

E3 | PEOPLE LIVING WITH HIV IN INDIA: THE STRUGGLE FOR ACCESS

The first case of HIV in India was reported in 1986. Three decades later, there are an estimated 2.1 million Indians living with HIV (NACO, 2015). AIDS-related deaths have decreased by 54 per cent since 2007 and according to the government, this decline has been accompanied by an expansion in access to anti-retrovirals (ARVs) in the country. It is estimated that between 2004 and 2014 around 450,000 lives have been saved in India as a consequence of enhanced access to ARVs¹.

A story of consistent struggles waged by People living with HIV (PLHIV) in India, supported by national and international solidarity, lies behind the successes achieved as regards HIV treatment in India. In many ways it mirrors the struggles of PLHIV in many countries across the world; but in taking on legal battles to challenge patent monopolies on HIV treatment, networks of PLHIV in India have had a lasting impact not only nationally but globally. By the late 1990s triple combination therapy for HIV was approved, revolutionizing the lives and treatment of PLHIV. But treatment cost as much as US\$ 15,000 per patient per year (MSF, 2005) – unaffordable to almost all patients in low- and middle-income countries (LMICs). In 2001 the situation changed dramatically when an Indian generic manufacturer (Cipla) offered treatment at less than a dollar a day (US\$ 350 per year) – representing a 97 per cent drop in prices. (WHO, 2001). From a death sentence for millions in LMICs, almost overnight, HIV patients were offered a chance to live normal and fulfilling lives.



Image E3.1 Demonstration in 2005 against amendment of Indian Patent Act (Kajal Bhardwaj)

These dramatic events had little meaning for Indians living with HIV. While Indian companies started providing medicines to government-sponsored treatment programmes abroad, the Indian government continued to resist starting its own treatment programme. This forced Indian PLHIV networks to undertake a massive campaign for access to ARVs in India. After years of struggle and advocacy, the Indian government finally announced its plan to provide free anti-retroviral treatment on 1 December 2003². Since then the role of PLHIV networks in treatment access in India has taken many shapes and forms; a key aspect of this work relates to trade, intellectual property and generic competition.

Changes in India's patent law

India's engagement with the issues of patents and access to medicines pre-dates the formation of the World Trade Organization (WTO) in 1995. India, after independence from British rule in 1947, retained the colonial patent system that allowed 14 years of patent protection on medicines. As a consequence India primarily depended on imported medicines and medicine prices in India were one of the highest in the world. In 1972 India introduced a new patent regime, and product patents on medicines were abolished, thus allowing domestic companies to manufacture and sell patented medicines at 1/10 to 1/5 of their price in the global market. This led to the establishment of a strong and vibrant generic pharmaceutical industry in India. By the late 1990s Indian generic medicines had become the lifeline for patients in most LMICs.

In 2005 India amended its patent law to fully comply with its obligations under the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)³. TRIPS required India to start granting 20 year product patents on medicines that give patent holders exclusive rights over the manufacture, sale, use, offer for sale and import of the patented medicine. The exclusion of competition usually results in high prices and restricted availability. The impending change in India's patent regime and its impact on the continued production and supply of generic ARVs in India and abroad attracted significant national and international concern from public interest groups and the United Nations⁴.

For PLHIV networks in India, other health and public interest groups like the National Working Group on Patent Laws (NWGPL) and the Jan Swasthya Abhiyan (Peoples Health Movement, India) that had long been active on these issues, became critical sources of technical information and analysis. Multiple national and international letters of concern were written asking the Prime Minister, various ministries and members of Parliament to consider the serious implications of the amendments on public health (Health GAP, 2004). In February 2005, PLHIV marched along with health groups, trade unions, farmers' groups, environmental groups and many others in public rallies in Delhi, Mumbai, Bangalore, Kolkata, Chennai, Hyderabad, Dharwad, Panjim,

Pune and Thirupati⁵ to protest the amendments. Working with the Affordable Medicines and Treatment Campaign (AMTC) of the Lawyers Collective, the networks demanded that the amendments to the patent law include⁶:

1. A clear definition of patentable criteria;
2. No patents for new usage and dosage of known medicines;
3. Provision for pre-grant opposition as before, to stop frivolous patents;
4. Simple procedures with a time limit for the granting of compulsory licences; and
5. (The) introduction of a ceiling on royalties to multinational corporations.

