CHAPTER 5


Health as a Human Right

Health is one of the fundamental basic needs of all human beings. In legal terms, fundamental human rights treaties recognize the right to the ‘enjoyment of the highest attainable standard of physical and mental health’. Health is now beginning to be seen in the context of human rights protection in response to debilitating, life threatening and life altering diseases like HIV/AIDS, cancer, tuberculosis, malaria and a whole host of infectious disease which are seriously neglected in terms of international attention and research. Denying the rights of people living with these diseases imperils not only their well-being, but life itself. Across the globe more than 40 million people live with HIV, half of whom are women, and half the new infections are occurring in young people under 25. Many millions more are affected. World Health Organization identifies a select group of 13 tropical diseases that afflict the poor and powerless in the developing regions of sub-Saharan Africa, Asia, and the Americas, broadly termed as ‘neglected diseases’ (NDs). Together, they cause an estimated 500,000 to 1 million deaths annually and cause a global disease burden equivalent to that of HIV-AIDS. However, their overall toll cannot be measured by mortality alone. Generally speaking NDs cause more chronic life-long disabilities and morbidity rather than death; for instance, Chagas disease causes a chronic and disabling heart condition; hookworm, chronic intestinal blood loss and anemia; onchocerciasis, blindness and intense itching that results in chronic skin changes; guinea worm, localized pain that prevents temporary disuse of a lower limb. NDs also have a huge social impact due to lost educational potential, reduced economic productivity, and stigma. Schistosomiasis and hookworm impair the ability of school-aged children to learn in school, while guinea worm and river blindness result in missed days of

work for adults, especially the family breadwinner. Therefore, NDs not only occur in the context of poverty, but through their adverse social impact may also promote poverty. 7

Addressing health needs is increasingly seen as critical for poverty alleviation and human development. Globalization, and its scale, has ensured that these problems are no longer viewed as mere local health concerns. There is an awareness of both of the plight of the affected people and the global and epidemic nature of these diseases. The sheer scale of the problems and its endemic link with poverty has been a prime stimulus in the linking of health needs of peoples with the human rights discourse. Health rights being now seen as human rights and in some countries like India, as a right to life. In Surjeet Singh v. the State of Punjab (1966-2-SCC-366), dealing with the case of medical reimbursement, the Supreme Court held that “self preservation of life is a necessary condition of the right to life enshrined in art.21.”

Article 21 of the Indian Constitution guarantees protection of life and personal liberty by providing that no person shall be deprived of his life or personal liberty except according to the procedure established by law. As a result of liberal interpretation of the words ‘life’ and ‘liberty’, Article 21 has now come to be invoked almost as a residuary right. Public interest petitions have been founded on this provision for providing special treatment to children in jail; against health hazards due to pollution; against health hazards from harmful drugs; for redress against failure to provide immediate medical aid to injured persons; against starvation deaths; against inhuman conditions in after-care home and on scores of other aspects which make life linked to conditions of living rather than to existence. The expanded meaning of right to life is wholly justified: to

7 ibid
8 The Supreme Court has held in a number of cases that the right to life, enshrined in article 21, under the Constitution does not stand for animal existence but the right to life with human dignity. Right to health is now recognized as the fundamental right India. In the Bandhua Mukti Morcha case (AIR 1984 SC 802), the Supreme Court held that article 21 closely linked Directive Principles of State Policy, particularly clause (e) and (f) of art. 39, art. 41 and art. 42. “It must include protection of the health and strength of workers, men and women, and tender age children against abuse, opportunities and facilities for children to develop in a healthy manner and in conditions of freedom and dignity, educational facilities, just and human conditions of work and maternity relief. These are minimum requirements which must exist in order to enable a person live with dignity In Randhir Singh’s case (AIR 1982 SC 879) and in Unnirakshana’s case (AIR 1993 SC 879) the Supreme court held that the Directive Principles that are linked to the Right to Life in Art. 21 (as in the case of those related to health) can be enforced, notwithstanding the injunction in art.37. (Case references from P.V.S. Giridhar, TRIPS and the Lifeline to Profits. Combat Law (Vol 2 Issue 2. Jun-July 2003): 75-76) In case of State of Punjab V/S Mahindrasingh Chawla, the Supreme Court of India held that right to life includes the right to health: “It is now settled that the right to health is integral to the right to life”. Similarly, in Paschim Bengal Khet Mazdoor Society, the Supreme Court held that the timely medical treatment in Govt. hospital is fundamental right. Case references by Justice A.D.Mane’s (Acting Chair person) Inaugural Speech at the Workshop on ‘Health & Human Rights’. Organized By CEHAT In Collaboration With Tata Institute Of Social Sciences at Mumbai On 5th December, 2005 Government thus has a constitutional obligation to provide health facilities 1882-2-SC-83. 214
make other rights meaningful and effective right to a healthy life is the basis underlying the constitutional guarantees.

This stand has also been, for instance, reiterated in various judgments of the Supreme Court of Venezuela, one of them being the case of Cruz Bermudez, et al v Ministerio de Sanidad y Asistencia Social (hereafter referred to as MSAS) (July 17, 1999). The main argument of the plaintiffs was that they did not have access to treatment to treat their HIV infection. This inaccessibility of treatment violated their right to have access to scientific and technological advances, right to health and right to life. They also alleged a violation of their right to liberty and security, as well as the right to equal treatment and non-discrimination. The Court in its ruling maintained that the rights to health, to life and to have access to scientific and technological advances are closely related. This close relationship among these rights was explained by the Court: "The right to have access to scientific and technological advances would permit HIV+ people to preserve their minimal living conditions (right to health), which in this case, means the possibility to live longer and in the long run, to find a cure for the disease."

The Venezuelan Court also held that the preservation of the right to life is a goal that the juridical order imposes on public authorities, and specially on the Legislature, which has to adopt measures to protect those assets - life and physical integrity - against any attack from third parties. Since the right to life is a positive right and not a negative right, it is imperative that the State adopt and enforce public health policies. Also, all the citizens have the right to receive protection of their right and there is a correlative duty on the State to overseer that such right is realized accordingly, especially when the citizen lacks sufficient means to afford health care.

That health is as fundamental as the right to life is, finds an echo in various international documents, covenants which have instated health as a human right. Human rights to health have become a provision in international covenants and conventions: in the Universal Declaration of Human Rights, the International Covenant on Economic, Social and Cultural Rights, the Convention on the Elimination of All Forms of Discrimination Against Women, the Convention on the Elimination of All Forms of Racial Discrimination, and the Convention on the Rights of the Child.

Human Rights relating to health are set out in basic human rights treaties and include the human right to: the highest attainable standard of physical and mental health, reproductive and sexual health; equal access to adequate health care and health-related services, regardless of sex, race, or other status; equitable distribution of food; access to safe drinking water and sanitation; an
Key International Provisions for Human Rights

"Everyone has the right to a standard of living adequate for health and well-being of himself and his family, including food, clothing, housing, medical care and the right to security in the event of sickness, disability. Motherhood and childhood are entitled to special care and assistance." -- Universal Declaration of Human Rights, Article 25

"The States Parties recognize the right of everyone to just and favourable conditions of work which ensure safe and healthy working conditions; the right to an adequate standard of living; the enjoyment of the highest attainable standard of physical and mental health. The steps to be taken to achieve the full realization of this right shall include those necessary for: the reduction of infant mortality and for the healthy development of the child; the improvement of all aspects of environmental and industrial hygiene; the prevention, treatment and control of epidemic, endemic, occupational and other diseases; the creation of conditions which would assure to all medical service and medical attention in the event of sickness." -- International Covenant on Economic, Social and Cultural Rights, Articles 7, 11, and 12

"States Parties shall ensure to [women] access to specific educational information to help to ensure the health and well-being of families, including information and advice on family planning. States Parties shall eliminate discrimination against women in health care; to ensure, on a basis of equality of men and women, access to health care services, including those related to family planning; ensure appropriate services in connection with pregnancy. States Parties shall ensure that [women in rural areas] have access to adequate health care facilities, including information counseling and services in family planning." -- Convention on the Elimination of All Forms of Discrimination Against Women, Articles 10, 12, and 14

"States Parties undertake to eliminate racial discrimination and to guarantee the right of everyone, without distinction as to race, colour, or national or ethnic origin, to equality before the law, the right to public health, medical care, social security and social services." -- Convention on the Elimination of All Forms of Racial Discrimination, Article 5

"States Parties recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health." -- Convention on the Rights of the Child, Article 24

adequate standard of living and adequate housing, a safe and healthy environment; a safe and healthy workplace, and to adequate protection for pregnant women in work proven to be harmful to them; freedom from discrimination and discriminatory social practices, including female genital mutilation, prenatal gender selection, and female infanticide; to education and access to information relating to health; The human right of the child to an environment appropriate for physical and mental development. Human Rights are based on mankind's increasing demand for a decent civilized life in which the inherent dignity of each human being is well respected and protected. They are fundamental to our very existence without which we cannot live as human beings. As ex UN Secretary General Kofi Annan said: "Human rights are what makes us human. They are principles by which we create the sacred home for human dignity." The notion of
human dignity and human rights are fundamental rights to every society including the persons in need of medical treatment.

The development of laws and covenants relating to health demonstrate that there is now a recognition that the state of an individual's health is often determined by factors beyond a person's medical condition. Health as a right-to-life approach heralds a paradigm shift in the understanding of health dynamics. The journey of understanding health from illness and medicine to health as human rights begins with the premise that health cannot be explained in isolation. Health outcomes of population in any geographical space depends on a range of factors: from medical ones like spread of virus, response of the drug to the disease, etc. to underlying factors thrown up by the larger socio-cultural and economic realities.

