



Our HEALTH Our RIGHT

The roles and experiences of PLHIV networks in securing access to generic ARV medicines in Asia





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The case studies in this publication are based on interviews conducted with key people in the access to treatment work in India and Thailand.



ABBREVIATIONS AND ACRONYMS

ACT UP	AIDS Coalition to Unleash Power
AGM	Annual General Meeting
AIDS	Acquired Immune Deficiency Syndrome
APN+	Asia-Pacific Network of People living with HIV/AIDS
ARV	Antiretroviral
ART	Antiretroviral therapy
AZT	Zidovudine
BMS	Bristol Myers-Squibb
CD4	Cluster of Differentiation Antigen 4
CIPIH	Commission on Innovation, Public Health and Intellectual Property
CL	Compulsory licence
CPAA	Cancer Patients' Aid Association
DE	Data exclusivity
DG	Director-General
DNP+	Delhi Network of Positive People
EU	European Union
FTA	Free-trade agreement
GIPAP	Glivec International Patient Assistance Programme
GPO	Government Pharmaceutical Organisation (of Thailand)
GSK	GlaxoSmithKline
Health GAP	Health Global Access Project
HIV	Human immunodeficiency virus
IDU	Intravenous drug user
INP+	Indian Network for People living with HIV/AIDS
IP	Intellectual property
IPR	Intellectual property rights
ITPC	International Treatment Preparedness Coalition
MNC	Multinational corporation
MNP+	Manipur Network of Positive People
MoPH	Ministry of Public Health
MSF	Médecins sans Frontières
MSM	Men who have sex with men
NACO	National AIDS Control Organisation
NACP	National AIDS Control Programme
NGO	Non-governmental organisation
NHSO	National Health Security Office

NMP+	Network of Maharashtra People living with HIV/AIDS
OI	Opportunistic infection
PCP	Pneumocystis carinii pneumonia
PLHIV	People living with HIV
PR	Public relations
PReMA	Thai Pharmaceutical Research and Manufacturers Association
PWN+	Positive Women's Network
R&D	Research and development
TAC	Treatment Access Campaign, South Africa
TD	Tenofovir
TDF	Tenofovir Disoproxil Fumarate
TDN	Thai Drug User Network
TTAG	Thailand Treatment Action Group
TNNP+	Tamil Nadu Network of People living with HIV/AIDS
TNP+	Thai Network of People Living with HIV/AIDS
TRIPS	Trade-related aspects of Intellectual Property Rights
UNAIDS	The Joint United Nations Programme on HIV/AIDS
UNDP	United Nations Development Programme
UNGASS	United Nations General Assembly Special Session
UPA	United Progressive Alliance
USTR	United States Trade Representative
VCT	Voluntary counselling and testing
WHO	World Health Organisation
WHO SEARO	WHO South-East Asian Regional Office
WTO	World Trade Organisation
UPA	United Progressive Alliance

FOREWORD

Access to affordable HIV medicines is more than just a legal or logistical issue. It is a matter of life and death for people living with HIV. It is a matter of productive life with dignity and impoverishment for the entire family. And finally, it is a matter of exercising basic human rights and the denial of such rights.

Asia Pacific Network of People Living with HIV/AIDS (APN+) and its national networks and other local positive groups in the region have been proactively addressing and acting upon the critical issue of access to affordable HIV medicines. We have been acting both at the national level and the international level.

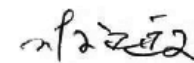
Our collective efforts and unwavering determinations to protect our fundamental right to health of highest quality have sparked international campaigns of protest against those who put profits over people's lives. Furthermore, not only have our efforts succeeded in increasing access to more affordable HIV medicines, vital medicines for other diseases such as cancer have also been made more affordable, benefiting millions of vulnerable people in Asia and elsewhere.

This book aims to inform networks of people living with HIV (PLHIV) and concerned civil society organisations about how patents can make their medicines more expensive and what they can do about it. It provides a step-by-step basic guide to enable these stakeholders to minimise the number of medicines that are patented in their country, and still ensure that medicines are affordable even if they are patented. The book also explains how some free trade agreements and other treaties can make medicines even more expensive.

This book gives concrete examples of how PLHIV networks in partnership with key partners have reduced the impact of patents on medicines, including for medicines for the wider population in Thailand and India. It provides a clear illustration of how small local and national actions led by PLHIV can generate tremendous global impacts in today's borderless and inter-connected world.

I hope this book will help positive networks and concerned civil society organisations to enhance an understanding of the critical subject, form strategies, and take actions on the ground. We shall not rest until the very last person who needs HIV medicines gains access to them.

Finally, I would like to thank all positive people, other civil societies and individuals in our region and other parts of the world for their hard work in making HIV medicines more affordable.



Shiba Phurailatpam

Regional Coordinator

The Asia Pacific Network of People Living with HIV (APN+)



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INTRODUCTION TO INTELLECTUAL PROPERTY, TRADE AND ACCESS TO MEDICINES

Sanya Reid Smith, Third World Network

1. INTRODUCTION

This chapter looks at why countries may be required to have intellectual property (IP) laws that can make medicines more expensive and what can be done about it.

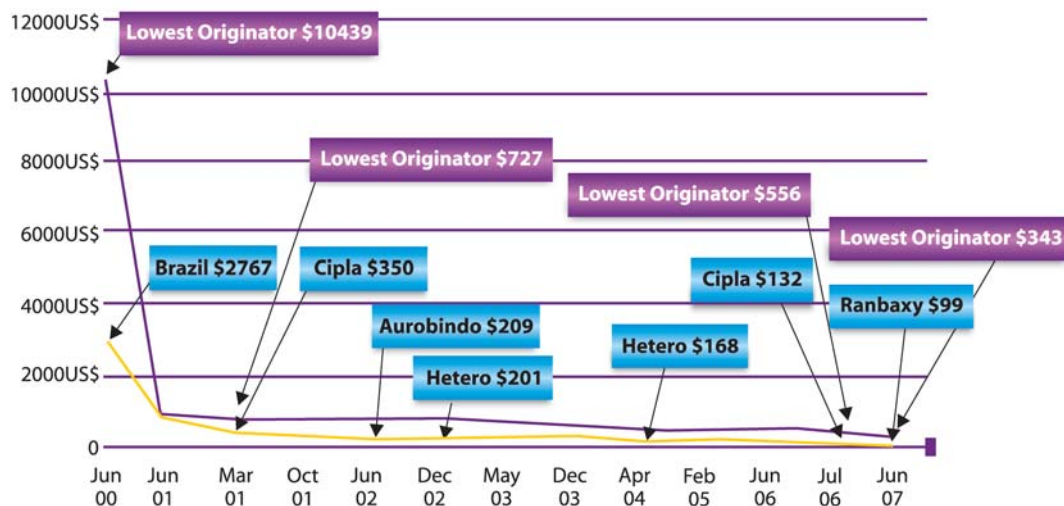
In the past, countries have been able to set the level of intellectual property protection that suited their level of development. However, since the World Trade Organization (WTO) began in 1995, there has been a minimum standard of intellectual property protection for the countries that belong to it. There are still some health safeguards that these WTO members can use. These are explained below.

This publication is relevant for developing and least developed countries confronting issues related to intellectual property rights and access to medicines. Not all countries are WTO members. For instance, see Table 1 which details the WTO and development status of some countries.

1.1 Number of PLHIV without access to medicines in Asia-Pacific

Universal access to treatment for PLHIV in the Asia-Pacific region remains a distant dream. According to estimates, only 26 percent of PLHIV in Asia and 28 percent across the Western Pacific region who need antiretroviral treatment are currently receiving it.¹

¹ See Report of the Commission on AIDS in Asia: 'Redefining AIDS in Asia', 26 March 2008, http://data.unaids.org/pub/Report/2008/20080326_report_commission_aids_en.pdf and WHO, UNAIDS and UNICEF, 'Towards Universal Access: Scaling up priority HIV/AIDS interventions in the health sector,' Progress Report 2008, <http://www.who.int/hiv/mediacentre/2008progressreport/en/index.html>



Adapted from "Untangling the Web of Price Reductions: A Pricing Guide for the Purchase of ARVs for Developing Countries". 10th Edition, July 2007, Médecins Sans Frontières. http://www.msf.org/source/access/2007/Untangling_the_Web_10th_ed_2007.pdf

1.2 Why are medicines expensive?

There are a number of reasons why medicines can be expensive. These can include intellectual property protection, tariffs (a tax on products that are imported into the country), other taxes inside your country, lack of price controls and other reasons specific to particular countries. This chapter will focus on the impact of intellectual-property protection on medicine prices and what networks of people living with HIV (PLHIV) and other concerned civil society organizations can do about it.

The impact of intellectual-property protection on medicine prices can be seen in a number of countries. In Malaysia, for example, patented medicines can be 1,044 percent more expensive than their generic equivalent.² This price difference can also be seen in the price of antiretrovirals, which used to be US\$15,000 per person per year but has fallen to US\$99, as shown by the graph below.³

1.2.1 What is a monopoly?

A monopoly means that only one company can sell the product. The company may therefore charge as high a price as it likes, so usually the monopolised product will be more expensive than a non-monopolised one. For example, if only one

company can grow bananas, they can charge as much as they want for bananas and we would all have to pay that price, because there is no other way to get them. A monopoly is the opposite of competition. Normally, governments want to encourage competition and prohibit monopolies to keep things cheap for the people.

1.2.2 What is a patent?

A patent is a monopoly, usually for 20 years, on inventions. A new medicine can be an invention, so medicines can be patented. If a medicine is patented, only the company that owns the patent can make, use, sell or import it unless one of the safeguards below is used.

Patent laws are usually national. Thus, theoretically, every country can choose whether or not to allow patents and write its own patent laws. However, there are international, regional and bilateral agreements that may require countries to have certain patent laws. These include the World Trade Organization (WTO) and free-trade agreements (see 'TRIPS-plus provisions that can make medicines more expensive', page 17 for more details).

When patents are national, companies have to apply for them separately in every country. All the

² 'TRIPS, Patents, Technology Transfer, Foreign Direct Investment and the Pharmaceutical Industry in Malaysia', Ida Madieha Azmi and Rokiah Alavi, *Journal of World Intellectual Property*, Vol. 4 No. 6, November 2001.

³ *Untangling the Web of Price Reductions: A Pricing Guide for the Purchase of ARVs for Developing Countries*. 10th Edition, July 2007, Médecins Sans Frontières. http://www.msf.org/source/access/2007/Untangling_the_Web_10th_ed_2007.pdf and http://www.msf.org/msfinternational/invite.cfm?objectId=63C0C1F1-E018-0C72-093AB3D906C4C469&component=toolkit.article&method=full_html.

countries covered by this book have national patent systems (i.e. none of them are currently involved in a regional patent office that grants a single patent that is valid in multiple countries).⁴

Regional patent offices would be likely to increase the number of medicines that are patented in the countries that are part of it, because the regional system makes a larger market for the medicine and so makes it more worthwhile for companies to spend the time and money applying for a patent. This would be a particularly likely outcome for countries whose small populations have meant they do not currently receive many patent applications, such as some Pacific island nations.

Key point:
Patents make medicines more expensive.

1.3 What is intellectual property?

Intellectual property is traditionally thought of as a reward for something that comes from the imagination. It includes copyright for books, movies, music, etc; trademarks for brand names such as 'Pfizer' and patents for new inventions, including medicines. Intellectual-property protection gives the intellectual property owner a monopoly for a certain number of years. A monopoly means that no one else can make, use, sell or import the medicine unless they get a voluntary or compulsory licence (see 'once a medicine is patented'). In the case of inventions, a patent can be thought of as an incentive to disclose how the invention is made (so at the end of the patent, everyone can make the invention); otherwise this knowledge may be kept secret and no one would ever be able to make the invention.⁵

Intellectual property protection is one of the rare cases when governments allow monopolies, but this right is limited very carefully.

1.4 What is a 'generic'?

A generic version of a medicine is the same chemical and works the same in your body as the

Box 1

CASE STUDY: NEPAL

Nepal is a member of the WTO as well as an LDC. As such, it does not have to allow patents on medicines until at least 1 January 2016.

This decision is already under implementation because TRIPS and the Doha Declaration apply automatically, overriding earlier Nepalese patent law. So Nepalese firms and State institutions can currently make or import, and sell, generic versions of any medicine, even the newest medicines. It can also export these generics to any country in which a patent for the medicine in question has not been given (or if, regardless of a patent, the importing country has issued a compulsory licence).

patented version. It is also as safe as the patented medicine. For example, Bristol-Myers Squibb makes Videx, which is the brand name for didanosine. The same didanosine may also be made by a generic company, such as Cipla, and called by another name, such as Dinex.

1.5 What is the World Trade Organization?

152 countries are members of the World Trade Organization (WTO).⁶ The WTO sets rules that its members must obey. These include minimum standards of intellectual-property protection. These intellectual-property rules are in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). However, TRIPS also has some safeguards that can be used to protect health. For example, among WTO members, those that are least-developed countries (LDCs) do not yet have to comply with the substantive requirements of TRIPS.⁷ (Table 1 shows which countries are LDC WTO members).

If a WTO member country does not comply with TRIPS, other WTO members can take it to the WTO court (a 'dispute settlement panel'). If it loses at this court, it can have taxes put on its exports by the importing country. This is a serious economic penalty for most countries, so most countries are very careful to comply with TRIPS.

There are special exceptions for LDC WTO members; see 'What does the WTO require?' (See Page 12)

4 As there are currently no regional patent offices in the Asia-Pacific region. http://www.wipo.int/directory/en/regional_offices.jsp.

5 See, for example: WIPO Roving National Seminar on Industrial Property, Ulf Jansson, Director Swedish Patent Office, Ethiopia, 2000, WIPO/IP/ET/00/9. http://www.wipo.int/edocs/mdocs/sme/en/wipo_ip_et_00/wipo_ip_et_00_9.pdf; WIPO Regional Training Course on Intellectual Property for Developing Countries of Asia and the Pacific, organized by the World Intellectual Property Organization (WIPO). Sri Lanka, 1999, WIPO/IP/CM/99/16, http://www.wipo.int/edocs/mdocs/sme/en/wipo_ip_cm_99/wipo_ip_cm_99_16.pdf

6 Not all countries in the Asia-Pacific region are WTO members; see Table 1

7 'Extension of the Transition Period under Article 66.1 for Least-Developed Country Members', decision of the Council for TRIPS of 29 November 2005, IP/C/40

Table 1: WTO and LDC status for countries covered by this book

Countries continue to join the WTO. Some of them may graduate from LDC status or become LDCs in the future. The table below was correct as of September 2007.

For updates, see

http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm

for whether a country is currently a WTO member. For whether a WTO member country is also an LDC, please see

http://www.wto.org/english/thewto_e/whatis_e/tif_e/org7_e.htm.

COUNTRY [w3]	WTO MEMBER ¹⁰	LDC
Afghanistan	A	Y
Bangladesh	Y	Y
Bhutan	A	Y
Cambodia	Y	Y
China	Y	N
Cook Islands	N	N
Fiji	Y	N
Democratic People's Republic of Korea	N	N
India	Y	N
Indonesia	Y	N
Iran	A	N
Kiribati	N	Y
Lao PDR	A	Y
Malaysia	Y	N
Maldives	Y	Y
Marshall Islands	N	N
Federated States of Micronesia	N	N
Mongolia	Y	N
Myanmar	Y	Y
Nauru	N	N
Nepal	Y	Y
Niue	N	N
Pakistan	Y	N
Palau	N	N
Papua New Guinea	Y	N
Philippines	Y	N
Republic of Korea	Y	N
Samoa	A	Y
Solomon Islands	Y	Y
Sri Lanka	Y	N
Thailand	Y	N
Timor-Leste	N	Y
Tokelau	N	N
Tonga	Y	N
Tuvalu	N	Y
Vanuatu	A	Y
Vietnam	Y	N

1.6 What does the WTO require?

1.6.1 Patents

Countries that are WTO members but are not LDCs must allow patents on medicines for twenty years. LDC WTO members do not have to allow patents on medicines until at least 1 January 2016. Non-members do not have to allow patents on medicines at all.

Key point:
Some countries must allow patents on medicines for 20 years

1.7 Data Protection

TRIPS allows generic companies to register their medicines without repeating the clinical trials.⁸ This is because countries that are WTO members but are not least-developed need only protect certain data such as clinical trial results from specified uses. TRIPS only requires protection of undisclosed data that took considerable effort to generate and is about new chemical entities. TRIPS says that the only thing that cannot be done with this data is that it cannot be used unfairly for a commercial reason. 'Unfair' has a very narrow definition in this context such as dishonest.⁹

LDC WTO members do not have to do even this level of data protection until at least 1 January 2016. Non-WTO members do not have to allow data protection at all.

1.8 WTO health safeguards

Although the list of safeguards below are all allowed by TRIPS, most countries have not fully implemented them in their national laws (such as their Patents Acts). For example, some countries may not allow pre-grant opposition or parallel importation, or may only allow compulsory licensing in a few situations and with unnecessarily difficult procedures.

⁸ Article 39.3 TRIPS. This is confirmed by for example: the UNCTAD-ICTSD Resource Book on TRIPS and Development: An authoritative and practical guide to the TRIPS Agreement (available at <http://www.iprsonline.org/unctadictsd/ResourceBookIndex.htm>); 'Protection of Data Submitted for the Registration of Pharmaceuticals', Carlos Maria Correa, South Centre and World Health Organization, 2002, available at <http://www.southcentre.org/publications/protection/protection.pdf> and Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement, Carlos M. Correa, Oxford University Press, 2007.

⁹ 'Protection of Data Submitted for the Registration of Pharmaceuticals', Carlos Maria Correa, South Centre and World Health Organization, 2002, available at <http://www.southcentre.org/publications/protection/protection.pdf>

¹⁰ Y = yes; N = no; A = in the process of joining ('acceding to' the WTO).

In most countries, these health safeguards probably have to be included in national law before you can use them. However, in a few countries, many international treaties directly apply and override any national laws, so it is not absolutely necessary to implement the safeguards in national laws explicitly. Nevertheless, even in this second type of country, it is better if health safeguards are clearly included in national laws to avoid confusion and unnecessary litigation.

In the medium to long term, PLHIV can successfully lobby to improve their national laws if these laws do not yet have all these health safeguards.

1.8.1 Before a medicine is patented

Non-WTO members do not have to allow patents on medicines at all unless this has been agreed under some other international, regional or bilateral treaty (see below, 'TRIPS -plus provisions that can make medicines more expensive!')

LDC WTO members do not have to allow patents on medicines until at least 1 January 2016. WTO members that are not least-developed and so have to allow patents on medicines can still minimize the number of medicines that are patented in their country. TRIPS allows this to be done in a number of ways. The main ones are listed below.

Prohibit patents on certain things

The WTO allows countries to prohibit patents on plants, animals, new uses of existing medicines and diagnostic, therapeutic or surgical methods. Many new medicines come from plants: for example, the last remaining effective malaria medicine in many areas is from a plant. If plants can be patented, these medicines may be more expensive.

Many medicines today are in fact new uses of an old medicine.¹¹ For example, AZT was first developed as a cancer medicine but was later found to be useful for HIV/AIDS.¹² Patents for 'therapeutic methods' can be another way of getting a patent on the new use of an old medicine. If patents for new uses were allowed, this would mean a medicine could have a twenty-year monopoly via the first patent, then a second twenty-year monopoly for the new use of that same medicine.

Indian law prohibits patents for minor changes to a

medicine. See Chapter 2 for the example concerning Novartis, which tried to get extra twenty-year patents for the same medicine (by making salt and crystal versions). Because Indian law does not allow patents for slight changes, Novartis was not allowed these extra patents.

Some developing countries are interested in copying this provision (Section 3(d)) of the Indian Patents Act, in order to minimise the number of patents on medicines in their countries by prohibiting patents for minor changes. However, these countries should keep in mind that although the provision in India's patent law is an important safeguard against evergreening, it may not effectively prevent the granting of frivolous patents in all situations. In fact PLHIV and activists in India have been demanding a much stricter standard to prevent this 'evergreening'. See Chapter 2 for a discussion on the amendments to India's patent law.

Government authorities, PLHIV and other activists in developing countries in Asia and the Pacific should contact international legal experts such as the World Health Organization and non-governmental organizations such as the Asia Pacific Network of People Living with HIV/AIDS (info@apnplus.org), Third World Network (twinkl@po.jaring.my), and the Lawyers Collective HIV/AIDS Unit (aidslaw@lawyerscollective.org) for technical support on making full use of the TRIPS flexibilities and in drafting strict criteria in their patent laws on what should not be patented.

Set high patentability criteria

Countries can set high criteria for what inventions are eligible for a patent. There are three criteria, all of which must be satisfied for an invention to receive a patent. These are that the medicine must be new ('novel'), inventive and industrially applicable. Countries can define what these terms mean. A commission set up by the British government recommended that developing countries should set these standards high so that fewer inventions pass these tests and receive patents.¹³ India's new patent law sets these standards quite high. For example, 'new' can mean it has never been done before, anywhere in the world. This would apply even if it was only in traditional knowledge told orally.

11 See for example Intellectual Property Rights, the WTO and Developing Countries: the TRIPS Agreement and Policy Options, Carlos M Correa, Zed Books, Third World Network, 2002

12 See for example: <http://www.niaid.nih.gov/publications/discovery/thiv.htm>


13 Integrating Intellectual Property Rights and Development Policy: Report of the Commission on Intellectual Property Rights. Commission on Intellectual Property Rights, London, 2002

The standards of 'inventiveness' applying to a medicine can also be set high. For example, adding two existing antiretrovirals together in one tablet is quite obvious because PLHIV have to take them together anyway (see the Combivir example at 2.2.1 on page 35 Chapter 2). If it is obvious, it is not really inventive and so should not get a patent.

Allow pre-grant patent opposition

According to TRIPS, countries can allow pre-grant opposition to patent applications. This means that anyone can object to any patent application any time before it is decided. For example, this could be because they do not think the medicine is really inventive. This has been used successfully by groups of patients in a number of countries in the world to prevent certain medicines from being patented, (see for example Chapter 2 and Chapter 3).

According to TRIPS, these objections can also be made after the patent is granted (see 'Post-grant opposition and revocation of the patent' on page 15).

 **Key point:**
TRIPS allows a number of ways to minimize the number of patents granted, including patents for medicines.

1.8.2 Once a medicine is patented

Remember that non-WTO members do not have to allow patents on medicines at all unless this has

been agreed to under some other international, regional or bilateral treaty (See Page 17, 'TRIPS-plus provisions that can make medicines more expensive').

LDC WTO members do not have to allow patents on medicine until at least 1 January 2016. However, if for some reason your country (even though it is not a WTO member or is an LDC WTO member) has allowed patents on a medicine, you can use all these TRIPS safeguards (and others) if they are in your law and you are not restricted by some other treaty. For WTO members that are not LDCs, there are a number of health safeguards in TRIPS that can be used, even if a medicine is patented. These are:

Early working (Bolar exception)

TRIPS allows a generic company to prepare or import a small sample of the generic medicine and submit it for registration to the DRA before the patent expires (see Boxes 2 and 3 for an explanation of medicine registration). This means that as soon as the patent ends, the generic can be approved and sold immediately. This is called the 'early working' or Bolar exception. Without this exception, the generic company would have to wait until the patent expires before it could apply to register its medicine. This could mean a wait of approximately two years after the patent expires before the generic medicine can become available.

Parallel importation

Parallel importation is another possible health safeguard permitted by TRIPS. Parallel importation means importing the patented medicine from another country where it is cheaper. For example, if a patented antiretroviral costs US\$5.00 per tablet in your country and the same patented medicine is sold in another country for US\$1.00 per tablet, you can import that patented medicine from the cheaper country. By the time transport costs are paid, it may only cost US\$1.50 per tablet.

Parallel importation is still importing the patented product. If there is a valid patent on a medicine in your country, you cannot import the generic version unless you issue a compulsory licence (see 'Compulsory licensing'). If there is no patent on the medicine in your country, then your country can import (or make) generic versions of the medicine without needing to do parallel importation or compulsory licensing.

If parallel importation is done by a profit-making company, it may not make the medicine much cheaper, since the company importing it may set a price only slightly lower than the existing price in

Box 2

WHY ARE MEDICINES REGISTERED?

Most countries have a drug regulatory authority (DRA) in their Department/Ministry of Health. Before allowing medicines to reach consumers, the DRA checks that all medicines are:

1. Effective (for example the medicine actually works to treat HIV/AIDS). This requires tests such as clinical trials on humans.
2. Safe (that the medicine has few harmful side-effects). This also requires tests such as clinical trials.
3. Good quality (for example the factory is clean).

If the medicine passes all three of these tests, it is registered (also known as given 'marketing approval') and can then be given to patients or sold in your country.

Some small countries do not have their own medicine registration system and instead they may rely on whether a medicine has been approved by another DRA (such as the US Food and Drug Administration).

your country (e.g. US\$4.95). In a number of countries, the government, government agency, state enterprise or government-linked company can do parallel importation and this can ensure the full price reduction is felt, for example it is likely to cost closer to US \$ 1.50 in the example given.

Compulsory licensing

Compulsory licensing is another health safeguard allowed by TRIPS. A compulsory licence means that even if the medicine is patented, the government can still allow someone else to make or import it without the patent owner's permission.

TRIPS allows compulsory licences to be given for any reason, such as for example when the patented medicine is too expensive. There need not be an emergency to use compulsory licensing. For example, licensing could be for public non-commercial use (the 'government use' type of compulsory licence), such as when a government imports the generic version of a patented antiretroviral for use in government hospitals.

If a government gave a compulsory licence to a generic company to make or import the patented medicine and sell it for a profit, for example through a private pharmacy, this is called a compulsory licence ('not government use').

TRIPS has certain procedural requirements for compulsory licences, such as initial efforts to negotiate a voluntary licence. This particular requirement does not apply in case of a national emergency or a government-use licence.¹⁴ TRIPS allows compulsory licences to be granted from the start of a patent except in the case of the patent owner failing to manufacture the product locally, in which case you would have to wait 3-4 years before applying for a compulsory licence.

Many countries, both developed and developing, have issued compulsory licences. See Chapter 3 (also <http://www.cptech.org/ip/health/cl/recent-examples.html>), which includes examples of compulsory licenses issued by developed countries, including licences for medicines (one case is Italy).¹⁵ Furthermore, 'in the us before 1950, there were over 40,000 cases of compulsory licensing. Although the

Box 3

HOW IS A GENERIC MEDICINE REGISTERED?

Medicine registration is usually national. That is, every country has to decide to register a medicine itself. The patented or branded medicine is almost always registered first. When the branded company registers its medicine, it has to give the DRA clinical-trial and other results to show that its medicine is effective, safe and of good quality.

In most countries, if a generic company then wants to register its version of the same medicine, it only has to show that it is chemically identical ('bioequivalent') and of good quality. This means that the generic company does not have to repeat the clinical trials.

Repeating clinical trials would be unethical, expensive, and take several years. Clinical trials often require a control group who also have the disease but receive only a placebo while the rest of the people in the trial get the medicine being tested. If the generic company had to repeat the clinical trials with a control group who only got a placebo when there is already a known effective medicine (because the branded medicine has already been approved as effective) this would be unethical, for example according to the World Medical Association's Declaration of Helsinki. In some countries, national laws or guidelines have incorporated the Helsinki Declaration, so such a repeated trial would also be illegal. * Other countries may have ethics committees that would not allow such repeated clinical trials.

* for example, Malaysia.

number of compulsory licences was lower after 1950, it still amounted to more than 10,000.¹⁶ Compulsory licences can be broad, such as that of Zimbabwe for any medicine used to treat HIV/AIDS.

A compulsory licence can last until the end of the patent, as in Indonesia. The royalty paid by the company that receives the compulsory licence to the patent owner can be quite small (0.5 percent in Indonesia). This allows the price of the generic to be very low (as low, in Indonesia, as cost plus 0.5 percent, the value of the royalty). TRIPS allows countries to set a maximum royalty in their laws, which simplifies these negotiations.

Post-grant opposition and revocation of patent TRIPS recognises that invalid patents can be granted unintentionally. Therefore, it allows challenges to patents after they have been granted.

14 But TRIPS allows countries to set a maximum period for these negotiations so that they cannot delay the compulsory licence too long. For example, Canada and the European Union set a maximum period of 30 days for trying to negotiate a voluntary licence: s21.04(3)(c)(i) of Chapter 23 Statutes of Canada 2004 (Bill C-9: The Jean Chrétien Pledge to Africa) and Regulation (EC) No 816/2006 Article 9.1.

15 For more information about US and Canadian compulsory licences, see also 'Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA', Issue Paper No. 5, Reichman and Hasenzahl, 2003, UNCTAD, ICTSD, http://www.ictsd.org/pubs/ictsd_series/ipsr/CS_reichman_hasenzahl.pdf; Non-Voluntary Licensing of Patented Inventions: the Canadian Experience. Reichman and Hasenzahl, 2002, UNCTAD, ICTSD, http://www.iprsonline.org/unctadictsd/docs/reichman_hasenzahl_Canada.pdf.

16 Benjamin Krohmal, Director of the US-based Consumer Project for Technology in The Right to Life by Kannikar Kijtiwatchakul, 2007, Bangkok.

Such challenges may be brought by anyone, at any time after the patent has been granted. For example, it could be because the patent is not new, not inventive enough, not industrially applicable, did not meet the procedural or other requirements of the patent law, or some combination of these reasons.

Thus, TRIPS allows post-grant opposition, invalidation, revocation and other similar procedures. Post-grant opposition is usually done at the patent office (administrative), whereas revocation can be through the patent office or the courts. Countries such as India allow both post-grant opposition and revocation. PLHIV groups in India have already started post-grant oppositions.

See the ddl case on Chapter 3 for an example of revocation.

 **Key point:**
Even if the medicine is patented, there are still safeguards in TRIPS that can be used to make the patented medicine more affordable

1.9 Information and Issues related to TRIPS -plus Provisions

1.9.1 What is TRIPS-plus?

TRIPS sets the minimum level of intellectual-property protection that WTO member countries must have. Thus, under TRIPS, countries may choose to have stronger intellectual-property protection than the minimum level it sets. This stronger intellectual-property protection that is more than what TRIPS requires is known as 'TRIPS -plus'.

If any **non-WTO** member gives any TRIPS level of intellectual property protection, then this is also

beyond what is required, unless, of course, the country has to set this higher level of protection because of some other treaty. Similarly, if any LDC WTO member is obliged to allow patents because of an international treaty, this can also be considered as TRIPS -plus (see 'What does the WTO require?').

Various reports have recommended that developing countries do not introduce TRIPS -plus provisions.¹⁷ Much concern has also been expressed about the impact of TRIPS -plus provisions on medicine prices – by, for example, by the United Nations Special Rapporteur on the Right to Health,¹⁸ the World Health Assembly,¹⁹ the WHO's Commission on Intellectual Property Rights, Innovation and Public Health,²⁰ ministers of health from ten Latin American countries,²¹ the ministers of health²² of the African Union and the Union's ministers of trade,²³ the UK Government's Commission on Intellectual Property Rights²⁴ and the Nobel-Peace-Prize-winning Doctors Without Borders.²⁵

1.9.2 How do your laws become TRIPS -plus'?

TRIPS-plus provisions can occur in a number of ways. Your country may have inherited a TRIPS -plus law. Or your government may have been pressured by another country to increase its intellectual property protection, for example via the USA's Special 301 Report (see Box 4). If this is the case, your government can always change this law to include the TRIPS safeguards, if it has not signed one of the treaties below. If your country has signed any of these, it cannot usually violate the TRIPS -plus provisions without being penalized in some way.