In reaching out to Members of Parliament, Indian PLHIV groups were joined by colleagues and representatives of international organisations who happened to be in India at the time. Wearing ‘HIV-positive’ t-shirts, the activists met several members of Parliament to explain the impact the amendments could have on the drugs they imported from India. In the parliamentary debates that took place over the amendments, access to HIV treatment featured repeatedly in the statements of various MPs. As one MP noted, “we all accept the fact that this Bill is perhaps one of the most important pieces of legislation that this Parliament is considering. I say this because it directly concerns the lives of billions of people and the livelihood of millions of people not only in India but in the lesser developed countries which are dependent on India for medical treatment from where medicines go. To give you an example, 70 per cent of the medicines used for AIDS treatment in the lesser developed countries are medicines made in India. They go from here only for the reason that they are available at prices which are affordable. Therefore, rushing through with a Bill of this importance is something that we should not do because we will be letting down our country and more importantly, or as importantly, we will be letting down countries that are dependent on us, that look up to India as a leader and look up to India as a country from where treatment is available to them at affordable costs.”⁷

In their quest to balance public interest with India’s WTO obligations, the Indian Parliament turned to the 2001 Doha Declaration on TRIPS and Public Health. Signed by all WTO members, the Doha Declaration states categorically that, TRIPS “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” (WTO, 2001). The Indian Parliament included multiple health safeguards in the patent law amendments including compulsory licences, the bolar and research exceptions, parallel imports, automatic licencing for medicines produced before 2005 and ensuring that the medicine registration system was separate from the patent regime. An additional key health safeguard was a provision restricting evergreening, i.e. the practice of pharmaceutical companies to extend their exclusive rights on a

medicine by making minor or obvious changes to the medicine and applying for additional patents. Section 3(d) of India's patent law prohibits patents on new uses of known medicines. It also prohibits patents on new forms of existing medicines unless the patent applicant can show a significant increase in efficacy⁸. The law also allows challenges to patent applications (pre-grant) and to patents (post-grant) by a broad range of parties.

'Patent oppositions' by PLHIV groups

Two of the public health safeguards described above have been used extensively by PLHIV groups in India since 2005, i.e. Section 3(d) and the patent opposition mechanisms. The first pre-grant opposition filed against a patent application for an ARV concerned a fixed-dose combination of zidovudine/lamivudine (AZT/3TC) marketed by GlaxoSmithkline (GSK) as 'Combivir'. Indian PLHIV groups collaborated with Thai groups who were also opposing GSK's patent application for this medicine in their own country, sharing information and holding joint public actions. Before the patent office could take a decision in this matter, GSK withdrew its patent application.

The first victory at the patent office for PLHIV networks came in the case of the pediatric version of the ARV Nevirapine. In 2006, the Indian Network of People living with HIV/AIDS and the Positive Womens Network filed a joint opposition against Boehringer Ingelheim's application for Nevirapine Hemihydrate, a syrup form of Nevirapine often used for treating children. Nevirapine was not be patentable in India as a pre-1995 medicine. Applying for an Indian patent on the syrup form of this medicine in 1998, the PLHIV networks argued, was an attempt at evergreening by Boehringer. The patent opposition argued that the medicine was not patentable under Indian law because the hemihydrate form of Nevirapine was "obvious to a person skilled in the art", that it was just a "new form" of an already known substance without any increased efficacy, and that the product was a "mere admixture" of ingredients that did not demonstrate any synergistic effects (Lawyers Collective, 2008). After a hearing, in June 2008 the Delhi Patent Office rejected Boehringer's application⁹.

Explaining their involvement in the case, P Kousalya, president of Positive Women's Network (PWN) stated, "we have been involved in looking at the issues of women and children in the context of HIV. We opposed the patent application on nevirapine hemihydrate to ensure that it remains available for our children and to make sure that the government doesn't say it is too expensive to provide. This is important not just for us but for PLHIV across the world. Accessing appropriate pediatric formulations of AIDS drugs is a particular problem around the world, and we hope that this decision can be a first step in making them more available" (Mathew, 2008).