Health has an organic link with development. Where there are enclaves of development co-existing with enclaves of deprivation there necessarily will emerge issues that are linked to access to health facilities. Questions of equal access across class, caste, gender, region, invariably raise issues of entitlements. Advocates of this approach felt that there was a need for accountability and the state has a responsibility towards maintaining the health of its citizens. The new approach acknowledged the fact those health outcomes are necessarily dependent on the structural and cultural dynamics in every community but there is a role for the state, which cannot be compromised upon. More importantly, health as an issue must have democratic participation of the civil society and encapsulate the needs and sentiments of people. It proposes to understand health as an enforceable right by the law of land across the globe. Internationally, the attempt to institutionalize health as a human right, found its way to the international conventions, pact and directives.

This rights-based approach to health has its seeds in the notions of welfare state. But its presence in the health movements and research is an aftermath of the experiences of globalization. WTO and its TRIPS regime have been important tools in the globalization of trade and institutionalization of globalized norms of trade. The TRIPS regime has brought about definitive changes in the dynamics of drug trade and research and has had far reaching impact on issues of drug access, availability, research, prices, disease control and so on. Until recently, providing patent protection for pharmaceuticals was a choice made by individual governments according to their level of industrial development. Today, pharmaceutical patents are globalized through the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), and then further reinforced through bilateral and regional arrangements (the
so-called TRIPS-Plus agreements. This chapter raises the issues of health rights in this context. Health as a human right promises to reformulate the health needs of the people into rights that meet the health needs of the vulnerable population's in a sustainable manner.

TRIPS AND THE RIGHT TO HEALTH

WHO estimates that currently one third of the world’s population lacks access to essential drugs. Over fifty percent of people in the developing world especially in Africa and Asia do not have access to even the most basic essential drugs. A group of international organizations recently estimated that less than 10 per cent of people living with HIV/AIDS in developing countries have access to antiretroviral therapy.

The TRIPS agreement is one of the treaties administered by the WTO and is meant to generally provide enhanced opportunities for international trade by laying down conditions under which a patent can be claimed and monopoly over use and distribution established. Patents, it is believed, constitute an incentive for research and innovation in general, as also for the development of research by the pharmaceutical industry. The rationale for granting exclusive rights on patented medicines is that the development of new drugs has a very high research and development component, has a usually high gestation period and is a costly process. At the same time it is relatively easy to reverse engineer and copy an existing drug. Thus in order to promote innovation and research in developing drugs for a world afflicted with disease, and challenged by new strains of virus and bacteria, innovation needs to be promoted and rewarded. Patents are forms of reward that accrue to the patent holder for his investment of resources in the innovation of a product. And these rewards are in the form of monopoly of use and exchange at monopoly prices i.e., at prices that are significantly higher than the non-patented counterparts. Patents, thus in a way, constitute a pre-condition for the involvement of the private sector in the development and production of new medicines. They offer exclusive rights to patent holders who benefit from a monopoly condition in the market. By obliging all governments to grant minimum 20-year patents, TRIPS shields pharmaceutical companies from generic competition globally. This results in higher prices for vital, new, medicines in rich and poor countries alike. The end result is that patented drugs are usually significantly more expensive than generic drugs (drugs not protected by patents). Because

patents are the primary rewards that provide research incentives. It logically follows that the patent system would stimulate innovation only where industry sees the opportunity for increasing sales and market share. This is one of the prime reasons why there has been a significant growth in the research and development of lifestyle drugs. The growth in lifestyle drugs, research, development and sales is significantly higher than for neglected diseases only because there is a strong monetary demand for the former.12

A dimension of the health industry being driven by commercial interest is the lack of requisite R&D for a group of diseases which are broadly called Neglected Diseases (ND). The cost of development of drugs for tropical disease seems to suffer from the syndrome of ‘high-input costs into research’ and weak monetary demand which translates into prospects for low returns. In theory, this could be addressed through the patent system which delivers commercial incentives for the costly process of developing vaccines and other drugs, but the prices that a firm would have to charge would prevent access by millions of people. The patent regime has still not been implemented in the LDCs which further reduce patent incentives for the pharma companies to invest in research of tropical and neglected diseases. Trouiller13 noted that 1,393 new medicines were launched globally between 1975 and 1999, but only sixteen were for tropical diseases and 13 drugs (1%) were for tropical infectious diseases, and 3 for tuberculosis. 10 of the 13 drugs were developed for veterinary or military purposes, leaving only three that were the result of genuine efforts to create drugs for neglected diseases. This enormous discrepancy is captured by the notion of the ‘10/90 gap’: 90 per cent of the global disease burden attracts ten per cent of research investments.14

There is no indication that drug development for the most neglected diseases by pharmaceutical companies will significantly improve in the near future. A recent study by the DNDi (Drugs for Neglected Diseases) working group and the Harvard School of Public Health questioned the

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world’s top 20 pharmaceutical companies on their R&D activities for malaria, tuberculosis, African trypanosomiasis, Chagas disease and leishmaniasis (5 of the 13 NDs listed by the WHO). 11 companies responded, representing 29% of the worldwide pharmaceutical market for 2002. Of these companies, 7 reported spending less than 1% of their R&D budget over the previous year on any of those five diseases, and eight spent nothing on the most neglected diseases (African trypanosomiasis, Chagas’ disease and leishmaniasis). None of the responding companies has brought a drug to market in the last five years for any of the most neglected diseases included in the survey.15

The patent system stimulates innovation only where industry sees the opportunity for increasing sales and market share. The poorest are hardest hit. While R&D of new therapies against tropical diseases has ground to a standstill, 14 million people die from infectious diseases each year, predominantly in developing countries.16 It implies that NDs, which are areas of weak monetary demand, remain outside the interest of patent seeking drug companies.17

Access to medicines depends on many critical elements: Research and development Affordable prices, distribution and dispensing of drugs, legal and policy instruments that the government can use to regulate prices, government support of research, sustainable financing and reliable supply systems. There are a host of factors that play a significant role in shaping people’s access to medicines, but drug prices remains a crucial factor in restricting or allowing access. This is particularly true of developing countries and least developed countries (LDCs). Due to limited financial resources in the developing world and persistent poverty, drug pricing has become the most important factor that restricts access to medicines.

There are many determinants of drug pricing. There are many factors influencing and maintaining the higher and unaffordable prices of drugs. While all elements are important, the question of high priced drugs which become unaffordable to the bulk of the population acquires prominence in the context of the TRIPS Agreement. One of the most important contributing factors is patents; patented drugs stand out because of their prohibitive prices in comparison to generic or non-

patented drugs. Patent politics have huge ramifications for drug access and consequently have enormous implications for access to health.

Two cases, the Brazilian and the South African, became international campaigns symbolizing the issue of access to drugs and the sovereign right of a nation to grant the right to health a higher priority than the Intellectual property rights. This manifested in the assertion of the right to either manufacture or import generic drugs of vital concern to the nation's health security. South Africa legislated in 1997 (Medicines and Related Substances Control Amendment Act)\textsuperscript{18} in order to override the TRIPS provisions and facilitate the import of generic anti retro viral (ARV) drugs for HIV/AIDS treatment under a practice termed parallel importing. The law also allowed compulsory licensing, giving the minister powers to permit local companies to manufacture generic versions of patented drugs. This amendment was partly a reaction to the severe HIV/AIDS crisis that the country had been facing, with 4.3 million of the country's 40 million people (more than 10%) estimated to be HIV-positive, making it one of the countries worst affected by the disease, and the lack of access to drugs because of the prohibitive prices of patented ARVs. Less than 1% of the 25 million people infected with HIV/AIDS in Africa were in year 2000 receiving anti-retroviral drugs, yet there were medicines available, proven effective in prolonging lives in western countries. The amended law sought to change this. The South African law was based on the premise that expensive drugs, such as the ARV drugs used in the treatment of HIV/AIDS, were unaffordable to large sections of society and that there was a need to import generic versions of the drug available 30-40% cheaper.\textsuperscript{19} Consequent lack of access to drugs was leading to a serious health crisis within the country.\textsuperscript{20} This law was a clear assertion of a possibility to override patent rights to facilitate availability and affordability of medicines in the interest of public health. The amendment was vigorously challenged by a group of pharmaceutical companies. As many as 39 pharmaceutical companies challenged the South African legislation on grounds that it was in contravention of the non-discrimination clause of


\textsuperscript{19} The cost of annual treatment with the triple-therapy cocktails, which have proven effective in inhibiting the development of HIV into AIDS, was between $10,000-15,000 per person in the United States. Cipla, an Indian pharmaceutical company, offered to sell generic versions of a triple-therapy drug cocktail for $350 per annual treatment to 20 programmes in Africa run by Doctors Without Borders (known by its French acronym as MSF). Cipla said it would be willing to sell the drugs to African governments for $600 per person. Gumisai Mutume, \textit{Pressure mounts for cheaper anti-AIDS drugs} (TWN, Washington, 9 Feb 2001)

Article 27 of the TRIPS agreement. The petition was eventually abandoned in Apr 2001 in the face of strong public opposition and mounting international pressures. The action of the pharmaceutical industry against the South African initiative led to widespread criticism of the TRIPS agreement by the developing world, NGOs and human rights activists.

