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Transcending Differences: The Challenge for Pharmaceuticals in the Post-TRIPS Indian Patent Regime

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In the absence of a universal patent law with global jurisdiction , members of the World Trade Organisation (WTO), have adopted and legislated national laws in their respective countries though some what different interpretations of the TRIPS Agreement. While the Patent Cooperation Treaty (PCT) was the first attempt for a near harmonized system by accepting a common application, PCT has little use during the prosecution phase of patent applications. One of the important issues which have been differently interpreted is related to the patentability criteria and exceptions to patentability dealt with under Articles 27.2 and 27.3 of the TRIPS Agreement. Thus Section 3(d) of the Indian Patents Act has turned out to be a contentious issue, the resolution of which may have serious consequences on inventions related to pharmaceuticals. The Novartis case on the Gleevec patents is a case in point. While the Act provides for granting of patents even for known substances if substantial enhancement of activity *vis-a-vis* known activity is established, in practical terms several obstacles to a fair assessment of what is substantial has turned out to be difficult. The provision for pre-grant opposition in the Indian Patents Act has led to a large number of applications from patent groups, pharmaceutical companies and non-governmental organizations. These and related matters are discussed in detail in this paper.

Keywords: TRIPS, PCT, patentability issue, pre-grant opposition

As an industry which relies extensively on a patent-based drug development process, the future of new products in the pharmaceutical industry will largely depend on how patent applications are prosecuted in various jurisdictions, some of which offer different standards of patentability sequence of a patent-based drug development process–be it, financial barriers to access to drugs, unjustifiable high profit margins on its products, disproportionate spending on marketing and advertising often exceeding its R&D budgets.[1] These issues are not peculiar to pharmaceuticals in the developed countries which have a focus on R&D and as a result rely heavily on a patent-based drug development process. The scene in an emerging market like India is no different.

Partly due to the unique development of patent law in various jurisdictions and partly due to inability to agree upon a uniform standard of prosecution of patents, dream of a universal patent law remains just that – an unfulfilled dream. Given this situation of non-cooperation between the countries, the PCT was hailed as a big step towards harmonization of patent laws despite it being a harmonization of procedure for filing patent application across different jurisdictions for preserving priority of the patent. The PCT offers only a common procedure for preferring application in various countries who are members to the PCT. It does not offer a common process of prosecution of the patent application. For that, patent applicant has to individually prosecute application in each of the patent offices where it wants to pursue its application. This brings about a critical flaw in the system. While application for patent filed in different jurisdiction will be the same, as the PCT requires a common application to be made as an original application in one of PCT member countries, based on which the priority is preserved, mode of prosecution is likely to be different often attracting certain unique provisions of patent law which may not be the same as the patent law in the country where the original application is made. This problem is best illustrated by the post-TRIPS changes made in the patent regime in India

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and the resultant effect on patent applications for pharmaceuticals. The Indian Patents Act introduced few provisions, combined effect of which can jeopardize the grant of a number of international applications filed through the PCT route. The problem in prosecuting patent applications in India is peculiar as the country chose a unique route in complying with its obligations under the TRIPS Agreement by opting for a 10-year transition period to bring about the prescribed changes to its patent legislation.

This paper discusses the challenge faced by pharmaceuticals in prosecuting a patent application in the post-TRIPS patent regime in India. It focuses on an issue that is likely to be faced by pharmaceuticals who have applied for product patents based on a PCT application in India. More specifically, this article analyses problems in prosecution of a PCT patent application and effect of exclusions to patentability and how they could be utilized to challenge a patent before grant by a pre-grant opposition procedure. Part I details substantive provisions on the exceptions to patentability and enumerates provision on patentability of known substances that could be attracted in the case of a pharmaceutical patent application. Part II details the procedural provisions on opposition of a patent before its grant (or pre-grant opposition, as it is commonly known). Part III studies interaction between substantive and procedural provisions which allows for an open challenge of patent applications before the grant and illustrates this issue with an account on Novartis' patent application for its anti-cancer drug, Gleevec. Part IV lists the conclusion.