Several victories in courts for PLHIV groups has ensured that generic versions of most ARVs continue to be available in India, and importantly,

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TABLE E3.1: Patent oppositions filed by PLHIV networks in India

MEDICINE	PATENT APPLICANT	PATENT OPPONENT	STATUS
Zidovudine/ lamivudine First-line ARV	GSK	Manipur Network of People living with HIV/AIDS, Indian Network for People living with HIV/AIDS	Patent Application Withdrawn
Nevaripine Hemihydrate (syrup) First-line ARV	Boehringer Ingelheim	Positive Womens Network and Indian Network for People living with HIV/AIDS	Patent Application Rejected
Tenofovir Fumarate or TDF (two applications) Preferred first -line ARV	Gilead Sciences	Delhi Network of Positive People and Indian Network for People living with HIV/AIDS; Brazilian Interdisciplinary AIDS Association (ABIA) and Sahara (Centre for Residential Care and Rehabilitation)	Patent Application Rejected
Amprenavir Second-line ARV	GSK	Uttar Pradesh Network of Positive People and Indian Network for People living with HIV/AIDS	Pending
Atazanavir Second-line ARV	Novartis	Karnataka Network for People Living with HIV and AIDS and Indian Network for People living with HIV/AIDS	ABANDONED; APPLICATION ON BISULPHATE REJECTED
Valgancyclovir OI medicine	F Hoffmann- La Roche	Tamil Nadu Network of Positive People and Indian Network for People living with HIV/AIDS	PATENT OVERTURNED
Abacavir Second-line arv	GSK	Indian Network for People living with HIV/AIDS	PATENT APPLICATION WITHDRAWN
Lopinavir Second-line arv	Abbott Laboratories	Delhi Network of Positive People, Network of Maharashtra by People living with HIV and AIDS and Indian Network for People living with HIV/AIDS	PATENT APPLICATION REJECTED
Lopinavir/Ritonavir (Soft Gel) Second-line ARV	Abbott Laboratories	Delhi Network of Positive People, and Indian Network for People living with HIV/AIDS	Patent Application Deemed Abandoned
Tenofovir or td First-line ARV	Gilead Sciences	Delhi Network of Positive People, and Indian Network for People living with HIV/AIDS	PATENT APPLICATION REJECTED
Ritonavir Second-line ARV	Abbott Laboratories	Delhi Network of Positive People, and Indian Network for People living with HIV/AIDS	PATENT APPLICATION REJECTED
Efavirenz (post- grant opposition) First-line ARV	Bristol Myers Squibb	Delhi Network of Positive People	Pending
Valgancyclovir (post-grant opposition) OI medicine	F Hoffmann- La Roche	Delhi Network of Positive People	PATENT OVERTURNED

Source: Adapted from Asia Pacific Network of People Living with HIV/AIDS (APN+) 2016

ensures that India continues to be a source of affordable ARVs for patients across the world. Table E3.1 summarizes cases where generic availability was ensured as a result of interventions by PHLIV groups. As can be seen, the threat of patent rejection often leads to companies withdrawing their applications. PLHIV networks have also been active in opposing patents on treatment for opportunistic infections and co-infections like TB and Hepatitis-C (Datta, 2015).

The Novartis Case

Between 2006 and 2013, the critical provision relied on by PLHIV groups in their patent oppositions was under a legal challenge in Indian courts, mounted by Novartis, the Swiss pharmaceutical company. The case related to the rejection of Novartis' patent application on *imatinib mesylate*, an important anti-cancer medicine used in the treatment of chronic myloid leukaemia (CML). Novartis sold its version, called Glivec (or Gleevec), at a global price of US\$ 2,500 per person per month while generic companies marketed their versions at one-tenth this price. Novartis originally obtained the patent on imatinib in 1993. Unable to get a patent on the molecule which pre-dated the TRIPS Agreement, in 1998, Novartis filed a patent application on the 'beta-crystalline' form of imatinib mesylate at the Chennai Patent office. In 2006, the patent application was rejected for, among other things, failing the criteria set in Section 3(d) of India's Patent Act.



Image E3.2 Protest against Novartis for challenging Indian Law (Delhi Network of Positive People)

Over the next eight years, Novartis first challenged the provision (Section 3(d)) itself claiming it violated the Indian Constitution and India's TRIPS obligations and then the interpretation of the provision, arguing for a lower standard of interpreting 'efficacy.' If successful, Novartis's challenge to Section 3(d) would have impacted access to medicines across the board – not just the cancer medicine in question but also other medicines for HIV. As the case progressed in the Indian courts, PLHIV groups took on the task of challenging the public positions of Novartis which claimed that nothing in its case challenged or impacted access to medicines. Legal battles over intellectual property rights, particularly where they impinge on public interest or public health are fought as much in the court of public opinion as they are in the courts of law. Over the duration of the case, PLHIV and health groups undertook protests, press conferences and various other activities to maintain public focus on the case. They also kept an eye on how the Indian government was defending Section 3(d) and INP+ wrote to the government, requesting that it deploy its best lawyers to argue the case¹⁰.