In 2001, Brazil was involved in international disputes about its program of access to AIDS medicines. At the core of the controversy was Brazil’s need to provide cheaper Anti Retroviral (ARV) therapy (drugs used in HIV/AIDS treatment) by allowing its own generic drug capacity to function and by allowing parallel import of generic drugs. Constrained by the TRIPS laws Brazilian government adopted a decree establishing rules concerning the granting of compulsory licenses in cases of national emergency and public interest. Compulsory licensing is a TRIPS measure that allows the government to permit domestic production or import of a patented product or process (in this case ARV drugs) without a necessary consent of the patent owner. It is one of the flexibilities on patent protection included in the WTO’s agreement on intellectual property, the TRIPS (Article 31). In that year, the WTO accepted a request for a panel by the United States, which was challenging Brazil’s patent laws, particularly the provisions that permitted the compulsory license of patents under special conditions. At its heart, the US challenge questioned Brazil’s commitment to producing Anti Retroviral (ARVs) — nationally. Explicitly, however, the United States was challenging the prospective patent violations that would occur as a result of Brazil’s program. In June 2001, the United States withdrew its complaint before the WTO. In September 2003, a presidential decree was issued that facilitated the importation of generic medicines

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23 Many patent law systems provide for the granting of compulsory licenses in a variety of situations. Specific situations in which compulsory licenses may be issued are set out in the legislation of each patent system and vary between systems. Developing countries, with low or non-existent levels of intellectual property protection, and limited access to new pharmaceutical products, are more likely than other countries to implement legislation permitting compulsory licensing under a broad range of circumstances, including to meet loosely defined “national requirements.” Some examples of situations in which a compulsory license may be granted include health emergencies, particular cases of national emergency or extreme urgency or in cases of public non-commercial use. In cases of health emergencies where it has acquired significant application, the endeavour is to allow the import or domestic production of cheaper generic drugs improve access to prescription medicine which otherwise could not have been possible under the terms of the patented drug.
24 It is significant to note that TRIPS, Article 31 does not use the term compulsory licensing; instead it refers to it as Other Use Without Authorization of the Right Holder. (Refer Annexure 3) of the TRIPS Agreement leaves Members the freedom to determine grounds for granting compulsory licences, provided that the conditions and procedures imposed by Article 31 are met, and taking into account the other provisions of TRIPS.
The Brazilian and the South African experience played a key role in changing expectations in the interpretation of the WTO's TRIPS Agreement. The two cases generated a vast surge in international public awareness on the impact of patents on the prices and on drug access in developing countries and Least Developed Countries (LDCs) and eventually led to ministerial conference culminating in the Doha Declaration on Public Health in November 2001. When the Doha Health Declaration, at the end of 2001, declared that the TRIPS Agreement ought not to stand in the way of AIDS responses, it in effect acknowledged the ethical and practical imperatives represented by South Africa and Brazil.

The Doha Health Declaration (Annexure 1) was a response to the public concerns. Huge public upsurge was generated following the Brazilian and South African cases. NGOs campaigned vigorously on the issue, arguing that the global patent rules known as the TRIPS Agreement would exacerbate the health crisis ravaging poor countries. International debate culminated in the Doha Health Declaration on TRIPS and Public Health, agreed at the WTO Ministerial in Doha in November 2001. This was an important step forward in the campaign for affordable medicines. It affirmed the primacy of public health over intellectual property rights, and the rights of governments to make full use of the public health safeguards in TRIPS. 25 The Declaration reaffirmed and clarified the flexibilities available under TRIPS Agreement, and proclaimed: “We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health....We affirm that the Agreement can and should be interpreted in a manner supportive of WTO Members’ right to protect public health and in particular, to promote access to medicines for all.” It spells out several flexibilities that WTO members can use to the full, such as the right to grant compulsory licenses and the freedom to determine the grounds for these. 26

The Declaration clearly outlines all the key flexibilities available in TRIPS, including:
- The right of countries to use compulsory licensing and to determine the grounds on which to grant them,
- The right of countries to determine what constitutes a national emergency or urgency, which can ease the granting of compulsory licenses,
- The right of countries to determine their own parallel import regimes, and

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25 Refer points 4, 5 and 6 of the Doha Health Declaration.
- The right of least developed countries (LDCs) to postpone providing pharmaceutical patents until at least 2016, and possibly longer.

Significantly, the Doha Declaration does not define the term 'public health'. A narrow interpretation of the term would clearly render many public health initiatives futile. It does recognize the obvious problems faced by developing countries in promoting public health, especially in the wake of epidemics like AIDS, malaria, tuberculosis, etc. But the very fact that the document restricts itself to certain specific epidemics creates a problem as the flexibility may be allowed only in the case of these particular diseases, if at all. The pharmaceutical industry would certainly like to interpret this provision restrictively, leaving out certain diseases prevalent in member countries which may not be internationally recognized as epidemics. For example, diabetes, cancer and certain tropical diseases that are endemic in the developing world may not be given the same importance even though they represent serious public health concerns in many countries.27

Another inherent defect is built into the system through the stipulation that member countries can make use of options such as the compulsory license mechanism to promote public health only when a health crisis has arisen, especially in the form of an epidemic affecting the populace at large. This limitation clearly weakens their right to utilize the apparent flexibility to take preventive and precautionary action before a disease becomes a full-blown crisis. The Declaration does recognize the problems posed by the pricing of drugs and the impact of this on access. At the same time, it accepts the importance of intellectual property rights for the development of new medicines.

It is important to point out that the Doha Health Declaration does not restrict patentability in the field of health even in the context of national emergencies, as Cullet points out.28 It only reaffirms the flexibility in the TRIPS agreement. It specifically focuses compulsory licenses as a means to improve drug access. It reiterates that countries have a right to determine the grounds on which compulsory licenses can be granted. Para 5 of the Doha Health Declaration29, clearly states:

29 DOHA WTO Ministerial 2001. Available at http://www.wto.org/English/thewto_e/minist_e/min01_e/minincl_trips_e.htm
a. In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

b. Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

c. Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

d. The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

The provisions of compulsory licensing are an extremely complex. For instance Article 31(f) of TRIPS ruled that licenses can be used mainly to supply to domestic market. Now this posed a challenge to those countries with health emergencies but with no generic production capacity of their own. Doha Health Declaration recognized in Para 6 that LDCs, who do not have generic production capacities of their own are curtailed by Art. 31(f) of the TRIPS agreement. In other words licenses could not be used to import generic drugs from other countries. This was a serious practical hurdle. LDCs would continue to be denied access to affordable drugs, if this interpretation of Art 31(f) were to continue. This clause also restricted developing countries that do have domestic drug production capacity (e.g. India) from exporting sufficient quantities of medicines to those that do not (e.g. Togo), making compulsory licensing a meaningless measure for many LDCs. 1992 United Nations Industrial Development Organization study indicated that 60 countries do not have the capacity for either active ingredients or formulation. Cognizant of the problem posed by Article 31.f, Paragraph 6 of the Doha Declaration instructed the TRIPS Council to “find an expeditious solution” to this issue by the end of 2002. Negotiations on art. 31(f) continued, with a lot of resistance from the US, to review 31(f). In August 2003 a waiver to 31(f) was implied, with a number of riders and provisos, allowing export through licenses.

30 "The use without authorization of the right holder" allowable as per Art 31 of TRIPS - "shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use." continues to prevail and exports from countries having generic production are barred.

In August, 2003, the WTO adopted the "August 30th decision" which allows the export of medicines produced under a compulsory license — restricted in the TRIPS agreement by the requirement that a compulsory license be ‘predominantly for the domestic market’. A country could import a generic version of the patented product by issuing a compulsory license to a company or agency to import the drug, and the government has the freedom to determine the grounds upon which such licenses are given. The imported drug can be from a country in which the drug is not patented, or in which the drug is patented, in which case the exporting country has also to issue a compulsory license. The applicant has to firstly negotiate to obtain a voluntary license from the patent holder (except in cases of public non-commercial use, situations of extreme urgency and national emergency) and if that fails, then a compulsory license can be granted. Adequate compensation has to be paid to the patent holder.

The August 30th solution is needlessly complex, says Ellen t’Hoen, Policy Director of MSF Access to Medicines Campaign, and is not likely to remove the real threat of dwindling generic production in countries such as India. The potential role of compulsory licensing in promoting access to medicines is replete with compelling issues. The issue of compulsory licenses is also mired in the politics of bilateral relations and has not proved the most uncontentious way to address critical public health concerns. In the absence of national patent legislations which protect public health concerns, compulsory licensing may not be the best strategy. Says Martin Khor of Third World Network, “If the Doha Declaration is to benefit patients of AIDS and other ailments in developing countries, these countries now have to establish appropriate provisions in their national patent legislation by using “to the full” the flexibilities in the TRIPS Agreement…In other words, whilst in recent years the goal for access to medicines had been significantly fought at the international level, action is now equally or even more important at the national level, where policy makers should focus on policy and practical measures to get medicines to poor patients”.

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32 Refer Annexure 4.
33 For details refer Martin Khor, Patents, Compulsory License and Access to Medicines: Some Recent Experiences. TWN: twnet@po.jaring.my. February 2007
35 Martin Khor, Patents, Compulsory License and Access to Medicines: Some Recent Experiences (TWN, 2007)
A number of developing countries, Indonesia, Malaysia, Mozambique, Zambia and more recently in 2005, Thailand, have made use of compulsory licensing or government use orders to enable the supply of more affordable generic drugs in recent years. However, access to medicines is being affected by new developments such as bilateral free trade agreements (FTA), 'TRIPS plus' agreements and the coming into force of India's new patent laws in 2005. Two factors in recent times have and will ensure that compulsory licensing will not be the most effective tool to facilitate the supply of generic drugs. First as Mogha Kamal Smith of Oxfam said, the space given to developing countries by the August 2003 agreement, is being taken away by bilateral and regional free trade agreements (FTAs) with developed countries, especially the United States. (Annexure 5). USA also seeks worldwide harmonization of intellectual property rules on a level at or above US law, which is stricter than TRIPS, known as TRIPS PLUS agreements.