Substantive Provisions on Patentability of Known Substances

Any invention should satisfy three tests of novelty, inventive step and industrial application for it to be patentable as per Section 2(1)(j) of the Patents Act 1970. In addition, invention should not fall under the exceptions laid down in Sections 3 and 4 of the Patents Act, 1970. The history of patent law is replete with exceptions to patentability. The exceptions to certain product patents were made usually on grounds of public policy. The exceptions to certain processes were made either because they were deemed not to be inventions or even if inventions, were deemed to be non-patentable as they did not otherwise satisfy the criteria of patentability.[2] There is no consensus with regard to the standard of patentability set by the TRIPS Agreement. Though the Agreement requires patents to be made available for any invention if the three ingredients of novelty, inventive step and utility are satisfied, it does not define these standards which have led member countries to define their own standards. The TRIPS Agreement also enumerates certain exceptions to patentability.[3] The exceptions to patentability contained in Articles 27.2 and 27.3 of the TRIPS Agreement are not exhaustive. Member countries are permitted to provide for exceptions in addition to the ones mentioned in Article 27 so far as 'patents shall be available and patent rights enjoyable without discrimination as to the place of invention, field of technology and whether products are imported or locally produced'.[4] Thus, exceptions to patentability under the TRIPS Agreement are open-ended.

The Indian Standard

The Indian Patents Act 1970 arguably has the longest list of exceptions to patentability. Sections 3 and 4 contain a list of inventions that are not patentable. Section 3 contains 15 clauses enumerating what shall not be inventions within the meaning of the Act. The nature of the list allows one to make some interesting deductions. The list includes matters that are incapable of being the subject matter of a legal monopoly [like an invention contrary to natural laws – Section 3(a)], matters excluded by policy [like inventions relating to atomic energy – Section 4] and matters protected by other forms of intellectual property rights [like literary, dramatic, musical or artistic work – Section 3(l)].

The exceptions to patentability may also be classified under two broad headings; absolute exceptions and limited exceptions. Absolute exceptions are necessarily unqualified exceptions from which there can be no derogation. Section 4 contains one such absolute exception in that inventions relating to atomic energy shall not be granted patents under the Act. In contrast, limited exceptions offer some scope for the exceptions to come within the purview of patentability subject to certain conditions. For instance, though Section 3(e) states that a mere admixture resulting in the aggregation of the properties of the components cannot be the subject matter of a patent, it does allow for patents for an admixture resulting in synergistic properties. The first part of Section 3(d) will also allow for patenting known substances if an enhancement of known efficacy can be demonstrated.

Exception to Patentability in Section 3(d)

The TRIPS Agreement does not contemplate an exhaustive list of exceptions leaving member countries flexibility to introduce further exceptions on the grounds of policy. Viewed in this context, Section 3(d) of the Patents Act may be viewed as an exception to patentability. The constitutionality of Section 3(d) was question by the pharmaceutical company, Novartis and its validity was upheld by the Madras High Court.[5] This provision is likely to have a significant effect on the patentability of pharmaceutical inventions.

The Three Parts of Section 3(d)

Section 3(d) comprises three parts and one explanation. The section states that the following are not inventions within the meaning of the Patents Act:

> (1) mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance [First part]; or
>
> (2) mere discovery of any new property or new use for a known substance [Second part]; or
>
> (3) mere discovery 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 [Third part].

The explanation reads:

For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

In this paper, only impact of the first part of Section 3(d) on pharmaceutical patent applications is discussed. Significantly, only first part of Section 3(d) was challenged by Novartis as the patent application filed by Novartis was affected only by the first part of Section 3(d). The second part of Section 3(d) affects product patents for new property or new use of a known substance and the third part of Section 3(d) may come into operation in cases of certain process patents.[6]

New Form of a Known Substance

The first part of Section 3(d) contains a conditional exception to patentability of a product. The effect of the first part is that it allows for the discovery of a new form of a known substance to be treated as an invention if there is an enhancement of its known efficacy. The first part of Section 3(d) states that mere discoveries cannot amount to an invention under the Patents Act. It follows that the properties pursuant to such discovery, which are devoid of any inventive step, will not be allowed to be the subject matter of a patent. The critical provision of this section lies in determination of efficacy of the known substance.