On 1 April 2013, the case finally ended with the Supreme Court upholding the strict interpretation of Section 3(d). The importance of the decision for HIV treatment was underscored by Loon Gangte of DNP+: "We are extremely pleased and relieved that the Supreme Court has recognised the public health importance of section 3(d). We have been filing several oppositions to patent applications on ARV medicines on the basis of section 3(d). This is a crucial victory for people living with HIV and other diseases who can continue to rely on India for access to affordable treatment."

The free trade agreements

In 2007, a new challenge emerged as India started negotiating free trade agreements (FTAs) with Japan and the EU. FTAs negotiated with developed countries usually feature commitments far in excess of those made at the WTO, including on intellectual property. Known as 'TRIPS-plus' measures, the provisions demanded by developed countries in these negotiations typically require longer and newer exclusive rights on medicines. They also feature investment chapters that allow 'investors' to sue sovereign governments over health policies. (See Chapter D5 on Investment agreements.)

In the case of the India-Japan FTA, leaked versions of the IP chapter indicated that Japan's interests lay in streamlining administrative matters and IP enforcement. In detailed submissions to the Indian government on the impact of Japan's demands, DNP+ highlighted not only the TRIPS-plus measures but also the potential impact of the investment chapter, noting that, "we expect the Indian government to deal with high prices of patented medicines not only through compulsory licences but also price control and regulation. However, we fear that the government may have tied its hands in taking such measures by signing on to an investment chapter like those

contained in other Japanese trade agreements" (Ahuja, 2010). In 2011, the India-Japan Comprehensive Economic Partnership Agreement was signed and in the final text, TRIPS-plus provisions appeared to have largely been rejected by the Indian government while the investment chapter included a specific exclusion for the use of TRIPS flexibilities.

Box E3.1: Campaign on the EU-India FTA

In 2009, a small group of protestors from networks of people living with HIV and other groups stood with banners outside the office of the European Union Delegation to India in New Delhi. As they chanted against the FTA and the demands being made of India by the EC, they were detained by the police. In 2010, people living with HIV continued to gather and protest outside the offices of the Indian Ministry of Commerce and Industry. In 2011, over 3,000 people from across India were joined by colleagues from South East Asia to march through New Delhi to voice their objection to the TRIPS-plus provisions of the EU-India FTA. A Press Conference held right after the rally which included the former UN Health Rapporteur on the right to Health, a representative from a cancer group and representatives from other countries who came for the rally was heavily reported in the media. The next day along with activists from Asia, the local networks met with various Indian official and the UN to raise community concerns on the harmful provisions in the EU-India FTA.

In 2012, as the EU-India Summit kicked off in Delhi in February with progress on the FTA identified as one its primary objectives, DNP+ delivered black coffins to the office of the Delegation of the EU in Delhi on one of the coldest mornings of the year. The motive was to highlight the deaths of people living with HIV/AIDS across regions who are reliant on production of Indian generic pharmaceutical that will be trammelled due to India-EU FTA. After that over 2000 people living with HIV marched through Delhi once more while protests against the EU-India FTA were also held in Asia, Africa, Latin America and the EU.

As a result of the persistent advocacy by PLHIV networks, the Commerce Ministry and Health Ministry started consulting them and other civil society groups on the text being proposed by the EU. In collaboration with legal experts an analysis of the EU text was submitted to the Indian government. Treatment literacy and outreach have been at the heart of this mobilization. The PLHIV networks spread information and awareness through community meetings. They have organized trainings on FTAs, Intellectual Property Rights for their members on an annual basis 2010 onwards.

The EU-India talks have now gone on for a decade. Leaked negotiating texts of the IP Chapter and the Investment Chapter in 2009, 2010 and 2011 showed that the EU was demanding ambitious TRIPS-plus measures including longer patent terms and new exclusive rights on medicines in the form of data exclusivity and TRIPS-plus IP enforcement measures¹¹. The alarm on these negotiations was raised by PLHIV groups who continue to make detailed submissions to the government of India, follow and report on each round of negotiations and hold regular rallies and public actions. (See Box E3.1.)