According to the Report of the Industry Trade Advisory Committee on Intellectual Property Rights (ITAC 15), which is part of the United States Trade Representatives (USTR's) formal advisory committee structure and represents the pharmaceutical industry, 'The Committee seeks to establish strong precedents in these FTAs in order to raise the global level of protection and enforcement globally, nationally and in regional and in multilateral agreements. The FTA process has become the principal process through which the IPR-based industries are able to ensure that the standards of protection and enforcement keep pace with new developments.'

A central element of the recent set of bilateral FTAs is the establishment of strong rules for the protection of intellectual property rights (IPRs). There are many restrictions that FTAs impose. For instance to effectively make use of compulsory licenses, generic drug manufacturers need to be able to obtain regulatory permission to enter the market. Provisions in the bilateral agreements impose an obstacle in this respect. All but two agreements (US-Vietnam and US-Jordan) prevent marketing approval of a generic drug during the patent term without the consent of the patent holder—an issue on which TRIPS does not impose any obligation. In other words, compulsory licenses may become ineffective in introducing competition from generic drug makers. The FTAs require developing countries to undertake commitments beyond those in TRIPS. For example, some FTAs require that countries not make use of "parallel imports" while others restrict the grounds for compulsory license.

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Table 1: Free trade related agreements with participation of Latin American and Caribbean countries*

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<tr>
<th>Country</th>
<th>Negotiated</th>
<th>Under Negotiation</th>
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<td>USA with</td>
<td>-1992: NAFTA</td>
<td>-Free Trade Agreement of the Americas (FTAA); Ecuador, Panama</td>
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<td>-2003: Chile</td>
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<td>-2005: US-Central America and Dominican Republic (CAFTA-DR)</td>
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<td>-2006: Peru, Colombia</td>
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<td>-2007: Uruguay</td>
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<td>EU with</td>
<td>-1997: Mexico</td>
<td>-Andean Community***; MercoSur**</td>
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<td>-2000: ACP Countries -Cotonou Agreement</td>
<td>-Regional bilateral economic partnership negotiations, built on Cotonou Agreement: Countries of CARIFORUM (Caribbean)</td>
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<td>-2002: Chile- 2003</td>
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<td>EFTA*** with</td>
<td>-2000: Mexico</td>
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<td>Republic of</td>
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<td>Korea with</td>
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<td>Japan with</td>
<td>2005: Mexico</td>
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<td>-2007: Chile</td>
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<td>Taiwan with</td>
<td>-2005: Panama</td>
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*Dates refer in general to the year of signing of the respective agreement  
**Argentina, Brazil, Paraguay, Uruguay, Venezuela  
*** Norway, Liechtenstein, Iceland, Switzerland  
**** Bolivia, Colombia, Ecuador, Peru

Sources:  
www.ustr.gov  
http://secretariat.efta.int  
www.bilaterals.org

Many of the FTAs also impose "data exclusivity" clauses which restrict the use of the patent holder's test data as the basis for granting safety approval of the generic versions of the same drug. FTAs are routinely used by the branded-drug companies to prevent or delay competition from generic drugs, which adversely affected the patients' access to medicines.

Section 301 is another tool employed by the pharmacy companies to bring about TRIPS compliance. Throughout the Uruguay Round (September, 1986) the USA repeatedly put on its "Special 301 watch list" countries that supposedly did not provide the kind of intellectual property protection it wanted. Take the case of fluconazole and its generic versions being marketed in Thailand in 2001. Fluconazole is a vital treatment tool for meningitis associated with HIV/AIDS infection. It was in early 2001 sold by Pfizer at $12 (about Rs.560) a tablet. At the same time, generic drug manufacturers in Thailand were offering an identical dosage at a price just in excess of 50 cents (about Rs.23). Pfizer fought a long process of attrition against this cut-rate offering, frequently threatening legal action for alleged infringements of its patent on the drug. It also lobbied successfully through the powerful industry organization, the Pharmaceuticals Research and Manufacture America (PhRMA) to have Thailand notified under Section 301 of the U.S. Trade Act as a country that provided inadequate standards of protection for intellectual property. If Pfizer was stopped in its tracks and deterred from following up on its threats, it was a tribute to the global mobilization on access to essential medicines. In its 2001 Report, Oxfam argues that: "these TRIPS provisions are hedged in by onerous conditions and, in practice, efforts to apply these measures have been fiercely contested by pharmaceutical companies, often with the backing of western governments."

A second factor that seriously threatens to affect supply and production of generic drugs is full TRIPS compliance by India from December 2005. India, known as the pharmacy of the world, is a leading supplier of generic drugs to the world. Generic drugs have not only been supplied under compulsory licensing to various countries (HIV drug, Efavirenz to Thailand being a recent instance in 2005), but have been instrumental and invaluable in providing competition leading to reduction of prices of patented drugs. Ellen 't Hoen, of Medicins Sans Frontieres, expressed concerns that the main source of affordable generic versions of new medicines may dry up in future as India allows for patents on medicines from 2005 to comply with its TRIPS obligations.

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40 Section 301 of the Trade Act is the principal statutory authority under which the United States may impose trade sanctions against foreign countries that maintain acts, policies and practices that violate, or deny U.S. rights or benefits under, trade agreements, or are unjustifiable, unreasonable or discriminatory and burden or restrict U.S. commerce
The 2006-2007 Novartis' patent claim for Glivec (Gleevec), a drug used to treat Leukemia and some forms of stomach tumors, demonstrates the threat that the TRIPS regime holds for production of generic drugs, the space that the Doha Health Declaration provides for countries to legislate in order to protect their health concerns, and the procrastinated nature of legal wrangles that ensue when a country attempts to build in safeguards even within the broad framework of TRIPS. The case (hereafter referred to as the Novartis/Glivec case) is significant because it became the global face of a battle to allow the supply of generic drugs and to protect the sovereign right of a nation to legislate in order to check the implications of intellectual property rights in health related products, for health is fundamental to our very existence without which we cannot live as human beings. Before Novartis/Glivec case study is undertaken, it is relevant that we briefly understand the key TRIPS provisions and amendments related to health in the Indian patent laws.

**Patent Laws in India**

The pharmaceutical industry views the patent system as essential to its business model. Under the basic concept of the patent system, an inventor is entitled to a limited monopoly (technically, a right to exclude) for a period of time, typically twenty years. Such exclusivity may permit high prices during the patent term; the consequent profit incentives provide the basis for the pharmaceutical industry to invest in the very costly development process that is necessary to bring new drugs to market. When a patent expires, the price normally falls as generic competitors enter the market. Generic production of drugs has, as demonstrated earlier are one of the prime market forces that regulate drug prices.

Initially a number of developing countries like India, however, viewed patent law quite differently and deliberately decided to deny patent protection to pharmaceutical products and to grant protection only to processes for producing pharmaceuticals. These countries believed that access to pharmaceutical products is so important that the products themselves should not be patented. In its 1970 patent law India excluded drugs from product patent protection, effectively choosing to provide low-cost drugs for its people at the expense of perhaps eliminating incentives to create new products. The 1970 Act, as originally enacted, prohibited the grant of product patents for drugs and pharmaceuticals; only process patents were allowed. As evident from Section 5 of the Indian Patents Act where only *methods or processes of manufacture* patentable – “claiming
substances intended for use, or capable of being used, as food or as medicine or drug, ... no patent shall be granted in respect of claim for the substances themselves, but claims for the methods or processes of manufacture shall be patentable.\textsuperscript{44} The Act specially indicated that patents are granted to encourage innovation and not merely to enable patentees to enjoy a monopoly for the importation of the patented articles.\textsuperscript{45}

This law was one of the reasons that the Indian generic drug industry was able to evolve to make and market copies of drugs still on patent in wealthier countries. India has become a major international supplier of drugs to countries where these products can be marketed legally because they have not been patented locally. India began to be known as the pharmacy to the developing world. This situation changed when India agreed to switch over to the product patent regime after becoming a member of the WTO in 1995. Though India became a member of the WTO in 1995, it was given a 10-year transition period to bring into effect the change in regime from granting process patents to product patents for drugs. The TRIPS Agreement being a minimum standard agreement requires its members to grant patents for inventions in all fields of technology for a period of 20 years if it satisfies the universally accepted criterion of patentability.

In order to harmonize its patent law with other patent regimes by implementing the provisions of the TRIPS Agreement, amendments in the Patents Act, 1970 (the 1970 Act) were carried out by the India through legislation in three stages- effective January 1, 1995 by Patents (Amendment) Act (1999), effective May 20, 2003 by Patents (Amendment) Act (2002) and effective January 1, 2005 by Patents (Amendment) Act (15 of 2005).

In conformity with TRIPS Agreement, India amended the Patents Act by the Patents (Amendment) Act 1999 \textit{effective from 1995}. The 1999 amendment brought one significant change from the perspective of drug patents. It left prohibition of product patent on food and health untouched but added a clause to section 5 which permitted the filing of a patent claim. It provided for receipt of product patent applications and for granting Exclusive Marketing Rights (EMRs) on such applications in the fields of pharmaceuticals and agricultural chemicals, till patent is granted or patent application is rejected. Product patents were to be filed only for products developed/ invented/innovated after 1995, the year in which India became a member of the WTO.

\textsuperscript{44} Section 5, Patents Act, 1970  
\textsuperscript{45} Section 83, Patents Act, 1970
The Amendment of 2002 was an endeavour to avoid confrontation with the WTO; India was under pressure from the USA and the WTO for lagging behind in the implementation of TRIPS guidelines. The circumstances implied that the balance of interests between inventors and the general public shifted in favour of the former. The Act included the main TRIPS requirements such as a 20-year uniform duration (earlier the process patent in the field of health and nutrition was only 7 years). In the field of compulsory licensing safeguards continued to be strengthened. Section 83 mentions that patents granted should not ‘impede protection of public health’.46

India was required to introduce product patent protection in these sectors from 1.1.2005 in accordance with the obligation under the TRIPS Agreement of the WTO. The Patents (Amendment) Act, 2005 (No. 15 OF 2005) was passed in March 2005, with effect from January 1, 2005. From the perspective of the chapter following were some of the significant changes in the Amendment.

