث تنتهي بإظهار ماهو سلبي وما هو إيجابي في قرار المحكمة العليا.

الكلمات المفتاحية: الملكية الفكرية. براءات الاختراع. أدوية.

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Legal Analysis

of the Problems That Were Involved In the Recent Battle for a Patent Between Novartis, A.G. and The Union of India

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Abstract

This article is with regard to the problems that had arisen for a Patent between a drug manufacturer, Novartis AG, and the Patent authorities of India. The drug in respect of which the patent was requested by Novartis was a new version of the drug (Gleevec) for the original of which Novartis had already a patent. Novartis contended that the new version of the drug was the result of its scientific research and could benefit a large number of patients suffering from Cancer and other related diseases, in and outside India.

The Madras High Court where the matter was first litigated refused to grant the request of Novartis. The manufacturer then sought an administrative remedy from the Drugs Appellate Board but could not succeed in that effort either. Then it approached the Supreme Court of India in its special leave jurisdiction. On 1st April 2013 the Supreme Court gave its decision upholding the verdict of the Madras High Court thereby denying Patent to Novartis for a new version of the drug.

The decision of the Supreme Court has been appreciated by some as a balanced interpretation of the Indian Patents Act, 1970 but it has been criticized by some others, particularly the pharmaceutical activists, as detrimental to scientific research and development (R & D). An analysis is furnished in this article about the legal problems relating to the questions that were involved in the controversy.

Patent being an aspect of Intellectual Property the discussion here starts with an explanation of the concept of Intellectual Property and shows how different kinds of interests emerged as forming part of Intellectual Property and different companies came up for the promotion of various kinds of medicines. This article also traces the development of law on patents at the national level and international levels concerning the system of Patents in medicines. The analysis also covers the method adopted by the Supreme Court in interpreting the relevant provision of the Indian law taking note of the view the Indian legislature had taken in accommodating the provisions of international legislation on Patents. It also takes note of the fact that Indian authorities discussed the problem of promoting research and development in science and technology and tried to keep the monopoly of the pharmaceutical companies at the minimum.

Finally, the discussion ends up with comments for and against the decision of the Supreme Court.

Keywords: Intellectual property. Patent . Drugs.

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