The TRIPS -plus provision may come through a bilateral or regional trade agreement (FTA) with a developed country, for example the USA, Japan or a European country. If any FTA provision is violated by your government, the other country that has signed the FTA with it can usually place tariffs (a kind of

17 See, for example: 'Public health Innovation and Intellectual Property Rights: Report of the Commission on Intellectual Property Rights, Innovation and Public Health', April 2006, WHO, and 'Integrating Intellectual Property Rights and Development Policy: Report of the Commission on Intellectual Property Rights', Commission on Intellectual Property Rights, London, 2002

18 Press release, 5 July 2004. Available at <http://www.unhcr.ch/hurricane/hurricane.nsf/view01/35C240E546171AC1C1256EC800308A37?opendocument>

19 WHA56.27, May 2003. http://www.who.int/gb/ebwha/pdf_files/WHA56/ea56r27.pdf

20 Public health, Innovation and Intellectual Property Rights, World Health Organization, April 2006. For example recommendation 4.21. <http://www.who.int/intellectualproperty/report/en/>

21 Declaration of Ministers of South America over Intellectual Property, Access to Medicines and Public Health, Geneva, 23 May 2006. The ministers of health were from Argentina, Bolivia, Brazil, Chile, Colombia, Ecuador, Paraguay, Peru, Uruguay and Venezuela. See <http://lists.essential.org/pipermail/ip-health/2006-May/009594.html>

22 Gaborone Declaration, 2nd Ordinary Session of the Conference of African Ministers of Health, Gaborone, Botswana, 10-14 October 2005, CAMH/Decl.1(II), <http://lists.essential.org/pipermail/ip-health/2005-October/008440.html>

23 AU Ministerial Declaration on EPA Negotiations, AU Conference of Ministers of Trade, 3rd Ordinary Session, 5-9 June 2005, Cairo, Egypt, AU/T/MIN/DECL. (III). See www.twinside.org.sg/title2/FTAs/General/AFRICAN_UNION.Cairo_Decl.doc

24 'Integrating Intellectual Property Rights and Development Policy: Report of the Commission on Intellectual Property Rights', Commission on Intellectual Property Rights, London, 2002. For example, pages 39, 49, and 113, http://www.iprcommission.org/graphic/documents/final_report.htm

25 'Access to Medicines at Risk Across the Globe', Briefing Note, MSF Campaign for Access to Essential Medicines, May 2004, www.accessmed-msf.org/documents/ftabriefingenglish.pdf

tax) on goods it imports from your country.

If your country joined the WTO after 1995, it may have had to agree to TRIPS -plus provisions to be allowed to join²⁶ (this also applies to countries that are now negotiating to join the WTO; see Table 1 on page 12). This is because, for a country to join the WTO, all existing WTO countries have to agree to let it in. If even one existing WTO country decides that your country must agree to TRIPS -plus provisions to be allowed into the WTO, your country will have to agree to it, or else it cannot join. If your country violates the TRIPS -plus requirements it had to agree to in order to get into the WTO, it can be sued by other WTO members; and if it loses, tariffs can be put on your country's exports.

TRIPS -plus provisions may also occur via a bilateral investment treaty (BIT). BITs generally have weaker penalties than FTAs. Usually, if your country violates a BIT, it can be sued by the foreign company involved at the international court. If it loses, it is supposed to pay a fine. But if your country does not pay that fine, no tariffs can be placed on its exports.

Developed countries may decide unilaterally to withdraw any special lower tariffs they give your country's exports under the generalized system of preferences (GSP), but GSP can be withdrawn whenever the developed country wishes to, for any reason because it is basically discretionary assistance.

1.9.3 TRIPS -plus provisions that can make medicines more expensive

More medicines may be patented

There are a number of types of TRIPS -plus provisions that may cause more medicines to be patented. Firstly, because patents are national, companies usually have to apply to each country individually. Sometimes the company will not bother to apply for a patent if only a few people in your country need that medicine. It is not worth their time and effort to do so for countries with small populations.

However, your country may have to join extra intellectual-property treaties that go beyond TRIPS and can mean your country will receive more

patent applications. These treaties include the Patent Cooperation Treaty (PCT) and the Patent Law Treaty (PLT). These treaties make it easier for a company to apply for a patent in many countries. The PCT basically allows the company to tick a box and the patent application will come to your country and pass the first steps of the procedure. The PLT also makes it procedurally easier to get a patent in another country.

If your country decides to join a regional patent office, this may also mean your country receives more patent applications because with one application to the regional office, it can get a patent in many countries (with a greater combined population to make the expense of getting a patent worthwhile).

If your country receives more patent applications for any of these reasons and keeps awarding patents at the same rates (for example to half of the applications), more medicines will be patented in your country.

Box 4

Special 301

A US law called 'Special 301' (19 USC 2242) requires the US Trade Representative (i.e. the American minister of trade) to identify countries that the USA thinks are not protecting intellectual property strongly enough (not providing TRIPS or TRIPS+ protection). The lowest warning level is placement on the Watch List, followed by transfer to the Priority Watch List. American law does not allow the US Government to punish countries on either of these lists.

However, the countries the US government thinks are worst at protecting intellectual property are called Priority Foreign Countries (PFCs). Ultimately the USA can raise taxes on exports from these countries.

However, if the PFC enters into genuine negotiations with the USA, the US government cannot raise taxes on its exports. If the country changes its laws or enhances enforcement to the level considered satisfactory by the USA, it is removed from the PFC list.

Many countries, both developed and developing, are included in the annual Special 301 report (including, in 2007, Canada and Italy), which lists Watch List, Priority Watch List and Priority Foreign Countries. Some countries take it seriously if they are listed on the Watch List or Priority Watch List. Other governments don't worry about it because no action can be taken against them unless they become a Priority Foreign Country.

²⁶ http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm gives joining dates for WTO countries .

Generally it is advantageous for country X to join the WTO if it has significant exports to WTO members that are facing higher tariffs than they would if a country X joined the WTO. This is because once it becomes a WTO member, a WTO member country such as the USA can only put the same tariff on country X's exports (for example shoes) as the USA applies to shoes coming from any other WTO country. This is known as most-favoured-nation (MFN) status).

There are a number of countries (for example in the Pacific) that are not currently WTO members. They do not have significant exports currently facing above-MFN rate tariffs from WTO countries. So if they joined the WTO, they do not have sufficient exports which would enjoy lower tariffs to outweigh the costs (for example of having to introduce intellectual-property protection) of joining the WTO.

Secondly, more types of medicines may be allowed to be patented because of limitations on the exceptions allowed under TRIPS. Under TRIPS, there is no need to give patents on plants and animals (see 'Prohibit patents on certain types of thing', on page 13). TRIPS -plus treaties, however, may require your country to give patents on plants and animals. Similarly, TRIPS does not require countries to give patents for new uses of old medicine, but a TRIPS -plus treaty may require your country to do this. For example, when AZT was developed as a cancer medicine, it may have received a twenty-year patent; then, when it was also found to be useful against HIV/AIDS, it could get another twenty years of patent protection because of this TRIPS -plus provision (20 years + 20 years = 40 years of monopoly).

Thirdly, while TRIPS allows pre-grant opposition (see 'Pre-grant patent oppositions', page 14), some TRIPS -plus treaties prohibit pre-grant opposition. Again, this can mean that more medicines will be patented. Your patent law is also TRIPS -plus if it limits who can object to a patent application (allowing generic companies, but not PLHIV to object, for example), or by limiting the time during which objections to a patent application can be filed to a few months only.

Patents may last for longer

TRIPS only requires patents to last for twenty years. Some FTAs may require patents to continue for longer than twenty years ('patent term restoration/extension'). This may be because your patent office is seen to be taking too long to decide on patent applications and/or the DRA is seen to be taking too long to register medicines.

However, if the patent office is rushed into making a decision, it may not have time to check all the existing inventions in the world to make sure the medicine seeking a patent is really new. This can lead to weak patents being granted for inventions that do not really deserve a patent because they do not actually meet the patentability criteria. These patents then have to be challenged in the courts, which takes time and money.

Similarly, if the DRA is rushed to approve a medicine, it may not have time to check whether the medicine is really safe, leading to medicines that have dangerous side effects being approved.

Parallel importation

TRIPS allows parallel importation (see 'parallel importation', page 14, for an explanation of this safeguard). However, some international agreements limit or prohibit parallel importation.

Data exclusivity

TRIPS only requires certain data to be protected from dishonest commercial use (see 'data protection', page 12). TRIPS allows generic version of medicines to be registered immediately, without having to repeat clinical trials. However, some treaties require 'data exclusivity'. Data exclusivity means that, for the duration of the data exclusivity period (often five years or more),²⁷ the generic version of the medicine cannot be approved because it is not allowed to rely on clinical trials of the branded medicine for approval. For a generic to be registered within the data-exclusivity period, the clinical trials (see Box 3 for the problems with this) have to be repeated. This data exclusivity can cause a delay in access to generic medicines in three situations:

²⁷ BITs or some FTAs such as some Japanese ones may require infinite data exclusivity. This means that a generic version of the medicine from the country that has signed the FTA or BIT with your country can never be approved; see 1.9.3.7 Impact of BITs.

Situation 1

There may be no patent in your country. This should mean you can immediately import or make the generic medicine, but if there is data exclusivity, you will have to wait until the data-exclusivity period ends before you can get the generic medicine. It may be quite common for there to be no patent in your country. Reasons for this include the following:

- no patent has been applied for in your country, or
- the medicine is not new or inventive enough to be granted a patent in your country, or
- the patent in your country is not in force because the fees have not been paid, or
- the patent in your country has expired, or
- the patent in your country has been revoked as it was invalid



Figure 1

Situation 2

There maybe a patent on the medicine and data exclusivity occurs entirely within the patent period. This can happen because dra approval is usually granted a few years after the patent starts; this is usually when any data-exclusivity period begins. Because data exclusivity is usually less than twenty years, it usually ends before the patent expires; see the figure 2 below.

This situation can cause health problems, because if a compulsory licence is issued for that patented medicine, it still cannot be registered and given to people who need it until the data exclusivity period ends (see Figure 2 below) – unless, the government decides to ignore its own medicine registration requirements. Ignoring them is not ideal because they are there to protect people from unsafe medicines (see Box 2).

Furthermore, generic companies in some countries slightly modify their version of the medicine so that it does not infringe on the patent – However, it is still the same chemical as the patented one so that the generic company can rely on the patented medicine's clinical trials to get registration by the DRA. With data exclusivity, any generic company that does this kind of modification must wait until the end of the data exclusivity period before it can be registered and reach consumers.

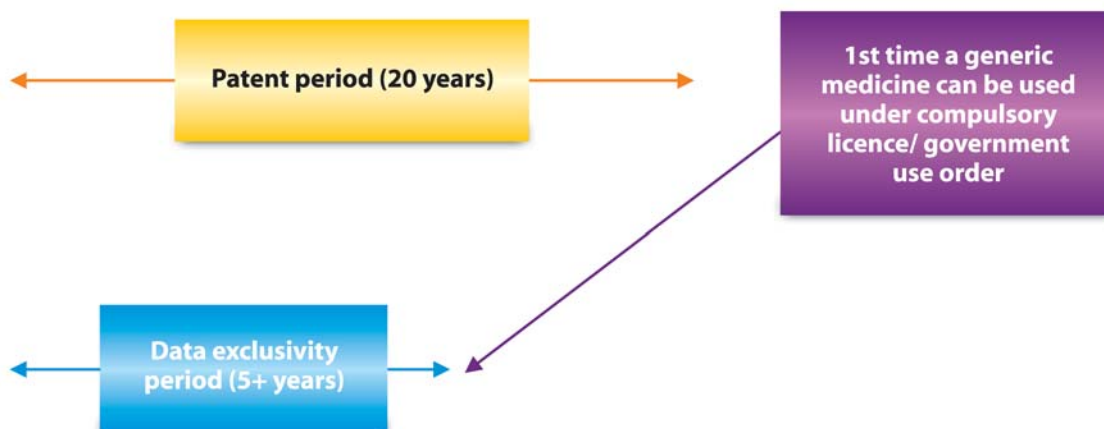


Figure 2

Situation 3

Patent with data exclusivity 'overhang'. Sometimes the patented medicine can be registered by the DRA quite late in the patent period (for example, because many clinical trials were needed to prove there were no dangerous side-effects); (see Figure 3). Or a second registration of the medicine may occur late in patent period, for example, because the medicine has been found to work for a new disease or a different group of people, such as children, creating a second data-exclusivity period. This may mean that the data exclusivity period continues even after the patent has finished.

This means that even though the patent has expired, generic versions of the medicine will not be available until the data exclusivity period ends, unless the DRA ignores its own registration requirements, (which can be problematic see (Box 2).

Infinite data exclusivity may occur because of Bilateral Investment Treaties (BITS) BITS or the investment chapter of some ftas, such as some Japanese BITS (see 'Impact of BITS'on page 21).

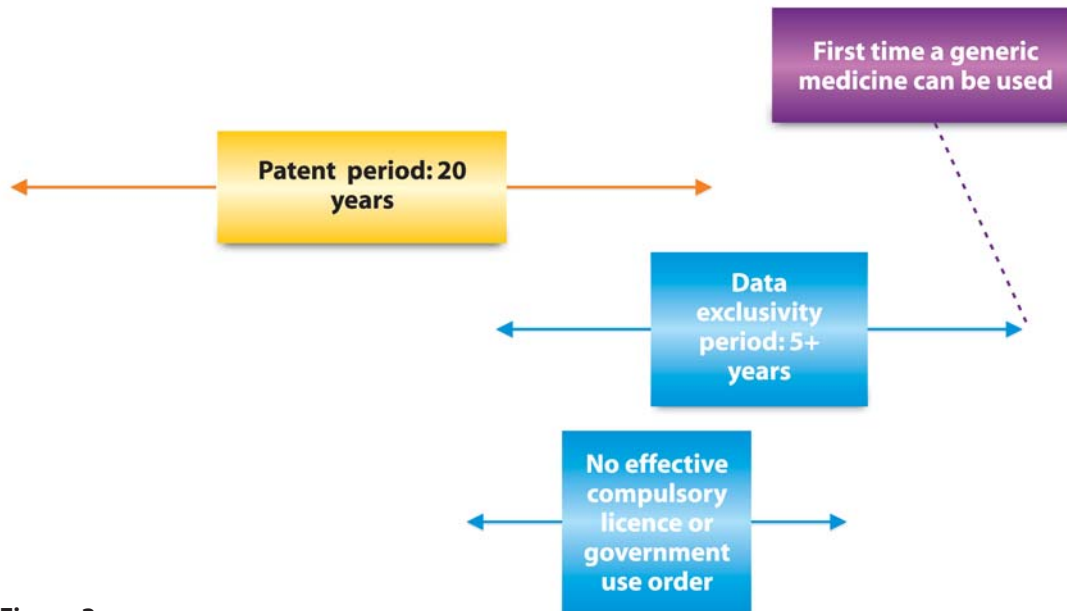


Figure 3

Linkage

The DRA checks whether a medicine works and is safe and of good quality (see Box 2). If the medicine meets these standards, it is registered or approved for marketing. The DRA is usually in the national department or ministry of health and its staff are usually pharmacists, chemists or other health professionals.

The patent office checks whether an invention is new, inventive enough and industrially applicable. If it passes all these tests, it grants a patent. Patent office staff are usually engineers, scientists or lawyers.

In most countries, the medicine registration and patent processes are completely separate.

TRIPS -plus treaties may require the DRA not to approve the generic version of a medicine until any patent has expired. This is known as 'linkage';

because it links medicine registration to whether or not there is a patent still operating. Without linkage, generic versions of medicines should be able to immediately be registered by the DRA and made available to consumers in two main situations:

- The generic company may have modified its medicine so that it does not infringe upon the patent but it is still the same chemical so can be registered by the DRA on the basis of patented medicine's clinical trials and other data; or
- There may have been a compulsory licence to import or make a generic version of the medicine.

With linkage, the generic version cannot be registered until the patent expires. This makes compulsory licensing ineffective (see Figure 4) unless the DRA ignores its own requirement to register medicines which is problematic; (see Box 2).

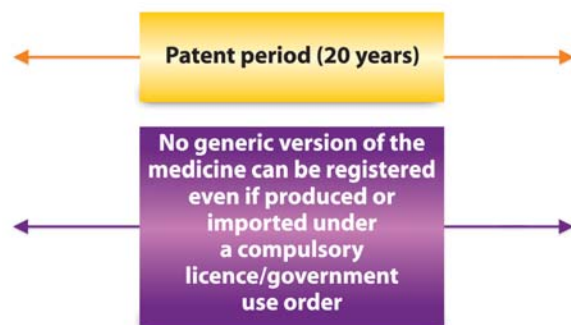


Figure 4

Linkage requires the DRA to become a patent police force.²⁸ For every registration application for a generic medicine, linkage requires the DRA to find out:

- whether there is patent in your country for that generic medicine;
- whether such a patent is still alive (meaning that patent maintenance fees have all been paid as required. These are often annual and often not paid on time, which can mean the patent lapses);
- whether that patent actually covers the generic medicine (only the courts in your country can really decide this and it often takes years, the testimony of many expert witnesses, lots of documentary proof and a lot of money; and
- whether the patent owner has agreed to give a licence to the generic company if all the above occur.

It is very difficult for the DRA to do all this, because it is not an expert on patents (even the European Union and US²⁹ DRAs admit this). As a result, a number of countries, including the Philippines, the European Union and Uganda have refused to do linkage.

Compulsory Licences

According to TRIPS, compulsory licences can be used in any situation. However, TRIPS -plus treaties such as US FTAs may limit compulsory licences to

three situations:

- government use (see explanation in 'compulsory licensing');
- national emergency or extreme urgency; and
- if the patent holder has been found to be anti-competitive

Anyway, even in these situations, linkage (see explanation in 'linkage') makes compulsory licences ineffective.

Compulsory licences may also be restricted because of BITs. See 'Impact of BITs', below.

Impact of BITs

Bilateral investment treaties, or BITs, are intended to protect the investments of each signatory country in the other; for example, a BIT between the United Kingdom and Bangladesh protects British investments in Bangladesh and Bangladeshi investments in the United Kingdom. There are usually many more developed-country investments in the developing country than vice versa.

BITs generally define 'investment' broadly, including things like patents and clinical-trial data. The treaty usually also has an 'expropriation' provision, so that if the countries who have signed the BIT do anything that reduces the value of the investment, they have to give the company from the other country compensation (usually at market value) and interest.

BITs only apply to medicines that come from companies that are from countries that have signed BITs with yours. It may mean that a compulsory licence reduces the value of the patent (which is considered to be an investment), so the BIT would require the government issuing the compulsory licence to pay compensation and interest. This could prevent your country from issuing a compulsory licence to obtain cheaper generic versions of medicines. It may also mean that there is data exclusivity forever, because the clinical trial data can also be considered as an investment. Thus, if your government ever registers the generic version on the basis of the originator company's clinical trial

²⁸ 'Access to Medicines at Risk Across the Globe' Briefing Note, MSF Campaign for Access to Essential Medicines, May 2004, www.accessmed-msf.org/documents/ftabriefingenglish.pdf.

²⁹ 'Trade Agreements and Access to Medications under the Bush Administration', prepared for Rep. Henry A. Waxman, US House of Representatives Committee on Government Reform - Minority Staff, Special Investigations Division, June 2005. See http://www.twinside.org.sg/title2/FTAs/Intellectual_Property/IP_and_Access_to_Medicines/TradeAgreementsandAccessToMedicationsUnderTheBushAdmini.pdf. It cites 59 Fed. Reg. § 50338, 50343 (Oct. 3, 1994) ('FDA does not have the expertise to review patent information. The agency believes that its resources would be better utilized in reviewing applications rather than reviewing patent claims.').

Box 5

Fast-Track Authority

Under the US Constitution, it is Congress (parliament) that has the power to negotiate foreign trade agreements. This can be complicated, however, since it means agreements must be negotiated with every Congressional representative. So sometimes Congress delegates the power to make foreign trade agreements to the Executive (US Trade Representative). Congress then just votes for or against the final free trade agreement text.

The most recent fast track authority expired in 2007 and has not been renewed. So any free trade agreements should currently be negotiated with more involvement by Congress.

Box 6

Summary List of Main TRIPS-plus Provisions

- Join extra intellectual property treaties that may mean more medicines are patented
- Requiring patents for 20 years on medicines for countries that are not WTO members or are LDC WTO members
- Removal of exceptions to patents allowed under TRIPS
- Prohibition of pre-grant opposition
- Patent term extensions
- Limitations on or prohibition of parallel importation
- Data exclusivity
- Linkage
- Limitations on compulsory licensing situations

data, it could be considered to be expropriation and so compensation and interest would have to be paid.³⁰ Failure to comply with the BIT usually means the government can be sued, but any fine may not be very enforceable (see 'How do your laws become TRIPS -plus' on page 16).

The investment chapters of some FTAs between developed and developing countries can be very similar to BITS, but are enforceable as FTAs (with tariffs on exports for failing to comply). Japanese FTAs, in particular, often do not have exceptions to expropriation for limitation on intellectual property rights the way US FTAs do. European Union FTAs, on the other hand, are currently unlikely to have these strong expropriation provisions.

Key points:

If your country agrees to a TRIPS -plus provision or agreement, this can undermine the safeguards in TRIPS.

TRIPS -plus provisions make medicines even more expensive

30 'IP Rights Under Investment Agreements: the TRIPS-plus Implications for Enforcement and Protection of Public Interest' Ermias Tekeste Biadgleng, Research Paper No. 8, South Centre, Geneva, August 2006, www.southcentre.org/publications/researchpapers/ResearchPapers8.pdf.



INDIA

Persons living With HIV and Access to Generic Medicines in India

Lawyers Collective HIV/AIDS Unit, India

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This chapter is the product of a collective effort of the Lawyers Collective HIV/AIDS Unit. Over the past decade of promoting a 'human-rights' based response to the HIV epidemic, access to treatment has emerged as one of the most critical areas of the Unit's work. Interviews for the chapter were conducted by Kajal Bhardwaj, Prathibha Siva, Ramya Seshadri and Sankar Rajakumar. Editorial comments and inputs were provided by Anand Grover, Julie George and Chan Park. The paper was written by Kajal Bhardwaj.

1. BACKGROUND

My idea of a better ordered world is one in which medical discoveries would be free of patents and there would be no profiteering from life or death.

*- Indira Gandhi, Prime Minister of India,
at the World Health Assembly, Geneva, 1981*

In 1994, the Indian government, after years of leading and shaping the resistance of developing countries to the inclusion of intellectual-property issues in the rules of the World Trade Organisation (WTO) capitulated to the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).¹ Over a

¹ Anitha Ramanna, "India's Patent Policy and Negotiations in TRIPS: Future Options for India and other Developing Countries", Paper presented at the National Conference on TRIPS: Next Agenda for Developing Countries, Hyderabad, India, October 11-12, 2002, available at www.iprsonline.org/ictsd/docs/ResourcesTRIPSanita_ramanna.doc

decade later, in March 2005, India fulfilled its commitment under TRIPS and modified its patent law in accordance with WTO rules.

These changes to Indian law have led to worldwide debate and concern regarding access to safe, effective and affordable generic medicines. At the centre of this debate are the hundreds of thousands of people living with HIV (PLHIV) all over the world, who rely on medicines from Indian generic manufacturers. This supply of generic medicines was possible under India's pre-2005 patent law that did not allow monopolies on medicines; all this has changed with India's law becoming TRIPS compliant and India is now granting monopolies on medicines.

However, the global crisis in access to HIV medicines that highlighted the effect of monopolies on the affordability and availability of medicines has had a profound impact on the manner in which intellectual property rules have been interpreted and applied in India. In particular the unrelenting efforts of Indian PLHIV networks along with other public interest groups have resulted in concrete legal and policy initiatives such as the inclusion of key public health safeguards in India's patent law and in holding the Indian government to its Constitutional and international human rights obligations on the right to health.

This chapter discusses the changes in approaches to intellectual property rules and patents spurred by the HIV epidemic and the role of PLHIV networks in India in ensuring access to generic medicines not only in India but around the world.

1.1 HIV in India

The first officially-recorded case of HIV in India occurred in 1986. Two decades later, there are an estimated 2.5 million Indians living with HIV. Of these, 39 percent are women and 3.8 percent are children.² While the route of transmission remains largely sexual, the government has recognised that injecting drug use is emerging as an important mode of transmission in some parts of the country.³

The Indian government's response to the epidemic began in 1987 with the establishment of the National AIDS Control Programme (NACP). In 1992,

the National AIDS Control Organisation (NACO) was set up as a department within the Ministry of Health and Family Welfare. HIV programming and policy is formulated and implemented in phases by NACO. Currently the third phase, NACP III, is being implemented.⁴

In 2002, India launched a National AIDS Prevention and Control Policy (NAPCP) that recognised and adopted the human-rights approach to HIV prevention, treatment and care. The NAPCP noted that 'although HIV/AIDS still defies a cure, infection can no longer be equated with imminent death. Advances in management of opportunistic infections and the development of effective anti-retroviral therapies mean that the illness associated with HIV infection can be treated. People living with HIV/AIDS can now live longer and better quality of lives.'⁵

1.1.1 The PLHIV movement in India

As in the rest of the world, the HIV epidemic in India has given rise to significant stigma and discrimination, which led, early on, to several PLHIV becoming activists. From Dominic D'Souza, who was incarcerated in the late eighties in Goa for being HIV-positive and went on to become one of the leading lights of the HIV movement to Ashok Pillai, who was one of the founding members of the Indian Network for People living with HIV/AIDS (INP+) and stunned India with an innovative advertising campaign that made his status public in an effort to help dispel myths about HIV. It is from these roots that many Indian PLHIV groups arose, among them INP+, the Manipur Network of Positive People (MNP+) in 1997, the Delhi Network of Positive People (DNP+) in 1998, and so on. Today, INP+ has a national presence in 22 states and 126 districts with more than 82,000 members.⁶ Several unaffiliated PLHIV groups have also sprung in India; among them is the Positive Women's Network (PWN+), which was set up in 1998 as a support group for women living with HIV. The plurality of the PLHIV movement in India is reflected by PLHIV groups such as the UDAAN Trust which was set up in 1992 with a specific focus on marginalised communities and is now an organisation for and by PLHIV.

1.1.2 India's HIV treatment programme

NAPCP marked the beginning of India's HIV treatment programme with the announcement of

2 See 'UNGASS Country Progress Report 2008 India', National AIDS Control Organisation, Ministry of Health and Family Welfare, Government of India, New Delhi, 2008 ("UNGASS Country Progress Report 2008 India")

3 Ibid

4 NACO, *National AIDS Control Programme, Phase-III (2006 - 2011): Strategy and Implementation Plan*, 2006 ("NACP III")

5 Ministry of Health and Family Welfare, Government of India, *National AIDS Prevention and Control Policy*, 2002 ("NAPCP"), Para 5.8.8

6 'Shobha Warrior, "A new offensive in India's war on AIDS," *Rediff Special*, 18 July 2007, <http://www.rediff.com/news/2007/jul/18spec.htm>

government support for the treatment of opportunistic infections (OIs) and for the prevention of parent-to-child transmission. The provision of ART was deferred due to 'prohibitive costs', with a commitment from the government to review this policy depending on the affordability of ARVs.⁷ On 1 April 2004, the government finally commenced the National ART Rollout Programme, with government centres providing free-of-charge first-line ARV treatment in the form of five medicines: stavudine/zidovudine, lamivudine and nevirapine/efavirenz. Scaling up was slow at first, with treatment available at only 25 centres.⁸

In the past few years, however, the programme has developed more rapidly. There are now 137 centres in 31 states providing ART to 118,052 adults and 8,347 children.⁹ NACO estimates that 25 percent of PLHIV in India require ART; the treatment programme currently covers 20 percent of adults and 35 percent of children in need of treatment.¹⁰ Of adults under treatment, approximately 30 percent are women.¹¹

According to NACP III, the government aims to open 250 ART centres by 2011, putting 300,000 PLHIV under treatment.¹² The scale-up has considerably reduced earlier problems such as supply interruption and long queues; however, the government's goals are insufficient to provide universal access.¹³ PLHIV continue to face problems of access to treatment for OIs, while the lack of effective treatment for co-infections is a matter of growing concern.¹⁴

The government also took a long time to announce second-line treatment provision, despite increasing reports of first-line resistance. On World AIDS Day 2007, following consistent pressure from PLHIV groups, NACO announced a limited second-line treatment programme. At present, second-line treatment is being provided only in Chennai (Tamil Nadu) and Mumbai (Maharashtra).¹⁵ The government had originally announced that second-line treatment would be rolled out in centres across

the country from 1 April 2008. According to a recent news report, NACO has now announced that it will rollout second line treatment in Delhi, Kolkata (West Bengal), Ahmedabad (Gujarat) and Hyderabad (Andhra Pradesh) in September 2008 and in the states of Manipur, Karnataka, Chandigarh and Uttar Pradesh in December 2008.¹⁶ However, the guidelines for putting PLHIV on second line treatment remain unclear; of particular concern are reports that only PLHIV living below the poverty line may be given second line treatment.¹⁷

1.2 India, TRIPS and patent law

India's engagement with the issues of patents and access to medicines goes back well before TRIPS and other global trade agreements. For decades after Independence, India retained a patent system inherited from the British - one that protected only the interests of patent holders. As a result, medicines had to be imported and were available only at very high, often exorbitant prices. The consequent lack of access to medicines for the majority of Indians led to the enactment of the Indian Patents Act of 1970, which provided only 'process' patents for medicines. This means that the actual medicine (or the 'product') was not under monopoly, only the process by which it was made. The Act allowed generic manufacturers to produce these medicines, so long as they made use of a process of manufacture that differed from the one patented. Even process patents were valid for only seven years. The result of this visionary piece of legislation is India's strong and vibrant generic pharmaceutical industry.

1.2.1 India's patent law becomes TRIPS-compliant

Between late 2004 and early 2005, the government took several actions to make Indian law TRIPS-compliant. This followed two previous amendments to India's patent law in 1999 and 2002. In late 2004, the government announced an ordinance to change the patent law (an ordinance is a short-term law that the government can pass when Parliament

7 NACP, Para 5.8.8

8 See National AIDS Control Organisation, *National Guidelines for the Implementation of the ART Programme*, Draft: Version August 2004, 9 August 2004

9 See UNGASS Country Progress Report 2008 India

10 Ibid.

11 Ibid

12 NACO, "National AIDS Control Programme, Phase-III (2006 - 2011), "Strategy and Implementation Plan," (2006) ("NACP III")

13 According to India's 2008 Country Progress Report, approximately 25 percent of PLHIV require ART which means 603,125 adults and 23,465 children. The NACP III goal of putting 300,000 on treatment then would not account for even half of those who need treatment. See UNGASS Country Progress Report 2008 India.

14 Findings of an unpublished survey of India's ART Rollout Programme conducted by the Lawyers Collective HIV/AIDS Unit in 2006 and 2007. On file with author.

15 'Cost of HIV treatment may dip', Times of India, 23 December 2007

16 Kounteya Sinha, "Second-line drug free to combat AIDS," Times of India, 27 June 2008

17 See, 'India launches world's largest social mobilization campaign against HIV', NACO Press Release, 1 December 2007 available at http://www.nacoonline.org/NACO_Action/Media__Press_Release/

The importance of the public health approach to intellectual property

'The pharmaceutical sector is a major user of the patent system. While only a small - and declining - number of new chemical entities are approved annually, thousands of patents are applied for to protect variants of existing products, processes of manufacture or, where admitted, second indications of known pharmaceutical products.