- The Patents (Amendment) Bill 2005 introduced product patent regime for food, chemicals and pharmaceuticals.
- Provision (Section 92A) for enabling grant of compulsory license for export of medicines to countries which have insufficient or no manufacturing capacity, to meet emergent public health situations (in accordance with the Doha Declaration on TRIPS and Public Health)
- Changes in Section 3 were made listed out the exceptions to patentability, i.e., what are not considered to be inventions. Section 3 (d) was added: “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”.

The enhancement in efficacy was further qualified in the Explanation,47 to the sub-section. The enhanced efficacy must exhibit significant differences in properties with regard to efficacy. Thus the dividing line between being an eligible subject matter to be considered for grant of a patent and not being patent eligible is the efficacy. Efficacy is an important criterion for there exists a

46 Section 83 (d), (e), (g) of the Patents Amendment (2002) Act
47 Section 3 lists out the exceptions to patentability, i.e., what are not considered to be inventions Explanation to Section 3 (d): “Salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations, and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.
class of patents, known as 'Selection Patents' (patent law jurisprudence in UK courts) where a patentee is granted a patent for 'a selection of substances' from the class to protect the newly discovered form or use. The grounds for granting these patents is the assumption that only a few chemical compounds from a class, which often happen to be very large; therefore, to grant patent for the whole class comprising several related chemical compounds may result in a broad monopoly. Therefore patent protection was granted to the new use or forms discovered for other members of a class of chemical compounds. The critical part here is that the novelty is derived from the use not the product. A selection patent will be tested for novelty and inventive step in the normal way but these may be found in the use. It is in this context that clause (d) of Section 3 assumes significance. It is an endeavour to ensure the 'novelty of use'. Being efficacious is a feature which may emphasize the use as an inventive step. Section 3(d) therefore makes it clear that a number of technical creations are not inventions, unless they present a significant increase in efficacy. The statute of India is therefore relying on utility to transform non-patentable inventions into patentable inventions

Section 3 (d) of the Indian Patent Law constitutes an important public health safeguard which prevents "evergreening" (making superficial changes to known inventions) and tweaking of old medicines to make or extend patent claims. These exceptions are significant for they seek to make patent claims for new drugs conditional on the novelty and the efficacy of the new innovation, thereby ensuring that patents for drugs are not claimed for mere incremental improvements over existing drugs.

This provision is in conformity with the Doha Health Declaration and one that is endorsed by the CIPIH report. 48 Each country can introduce a patent regime that is more suited to its socio-economic context. This is also in keeping with the 2001 Doha Declaration on the TRIPS Agreement and public health.

The product patent regime that India became a part of, had significant implications for the health industry and importantly, for the supply of affordable drugs to the rest of the world. There were safeguards introduced keeping in mind India's pharmaceutical export potential and public health concerns. The concern is based on the fact that over a period of time Indian drug companies will

lose the opportunity to develop processes for patent protected drugs in the country and therefore will cease to be a supplier of affordable generic drugs to millions across the world.

It is in the background of these changes and amendments to the Indian patent law that the Novartis patent claim for Glivec needs to be evaluated. In focus are two issues that are brought to the fore by this case: First, the right of a sovereign country to build in safeguards in its patent laws in order to safeguard the interest of its people. A related issue is also the viability and the de facto acceptability of the Doha provisions, especially section 4 and 5, which recognizes this right of a state and affirms the right of nations to use the exceptions of TRIPS. The second issue relates to the issue of drug access, so vital for the realization of health as a human right.

RIGHT TO HEALTH IN THE CONTEXT OF IPRs: A CASE STUDY OF THE GLIVEC BATTLE IN INDIA

Imatinib Mesylate (Glivec)) is a cancer drug crucial in prolonging the life of patients suffering from Chronic Myeloid Leukemia (Blood Cancer). Since Imatinib Mesylate controls the cellular action that allows the cancer to grow but does not cure the disease. This means that patients must take it for the rest of their lives, unless another type of treatment or cure is available. Glivec is produced and marketed internationally by the Swiss pharmaceutical company Novartis and various Indian generic producers like Cipla, Ranbaxy, Natco, and Hetero. Novartis sells Glivec at Rs. 1.44 million (US$ 26,000) per patient per year. Generic versions of the drug Glivec in the Indian market are priced at about Rs. 96,000 (US$ 2100) per patient per year. Novartis is charging high prices for Glivec worldwide: from about 25,000 USD to more than 50,000 USD per patient per year (50,000 CHF per patient per year in Switzerland). Gleevec® grossed 2.17 billion USD global sales to the company in 2005.

Patent Claim by Novartis

In 1998 Novartis had filed an application in the Chennai Patent Office for a patent on Glivec. Based on the patent application and a particular provision of the Indian Patents Act, Novartis in November 2003 obtained exclusive marketing rights (EMR) till patent was granted—in case the patent was rejected the EMR would be cancelled. It signified the first instance of grant of a patent.

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50 Ibid
patent-like right known as the EMR, which led to the world's first contentious case of EMR. In fact, the EMR operated like a patent monopoly preventing Indian pharmaceutical companies from producing affordable generic versions of the drug Imatinib Mesylate. Indian generic companies had to withdraw the production and sale of the generic versions of the drug for the domestic market and export to other developing countries. The access of Cancer patient's to generic Imatinib Mesylate was affected. With an over 10 fold increase in the price of the drug, Cancer Patients Aid Association and some of the NGOs who provided the more affordable generic versions to patients for their treatment had to withdraw their medical support to cancer patients. Patients of other developing countries who were importing generic versions of the drug were also seriously affected by the unavailability of the affordable versions.

In 2005 when India became TRIPS compliant in all fields of technology including pharmaceuticals for which applications had earlier been filed. India put in a key public health safeguard in the form of Section 3(d). Section 3(d) of the Indian Patents Act 1970, amended in 2005, disallows patents for marginally modified drugs, which do not constitute a novel molecule or original invention unless its improved efficacy can be proved. Section 3(d) of the Act states that "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" shall not be treated as an invention within the meaning of the Act.

Novartis' patent application on Glivec came up for examination in 2005. The patent law allows for any person or group to oppose a patent application and accordingly several pre-grant oppositions had been filed against the patent application of Novartis. Armed with this provision, pre-grant opposition was filed by Alternative Law Forum (ALF) and Lawyers Collective, on behalf of the Cancer Patients Aid Association (CPAA) in September 2005, against the Novartis patent application for Glivec, claiming that this application only concerned a modification of an already existing drug that did not improve its efficacy, as required by Section 3(d) of the Patent Act. Secondly that the non-availability and non-affordability of any form of Imatinib Mesylate to Chronic Myeloid Leukemia (CML) patients is violative of rights of the CML patients under Articles 14 and 21 of the Constitution.

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51 As did Cipla, Natco Pharma, Sun Pharmaceuticals and Ranbaxy in their own right. Natco Pharma, which launched a generic version of Gleevac under the brand 'Veenat', had also challenged the grant of EMRs to Novartis.
52 Text of the Writ petition No. 24759 OF 2006 in The High Court of Judicature at Madras. Clause16, p.12
In a landmark decision, the patent office in Chennai declared in January 2006 that Novartis patent application for Glivec was insufficient to meet the requirements of Section 3(d).

**Grounds of Rejection by the Chennai Patent Office**

There were two points in the Novartis patent claim which are specifically important. Novartis preferred to file an application for *beta crystalline form of imatinib mesylate* (Glivec) in 1998. Imatinib as a 'free base' molecule was invented by Novartis in 1992 and patented in the U.S. and other countries in 1993. Novartis however chose not to apply for a patent for the imatinib free base in India as India did not offer product patent protection in 1993 and was not committed to entertain patent applications for drugs and products developed prior to 1995 (the year it joined the WTO) It is pertinent to note that the 1993 U.S. patent of imatinib, disclosed the salt imatinib mesylate.53

But in 1998, Novartis came up with an application for a *beta crystalline form* of imatinib mesylate which was claimed to be a *new form of a known substance*. The text of Indian Decisions on Glivec Patent Application reveals that imatinib mesylate salt *inherently* existed in the beta-crystalline form which is more stable. This was confirmed by the opponents to patent application through multiple tests performed by the Indian Institute of Chemical Technology, Hyderabad and Indian Institute of Technology, Delhi. However, even if the newness of form was demonstrated by Novartis it had to cross the hurdle of 3(d). The new form of a known substance, as per 3(d) would be entitled for a patent if it results in *the enhancement of the known efficacy of that substance*. In full knowledge of this requirement of the Indian law, Novartis tried to demonstrate before the Controller how there was an enhancement of efficacy and submitted that there was an enhanced bioavailability of 30 per cent in studies conducted on rats. Bioavailability is one of the indicators of efficacy of a drug. The explanation to section 3(d) requires 'enhancement' be significant. Novartis' case suffered as they had produced a bioavailability study conducted on rats while the drug was admittedly in the market for many years and was consumed by humans. Then again, it was not shown how the 30 per cent increase was critical in the performance of the drug.

and how the increase in enhancement of efficacy made a difference when compared to known efficacy. 54

Following these grounds of pre-grant oppositions, the Assistant Controller of Patents & Designs, Mr V. Rengasamy, in his ruling said he was not convinced with the contentions of Novartis AG that the patent application claims a new substance. "It is only a new form of a known substance. It is found that this patent application claims only a new form of a known substance without having any significant improvement in efficacy. Further, stating that Novartis AG failed to prove enhanced efficacy of the beta-isomer over the known substance, the Assistant Controller has concluded that, "the subject matter of this (patent) application (filed by Novartis AG) is not patentable under Section 3(d) of the Patents Act 1970 as amended by the Patents (Amendment) Act, 2005." Novartis' application to patent the beta crystalline form of imatinib mesylate was rejected by Chennai Patent Office in January 25, 2006.