Efficacy of a Drug

This provision is most likely to come into effect in case of new forms of known drugs as witnessed in the Novartis case. Efficacy of a drug involves a degree of potency as a drug. Bioavailability of a drug is one of the characteristics that affect the efficacy of a drug. For drugs, reference to a 'property' of a known substance means the physicochemical properties of the drug such as the solubility of the drug in aqueous and other media, stability of the drug in solution, bioavailability, interactions between the drug and excipients (inert substances) etc. The first part of Section 3(d) uses the term 'efficacy' to describe the property of a drug. It deals with an increase or improvement of a known property of a known substance.

The importance of two factors should not be misplaced in determining the scope of the first part of Section 3(d). First, the fact that said clause deals with known substances. Whether a new form of an old and known substance could itself qualify it as a new substance for the purpose of novelty and obviousness is an issue on which there is no consensus. One only needs to look into the practice followed by various countries in the case of selection patents to understand the lack of agreement with regard to granting patents for known substances.[7] Secondly, the first part of Section 3(d) regards an invention as any improvement (enhancement) on the known property (efficacy) of a known substance.

Determining Efficacy

The enhancement of known efficacy has to be determined by the Controller. The standard of efficacy applied for determining the patentability of an invention has to be developed by the Patent Office and the courts, and applied on a case to case basis. The spirit of the provisions in the Patents Act does indicate that the threshold of efficacy is likely to be high. The bar against selection of patents and Swiss

form of claims under Section 3(d) of the Patents Act would further strengthen the requirement of a higher standard of efficacy.

The first part of Section 3(d) will be relevant in determining novelty of a known substance.[8] It has an in-built guideline as it refers to two comparative concepts ie 'known efficacy' and 'enhanced efficacy' for determining patentability of new forms of known substance. The first part states that the 'enhanced efficacy' has to be determined *vis-à-vis* the 'known efficacy'. As first part of Section 3(d) pertains to known substances, it is quite reasonable to assume that efficacy or effectiveness of the substance will also be known. Thus, with the 'known efficacy' as the benchmark, the Controller has to look at the 'enhanced efficacy' and decide whether there has been a significant difference in the efficacy of the new form compared to the existing form. As for the applicant, it will be essential to demonstrate the enhancement of efficacy in the patent application.

Procedural Provisions on Opposition before the Grant

Opposition proceedings to the grant of a patent signify the first instance at which a challenge can be made to the grant of a patent under the Patents Act, 1970. Like the patent laws of various countries, opposition proceedings can be instituted before the authority which grants the patent, ie, the patent office. The opposition proceedings under the Act can be broadly divided into two, i.e., opposition before the grant of a patent (pre-grant opposition) and opposition after the grant (post-grant opposition). The Act also provides for opposition proceedings to oppose amendments, restoration of lapsed patents, surrender of patents, corrections of clerical errors and grant of compulsory licence.

Of the 7000 and odd patent applications for pharmaceutical products pending before the Patent Office, opposition proceedings have been initiated for more than 150 applications. The initial trends demonstrate a preference shown to pre-grant opposition in India for a variety of reasons. First, the large number of mail-box applications pending before the Patent Office has stirred the curiosity of the pharmaceutical industry which has witnessed a comparatively low number of new molecules being developed during that period. Secondly, relatively simple and cost-effective procedure of pre-grant opposition has attracted many pharmaceutical players to the Patent Office. Thirdly, challenging patents is a business strategy in itself which is bound to be employed in India, given the presence of a strong home-grown generic industry. Fourthly, the unrestricted nature of initiating a pre-grant opposition, which is open to any person, is likely to attract pubic interest groups to impose a challenge to patents which can have wide public health implications.

