

## **INFORMATION MATERIAL**

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### **WHAT IS SECTION 3 OF THE INDIAN PATENTS ACT?**

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Section 3 is included in chapter 2 of the **Indian Patents Act, 1970**. Chapter 2 deals with **inventions that are NOT patentable**. Section 3 specifically lists the non-patentable inventions. Among other things it includes, inventions which are frivolous, claims anything obvious, contrary to well established natural laws, intended use of which would be contrary to law or morality or injurious to public health, the mere discovery of a scientific principle or the formulation of an abstract theory, a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components, mere arrangement or re-arrangement or duplication of known devices, a method of agriculture or horticulture, and so on.

Two specific clauses of interest to us are

**Section 3 (d), which states that the mere discovery of any new property or new use for a known substance, or of the mere use of a known process is not an invention, until such known process results in a new product or employs at least one new reactant.**

and

**Section 3 (i), which states that any process for the medicinal, surgical, curative, prophylactic or other treatment of human beings, or similar treatment of animals or plants to render them free of disease or to increase their economic value or that of their products is not an invention.**

The other sections in Chapter-2 of the Indian Patents Act, 1970 are Section 4 and Section-5. Section 4 deals with inventions relating to atomic energy, which are not patentable, and section 5 – the lifeline of the Indian drug industry, ruled out giving patent for substances (products) which could be used as food, medicine or drug. It also ruled out product patent for inventions relating to substances produced by chemical processes including alloys, optical glass, semi-conductors and inter-metallic compounds. Section-5 stated that patents would be allowed only the processes (or methods) of manufacture of these substances.

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### **OK, THAT'S GOOD, BUT CAN YOU EXPLAIN SECTION 3 (d) IN SIMPLE TERMS?**

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Section 3(d) in simple terms means that **NO PATENT WILL BE GRANTED:**

- on additional (“incremental”) improvements of any drug (“active molecule”) which do not show any improvement in efficacy.
- for mere discovery of a new property or a new use of a already known substance.
- for the mere discovery of the use of a known process/ apparatus unless it results in a new product or employs at least one new reactant.

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## WHAT CHANGES DID THE PATENTS (AMENDMENT) ACT, 2005 BRING IN SECTION 3(d) OF THE INDIAN PATENTS ACT, 1970?

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In section 3 (d), the Patents (Amendment) Act, 2005 made the following change:

Indian Patents Act, 1970	The Patents (Amendment) Act, 2005
<p>The following are not inventions within the meaning of this Act:</p> <p><b>Section 3(d)</b></p> <p><b>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.</b></p>	<p>The following are not inventions within the meaning of this Act:</p> <p><b>Section 3(d)</b></p> <p><b>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 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.</b></p>

The Patents (Amendment) Act, 2005 also gave the following explanation that—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 addition, the Patents (Amendment) Act, 2005 completely did away with section-5 of the Indian Patents Act, 1970 thereby paving the way for patents on the substances which could be used as food, medicine or drug (product patent).**

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## WHAT IS THE USE OF SECTION 3 (d)?

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Section 3(d) helps to keep a check on frivolous patent claims by companies leading to ever-greening of patents. Ever-greening refers to tactics used by pharmaceutical companies for extending the monopoly of already patented drug. They do this by many means including modifying the existing drug (“active molecule”) to a different form like polymorphs, isomers, etc. and applying for a patent for the same drugs (in its new form) leading to extension of its patent. This will block the entry of generic companies. Excerpts of an article from The Wall Street Journal gives an insight into how companies try to extend patents.

### **PRILOSEC'S MAKER SWITCHES USERS TO NEXIUM, THWARTING GENERICS**

The heartburn drug Prilosec is one of the best-selling prescription medicines in history. Sales in the past five years alone amount to \$26 billion. The reason is not only its popularity but its steep price: about \$4 per pill.

AstraZeneca PLC, Prilosec's maker, has been able to charge this much because it owned the drug's patent. But the patent's expiration date was April 2001. By now, cheap knockoffs should be flooding the market and saving millions for retirees, insurers, government health plans and corporations, such as General Motors Corp., which spends \$55 million a year just to buy Prilosec for its employees and retirees.

Yet, no generics have been launched. The reason? Seven years of planning by a group of marketers, lawyers and scientists within the drug's maker. The group called itself the Shark Fin project after the dismal shape the sales chart would trace if they did nothing: an inverted-V.

Beginning its work in 1995, the team came up with a list of nearly 50 possible solutions to the patent-expiration disaster facing the company. Among the best would be finding a new heartburn drug that worked significantly better. Among the worst: launching a successor drug that was virtually no better but had several more years of patent exclusivity. The group also constructed an elaborate legal defense of Prilosec's patents.