The Novartis Challenge

On 17th May 2006 the Swiss pharmaceutical company Novartis Ltd. filed two cases challenging the rejection of the Glivec patent application and the Indian Patent Law. Not only did Novartis appeal the patent office decision, but in a rather controversial move, it challenged the TRIPS compatibility and constitutionality of section 3(d). Aggrieved by the order of the Controller, Novartis approached the Madras High Court with two batches of writ petitions:

1) Challenging the constitutional validity of section 3(d)
2) Challenging the patent order of the Chennai Patent office rejecting the Glivec patent application filed by Novartis.

The First Case:

In the writ petition challenging the constitutional propriety of section 3(d) and its compliance with TRIPS, Novartis took a contradicting plea that the provisions section 3(d) was vague and arbitrary. In the Writ Petition No. 24759 of 2006 in the High Court of Madras, section S and T, the petitioner Novartis alleged the following:

54 Serious technical challenges were submitted to the Controller about the enhanced efficacy of the new compound by Natco Pharma Ltd]. C.R. Sukumar, “Novartis loses patent claim on cancer drug — Patents Controller upholds Natco contention,”. Financial Daily. The Hindu. (Jan 26, 2006)
That section 3(d) of the Patents Act, 1976; amended by Patents (Amendment) Act 15/2005, is unconstitutional on the ground that it violates Article 14 of the Constitution of India i.e the Right to Equality as it discriminates against the pharmaceutical sector vis a vis other technology sectors.

The “new Section 3(d) is arbitrary and illogical, is in violation of India's obligation as a signatory to the TRIPS”:

3(d) “is not at all permissible under the TRIPS Agreement. Article 1(1) of the TRIPS Agreement...“The new added section 3(d) is in clear violation of Article 1(1) of the TRIPS Agreement” which reads as follows:-

"Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this agreement, provided that such protection does not contravene the provisions of this Agreement........ " (Emphasis supplied).

3(d) violates Article 27 of the TRIPS Agreement, which provides “for uniform condition of patentability without discrimination as to the subject matter involved”. Under Article 27 of "TRIPS", all inventions, subject to paragraphs 2 and 3 of that Article, are patentable.

That the drug invented, i.e., Glivec, is patentable.

That a discovery becomes an invention if the substance in question results in enhancement of known efficacy is a very ingenious concept. This concept at a discovery ‘graduating into a patentable invention solely on the basis of efficacy defies logic’. 55

The Second Case:

Statutory appeals were filed by Novartis, challenging the rejection of its patent application by the Chennai Patent Control Office. Novartis' application to patent the beta crystalline form of imatinib mesylate was rejected by Chennai Patent Office in January 25, 2006. In April 2007, the High Court transferred the statutory appeals to the Intellectual Property Appellate Board (IPAB). This case is pending before the IPAB but it is believed to be likely that the patent rejection would be upheld. Also section 3(d) is compatible with TRIPS, as it is an "obviousness" standard that member states are free to define in a manner consistent with their national policy. Section 3(d) does not "discriminate" against the pharmaceutical sector but only makes a "justified"

55 Refer, Novartis petition at The High Court of Judicature at Madras (Special Original Jurisdiction) w.p.no.24759 of 2006
differentiation, given the specificity of salt forms in the pharmaceutical sector i.e. other technology sectors such as mechanicals, electronics etc do not face "different salt form" kind of issues. To win, Novartis must convince the IPAB that (a) in relation to 3(d)-the 30% increase in bioavailability is an enhanced efficacy and so the beta crystalline form is patentable, and (b) the beta crystalline form of the mesylate salt is not an obvious form of the free base form.

Cancer Patients, public interest and health groups demand withdrawal of cases
As a legal battle launched by the Swiss pharmaceuticals multinational Novartis against India's patents law warmed up, health activists geared up to mount a campaign against drug monopolies and the people's right to medicines at affordable prices. An international campaign by Médecins Sans Frontières (MSF), OXFAM, Knowledge Ecology International, Health Action International, Third World Network, Delhi Network of Positive People, India, Centre for Trade and Development, India, Instituto Brasileiro de Defesa do Consumidor, Brazil, Associação Brasileira Interdisciplinar de Aids, Brazil, Grupo de Trabalho da REPRIB sobre Propriedade Intelectual (GTPI), Brazil, Berne Declaration, Switzerland, states that the real issue is about Novartis challenging India's right to independently interpret and implement the TRIPS Agreement.

At stake was, and in many ways still is, not just the fate of the Indian drug industry, described as "the pharmacy of the developing world", but the life and well-being of hundreds of millions of users of generic drugs the world over. "We have opposed patent applications for crucial AIDS drugs", says Elango Ramchandar, president of Indian Network for People with HIV/AIDS. "Our survival depends greatly on winning these patent oppositions. Novartis is a test case for us." The Glivec/Novartis case has ramifications beyond the provisioning of Glivec at affordable prices. If Novartis were to win the case it would set a precedent for the 9000 cases pending in the mailbox, some of them for minor, incremental changes brought about. A large chunk of these have been filed by the local units of drug majors such as Merck, AstraZeneca and Pfizer. Whether patents on these medicines are granted may depend on the outcome of this case. If Novartis were to prevail, India would cease to be the pharmacy of the developing world, and access to medicines will be further threatened. "Novartis is trying to shut down the pharmacy of the developing world," said Dr. Unni Karunakara, Medical Director of MSF's Campaign for Access to Essential Medicines, in New Delhi.56

56 Available at http://www.accessmmed-msf.org/prod/publications.asp?scntid=29120071123437&contenttype=PARA&
Ninety-one organizations and personalities from around the world also made a call to Novartis to drop the case in an open letter in October 2006 to Daniel Vasella, Chairman and CEO of Novartis.:

Dear Mr. Vasella,

Alerted by Indian patients with cancer, health organizations and public interest groups, we are writing to you to express our concerns regarding the legal proceedings that Novartis has started in May 2006 in order to challenge the rejection of its patent application for imatinib mesylate (Glivec®/Gleevec®) as well as the compliance of the Indian Patents Act with the World Trade Organization’s Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). We are joining the Indian organizations in their demand that Novartis withdraws these cases.

In particular, we are extremely concerned with Novartis’s challenge of Section 3(d) of the Indian Patents Act, which Novartis claims is not compliant with the TRIPS Agreement.

Section 3(d), which prevents the grant of patents for new forms or new uses of known substances, is one of the recognized flexibilities of the TRIPS Agreement that countries are utterly free to adopt in their legislation. The importance of these flexibilities has been highlighted by the United Kingdom Commission on Intellectual Property Rights in its 2002 report as well as by the World Health Organization Commission on Intellectual Property Rights, Innovation and Health in its 2006 report.

Such a challenge is in contradiction with the spirit and the letter of the Doha Declaration on the TRIPS Agreement and Public Health. The Declaration states that the TRIPS Agreement ‘can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all’. With this challenge, Novartis

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is seeking to limit the ability of the Indian Government to take measures to protect the public health of its population and to have a patent system adapted to the Indian socio-economic context.

We are very concerned that the changes sought by Novartis in the Indian Patents Act could negatively affect access to essential generic medicines (in particular HIV/AIDS medicines) not only in India but also in all the developing countries that import Indian generic medicines.

Novartis sells Glivec®/Gleevec®, a life-saving medicine at prohibitive prices in India (Rs. 1.44 million, or US$ 26'000, per patient per year) and in other developing countries. This price is well above the financial capacity of the majority of patients in developing countries. Novartis recognizes that only a small number of patients in India are paying for the medicine.

Access to health care and medicines in developing countries depends on different factors and requires solutions at various levels. However, it is everyone's duty to remove barriers within its own abilities.

We are shocked that five years after the end of the trial brought by Novartis and other pharmaceutical companies against the South African government, Novartis is trying again to restrict the flexibility given to a country to adapt the TRIPS Agreement to its public health needs.

The undersigned organizations demand that Novartis withdraws the cases against the Indian Patents Act and the decision of the Indian Patent Office on Glivec®/Gleevec®.

Sincerely yours,

Julien Reinhard
Campaign Director
Berne Declaration
Leading medical journals such as The Lancet, global health organizations and officials in many countries have all asked Novartis to drop the case. MSF launched a petition that now has nearly a quarter of a million people from over 150 countries who expressed their concern about the impact of the Novartis case on access to medicines in developing countries. This campaign may have had an important bearing on the case.

**Court Ruling, 6th August, 2007**

The Chennai High court ruled that it wasn't the proper forum for deciding whether the laws were compliant with WTO rules. The court ruled that the matter with reference to contravention of the TRIPS agreement be taken to the Dispute Settlement Board, instituted as part of the TRIPS framework and that it was outside the purview of the court to adjudicate in this matter. Consequently the matter in the court hinged on Section 3d and its implications. [Clause 8 of the judgment]

The bench, comprising Justice R Balasubramanian and Justice Prabha Sridevan, upheld the amended act and upheld the validity of Section 3(d). It said that "India, being a welfare and a developing country, which is pre-dominantly occupied by people below poverty line, it has a constitutional duty to provide good health care to its citizens by giving them easy access to life saving drugs. In so doing, the Union of India would be right, it is argued, to take into account the various factual aspects prevailing in this big country and prevent "evergreening" by allowing generic medicine to be available in the market.