Since patents confer exclusive rights regarding the production, sale and use of the patented subject matter, they can be used to restrain competition and set prices higher than those that would have existed if competitive products were available. This is the very purpose of the patent system, which is generally justified as necessary to encourage investments to develop new products and processes.

Given the substantial effects that patents can have on competition and, hence, prices of medicines, the criteria that are applied to examine and grant pharmaceutical patents are extremely relevant for public health policies, and not only a matter of concern for patent and industrial policy. **Policy makers in the health area, as well as patent examiners, should be aware that decisions relating to the grant of a patent (which is generally presumed valid until proven to the contrary) can directly affect the health and lives of the people of the country where the patent is granted and enforced.'** (emphasis added)

- Excerpt from ICTSD, WHO, UNCTAD (2006) Guidelines for the examination of pharmaceutical patents: developing a public health perspective - A Working Paper, 2007

is not in session, but for which it must later obtain parliamentary approval). The ordinance was issued to comply with India's 1 January 2005 deadline for TRIPS compliance.¹⁸

Public-interest groups immediately pointed out that the ordinance did not provide any safeguards for public health. India's law was now switching over to a product-patent regime. This meant that the medicine itself would be patented and generic manufacturers would no longer be able to devise different processes to make the same medicine. The company holding the product patent then has a monopoly on the manufacture and sale of the medicine. They pointed out that this would directly affect the availability and affordability of medicines and demanded that the patent law as finally approved by Parliament should provide for access to affordable medicines.

As a result of the campaigns by PLHIV and public-interest groups discussed below, Parliament, when

amending India's patent law, included key public-health safeguards through the use of flexibilities built into the TRIPS agreement. It thus attempted to balance the country's obligations under TRIPS with guarantees of life and health written into the Indian Constitution.

1.2.2 Using TRIPS flexibilities: making full use of the transition period

India, having signed the TRIPS agreement in 1994, was obliged to consider patent applications on all post-1995 medicines and grant product patents on deserving ones. However, this obligation did not come into effect until 2005. The country made full use of this transitional period, only making the last necessary changes to its laws in 2005.

As required under TRIPS, India instituted a 'mailbox' facility during the transition period to allow patent holders to safeguard their claims on medicines (and other products).¹⁹ Companies could file patent applications during the transition period that would be processed when the mailbox was 'opened' in 2005. Tens of thousands of applications for patents on medicines were submitted in this way. They are now being examined by the Indian Patent Office.

1.2.3 Using TRIPS flexibilities: key public health safeguards in India's patent law

In response to concerns raised by PLHIV and public-interest groups, the Indian Parliament made considerable use of TRIPS flexibilities to include public health safeguards in India's patent law. Some of these safeguards are discussed below.

*What cannot be patented*²⁰

One of the key provisions of the Patents Act 1970 specifies what products and processes cannot be patented. These include discoveries, plants and animals, business methods and, traditional knowledge among others. Of particular note is Section 3(d), which guards against the common practice of 'evergreening' by the pharmaceutical industry which extends patent terms by making modifications to original molecules (also known as 'new chemical entities') or finding new uses or new forms of existing medicines. For example, a company may take a medicine sold in tablet form, convert it into a syrup and apply for a patent on the latter. Under Indian patent law the syrup form would not be eligible for patent, as it is merely another form of an already-known substance. This

18 The Patents (Amendment) Ordinance, 2004 (Ord No. 7 of 2004).

19 The Patents (Amendment) Act, 1999 (No.17 of 1999)

20 S.3, Patents Act, 1970

provision contains important grounds on which PLHIV networks and other patient groups can oppose patent applications.

*Continued supply of generic medicines made before 2005*²¹

The Indian Parliament recognised the importance of ensuring the continued availability and affordability of medicines that were already being produced by Indian generic manufacturers before 2005 (i.e. before India's patent law became TRIPS compliant.) The changes to the patent law accordingly provide that if a medicine is patented in India but was being manufactured by an Indian company before 2005, that company can continue to manufacture the medicine. It will, however, have to negotiate what the Act terms a 'reasonable royalty' payment to the patent holder. Supply of the medicine could continue, but the added royalty cost is likely to lead to a price increase and could, ultimately, have an impact on whether the generic company continues its manufacture.

*Pre and post-grant oppositions to patents*²²

Pre-grant oppositions (oppositions filed before a patent is granted) have always been part of India's patent law. In the course of amending the law in 2005, however, the government sought to remove this very important safeguard against the granting of patents for frivolous products and processes. Public action led to the safeguard being retained: under present law, a pre-grant opposition may be filed by 'any person'.

The process is aimed at assisting the Patent Office with all available information on the product or process on which a monopoly is sought. Ultimately, it is the responsibility of the Office to ensure that patents are granted only to genuine applications. However, with tens of thousands of applications to examine, the role of oppositions is critical in bringing frivolous or tendentious applications to light.

A post-grant opposition (one filed after a patent is granted) by any 'interested person' is possible under Indian law for up to a year after publication of the granted patent. Since the Indian Patent Office has four offices in different parts of the country processing tens of thousands of applications on medicines, some may quite easily be patented before health groups can oppose them. This makes the post-grant opposition process vitally important. It is,

of course, harder and costlier than the pre-grant process (it costs money to file a post-grant opposition, while filing a pre-grant opposition is free. It also involves a difficult and time-consuming trial-like procedure and is generally much more formal. Nevertheless, PLHIV groups are likely to use this process more and more often in the coming years.

Interestingly, developed countries that oppose public-health safeguards in patent law will try to ensure that only one chance for parties to file a patent-grant opposition is allowed, claiming that the patent procedure is made too cumbersome when multiple oppositions are permitted. From the public health perspective, however, it is critical that both pre- and post-grant opposition proceedings are provided for in law. The former is particularly important because of the difficulty of opposing or revoking a patent once it is granted. Even if a patent is challenged after it is granted, it remains in force during the period of the challenge, impeding access to the medicine for those who need it.

*Compulsory Licensing*²³

A compulsory licence is one that forces a patent holder to allow another company to manufacture or import a medicine. There are three ways to obtain a compulsory licence under Indian law.

1. A manufacturer interested in making a patented medicine must wait for three years after a patent has been granted and then apply for a compulsory licence on various grounds, including that the patented medicine is not

Preventing 'evergreening': Section 3(d) of the Indian Patents Act, 1970

(d) 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, complexes, 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.

21 S.11A(7), Patents Act, 1970

22 S.25, Patents Act, 1970

23 84, 92, 92A, and 100, Patents Act, 1970

The unavailability of treatment also resulted in a multitude of quack 'cures' for AIDS across India, and the networks were soon swamped with cases of PLHIV who had wasted their life savings on them to no effect. In 2003, MNP+ organised a 'march for life,' inaugurated by the Governor of Manipur, to demand that the Indian government start providing treatment for PLHIV.

At the beginning people died like anything...like flies. One after the other. All we saw was people losing their lives to the disease. I remember when I first got access to some treatment - it was a project that was giving only two medicines - it was the wrong approach and many people who started that treatment with me didn't survive. I got lucky. We knew then that the only proper way of getting treatment to people was from the government.

- Elango Ramachander, INP+

Finally, on 1 December 2003, the Indian government announced its plan to provide free anti-retroviral treatment.²⁷ Since then the role of PLHIV networks in treatment access in India has taken many shapes and forms: they have become central to the national rollout programme.

1.3.3 PLHIV take on patents

In 2005, with India's patent law becoming TRIPS-compliant, a new focus in the treatment-access work of PLHIV groups emerged. India was now granting twenty-year patents or monopolies on medicines. PLHIV and other groups in India had come to know the impact of such monopolies on the availability and affordability of medicines from the experiences of patients in other countries as well as those in India, and they feared the consequences.

A clear example was, in fact, already before them. When India introduced the 'mailbox' facility (see 1.2.2 above), it was also required to provide exclusive marketing rights to any company that had filed a patent application in India under certain specified circumstances. The Swiss multinational pharmaceutical company Novartis AG (Novartis) tried to use this provision to halt generic production of imatinib mesylate, a crucial blood-cancer drug. Novartis's price for this medicine was Rs. 120,000 (approximately US\$ 2700) per patient

India: the global supplier of generic ARVs

- Globally since July 2005, 70% of treatments purchased by UNICEF, IDA, the Global Fund and the Clinton Foundation for patients in 87 developing countries have been obtained from Indian suppliers. 80% of ARVs MSF uses in treatment projects in over 30 countries are purchased in India.

- Six of the seven generic producers with whom the Clinton Foundation has negotiated lower prices for first- and second-line ARVs are Indian.

- In 2007, 73% of ARVs delivered by PEPFAR and 93% delivered through PEPFAR's Supply Chain Management System (SCMS) project were generic formulations. PEPFAR partners saved an estimated \$64 million - a 46% reduction in the cost of drugs - by buying generic versions instead of innovator drugs.

- From 'Examples of the importance of India as the "pharmacy for the developing world"', MSF Campaign for Access to Essential Medicines, 'Antiretroviral (ARV) Price List,' Clinton Foundation, ; and 'The Power of Partnerships: Fourth Annual Report to Congress on PEPFAR (2008)', The United States President's Emergency Plans for AIDS Relief

per month, while Indian generic manufacturers were already providing it at prices ranging from Rs. 9,000-12,000 (approximately US\$ 208-231), or ten percent of Novartis's price.²⁸

Another matter of concern for the PLHIV movement was the fact that the Indian government repeatedly cites high medicine costs as a reason for delaying the provision of comprehensive access to treatment for PLHIV (as, for example, in the case of second-line treatment). Patents on newer medicines and consequent high prices would, they knew, have a definite negative impact on the commitment of the government to provide universal access to treatment.

Indian groups also noted the fate of their colleagues abroad. PLHIV in China were unable to take fixed-dose combinations because of patents on individual medicines. In South Africa, PLHIV groups were forced to approach the Competition Commission because of the high cost of ARVs.²⁹

With India's generic manufacturers now the main suppliers of safe, effective and affordable HIV medicines to the developing world, PLHIV also realised that the patent regime in India bore serious

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

28 Affordable Medicines and Treatment Campaign, "Cancer Patients Aid Association Challenges EMR on Gleevec," 7 August 2004.

29 See Medecins Sans Frontieres, "Field News: China," 2007 and Treatment Action Campaign, "TAC complains to the Competition Commission about the anti-competitive conduct of the world's largest pharmaceutical company," 7 November 2007.

implications for access to treatment by PLHIV in many other countries. Facing such a clear and direct threat to treatment access, Indian PLHIV began engaging with the intellectual-property system to ensure continued access to safe, effective and affordable medicines for patients, not only in India, but all over the world.

2 PLHIV NETWORKS AND ACCESS TO GENERIC MEDICINES IN INDIA

2.1 Ensuring the inclusion of public health safeguards: 2005 patent law amendments

When I first heard about patents I knew vaguely it had something to do with my medicines. But as I got deeper and deeper into it I realised that this was something that affected everyone - not just PLHIV but other patients, farmers, workers, consumers...

- Elango Ramachander, INP+



A protestor holds up her poster against patents at the Delhi rally on the Global Day of Action on the Patent Amendments, 26 February 2005, Delhi

When the Indian government began taking steps to amend India's patent law in order to make it TRIPS-compliant, a flurry of activity ensued among public interest groups. Groups in India have long been active on issues related to intellectual property. For instance, the National Working Group on Patent Laws (NWGPL) has been active on these issues since the late 80s and convened four Peoples Commissions on Patents. The Peoples Health Movement (PHM) and the Affordable Medicines and Treatment Campaign (AMTC) has also been working on sensitising civil society on the impact of TRIPS since well before 2005. For PLHIV, these groups became the source of critical technical information on patents as well as important partners in the campaign against the amendments. All these groups came together to protest the amendments and began writing letters to Members of Parliament (MPs) and the various ministries involved on the critical need to include public-health safeguards in the proposed amendments.

In December 2004, INP+ joined over sixty international organisations in writing to the Prime Minister protesting against the amendments.³⁰

Worldwide concern over the proposed changes to India's patent law led to the creation of an informal network of groups and individuals working to ensure access to treatment, food, information, called the Global Campaign against the Indian Patent Amendment (GCAIPA). The network included the NWGPL, AMTC, PHM and the Association for India's Development.³¹

When the patent amendments came up we knew we had to take action. We started speaking to lawyers to understand what was going on. We organised a massive rally, wrote to the Prime Minister, to members of parliament...even to the President, to make sure that our medicine supply was not affected.

- Loon Gangte, DNP+

26 February 2005 was declared the 'Global Day of Action' on the amendments. The date was chosen to coincide with the second day of the Parliamentary session that would consider the amendments. Protests were held across the world. In India, PLHIV groups, health groups, trade unions, farmers' groups, environmental groups and many others held public rallies in Delhi, Mumbai,

30 Healthgap, "International sign-on letter of concern to Prime Minister Manmohan Singh of India regarding the government's proposed amendments to the Patents Act and undermining medicines access for people in need-in India and around the world," 16 December 2004

31 "Global Coalition against the Indian Patent Amendment, "26 February is the Global Day of Action against Indian Patent Ordinance," Press Release, 8 February 2005

Bangalore, Kolkata, Chennai, Hyderabad, Dharwad, Panjim, Pune and Thirupati³² to protest the proposed amendments and demand that the amendments to the patent law include:³³

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 a letter dated 20 March 2005, DNP+ and MNP+, along with activists and groups in India, addressed the Prime Minister, the President, the Chairperson of the alliance in power, the Minister of Health and Family Welfare, the Minister of Chemicals and Fertilizers, the Minister of Commerce and Industry, the Minister of Science and Technology and the Chairperson of the Parliamentary Forum on HIV/AIDS. They expressed concern at the failure of the government to consider the serious implications of the amendments on access to treatment and asked for various public health safeguards.

A few words on India's current political situation are in order here. At present, the government in power at the centre in India is a coalition of parties known as the United Progressive Alliance (UPA). Coalition politics, as always, implies a number of different players and interest groups with varied and often competing agendas. Recognising this, health groups and PLHIV approached all members of the UPA. The groups had strong potential allies among the Left parties, which agreed that critical amendments needed to be made to the Bill proposed by the Government.³⁴

The debate on patents was one that had to take place not only in Parliament but also in the public domain. But at first, PLHIV networks and health groups struggled to gain media attention. This was partly due to a mistaken early focus on the business press: like everyone else including the media

Global day of action on the amendments to India's patent law: international events

Geneva: NGO Forum for Health sends letter to the Indian Government through the Indian Ambassador to the UN, opposing the amendments to the patent law.

Germany: BUKO Pharma Campaign sends protest letters to various ministers and to the Indian Embassy in Germany. German Network against AIDS (which all major NGOs in Germany are part of) sends fax to the Indian Embassy in Germany.

Morocco: The Coalition for the Right to Care and Access to Medication in Marrakech issues a press release condemning the amendments; a PLHIV writes an open letter to the Indian Ambassador to Morocco.

Burkina Faso: PLHIV dependent on Indian generic HIV medicines rally at Ouagadougou, Burkina Faso, chanting slogans such as 'Génériques toujours!' ('generics forever!') and 'Inde: sauveur hier, criminel aujourd'hui' ('India: saviour yesterday, criminal today').

United States of America: The Association for India's Development, INSAAF, Global AIDS Alliance and such other organizations organized a rally in front of the Indian Embassy in Washington. Some individual chapters of these organizations also send press notes to the Indian media.

France: Act-up Paris, ATTAC and Solidarité Sida organized a protest Rally in front of the Indian Embassy in Paris.

South Africa: Treatment Action Campaign in South Africa picketed against the Patents Amendment and submitted a memorandum addressed to the President and Prime Minister of India.

South Korea: People's Health coalition for equitable society and Human Right Advocacy Group NANURI+ in response to the Global Call submitted a memorandum to the Indian Ambassador.

- From 'Global Events around 26 Feb 2005, the Global Day of Action against the Indian Patents Amendment', Global Campaign against Indian Patents Amendment (GCAIPA), 16 March 2005.

themselves, networks and groups assumed that discussion of patent-related issues would be most effective if it took place in the business sections of newspapers, the so-called 'pink pages'. When this mistake was realised, a new strategy emerged, focusing attention on 'international media' which was reporting more readily on the public health impact of the amendments, 'opinion/editorial desks' of newspapers and on 'health correspondents' and

32 Global Campaign Against Indian Patents Amendment, 'Global Events around Feb 26th 2005, The Global Day of Action against the Indian Patents Amendment', 16 March 2005

33 Affordable Medicines and Treatment Campaign, "Concerns Regarding Patents Bill 2005 Introduced in the Lok Sabha," 18 March 2005.

34 Letter from national and international groups to the Left parties, 20 March 2005. On file with author.



Health groups, trade unions and PLHIV in Bangalore demand a public debate on the amendments to the patent law, 26 February 2005

columnists. Public-interest groups also advertised in a leading daily newspaper to inform the public about the patent-law amendments and their impact on access to medicines.

International support proved critical when India's patent law was being amended. International treatment activists who were present in India at the time converged on Delhi to meet with MPs and highlight the importance of building public-health safeguards into law. International organisations such as MSF, Oxfam, Global AIDS Alliance, Health GAP, ACT UP Paris and the Canadian HIV/AIDS Legal Network were active in this campaign, issuing press releases, action alerts or writing to the government to protest against the amendments.³⁵ The government also received letters of concern from UNAIDS, the UN Special Envoys for HIV/AIDS in Africa and the Asia/Pacific region and WHO.³⁶ The national and international public action resulted in a robust debate in Parliament, with several MPs expressing concern over the impact of the amendments on health. The outcome of this debate was that the amendments to the 1970 Patents Act, included the key public-health safeguards discussed above.

However, not all the public health safeguards that activists were demanding were included in the amendments. One of the key provisions that public

interest groups were demanding was a prohibition on 'evergreening'. The demand was based on increasing evidence from around the world that the majority of new medicines were minor modifications of existing medicines. For instance the 1999 Human Development Report noted that between 1981 and 1991, less than 5% of drugs introduced by the top 25 companies in the US were therapeutic advances.³⁷ A 2002 study by the National Institute for Health Care Management Foundation (NIHCM) of 1035 new medicines approved by the USFDA between 1989 and 2000 showed that 65% of the medicines that were approved contained active ingredients already on the market and of these the overwhelming majority (558 medicines) differed from earlier medicines only in dosage form, route of administration, or were combined with another active ingredient while the remaining other medicines were identical to products already available on the market.³⁸ The NICHM report noted that modifying older products enables brand manufacturers to extend their intellectual property protection by patenting new features of the modified medicines.



A hindi leaflet brought out by the Affordable Medicines and Treatment campaign in 2002 explaining why medicines are cheap in India and why that would change in 2005

35 See for instance, Affordable Medicines and Treatment Campaign (AMTC), ACT UP Paris, Alternative Law Forum and Medecins Sans Frontiers (MSF), "Patent Bill is introduced with NO change," Action Alert, 19 March 2005; Global AIDS Alliance, Association for India's Development and Health GAP, "India Could Cut-off Africa's Access to Affordable AIDS Drugs; Indian Parliament May Begin Considering the Issue March 9," Action Alert, 6 March 2005; Letter from Jeremy Hobbs, Executive Director of Oxfam International to the Indian Prime Minister, 15 March 2005 (on file with author) and Letter from Canadian HIV/AIDS Legal Network to the Indian President, 26 March 2005 (on file with author).

36 See Letter 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 Envoys for HIV/AIDS to the Prime Minister and President of India, 11 March 2005 (on file with author); Letter from Achmat Dangor, UNAIDS to Minister of Commerce and Industry, 23 February 2005 (on file with author); and Letter from Jim Yong Kim, HIV/AIDS Director of the World Health Organization to Minister of Health and Family Welfare, 17 December 2004 (on file with author).

37 UNDP, *Human Development Report 1999*, New York, 1999.

38 National Institute for Health Care Management, *Changing Patterns of Pharmaceutical Innovation*, May 2002.

The role and experiences of PLHIV networks in securing access to generic ARV medicines



PLHIV Protest in Delhi on 26 February 2005, The Global Day of Action, against the amendments to India's patent law

Section 3(d) was thus meant to be a complete ban on evergreening. However the law, as it now stands could allow patents on evergreening if the company applying for the patent can show that the medicine has increased efficacy. This provision means that each patent application for an evergreened medicine has to be examined by the patent office to see if there is improved efficacy. In resource poor settings, this conditional prohibition on evergreening may not be effectively implemented. Indeed even in India, where resources for the patent system are comparatively better than in other developing countries, there are now increasing reports of patents being granted for medicines that are minor improvements of existing medicines. (See Section 2.3.5)

2.2 Using the public health safeguards: opposing patent applications

Taking on pre- and post-grant oppositions has been the biggest and most challenging work for us - and most effective! Since the oppositions have been filed we have started seeing some positive results... we are finally seeing the fruits of what we have sown... not just in India but across the world. The work we are doing here is impacting access to medicines across the world. The research done here is being used in other countries. We are questioning the whole paradigm... we are asking how this kind of profiteering from life can be justifiable - and we want an answer.

- Loon Gangte, DNP+



PLHIV join trade unions, farmers groups and other health groups to protest the patent amendments, 26 February 2005

Based on the public-health safeguards included in India's patent law, PLHIV groups in India have, to date, filed 14 patent oppositions (see table 1 on page 34). Of these, twelve are pre-grant oppositions while two are post-grant oppositions.

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 (see Chapter 4 Joint section on Thai-India Joint Actions: Opposing the Combivir/Combivir patent applications.)

Separately, the Cancer Patients' Aid Association (CPAA) filed a pre-grant opposition against Novartis

AG's (Novartis) patent application for imatinib mesylate, a key anti-cancer medicine. This action eventually resulted in a legal challenge to India's patent law from Novartis.

Sankalp Rehabilitation Trust, a group working with drug users, filed a post-grant opposition against a patent granted to F Hoffmann-La Roche (Roche) on pegylated interferon (brand name- Pegasys).

So far, PLHIV groups in India have been predominantly engaged in challenging patent applications (as of June 2008) by multinational pharmaceutical companies. This is in contrast to Thailand, where, along with challenges to patent

applications, a significant component of treatment-access work has been related to compulsory licensing. Compulsory licences are relevant where patents have been granted on medicines in India, however, applications for patents are still being examined. Though some important medicines have in fact been granted patents, Indian patent law provides several levels of challenge and PLHIV groups are presently focused on ensuring that only valid patents are granted. As newer medicines receive valid patents or public interest groups are unable to successfully challenge invalid patents, however, compulsory licensing will become an important aspect of treatment-access work in India as well.

Table 1: Oppositions to patent applications filed by PLHIV networks in India

Medicine	Who has applied for the patent and where	Who has opposed the patent application	When was the opposition filed	What is the status of the patent application
Zidovudine/ lamivudine <i>First-line ARV</i>	GSK Kolkata	MNP+, INP+	March 2006	Patent Application Withdrawn
Nevaripine Hemihydrate (syrup) <i>First-line ARV</i>	Boehringer Ingelheim Delhi	PWN, INP+	May 2006	Patent Application Rejected
Tenofovir Fumarate or TDF (two applications) <i>Second-line/alternative First-line ARV</i>	Gilead Sciences Delhi	DNP+, INP+	May 2006	Pending
Amprenavir <i>Second-line ARV</i>	GSK Delhi	Uttar Pradesh Network of Positive People, INP+	July 2006	Pending
Atazanavir	Novartis Chennai	Karnataka Network for People Living w/ HIV and AIDS, INP+	July 2006	Pending
Valgancyclovir <i>OI medicine</i>	F Hoffmann-La Roche Chennai	Tamil Nadu Network of Positive People, INP+	July 2006	Patent Granted
Abacavir <i>Second-line ARV</i>	GSK Kolkata	INP+	July 2006	Patent Application Withdrawn
Lopinavir <i>Second-line ARV</i>	Abbott Laboratories Mumbai	DNP+, Network of Maharashtra by People living with HIV and AIDS, INP+	August 2006	Pending
Lopinavir/Ritonavir (Soft Gel) <i>Second-line ARV</i>	Abbott Laboratories Mumbai	DNP+, INP+	August 2006	Patent Application Deemed Abandoned
Tenofovir or TD <i>Second-line/alternative First-line ARV</i>	Gilead Sciences Delhi	DNP+, INP+	September 2006	Pending
Ritonavir <i>Second-line ARV</i>	Abbott Laboratories Mumbai	DNP+, INP+	September 2006	Pending
Efavirenz (post-grant opposition) <i>First-line ARV</i>	Bristol Myers Squibb Mumbai	DNP+	February 2007	Pending
Valgancyclovir (post-grant opposition) <i>OI medicine</i>	F Hoffmann-La Roche Chennai	DNP+	June 2008	Pending

2.2.1 Challenging multiple patent applications on tenofovir

PLHIV groups are challenging three patent applications filed by Gilead Sciences (Gilead) in relation to the ARV tenofovir. Tenofovir is an important alternative first-line and second-line ARV. It has emerged as an important option for PLHIV who need to be switched to newer medicines as a result of side effects or resistance to first line medication and features in the updated WHO ART guidelines for HIV/AIDS treatment in developing countries.³⁹ With fewer known side effects, Tenofovir is widely prescribed in the US and Europe. Due to high costs, it has only recently been introduced in treatment programmes of developing countries. NACO took some time to announce its inclusion in the Indian treatment programme because of high costs.⁴⁰ Again, it is competition from Indian generic manufacturers that has resulted in lower prices for this important ARV. In April 2008, the Clinton Foundation HIV/AIDS Initiative and UNAIDS announced significantly lower prices for Tenofovir after agreements with Indian generic manufacturers on a price of US\$159 for fixed dose tenofovir and lamivudine per patient per year.⁴¹

A rally and a press conference

Two of the pre-grant oppositions related to Tenofovir were filed on 9 May 2006 by INP+ and DNP+. To coincide with the filings, DNP+ organized a protest march on 10 May 2006, which was joined by many Delhi based NGOs. With the words 'HIV POSITIVE' emblazoned across their t-shirts, over two hundred people marched through Delhi beating drums, carrying placards declaring 'We Oppose Patents to Save Lives' and 'Patents against Patients' and shouting slogans against the patenting of essential medicines.

The incredible turnout and the energy of the protest soon had members of the PLHIV networks scaling police barricades and shouting their opposition to patents even as they were detained by the police and led into Delhi's Parliament Street police station. Inside the police station, network members asked the police how they could detain them when they were asking for the protection of their fundamental rights. Emotions ran high as several network members addressed the group about what could happen to their lives if medicines became monopolized. A memorandum of demands was then sent to the Prime Minister.



DNP+ holds a rally to coincide with their opposition to Gilead's tenofovir patent, 10 May 2006, Delhi



Beating drums and blowing whistles, the protesters march in Delhi demanding that the government refuse patents in AIDS medicines, 10 May 2006



Activists protest as they are detained by the police during the rally, 10 May 2006

³⁹ World Health Organisation, *Antiretroviral therapy for HIV infection in adults and adolescents in resource limited settings: Towards universal access, Recommendations for a public health approach*, 2006 revisions, available at <http://www.who.int/hiv/pub/guidelines/adult/en/index.html>.

⁴⁰ AIDS shock to reality, Deccan Herald, 2 December 2007

⁴¹ Michael Carter, "Deal lowers price of second-line therapy and makes new paediatric formulations available to poorer countries," *aidsmap news*, 29 April 2008

Media coverage of the tenofovir patent oppositions

'A legal challenge has been launched in India against a patent application for a vital AIDS medicine... The wrangle is one of the first big tests of last year's patent law curbing the right of firms to make copycat versions of medicines that have slashed the prices of anti-retroviral AIDS treatment and other medicines in the Third World.'

- 'Indian Group Challenges AIDS drug patent,' *The Dawn*, 12 May 2006 (Pakistan)

'Protesters chanted "We want tenofovir" and wore T-shirts blazoned with the words "HIV positive". NGOs say India is largely in denial about an epidemic affecting more than 5m people. Lawyers advising the NGOs say the patent office should reject Gilead's application on the grounds that the Californian group is trying to patent a new form of a pre-existing medicine without evidence of enhanced therapeutic efficacy. Indian medicine companies, such as Cipla, have developed a low-cost generic version of tenofovir, priced in India at a seventh of international levels and would be likely to have to cease production or pay steep royalties if a patent was granted.'

- Andrew Jack and Jo Johnson, 'HIV/AIDS victims in India protest over drug patent,' *Financial Times*, 11 May 2006 (UK)

'The Indian patent office is processing about 9,000 patent applications, most of them filed by international pharmaceutical companies. Patient advocates warn that the supply of a wide range of vital medicines to people in the developing world may be jeopardized.'

- Amelia Gentleman and Hari Singh, 'AIDS drug provokes patent battle in India,' *International Herald Tribune*, 11 May 2006 (International)

'In our HIV treatment programmes, high prices and a lack of availability is severely restricting access to treatment. We clearly need more than one source for essential medicines,' said Head of Mission of Médecins sans frontières in India, Hans van de Weerd.'

- 'AIDS-affected people protest pharma company's move,' *The Hindu*, 11 May 2006 (India)

After the rally, a press conference was addressed by representatives of DNP+, Cancer Patients Aid Association, MSF, Lawyers Collective HIV/AIDS Unit and the Alternative Law Forum about the day's events, the reasons for the filing of the oppositions and the implications for public health. The successful rally saw extensive national and international coverage. Apart from coverage in newspapers and on the internet, a leading Indian news channel also covered the rally and the story was aired repeatedly on national television.

Gilead announces voluntary licences but PLHIV continue their opposition

In August 2006, Gilead Sciences announced voluntary licences to Indian companies for the manufacture of Tenofovir.⁴² The announcement 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.

In fact, the voluntary licences undermined the patent opposition process. Following the Gilead announcement, several generic companies that had been opposing the Tenofovir patent applications withdrew from the process, leaving only the PLHIV networks and one generic company opposing the applications.

By Gilead's own admission, its voluntary licences placed restrictions on the countries to which Indian companies could supply their versions of the medicines. It was learnt that Brazil and China were among the countries to which export was prohibited. Realising this, Indian groups, along with some prominent voices from the North, voiced their criticisms of the voluntary licences.⁴³ Knowledge Ecology International, an NGO, requested the US government body that investigates anti-competitive practices to examine Gilead's voluntary licences.⁴⁴

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

42 Gilead Sciences, "Gilead Announces Licensing Agreements with Three India-Based Companies for Manufacturing and Distribution of Generic Versions of Viread in the Developing World," Press Release, 14 August 2006, available at http://www.gilead.com/pr_895671

43 See for instance, Nathan Ford et al, "Tough choices: Tenofovir, tenders and treatment," *South African Journal of HIV Medicine*, Vol 9, No 1 (2008).

44 KEI request for investigation into anticompetitive aspects of Gilead Voluntary Licenses for patents on Tenofovir and Emtricitabine, 12 February 2007 available at <http://www.keionline.org/misc-docs/ftcgilead12feb07.pdf>

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?

