

Atten:

Secretary,
United States International Trade Commission,
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UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, DC
Investigation No. 332-543
Trade, Investment, and Industrial Policies in India: Effects on the U.S. Economy

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Executive Summary

We are legal academics with expertise in patent law, trade law, the TRIPS agreement and the law of India. Each of the signatories has engaged in this field for more than 10 years and has closely followed the developments within India in relation to the prescriptions of the TRIPS agreement.

We make this submission as legal academics to make the core point that, whatever effect India's policies may have on the profits on multinational companies, including those headquartered in the U.S., India's recent enactment and implementation of its patent law is fully in accord with the World Trade Organization's Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). Further, India has demonstrated its adherence to TRIPS and to non-protectionism and a national treatment regime by revamping its systems, instituting massive changes to further intellectual property rights and by establishing prudent IP standards that apply equally to both domestic and foreign companies. Each of these standards remains in conformity with the TRIPS agreement and carefully calibrated to accommodate its national objectives within the scope of the flexibilities accorded under the TRIPS agreement.

Countries remain free after TRIPS to tailor their intellectual property laws to their domestic social, economic and cultural needs as they define them, within the bounds of the treaty. Accordingly, as recognized within the World World Trade Organization and the TRIPS Agreement, there is a great deal of lawful pluralism among WTO Members about standards of patentability and about key flexibilities, including both patentable subject matter and grounds for compulsory licenses. India's laws and implementation thus far remain well within the lawful pluralism allowed by TRIPS.

Specifically, TRIPS Article 31 permits compulsory licenses for ANY reason, including the historically sanctioned grounds of insufficient working of an invention in the country. This flexibility was explicitly clarified in the 2001 Doha Declaration on the TRIPS Agreement and Public Health. Similarly, TRIPS leaves countries free to define patentability criteria, including to define what is not an invention. Along the same lines, each member of the WTO has the sovereign right to determine and establish the threshold for the nonobviousness/inventive-step requirement. Thus, India is within its rights to establish that the new forms or uses of existing and known molecules that do not significantly increase the therapeutic effectiveness of such substances are not entitled to patent protection.

Most of the questions on the survey used by ITC are irrelevant to the task of ascertaining whether India's policies violate TRIPS.

Patents

1. India Patent History:

India, like many developing countries around the world, reformed its patent laws during its period of most rapid industrialization to tailor them to its domestic social and economic needs. What is important about this history is that the WTO TRIPS agreement restricted the range of options available to India and other countries in effecting such tailoring, but did not alter the goal itself. Indeed, the Preamble and Articles 7 and 8 of TRIPS clearly and forcefully posit that countries retain the sovereign ability to adjust their intellectual property laws and their implementation to serve local needs. The Preamble of TRIPS recognizes an “underlying public policy objective of national systems for the protection of intellectual property, including developmental and technological objectives.”¹ Article 7 reiterates this position that the TRIPS’ objective to protect and enforce IP rights “should contribute . . . to a balance of rights and obligations” of members in a manner conducive to social and economic welfare.² Article 8 recognizes members’ rights to adopt public interest or public health measures consistent with the TRIPS provisions.³ The right of WTO Members to take local realities into account and to adapt TRIPS’s minimum standards pluralistically is further clarified in TRIPS Article 1.1.⁴

Historically, India embraced process-patent-only protection in specified fields rather than product patent protection, particularly for food and pharmaceuticals, in order to prioritize domestic issues like access to medication and food security. India was not alone. In the period before TRIPS, nearly 50 countries exempted pharmaceuticals from product patent protection and an additional 10 exempted pharmaceuticals from process patents as well.⁵