Fifteen months after the patent expiration, the market shows how deftly the planners handled their crisis. Prilosec still has its exclusivity, having kept the generics at bay with a series of lawsuits and peripheral patent claims. Meanwhile, AstraZeneca has begun establishing a successor heartburn drug in the market. And, knowing it can't fend off Prilosec generics forever, it is spending half a billion dollars a year to convert Prilosec users to the new branded product, called Nexium, which like Prilosec carries a steep price of some \$4 a pill.

By Gardiner Harris, Staff Reporter of THE WALL STREET JOURNAL

[Source: From: Kirsten Myhr [myhr@online.no](mailto:myhr@online.no), Fri, 7 Jun 2002, <http://www.essentialdrugs.org/edrug/archive/200206/msg00014.php>.

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## WHO IS OPPOSING SECTION 3 (d) AND WHAT IS BEING DONE ABOUT IT?

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Section 3(d) is under attack from a Swiss pharmaceutical company Novartis who claims that the provisions contained in the section are unconstitutional and not compliant with TRIPS.

In January 2006, the Indian Patents Office in Chennai rejected Novartis AG's application for a patent on 'Imatinib Myselate' (Gleevec). The basis of the rejection was that the application claimed not an invention but 'only a new form of an old drug'. The patent application was opposed by Natco Pharma Ltd, a Hyderabad-based pharma company and supported by cancer groups and other generic companies. Natco filed a pre-grant opposition petition before the Controller of Patents & Designs, as provided in the amended Patents Act and Rules. The patent application was rejected on 25 January 06 after due hearings on three grounds - anticipation by prior publication, obviousness, priority and also on the ground that the product was a derivative of a known substance.

However in May 2006, Novartis filed two cases against the government of India and the Cancer Patient's Aid Association (CPAA) challenging the rejection of its patent application and questioning the validity of section 3(d) of the Indian Patents Act. *"Imatinib Myselate (Gleevec) is a life saving drug essential in prolonging the life of patients suffering from Myeloid Leukemia (Blood Cancer). The order of the Chennai patent office brought relief to thousands of cancer patients as it prevented a patent monopoly on 'Gleevec' till 2018"*. The case was important because the important cancer drug which was produced and marketed by Novartis was sold at a whopping Rs. 1,20,000 (\$ 2500) per patient per month while generic versions of 'Gleevec' in India were priced at fraction of that amount, i.e. about Rs. 8,000 (\$ 175) per patient per month. The cancer groups provide the more affordable generic versions of 'Gleevec' to Indian cancer patients.

On September 12, 2006, CHC, Lawyer's Collective, Karnataka Cancer Society, Karnataka Prantiya Raitha Sangha, Karnataka Prantiya Krishi Collie Karmekara Sangha, Student Federation of India, BGVS, Samraksha, Freedom Foundation, Milana, KNP+, Action Aid, AMTC, Abhya, Pragathi, CIEDS/Karnataka Social Forum/WSF, Sangama, JAA-K and many other civil society groups had a public protest in front of Mahatma Gandhi statue on MG Road where more than 200 people stood peacefully on M.G. Road in solidarity with the cancer patients, with black ribbon tied around their forehead as mark of the protest and each of them carrying placards and shouting slogans. 1000 pamphlets were distributed to the public to raise public awareness. News and photograph about the protest were carried in Times of India, Prajavani and Vijay times. As a follow-up, letters were sent by the CHC and the Bangalore groups to Novartis AG in Switzerland and its subsidiary, Novartis in India asking them to withdraw the case. The case was being heard in the Chennai High Court.

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## WHERE CAN I ACCESS THE INDIAN PATENTS ACT AND ITS AMENDMENTS?

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For the full text of the Indian Patent Act and its amendments, visit: [www.patentoffice.nic.in](http://www.patentoffice.nic.in)

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## WHAT IS TRIPS?

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TRIPS or Agreement on Trade Related Aspects of Intellectual Property Rights was negotiated at the end of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) treaty in 1994. Its inclusion was the culmination of a program of intense lobbying by the United States, supported by the European Union, Japan and other developed nations. Campaigns of unilateral economic encouragement under the Generalized System of Preferences and coercion under Section 301 of the Trade Act played an important role in defeating competing policy positions that were favoured by developing countries, most notably Korea and Brazil, but also including Thailand, India and Caribbean Basin states. In turn, the United States strategy of linking trade policy to intellectual property standards can be traced back to the entrepreneurship of senior management at Pfizer in the early 1980s, who mobilized corporations in the United States and made maximizing intellectual property privileges the number one priority of trade policy in the United States (Braithwaite and Drahos, 2000, Chapter 7).<sup>1</sup>

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## WHAT IS ARTICLE 27 OF TRIPS?