- Loon Gangte, DNP+

PLHIV groups take the patent office to court for denying information

As PLHIV groups continued their opposition to Gilead's patent applications, the Delhi Patent Office contacted them with information about a hearing scheduled for the oppositions. When asked whether Gilead had filed a reply to the oppositions, the Office admitted that they had, but refused to provide the groups with a copy. On 14 November 2006, DNP+ accompanied its lawyers to the patent office to discuss the matter with officials. The day-long visit did not achieve any results. An application for a copy under India's right to information law was also rejected by the Patent Office. Only after INP+ and DNP+ approached the Delhi High Court did the Patent Office agree, in court, to supply a copy of the reply. In the order of the High Court dated 24 January 2007, the Court noted that the Patent Office had stated that such documents would now be supplied as the norm, meaning that the practice would apply

across the board to all patent offices.⁴⁵ This created an important precedent for public-interest groups.

Gilead's patent applications are still pending at time of writing (June 2008).

2.2.2 First victory at the patent office for PLHIV networks - Nevirapine syrup patent application rejected!

On 9 May 2006, INP+ and PWN+ filed an opposition against Boehringer Ingelheim's (Boehringer) application for Nevirapine Hemihydrate, a syrup form of Nevirapine appropriate for paediatric usage. The application was essentially for a new form (syrup) of an existing medicine. 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.⁴⁶

A hearing on the opposition was held in August 2007. On 11 June 2008, the Delhi Patent Office rejected Boehringer's application, based on the patent opposition by the PLHIV groups. This was the first victory for PLHIV groups on an opposition

Brazilian AIDS Group files an opposition in India: challenges tenofovir patent application

The importance of India to global access to medicines has been underscored by a pre-grant opposition filed by a Brazilian AIDS advocacy group in India. On 26 June 2008, ABIA (Brazilian Interdisciplinary AIDS Association) joined an Indian NGO, SAHARA (Centre for Residential Care & Rehabilitation) to oppose Gilead Sciences' patent application for tenofovir. The opposition argues that the medicine consists of a previously known compound, and should not be considered an invention according to India's Patents Act.

The price for Brazil is US\$ 1387 per patient per year. As seen above, UNITAID and the Clinton Foundation have recently announced lower generic prices for second line medicines including US\$ 159 per patient per year for fixed dose tenofovir and lamivudine.

Gilead has also applied for patents on tenofovir in Brazil and the high price of the drug resulted in the Brazilian Health Ministry issuing a decree in April 2008 declaring it to be a drug of 'public interest.' This is the first step in issuing a compulsory licence in Brazil. Civil society groups have also filed an opposition to Gilead's patent application on tenofovir in Brazil.

However, should Brazil reject Gilead's patent application for tenofovir or issue a compulsory licence, the question will be where the government would then source the generic version of this medicine from. Like most other developing countries, Brazil will look to Indian manufacturers; however most of these companies have signed a voluntary licence with Gilead Sciences that does not allow them to sell generic tenofovir to Brazil. (See Section 2.2.1).

The rejection of the tenofovir patent application in India as well then becomes equally important for the Brazilians. Concerned about the impact of an Indian patent on access to tenofovir in Brazil, ABIA has filed the opposition as India's patent law allows 'any person' to submit a pre-grant opposition. If the Indian patent office rejects the patent application, Indian companies that did not sign the Gilead voluntary licences will be free to export this important medicine to Brazil and other developing countries.

- See ABIA and SAHARA, *Brazilian AIDS Group Opposes Patent in India*, Press Release, 26 June 2008

⁴⁵ *Indian Network for People living with HIV/AIDS and anr v. Union of India and ors*, WP(C) No.18834-35/2006 and CM No.15571/2006, Delhi High Court, Order dated 24 January 2007.

filed by them and a press release was immediately issued announcing the landmark decision which was sent to all leading newspapers and was posted on key e-lists.⁴⁷

"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," said P Kousalya, president of Positive Women's Network (PWN). "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," she said."

- Joe C. Mathew, 'Govt turns down German pharma firm's patent plea,' Business Standard, 20 June 2008

The case of Nevirapine syrup is yet another example of the practice of evergreening by pharmaceutical companies. Nevirapine was invented in 1989 and would not be patentable in India as it is a pre-1995 medicine. By applying for an Indian patent on the syrup form of this medicine in 1998, Boehringer was attempting to extend its monopoly. The Delhi Patent Office, however, agreed with INP+ and PWN+ that the medicine was not patentable under Indian law.⁴⁸

2.3 Protecting public health safeguards: Section 3(d) and the imatinib mesylate case

The Imatinib Mesylate case is one of the most important ongoing legal battles over the right of all countries to take measures to protect the life and health of their citizens and over the right of access to treatment. The case revolves around Imatinib Mesylate, an important anti-cancer medicine used in the treatment of chronic myeloid leukaemia (CML). As noted elsewhere, Novartis sells its version, called Glivec (or Gleevec), at a global price that works out to Rs. 120,000 (approximately US\$2700) per patient per month while Indian generic companies market their versions at one-tenth this price.

The story of this lowly salt began in 1993, when Novartis obtained a patent on the molecule

"The price at which Glivec has been offered for sale by Novartis is cause for considerable discomfort" - Glivec scientist

In an opinion piece published in an Indian newspaper, Dr. Brian Druker, the scientist who was the key researcher behind the discovery of imatinib wrote about the history of the medicine and what he felt about the abuse of patent monopolies.

Dr. Druker highlighted the fact that in debates on patents and access to medicines the role of scientists and the resources of the public sector are often overlooked. Discussing the history of the development of imatinib, he noted that the basic research dated back to the 1960s. His own involvement in the research spanned over a decade starting in the 1980s.

Discussing the manner in which the medicine was now being marketed, he wrote:

"However, the price at which imatinib has been offered for sale by Novartis around the world has caused me considerable discomfort. Pharmaceutical companies that have invested in the development of medicines should achieve a return on their investments. **But this does not mean the abuse of these exclusive rights by excessive prices and seeking patents over minor changes to extend monopoly prices.** This goes against the spirit of the patent system and is not justified given the vital investments made by the public sector over decades that make the discovery of these medicines possible...

...Public institutions around the world have continuously played a critical role in the research that leads to vital new medicines reaching the market. Without access medical research becomes a luxury good. Most of my colleagues would be very uncomfortable if we felt that this would be the result of our decades of effort."

- From Brian Druker, "Don't Abuse Patents: scientists," Mint, 15 August 2007

Imatinib, developed by a group of scientists led by Dr. Brian Druker.⁴⁹ As all pharmaceutical companies do, Novartis continued its work on Imatinib, creating salt and crystalline forms of it, and applied for patents on each new form. One of these was the 'beta-crystalline' form of Imatinib Mesylate. In 1998, Novartis filed a patent application on this form of Imatinib Mesylate at the Chennai Patent Controller's office. This was examined after 2005, when India's patent law changed.

2.3.1 The battle in the courts

In 2005, the CPAA filed a pre-grant opposition against Novartis's patent application for Imatinib Mesylate, claiming, among other things, that Novartis's alleged

⁴⁶ Lawyers Collective HIV/AIDS Unit, "Indian patent office rejects AIDS drug patent application," Press Release, 19 June 2008.

⁴⁷ Ibid

⁴⁸ The decision of the Patent Office in the Nevirapine syrup case is available at <http://www.lawyerscollective.org/content/patent-nevirapine-rejected>

⁴⁹ Brian Druker, "Don't Abuse Patents: scientists," *Mint*, 15 August 2007 available at <http://www.livemint.com/2007/08/15003521/Don8217t-abuse-patents-sci.html>

'invention' lacked novelty, was obvious to 'a person skilled in the art', that it was merely a 'new form' of a 'known substance' that did not enhance the substance's efficacy, and was thus not patentable under Section 3(d) of the Patents Act, 1970.

In January 2006, the Chennai Patent Controller, in a landmark decision, rejected Novartis's patent application, stating, among other reasons, that the product failed the test of Section 3(d) (it is important to note that these were not the only grounds on which the application was rejected).⁵⁰

Nearly five months later, Novartis filed a case in the Madras High Court at Chennai against the decision. The company did two things. Firstly, it challenged Section 3(d) as not being TRIPS compliant and not being valid under the Indian Constitution. Secondly, it challenged the Chennai Patent Controller's order rejecting the application.

It was the first case that took centre stage in the debate on intellectual property and the right to health. The second case is still pending.



2.3.2 The battle on the streets

Novartis's challenge to Section 3(d) had an impact on access to medicines across the board - not just HIV medicines but also those used to treat heart disease, cancer, diabetes and blood pressure. As noted above (See 1.2.3 page), this provision is an important safeguard against the practice of evergreening employed by pharmaceutical companies to extend their patent monopolies by making small changes to existing medicines. As the CPAA prepared to do legal battle for access to generic Imatinib Mesylate and for Section 3(d), PLHIV groups, together with national and international NGOs, were prepared to fight the battle for public opinion. Over the duration of the case, PLHIV and health groups undertook protests, press conferences and various other activities to keep up the public pressure and focus on the case, sparking energetic debate about the patent system and its impact on access to medicines.

A worldwide campaign asking Novartis to drop the case included a series of international protests, in which aid agencies, treatment activists and NGOs joined.⁵¹ Religious leaders, investors and politicians wrote to Novartis, asking it to withdraw its actions; among them were Archbishop Desmond Tutu of South Africa, the German Minister of Economic Cooperation and Development, and the Norwegian International Development Minister and the Former President of the Swiss Confederation.⁵² The European Parliament also held a hearing on the case.⁵³

PLHIV networks kept a close eye on proceedings as hearings commenced. INP+ wrote to the government, requesting that it deploy its best lawyers to argue the case.⁵⁴ The networks' concerns were echoed by international patients' and health groups, who wrote to the Indian Prime Minister, asking that the government vigorously defend its law.⁵⁵ PLHIV groups in India also held a series of rallies to highlight the critical bearing of the case on the issue of access to medicines. **'Snapshots of the fight for Section 3(d)' in the following pages provide a bird's eye view of the campaign and the various actions taken in India and abroad on the case.**

50 Statement by the Affordable Medicines and Treatment Campaign on the rejection of the Glivec patent, 26 January 2006. On file with author.

51 For a record of the advocacy around the case, see the CPtech page in India at <http://www.cptech.org/ip/health/c/india/> and the website of MSF's Campaign for Access to Essential Medicines at <http://www.accessmed-msf.org/>

52 See Ecumenical Advocacy Alliance, "Church leaders call on Novartis to drop the case in India," Press Release, 14 February 2007; Tove Iren S. Gerhardsen, "Opposition Gains Support Against Novartis Patent Lawsuit In India," Intellectual Property Watch, 15 February 2007; Norway asks Novartis to withdraw case, Economic Times, 1 May 2007; Berne Declaration, Médecins Sans Frontières and Oxfam International, "Former Swiss President joins Call for Novartis to Drop its Case in India," Press Release, 15 February 2007 and Letter from Interfaith Center on Corporate Responsibility to Novartis CEO Daniel Vasella, 16 January February 2007.

53 See Letter from Five Members of the European Parliament to Novartis CEO Daniel Vasella, 9 February 2007 (on file with author) and Novartis case Statement of the Indian Ambassador at the European Parliament, 11 April 2007, available at <http://www.essentialdrugs.org/edrug/archive/200704/msg00055.php>

54 Letter from INP+ to the Prime Minister, 24 January 2007, on file with author.

55 Letter from International Treatment Preparedness Coalition to the Prime Minister, 26 January 2007, on file with author.

SNAPSHOTS OF THE

The world wide campaign asking

When Novartis filed its case dragging the Indian Government and cancer patients to court over Section 3(d) of the Patents Act 1970, it sparked outrage across the world at the attempt of a multinational pharmaceutical company to challenge India's sovereignty to enact law protecting and fulfilling the fundamental right to health of its citizens. We present snapshots of the global campaign on the Novartis case.



12 September 2006 -Over 200 people protest in Bangalore including representatives of the Karnataka Cancer Society, the Karnataka Network of Positive Persons (KNP+), the Peoples Health Movement, Action Aid, Freedom Foundation, the Karnataka Prantiya Raitha Sangha, the Karnataka Prantiya Krishi Collie Karmekara Sangha, the Students Federation of India, Bharatiya Gyan Vigyan Samithi (BGVS), Samraksha, Milana, Abhya, Pragathi, CIEDS/Karnataka Social Forum/WSF, Sangama, Community Health Cell (CHC)-Sochara, Samraksha, Accept Society, SPAD/VMS (Vijaya Mahila Sangha), Asha Foundation, INSA-INDIA, students from University Law College and St. Joseph College and the Affordable Medicines and Treatment Campaign. Protests were also held in Mumbai.

"This month, on the 26th of January, as Indians we will be celebrating the 57th year of the highest law of the land - the Constitution of India coming into force. Ironically in the same month, multinational pharmaceutical company Novartis is challenging the very heart of the Indian Constitution - the right of every Indian citizen to life and health! ...Today, we write to you to express our grave concern over Novartis' legal action in the Chennai High Court to challenge this very critical public health safeguard of Indian law (Section 3(d) - ed)..."

...Like they did to the South African government several years ago when it passed a law to ensure continued access to affordable medicines, Novartis has also dragged the Indian government to court challenging Section 3(d) for 'not being TRIPS compliant'. In both cases Novartis used the same excuse -were fighting to protect intellectual property. By the time Novartis and other companies were pressured by civil society to withdraw their unjustified litigation in South Africa, hundreds of thousands of persons died of AIDS unable to access affordable medication thanks in large part to Novartis' actions; a high price for patent rights. We do not wish to share the fate of our South African friends and colleagues..."

The public health safeguards of India's patent law have a very real and human impact in our lives and those of millions of other patients - not just people living with HIV, but those living with cancer, asthma, heart disease, and mental illness..."

- Excerpts from the letter written by the Indian Network for People living with HIV/AIDS to the Prime Minister on 24 January 2007

"Novartis' legal tactics in this case have raised the stakes higher than the several thousand Indian patients relying on Glivec, to involve the millions of people kept alive today by generic AIDS drugs from India."

- Interfaith Center on Corporate Responsibility (ICCR), an international, interfaith coalition of institutional investors

"I do not dispute your right to apply for a patent or appeal a denial. I am concerned, however, that your attempt to influence domestic Indian law could have a severe impact on worldwide access to medicines."

- US Congressman Henry A. Waxman to Novartis CEO

"People, not profits, must be at the center of patent law for medicines."

- Archbishop Desmond Tutu condemning Novartis actions

"India contributes in very significant ways to the overall production capacity for life saving generic drugs, with major exports to developing countries. It is important for global health that this contribution can continue...Health is one of the most important long-term international challenges of our time. Life and health are our most precious assets. Investment in health is fundamental to economic growth and development. Therefore, international trade policies and agreements need to be placed within the context of protecting and promoting health and welltoeing. Global health security is depending on each country having the capacity to safeguard public health."

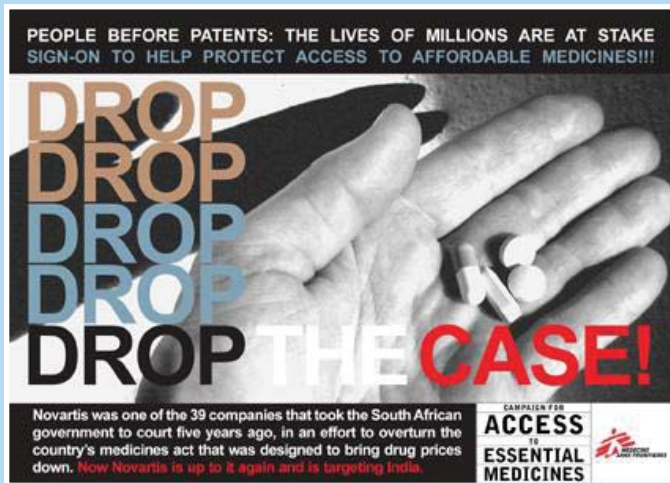
- Eric Solheim, Norway International Development Minister



26 January 2007 - In Washington, activists from Health GAP, Stop HIV/AIDS Alliance (SHAI), Students Against Global AIDS and the Global AIDS Alliance present Novartis with the 'Golden Coffin' award for pursuing its case. (Photo: Reuters/Jim Young).

FIGHT FOR SECTION 3(D)

Novartis to 'Drop the Case' in India



MSF, Oxfam and Care launched campaigns to collecting signatures from people to ask Novartis to drop its case. Nearly half a million people worldwide voiced their concern about the case including Health Minister Anbumani Ramadoss, Archbishop Desmond Tutu, Global Fund Director Michel Kazatchkine, members from the European Parliament and the US Congress, former Swiss President Ruth Dreifuss, former UN Special Envoy for AIDS in Africa Stephen Lewis, German Development Minister Heidemarie Wieczorek-Zeul, Norwegian Development Minister Erik Solheim, as well as authors John Le Carré and Naomi Klein. The drop the case petitions of the various international organisations gathered nearly half a million signatures which were handed over to Novartis after the Madras High Court judgment.



14 February 2007 - Protestors brave a blizzard in Boston to present Novartis with a 'patent-claim, broken heart' award on Valentines Day. (Photo: Linda Haas, Global Justice)



14 February 2007 - Health and HIV groups march in Chennai before one of the court hearings.

"The EU has endorsed WTO rules allowing compulsory licensing of patented products and processes to ensure access to affordable medicines for poor countries. We are glad that the European Parliament has taken a very proactive role in urging Novartis to drop its litigation. It has recognised the importance of India with regard to access to medicine for developing countries and called on the EU to support India in further implementing its intellectual property laws in a manner that will create an environment that will continue to encourage and facilitate investment by the Indian generic manufacturing industry in providing affordable essential medicines for developing countries."

- Statement of the Indian Ambassador to Belgium at a hearing called by the European Parliament on the Novartis case in April 2007. Representatives of Novartis, MSF and Oxfam were also invited to present their views.



The Berne Declaration, a Swiss NGO with 21,000 members protesting in front of Novartis' offices in Switzerland. The NGO along with other groups stormed the Novartis AGM on 6 March 2007 demanding an explanation on why Novartis was intent on endangering access to medicines in India. (Photo: Claude Giger)



29 January 2007- Delhi Network of Positive People (DNP+) and Indian Network for People living with HIV/AIDS (INP+) held a massive rally in Delhi and hundreds of people marched through Delhi urging Novartis to drop its case.

On 10 April 2007, Dr. Anbumani Ramadoss, Minister of Health and Family Welfare, stated that the government was very concerned about the implications of the case and urged Novartis to desist from its actions. Indicating the seriousness of the issue, he went on to say that India had not used compulsory licensing yet and should not be pushed towards this.

Responding to the campaign, the Public Affairs Department of Novartis issued an open letter on 5 February 2007 explaining 'Why Novartis thinks improving patent law will benefit patients and society'. It also wrote individually to leading civil-society organisations that had voiced their concerns about the case.⁵⁶ The company claimed that its legal actions in India did not challenge 'provisions that provide for access under... (TRIPS) and the Doha Declaration.'⁵⁷

Novartis's letter met with immediate criticism. As Brook K. Baker, Professor of Law at the Northeastern University School of Law pointed out,

*Novartis's lawsuit directly challenges... the right to strictly define... 'the baseline standards of patentability' so as to exclude patents for minor variations of existing chemical entities, for new uses of known chemical entities and for mere combinations of existing entities. Novartis and other medicine companies want to impose the same loose standards of patentability for India and other developing countries that they have gained in the IP-crazed courts and legislature of the US and Europe.*⁵⁸

Novartis also highlighted its Glivec International Patient Assistance Programme (GIPAP), claiming that it was supplying the medicine free of charge to cancer patients in India and across the world. On that basis, the company rejected charges that access to the life-saving medicine was being compromised. On 28 January 2007, the Max Foundation (through which the GIPAP programme is implemented) issued a statement in which it implored the CCAA to 'set politics aside' and refer its members to Max so as to give 'these patients an opportunity to have a second chance in life'. The statement also asserted that 'Glivec may be available at no cost.'⁵⁹

In response to these assertions, the CCAA wrote a letter to the Max Foundation about the experiences of some of its patients, which included long delays in obtaining the medicine, having to undergo unnecessary tests and having no assurance of uninterrupted, free lifelong treatment. The letter also highlighted a *New York Times* article that

detailed experiences from South Korea, Hong Kong and New Zealand, where Novartis had allegedly used patients already on Glivec to pressurise governments to pay for the medicine, as well as a criminal complaint filed in Argentina for similar reasons. Pointing out that the case filed by Novartis went beyond imatinib mesylate by challenging Section 3(d), the CCAA concluded,⁶⁰

Our deeply considered view is that patients are entitled to affordable medicines and treatment as a matter of right. Undoubtedly, charity, aid and donation do assist some patients in accessing medicines. However, we strongly deplore the use of such charitable actions to justify actions of corporate sponsors that would take away a patient's right to affordable medicines and treatment.

2.3.3 Madras High Court dismisses Novartis's petitions - patients rights protected

On 6 August 2007, nearly a year after it was filed, the Madras High Court dismissed Novartis's case. The judgment followed a series of hearings held between January and April 2007. Upholding Section 3(d), the Court clearly recognised the sovereign right of the Indian Government to protect public health, saying that

*We have borne in mind the object which the Amending Act wanted to achieve, namely... to provide easy access to the citizens of this country to life saving medicines and to discharge their Constitutional obligation of providing good health care to its citizens.*⁶¹

The Court made detailed observations on the requirement of efficacy in Section 3(d) and ruled that the fact that the term was not defined did not make the provision vague and arbitrary as Novartis had claimed. The Court also held that a domestic court was not the place to raise the issue of TRIPS compliance, which it judged a matter for the WTO Disputes Settlement Body to consider.

It is important to note that this judgment came from a High Court of one of India's states. Thus, Novartis may still appeal against the decision in the

56 Novartis, "An open letter from Novartis regarding the Glivec legal challenge in India: Why Novartis thinks improving patent law will benefit patients and society" 29 January 2007 available at <http://www.maketradeair.com/assets/english/novartis-open-letter-organizations.pdf>
57 *Ibid.*

58 Brook Baker, "A deconstruction of Novartis's defense of its challenge to the India patent regime," 7 February 2007, available at <http://www.cptech.org/blogs/pdisputesinmedicine/2007/02/deconstruction-of-novartiss-defense-of.html>

59 The Max Foundation, "Regarding Novartis' Medicine Glivec and Patent Protection in India," 28 January 2007 available at <https://www.maxaid.org/Default.aspx?trgt=newsstories&choice=66>

60 Cancer Patients Aid Association Responds to Max Foundation, 12 February 2007 available at <http://mail.sarai.net/pipermail/commons-law/2007-February/002316.html>

61 *Novartis AG and another v. Union of India and others*, Madras High Court [W.P. No.s 24759 and 24760 of 2006]

Supreme Court of India. However, the company has indicated that it will not be appealing.⁶²

We fought for patients' rights in this litigation, and we are greatly relieved that the Court has ruled in our favour, and recognised that patients need protecting more than patents. The issue is not merely of providing affordable drugs to patients in India, but also to patients in other countries, as India is the source of generic drugs to over hundred countries. This landmark victory will help avoid many deaths from life-threatening diseases in India and other countries.

- Y.K. Sapru, founder and chairman of CPAA in Joint Statement by CPAA, MSF, DNP+ and Lawyers Collective on Novartis Judgment, 7 August 2007

2.3.4: Novartis' challenge to the patent controller's order is still pending

While the case on the public health safeguards in India's patent law is over, Novartis still has an appeal pending against the order of the patent controller rejecting their patent application for Imatinib Mesylate. This case is before the Intellectual Property Appellate Board which will look at whether under Indian law, Novartis should get a patent. The origin of all this is of course the Patent Office in Chennai saying that Novartis did not deserve a patent not

only because of Section 3(d) but also because their medicine was obvious and that it was already published in Novartis's own 1993 patent application. This case is as important as the one challenging India's law and cancer patients will require the continued support of other patients groups as it will demonstrate the interpretation and application of the public health safeguards in India's law.

2.3.5 Continuing vigilance: concern over the implementation of Section 3(d)

Section 3(d) being upheld was a major victory. However groups in India are now concerned about its proper implementation. Although this provision is meant to protect against evergreening, there are increasing reports of patent applications that relate to changes to existing medicines being patented. Take the case of Valgancyclovir which has been granted a patent. Valgancyclovir is an important medicine to treat cytomegalovirus (CMV), a common OI affecting PLHIV. CMV, if left untreated, can lead to blindness. The cost of a full course of treatment with Valgancyclovir in India is Rs. 270,000⁶³ (approximately US\$ 6200). Due to high costs, PLHIV who need CMV in developing countries are treated with the older version of the medicines, which either has to be injected directly into the eye or given intravenously during a long hospitalisation.⁶⁴ Valgancyclovir is a new version of these medicines (i.e. a new form of a

Evergreening: A widely recognised problem

'A common belief is that patents are normally granted to protect new medicines, but while the number of patents annually obtained to protect genuinely new pharmaceutical products is small and declining, thousands of patents are granted for pharmaceuticals. A large number of patents cover minor modifications of older existing drugs. According to a report of the National Institute for Health Care Management in the United States, in the 12-years period 1989-2000, just 153 (15%) of all new drug approvals were medicines providing a significant clinical improvement.'

- ICTSD, WHO, UNCTAD (2006) Guidelines for the examination of pharmaceutical patents: developing a public health perspective - A Working Paper, 2007

'The FTC...discovered that some brand name drug manufacturers may have manipulated the law to delay the approval of competing generic drugs. When a drug patent is about to expire, one method some companies use is to file a brand new patent based on a minor feature, such as the color of the pill bottle or a specific combination of ingredients unrelated to the drug's effectiveness ... In the meantime, the lower-cost generic drug is shut out of the market ... This is not how Congress intended the law to work... Our message to brand name manufacturers is clear: you deserve the fair rewards of your research and development; you do not have the right to keep generic drugs off the market for frivolous reasons.'

- President takes action to lower prescription drug prices, Office of the Press Secretary, The White House, 22 October 2002

'Evergreening can occur in a number of ways but typically...it arises when companies file and obtain patents, subsequent to the original patent, on other aspects of the same compound or reformulations of the original compound in ways that might be regarded as of no incremental therapeutic value, but which are nevertheless patentable. For instance, strategies include a similar but different dosage form such as capsules rather than tablets, salts, esters, or crystals (polymorphs) of the same product or other changes dependent on the ingenuity of the formulators and the lawyers.'

- Public Health, innovation and intellectual property rights: Report of the Commission on Intellectual Property Rights, innovation and public health, World Health Organisation, 2006

62 Research-oriented cos may stay away: Novartis, *The Hindu Business Line*, 7 August 2007

63 Delhi Network of Positive People, AIDS group files opposition against AIDS-related drug, Press Release, 27 June 2008. On file with author.

64 Medecins Sans Frontieres Campaign for Access to Essential Medicines, *IGWG Booklet: Putting patients first: New Directions in Medical Innovation*, 19 May 2008.

known medicine) and should not be patented under India's law.

However, the Chennai patent office granted a patent for this medicine to Roche in 2007. This was despite a pre-grant opposition filed by PLHIV groups. Contrary to the Patents Act, 1970, the patent office did not give the groups a hearing. The grant of this patent (and others like it) is a cause of concern as it appears that the patent offices may not be implementing fully the public health safeguards like Section 3(d). Now DNP+ has filed a post grant opposition to this patent. PLHIV groups are coming across an increasing number of patents granted that may be for minor changes to existing medicines.

2.4 TRIPS-plus monopolies - data exclusivity in India

Like other countries in South and Southeast Asia, India is under pressure to introduce TRIPS-plus monopolies on medicines such as data exclusivity (DE) into its law. An Inter-Ministerial Committee was set up in 2004 to examine India's obligations under Article 39.3 of TRIPS in relation to data protection (See Chapter 1).⁶⁵ Bilateral pressure on this issue has taken the form of the Special 301 report of the United States Trade Representative (USTR). India has

featured consistently as on the USTR's 'priority watch list' including in 2005,⁶⁶ 2006,⁶⁷ 2007⁶⁸ and now in 2008⁶⁹ for, among other things, failing to provide data protection. A reading of the 2005 Special 301 report makes it evident that the USTR believes that the requirement for data protection will be fulfilled only by providing data exclusivity. As seen in the Chapter 1, data exclusivity delays the entry of generic medicines and is not a requirement under TRIPS.

2.4.1 Advocacy on data exclusivity

In opposing data exclusivity, PLHIV groups worked with several partners to keep track of and understand the actions of the government. With the Inter-ministerial Committee being unable to arrive at any conclusion as to whether India was required to adopt data exclusivity, media reports indicated that the Prime Minister's Office was putting pressure on the Committee to make a decision.⁷⁰ This pressure revived the debate on this issue in 2006 and health groups started to keep track of these developments and the positions taken by different ministries - particularly the Ministry of Health and Family Welfare, which appeared to have taken a stand against the adoption of DE from the very beginning.⁷¹

The groups' first priority was to counteract an intensive campaign by industry promoting the view that DE was required by TRIPS.⁷² As was the case with oppositions to patents, energetic public debate was needed to counter this and link DE to the issue of access to treatment. Early media reports indicated that the relevant authorities were under intense pressure to adopt DE and that the Ministry of Health and Family Welfare might agree to it. Against this background, representatives of health groups approached the media to put forward their point of view.⁷³ They also briefed and lobbied members of Parliament and bureaucrats in the various relevant ministries on the issue. The groups took heart when the Chairperson of the Parliamentary Standing Committee on Commerce publicly criticized any move to accept DE.⁷⁴



An article cautioning India against data exclusivity in the *Economic Times*, 28th May 2007

65 P.T. Jyothi Datta, "Consumer fora seek to take part in drug-related debates," *The Hindu Business Line*, 12 April 2004

66 Office of the United States Trade Representative, *2006 Special 301 Report*, Released 24 April 2005.

67 Office of the United States Trade Representative, *2006 Special 301 Report*, Released 28 April 2006.

68 Office of the United States Trade Representative, *2006 Special 301 Report*, Released 30 April 2007.

69 Office of the United States Trade Representative, *2006 Special 301 Report*, Released 25 April 2008.

70 P.T. Jyothi Datta, "The data-exclusivity debate heats up," *The Hindu Business Line*, 20 June 2006.

71 Health Ministry Fights For Select Usage of 'Exclusive Data' By DCGI, *The Financial Express*, 11 March 2004

72 See for instance, Uttam Gupta, Data exclusivity vs patent: The myths and the realities, *The Hindu Business Line*, 16 May 2006; Dr Milind Antani and Prashant Iyengar, "Towards a Law on Data Exclusivity," *PHARMABIZ.com*, 5 January 2005; and Protection of pharma cos' research - 'Data exclusivity must for consumer safety', *The Hindu Business Line*, 30 April 2003; and Shoibal Mukherjee, "Here's a penny for your pill," *Hindustan Times*, August 8, 2006

73 See Sarah Hiddleston, "Data for leverage," *Frontline*, Volume 23 - Issue 16, Aug. 12-25, 2006; Anand Grover, "In public interest, data exclusivity shouldn't be made a law," *Indian Express*, 12 July 2006; and Joe C. Mathew, "NGOs play 'decision' to provide 5 year data exclusivity," *PHARMABIZ.com*, 20 September 2006.

74 Joshi cautions govt on data exclusivity, *The Financial Express*, 17 June 2006

On 29 June 2006, INP+ wrote to the Prime Minister, urging him to reject DE.⁷⁵ Similar letters⁷⁶ were also sent to the government by the Global AIDS Alliance, the Bangalore HIV/AIDS Forum, the Medico Friends Circle, the People's Health Movement, Torchbearers (a mental-illness advocacy group), MSF and the Lawyers Collective HIV/AIDS Unit, while the Stop HIV/AIDS Initiative (SHAI) launched an online petition campaign urging the rejection of DE.⁷⁷

As public debate intensified, the groups learnt that while the Inter-ministerial Committee appeared to agree that DE was not a TRIPS requirement, it was reportedly considering its adoption anyway as an incentive for foreign investment.