The Indian Patent Act of 1970,⁶ (IP70) along with other mechanisms such as drug and industrial policies were all part of the repertoire of tools used by India to achieve its national priorities. In gist, the process patent regime of IP70 excluded protection of the end-product, but protected the method or the process of making the product. The process patent regime encouraged competitive innovation in the methods of making known products, thus, it enabled production of products patented elsewhere using different processes, incentivizing the development of more efficient production processes. The system’s encouragement for process innovation was the first step to establishing India’s generic drug industry, much like how Germany established its chemical process industries in the 1800s. Under IP70, the term of process protection over food, drug, and medical inventions was limited to five years.⁷ A license of right authorized any person to manufacture a patented product, without having to seek the patentee’s approval.⁸ Inventions relating to food, chemicals, and pharmaceuticals, were automatically deemed to be endorsed with a license of right three years after the patent issues. Further, the government could, in the public interest, compulsorily license the patent if the invention was either not reasonably priced or not worked to satisfy the reasonable requirements of the public.

¹ Annex IC to the General Agreement on Tariffs and Trade, Uruguay Round, World Trade Organization, done at Marrakesh, Apr. 15, 1994, 33 I.L.M 1981 (1994), reprinted in WORLD TRADE ORGANIZATION, THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 365 (1995) [hereinafter TRIPS] at art. 27(1).

² *Id.* art. 7.

³ *Id.* art. 8.

⁴ *Id.* art. 1.1

⁵ PAUL GOLDSTEIN, INTERNATIONAL INTELLECTUAL PROPERTY LAW at 302 (2001).

⁶ See Patents Act of 1970, 27 INDIA A.I.R. MANUAL 450 (1979) (hereinafter IP70).

⁷ *Id.* § 53(1)(a) (1979).

⁸ *Id.* § 88.

2. Changes Under the 2005 Amendment:

Many of these policies – although not their ultimate aims, were required to be changed by TRIPS. India has been faithful to its obligations under TRIPS, amending its Patent Act and taking many other measures at considerable expense to comply with its obligations while maintaining what flexibility it has under TRIPS to continue to further legitimate domestic policies. Indeed, in many respects India has been more forthcoming in amending its laws and policies to comply with TRIPS than has the United States.

i. Pharmaceutical Product Patent Regime:

India's most important TRIPS-fulfilling amendment—the institution of a pharmaceutical product patent regime—was instituted in 2005. India had previously adopted the TRIPS compliant international standard of patentability based on the requirements of novelty, inventive step, and industrial applicability (utility) with respect to other fields of technology. India was required to grant patents on pharmaceutical product inventions as well as process inventions because the TRIPS Agreement prevents discrimination against particular fields of technology.

India's definition of *novelty* or “new invention” includes world-wide prior art which was much broader than the requirement that prevailed in the United States under 35 U.S.C. § 102, under which any use of the application material within the United States (only) defeated novelty. Only in 2011 would the America Invents Act introduce the concept of worldwide novelty,⁹ even though this provision was heavily criticized as obstructing small-scale industries.

India's *inventive step* requirement requires that the “feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art.”¹⁰ This requirement for inventive step has been widely noted as being much more stringent than the nonobvious requirement in the United States, but many countries have different, indeed stricter standards for inventive step than does the United States.¹¹ In fact, the U.S.'s weak standard has been a significant causative factor for the degenerating quality of the patents in the U.S.

India has also adopted, within the framework of allowable pluralism under TRIPS, a stronger definition of industrial applicability than the United States. The United States' weaker standard of utility has historically allowed the patenting of business methods and other more abstract innovations, unlike India and many other countries that either exclude such matters as unpatentable or consider them not to have industrial applicability. This is one of many permissible policy differences allowed under TRIPS. In this regard, it is also important to note that India has codified a number of exclusions to patentability that are similarly excluded by many other countries – abstract ideas, theories of science, plants and animals, etc.,

⁹ Leahy Smith America Invents Act, Pub. L. 112-29, (H.R 1249) at § 102.

¹⁰ Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005, at § 2(ja) (hereinafter PTA, 2005); See also Srividhya Ragavan and Feroz Ali Khader, *Proof of Progress: The Role of Obviousness Standard in the Indian Patent Office*, GLOBAL PERSPECTIVES ON PATENT LAW (FORTHCOMING). Ed. Ruth Okediji, Margo Bagley, Jay Erstling. Oxford University Press, 2014 (discussing how the standards of obviousness in India sets a higher bar when compared to the United States).