As global concern over this FTA increased over its potential impact on the manufacture, supply and distribution of generic medicines in and from India, even the European Parliament repeatedly issued resolutions directing the European Commission to ensure that access to medicines is not affected by the FTA. In May 2011, the European Parliament specifically asked the EC not to demand data exclusivity of the Indian government and recognized the importance of the use of TRIPS flexibilities by India. In April 2011, the Indian Prime Minister's Office issued a press release stating that nothing in the EU-India FTA would go beyond TRIPS or India's domestic law (PMO, 2011). Even as key TRIPS-plus demands like patent term extension were dropped by the EU negotiators, others remain on the table. As attempts to restart the negotiations on the EU-India FTA were made in 2017, PLHIV networks once more protested outside the EU offices in Delhi highlighting their ongoing concerns on the negotiations.

The Voluntary Licences

The introduction of product patents in India law has also had an impact on the business models and commercial considerations of Indian generic companies. Several top Indian companies have been acquired by MNCs or have tie-ups with them. But these buy-outs and tie-ups also mean that these companies are now unlikely to challenge patents, launch new medicines and take on MNCs in legal battles. MNCs have also altered their approach over time to offer voluntary licences to leading Indian generic exporters to counter the impact of the use of TRIPS flexibilities in India.

For instance, in 2006, patent oppositions were filed by PLHIV networks and generic companies against the patent applications filed by US MNC Gilead Sciences related to the ARV *tenofovir*. Within a week, Gilead offered voluntary licences to generic companies for the production and supply of *tenofovir* in a limited number of developing countries. Several generic companies took these licenses even though Gilead had no product patents on *tenofovir* and as a condition of taking those licenses withdrew their patent oppositions. As public interest groups and at least one generic company persisted with their oppositions, these product patent applications were later rejected by the patent office. Later in 2011, Gilead issued fresh licences to four generic companies and to the Medicines Patent Pool with a limited number of countries for

these companies to supply to. Despite the health safeguards in the Indian law and the restrictions on their ability to manufacture and supply medicines in key developing countries, generic companies have continued to sign similar voluntary licenses on other medicines as well (Lawyers Collective, 2012).

The voluntary licences, particularly those issued through the Medicines Patent Pool have revealed interesting differences in approach within public-interest groups. Voluntary licences are among the few options for improving treatment access available to patient groups in countries where pharmaceutical companies have obtained patents. Accordingly, some international groups welcomed the issue of voluntary licences. However, in India where the patent system is quite different from other countries, it remains to be seen which medicines receive patents. Only then will the matter of considering voluntary licences arise. With the current licences there has been growing concern that these may be undermining the patent opposition process (I-MAK, 2011). As in the case of the Gilead licences, once licences are signed, generic companies have withdrawn their patent oppositions leaving only the PLHIV networks opposing the applications. This occurred recently with the licenses for the new hepatitis C medicines (Babu, 2015).

Although India is included in each of these licences, PLHIV networks persist with their patent opposition work. As they commented: “Why are we still opposing the Tenofovir patents in India? Well, what guarantees are there with the voluntary licences? How long will they last? Mostly we are standing up for our Brazilian and Chinese colleagues who will suffer as a result of this game that Gilead is playing. In all respects, as long as one company and one company alone makes decisions about how and by whom medicines will be supplied, we will remain at their mercy. This is an unacceptable situation when it comes to protecting health and saving lives. In any case they don’t even deserve a patent under Indian law, so where does the question of voluntary licences arise?^{12”}

Future struggles

Since 2005, PLHIV networks have successfully raised the visibility of the debate around the very complicated issue of patents and health. The successful use of patent oppositions has inspired similar work in other countries while some developing countries have adopted or are considering adopting legal provisions similar to those in India’s patent law. The Philippines introduced a provision similar to Section 3(d) in its own patents law in 2008 (Dalangin-Fernandez, 2008).