Opposition to data exclusivity was building, but the work of the health groups was far from done. Advocacy on DE continued. Indian groups charted their own course in this debate, opting to oppose DE entirely, against the advice of some who argued for a 'middle path' involving acceptance of some mechanism that would require generic manufacturers to compensate multinational companies. Responding to this proposed strategy, DNP+ and other groups pointed out that such an option had already been considered by the Committee and rejected as unworkable. Indian groups also explained that the Indian experience with intellectual property had been quite different from that of other countries and that it argued the need for the country to retain the power to devise and test new and innovative strategies in order to challenge monopolies on medicines.

The result of this continued opposition by health groups has been peculiar and telling. On 31 May 2007, the Department of Chemicals and Fertilizers issued a report on data protection.⁷⁸ At first, there was some confusion as to whether or not the Inter-Ministerial Committee had formally issued this report. It then came to light that it was only a report issued by the Department, most likely because the official in charge of the issue would soon be retiring. It was effectively a position statement on behalf of the Department.

As a result of the advocacy by health groups, the Department, in its paper, appeared to tread a careful line on data exclusivity for medicines. It

clearly admitted that DE was not a TRIPS requirement but nevertheless recommended its adoption, arguing that it would ensure quicker access to new medicines, promote research and development and - curiously - address the problem of spurious medicines. For agricultural chemicals the other sector likely to be most affected by DE, the paper recommended immediate implementation of DE. There had been no advocacy from the farmers or other groups on this issue with the Inter-Ministerial Committee.

In the case of pharmaceuticals, the report recommended that DE be adopted at a later stage with the inclusion of public-health safeguards similar to those built into the patent law.

The report came in for heavy criticism from public interest-groups, which argued that the regulatory body for the registration of medicines should not be linked with the Patent Office.

2.4.1 A difficult issue to track and oppose

The issue of DE challenged public-interest groups with its highly technical nature and the difficulty of influencing a closed government process where access to information was extremely difficult.

Another difficulty was that of keeping track of inter-governmental meetings on the subject in order to push back against the intense bilateral pressure faced by the Indian government - as when, for example, the USTR reportedly met with officials of the Ministry of Health and Family Welfare in early 2008 to lobby for a change in the Ministry's stand against DE.⁷⁹

2.5 Joining Hands with the World

2.5.1 'Big Pharma, quit India'

As activists, we spend a lot of time at national and international conferences. So many of these are organised by governments or in collaboration with multinational pharmaceutical companies and it gives us an opportunity to take our message directly to them. Sometimes we find that the agenda set for the conferences doesn't address our concerns, so activists must find different ways to

75 Letter from INP+ to Prime Minister on data exclusivity, 28 June 2006, on file with author.

76 Letters on file with the author.

77 Online petition to Prime Minister to reject data exclusivity, 4 July 2006, available at <http://petitions.aidindia.org/data-exclusivity/>

78 Satwant Reddy and Gurdial Singh Sandhu, *Report on Steps to be taken by Government of India in the context of Data Protection Provisions of Article 39.3 of TRIPS Agreement*, 31 May 2007

79 Rupali Mukerjee, USTR pushes for drug data protection, *Times of India*, 15 April 2008

make their voices heard. At Toronto our protest did so well. Ratan (MNP+) and I worked so hard for that - we pushed and pushed - we went without dinner - we worked day and night to make it a success. And of course, when other people push with us, we must push with them
- Loon Gangte, DNP+

On 15 August 2006, India entered its sixtieth year of independence. Several representatives of INP+, DNP+, MNP+, PWN+ and various NGOs working on HIV marked India's Independence Day at the sixteenth International AIDS Conference in Toronto by staging a protest against the grant of product patents and the numerous patent applications filed by multinational pharmaceutical companies in India. The protest invoked the call of the Quit India Movement during India's struggle for independence from British colonialism. Carrying kites in the colours of the Indian flag, the protestors surrounded these companies' booths, chanting 'Big Pharma, quit India', 'Lives before profits' and 'AIDS medicines now!' Leaflets explaining the reason for the protest were distributed to thousands of conference participants as the protestors marched to the media hall to address journalists from around the world on the impediments caused to access to medicines by the product-patent regime adopted by India.⁸⁰



An Indian activist dressed as Mahatma Gandhi leads a protest against patents in India on essential medicines on India's Independence Day at the sixteenth International AIDS Conference, 15 August 2006, Toronto



Big pharma, quit India: Activists from around the world surround the booths of multinational pharmaceutical companies demanding the withdrawal of their patent applications in India, 15 August 2006, Toronto

80 See India's WTO compliance threatens AIDS drugs. *The Economic Times*, 16 August 2006 and Protest hits AIDS summit, *The Standard*, 17 August 2008

Protests across India against Abbott's actions in Thailand

Condemning Abbott - from Bangalore to Bangkok

A hundred people marched outside Abbott Laboratories' distribution outlet in Bangalore carrying banners proclaiming 'Abbott's Greed Overrides Patient's Needs' and 'Abbott - Concerned with Money Not Lives'. Representing positive people's networks and rights activist from across the city, protestors denounced the company for its callous actions against the Thai people and supported the Thai government and the Thai Network of People Living with HIV/AIDS. The groups formed a human chain and observed a minute-long silent prayer in memory of all those who have died because of the unavailability of ARVs. A Memorandum of Demands was submitted to Abbott, which included the re-registration of the seven medicines Abbott has removed from the Thai market; registering and making available lopinavir/ritonavir in all developing countries; and establishing affordable prices for lopinavir/ritonavir in more countries.

'Thai government, you are a hero' - solidarity rally in Delhi

200 people from PLHIV networks and NGOs rallied in support of Thailand. Wearing white t-shirts with the words 'HIV Positive' across the front and 'Treatment for All' on the back, the ralliers marched and shouted slogans. Some members burnt an effigy of Abbott's CEO amidst clapping and cheering. The groups called on the Indian government to consider similar actions to provide essential medicines in India. At the police barricade, they sang Hum Honge Kaamyab (We Shall Overcome). A smaller group then went to the Thai Embassy where they met with a government representative. They garlanded him and presented him with boxes of sweets and a Memorandum of Support. Delegates explained that they supported the Thai government's actions and expressed the hope that Thailand would not succumb to international pressure and withdraw the licences.

'Greedy Abbott', 'shame shame' - Mumbai denounces Abbott

About 85 people from positive networks and rights groups protested outside Abbott Laboratories' Office in Mumbai. Protestors distributed bilingual fliers explaining the issues to office-goers in the vicinity and to commuters in cars at the traffic signals and bus stop. A black t-shirt with the words 'Greedy Abbott' painted on one side and 'Shame Shame' on the other was stuffed with balloons and tied between two poles on the central median to attract the attention of passers by. A six-member delegation met with company officials and submitted a charter of demands. The members expressed their deep concern over Abbott's decision to withdraw medicines from the market and stated their opposition to pharmaceutical companies threatening countries and holding patients to ransom.

In discussions at the end of the day, most groups felt that the protest had been successful because of its simple, easy-to-identify-with messages and the colourful kites and posters used by the Indian marchers. Also effective was the idea of one of the Indian activists to dress up as Mahatma Gandhi and lead the march.

Over the next few days, Indian activists joined other treatment-access protests, lending their support and ideas to activists from other countries. Finally, at the closing ceremony of the conference, Indian PLHIV groups joined other activists from around the world and demanded (and got) space and time to voice their own concerns regarding treatment access.

2.5.2 Protesting Abbott's actions in Thailand

It's a great thing that Thai Government is not bending down to the pressures of Abbott and other Pharma MNCs. The Thai government has bravely upheld the right to access to medicines of people by granting these compulsory licences. This is a lesson, which governments of other developing countries have to learn. This situation can arise in India. Very soon many of PLHIV on treatment would require second-line treatment. Currently the government in India is not providing second-line treatment. Considering the average income of people in India, it would be



PLHIV groups in Delhi rally in support of the Thai Government's compulsory licenses, 26 April 2007

difficult for people to afford to buy these medicines. If they don't have these medicines they will develop opportunistic infection and die
- Jaya Nair, UDAAN trust

In late 2006 and early 2007, the Thai government took the path-breaking decision of issuing compulsory licences on two ARVs and a heart disease medicine (See Chapter 3), in keeping with its commitment to achieve universal access to essential medicines for all its citizens. The announcement followed two years of failed negotiations with pharmaceutical companies. The issue of compulsory licences met with an extraordinary response from

Abbott, which withdrew registrations for seven of its new medicines from the Thai market. Health groups were also surprised by a statement from the then new Director-General (DG) of the WHO, Margaret Chan, who reportedly stated that there had to be a balance in issuing compulsory licences, saying, 'We can't be naive about this. There is no perfect solution for accessing medicines in both quality and quantity.'⁸¹

Such a statement by the WHO's top official was obvious cause for concern. On 9 February 2007,

DNP+ and other health groups wrote to the Southeast Asian Regional Office (SEARO) of WHO, asking for immediate clarification.⁸² WHO SEARO, in its reply, stated that

*WHO remains totally committed to promoting access to essential and life-saving treatment for all and fully supports the use of the flexibilities within the TRIPS Agreement, including compulsory licensing, to facilitate access to affordable medicines. We consider Thailand's recent decision to issue compulsory licences for three medicines to be in line with the TRIPS Agreement and the Doha declaration.*⁸³

WHO SEARO further regretted the confusion caused by Ms. Chan's statements and pointed out that the WHO DG had since clarified her statement, which had been made in the context of ensuring a balance between the immediate and urgent need to provide affordable medicines to those who need them and the need to provide continuous incentives for innovation.

On 26 April 2007, PLHIV groups in India joined a global day of action, taking to the streets in three cities to support the issue of the Thai compulsory licences and protest against Abbott's actions.



Protests in front of Abbott's offices in Mumbai, 26 April 2007



After the rally, PLHIV gather at the Thai embassy in Delhi and congratulate Thai Government officials on the compulsory licences, 26 April 2007, Delhi

81 WHO raps compulsory licensing plan Govt urged to seek talks with drug firms, *Bangkok Post*, 2 February 2007

82 Letter from Delhi Network of Positive People to WHO SEARO, 9 February 2007. On file with author.

83 Letter from WHO SEARO to Delhi Network of Positive People, 16 February 2007. On file with author.



Groups picket Abbott's offices in Bangalore, 26 April 2007

3. LESSONS LEARNED


From court battles to street protests, and from press conferences to meetings with the government, PLHIV groups in India have employed a number of strategies in their efforts to ensure the availability of affordable generic medication. Some of the bigger campaigns discussed above demonstrate the effectiveness of a combination of strategies and indicate the difficult and challenging environment within which the battle for treatment access is being waged in India. These campaigns also highlight the collaborative nature of the movement in India, with PLHIV groups taking the lead in certain areas and, elsewhere, collaborating with or supporting other groups. The lessons learned from the use of varied strategies and actions by PLHIV are discussed below.

3.1 Legal Action

Access to medicines and treatment is closely linked to legal issues. PLHIV groups in India regularly take legal action to ensure that the government fulfils its obligation to provide treatment or to prevent the actions of private parties (such as pharmaceutical companies) infringing on the right to health. Their actions range from filing cases to opposing patent applications.

As seen above, PLHIV groups use the provisions of the Indian Patents Act, 1970 to engage

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इस भाग में पिन पृष्ठ संख्या दी जाती है जिससे कि वह अलग संकलन के रूप में रखा जा सके।
 Separate paging is given to this Part in order that it may be filed as a separate compilation.

MINISTRY OF LAW AND JUSTICE
 (Legislative Department)
New Delhi, the 5th April, 2005/Chaitra 15,1927 (Saka)

The following Act of Parliament received the assent of the President on 4th April, 2005, and is hereby published for general information:—

THE PATENTS (AMENDMENT) ACT, 2005
 No. 15 OF 2005

[4th April, 2005.]

An Act further to amend the Patents Act, 1970.

BE it enacted by Parliament in the Fifty-sixth Year of the Republic of India as follows:—

1. (1) This Act may be called the Patents (Amendment) Act, 2005. Short title and commencement.

(2) Sub-clause (ii) of clause (a), and clause (b), of section 37, sections 41, 42, 47, 59 to 63 (both inclusive) and 74 shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint; and the remaining provisions of this Act shall be deemed to have come into force on the 1st day of January, 2005.

2. In section 2 of the Patents Act, 1970 (hereinafter referred to as the principal Act), in sub-section (1),— Amendment of section 2.

(a) after clause (ab), the following clause shall be inserted, namely:—
 (aba) "Budapest Treaty" means the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent

Legal Actions

meaningfully with the legal system. They do this in close consultation with public-interest lawyers and experts on intellectual property rights (IPR), who can help them understand the issues and determine which patent applications to oppose. They have also collaborated with scientists and medical experts to identify important medicines and determine whether they meet the criteria for patentability. This technical collaboration is necessary because a patent application - or even a patent - on a medicine is no indication of its medical relevance or usefulness.

PLHIV groups have also gone to court, even to the Supreme Court of India, to seek enforcement of Constitutional guarantees of life and health.⁸⁴ The Supreme Court has held that the guarantee of the right to life includes the right to health and has further held that the maintenance and improvement of public health must rank high amongst the State's obligations, being indispensable to the very existence of the community.⁸⁵ The Supreme Court has evolved the concept of public-interest litigation, allowing groups or individuals to approach the courts to ensure the protection and free exercise of fundamental rights.

There have been several cases in which the courts have enforced these Constitutional guarantees. When MNP+ approached the Guwahati High Court (Imphal Bench) in 2007 on the issue of the availability of CD4 machines, it received a favourable order.⁸⁶ In January 2007, the Supreme Court stopped the sale of a product that claimed to cure AIDS.⁸⁷ In March 2007, the Karnataka Network of Positive People won a similar injunction to stop the manufacture, advertising or sale of false cures and treatments for HIV, with a judicial direction to the government to be more vigilant in such cases.⁸⁸

In 2005, the Indian Parliament enacted the Right to Information Act, under which any Indian citizen may file an application to a public body to obtain various kinds of information. Any information received may be used in the media as well as in litigation. Groups are now using 'right to information' applications to get information about the patent system, government policy discussions and decisions, and so on.

3.2 Direct Action

HIV is a unique disease - in no other illness are the people suffering from the particular disease fighting their own battles. This is really the first instance of an empowered patients' group. And as patients they have successfully articulated their demands for treatment and participated in ensuring that treatment is available.

- Amit Sengupta, People's Health Movement

Today, promoting treatment access is an integral part of the work of PLHIV groups in India. In pursuing access, these groups have had to work especially hard to understand how intellectual-property rights impede access to healthcare and devise strategies to overcome this.

The direct actions of the PLHIV networks begin at home. At the heart of their work on treatment access are continuous awareness and information programmes for their own members.

Awareness for our members has been a very important part of the campaign. We make several presentations on access to treatment and discuss issues like TRIPS, parallel importing and compulsory licences. We also talk about medicine price control. We have held several trainings like this.

- Ratan Singh, MNP+

We talk to our members about the issue all the time. Sure, they may not know all the technicalities. But they know the basics... They understand how one company owning a medicine means more expensive medicines for them; it means someone else controls whether they get a medicine or not.

- Elango Ramachander, INP+

One of the greatest challenges has been in translating and simplifying IPR issues. It is only when we work on treatment literacy that we can do advocacy. Of course this is totally missing from the mandates of donors, governments, etc. The information we get from the lawyers is quite technical and it is difficult to sensitise people with that level of information. That's why DNP+ has consistently followed up patent issues and now after all this time we can understand and

84 See Article 21, Constitution of India

85 *Vincent Panikurlangara v. Union of India* (1987) 2 SCC 165

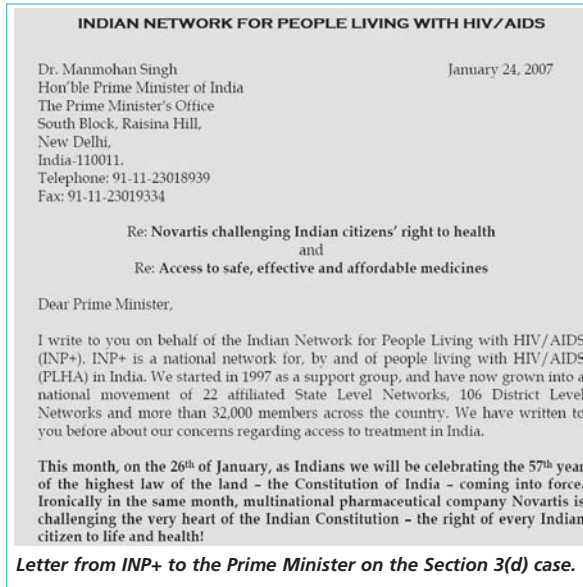
86 HC directs govt to install CD4 machines, *Imphal Free Press*, 26 June 2007

87 *Indian Network of Positive People v. T.A. Majeed & Ors.*, Supreme Court of India, SLP (Civil) No(s). 5527/2004, Order dated 3 January 2007.

88 *Karnataka Network for People living with HIV/AIDS v. Balachandra K. Pagali Nayak and ors*, Karnataka High Court, W.P. No. 8852/2006 (GM-RES), Order dated 27 March 2007

explain the issues with great ease. It is a skill that few patients' groups not just in India but even abroad possess. I really saw that at the first IPR meeting we had in Bangkok. It is very important to learn about the issue properly.

- Loon Gangte, DNP+



Treatment literacy is the first and most basic component of awareness. DNP+ held one of the first ever treatment-literacy workshops to teach its members about HIV treatment, its availability, diagnostics, generic names of medicines, side-effects, toxicity and other critical issues. It also brought out a treatment-literacy booklet in English and Hindi; this, admittedly, is not perfect, but - as Loon Gangte says - it is meant to start debate and discussion. DNP+ also holds a treatment session every month. PLHIV groups believe that the more people know about treatment, the more likely they are to be actively involved in taking treatment.

Campaigns allow us to put across to the government the importance of health rights and medicines. We have learnt innovative ways to draw attention and send our message to the public like balloon figures, fliers in regional languages, placards and slogans.

- Jaya Nair, UDAAN Trust

With increased awareness of treatment issues, PLHIV groups organize and participate in protests and marches on a regular basis to voice their concerns and demands. Whether they are marching through the Indian capital or protesting in front of the offices of multinational pharmaceutical companies, these actions not only put the causes supported by PLHIV in the public eye but are also

highly empowering, giving HIV-positive people a means to articulate their concerns and problems and show their unity and collaboration with other groups. Apart from rallies and protests, on any issue of concern, they also write letters to law and policy makers putting down on paper their concerns. On issues that require larger national or international support, action alerts are issued asking for support in writing letters or lending solidarity at a rally or asking groups to organise their own rallies in support. PLHIV are also active in speaking at public forums and making presentations on issues related to access to treatment.

Access to medicines and treatment are all linked to the larger issue of the obligation on the government to respect, protect and fulfil the right to life and health of all persons. PLHIV networks have been extremely active in maintaining consistent pressure on the government to improve its national HIV treatment programme by documenting the access barriers that PLHIV face and highlighting the need for second-line treatment. PLHIV networks are also clear on the need to do their part, and have become important partners in the programme through treatment, counselling and care services. The networks have also conducted and publicised research on HIV treatment.

Opportunities.....

- Indian Patent law doesn't consider discoveries "new form or new use of known substances" as invention, unless an enhancement in efficacy is proven.
- Section 3(D) of Indian Patent Law- an important public health safeguard.
- DOHA declaration- ensure access to medicine for all.
- Any person including PLHA networks can file opposition before grant of patent

Slide from a presentation by DNP+ on patents and access to treatment

3.3 Media and Communications

Public Relations! Every pharmaceutical company has a virtual army of people and organisations working on keeping their version of the story out there and updated and in the public imagination and memory - and to keep them looking good. Living in a media-savvy and media-saturated world means we must fight fire with fire and more importantly 'spin' with the truth.

- Leena Menghaney, MSF Access Campaign Manager, India

The importance of public information and opinion, not only with regard to access-to-treatment issues but more generally, is now clearly understood by most PLHIV and health groups. As cheaper and more varied forms of communication have emerged, the media has become central to the debate, the shaping of public opinion and the mobilisation of popular support. Traditionally, however, they have been reluctant to cover both sides of the issue in relation to patents. In the debate over intellectual property, they largely ignored the 'ranting and raving' of activists. Regarding the issue related to commerce and profit, the financial editors of newspapers and TV channels paid little, if any, attention to criticism of the patent system by health activists and patients' groups.

The amendment to the Patents Act in 2005 marked a watershed in media advocacy in India with respect to access to treatment. Initially, criticisms of the proposed amendments by health groups were rarely covered. In fact, the 'business' sections of several papers and news channels succeeded in getting stories on the effects of patents on health cancelled. It was only when the international media began covering the changes in India's law that local coverage picked up. This was supplemented with public demonstrations in protest against the amendments and constant direct engagement with lawmakers and policymakers.

One of the most important strengths of the PLHIV movement has been the heightened visibility of issues related to treatment; coverage of these issues in the media has increased and the reporting has been good.

- Amit Sengupta, Peoples Health Movement

PLHIV groups use all forms of communication. The proliferation of news media furnishes more avenues of communication, while the Internet provides space for regular and daily issue updates as well as online campaigns and petitions.



A news report on the Tenofovir rally in a Hindi Newspaper

Actions associated with access to medicines (in particular, those related to patents) require communication strategies to make optimum use of the different available media vehicles, such as opinion pieces, stories in local and regional media, exclusives, media briefings and press conferences. All this takes time and money, so the chosen strategy must depend on the issue or action in question and how much support it needs. Thus, pre- and post-grant oppositions were accompanied by major media campaigns (as in case of Lamivudine/Zidovudine and Tenofovir), later ones made do with press releases and updates on the internet.

Generally all events and actions will be accompanied by a media kit consisting of the following:

- a briefing note that explains the background of the issue and why the networks are concerned;
- a media advisory to inform the media of any events, public or legal action being taken, and
- a press release to furnish information on the event or issue and quotes from key people involved with it.

PLHIV groups have found that it is important to work with the international as well as local media. Most international news organisations have a presence in India and PLHIV groups ensure that they are invited to all media events. International coverage is important not only in shaping global opinion, but also, in creating pressure on domestic media to cover the issue. This was the case with the campaign on the 2005 Patent Amendments, where the domestic media was indifferent until shown the way by their international counterparts.

Of course, the debate nearer home is as or more important. In terms of local and regional coverage, PLHIV networks in India work not only with leading English dailies but also with local and regional media. Providing information in languages other than English is an important aspect of this work. During the action on Thai compulsory licences, press releases were issued in several regional languages to ensure coverage in local newspapers.

One of the main lessons emerging from the past few years of media advocacy is the importance of health correspondents. Most newspapers and news channels have staff specialising in health coverage, with whom health groups and PLHIV networks can build contacts. Working with the media is not always easy. Where debates on patents and health are still at an early

stage, health correspondents may have to be persuaded that the issue is important enough to warrant their attention. Once that attention has been caught, however, the work becomes much easier. Networks may find they need one or two people dedicated to the task of providing accurate and proper information to journalists, who may call at any time of day or night.

Journalists also appreciate reading materials, information resources and contact details of key people. As relationships with reporters operate mainly on a reciprocal basis, the rule of thumb is to be as helpful as possible. In this way, networks build good connections with reporters, newspapers and news channels, facilitating the transission of information and perspectives. A good relationship with a reporter can make all the difference in terms of quality and scope of coverage.

Coverage in newspapers is not limited only to reports. Newspapers also provide space for opinion pieces and editorials. The former is often written by an author who has expertise or experience relating to the subject under discussion; he or she may represent a particular group or point of view. Through the use of opinion pieces, health groups can speak directly to readers, presenting all the relevant facts and arguments - including those reporters might not mention. While some newspapers give space on their editorial pages to a single piece, others may choose to present a variety of opinions, effectively hosting a debate.

Sometimes a media briefing is useful. Selected journalists are called to a meeting, briefed on the issue at hand and encouraged to file stories on it. Larger events normally merit a full-fledged press conference. Typically, this consists of a series of presentations to representatives of the media, covering different aspects of the issue. Often, these are made by representatives of different organisations or interest groups. For instance, a press conference called during the Section 3(d) case saw presentations by delegates from PLHIV groups, MSF, the People's Health Movement (PHM) and the Centre for Trade and Development (Centad). The PLHIV delegates explained the need for generic HIV medicine production, MSF discussed the international ramifications of the case, PHM (a public health group) discussed the broader concerns of the health movement and the monopolisation of healthcare and Centad discussed issues on trade, research and development. The issue of patents on medicines was examined from many angles, providing the media and ultimately the public with a complete picture.



Loon Gangte, President of DNP+ being interviewed on the tenofovir opposition, 10 May 2006

Dead Man Walking

Generic drugs only hope for many AIDS patients
Richard Ruckelshaus

Chances are you have never heard of the drug, generic tenofovir, let alone Section 3(d) of India's Patent Amendment Act of 2005. But a court case in India this month involving both could determine whether people throughout the world have access to life-saving medicines for diseases like HIV/AIDS or dengue in coming years.

I am intimately familiar with the drug, marketed by the Swiss-based multinational Novartis as Glaxo, because my life depends on it. In October 2006, I received a diagnosis of HIV, chronic hepatitis C, and chronic kidney disease. Six months later, the Federal Drug Administration approved Glaxo. Years of newspaper and privately funded research went into the drug's development, and it was all but guaranteed my cure.

Novartis has filed suit against India's government because an Indian court rejected its patent application for a new form of the original compound. The company is challenging both the patent office decision and a key public health watchdog within India's Patent Act that aims to reserve patents for real innovations over 10 years.

India's generic medicine industry is often called "the laboratory of the developing world" because it produces quality drugs at dramatically more affordable prices. Generic competitors in what brought prices down for antiretroviral (ARV) medicines for people living with HIV/AIDS was a major factor in the success of India's AIDS treatment programmes. Throughout the world, only generic ARVs made in India, including more than 80 per cent of the 100,000 tablets issued by Doctors

Without Borders in more than 10 countries last year, are the ARVs purchased by UNICEF, the International Dispensary Association, the US Global Fund, and the Clinton Foundation to treat patients in 87 developing countries from generic Indian sources as well.

In Mumbai, the experience of generic ARVs was brought home to me a few years after I was diagnosed with leishmaniasis. I saw first-hand how hope had replaced despair for thousands of people throughout the impoverished country when, just a short time earlier, AIDS devastated whole communities. Like me, without treatment, many of the people I met must have died. And without a generic

number of leishmaniasis sufferers, and in any event, a drug delivery system based solely on donations is vulnerable to shifting political winds and the drug cartels' withdrawal for any reason. The company also claims on their website that their recent case is actually about increasing access to medicines because strict intellectual property (IP) protection keeps "the foundation for the massive investments made by the pharmaceutical industry in R&D that are vital to medical progress."

While this may sound good in a press release, it is not true for most people in the world. A growing body of evidence - most recently the WHO's Commission on Intellectual Property and Public Health - indicates that increased patent protection has done little or nothing to increase innovation in treatments for the afflictions of the developing world. Of the 100 new chemical entities marketed worldwide between 1975 and 2004, only 10 were the diseases that affect 90 per cent of the world's population.

To many people, Novartis is known as a case of drug vs. South Africa. Novartis was one of 10 drug companies that used South Africa in 1998 to block legislation aimed at improving that country's access to essential medicines. At the time, the companies tried to use the same arguments, predicting the sky would fall - an threat and a

of South Africa were allowed to stop around for the poorest people. Novartis filed that case in 1998, but Novartis has spent billions of dollars in profits, including a \$1 billion in 2005 alone.

I am grateful everyday that a treatment was found to prolong my life. But one day I was cheerful about this as one would like, knowing that AIDS kills more people each year - nearly three million - than the number of people in any human state of Malawi. Of whom one thinks of the people in Malawi and around the world who would be most affected if Novartis gets its way today in India. Quite simply, the company should stop its case. The article is the work of Doctor Without Borders.

An opinion piece on the Section 3(d) case in the Times of India, 9th March 2007

3.4 Legislative Advocacy

Direct engagement with lawmakers and policymakers is an important part of the work done by PLHIV networks in India. Contrary to the perception (formerly common in civil society) that elected representatives are hard to reach and unwilling to take up human-rights issues, they have turned out to be far more approachable than previously thought.

Legislative advocacy by PLHIV networks works at three levels:

The bureaucracy

India has an extensive bureaucracy entrenched at all levels of government. Policy and important decisions are often made by bureaucrats. In the

case of patents, PLHIV have had to work with three separate ministries: the Ministry of Chemicals and Fertilizers, the Ministry of Commerce and Industry and the Ministry of Health and Family Welfare. Lobbies in India often operate covertly. PLHIV groups have realised that representatives of multinational companies and Western governments are constantly meeting with different government functionaries - making it necessary for them, too, to do the same.

The Executive

Above the bureaucracy is the Executive, which comprises the Prime Minister and Cabinet Ministers. It is at this highest level of government that final decisions are made on contentious matters. Regarding data exclusivity, it was the Prime Minister's Office that created pressure for a decision on the matter by an inter-ministerial committee. Therefore it became necessary for health groups to write to the Prime Minister expressing their concerns.

At the state level, MNP+ has developed a good working relationship with the Governor of Manipur. The Governor actually called for reports from the heads of state departments concerning action on treatment issues prioritized by the network, later discussing the reports with members.

Legislators

Finally, PLHIV networks work actively with legislators, the elected representatives of the

people at national and state level. Network representatives meet regularly with individual members of Parliament (MPs) to discuss their concerns. MPs have often raised treatment access issues in Parliament. PLHIV also engage with the Parliamentary Forum on HIV/AIDS, a non-partisan group of MPs and the Indian Medical Parliamentarians forum, a group of MPs from different parties who are also medical professionals. Both these forums have been extremely active on issues of healthcare and access to treatment.

Advocacy with MPs was of particular importance during the passage of the patent law amendments as it was only with the intervention of coalition parties that the government agreed to include public-health safeguards in the law. The advocacy and worldwide campaign also led to extensive debates in Parliament on the amendments.

3.5 International Actions

International alliances have played a crucial role in our work. The International Treatment Preparedness Coalition has given an important platform for taking this work forward.

- Ratan Singh, MNP+

Since changes in India's patent law have affected access to treatment across the world, close collaboration with the international community is an integral factor in the actions of Indian groups. International support and assistance was critical



PLHIV protest in Delhi on 26 February 2005, the Global Day of Action, against the amendments to India's patent law.

over the period in which Indian patent law was being amended, as well as during the Novartis case. International groups and experts have also helped Indian groups understand IPR issues and learn about the strategies, actions and experiences of colleagues in other countries.

The relationship has been mutually beneficial. Indian groups have readily espoused the causes of friends and colleagues around the world, participating in protests against Abbott Laboratories' action in Thailand and the South African government's retrogressive stance on HIV.

Internet platforms like the International Treatment Preparedness Coalition (ITPC) and list serves make international actions easier, helping coordinate and announce international days of action such as, 26 February 2005, the day chosen for action on the 2005 amendments to the patent law. Petitions urging Novartis to drop its legal actions in India and to ask the Indian government to reject data exclusivity were also circulated online.