Importance of Opposition Proceedings

An opposition is instituted to challenge an application before its grant or to revoke a patent already granted on the grounds enumerated in Section 25 of the Act. The logic of opposition by peers proceeds from the fact that a patent application will disclose technical information about the area in which the invention is claimed which is not easily available to the public at large. All patent systems recognize the fact that the information required to reject or grant a patent is not easily available to the patent office. Patent offices though reasonably equipped with resources on technical and scientific information, repeatedly face difficulties in keeping pace with the rapid growth of science and technology. Recognizing the fact that the competitors of an inventor are likely to have more information about an invention, the law has devised a system of opposition where information with regard to an invention is supplied by peers in respective fields of technology. Being the first instance of challenge to a patent application or a granted patent, opposition proceedings have certain distinct advantages over revocation proceedings available before a judicial authority which are as follows:

(i) The challenge to the patent can be made before the granting authority;

(ii) As the challenge is made by peers in that particular field of technology, oppositions can be a significant means to empower the Patent Office with information which would not be normally available to it. This can improve the examination procedure and reduce errors cause by lack of information;

(iii) Opposition proceedings are time-bound and will not be plagued by delay associated with the suits pending before the civil courts; and

(iv) The procedure of opposition envisaged under the Act is cost-effective and efficient.

Pre-grant opposition offers any person an opportunity to challenge a patent before its grant. By enabling stakeholders who are likely to have an interest in the patent application to oppose the same on any one of the eleven grounds mentioned in Section 25(1), the Act has provided for an open challenge mechanism by which critical information relating to the field of the patent application is supplied to the patent office. This process enables the patent office to make an informed decision on the patent application under opposition thereby drastically reducing the error that could occur during examination.

The Novartis Case: Applying Section 3(d) through Pre-Grant Opposition

Though the TRIPS Agreement attempts to create a uniform patent regime, the inherent flexibilities in the Agreement coupled with emerging market's need to protect public health and promote access to medicines has resulted in a minimum-standard global regime with distinct national differences in prosecution and protection of patents. The post-TRIPS era has witnessed difficulties faced by many pharmaceutical companies in prosecuting their patents largely due to the exceptions to patentability which can be applied to challenge a patent application before its grant. An open opposition procedure which enables any person to oppose a patent application before its grant has increased number of challenges to patent application is evident from the number of patent oppositions initiated by patient groups in India. Table 1 illustrates the patent applications and the status/outcome of opposition proceedings initiated by patient groups in cases where the drugs affected public health concerns. The most significant of these opposition proceedings was the pre-grant opposition to Novartis' patent application for its drug, Imatinib Mesylate brought about by some leading generic companies and a patient group is discussed in detail.

Table 1—Pre-grant oppositions filed by Indian patient groups

Drug	Applicant	Patent Office	Opponent	Status of application
Imatinib mesylate	Novartis	Chennai	Cancer Patients Aid Association	Rejected
Zidovudine/lamivudine	GSK	Kolkata	Manipur Network of Positive People & Indian Network for People living with HIV/AIDS	Withdrawn
Nevaripine hemihydrate	BI	Delhi	Positive Womens Network & Indian Network for People living with HIV/AIDS	Decision awaited
Tenofovir fumarate or TDF	Gilead Science	Delhi	Delhi Network of Positive People & Indian Network for People living with HIV/AIDS	Pending
Amprenavir	GSK	Delhi	Uttar Pradesh Network of Positive People & Indian Network for People living with HIV/AIDS	Pending
Atazanavir	Novartis	Chennai	Karnataka Network for People Living with HIV and AIDS & Indian Network for People living with HIV/AIDS	Pending
Valgancyclovir	Roche	Chennai	Tamil Nadu Network of Positive People & Indian Network for People living with HIV/AIDS	Granted
Abacavir	GSK	Kolkata	Indian Network for People living with HIV/AIDS	Withdrawn
Lopinavir	Abbott	Mumbai	Delhi Network of Positive People, Network of Maharashtra by People living with HIV and AIDS & Indian Network for People living with HIV/AIDS	Pending
Lopinavir/Ritonavir	Abbott	Mumbai	Delhi Network of Positive People & Indian Network for People living with HIV/AIDS	Deemed abandoned
Tenofovir or TD	Gilead Sciences	Delhi	Delhi Network of Positive People & Indian Network for People living with HIV/AIDS	Pending
Ritonavir	Abbott	Mumbai	Delhi Network of Positive People & Indian Network for People living with AIDS	Pending