¹¹ See, e.g., Amy Nelson, *Obviousness or Inventive Step as Applied to Nucleic Acid Molecules: A Global Perspective*, 6 N.C. J. L. & Tech. 1 (2004); Request for Comments on the International Effort to Harmonize the Substantive Requirements of Patent Law, 66 Fed. Reg. 15,409, 15,409–11 (Mar. 19, 2001) (listing seventeen differences between U.S. patent law and the law of other developed countries).

even where the same creations could subject to patent in the U.S. Perhaps the most important exclusion from patentability, discussed further below, is India's Section 3(d).

ii. Section 3(d):¹²

Granting secondary patents or evergreening is a controversial issue, not just in India but also in the United States. The term *evergreening* refers to strategically patenting different forms of a medicine's active ingredients, new uses, and/or new formulations and staggering such protection to extend monopoly control over various forms/uses of the medicine beyond the 20-year term of protection. Granting secondary patents, which promotes evergreening, is a controversial issue not just in India but also in the United States.¹³ The low standards of inventiveness in the US has been alleged. Such strategic patenting became commonplace in the United States thanks to the steady lowering of standards, especially for determining nonobviousness, has in turn contributed to such strategic patenting, which is now subject of much scrutiny in the United States.

The struggles of the United States with a barrage of secondary patents on medicines have served as a lesson to other countries, including India.¹⁴

In the United States such patents are easily issued although they can be invalidated by litigation. Rather than accepting the resource investment, cost, judicial time and the loss of access to the public inherent in the U.S. model for combating evergreening, India's Section 3(d), enacted in the 2005 amendment,¹⁵ prohibits patenting of new uses of known substances, including medicines. Similarly, patenting new forms of known substances is not allowed unless there is evidence of significantly enhanced efficacy. The logic of this interesting provision is along the exact lines of the opinion of the Court of Appeals for the Federal Circuit (CAFC) in the case of *Pfizer v. Apotex* involving the Pfizer's patenting of the besylate form of amlodipine (salt form) which Apotex claimed was obvious in the light of Pfizer's own patent on the base compound amlodipine.¹⁶ The CAFC, in agreeing with Apotex that the patent on the besylate form was invalid, highlighted the besylate form lacked the *unexpected superior results* from the base compound in order for the salt form to be patented.¹⁷ Indeed, the Manual for Patent Examination Procedure in section 716.02 and in 2144.09 specifically memorializes *unexpected results* as a test to demonstrate nonobviousness of structurally similar compounds like isomers and homologues.¹⁸ Thus, India's standard is well within the lines of what has been allowed in the United States.

The Novartis judgment, which has become central to Congressional criticism of India's IP regime, was decided significantly on the basis of the absence of any evidence of enhanced efficiency, a valid criteria for assessing patentability as described above.¹⁹ In essence, the Supreme Court of India, in a well-reasoned decision, found that beta-crystalline form of imatinib mesylate, was revealed and claimed in a pre-TRIPS patent and thus was time barred from patentability in India unless it showed significantly

¹² Id. at § 3(d)

¹³ See GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY. FEDERAL TRADE COMMISSION 2002

¹⁴ See Thomas Faunce and Joel Lexchin, *Linkage' Pharmaceutical Evergreening in Canada and Australia*, Aust -New Zealand Health Policy (Biomed Central) (2007); EVERGREENING OF PHARMACEUTICAL MARKET PROTECTION, EUROPEAN GENERIC MEDICINES ASSOCIATION.

¹⁵ PTA, *supra* note 9, § 3(d).

¹⁶ *Pfizer v. Apotex*, 488 F. 3d 1377 (Fed. Cir. 2007); *see also* *Pfizer v. Apotex*, 480 F.3d 1348 (Fed. Cir. 2007).