While international support and actions are important, Indian PLHIV groups have learnt that they must also chart their own course in the drive for treatment access on certain issues, especially given the peculiarities of Indian law, which set its patent regime apart from other countries.

4. CURRENT AND FUTURE CHALLENGES

Despite the incredible successes of the past few years, the PLHIV movement, health groups, human-rights organisations and activists know they face several challenges.

There are practical and functional problems faced by all organisations, as well as those that arise when working in coalitions and undertaking joint campaigns. MNP+ points to the challenge posed by the sheer diversity of the epidemic in India, and also to the difficulty of focusing national attention on problems in the Northeast of the country. The UDAAN Trust cites the problem of maintaining campaign continuity when results often take a long time and the difficulties faced by public interest groups in providing consistent follow-up of a particular issue or campaign.

Others problems are linked to the way the Indian government functions, to peculiarities of the HIV movement and the agenda-setting role of donor and international agencies.

With respect to the government, most people



An activist takes a break during one of the patent protests.

interviewed for this chapter asked why its spending on health and HIV was so low. Some pointed out the dangers of over-reliance on foreign funds while others expressed concern at the lack any concerted effort to institute public-sector manufacture of essential medicines. They also noted that, in many cases, government interventions and treatment programmes have relied heavily on PLHIV networks and other groups to provide services.

Several networks feel that international agencies, particularly funding agencies, set their own agendas (which seldom include campaigning for treatment) and often lack accountability.

In the Northeast, networks are caught between the government and non-state actors who have their own views on the epidemic and how it should be dealt with. Commencing intervention and treatment, particularly for drug users and other marginalized groups, has been difficult.

4.1 Opposing patents: a long and tough battle

With respect to issues on IPR, simplifying essential information to make it comprehensible to network members and the public is a continuing challenge. Groups are pressing on with their work on treatment literacy, collaborating with lawyers and researchers to understand and circulate information on patents. Several of the actions of PLHIV groups on this issue relate to the law and require resources, time, commitment and energy. Few lawyers in any country devote time to voluntary work. The ones that do are usually unable to cope with the sheer scope and volume of work associated with intellectual property and public health.

Consider, for example, oppositions to patent applications. At any given time, tens of thousands of patent applications for medicines are being

examined by the Indian Patent Office. PLHIV and patient groups have managed to file oppositions to only a small number. There are multiple patent applications related to a single medicine making the work of opposing patents all the more complicated. The patent system is very difficult to navigate, with its four offices in different parts of the country and no centralised, searchable database of applications pending with the respective offices. Moreover, the fees that must be paid to obtain information from the Patent Office tend to be beyond the means of most civil society groups. Still more money (and time) is needed to research and prosecute an actual case. Quite possibly many of the applications now pending deserve to be rejected, but the fact is that the offices are overwhelmed, and without the vigilance of patient groups, several may receive patents.

PLHIV are now extremely concerned about the proper implementation of Section 3(d) by the Patent Office. PLHIV and patient groups have concerns regarding the functioning of the four patent offices, access to information about patent applications, the training of patent examiners at US and EU patent offices and reports that the government is being pressured by industry to issue norms on the application of Section 3(d), which may well dilute the provision. Ensuring the proper application of the public health safeguards in India's patent law is an ongoing challenge, demanding constant vigilance by public interest groups.

4.2 Countering industry PR: Do patents really encourage innovation?

Following the judgment in the imatinib mesylate case, Novartis and various multinational pharmaceutical industry associations have expressed concern that public health safeguards in Indian law are a deterrent to medical innovation and will discourage foreign investment in India. KM Gopakumar of Centad points out, however, that the period when India was strengthening its patent laws saw a decline in investments in R&D by Novartis.⁸⁹

The WHO's Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH) has also provided evidence to counter these arguments.⁹⁰ The CIPRH report indicates that the implementation of the TRIPS agreement in developing countries will not significantly boost research and development in pharmaceuticals for diseases relevant to developing countries. Instead, it notes, it is lack of market incentives that deters research and development and not the level of intellectual property protection. There is today a critical gap in R&D funding for diseases that most affect the developing world.⁹¹ This gap was first identified in 1990 as the 10/90 gap, that is 90% of global spending on medical innovation invested in less than 10% of the world's health problems.⁹² This gap continues to persist - of the 1,556 new chemical entities marketed between 1975 and 2004, 1.3 per cent were for tropical diseases and tuberculosis.⁹³ In the case of tuberculosis, the current test for TB is 125 years old, not 100% effective and cannot detect all types of TB; the medicines used in treatment today were developed over 40 years ago.⁹⁴

4.3 Compulsory licensing: creating political will

A big challenge in the struggle to ensure access to medicines is the battle to institutionalise the issue of compulsory licences. New medicines (that PLHIV will have to turn to as resistance to first-line medicines increases) may well be granted patents in India. Some already have, and already there have been instances of new medicines that may not have deserved a patent receiving one. If patents and high prices create barriers of access to these treatments, the government will have to consider issuing compulsory licences for their production.

Such a move requires tremendous political will and considerable public support. One generic company is already seeking a compulsory license that will allow it to export medicines to a neighbouring country. So far, it has had to spend six months on mere preliminaries. Though the provisions for compulsory licensing in India's law are extremely patient-friendly compared with the laws of other countries, they are

89 See K.M. Gopakumar, "Novartis' Response: A reality check," From the Lawyers Collective, Vol 22, No. 7, August 2007.

90 World Health Organisation, *Public Health, innovation and intellectual property rights: Report of the Commission on Intellectual Property Rights, innovation and public health*, 2006.

91 See Médecins Sans Frontières Access to Essential Medicines Campaign and the Drugs for Neglected Diseases Working Group, *Fatal Imbalance: The Crisis in Research and Development for Drugs for Neglected Diseases*, September 2001.

92 Global Forum for Health Research, *The 10/90 Report on Health Research 2003-2004*, 2004

93 MSF Campaign for Access to Essential Medicines, "What is wrong with R&D today?" available at <http://www.accessmed-msf.org/main/medical-innovation/introduction-to-medical-innovation/what-is-wrong-with-r-d-today/>

94 Treatment Action Group, *Tuberculosis Research and Development: A critical analysis*, Second Edition, October 2006

difficult to invoke and procedurally cumbersome.

The use of compulsory licensing in India has already come under attack from multinational pharmaceutical companies, who are promoting the idea that compulsory licences can only be granted in emergencies. The truth is otherwise Indian law contains multiple grounds for granting a compulsory licence, including circumstances where medicines are not affordable or available. Indeed TRIPS does not limit the grounds on which a country may issue compulsory licences.

4.4 Tracking and resisting bilateral and pharma pressure: data exclusivity and patent linkages

The patent system is, of course, only one part of the intellectual property regime. PLHIV groups must continue their vigil on the introduction of other monopolies - as in the case of data exclusivity, which, certain sections of the Indian government and western lobbies will surely continue to campaign for. This is evident from meetings between the USTR and the Indian MoH and reports of a free-trade agreement being negotiated with the EU.⁹⁵ Recently, India's drug regulator has announced that it will introduce patent linkages (see Chapter 1), meaning that it will not grant marketing approval for a generic version of a patented medicine, regardless of whether the patent is valid or not.⁹⁶

4.5 Facing new truths

While this paper focuses mostly on the actions of the PLHIV networks in relation to patents and intellectual-property rights, it is important to remember that this work forms an important component of the greater task of ensuring treatment access. PLHIV groups continue to struggle with the government HIV treatment programme. Second-line treatment was announced only in 2007 and is being provided at only two centres. Medicines for opportunistic infections, the first to be announced under the government programme, are still extremely difficult to obtain. In the Northeast, co-infection with hepatitis C is emerging as a critical issue. Meanwhile, an important hepatitis C drug has already been patented in India. And notwithstanding an existing and much-touted government programme on TB, HIV co-infection with TB is not getting the attention

it requires - particularly considering the emergence of multidrug-resistant TB.

There has also been a dramatic shift in international and national commitment towards providing treatment. From the heyday of the ambitious '3 by 5' programme, which spurred worldwide action, PLHIV groups are now facing a situation where domestic and international commitment is weakening. New estimates have halved the number of people said to be living with HIV in India. Several PLHIV interviewed for this chapter predicted that this would have a definite and negative impact on government commitment.

5. CONCLUSION AND RECOMMENDATIONS

After 1995, most of us had resigned ourselves to living with patents. HIV was an unusual disease in that it was devastating the North and the South. Frankly had it affected only the South it would not have got the attention it has. With strong advocacy in the North, treatment for HIV got a major push. And then when it wasn't available to the rest of the world, groups in the North and the South took up the issue of treatment and patents. HIV has challenged the paradigm; it has questioned the patent system in a way no other issue has.

- Amit Sengupta, Peoples Health Movement

Since 2005, PLHIV networks have successfully raised the visibility of the debate around the very complicated issue of patents and health. The inclusion of health safeguards in India's patent law and the dramatic upholding of one of these safeguards by an Indian court brought heart, vigour and energy to the movement for access to treatment. The unprecedented scale of national and international protests and actions on the Section 3(d) case drew attention to the plight of millions of patients around the world who depend on safe, effective and affordable generics from India. This has spurred the debate on IPR protection and research into medicines.

Challenges to patent monopolies arose naturally from the other work of PLHIV groups on the government treatment programme. It is telling that state HIV treatment programmes around the world commenced only when safe, effective and affordable Indian generics pushed down the prices of first-line medicine. Yet even today, cost is the

⁹⁵ Peter Mandelson, EU-India FTA to boost global growth, *The Economic Times*, 30 November 2007.

⁹⁶ Generic cos may not get nod to sell patented medicines, *Economic Times*, 26 April 2008

most important reason why governments refuse to provide universal access to treatment. The greater the pressure on governments from patients' groups to continue the provision of treatment, the greater the governments' commitment to ensuring the availability of affordable medicines. After all, the government, too, must buy its medicines.

This highlights the role and responsibility of the Indian government in ensuring access to treatment: under its Constitutional and international obligations, it has a duty to protect and preserve the health of its citizens. In relation to intellectual property rights, there are two critical areas in which the government has to act. It must ensure the strictest scrutiny of patent applications and seriously consider measures to overcome patent barriers to affordable medicines.

The work of PLHIV networks has revealed the cracks in a global patent system that has seen most countries grant monopolies on medicines indiscriminately to pharmaceutical giants, raising the cost of these medicines beyond the reach of patients. As difficult as the work on patents is, the Indian experience shows the indisputable benefits of ensuring that legal systems in developing countries can and do make full use of the flexibilities under TRIPS, so that only deserving products are granted patents. Challenging a patent after it has been granted or campaigning for compulsory licences is considerably more difficult than ensuring the strict scrutiny that will, in the majority of the cases, result in a patent being denied. Adopting obligations to grant patents only from the date required under TRIPS in India has allowed the generic manufacture of more medicines.

This is particularly in apparent contrast with other developing countries that have not balanced their commitments under TRIPS with their obligations to ensure access to treatment. In China, for example, PLHIV have no access to fixed-dose combinations (which are the standard treatment for HIV today), because of patents on the individual medicines. In Brazil, automatic patents for medicines that were granted patents in other countries have forced groups to work on building the political will to grant compulsory licences, while in South Africa people have had to approach the country's Competition Commission regarding the prices of patented drugs.

The flexibilities under TRIPS have been recognised

and endorsed by the international community in the Doha Declaration, by which each WTO member is bound. Developing and least-developed countries in the process of implementing TRIPS must use these flexibilities to the fullest. Doing so is no easy task - even India has not made full use of them. But its example has led to the Philippines introducing a provision similar to Section 3(d) in its own patents law.⁹⁷

The importance of generic production has been underscored by the recent announcement of significantly lower prices for second-line medicines negotiated with generic companies by the Clinton Foundation's HIV/AIDS Initiative. The lower prices indicate that competition from and among generic producers is the single most important factor in ensuring the affordability of essential medicines, whether they are ARVs, OI prophylaxes or medicines for co-infections.

The experience of developing countries in attempting to include public-health safeguards clearly shows the power of bilateral pressure. Where the obligations imposed by TRIPS have proved to be a heavy burden on patients, countries have been pressured to adopt 'TRIPS-plus' provisions through FTAs or as part of the agenda of other bilateral negotiations. The Doha Declaration's recognition and reaffirmation of the rights of each WTO member to implement TRIPS flexibilities is binding on every member, but despite this, some continue to undermine the ability of developing and least-developed countries to implement these flexibilities. The international community must reflect on its role in creating barriers that prevent patients' access to treatment and its reluctance to hold accountable countries that are instrumental in the creation of these barriers.

In 2006, the CIPIH report confirmed that the patent system has failed to provide incentives for medical R&D on diseases that are prevalent in developing countries. Serious consideration must now be given to re-thinking the mechanisms that promote innovation in medicine and ensure access to such innovation. This is the responsibility of every government.

Based on the CIPIH report, the World Health Assembly in May 2008 adopted a 'Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property'⁹⁸ that clearly recognises the

97 Lira Dalangin-Fernandez, Philippine's Arroyo signs cheaper medicines law, *Philippine Daily Inquirer*, 6 June 2008

98 *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property*, Sixty-first World Health Assembly, WHA61:21, 24 May 2008

need for alternative incentives for innovation and for improving and ensuring access to medicines. It is essential that public-interest groups promote the implementation of this resolution, which may help create alternative models for promoting innovation in the medical field, an outcome developing countries urgently need.

Whether in relation to patents and other intellectual property monopolies or the government's treatment programme, the struggles of the HIV movement are representative of the problems in providing treatment for most health conditions. HIV treatment activists should be more vocal in their support for similar work or action on other health conditions, as in the case of the Thai compulsory licences on cancer medicines. Lessons learned in the work on HIV should translate to other diseases. PLHIV groups should reach out to other patients' groups, and there should be national and international recognition of widely-experienced problems relating to access to medicines. The broader issues after all relate to the availability, accessibility and affordability of medicines and the same concerns are

there for medicines of other major diseases.

As it has on issues of stigma and discrimination, doctor-patient relationships, the rights of marginalised groups and so on, HIV has altered the prevailing discourse on intellectual-property rights. It has not only forced legal and policy changes on intellectual property and access to medicines but has also challenged public perception and notions that patents are good for public health and lead to innovation. The work of PLHIV networks has led many to ask. What medical innovations have actually taken place? Are they relevant to diseases faced by people in developing countries? If and when such medicines are discovered, will they be available to the people who need them, at affordable prices? PLHIV networks, side by side with various other groups in India and abroad, are today engaged in what has become the defining battle for access to treatment - not just in India, but across the world. The battle is long and hard, but it is one that people living with HIV are committed to fight. And with the lives and health of millions at stake, they are determined to win.

KEY RECOMMENDATIONS FOR PLHIV NETWORKS

- Working on intellectual property requires **constant capacity building** for PLHIV and their networks as these can be technical issues. You should **contact public interest lawyers** in your countries and **international legal experts working on public health approaches to intellectual property**. You should also **approach the WHO** to seek technical assistance on these issues.
- **Keep track of changes** in the intellectual property regimes in your country. These changes may come about as a result of the deadline for complying with TRIPS, negotiations on a free trade agreement and formal or informal bilateral pressure and lobbying.
- Your government should not change its intellectual property laws till the **entire transition period is over**.
- Ensure that your government makes **full use of TRIPS flexibilities** in its intellectual property laws. In particular, your patent laws should incorporate a **public health approach** to the grant of patent monopolies and **include among other public health provisions**:
 - provisions for **pre and post grant oppositions that allow patients and health groups to oppose patents**;
 - **strict patentability criteria**;
 - a **prohibition on evergreening**;
 - **broad grounds and simple procedures for the issue of compulsory licences**; remember that **emergency is only one of the grounds** and there can be several others; and
 - an **early working provision** that allows faster entry of generics on patent expiry.
- Ensure that your government **rejects all TRIPS-plus provisions** like extension of patent terms, data exclusivity, patent linkages, etc. Again the pressure to adopt such measures may come through free trade negotiations or informal bilateral and industry pressure as in the case of India.
- Be prepared to **engage with the legal system** whether it is to enforce constitutional and human rights guarantees of health in your country or to take on the actual work of challenging patents.
- **Take advantage of the wealth of knowledge and experience around the world** on this issue. If you are challenging patents, contact legal organisations in other developing and developed countries that are doing the same work and may have already opposed patents on medicines you are interested in opposing as well. Many developing countries are also resisting TRIPS-plus measures have developed considerable information and reports on these issues. For instance you could contact the Third World Network, the Lawyers Collective HIV/AIDS Unit (India), MSF and many others.
- Public health safeguards in your law could be undermined in practice for instance where patent examiners do not apply the safeguards or are trained in developed countries' patent systems that are different from your own. You can encourage your government to consult documents such as the Guidelines for the examination of pharmaceutical patents: developing a public health perspective - A Working Paper, January 2007 brought out by ICTSD, WHO and UNCTAD or consult organisations in developing countries doing similar work.
- You need global support to resist international pressure. Pressures on developing and least developed countries originate from countries where apart from several public interest groups, academics, law and policy makers and many others are already actively working on ensuring the affordability and accessibility of medicines. **Contact like minded public interest groups in other countries for advocacy and campaign support**.
- Work with **media** and use all methods and forms of communication at your disposal.
- **Sensitise law and policy makers** in your country as ultimately they will take the decisions on how your country implements TRIPS. Remember that those interested in pushing for greater intellectual property protection are doing this already and it is essential that law and policy makers are made aware of both sides of the debate and the impact of patent monopolies on health.
- The issues related to monopolies on medicines are not specific only to HIV; **work with patient and health groups** in your country to sensitise them on issues related to affordability and accessibility of medicines and develop a common understanding and agenda for action on intellectual property related issues. Ensure that there is regular communication and sharing of information with health groups.
- Patent monopolies and other intellectual property provisions have an impact across different fields - agriculture, software, food, environment and so on; **network with the broader public interest and human rights movement** to identify common areas of concern and opportunities of collaboration and support. You will need all the help you can get!
- Remember that working on patents and other aspects of intellectual property laws requires a **long term strategy** and successes may take time to materialise. As the pressure on your country to adopt a stronger intellectual property regime will likely be constant, it will require constant vigilance to counter such pressure.
- And most importantly, **speak out!** Those affected by monopolies on medicines can best explain the impact on their lives and health. This is not an issue exclusively for experts or academics. The PLHIV movement has had the most significant impact on instituting a public health approach to intellectual property laws.

SOME WORDS OF ADVICE

"Never ever compromise on access to treatment. It is our first right. We know all this negotiation for medicines is purely political - foreign governments and big pharma lobby with our government. Our voices need to be just as loud if not louder. We have learnt many lessons in our dealings with pharmaceutical companies. One particular company when we met them on the patent issue actually asked us to market their medicines for them and in exchange they would give us the medicines for free!! Ashok Pillai had the right idea when we started - not to create alliances with companies and after some of our current programmes are over we should consider going back to that stand. We cannot compromise our principles and our fights - if we are not free to do or say what we believe, we have already lost the war. Our campaigns must be sustained - one World AIDS Day is not enough - the campaign must be long term."

- Elango Ramchander, INP+

"The first question we have to ask is if it's OK that with treatment available people continue to die or fall into prolonged illnesses. Are we happy just writing a condolence letter or lighting a candle? If the answer is 'no' your movement starts there and then. You have to get angry before you can do anything. Networks must constantly ask themselves - 'who are we?' 'who are we working for?' The most important thing is to save lives. For all of us now there is lots of travel, lots of hotels, lots of meetings - all that is fine but at the end of the day we have to face ourselves and our constituents. We must always call a spade a spade. There is this trend of us becoming like contractors when the government or some donor or other persons fund us - so we must ask are we working for ourselves or the donors? Getting money is easy - write a proposal and send it - will it shut your mouth? Every single night we have to re-commit ourselves to this fight."

- Loon Gangte, DNP+

"It is important to take action against MNCs who are trying to monopolise treatment as this violates the basic health rights of common man. Apart from food, clothing and housing, medicines for PLHIVs have become a basic necessity and by monopolizing essential medicines the MNCs are violating the basic health rights of PLHIVs, which is criminal. That's why there is a need to stand up and fight united against these criminal advances of MNCs. We should all unite together for this cause and we require the backing and support of our government. We have learnt from the Thai government, we feel that the networks should support the governments who stand against patents and provide access to medicines and treatment. The networks should mobilize other stakeholders like media, civil society, doctors, etc to join this campaign."

- Jaya Nair, UDAAN Trust

In India positive people have been successful in fighting against patents. This has been possible because of the joint effort with lawyers and other activists. Positive networks like ours have a great role to play in protecting health in this commercialized health setup. We have to get the government to issue compulsory licences if the MNCs get patents for second line and third line regimens. This is not only going to affect positive persons but also other patients groups and that is why we have to oppose and protest against the medicines getting patented by MNCs. Other networks should also educate themselves and oppose patents and other IPR related issues.

- Kousalya, PWN+

In India one of the big mistakes was that the health movements did not give adequate attention to HIV. There is a danger when this happens as a health problem then takes on a separate trajectory with different health movements looking at different issues instead of the big picture. And HIV particularly is a big picture disease - it cuts across gender, age, poverty, trade issues. Access campaigns should not get too medicine focused. Health systems have to be a major part of the campaign as does the rational use of medicines. Working to ensure access to treatment is a big responsibility and its best to have well thought out strategies. In India a combination of actions has worked - people on the street supported by media and larger organizations have been quite effective. On organizational levels, PLHIV movements and groups should be careful not to become fragmented and become individual based.

- Amit Sengupta, Peoples Health Movement

PLHIV networks are very enthusiastic people but they need to be more organised, more professional and they have to improve communication techniques so that larger number of people to be acquainted with the issues. They should join hands and work together with other groups - as the issue is about unaffordable drug prices and frivolous patents. The groups should work jointly with other organisations like MSF, OXFAM and many others like trade unions so that we achieve our objective. We need to bring the general public into the campaign. MNCs are trying to misuse the Indian Patent Act by trying to get frivolous patents. We have to be alert of the profiteering motives of the MNCs which are at the expense of the life of people in India. As campaigns we are not attacking the root-cause - we are attacking in a piecemeal manner. We need a provision in the law which will make life saving drugs affordable for the poor. MNCs should be rewarded for their research but at the same time the poor should be able to afford treatment.

- Y.K. Sapru, CCAA



THAILAND

Brigitte Tenni, Thai Network of People Living with HIV (TNP+)

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1. BACKGROUND

1.1 The Creation of TNP+

To date, over one million people in Thailand have been infected with HIV and more than 400,000 have died of AIDS.¹ After the first case of HIV was detected in 1984, the epidemic spread quickly from vulnerable groups such as sex workers, men who have sex with men (MSM) and injecting drug users (IDU) to the general population, most notably in the north and north-east of the country.² By the early 1990s, over 100,000 Thais a year were being infected.³ Increased awareness of the way in which HIV is transmitted and a concerted national campaign to increase the

1 UNAIDS/WHO, *AIDS Epidemic Update*. December 2006. Geneva; 2006

2 Phanuphak P, Lochareernkul C, Panmuong W, Wilde H., 'A report of three cases of AIDS in Thailand', *Asian Pac J. Allergy & Immunol.* 3:195-199; 1985

3 UNDP, *Thailand's Response to HIV/AIDS*. 2004

use of condoms helped reduce the incidence of HIV infections to 19,000 per year by 2003.⁴

Thailand has since become internationally renowned for its swift and effective response to the AIDS epidemic. It is one of few countries in its region to provide universal access to standard care and treatment for its HIV-positive population. By the end of 2006, over 80,000 people living with HIV/AIDS (PLHIV) were receiving ARV medication through the public healthcare system.⁵ This achievement has resulted from a combination of political will, the ability to produce generic ARV medicines locally and, perhaps most notably, strong PLHIV advocacy and civil-society groups.

The Thai Network for People Living with HIV/AIDS (TNP+) was formed in 1998 in recognition of the need to coordinate the activities of existing PLHIV groups around the country. TNP+ is made up largely of farmers, agricultural workers, housewives, factory workers and the unemployed and is highly representative of the rural poor.

Prior to 1998, PLHIV groups were isolated and lacked both cohesion and the ability to advocate political and social change. Many HIV-positive people were unaware of treatment options and were uninformed of the many healthcare issues involved in a positive diagnosis. The majority of existing PLHIV groups were situated in the upper north and the north-east, where the greatest number of PLHIV lived.

Initially, most PLHIV group activities were focused on providing help and support to members. These activities included monthly meetings that provided opportunities for members to meet with friends and share up-to-date information. PLHIV groups also undertook home visits to support their friends in times of ill-health and provided economic support and funds for the education of children affected by HIV/AIDS. Many PLHIV joined groups for moral support and to feel understood by people who were experiencing similar hardships. As former TNP+ chairperson, Kamon Uppakaew says,

It was particularly important to have this space (TNP+) in our lives because we didn't have (it) in society – especially in the beginning, when there was very little acceptance of us – an emotional space where we could share our experiences with each other and be able to face the things that we

had to face with friends. It was also because we didn't want to die – we wanted to live.

PLHIV groups continued to build on their existing capacity, expanding their services to include the dissemination of HIV/AIDS information to people in affected communities, educating them about the problems facing PLHIV and involving them in problem-solving strategies for HIV/AIDS-related issues.

In time, many groups found that these activities did not address some of their peers' most pressing needs. It became evident that many group members had not yet received appropriate treatment. Human-rights violations against PLHIV and children affected by HIV/AIDS were still commonplace. Also, there was very little public knowledge about HIV/AIDS, resulting in widespread misunderstanding, fear and discrimination.

To combat this, PLHIV groups from different parts of the country began meeting to share and explore new strategies and methods of addressing stigma and discrimination and to work towards gaining greater access to quality care and treatment. This created a provincial and regional network of PLHIV working on HIV/AIDS and advocacy issues.

In 1997, the first meeting of PLHIV groups from all over the country took place at the Royal Hotel in Bangkok. It was known as the Assembly of Thai PLHIV. Three regional networks were established: one in the upper north region, one in the central region and one in the north-east region. Each network devised goals and a work plan and elected a committee to serve as a working group to address HIV/AIDS problems in its region. Their directives, however, were regionally focused, since they had not yet devised a common strategy for working at the level of national policy.

In 1999, the second National TNP+ Assembly was held in Nong Khai Province in the north-east of Thailand. Group leaders from six regions – upper north, lower north, north-east, central, east and south – participated. At that time, the southern regional network had not yet been established, but representatives from some southern groups participated in the meeting.

At the Assembly, the network devised common goals, a working plan and practical working

⁴ Ibid.

⁵ World Bank, *The Economics of Effective AIDS Treatment: Evaluating Policy Options for Thailand*. 2006

guidelines on access to treatment. It also gained support from and aligned itself with NGOs, AIDS ACCESS Foundation and MSF Belgium in Thailand. Initial activity focused on the prevention and treatment of opportunistic infections (OIs) and later expanded to work on accessing ARV treatment.

The second Assembly marked a turning-point in the development and direction of TNP+. It was the first time PLHIV devised clear goals and strategies for themselves within a unified national network. It also signalled the beginning of the long struggle for access to quality care and treatment.

1.2 TNP+ today

Since its inception, TNP+ has tried to represent the aims and aspirations of all PLHIV in Thailand and to involve PLHIV in decisions that affect their lives and their future.

TNP+ aims to ensure:

- equitable access to an acceptable standard of healthcare, including prevention and treatment of OIs, ARV and reproductive health for all PLHIV including women, children, MSM, IDUs, sex workers, unregistered populations, migrants and prisoners;
- that PLHIV can live in the community free from stigma and discrimination and can participate freely in activities aimed at solving HIV-related problems;
- that PLHIV groups function smoothly, with adequate communication, coordination and cooperation between group leaders and group members, so that all members have the opportunity to participate in group activities;
- financial transparency and accountability of PLHIV groups and TNP+ as a whole; and
- that PLHIV networks operate in a clear and precise manner with coordination between their constituent groups.

Currently, TNP+ supports seven regional networks, comprising over a thousand PLHIV groups and over 100,000 PLHIV nationwide. Its central committee is made up of two representatives from each region. Its central administrative office is in Bangkok (see Annex 2 for an organogram of TNP+).

TNP+ receives the bulk of its funding from MSF Belgium and the Global Fund to Fight AIDS, TB and

Malaria (GFATM). It also receives support from UNDP and Forum Syd.

Over the past years, TNP+ has been heavily involved in numerous advocacy campaigns aimed at improving access to treatment for PLHIV and to promote the involvement of PLHIV in their own healthcare and treatment and in policy decisions that affect their lives. Barriers to achieving these aims have been local, national and increasingly international in nature. TNP+ has tackled these issues as they arose. In doing so, it has had to educate itself about complex issues and draw on its unity and collective strength. This has not always been easy; it has often taken many years of hard work and determination to achieve its goals. Advocacy work has seen TNP+ challenge Thai laws and policies and file lawsuits against multinational pharmaceutical companies. The network has also worked persistently to oppose bilateral trade agreements and international treaties that seek to strengthen intellectual property rights in Thailand and threaten to deny access to generic medication. These campaigns will be described in detail below.

2. ACCESS TO TREATMENT CAMPAIGNS

The role of PLHIV networks in securing access to generic ARV medicines and the supporting role of partner organisations

2.1 Public healthcare scheme

Prior to 2001, Thailand lacked a public health system that provided universal access for all Thai citizens. The three health insurance schemes that existed were:

- private health insurance
- health insurance scheme for public servants
- employees' health insurance

These schemes excluded most Thai citizens, who were left to fund their own healthcare. Prior to the 2001 election that brought Thaksin Shinawatra and his Thai rak Thai party to power, TNP+, together with other civil-society groups, campaigned for the introduction of a universal healthcare scheme that covered all Thais. It was clear that the creation of a universal public healthcare scheme was essential for the sustainability of any comprehensive care and treatment package for PLHIV. TNP+ joined an alliance with

- AIDS networks
- The Foundation for Consumers
- Disabled People's Network



ARV for 30 Baht⁶ scheme protest, Bangkok

- slum communities
- women's networks
- youth networks
- seniors networks
- labour networks
- networks of ethnic minorities
- farmers networks and
- community banks

to collect 50,000 signatures in support of the introduction of such a scheme. This took more than a year. The petition was finally presented to Parliament in 2001 (the 1997 Thai Constitution affirms that if 50,000 supportive signatures are collected, a bill can be presented to parliament).⁶

Thai rak Thai, recognising the popularity of the proposed scheme, introduced a bill based on what the people's alliance initiated, making Thailand one of the first middle- or low-income countries to introduce universal healthcare coverage. The National Health Security scheme was launched by

the newly elected Thaksin government in April 2001 and became widely known as the '30 baht scheme' after the standard fee assigned for all treatments. This system covered all previously uninsured people and those from the lowest income groups – in all, more than 47 million people or 75 percent of the population.⁷

Although universally popular with Thais, the scheme failed to include ARV treatment for HIV/AIDS and other conditions considered too expensive to treat, such as kidney dialysis. This was bitterly disappointing, given how hard the AIDS network had campaigned on behalf of the scheme and the fact that AIDS was now one of the leading causes of death in Thailand. There were reassurances from the government that when treatment for HIV fell below 2,500 baht a month, it would be considered for inclusion in the public-health system.

In 2002, the Government Pharmaceutical

⁶ Constitution of the Kingdom of Thailand, Foreign Law Division, Office of the Council of State 11 October 1997.

⁷ Tangchareonsathien, V., data from *Health and Welfare Survey 2003*, conducted by National Statistics Office, Thailand.