It ruled that "there is no ambiguity or vagueness in the expressions under attack as found incorporated in the amended section and the explanation attached to it." Further it added that one of the fears of the petitioners was that the amended section 3d could lead to arbitrary interpretations and misuse. The conclusions of the Court ruling was that "no law can be declared illegal because there is a possibility of its misuse" and "the Legislature has a duty to safeguard the economic interest of the country."

The court held that the amended section is not in violation of Article 14 of the Constitution of India. Section 3(d) does not "discriminate" against the pharmaceutical sector but only makes a "justified" differentiation, given the specificity of salt forms in the pharmaceutical sector i.e. other

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technology sectors such as mechanicals, electronics etc do not face "different salt form" kind of issues.

THE GLIVEC CASE IN A LARGER PERSPECTIVE

It is important to underscore why the Glivec case is so significant in understanding the manner in which intellectual property rights in medicinal drugs is infringing health rights. Novartis claims that this battle is for protection of its intellectual property on grounds of principle. Glivec, through the GIPAP programme is being distributed widely and successfully among the needy and poor." In 2006, our access-to-medicines program reached 33.6 million patients. Novartis spent USD 755 million last year alone. ... The Glivec International Patient Assistance Program (GIPAP) is one of the most far-reaching patient assistance programs every implemented on a global scale. In India, 99% of patients who receive Glivec receive it free from Novartis [6,600 people].

The patent right for Glivec, it was therefore claimed, would not conflict with health interests because Novartis is distributing Glivec free of cost to around 7000 patients in India. Novartis says that there is virtually no commercial market for Glivec in India. It is distributing drugs free of cost to 99% of the CML patients in India. Its official website quotes that the price of Glivec is almost irrelevant in India as 99% of the patients who need the medicine receive it free from Novartis through the Glivec International Patient Assistance Program (GIPAP). The pharma giant claims that the law suit was in order to "align Indian IP laws with TRIPS", the World Trade Organization's agreement on intellectual property. The claims made are debatable. Novartis claims to benefit 7000 patients in India so far; CENTAD (Centre for Trade and Development), an independent, not-for-profit organization cites the prevalence of about 27000 new cases of CML every year. Almost ten patients die every day from CML and that the demand for this drug is nearly 30 lakh capsules per month. Such demand can not be met by giving patenting right to a single entity.

60 Quoted from Brook K. Bakerhttp://www.cptech.org/ip/health/c/india/hgap02072007.html .
Novartis' GIPAP programme is fraught with inequities and irregularities as has been demonstrated by the cases in Brazil, Argentina, Korea. One of the first conflicts over Glivec occurred in South Korea when patients protested over the price of Glivec and the lack of insurance cover for the drug. The Ministry of Health and Welfare announced official Glivec price and official insurance coverage. Novartis refused to comply with the official Glivec price and threatened to pull Glivec out of the South Korean market; CML patients could not obtain Glivec because of supply instability. Novartis reached a settlement with the Government after a long standoff. The government agreed to reimburse Novartis 80% of the 'global average price' ($27,000), and Novartis and the consumer were to each shoulder 10% of the cost of Glivec. In addition to this there are some patients who cannot afford even the proposed 10% of the cost of the medicine. Generic versions of Glivec have not been given marketing approval by the South Korean government. South Korean law nevertheless has an exception called the 'personal use' exception, which allows patients to procure the generic drug individually. Nearly 50 South Korean patients are currently importing the generic version (Veenat) produced by Natco India Ltd at $1 per tablet as opposed to the $20 charged by Novartis. Hence the outcome of the litigation in India has a direct impact on access and affordability elsewhere.

In India too the GIPAP has not been without contention. Novartis began its donations of Glivec with a warning that it would halt the program if the government let local companies eat into its profits by selling generic versions of the drug. Hundreds of Indian cancer patients got Glivec free, and commercial sales soared, as well. But after India cleared generic Gleevic for sale, Novartis made good on its threat in April 2003, saying it would leave it to Indian companies to meet the needs of the patients. It suddenly discontinued its free Glivec program without caring for the patients depending upon that. New York Times described the Glivec donations as both the

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63 For a brief synopsis of the issues see, Charity for Monopoly Rights: Some Global Experiences of Drug Donation Programs of Pharmaceutical MNCs. Care, India, Draft Document. 2007; Also see http://www.essentialdrugs.org/edrug/archive/200608/msg00070.php

64 In wealthier countries like South Korea, Hong Kong and New Zealand, Novartis has encouraged patients who have received free drugs to become advocates for high priced drugs to be included in the insurance cover, pressing public health systems to pay high prices for the drug. See, “Drug Maker's Vow to Donate Cancer Medicine Falls Short,” The New York Times, June 5, 2003

65 For details see Request for a Compulsory License from KIPO (Korean Intellectual Property Office) to grant a compulsory license for registered patent No. 261366 (Glivec patent) in accordance with Article 107(1)(iii) of the Korean Patent Law.

promise and the perils of corporate philanthropy. This drug donation program was resumed only after the EMR was granted in November 2003 which removed, as mentioned earlier, the generic versions from the market.

The Cancer Patient Aid Association's petition (22\textsuperscript{nd} Jan, 2007) in the Chennai High Court, brings various evidences of denial of access to Glivec to many genuine patients in India including the workers who have insurance coverage under the Employees State Insurance Scheme or the Central Health Insurance Scheme, but are not reimbursed cost of treatment of diseases like chronic myeloid leukemia (CML).\textsuperscript{66} Philanthropy has been often used as pressure tactics to increase intellectual property protections in developing countries. It has also been used, as in India, to lobby or pressure a country not to use TRIPS safeguards or to introduce their own safeguards to protect public health, as was the case with Section 3d. While patenting or becomes a logical corollary to cover the cost of R&D and innovation, for diseases in poor countries, drug donation and discounted drugs for the much-hyped corporate social responsibility become the legitimizing principle for forcing patenting and discouraging generic life saving drugs in those countries, to protect the market from generic drugs. Innovation, patenting, high pricing-and drug donation form a vicious circle of the corporate logic of pharmaceutical industries, which deny access to essential drugs to millions of people in the least developed and developing countries. The politics of drug donation is beyond the scope of this study but it would suffice to say here that philanthropy is often, in these cases, driven by commercial and vested interests.

The core issue being debated is not the success or the failure of Novartis’ GIPAP programme or even the merits and the flaws of corporate philanthropy and social responsibility (CSR).\textsuperscript{69} The point being argued here is that donations or forms of corporate philanthropy ought not to add weight to a patent claim –‘What the harm in granting a patent claim; after all 99% of the patients are receiving the drug free of cost’. Donations cannot become a cover up argument for no public interest infringement. Further it cannot become a proxy for rights. Drug donation is neither a viable nor a sustainable alternative to freely available generic drugs. There are many life saving drugs like Glivec that need to taken life long, sometimes instead of 400 mg per day, up to 600 or even 800 mg per day.\textsuperscript{70} Few drug donation programs can sustain this. However, corporate

\textsuperscript{68} Text of the Writ Petition No. 24759, in The High Court of Judicature at Madras (2006). Refer p. 28, 29.
\textsuperscript{69} For the successes of GIPAP see Roger Bate, "India and the Drug Patent Wars India and the Drug Patent Wars," \textit{Health Policy Outlook. AEI Online}, Feb7, 2007
\textsuperscript{70} Joana D. Ramos, "Cancer in Global Perspective," 3rd Annual Western Regional International Health Conference. \textit{Politics, Social Justice and Global Health} \url{http://ramoslink.info/}
donations are not a sustainable solution: (1) they are frequently hard to access, (2) they are revocable, (3) they are not offered across the broad spectrum of patented medicines that poor people need, and (4) they are designed primarily to forestall generic competition by removing market incentives. The assumption that the issue of public health and access to drugs can be addressed through donations, philanthropy and corporate social responsibility is fundamentally flawed in as much it does not even begin to see health as a human right or a right to life.

For health to be approached a right, the issue of access to drugs becomes fundamental to the claim. It is in this context that the Glivec case assumes importance and it is for this reason that it became the face of the global campaign to save generic production of drugs in India. India has been a very large player in the production and exports of generic medicines the world over. The following figures compiled by MSF highlight the importance of India as a crucial player in access to affordable medicines. "Indian drugs account for at least a quarter of all medicines we buy, and form the backbone of our AIDS programmes, in which 80,000 people in over 30 countries receive treatment. Over 80% of the medicines we use to treat AIDS come from India. We cannot stand by and let Novartis turn off the tap," added Dr. Karunakaran.