Source: Delhi Network of Positive People, January 2008

Novartis' Application for Gleevec in India

In 1993, Novartis filed a US patent application for the anti-cancer drug, Gleevec (imatinib) and was granted US Pat No 5521184 for the same on 28 May 1996. At that point due to the fact that the Indian law did not offer product patents for pharmaceuticals no application was filed in India. With the regime change brought about by the TRIPS Agreement, which provided for filing mail box applications and Exclusive Marketing Rights (EMR), Novartis filed an application (No 1602/MAS/98) on 17 July 1998 for the beta crystalline form of imatinib mesylate. In November 2003, the Controller of Patents granted EMR to Novartis. The drug containing lmatinib mesylate did not enjoy patent protection in India, though it was patented in various other countries. Under Chapter IVA of the Patents Act, 1970, Novartis was able to obtain an EMR for imatinib mesylate. The grant of EMR meant that Novartis could exclusively sell and distribute the drug imatinib mesylate which is the subject matter of EMR. This move affected six Indian pharmaceutical companies who have been manufacturing the same drug, lmatinib mesylate, under different trade names. These companies and an NGO instituted pre-grant opposition against Novartis' patent application for Gleevec.

After a string of infringement actions instituted by Novartis on the basis of its EMR and after two contradicting High Court decisions[9], the Controller of Patents rejected the patent application for Gleevec.[10] On 25 January 2006, the Controller of Patents refused to proceed with the patent application for this drug pursuant to opposition proceedings initiated by the competitors. With the rejection of Novartis' patent application for Gleevec, Novartis appealed against the Controller's decision and challenged the constitutional validity of Section 3(d) which was one of the main grounds on which its application was rejected.

At the heart of the Novartis case was the issue of standard of patentability under the Indian Patents Act. The TRIPS Agreement being a minimum standard agreement requires its members to grant patents for inventions in all fields of technology for a period of 20 years if it satisfies the universally accepted criterion of patentability. It is widely proclaimed that the Indian Act, after a series of amendments which concluded in the year 2005, is in full compliance with the obligations under the TRIPS Agreement. The time that Novartis chose to enter India was the one in which rampant changes were made to the Indian law. To put Novartis's case in perspective, the Indian Patents Act 1970 underwent three critical amendments in 1999, 2002 and 2005 which brought the Patents Act in compliance with the TRIPS Agreement, since Novartis filed its patent application in 1998.

The Novartis case had many firsts to its credit. It signified the first instance of grant of a patent-like right known as EMR, which led to the world's first contentious case of EMR. It was also the first time a foreign multinational questioned the constitutional validity of a provision of the Indian Patents Act. As soon as the law changed in India, Novartis preferred an application for β crystalline form of imatinib mesylate (Gleevec) in 1998. Imatinib as a free base molecule was invented by Novartis in 1992 and patented in US and other countries in 1993. Novartis however choose not to apply for a patent for the imatinib free base in India as India did not offer product patent protection in 1993. It is pertinent to note that the 1993 US patent of imatinib disclosed the salt imatinib mesylate.

But in 1998, Novartis came up with an application for a β crystalline form of imatinib mesylate which was, in the terms of Section 3(d) of the Patents Act 1970, a new form of a known substance. The application was challenged by the generic companies and an NGO by way of pre-grant opposition on many grounds, *inter alia*, that the subject of any claim of the complete specification is not an invention within the meaning of the Act, or is not patentable under the Act, in particular under Sections 3(d) of the Act.[11] Section 3(d) of the Act states that 'mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance' shall not be treated as an invention within the meaning of the Act. Phrased differently, it meant that the new form of a known substance will be entitled for a patent if it results in the enhancement of the known efficacy of that substance. Novartis tried to demonstrate before the Controller how there was an enhancement of efficacy and submitted that there was an enhanced bioavailability of 30% in studies conducted on rats. The bioavailability of a drug refers to the extent to which and the rate at which the drug appears in the blood stream after administration in dosage form. It is one of the indicators of efficacy of a

drug. The Controller rejected this submission and held that Novartis had failed to demonstrate the enhancement in efficacy as required under the Act.