Organisation (GPO) commenced manufacture of a single-pill triple ARV regimen, which significantly reduced the price of treatment. However, the government proved reluctant to fulfil its policy promise once the price reduction had been announced. TNP+, together with several other activists, PLHIV, NGOs and interested parties began a campaign to address the injustice of their exclusion from the public health scheme. They held a protest in front of Government House in November 2001 to publicise their cause. The Health Minister at the time, Sudarat Kayuraphan, personally promised to guarantee treatment for HIV/AIDS but cautioned that it would be a staggered process, requiring further investigation and strengthening of the healthcare system. The promise was finally kept in October 2005.⁸ At the outset, only first-line treatment was covered; this was made possible and affordable by the GPO's ability to produce standard-quality generic ARVs.

2.2 Opposing the strengthening of patent laws

In September 1998, around 30 representatives from several NGOs, including the Thai NGO Coalition on AIDS, the Coordinating Committee for Primary Healthcare of Thai NGOs, AIDS ACCESS Foundation and MSF Belgium demonstrated in front of the US Embassy to demand that the US stop pressuring Thailand to amend its 1992 patent law.⁹ Although this was a very small protest and failed to stop the



Protesting outside government house, Bangkok



ARV for 30 Baht' scheme protest, Bangkok

patent law being tightened, coverage in the local English press sparked interest among large international NGOs such as MSF, leading to their involvement in and support for future access campaigns.

2.3 Bringing down the price of medicines: The ddl case

Before 1997, there was little understanding within the PLHIV community of HIV/AIDS. Access to ARVs was negligible due to underdevelopment of the public health system and the exorbitant price of such medicines. In a bid to make ARV medication cheaper and more accessible to needy PLHIV, TNP+, together with a coalition of NGOs, PLHIV and academics, lobbied the government to issue a compulsory licence (CL) allowing the Government Pharmaceutical Organization (GPO) to produce generic didanosine (ddl) tablets. This was an important ARV drug at the time, patented by Bristol-Myers Squibb (BMS), a US pharmaceutical company. The GPO, meanwhile, had carried out research on the production of a generic version of ddl with a soluble antacid buffer and had ordered raw materials for its production in the event of a CL being granted.

In late 1999, TNP+ staged a three-day protest in front of the Ministry of Public Health (MoPH) in an attempt to push the government to issue a CL for ddl in tablet form. This marked a turning point in

8 Kiatying-Angsulee N, Sringernyuan L, Haritavorn N. *Beyond the Targets: Assessment of Public and Private ARV Treatment Programmes – Thailand Country Working Paper*. HAI Europe; May 2006. <http://www.hai-europe.org> Statistics Office, Thailand.

9 Assavanond A., 'NGOs rally against patent law changes: Call on US to stop pressuring Thailand'. *Bangkok Post*, 5 Sept 1998.

PLHIV activism: the first time the PLHIV network came together to articulate publicly its members' right to healthcare. PLHIV made up over half the 200 people who participated in the protest. Academics, lawyers and experts in the field came to speak with them during those three days, to show solidarity and help educate them further about these often complex issues. The protest generated considerable media coverage and interest from politicians and NGOs.

Despite the best efforts of PLHIV, the Thai government refused to issue a CL, fearing economic implications and reprisals from the US. Not to be discouraged, the alliance endeavoured to get the patent on ddl revoked in the Intellectual Property Court on the grounds that it had been unlawfully issued.

An unlikely alliance was formed between PLHIV, NGOs, the Law Society of Thailand, pharmaceutical academics and the Foundation for Consumers. TNP+ played a pivotal role in this alliance, which was also joined by the Drugs Study Group, a network of university academics formed to fight for improved and protected consumer access to medicines. TNP+, like many other HIV/AIDS NGOs, lacked information and expertise concerning patent law and the rules and regulations of the World Trade Organisation (WTO). It relied on experts for advice and direction. In 2001 the alliance filed a lawsuit against BMS for revocation of the ddl patent.

After careful investigation and analysis, three major objections to the granting of the patent had been discovered. They were:

1. The patent registration process was flawed.

The 1992 Thai Patent Act came into effect on 1 August 1992. BMS had applied for a patent on ddl on 7 July of that year, some three weeks prior to the Act becoming effective. Hence there was no drug patent law in existence when BMS applied for the ddl patent.

2. Lack of dosage specification. On 15 December 1993, the Department of Intellectual Property accepted a BMS application that covered all formulations of ddl with an insoluble antacid buffer within a unit dosage of 5-100mg. When the patent was issued to BMS on 22 January 1998 there was no indication of unit dosage. The patent on ddl was, effectively, much

broader than initially stated, lacking clear limits.

3. The invention did not contain a significant inventive step. Didanosine (ddl) was invented by the American Health Institute. This US government body granted the right of production to BMS, which marketed the drug in tablet form combined with an antacid buffer. BMS's ddl patent application was rejected twice in the US before finally being granted on appeal. The reason given for the initial rejections was that adding a well-known antacid buffer did not constitute an inventive step. The Thai group similarly rejected BMS's inference that the addition of an antacid buffer constituted an inventive step and therefore furnished grounds for granting a patent.¹⁰

Two lawsuits were filed in the Intellectual Property (IP) Court. The first aimed at restoring the unit-dosage limits on the original patent. It also sought clarification in court as to who might be deemed an 'interested party' in the case (in the past, cases in the IP Court had only been brought by rival companies, never by individuals or consumers; this was the first case in which the IP Court allowed a legal challenge by consumers).

Several PLHIV were chosen as plaintiffs in the case. The court ruled in their favour on both issues, stating that, "the three plaintiffs have the right to pursue this case. Invention details and patent-rights details are deemed significant to the invention. The exclusion from the patent-rights details is an addition of significant meaning to the invention, which is legally prohibited."¹¹ The case was concluded on 1 October 2002 after a period of one year and five months in court. In the meantime, two of the plaintiffs had died.

The second case pleaded to have the patent withdrawn on the grounds that:

1. the invention was not eligible for protection in relation to the 1979 Patent Act, which was in force until 30 September 1992;
2. the invention was not new, as significant details of the invention were already in the public domain; and
3. the enteric-coated ddl did not comprise a higher level of invention according to Clause 5

10 Wisartsakul W. *Civil Society Movement to Revoke the Thai Patent on ddl*. Médecins sans Frontières Belgium; July 2004.

11 Ruling, Central Intellectual Property and International Trade court, October 2002

(2) and Clause 7 of the Thai Patent Act.

Three PLHIV and the Foundation for Consumers were the plaintiffs in this case, bringing suit against BMS as first defendant and the Thai Department of Intellectual Property Rights as second defendant. They requested that the court revoke the existing patent on ddl and order the defendants to reimburse the plaintiffs for all legal costs incurred.¹²

During the case, BMS made several attempts to compromise both on the price and the distribution rights for ddl and stavudine, another BMS-produced ARV. It proposed to appoint the GPO distributor for ddl and even offered to reduce the price of the medicine. However, the case had been brought not only to help make drug prices more affordable but also to demonstrate to the public that the Department of Intellectual Property Rights had wrongly granted a patent to BMS and that this was unacceptable. The plaintiffs therefore rejected BMS's offers. The two court battles combined took over three years to conclude and required unyielding dedication from a wide network of activists.

In December 2003, after intense pressure, BMS voluntarily terminated its claim on the ddl patent.¹³ This was a huge victory for PLHIV in Thailand. It meant that the GPO could now produce ARV medication and make it available at a fraction of the previous cost. It was also a victory for basic human rights, highlighting the principle that access to safe and affordable medication is a right that should be enjoyed by all.

Former TNP+ chairperson Kamon recently explained the significance of this victory for the PLHIV movement and the battle to improve access to medicines:

This was an important advocacy lesson. It relates to our work on Combid and the current Abbott fight. Pharmaceutical companies now know that if they're going to work in Thailand they could lose these kinds of cases. That is what we have shown through our movement.

In addition to these courtroom battles, much was done behind the scenes to raise public awareness of the issues facing PLHIV in Thailand. It was a conscious goal of the working group to raise awareness not only of the ongoing court case, but



Dedication from a large network of activists resulted in huge victory for PLHIV's in Thailand

also to highlight the issue that patents on medicines 'affect you and need your attention.'¹⁴ This was accomplished by lobbying politicians and mobilizing the media. TNP+ volunteers were responsible for issuing press releases and keeping journalists informed of the trial proceedings. They also arranged academic seminars and newspaper and television appearances, all with the intention of garnering public support and creating greater public awareness of the effect drug patents can have on patients' access to medication.

2.4 US-Thai free trade agreement

In recent years, the US has been pursuing bilateral free-trade agreements (FTAs) with numerous countries in an attempt to enforce protectionist measures above and beyond what is required by the WTO. The US and Thailand began negotiations on a bilateral FTA in June 2004. To date there have been six rounds of talks, two in Thailand and four in the USA. Although the talks are shrouded in secrecy, it is expected that the proposed agreement will cover agriculture, investment, the service industry and intellectual-property rights in the same fashion as other bilateral agreements the US has signed to date.

TNP+ is concerned that a Thai-US FTA will strengthen existing patents on medicines, leading to an increase in the price of drugs. For a country with a large PLHIV population, such an outcome could jeopardise the government's ability to provide universal access to ARVs through the national healthcare system. Consequently, TNP+ has been instrumental in disseminating information about the implications for Thailand of signing the agreement.

TNP+ is also concerned about the deficiency of democratic consultation and input with respect to

¹² Wisartsakul W. *Civil Society Movement to Revoke the Thai Patent on ddl*. Médecins sans Frontières Belgium; July 2004.

¹³ *Ibid*

¹⁴ *Ibid*

the proposed agreement and negotiations towards it. Unlike the United States, Thailand does not require an FTA to pass through any parliamentary process prior to signature. There is no scope within the approval process for civil-society scrutiny or input. In addition, both the text of the proposed FTA and the talks on it are in English, creating a power imbalance in negotiations favourable to the United States.

Parts of the text of the proposed agreement, leaked to the press, confirm fears about the extent of US demands. In the ip chapter, the agreement proposes to

- extend the patent life of a drug to accommodate 'unreasonable' delays in the granting of a patent;
- allow the patenting of therapeutic and diagnostic procedures;
- extend the responsibilities of the FDA to include acting as a patent watchdog;
- enforce a data-exclusivity period of five years;
- restrict the grounds for compulsory licensing and parallel imports;

- prohibit the revocation of patents;
- enforce accession to patent cooperation treaties; and
- prohibit pre-grant opposition to patents.¹⁵

The right to produce patented drugs would be restricted under such an agreement. In consequence, local pharmaceutical companies currently producing generic ARV medication, as well as the Government Pharmaceutical Organization of Thailand (GPO), may be unable to turn a profit from the manufacture of generic drugs, or find them too expensive to produce.

TNP+ staged numerous protests during each of the negotiating rounds held in Thailand. It was joined in these protests by other NGOs, activists and various groups affected by the FTA, such as farmers and agricultural workers.

The second round of negotiations, held in Pattaya in December 2004, saw over 2,000 protesters taking to the streets to demonstrate. In January 2006, during the sixth round, over ten thousand people congregated in Chiang Mai to register their



Civil Society Group protesting a US-Thai FTA, Chiang Mai

15 Draft text, US-Thai Free Trade Agreement, 2006.

opposition and improve public understanding of the negative ramifications of the proposed agreement. About half the protesters at Chiang Mai were TNP+ members. Others included representatives of the agricultural workers' network, farmers' networks, the Land Reform Network, the Assembly of the Poor, the slum network, the labour network, the Foundation for Consumers and members of an NGO formed specifically with respect to the agreement, FTA Watch.

The protestors, although unsuccessful in putting a permanent stop to the talks, were successful in delaying them and having them move to an alternate location. They were also able to gain substantial media coverage and stimulate debate on the FTA issue in Thailand. The demonstrations were front-page news for weeks, greatly helping to raise public awareness of the US-FTA issue.

Besides organizing and participating in these protests, TNP+ members took part in a speaking tour of the US in order to draw attention to the issue in that country. The subject of the tour was the negative ramifications of a US-Thai FTA on access to medicines in Thailand. It was sponsored by Oxfam America in conjunction with Engage, an NGO based in the US, and took place in December 2006. Three speakers participated: Boripat Donmon from TNP+ East, Sangsiri Teemanka, an activist from AIDS ACCESS Foundation, and Jiraporn Limpanont, a pharmaceutical expert from Chulalongkorn University. The touring group visited eight cities and spoke to Congressmen and -women with the aim of influencing policy from the US side.

Subsequent to the military coup of September 2006, the US government suspended FTA negotiations until a democratically-elected government was again in power in Thailand. This effectively meant that the proposed agreement could not be passed by Congress before the expiration of US 'fast-track' authority in July 2007 (fast-track was a special authority granted the President of the United States to negotiate trade agreements that Congress could approve or disapprove *in toto* but was not permitted amend or delay). With the expiry of fast-track, any proposed trade agreement would now come under close Congressional scrutiny and debate, making its passage considerably more difficult.

The new Thai Constitution of December 2007 includes a clause that specifically requires civil-society participation in future FTA negotiations. All bilateral trade agreements must now be presented in parliament for debate and approval. This has



TNP+ members protest a US-Thai FTA, Chiang Mai

been celebrated as a small victory for opponents of the FTA.

TNP+ continues to monitor the process of negotiations closely and to ensure that its members are well informed of the situation. It hopes to strengthen its alliances with other countries facing FTAs with the US, such as Malaysia and South Korea, and will be ready to continue the fight if future governments decide to resume negotiations.

2.5 Compulsory licensing

After eight long years of lobbying, the Thai government issued compulsory licences (CL) for two ARV drugs, Efavirenz and lopinavir/ritonavir (Kaletra) and for clopidogrel, an anti-clotting agent, on 26 January 2007.

Following the announcement of its decision to issue a compulsory licence for Efavirenz in November 2006, the government was immediately locked in talks with Merck, which holds the patent on Efavirenz in Thailand until 2013 (Abbott laboratories holds the patent for lopinavir/ritonavir, which is sold under the brand name Kaletra, while Sanofi Aventis currently holds a patent for clopidogrel, which is sold as Plavix). Concurrently, the Thai Ministry of Foreign Affairs and the Ministry of Commerce were pressurized by the Thai Pharmaceutical Research and Manufacturers' Association (PRReMA), the US ambassador and the Swiss ambassador to prevent the issue of these licences by the government. Despite this pressure, the Thai Health Minister, Mongkol na Songkhla, signed the licences and imported a generic version of Efavirenz manufactured by the Indian pharmaceutical company Rambaxy.

The Government Pharmaceutical Organisation (GPO) has plans to manufacture generic Efavirenz but is still completing bio-equivalence studies. It is expected that production will be possible in six months' time. The government also has plans to import a generic version of Kaletra from another Indian generic company, Matrix, though it has not yet done so as it currently holds a stockpile of Abbott-manufactured Kaletra. At time of writing, the GPO is researching the possibility of manufacturing a generic version of Kaletra in Thailand.

This was a ground breaking decision for Thailand's military regime and came after years of lobbying previous governments by TNP+, AIDS ACCESS Foundation, MSF, academics and other HIV activists and organisations. A coup saw Thaksin deposed from power in September 2006, and a military government installed.

A working group was set up by the National Health Security Office (NHSO) in 2004 to look into the possibility of issuing CL and providing the MoPH with technical advice concerning this issue. This working group has included NGO representatives, among them TNP+, since its inception.

Thailand tightened its patent law under pressure from the US trade representative in 1992. A further amendment in 1998 resulted in a patent law that is stricter than what is required by WTO regulations. However, the ability to issue compulsory licences

was retained as a viable legal option in order to ensure access to high-quality yet cheaper versions of patented ARVs. In 2006, the World Bank identified the use of compulsory licences by Thailand to procure less expensive generic medicines as a strategy to address excessive costs associated with providing second-line treatment.¹⁶ It is estimated that the compulsory licence for Kaletra alone will save Thailand as much as US\$24 million a year.¹⁷

In a defiant response to the compulsory licence, Abbott Laboratories withdrew all its medicines awaiting registration and refused to register any new pharmaceutical products in Thailand. This denied Thais access to Aluvia, the new heat-resistant formulation of Kaletra, as no generic equivalent was on the market at the time. Kaletra is WHO standard medication and is of obvious value in a tropical country like Thailand.

Abbott also refused to negotiate use royalty with the Ministry of Public Health. Merck and Sanofi Aventis have rejected the 0.5 percent offered by the government.

TNP+ and AIDS activists around the world rallied together to condemn Abbott's actions. TNP+, together with

- AIDS ACCESS Foundation
- Thai Foundation for Consumers
- Thai Rural Doctors society
- Thai Chronic renal failure network
- Thai Alternative Agriculture network
- Thai Parents network
- Thai Rural Pharmacist society
- Thai NGOs Coalition on AIDS and
- FTA Watch

called for a global boycott of Abbott products and held protests outside the company's offices, demanding that it register essential medicines in Thailand. A global day of action was scheduled for 26 April 2007 to garner global support for the Thai government's decision and to denounce Abbott's tactics. In Bangkok, TNP+, AIDS ACCESS Foundation and an alliance of supporting organisations and individuals marched to the Thai Ministry of Commerce's Intellectual Property office to demand that the Thai Trade Competition Commission instigate criminal proceedings against Abbott for being in breach of Thai competition law 25(3), which prohibits a dominant firm from



A large crowd in Thailand protests Abbott Laboratories' decision to withdraw all their medications awaiting Thai registration

16 World Bank, *The Economics of Effective AIDS Treatment: Evaluating Policy Options for Thailand*. 2006

17 Reuters, 'Thailand allows copycat AIDS, heart disease drugs', Bangkok; 2006.



One of the many protests against Abbott Laboratories' that took place across the globe in alliance with Thailand

suspending, reducing or restricting services, production, purchase, distribution, deliveries, or importation without justifiable reasons¹⁸

The demonstration then made its way to the business district to engage and educate the public concerning this issue.

Actions against Abbott took place across the globe in solidarity with the Thai initiative. Groups from Argentina, Brazil, Canada, China, France, Germany, India, Indonesia, Japan, Nepal, Singapore, South Korea, the UK and the US participated in demonstrations to coincide with Abbott's annual general meeting, which was held on 27 April at the company's headquarters in Chicago. TNP+ activist and chairperson Wirat Purahong and long-time HIV activist and former Thai senator Jon Ungpakorn flew to the US to participate in a speaking tour highlighting the importance of CLs as a legitimate means of improving access to essential medicines and denounce Abbott's actions and attempts to prevent other developing countries from making use of the exemptions granted them in TRIPS. Jon and Wirat also attended the Abbott AGM at the



A large Anti-Abbott protest in India

invitation of a group of Abbott shareholders.

Just prior to its AGM, Abbott agreed to register new-formula Kaletra on condition that the Thai government did not issue a compulsory licence. TNP+ denounced this demand as blackmail, pointing out that they failed to address Abbott's decision to withdraw six other drugs awaiting registration. To date, the Thai government has not agreed to these demands.

¹⁸ Section 25, Thailand Competition Act 1999.



Anti-Abbott protesters hand out leaflets in China



Protesters in Nepal arrange a sit-in against Abbott

2.6 Price reductions

After the compulsory licence was issued, Thai health authorities purchased a WHO pre-qualified generic form of Efavirenz from Ranbaxy. The cost of treatment with Ranbaxy's generic is 650 baht (US\$20) per patient monthly, compared with the Merck price of 1,400 baht (US\$43). More than 66,000 bottles were imported on 5 January, 2007. This stock was expected to last three to four months, allowing healthcare providers to treat an additional 20,000 people for the same cost. Subsequent to the issue of the CL, Merck and

Abbott offered significant price reductions – a move that demonstrates how CLs can dramatically reduce the price of essential drugs. Merck offered to reduce the price of Efavirenz to \$23 per bottle; however, this offer was rejected as the price was still higher than that of the Indian generic.

Encouraged by Thailand's efforts, the Brazilian government announced that it had taken the first step towards issuing a compulsory licence to import the Indian generic version of Efavirenz. The decision came after the original manufacturer, Merck, refused to sell the drug to the Brazilian government at the same price it had offered the Thai government. The Brazilian government demanded a price of US\$0.65 per daily treatment, compared to the current price of around \$1.60 – a price reduction of almost 60 percent. Efavirenz is currently used by 75,000 patients in Brazil, and costs the Brazilian government \$43.8 million a year.

2.7 Abbott responds

On the eve of its AGM, Abbott announced plans to reduce by more than half the cost of Kaletra in Thailand and more than forty other low- and low-middle-income countries. The company offered to provide Kaletra in these countries for \$1,000 per patient per year, less than the cost of generic

versions of the drug (originally, the company's price was \$2,200) (Abbott provides the drug at a cost of \$500 per patient per year in 69 of the poorest developing countries, including all of Africa¹⁹). However, Kaletra is not registered in all countries where the price reductions are being offered, making the new deal meaningless.

This price reduction did not affect the availability of the drug in Thailand, where Abbott still refused to register it.

2.8 USTR downgrades Thailand

On 1 May 2007, the US Trade Representative Office (USTR) downgraded Thailand from 'watch list' to 'priority watch list'. The US Ambassador to Thailand, Ralph Boyce, said that the Ministry of Health's decision to issue CLs was only one factor in the decision. However, it was one of the main reasons cited in the USTR's Special 301 report.²⁰ Pressure from Abbott Laboratories and other pharmaceutical companies affected by recent CLs has also been cited by many others as a critical factor. United States law

enables the US to take trade action or seek dispute settlements with countries placed on these lists.

The downgrade came despite the USA having conceded that the Thai-issued CLs were in complete compliance with WTO rules and Thai law. Their concern, they said, was due to a 'lack of transparency exhibited in Thailand.'²¹



South Koreans also organize a protest against Abbott



Protesters in the US hold an event to coincide with Abbott's AGM

19 Abbott Laboratories, 'Abbott Agrees with WHO Director-General to Expand Access to Kaletra/Aluvia (lopinavir/ritonavir)'. Abbott Park, Illinois; 10 April 2007.

20 USTR Special 301 report, May 2007.

21 *Ibid.*

TNP+ is not alone in viewing this decision as reflecting the strong influence that drug companies have over the USTR and their desire to prevent developing countries from making use of the flexibilities afforded them in the WTO's TRIPS agreement. The Doha agreement explicitly states that TRIPS can and should be interpreted in light of the goal 'to promote access to medicines for all.'²² This action by the USTR and drug companies is out of step with WTO rules and sets a dangerous precedent against other developing countries wishing to issue compulsory licences for essential medicines. TNP+ believes that the USTR and pharmaceutical companies must respect the rules of the WTO in the interests of public health.



Thai protesters respond to the US decision to downgrade Thailand to "Priority Watch List"



Banners draped from an overpass in protest of the US



The Grim Reaper waiting outside Abbott Laboratories on the International Day of Action, UK

AIDS activists responded to the US decision with a demonstration in front of the country's embassy in Bangkok.

In June 2007, ACT UP, a long time AIDS activist group based in Paris, informed TNP+ that they were being sued by Abbott for action taken while participating in the International Day of Action against Abbott on 26 April 2007. Led by ACT UP, thousands of people around the world had participated in a 'net strike' that saw Abbott's website bombarded with hits and forced a slowing of its server. Abbott decided to take legal action against this 'denial of service'. If the action was successful, ACT UP could have been fined more than US\$50,000, plus costs. This was seen by ACT UP as a clear attempt by Abbott to silence it and deny the organisation the right of free speech. The court case was due to take place in October, 2007.

French law stipulates that it is forbidden to limit access to a website unless the defendant had a 'legitimate motive'. TNP+ believes that holding companies accountable for unethical conduct and highlighting the denial of essential medicines in the name of profit can surely be interpreted as a legitimate and honourable motive. It welcomed the opportunity to debate Abbott's actions in a court of law.

TNP+ and ACT UP issued a joint statement inviting Abbott to meet with them at the International AIDS Society (IAS) conference in Sydney in July 2007. A representative from Abbott France responded by

²² World Trade Organisation Ministerial Declaration. Ministerial Conference, Fourth Session, Doha; 9-14 November 2001.

agreeing to meet with ACT UP and to withdraw the lawsuit unconditionally. ACT UP accepted the offer but vowed to continue the call for a global boycott of Abbott products until Abbott agreed to register medicines in Thailand.

2.9 Summary

The Thai government's welcome decision to issue a CL vindicates TNP+'s hard work on this issue. Abbott's response, however, was unexpected and disappointing.

What was more unexpected was the international interest in the case and the global spotlight in which Thailand found itself over the issue. TNP+, in particular, was inundated with requests for interviews and stories by the Thai and international media. It was also swamped with offers of support and messages of solidarity. This was a source of great inspiration to TNP+, encouraging its members to continue their campaign. Although it has always received valued support from activists overseas and from INGOs, this marked the first time TNP+ took a campaign to the global level, calling for international action and a worldwide boycott. It was very exciting to see PLHIV and activists in so many countries working to support Thailand's CL. It was also very gratifying to see involvement, not only by traditional activist groups but also by politicians and UN departments. The Thai government received letters of support from the French and UK governments, UNAIDS and many Congressmen and Congresswomen in the US. There was also a public meeting and explicit words of support from former US President Bill Clinton. After some initial hesitation, the Thai government also received a supporting statement from WHO.

The global boycott petition launched by TNP+ received a very large number of signatures and attracted the interest of human-rights and advocacy groups around the world. TNP+ saw the issue not just as one relating to HIV/AIDS but as having the potential to affect nearly everyone; the withdrawal of life-saving medicines by drug companies for profit-related reasons has strong implications for the wider community. TNP+ wished to convey the message that such behaviour was unacceptable and intolerable, and to ensure that drug companies implicated in future CLs would not consider the withdrawal of medication as a legitimate response

to the implementation of TRIPS flexibilities.

Dr. Mongkol later went on to sign ministerial announcements in January 2008 for licensing the following drugs: Letrozole, a breast-cancer medicine produced by Novartis; Docetaxel, a breast- and lung-cancer drug made by Sanofi Aventis; Erlotinib, which is manufactured by Roche and used in the treatment of lung, pancreatic and ovarian cancer; and Imatinib, a leukaemia drug manufactured by Novartis.²³

In April, 2008, the GPO signed an agreement with the Indian generic company, Dabur, to import Doxetaxel. It also has plans to issue terms of reference (the first step in the procurement process) for Erlotinib. NATCO, another Indian generic company, has been contacted with regard to this.

3 THE MEANINGFUL INVOLVEMENT OF PLHIV

3.1 Comprehensive Continuum of Care (CCC) projects

Many of campaigns described in this document were aimed at obtaining access to medication, since there existed an urgent need for ARVs among PLHIV in Thailand at the time. However, TNP+ has another important goal: of involving PLHIV in their own healthcare and the decisions that affect their lives. The pursuit of this goal has led to the setting-up of a network of Comprehensive Continuum of Care (CCC) centres for PLHIV in Thailand and has helped reduce the stigma associated with being HIV-positive.

Early in the epidemic, it became apparent that PLHIV in Thailand were dying needlessly of preventable opportunistic infections through lack of access to ARVs, prophylaxis and treatment. To combat this, TNP+, in partnership with the AIDS ACCESS Foundation and MSF Belgium, launched a campaign in 2000 to increase access to OI prophylactics, in particular Co-trimoxazole, which is used to treat *Pneumocystis carinii pneumonia* (PCP), a disease responsible for many fatalities among PLHIV.²⁴ The project began by training PLHIV group leaders to screen for OIs, administer basic treatment and know when to refer the patient to a doctor. This enabled group leaders to give their members accurate information about home treatment and

²³ 'Chiaya's Plan for CL policy review hits major hurdle', *Bangkok Post*, 20 February 2008.

²⁴ Kumpitak A, Kasi- Sedapan S, Wilson D, Ford N, Adpoon P, Kaetkaew S, Praemchaiporn J, Sae- Lim A, Tapa S, Teemanks S, Tiendunom N, Upakaew K. *Involvement of People Living with HIV/AIDS in Treatment Preparedness in Thailand: Case Study*. Geneva: WHO; 2004.

the treatment of symptoms with respect to some common OIs. Thus, a distinct caring role for PLHIV was developed.

The project also promoted cooperation and coordination with the public healthcare system. Rather than being passive consumers of healthcare, PLHIV thus became valuable partners in care provision. This helped build their pride and confidence even as it enabled them to care more actively for their own health. It also gained them respect and admiration from public health workers. Suwimon Pokong, a TNP+ member from the lower north, says,

After I got involved in TNP+ work, I came to feel I was still a person of value and learnt that I could do more with my life. Initially, I felt helpless; now I feel like I can do many things that benefit society.

Information about ARVs was included in the training curriculum from the second year onward, after the Government Pharmaceutical Organization (GPO) had begun production of generic ARV medicines in Thailand, making them accessible to greater numbers of PLHIV. In 2002, the MOPH further expanded access to ARVs and invited interested hospitals to become involved in a 'comprehensive continuum of care' (CCC) programme, in which ARVs would be provided by a multidisciplinary team of doctors, nurses, pharmacists and laboratory technicians. TNP+ and its partners decided to develop further the role of PLHIV as partners in the provision of comprehensive and continuous care by allowing PLHIV to provide treatment support. This included psychological support, counselling, home visits and help in adherence to treatment support. In order to do this, PLHIV group leaders had to follow and qualify in three subject areas: OIs and ARVs, counselling and 'continuum of care'.

There are currently over 200 CCC centres in Thailand and more are planned. To promote sustainability, the National Health Security Office (NHSO) has agreed to take over responsibility for 78 of these centres in the past year, increasing this number in years to come.

4. SINCE THE ELECTION

The Royal Thai Military staged a bloodless coup in September 2006 against the government of Thaksin Shinawatra. This was the culmination of a year-long

political crisis involving Thaksin and his political opponents. The coup leader and leader of the Council for Democratic Reform under Constitutional Monarchy, General Sonthi Boonyaratglin, told foreign diplomats that a civilian government and prime minister would be appointed to run the country within two weeks and that the Constitution would be amended for a rapid return to democracy through a national election in a year's time.

Dr. Mongkol na Songkla was appointed Health Minister for this interim period, during which he initiated grants of compulsory licences.

The *People's Power Party (PPP)*, headed by Samak Sundaravej, won the subsequent elections in December 2007. Samak won Thaksin's support to head the PPP, widely deemed to be an incarnation of Thaksin's former *Thai rak Thai* Party, which had been disbanded following a constitutional tribunal. The new Minister of Health, Chaiya Sasomsab, called for a review of CLs for cancer drugs on his first day in the post. He immediately came under strong opposition by Thai and international civil-society groups. His proposal encountered a further obstacle after officials from three ministries stated that the licences could not be revoked. The cause of civil society received a further boost when the World Health Organization (WHO) mission to Thailand declared its support for the use of TRIPS to improve access to essential medicines. The timely release of a 31-page report, 'Improving Access to Medicines in Thailand: The Use of TRIPS Flexibilities', stated that the use of compulsory licences is one of several WTO mechanisms to be used for improving access to essential patented medicines that would otherwise be too expensive for public-health insurance schemes to afford.²⁵

Mr. Chaiya was obliged to reverse his decision, however, when the permanent secretaries of the Commerce, Foreign Affairs and Public Health Ministries had concluded that the ministerial announcements on four cancer drugs made by former Public Health Minister, Dr. Mongkol na Songkhla were legitimate and could not be abrogated.

Despite this withdrawal, Mr. Chaiya has asserted strongly that the current government is unlikely to grant any further CLs. To help ensure this, he has rid relevant institutions of a number of key health personnel supportive of compulsory licensing.