These successes have not come easily. PLHIV groups are under-resourced and over-stretched. The safeguards in the Indian law are facing a persistent onslaught from several MNCs; Novartis was just one of them. Bayer sued the Indian government in its attempt to enforce patent linkage (demanding that drug regulatory agencies enforce patent protection) in India; something



Image E3.3 HIV activists occupy office of the National AIDS Control Organisation (NACO) to protest against stock-outs of medicines (Delhi Network of Positive People)

Bayer does not even enjoy under EU law¹³. Roche has used litigation in an attempt to enforce higher standards for the granting of temporary injunctions in patent infringement cases¹⁴. Developed countries are not only using FTA negotiations but are also using bilateral pressure such as through the US Special 301 law. This highlights the role and responsibility of the Indian government in safeguarding and using the public health safeguards in India's patent law. PHLIV groups fresh challenges in a situation where the Indian Government has shifted its position on Intellectual Property Rights (IPRs) and there are fears it is beginning to align its positions with those of developed countries (Galhotra and Krishnan, 2016). This comes at a particularly worrying time as pressure from Japan to adopt TRIPS-plus measures has re-emerged in the context of the ongoing negotiations on the Regional Comprehensive Economic Partnership (RCEP).

As difficult as the work on patents and health is, the Indian experience shows the benefits of using the legal system for making full use of the flexibilities under the TRIPS AGREEMENT. But most importantly it shows that community groups like people living with HIV are at the heart of the successful use of these flexibilities.

Notes

1 See: <http://naco.gov.in/sites/default/files/HIV%20Facts%20&%20Figures.pdf>

2 World Health Organization, "Accelerating the scale-up of HIV/AIDS treatment and care," available at http://www.whoindia.org/en/Section3/Section125_1433.htm

3 Amendments to India's patent regime

to comply with TRIPS started with the Patents (Amendment) Act, 1999, followed by the Patents (Amendment) Act 2002 which, among other things, extended the patent term to 20 years and the final set of amendments was made in 2005 in the Patents (Amendment) Act 2005 which introduced the product

patent regime in India as well as key health safeguards. See Patents (Amendment) Act, 1999, No. 17 of 1999 available at http://ipindia.nic.in/ipr/patent/patact_99.PDF, Patents (Amendment) Act, 2002, No. 38 of 2002 available at <http://ipindia.nic.in/ipr/patent/patentg.pdf> and Patents (Amendment) Act, 2005, No. 15 of 2005 available at http://ipindia.nic.in/ipr/patent/patent_2005.pdf.

4 See Letters from:

Nafis Sadik, M.D. Special Envoy of the UN Secretary-General HIV/AIDS in Asia and the Pacific and Stephen Lewis, Special Envoy of the UN Secretary-General HIV/AIDS in Africa U.N. Special Envos for HIV/AIDS to the Prime Minister and President of India, 11 March 2005; <http://www.pambazuka.org/global-south/africaglobal-india-should-ensure-global-access-through-patent-law>

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Jim Yong Kim, HIV/AIDS Director of the World Health Organization to Minister of Health and Family Welfare, 17 December 2004 <http://www.cptech.org/ip/health/c/india/who12172004.html>

5 See Global Events around Feb 26th 2005 at: <http://www.apnplus.org/wp-content/uploads/2016/01/Our-Health-Our-Right-The-roles-and-experiences-of-PLHIV-networks-in-securing-access-to-generic-ARV-medicines-in-Asia.pdf> pp. 30-31

6 See: Affordable Medicines and Treatment Campaign, "Concerns Regarding Patents Bill 2005 Introduced in the Lok Sabha," 18 March 2005. See: <http://www.cptech.org/ip/health/c/india/amtco3182005.html>

7 See: <https://indiankanoon.org/doc/1704755/>

8 Section 3(d) of India's Patents Act, 1970 reads: "The following are not inventions within the meaning of this Act...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. *Explanation:*

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

9 The decision of the Patent Office in the Nevirapine syrup case is available at <http://www.lawyerscollective.org/content/patent-nevirapine-rejected>

10 Letter from INP+ to the Prime Minister, 24 January 2007, see: <http://www.tribuneindia.com/2007/20070131/nation.htm>

11 See Text of Free Trade Agreements: EU, available at <http://www.bilaterals.org/spip.php?rubrique52>

12 Loon Gangte, DNP+ cf Our Health, Our Rights, APN+ <http://www.apnplus.org/wp-content/uploads/2016/01/Our-Health-Our-Right-The-roles-and-experiences-of-PLHIV-networks-in-securing-access-to-generic-ARV-medicines-in-Asia.pdf>

13 See: <https://www.escr-net.org/caselaw/2013/bayer-corporation-and-anr-v-union-india-ors>

14 See : <https://indiankanoon.org/doc/13140110/>

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