¹⁷ 480 F.3d at 1368; *see also* *In re Swain*, 33 C.C.P.A. 1266, 156 F.2d 246, 247-48 (1946).

¹⁸ Manual for Patent Examination Procedure § 2144, § 716 (8th ed., rev. 2012).

¹⁹ *Novartis AG v. Union Of India & Ors*, Civil Appeal No. 2706-2716 of 2013.

enhanced efficacy.²⁰ Unfortunately for Novartis, the Supreme Court of India found that Novartis offered no evidence of increased efficacy of the relevant compound whatsoever, and thus that the patent was unmeritorious under section 3(d).²¹ Whatever the effect on Novartis's bottom line or on balance of payments with the U.S., this was an eminently reasonable, and TRIPS-permissible, decision.

TRIPS does not require its member countries to be persuaded by the issue patents of other countries. The argument that several other countries agreed that Gleevec was patentable despite being a mere variation of an existing, previously patented chemical entity is inconsequential to India's own patent determination. If a country chooses to adopt a higher bar for determining patentable subject matter and/or inventive step under TRIPS, it is well within the member's rights to do so. Indeed, Japan has a record of allowing approximately 14% of patents that are granted in the United States. Having a higher bar with standards is well within the rights of a sovereign nation and well-established under the principles of the World Trade Organization. India's Section 3(d) and the Novartis judgment fall well within the ambit of the TRIPS agreement.

iii. Opposition Procedure:

Another important feature, the opposition mechanism, embodies a pre- as well as a post-grant opposition procedure.²² Pre-grant opinions conserve administrative time otherwise spent on examining a patent application that could later be invalidated, in addition to preserving judicial time. As for the procedure, under § 25, any third party can oppose a patent after publication of the application and before the grant for reasons of patentability, wrongful acquisition, inadequate disclosures, etc.²³ On similar grounds, any interested person may oppose the patent within one year of the grant of patent.²⁴ The grant structure circumvents one of the India's debilitating constraints, being the backlog in the judicial system. Hence, the grant opinions seemingly have more economic value when compared to the USPTO's administrative opinions, for instance, not least because there are few judicial opinions on the question of inventiveness, but perhaps also because of the influence of a combination of other factors such as the time taken to resolve disputes in India.

WIPO has researched opposition procedures in depth and found substantial variation in countries approaches to both pre- and post-grant procedures, but clearly does not consider them unauthorized by TRIPS. Indeed, TRIPS Article 62.4 explicitly references and thus indirectly condones the use of opposition procedures.

iv. Intellectual Property Office Modernization:

When India amended its patent legislation, the government of India through the Department of Commerce modernized the different intellectual property offices at great expense.²⁵ Additionally, India has worked to relieve patent disputes from the most debilitating constraint of all: the Indian Court system. India has established the Intellectual Property Appellate Board (IPAB), as the special appellate administrative tribunal from 2007 to hear patent appeals from the decisions of the Controller (provided it includes a technical member).²⁶ Akin perhaps, to the Court of Appeals for the Federal Circuit in the United States,

²⁰ *Id*

²¹ *Id*.

²² PTA, *supra* note 9, at, §§ 18, 35.

²³ *Id.*, § 25 (c), (e), (h).

²⁴ *Id.*, 89, § 25(k);

²⁵ Press Release, Department of Commerce (India), Government's Initiatives in Revamping Intellectual Property Show Results (Feb. 7, 2002).

²⁶ Notifications No.12/15/2006-IPR-III (2/4/2007), Ministry of Commerce & Industry, (India).

the review of the decision of the IPAB can be sought by the losing party by filing a writ petition on the grounds that there is a question of law requiring the attention of the High Court or that there is illegality or miscarriage of justice. The Supreme Court of India has established that all decisions of tribunals including the IPAB are subject to review before the Division Benches of the High Court (two-judge benches) within whose jurisdiction the concerned tribunal falls.²⁷ The establishment of the IPAB signifies India's commitment to implementing the patent statute.

v. Compulsory Licensing:

India has one of the most sophisticated compulsory licensing provisions of any country -- one that fully conforms to the TRIPS agreement as clarified by the Doha Declaration.