25 World Health Organisation, *Improving Access to Medicines in Thailand: The Use of TRIPS Flexibilities*. 2008.



One of the many anti-Thaksin demonstrations in Bangkok

Siriwat Tiptaradol, chairman of the panel responsible for negotiating price cuts with cancer drug firms, was transferred from his position as Secretary-General of the Food and Drug Administration to an inactive post as inspector at the Health Ministry. The Permanent Secretary for Health, Prat Boonyawongvirote, and the chief of the Disease Control Department, Thawat Sundarajan, both resigned, reportedly under pressure from Mr Chaiya.

Mr Chaiya also sacked the entire board of directors of the GPO and replaced it with a new board chosen by him. Previously, he had made it publicly known that he wished to have the state enterprise's chairman, Dr Vichai Chokewiwat, replaced. Dr Vichai had been appointed chairman of the GPO in November 2006 after serving previously in several key positions at the Health Ministry, where he played an integral and supportive role in the granting of compulsory licences.

The newly appointed GPO chairman, Thirachai Wuthitham, is a former manager of the national football team who ran for parliament but failed to get elected. He has no known knowledge or

experience relevant to pharmaceuticals and is perhaps best known as a co-investor in the Manchester City Football Club of former Prime Minister, Thaksin Shinawatra.²⁶ Other new board members include the wife of an army general close to Thaksin and a property investor with no knowledge of medicine or pharmaceuticals.

Dr Vichai took his case to the Administrative court who ordered that he be reinstated along with five other deposed members of the GPO board. Chaiya was said to be unhappy with the verdict and vowed to petition the Supreme Administrative Court within 30 days.

On July 9, the Thai Constitutional court ordered Chaiya to stand down from cabinet after it found that he "had violated asset disclosure rules" by failing to disclose some of his wife's shareholdings within 30 days of being sworn in as a Cabinet minister. Chaiya is said to have accepted the decision. A successor has not yet been appointed.²⁷

The current government also announced its intent to forge ahead with plans to sign an FTA with the

²⁶ Bangkok Post Editorial, 'Is he good for our health?' 23 May 2008.

²⁷ Reuters. Thai court orders Health Minister to Quit. 9 July 2008



A Thai soldier in front of the Democracy Monument in Bangkok after the coup

USA, which is thought to be waiting for the current Thai political climate to stabilise before proceeding further with negotiations.

5. LESSONS LEARNT

5.1 Strengths

It is possible to cite numerous reasons for the success and strength of the Thai PLHIV network. However, hard work, together with a willingness to explore uncharted territory and acquire expertise in the relevant laws, international treaties, rules and regulations have been key factors. Many TNP+ members have paid tribute to the great value of the technical assistance they have received and the relationships they have developed. The assistance has come from many quarters, both within Thailand and abroad. Without it, the struggle would have been harder and success considerably limited.

Support has come, not only from those who work on HIV/AIDS issues but also from governmental departments, agricultural and farmers' groups, lawyers, pharmacists, INGOs and academics. International support has also gained in strength, as was demonstrated in April 2007 with the international 'day of action' against Abbott Laboratories.

TNP+ is indebted to the many individuals and organisations who took part in these actions or stood in solidarity with TNP+ – particularly those who helped coordinate the action, including, among others ACT UP, Health GAP, Student Global AIDS campaign, MSF, Oxfam, the International Treatment Preparedness Coalition and APN+.

Success in Thailand has been determined in large measure by PLHIV themselves and their determination to lead better, healthier lives within communities that accept and understand them. Many PLHIV have stated that the major driving force behind their activist work was their basic need for life-saving medicines. Activism, to them, was the only option. The only way to postpone imminent death was to work together, leveraging their unity and solidarity to obtain care and treatment. Having discovered that they could impel major policy changes in this way, they were inspired to work harder for greater rewards.

As Wirat Purahong, a past chairperson of TNP+, says,

I saw the power of our friends...we come together and walk together and raise issues so those at the policy level know that we are in society and we can shake the system and shake the policy.

Despite many past periods of instability and countless military coups, Thailand has a strong history of civil-society movement and political activism. Arguably, this has enabled PLHIV activism to thrive here, in contrast to many countries in the region where political factors have limited the ability of PLHIV activist groups to emulate the Thai movement. It has also meant that TNP+ actions have often been accepted and admired by the general public and the communities in which they live.

Political will, though often slow to surface, has also been helpful. Without it, some initiatives, such as the campaign for compulsory licences, would have been in vain. Even in times when TNP+ campaigns seemed to go against government policy, some of our more altruistic politicians were listening and were willing to engage in productive dialogue. It is hoped that this will continue with future administrations.

6. CURRENT AND FUTURE CHALLENGES

Despite these successes and the ground gained in access to treatment, many challenges remain. TNP+ and its partners continue to work to ensure access

to quality care and treatment for PLHIV and the preservation of their basic human rights. Past successes and international alliances have taught TNP+ the value and power of unity, educating the public and working together for the common good. Below are some of the current issues and future challenges that TNP+ faces in its drive to ensure access to quality generic medication for all.

Issues relating to children

Thailand currently has no access to children's ARV formulas. Adults tablets must be broken into small size for children. This reflects a lack of commitment by the major drug companies towards researching suitable regimes and formulations for children. This is unacceptable, and it is an issue that TNP+ intends to pursue in the future.

TNP+ is also concerned about the lack of skills and information among those working with HIV-affected and infected children in Thailand. This group requires special attention, in particular sound psychological care and expertise in issues of disclosure and sexuality.

Access for migrants and those without ID cards

As stated previously, access to the national health security scheme is universal for Thai citizens in possession of a national identity card. But Thailand is also home to many seasonal migrant workers and hill-tribe ethnic minorities. These groups lack the appropriate identity cards and are thus denied access to the public healthcare system.

Hill-tribe groups, often found in the north of Thailand, may have lived in Thailand for generations but remain effectively stateless because they lack documents and registration. In addition to the obvious health and economic implications of being denied free healthcare, they are also deprived of public education, contributing to a bleak future – and, arguably increasing their vulnerability to HIV.

Migrant workers in Thailand come mainly from surrounding countries such as Laos, Vietnam, Cambodia and Myanmar. Most are unregistered and receive low wages for mainly manual work, and a great many cannot afford to pay for private healthcare. Some migrant workers are registered and can obtain care through a pre-paid insurance scheme.

TNP+, together with its partners, aims to lobby for greater access to quality healthcare and ARVs for these groups. It has commenced surveying areas in

the north in order to make an accurate assessment of the number of support-group members without citizenship. The results of this study will be used to lobby the government and other relevant stakeholders to provide care for this needy and often neglected population.

Access to second-line treatment

Although the national healthcare scheme includes first-line treatment for Thai PLHIV, it has very little capacity for providing second-line treatment. It is estimated that approximately 8,000 of the 100,000-plus PLHIV currently receiving treatment require second-line therapy. Of these, only 1,200 are receiving such therapy via the public health system.²⁸ This is largely due to the high cost of medicines, most of which are currently under patent.

TNP+ is concerned about the sustainability of the current healthcare system given that more and more PLHIV will need second-line in the future. Sustainable ways must be found to ensure continual access to quality standard treatments. As new medicines are created and come onto the market, they are certain to be patented, leaving Thai PLHIV once again to face the same issues with regard to affordable access.

Voluntary counselling and testing (VCT)

Most HIV-positive people in Thailand test late. By the time they become aware of their status, their immunity is low and they may already be quite ill. Indeed, they often test for HIV only when they become ill. Women often become aware of their status when they are pregnant, or when their partners contract an opportunistic infection.

TNP+ and AIDS ACCESS Foundation, in conjunction with the NHSO, wish to rectify this situation. Although HIV testing services are widely available throughout Thailand, they are not all of standard quality. Not many include pre- and post-test counselling. TNP+ believes that if people knew their status earlier, they would be better equipped to prepare themselves for the future and to make informed decisions about their treatment options. Conversely, those who test negative will also have an opportunity, through counselling, to assess the true risks to their lives and adjust their behaviour accordingly.

TNP+ aims to start a campaign to promote the uptake of voluntary counselling and testing among the general public and to strengthen the quality of VCT already available. Clear and

responsible messages will be used to educate people about HIV in practical, constructive ways, avoiding the scare tactics of the past – which have only acted to the detriment of prevention campaigns. In the past, MSF Belgium, TNP+ and AIDS ACCESS have collaborated to disseminate the message that ‘AIDS can be treated’. This informs people that treatment is available and helps break down stigma and discrimination and the notion that HIV is a fearful, untreatable and terminal condition. It is hoped that this will also encourage HIV-positive people to access ARVs in a timely manner, before they fall seriously ill.

Services for men who have sex with men (MSM)

Similarly, healthcare services in Thailand are not always friendly and readily accessible to men who have sex with men (MSM). Preventative information rarely recognises their unique vulnerability to HIV, which is viewed in Thailand largely as a heterosexual disease. Government prevention strategies are inadequate to address the specific needs of this group, whose members are sometimes met with prejudice when seeking treatment; it has been left largely to NGOs to provide services and disseminate prevention information. TNP+ aims to promote the inclusion of MSM in decisions that affect them, and to work towards addressing the imbalance in ARV access and service provision.

Services for injecting drug users (IDUs)

Thailand’s HIV prevention efforts in the early nineties saw a reduction in the national prevalence rate; the annual incidence of new infections also fell dramatically. Past prevention campaigns have, however, failed to reduce prevalence among injecting drug users. In fact, prevalence amongst IDUs has risen²⁹ since the beginning of the epidemic. This is largely due to the lack of comprehensive harm-reduction programmes and an extremely punitive official approach to drug use.

In 2003, the Thaksin government launched its ‘war on drugs’, which saw thousands of users extra-judicially murdered and thousands more incarcerated.³⁰ Overcrowding in prisons and lack of access to clean injecting equipment has often been cited as a factor in the explosion of HIV among this subgroup.

TNP+ would like to see more comprehensive and user-friendly services for IDUs and the introduction

of harm-reduction policies that have been proven to limit the spread of HIV in this subsection of the community. TNP+ is concerned about Hepatitis C co-infection among the drug user community and plan to work more closely with IDU groups on these issues.

7. CONCLUSION AND RECOMMENDATIONS

The sustainability of the current programme for universal access to ARVs relies on the ability of the GPO to continue producing quality generic medications at affordable prices. Any threat to production will jeopardise the MOPH’s ability to supply ARVs for all who need them. This will be especially pertinent in the future, when more PLHIV will require second-line drugs and as new drugs are developed and, almost certainly, patented.

Thailand needs to ensure that it does not bow to international pressure to strengthen IP laws when signing bilateral trade agreements and acceding to international treaties. The State must retain its power to issue compulsory licences where necessary and build the capacity of the National Intellectual Property Office to assess the validity of future patent applications.

Conversely, access to generic medication in developing countries is also a global responsibility. Governments in developed countries need to respect the right of developing countries to use the flexibilities afforded them and to abide by the rules they have helped frame. International agreements are worthless without the political will to implement them as intended. Governments in developed countries also need to limit the influence that multinational drug companies have on foreign policy and international agreements; their interests often lie solely in profit and the creation of monopolies, leaving little room for the production or import of generic alternatives.

Access to medicines is a basic human right and should be the cornerstone of any universal healthcare scheme. Continual dialogue and collaboration between government and civil-society groups is essential to ensure adequate public participation and transparency in policy decisions that have a potential impact on the availability and affordability of medicines. Healthcare initiatives should also be sustainable and cost-effective and involve affected and infected populations. For

29 WHO. *HIV in Asia and the Pacific Region* 2003.

30 Human Rights Watch, *Not Enough Graves: The War on Drugs, HIV/AIDS, and Violations of Human Rights in Thailand*. 2006 [cited 2007 June 27]; [3 screens]. Available from: <http://www.hrw.org/campaigns/aids/2004/thai.htm>

developing countries, this will undoubtedly necessitate the use of generic medications. As the world moves towards a more stringent patent system, it cannot be overstated how crucial access to generic medications will become.

8. USEFUL LINKS

For more information, please view the links below:

www.thaiplus.net

<http://www.abbottsgreed.com>

<http://www.actupparis.org>

<http://www.accessmed-msf.org/>

<http://www.AIDSaccess.com>

<http://www.petitiononline.com/bcottabb/petition.html>

<http://www.fightglobalAIDS.org/>

4

THAI-INDIA JOINT ACTIONS: OPPOSING THE COMBID/COMBIVIR PATENT APPLICATIONS

1. THAI-INDIA JOINT ACTIONS: OPPOSING THE COMBID/COMBIVIR PATENT APPLICATIONS

The access to treatment movements in Thailand and India found a pertinent reason to utilize their collective experience and solidarity when they discovered they were facing the very same issue. GlaxoSmithKline (GSK), a multinational pharmaceutical company based in Great Britain, applied for a patent on a fixed-dose combination of two ARV medicines, Lamivudine (3TC) and Zidovudine (AZT), in both Thailand and India. GSK markets this combination as Combid in Thailand and Combivir in India. This particular ARV combination is commonly used in first-line HIV regimens, and it is important for many PLHIV who cannot take Stavudine (d4T) due to lipodystrophy side effects.

In both countries, the first instance of using the pre-grant opposition mechanism by PLHIVs was to oppose the patent applications for this combination medicine.

1.1 Opposing the Combid patent application in Thailand

On 27 October 1997, the pharmaceutical company GlaxoSmithKline (GSK) applied to the Department of Intellectual Property for a patent on the drug Combid in Thailand. Combid is a combination of the existing drugs, Lamivudine (3TC) and Zidovudine (AZT), commonly used in first-line HIV regimens.

At the time, the Thai GPO was able to produce a generic version of the same compound under the name 'Zilavir'. If a patent was granted, the GPO would no longer be able to



GSK's greed - Protesting GSK's Combid patent application, Bangkok.

produce Zilavir. PLHIV who currently take this drug would have to alter their regimen to take two tablets instead of one, complicating issues of adherence. This would also drastically increase the price of the medicine - GSK's version of the medicine was six times more expensive than the government-produced generic version.

TNP+ was concerned about the potential negative impact of a Combid patent and joined with other interested parties to register its opposition. The Health and Development Foundation, an alliance of lawyers, academics and pharmacists, lodged several objections to the grant of a patent for Combid. The first objection, lodged in May 2000, was on the grounds that Combid was not a new entity but merely a combination of two existing, widely-used medicines and, hence, the combination did not constitute an inventive step. The case was dismissed in October 2005 on the grounds of a lack of evidence.

An appeal was lodged with the Department of Intellectual Property by the Health and Development Foundation in December 2006; additional information was supplied to support the case. This appeal was under investigation by the

Department of Intellectual Property.

In addition to the aforementioned opposition, other conflict of interest issues in relation to this patent application were raised:

- A member of the Committee for Patents in the Department of Intellectual Property (IP) is married to an employee of GSK. This individual's employment was terminated in response to a complaint by the AIDS ACCESS Foundation.
- Another member of the Committee previously conducted a study for GSK. A complaint regarding this matter was submitted to the Minister for Commerce.

TNP+ and its partners have grown increasingly concerned at evident inconsistencies in decisions made by the Department of Intellectual Property and have publicly questioned whether the office of IP possesses adequate capacity or expertise to assess patent applications. This is a matter of particular concern given the pending Thai-US FTA and the subsequent additional responsibilities this will bring to the department.

1.2 Indian PLHIV groups' first pre-grant opposition: Combivir

While Thai groups began their campaign against GSK's patent application for the AZT/3TC combination as early as 2000, Indian groups were confronted with GSK's patent application only in 2005 when India changed its patent law to become TRIPS-compliant. In India, the concern over this patent application was not only for the local availability of a generic version of the medicine, but also for its implications on access to treatment for PLHIV around the world. Thus, the actions in India received much international support. The Treatment Access Campaign (TAC) and the AIDS Law Project in South Africa issued a statement expressing their support and solidarity¹:

"In combination with another ARV medicine, the fixed-dose combination of AZT/lamivudine is used extensively in HIV treatment programmes across the world. Many of these programmes are reliant – as are people living with HIV/AIDS in India itself – on generic versions of AZT/lamivudine that are currently manufactured in India. Granting GSK a patent on Combivir will inevitably result in increasing the costs of ARV treatment in India and abroad. Even in South Africa, where the fixed-dose combination product is produced under licence, many people rely on generic AZT/lamivudine imported under licence from India. The absence of affordable imports of the essential medicine will reduce domestic competition significantly, potentially resulting in higher medicine prices and consequently limiting treatment access."

GSK's patent application was for an invention that combined two existing medicines and used a substance called a 'glidant' that binds the two medicines together in the right dosage. In this case the glidant of choice was silicon dioxide, or in layperson terms – sand! With the provisions of India's patent law making it clear that combinations of existing medicines could not be patented in India, INP+ and MNP+ filed an opposition to GSK's patent application on 30 March 2006.²

"Once the patent licence is given, the company would decide the price of the medicine according to their wish and the currently highly

beneficial HIV/AIDS medicines Zidovudine and Lamivudine which are made available to HIV patients free of cost might become unavailable to the people which would be hard blow to the HIV patients".

- Ratan Singh, MNP+ in the *Sangai Express*, 23 April 2006

1.3 7 August 2006 - Joint rallies and protests in Bangkok and Bangalore

To demonstrate their unified opposition to GSK's unjust application for a patent for 'Combid/Combivir', simultaneous demonstrations were held on 7 August 2006 in Thailand and India. Indian groups demonstrated in front of the GSK offices in Bangalore while TNP+ and their partners from AIDS ACCESS Foundation and representatives from other NGOs such as Thai Drug User Network (TDN) and Thai Treatment Action Group (TTAG) rallied outside the GSK offices in Bangkok. Both groups demanded that GSK withdraw its Combid/Combivir patent application immediately in the interests of public health and fairness.

The joint actions prompted an immediate response from GSK. They issued a press release on 10 August 2006 stating that they had withdrawn or was in the process of withdrawing the patent application for Combivir in all countries where it had been filed.³ Despite these public messages there was no confirmation of this from the Indian patent office. On 5 September 2006 DNP+ wrote to GSK asking



Sand is not an Invention - Indian groups protest GSKs' patent application combining two known medicines - lamivudine and zidovudine with a 'glidant' - in this case SAND!

1 TAC and AIDS Law Project statement in support of Indian opposition to patent protection for GSK's Combivir, 30 March 2006

2 Lawyers Collective HIV/AIDS Unit, "Indian Groups File First Opposition against Patent Application for AIDS Drug," Press Release, 30 March 2006

3 GSK, "GSK patents and patent applications for Combivir," Press Release, 10 August 2006

them if there was any truth in the media reports of their withdrawal of the Combivir patent application. On 13 March 2007, over six months after GSK's claim that they had abandoned their patent application, the Kolkata Patent office in India confirmed that the patent application had indeed been withdrawn.⁴

The campaign has been hailed as a great success for Thai and Indian civil society and for PLHIV around the world. It is testimony to what can be achieved with unity, determination and a belief in the right for affordable access for all. The joint campaign has demonstrated the importance and effectiveness of sharing information and communicating with like-minded groups in other countries – particularly in developing and least developed countries that are facing similar issues.



7 August 2006: PLHIV protest outside GSK offices in Bangkok, Thailand.



7 August 2006: Indian groups demonstrate outside GSK offices in Bangalore, India.

"...Thai activists in Thailand demonstrated in front of GlaxoSmithKline (GSK) office to demand the withdrawal of its patent application in Thailand or Combivir, a fixed-dose combination of two essential AIDS medicines *zidovudine/lamivudine*. Indian public interest groups have joined the public action and protested in Bangalore in front of the local GSK office against the patent application for Combivir. GSK has filed applications for a patent on Combivir in many developing countries affected by HIV/AIDS including India and Thailand ...

... "People Living with HIV/AIDS in India and Thailand are also appealing to the government to refuse the patent and have lodged a legal objection to GSK's patent application on the grounds that it is not a new invention but simply the combination of two existing medicines. "Simply combining two medicines does not constitute an invention and therefore does not deserve a patent," explains Loon Gangte of Delhi Network of People Living with HIV/AIDS."

... "Generic antiretroviral medicines are the basis of life-saving antiretroviral therapy relied upon by more than 80,000 people with HIV/AIDS currently receiving treatment in Thailand," says Mr. Wirat Puraong, Chairperson of the Thai Network of People Living with HIV/AIDS. In India there are 5.3 million people living with HIV/AIDS many of whom receive generic medicines manufactured by Indian pharmaceutical companies under the national HIV/AIDS treatment program..."

- Excerpts from joint Indian and Thai press release dated 7 August 2006

4 Letter from Kolkata Patent Office, 13 March 2007. On file with author.



ANNEXES

ANNEX 1: LIST AND CONTACT INFORMATION OF PERSONS INTERVIEWED, CHAPTER 2, INDIA

LOON GANGTE

Delhi Network of Positive People (DNP+)

DNP+ was founded in 1999 as a support group of individuals with HIV. DNP+ actively lobbies for treatment access for HIV positive people and provides services such as counselling and support services to the community. DNP+ has along with other groups filed eight oppositions to patent applications.

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P. KOUSALYA

Positive Women's Network (PWN+)

PWN+ was initially started in 1998 as a support group for supporting women who faced discrimination due to family members, health care settings and other legal issues faced by women like property and maintenance issues. PWN+ now also focuses on positive children and their rights. Later they became involved with the national level campaign demanding the government give free ARVs. PWN+ has filed a grant opposition against the patent application for *Nevirapine Hemihydrate* along with INP+.

Email: poswonet@hotmail.com, poswonet@pwnplus.org

Website: <http://www.pwnplus.org>

K.M. GOPA KUMAR

Center for Trade and Development (Centad)

Centad is an independent, not-for-profit organisation registered under the Indian Societies Act that carries out policy research

and advocacy on issues around trade and development, with a focus on South Asia. Centad aims to strengthen the ability of governments and communities to make trade and globalisation work for development. Its focus currently is on South Asia (India, Pakistan, Nepal, Bangladesh and Sri Lanka). On the issue of patents and IPR, Centad has worked closely with community groups offering technical support while also playing an important role in advocacy on issues related to patents and access to medicines.

Email: centad@centad.org, kmgkumar@gmail.com

Website: www.centad.org

LEENA MENGHANEY

Campaign for Access to Essential Medicines - MSF (India)

Medecins Sans Frontieres (MSF) is an international aid organisation that provides medical assistance to populations in distress in more than 80 countries. The Campaign for Access to Essential Medicines is an international project of MSF; its objectives include making new "life-saving & essential" medicines, vaccines and diagnosis tools affordable and accessible. MSF is treating more than 100,000 people living with HIV and AIDS in thirty countries including India. Most of their patients are receiving affordable generic medicines manufactured in India. Since March 2005, with the introduction of product patents on pharmaceuticals in India, the Campaign has provided technical support for the oppositions to the patent applications filed by the PLHIV networks.

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Website: <http://www.accessmed-msf.org/>

JAYA NAIR

UDAAN Trust

UDAAN Trust started work in 1992 on issues and rights of marginalized groups (men who have sex with men and male sex workers). Their work focused on health and human right issues of marginalized groups and took on HIV related issues when people started testing HIV-positive. Over time, their work has also expanded to cover women and children infected with or affected by HIV/AIDS. In 2004 they started their first drop-in- centre (in central and suburban Mumbai) for infected and affected persons. Today UDAAN is seen as an organization by and for PLHIV. This reflects in the constitution of its Board. Each of the ten board members is a PLHIV and self identified as persons from marginalized communities. They have 17 registered networks in Maharashtra. UDAAN ensures that people registered with them have access to treatment. For people who need second line treatment they approach private donors.

Email: udaantrust@vsnl.net

Website: <http://www.udaantrust.org/>

ELANGO RAMACHANDER

Indian Network for People living with HIV/AIDS (INP+)

INP+ is a non-profitable community based organization of people living with HIV and its secretariat in Chennai. Formed in February 1997 by twelve people living with HIV, INP+ is a national network of, for and by people living with HIV/AIDS in India. The organization aims to improve the quality of life of people living with HIV in India. INP+ exists to provide a sense of belonging and togetherness to people living with HIV. INP+ believes that unless the rights of people living with HIV are recognized and respected, prevention would not be effective. The membership of INP+ is open to all Indians living with HIV, irrespective of gender, caste, religion etc. INP+ has filed 12 oppositions to patent applications for HIV medicines.

Email: inp@inppplus.net

Website: <http://www.inppplus.net/>

AMIT SENGUPTA

Peoples Health Movement –India (PHM)

PHM is the India regional circle of the People's Health Movement, a growing coalition of people's organisations, civil society organisations, NGOs, social activists, health professionals, academics and researchers that endorse the Indian People's Health Charter and the People's Charter for Health – consensus documents that arose out of the Jan Swasthya Sabha (National Health Assembly) and the

People's Health Assembly held in December 2000 when concerned networks, organisations and individuals met to discuss the Health for All Challenge. There are 21 major national networks that constitute the PHM. The movement is organised through state level and issue based circles. PHM works on several campaigns including a right to healthcare campaign and has been active in critiquing the amendments to the Indian Patent Act and in supporting challenges to patent applications.

Email: ctddsf@vsnl.com

Website: <http://phm-india.org/>

RATAN SINGH

Manipur Network of Positive People (MNP+)

MNP+ was set up in 1997 by a group of ex-drug users who were living with HIV and has several district level networks. MNP+ works on diverse issues related to HIV in the north-east including discrimination, prevention, human rights, treatment, etc. MNP+ works on creating self help groups for PLHIV, conducts meetings and workshops and provides care and support. Their work on treatment includes work on the government's treatment programme, campaigning for treatment for IDUs and for second line treatment, approaching courts on treatment related issues like the availability of CD4 machines and on patents. MNP+ along with INP+ filed the pre-grant opposition to GSK's application for Combivir.

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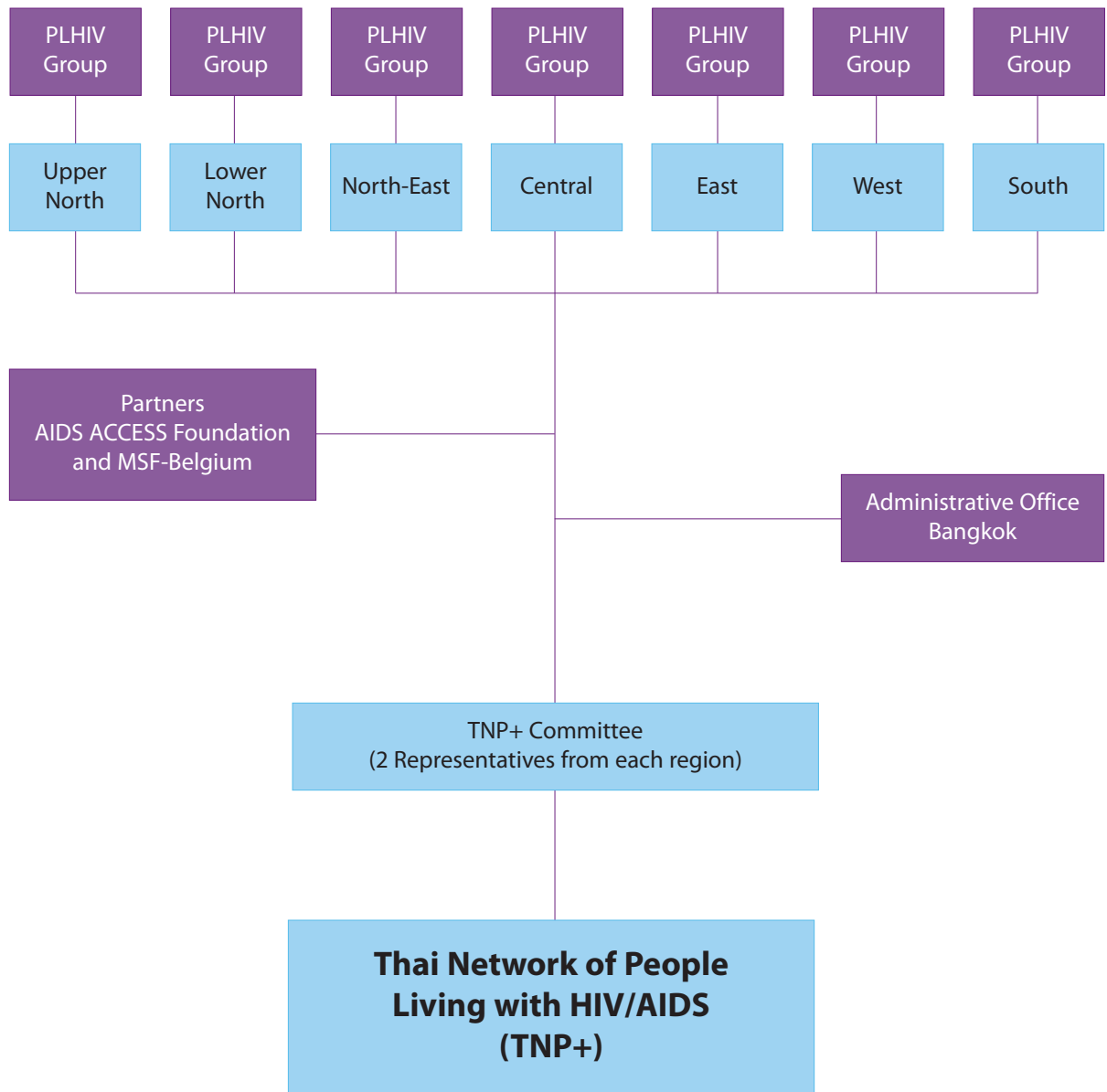
Y K SAPRU

Cancer Patients Aid Association (CPAA)

Established in 1969, CPAA has a tradition of untiring service to needy cancer patients from all over India, and even from neighbouring Bangladesh, Bhutan, Nepal and Pakistan. CPAA is an empathetic, reassuring, non-medical presence that has supported the treatment and overall needs of more than 40,000 cancer patients. Cancer Patients Aid Association (CPAA) is a registered charitable non-governmental organisation (NGO) working towards the Total Management of Cancer as a disease. CPAA has been involved in extended litigation against Novartis on Imatinib Mesylate dating back to 2003 and filed the pre-grant opposition against Novartis' patent application. They were one of the parties in the Section 3(d) case.

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2002-2005 Coordinator for central region of TNP+
1997-present member of TNP+

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2004-2006 Western region committee member of TNP+

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Vice Chairman of the Centre for AIDS Rights
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1997-1999 Vice Chairperson of TNP+

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ANNEX 4: LIST OF ARTICLES FOR CHAPTER 3, THE TNP+ EXPERIENCE

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ANNEX 5: ELECTRONIC RESOURCES FOR CHAPTER 3, THE TNP+ EXPERIENCE

<http://www.worldbank.org/>
<http://www.accessmed-msf.org>
<http://www.bilaterals.org>
<http://www.ftawatch.org>
<http://www.hivnat.org/>
http://www.who.int/medicines/areas/policy/doha_declaration/
<http://www.abbottsgreed.com>
http://www.unaids.org/en/HIV_data/epi2006/
<http://www.eng.moph.go.th/>
http://www.wto.org/english/tratop_e/trips_e/trips_e.htm
<http://www.fightglobalaids.org/resources/resources.php>
<http://www.bangkokpost.net/>
<http://www.nationmultimedia.com/>
http://www.cptech.org/blogs/ipdisputesinmedicine/2007_03_01_archive.html
<http://www.essentialdrugs.org/edrug/archive/200405/msg00005.php>

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