Enhancement of Efficacy

The case failed as Novartis failed to discharge the burden of showing enhancement of efficacy. This was due to the indiscriminate adoption of its PCT application without taking the special needs under the Indian Patents Act into account. Section 3(d) has an in-built guideline for determining the enhancement of efficacy. It states that with 'known efficacy' as the benchmark, the person seeking patent has to show the enhancement of efficacy. The explanation to Section 3(d) requires such enhancement to be significant. Novartis' case suffered as the patent application did not shown how 30% increase was critical in the performance of the drug and how increase in enhancement of efficacy made a difference when compared to known efficacy.

Troubles with the Law

Aggrieved by the order of the Controller, Novartis approached the Madras High Court with two batches of writ petitions: One challenging the constitutional validity of Section 3(d) and the other challenging the order of the Controller with the request for quashing the same as the appeal mechanism (appeal from a Controller's order to the Intellectual Property Appellate Board - IPAB) under the Patents Act has not come into force by then. In the writ petition challenging the constitutional propriety of Section 3(d), Novartis took a contradicting plea that the provisions in Section 3(d) are vague and arbitrary despite trying its best to plead its case on the lines of Section 3(d) before the Controller. Though the Madras High Court had dismissed the writ petitions filed by Novartis challenging Section 3(d), the High Court had directed the transfer of other batch to IPAB questioning the order of the Controller after converting the same into a statutory appeal.

The judgment of the Madras High Court and the impact of Section 3(d) must be understood better by knowing what it permits and what it prohibits. Patents for pharmaceutical substances today fall into two broad categories: Radical innovation and incremental innovation. Without doubt, the law with regard to radical innovation in India is just the same as it is in any part of the globe; the Patents Act 1970 grants patents for radical innovation if the three prerequisites of novelty, inventive step and industrial application are satisfied. The second category, incremental innovation is an area where there is no consensus with regard to what actually amounts to incremental innovation and the extent to which such innovations should be protected. In any case, the language of Section 3(d) permits incremental innovation. But it is for the applicant to demonstrate why a fresh patent should be granted to a known substance; for which he will have to demonstrate an increase in efficacy of the substance over the known efficacy. The applicant has to demonstrate this in its patent application and the failure of Novartis to do so has been an important cause for all its troubles.

Conclusion

The process of applying for patents in multiple jurisdictions through the PCT has its obvious advantages. But one likely pitfall which pharmaceuticals should be cautioned about involves differing standard of patentability among the countries. The wisdom of adopting the PCT application indiscriminately may be disastrous when viewed in the light of the Section 3(d) of the Patents Act and its interaction with Section 25(1) which allows for opposition before the grant. Section 3(d) requires the applicant to demonstrate enhanced efficacy. It also requires the applicant to prove the extent to which there is an enhancement over the known efficacy. If the patent application (in most cases a copy of the PCT application) does not contain details, proofs or tests demonstrating the enhanced efficacy, it would certainly jeopardise the changes of grant of the patent in India, as has seen in the case of Novartis' application for its patented drug, Gleevec.

The Patents Act also provides for third-party interventions before the grant of a patent. As a procedure which can be conducted by the generic company's in-house personnel or by an NGO before the patent office, pre-grant opposition offers a fair chance for technical and scientific arguments to be heard and is extremely cost-effective. Many companies in India have employed pre-grant opposition effectively with startling effect on the revenues and market shares of some patent-holders. Given the unique post-TRIPS changes in the Indian patent laws and opening up of the markets to new players, it becomes imperative for any pharmaceutical company operating in India to integrate its national legal strategies to its larger strategies on filing international application through the PCT route. This

can be achieved only by understanding the local market in which one operates and the legal rules that regulate the market.

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3 The relevant portion of Article 27 of the TRIPS Agreement reads:

"(2) Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect 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 their law.

(3) Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement."

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