Section 84 of the Indian patent statute allows the government to compulsorily license a patent three years after grant.²⁸ Applicants seeking compulsory licenses should provide proof that the applicant attempted to negotiate a license with the patent owner as required under the TRIPS agreement, and must do so for a minimum period of six months.²⁹ As for the grounds, third parties can seek a license on the grounds that the (a) reasonable requirements of the public with respect to the patented invention have not been satisfied, (b) that the patented invention is not available to the public at a reasonably affordable price, or (c) that the patented invention is not worked in the territory of India.³⁰ The term *reasonable requirements of the public* is broad and can be deemed to be not satisfied if an existing industry or trade in India is affected; the demand for a patented article is not met by the patent holder, or the market is affected directly or because of the patent holder's activities. These grounds are fully in accord with traditional grounds for compulsory licenses dating back to the earliest patent laws, and explicitly sanctioned in Paris Convention Article 5(A).

Under Section 92, a compulsory license can be granted where the government provides notice of the existence of a national emergency such as a public health crisis or where it intends to use the patented subject matter for non-commercial public use.³¹

Section 90(1)(vii) allows for export of non-predominate quantities compulsorily licensed products and Section 92A requires export of patented pharmaceuticals to "any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory licence has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India."

India's provisions with reference to compulsory licensing are fully compliant under Article 31 of the TRIPS agreement. Generally, TRIPS allows countries to determine the grounds for issuing compulsory licensing. In any event, India has issued only one compulsory license so far and did so in a case where there was egregious pricing and lack of supply to the market. Although U.S. critics have focused on the local-working rationale of the Patents Office decision granting a compulsory license, there were in fact three independent grounds for the license: insufficient supply, excessive pricing, and lack of an adequately explained total failure to work locally. Each or any of these grounds, including local working,

²⁷ L. Chandra Kumar v. Union of India & Others, AIR 1997 SC 1125 (1997) (India); *See also* Union of India v. R. Gandhi, President of Madras Bar Association, (2010) 5 SCALE 514.

²⁸ *See* PTA, *supra* note 9, at § 84.

²⁹ *Id.*, § 84(5)(4).

³⁰ *Id.*, § 84.

³¹ *Id.* § 92.

is legally sufficient and justified under international and national law.³² India was well-within its rights to issue the license on Bayer.³³

In any event, the facts of the Bayer situation demonstrates that for the United States to expect India to not take steps because Bayer or other companies feel that is unfair would be at the cost of its political leadership position. In gist, at a time when India housed approximately 20,000 patients with liver cancer and about 9,000 patients with kidney cancer between the years 2008 to 2010, a negligible amount of Bayer's Sorafenib was imported into the country. In fact, no importation ensued in 2008, a year when Bayer recorded a worldwide profit of over \$678 million in the rest of the world. The patent holder's inability to fulfill its duty of catering to the demands of the market notwithstanding, Bayer's pricing of the drug bordered on the ridiculous. The selling price which Bayer charged at an egregious price of Rs.2,80,428 per month (about \$5,000) was nearly five times higher than the median *annual* income in India. Indeed, as a mark of its careful scrutiny, the Indian patent office rejected an application to compulsorily license Dasatinib.

vi. Bolar Provision:

Sections 107A, a bolar-type or "early working" provision, introduced via the 2005 amendment, allows for storage of patented material during the patent term to facilitate marketing immediately after the expiration of the patent term.³⁴ Use of the patent for research, data gathering, and seeking regulatory-approval, both domestically and abroad, are exempted from being construed as infringement. The New Delhi High Court approved the operation and the constitutionality of the provision in *Bayer v. Cipla*.³⁵ Such regulatory exceptions fall within the ambit of Article 30 which allows every country to consider the legitimate interests of third parties in structuring such exceptions. Indeed, bolar exceptions have been considered in a WTO dispute opinion of a panel "Canada — Patent Protection for Pharmaceutical Products" - (adopted on 7 April 2000) upholding Canada's bolar and regulatory exceptions, similar to that of India's. Even though the U.S. has attempted to block the use of Bolar type provisions to allow a patent exception for purposes of exporting patent protected subject matter for purposes of obtaining regulatory approval in some of its bilateral and regional trade agreements, it is completely lawful for countries like India to allow such foreign registration as a limited exception under Article 30.

vii. Exhaustion of Patent Rights:

Section 107A(b) embraces an international exhaustion of the rights of a patent owner.³⁶ Thus, the sale or importation into India of a legally procured patented item from anywhere in the world will not amount to infringement.³⁷ That is, there is no need for authorization by the patentee or his assignee as long as the product was sold with due permission of the patent owner (or assignee). In fact, even importation of a product acquired from sources other than the patent owner (or assignee), for instance, from countries not yet recognizing product patent protection, would be covered by the section. Article 6 of the TRIPS Agreement explicitly allows members to choose a regime of exhaustion and ensures that they be challenged under the WTO dispute settlement system. The Doha Declaration, under paragraph 5, has

³² Michael Halewood, *Regulating Patent Holders: Local Working and Compulsory Licenses Under International Law*, 35 *Osgoode Hall L.J.* 243 (1997).

³³ See generally, Srividhya Ragavan, *Patients Win Over Patents*, THE HINDU, (March 7, 2013).

³⁴ Patents Act, *supra* note 9, at § 107(A)

³⁵ *Bayer Corp. v. Union of India*, (2009)41 PTC 634(Del).

³⁶ PTA, *supra* note 9, § 107A(b)

³⁷ *Id.* § 107A(b).

reaffirmed that Members do have this right, stating that each Member is free to establish its own regime for such exhaustion without challenge.³⁸

Agriculture

India, like other developing nation counterparts, took advantage of the flexibilities in Article 27(3) of the TRIPS agreement which mandates establishing a protection regime “either by patents or by enacting an *effective sui generis* system.” In light of Articles 7 and 8 of TRIPS, the *effectiveness* of a plant protection regime established under Article 27 must be judged by its ability to accommodate local/national welfare and economic goals. Such a reading of the *effectiveness* requirement fits more comfortably with the other sub-sections of Article 27 which provides that members *may* choose to protect biological or microbiological materials. Member’s flexibility to establish an *effective* system increases when using a national yardstick. Considering this, India enacted the Protection of Plant Varieties and Farmers Rights Act of 2004 (PPVFA)³⁹ under which three separate varieties can be registered, being: (1) New Variety; (2) Extant Variety, which refers to an existing variety discovered for the first time; and (c) Farmer’s Variety, based on community property concepts.⁴⁰

New variety: A variety would be eligible for protection as *new* provided it is novel, distinct, uniform, and stable—a threshold similar to the UPOV requirements.⁴¹ Examination guidelines set out the principles used for testing the distinctiveness, uniformity, and stability (DUS Guidelines) of a variety to determine its registration status.⁴² Information such as (1) the geographical origin of the material; and (2) any contribution by farmer, community, or organization to the development of the variety, (3) information about the use of genetic material conserved by any tribal or rural families in the breeding are required to be given in the application.⁴³

Extant Variety: In order to ensure that an appropriate bar is instituted in a country that is rich in biodiversity and traditional farming practices, the extant variety register was created to as a compilation of matters known and existing in the public domain. This classification indirectly creates a higher bar to determine distinctiveness of a new variety. Indeed, the extant variety classification takes care of India’s obligation under the Convention on Biological Diversity (CBD) to which it is a signatory.⁴⁴ The Convention requires member states to take adequate steps to preserve biological and genetic materials. Section 28 of the PPVFA provides that the government, as the owner of the extant varieties, enjoys the right to determine their production, sale, marketability, distribution, importation, or exportation. Government ownership over the materials ties in with the objective of protecting biodiversity and allowing the government to negotiate with bioprospectors. An Extant Variety Recommendation

³⁸Annex IC to the General Agreement on Tariffs and Trade, Uruguay Round, World Trade Organization, done at Marrakesh, Apr. 15, 1994, 33 I.L.M 1981 (1994).