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Article 27 relates to “Patentable Subject Matter”. Paragraph 1 of Article 27 basically states that patents shall be available for any inventions, whether products or processes, in all fields of technology, (1) provided that they are new, (2) involve an inventive (non-obvious) step and (3) are capable of industrial application (useful). It further states that patents should be available without discrimination (1) as to the place of invention, (2) the field of technology being used and (3) whether products are imported or locally produced.

Paragraphs 2 and 3 of Article 27 deals with sections which can be excluded from patentability inventions. Paragraphs 2 states that countries can prevent commercial exploitation of things which are necessary to protect *public* order or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment. It lays down the condition that the above can be done “provided that such exclusion is not made merely because the exploitation is prohibited by their law”.

Paragraphs 3 of Article 27 states that members can 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. It adds that, “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 clause itself says that 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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<sup>1</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights. (2007, February 18). In *Wikipedia, The Free Encyclopedia*. Retrieved 11:30, February 26, 2007, from <http://en.wikipedia.org/>

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## OK, THAT'S GOOD, BUT CAN YOU EXPLAIN ARTICLE 27 IN SIMPLE TERMS?

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The Article 27 under Section 5 of TRIPS talks about patentable products. Article 27 has 3 paragraphs.

Article 27 (1) talks about availability of for all inventions and for both processes and products. It states that there will be no discrimination in any field of technology on patenting.

Article 27(2) talks about inventions that can be prevented from commercial exploitation, mainly to protect public order or morality, to safeguard life and health of human, animals and plants, and to avoid serious harm to environment.

Countries cannot exclude certain inventions from commercial exploitation even though the exploitation of these is prohibited under local law. In other words, they have to grant patents regardless of any prohibition on the commercial exploitation of such a patent. For, example Indian patent laws did not provide for patents in pharmaceutical products but under the TRIPS agreement they could be forced to extend such protection from the year 2005.

Article 27 (3) (a) and (b) includes a list of products that can be excluded from patentability. These include diagnostic, therapeutic and surgical methods for the treatment of humans or animals; plants and animals, and essentially biological processes for the production of plants or animals. It explicitly says that microorganisms, and non-biological and microbiological processes for production of plants and animals cannot be excluded.

Article 27 (3) says that “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 interpretation of this last clause has been extremely contentious. The term *sui generis* (Latin for 'of its own kind or gender/genus') is not defined in the agreement, but it is generally believed that it enables member countries to fashion their own protection scheme for plants. Possible protection mechanisms include the Plant Breeder's Rights system offered by International Union for the Protection of New Varieties of Plants (**UPOV) Convention**, plant patents or a licensing regime. More than one form of plant protection can be implemented in a given member country.

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## WHAT IS THE CONTROVERSY SURROUNDING ARTICLE 27 (3)?

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One of the controversies of **Article 27.3** focuses on the meaning of '*sui generis*' and exactly what is considered an 'effective' form of plant variety monopoly right. In part because of the difficulties with this provision, Article 27.3 was to be reviewed in 1999, four years after the entry into force of the agreement. The review has never been completed, and this Article remains a hot issue. To date, some 30 countries are calling for further discussion on Article 27.3, and some have proposed:

1. rewriting the Article to exclude patents for any organisms or genetic material (although ostensibly countries could achieve this by defining these subject matters as "discoveries" and not "inventions");
2. defining in detail what an effective plant variety development right system is;
3. extending exclusionary rights of some sort to traditional or indigenous knowledge; and
4. making explicit linkages with obligations for the conservation and use of biodiversity, including mandatory disclosure of the source of genetic materials used in a patented invention, and creating obligations to record arrangements for access to genetic resources as evidence of prior informed consent.

It remains to be seen whether any of these proposals will be adopted.

Source: <http://www.patentlens.net/daisy/patentlens/415.html>

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## WHERE CAN I GET A COPY OF ARTICLE 27 AND THE TRIPS AGREEMENT?

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- For the full text of the TRIPS and other WTO agreements, visit: <http://www.wto.org/>



**Compiled by:** Naveen Thomas, Community Health Cell (CHC). May 2007  
Thanks to Ramya Sheshadri, Lawyer's Collective HIV/ AIDS Unit, Bangalore for inputs.

**For copies, contact:** The Librarian, No.367 (No. 359), Srinivasa Nilaya, Jakkasandra 1st Main, 1st Block, Koramangala, Bangalore - 560 034. **Tel:** 080-25531518, 25525372.  
**Email:** [clic@sochara.org](mailto:clic@sochara.org), [chc@sochara.org](mailto:chc@sochara.org) **Website:** [www.sochara.org](http://www.sochara.org)