³⁹The Protection of Plant Varieties and Farmers’ Rights Act, No. 53 of 2001; INDIA CODE (2001), [hereinafter “PPVFA”]

⁴⁰*Id.*, § 15(2).

⁴¹*Id.*, § 15.

⁴²*See* General Guidelines for the Examination of Distinctness, Uniformity and Stability and the Development of Harmonized Descriptions, Protection of Plants Varieties & Farmers’ Rights Authority, Department of Agriculture and Cooperation, Government of India, NASC Complex, IARI, New Delhi-110012 [hereinafter “DUS Guidelines”]

⁴³*Id.*, § 18(1)(e), 40.

⁴⁴Convention on Biological Diversity, June 5, 1992, 1760 U.N.T.S. 79 [hereinafter “CBD”].

Committee (EVRC) develops appropriate procedures for examining applications to register an extant variety.⁴⁵ By the end of 2010, from a pool of 297 applications, 123 extant varieties were registered.

Farmer's Variety: Within this *variety* typology fall plants which are traditionally cultivated and evolved by the farmers in their fields, or is a wild relative or land race of a variety about which the farmers possess the common knowledge.⁴⁶ The reason for protecting farmers' rights is the underlying assumption that genetic diversity is enhanced when varieties are adapted using traditional farming techniques.⁴⁷ By 2010, after considering 44 applications three varieties of rice—Indrasan, Hansraj, and Tilak Chandan—became the first of the farmer's varieties registered in India, and perhaps, also in the world.

Other features of the PPVFA are all part of the *sui generis* system that allows a country to tailor a regime that protects plant varieties while making adequate allowances for local issues. The creation of the Gene Fund, for instance, is another feature created by the central government for the benefit of the farmers.⁴⁸ The fund helps reward farmers whose existing variety/material is used as a source to create a new variety.⁴⁹ Similarly, the PPVFA allows farmers to retain their traditional right to save and reuse seeds from their harvests with some restrictions and conditions. The PPVFA has also introduced a right to community compensation in recognition of traditional knowledge contributions. Section 43 reflects a community property philosophy by providing that “[b]reeders wanting to use farmers’ varieties for creating essentially derived varieties (EDVs) cannot do so without the express permission of the farmers.”⁵⁰ Thus, communities can stake a claim of contribution from breeders if a new variety is derived from information or a contribution is made by the local community.⁵¹ If the community’s claim for compensation is established, the breeder must deposit the compensation in the Gene Fund.⁵² Lastly, the PPVFA provides for “benefit sharing” – which refers to sharing a proportion of the benefits accruing to a breeder of a new variety with qualifying claimants, if any, who could be indigenous groups, individuals, or communities.⁵³ That concept, first envisaged in the CBD, has been more clearly expounded on the PPVFA and structured to work closely with the community rights principle detailed earlier. Thus, the statute mandates that before registering any new variety, the statutory authority should invite claims for benefit sharing.⁵⁴

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⁴⁵ See Protection of Plant Varieties and Farmers’ Rights Regulations, 2006, Gazette of India, Notification (Dec. 7, 2006).

⁴⁶ PPVFA, *supra* note 38, § 2(l).

⁴⁷ *Id.*

⁴⁸ See PPVFA, *supra* note 38, §§ 39, 45.

⁴⁹ *Id.* § 39.

⁵⁰ See PPVFA, *supra* note 38, § 48.

⁵¹ *Id.*

⁵² *Id.*

⁵³ *Id.* §§ 2(b), 26.

⁵⁴ *Id.* § 26.

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