1. 67% of medicines produced in India are exported to developing countries.
2. 75-80% of all medicines distributed by the International Dispensary Association (IDA) to developing countries are manufactured in India. (IDA is a medical supplier operating on a not-for-profit basis for distribution of essential medicines to developing countries.)
3. In Zimbabwe, 75% of tenders for medicines for all public sector health facilities come from Indian manufacturers
4. The state procurement agency in Lesotho, NDSO, states it buys nearly 95% of all ARVs from India. 71
5. India ranks second on the list of countries from which UNICEF purchases medical supplies. India has a considerable lead over all countries below it on the list, and Belgium only ranks first because of vaccines (e.g. combination vaccines are not yet being produced in India).
6. If vaccines are excluded, India is the source of approx. 50% of the essential medicines UNICEF distributes in developing countries

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71 Source for (1) to (4): Campaign For Access to Essential Medicines. Examples of the importance of India as the "Pharmacy of the World" http://www.accessmedmsf.org/documents/Overview%20Jan%202007%20FINAL.doc
In recent times, the most striking success of Indian pharmaceutical companies has been their ability to provide access to HIV/AIDS drugs at an affordable price. In fact the issue of access to drugs and the need to make cheaper drugs available arose primarily in the context of HIV/AIDS. India is the world’s primary source of affordable Anti Retrovirals (ARVs - for HIV treatment), as it is one of the few countries with the capacity to produce these newer medicines as generics. Therefore, all AIDS programs use India as their main source of products. A three-in-one cocktail pill introduced by the generic manufacturers substituted two pills for six pills per day. Thus the FDCs (Fixed Dose Combinations- AZT/3TC) increased the accessibility as well as availability of ARV drugs. The introduction of FDCs became possible only because of the absence of product patent protection in India. National treatment programs in India, Burkina Faso, Mongolia, Central African Republic, Malawi, Peru, the Republic of Kyrgyzstan, Cambodia, Ukraine, and Swaziland rely heavily on generic AZT/3TC. The availability of affordable quality generic versions of Combivir (AZT/3TC) and other anti-retroviral medicines has allowed developing countries to put more people on treatment and thus extend their lives.

- **80%** of ARVs MSF uses are purchased in India and are distributed in treatment projects in over 30 countries.
- Over **90%** of all patients using AZT/3TC in MSF projects are on generic versions of the drug.

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• Globally, 70% of the treatment for patients in 87 developing countries, purchased by UNICEF, IDA, the Global Fund (GFATM) and the Clinton Foundation since July 2005 has come from Indian suppliers.

• PEPFAR, the US President’s AIDS initiative also purchases ARVs from India for distribution in developing countries, thus resulting in cost-savings of up to 90%. 89% of the generic ARVs approved by the US Food and Drug Administration for PEPFAR are from India.

• 90% of the ARVs used in Zimbabwe’s national treatment programme come from India.

Source: Campaign For Access to Essential Medicines. Examples of the importance of India as the “Pharmacy of the World”

http://www.accessmed-msf.org/documents/Overview%20Jan%202007%20FINAL.doc

Active Pharmaceutical Ingredients (APIs) or raw materials from India are also exported to other countries for production of affordable medicines. This has been key in the success of national AIDS programmes’ ability to provide universal free access to ARVs. As an example, generic production of medicines in Brazil is heavily dependent on APIs purchased from India. At the third meeting of the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH), Brazil stated: “Brazil is concerned whether the application of TRIPS in India and China may affect access to APIs, and thus their treatment programme.” 73

The generic versions of ARV that India produces are much cheaper. “In every case generic prices present an opportunity for cost savings; in some cases, the branded price per pack of a drug is up to 11 times the cost of the approved generic version.” 74 (Refer Table 2)

Table 2: Comparison of retail prices of the innovators brands of brand forms of nine essential drugs and their generic equivalents in July 2002. The differences in retail prices between the generic and the brand forms expressed as a percentage of the generic prices are given.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Retail Prices</th>
<th>Difference in prices as a % of the retail price of generic forms</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Generic</td>
<td>Innovators brand</td>
</tr>
<tr>
<td>Amoxycillin</td>
<td>1.75</td>
<td>9.90</td>
</tr>
<tr>
<td>Cotrimoxazole</td>
<td>0.80</td>
<td>9.19</td>
</tr>
<tr>
<td>Diazepam</td>
<td>0.07</td>
<td>7.84</td>
</tr>
<tr>
<td>Diclofenac</td>
<td>0.58</td>
<td>24.70</td>
</tr>
<tr>
<td>Erythromycin</td>
<td>4.00</td>
<td>7.23</td>
</tr>
<tr>
<td>Furosemide</td>
<td>0.35</td>
<td>1.68</td>
</tr>
<tr>
<td>Propranolol</td>
<td>0.40</td>
<td>3.75</td>
</tr>
<tr>
<td>Ranitidine</td>
<td>1.64</td>
<td>13.98</td>
</tr>
</tbody>
</table>

Source: K. Bala “Towards affordable and quality medicines to all Sri Lankans” compiled from Sales figures at the Rajaya Osu Sala, Bambalapitiya, Sri Lanka

The importance and affordability of generic drugs cannot be overemphasized. Examples are many. In March 2001, an Indian company, Cipla, announced that it would offer the combination of anti-AIDS drugs at a cost of 600 dollars per patient per year (to MSF), and later announce that they could bring down costs to 350 dollars. The offer by Cipla created ripples in the international drug industry because the prices of these drugs in the US and other developed countries are between $10,000 and $15,000 per patient per year. Cipla’s offer was matched within weeks by two other generic drug producing companies, Hetero Drugs and Ranbaxy. These offers are, till date, by far the cheapest that have been made anywhere in the world. In other words, Indian companies are now offering drugs to treat AIDS at prices that are one fortieth of global prices! Such a precipitous fall in prices can revolutionise AIDS treatment in developing countries, and save millions of lives.  

The immediate fallout of the Cipla offer has been very positive. Almost every drug TNC was forced to announce substantial reductions in their drug prices. MSF has witnessed the impact of

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75 Kavaljit Singh, Patents vs. patients: AIDS, TNCs and drug price wars. TWN. Available at http://www.twnside.org.sg/title/twr131c.htm
patents on the prices and availability of medicines, in particular newer medicines, and has documented the patent practices in the countries where it works.  

The following table gives an idea of some current prices of AIDS drugs. (See figure 1)

**Table 3: The Price War**

<table>
<thead>
<tr>
<th>Drug (Company)</th>
<th>US Price</th>
<th>Cipla</th>
<th>Hetero</th>
<th>Latest Company Offer in Africa</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zerit (Bristol-Myers)</td>
<td>3,589</td>
<td>70</td>
<td>47</td>
<td>252</td>
</tr>
<tr>
<td>3TC (Glaxo)</td>
<td>3,271</td>
<td>190</td>
<td>98</td>
<td>232</td>
</tr>
<tr>
<td>Crixivan (Merck)</td>
<td>6,016</td>
<td>N.A.</td>
<td>2,300</td>
<td>600</td>
</tr>
<tr>
<td>Combivir* (Glaxo)</td>
<td>7,093</td>
<td>635</td>
<td>293</td>
<td>730</td>
</tr>
<tr>
<td>Stocrin (Merck)</td>
<td>4,730</td>
<td>N.A.</td>
<td>1,179</td>
<td>500</td>
</tr>
<tr>
<td>Viramune (Boehringer)</td>
<td>3,508</td>
<td>340</td>
<td>202</td>
<td>483</td>
</tr>
</tbody>
</table>

Note: Prices are for AIDS drugs per patient per year in the US and Africa offered by drug TNCs and two Indian generic drug companies. Prices are in US dollars.

* AZT and 3TC

N.A. - not available.

Source: Wall Street Journal

Country case studies reveal the extent to which competition from non-patented drugs has driven down the cost of patented medicines. When Thailand ended the exclusive patent period for flucanazole (used in the treatment of HIV-related meningitis) prices fell by 80 per cent in 6 months. In Pakistan, patented antibiotics used to treat childhood diarrhea cost eight times more than the non-patent equivalents made in neighbouring India. Patents clearly increase the cost of medicines.  

There have been challenges and continuing attempts by big pharma giants to stall by all means available, the supply of generic drugs. A classic case has been Glaxo’s Combivir, an HIV/AIDS drug. Probably, the most widely-used fixed dose combination (FDC) of ARVs is Glaxo’s Combivir. India’s patent law provides that you can’t get a patent by simply combining two old molecules into a single product. Now, Cipla and other Indian companies produce FDCs. Ghana, where 5% of the adult population in 2000 was HIV positive, in an effort to increase drug access, a drug distributor in Ghana called Healthcare, Ltd. bought low-cost generic AZT+3TC from a generic drug company in India called Cipla, Inc. Glaxo owns the patent rights to

76 “Drug patents under the spotlight - Sharing practical knowledge about pharmaceutical patents.” Médecins Sans Frontières (MSF), June 2004.

AZT+3TC (brand name Combivir) in the US, where they charge about $10 per pill. In India, the drug costs about 90 cents per pill. Glaxo SmithKline found out Cipla was importing generic medication to Ghana and accused Cipla of violating their Combivir patent rights. Glaxo threatened to take Cipla to court if they continued to import AZT+3TC to Ghana. Cipla discontinued its supply in 2000. 

Figure 1 shows the effect of generic competition on the price of first-line AIDS triple therapy.

![Figure 1. Effects of Generic Competition on ARV Prices](image)


GSK has filed applications for a patent on Combivir in many developing countries affected by HIV/AIDS including India and Thailand. In 2006 patent applications were filed by GSK in both Thailand and India. Thai activists in Thailand demonstrated in front of GlaxoSmithKline (GSK) office to demand the withdrawal of its patent application in Thailand on Combivir, a fixed-dose combination.

78 www.globaltreatmentaccess.org/content/camp/gsk/ghana.html
combination of two essential AIDS drugs zidovudine/lamivudine. Indian public interest groups joined the public action and are protesting in Bangalore in front of the local GSK office. Patient networks in March 2006 opposed the multinational's patent application on Combivir at the Patent Office in Kolkata. People Living with HIV/AIDS in India and Thailand appealed to the government to refuse the patent and 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 drugs. GSK's patent application on Combivir was opposed in India on technical and health grounds by the Manipur Network of Positive People, under the aegis of the Indian Network of People Living with HIV/AIDS. In June 2006, GSK instructed its agents in Thailand and India to withdraw this patent application. This means that GSK has no patent protection on Combid/Combivir in Thailand or India, and is not seeking any.

Globally, ARVs remain beyond the reach of the majority of people with HIV/AIDS. Of the 6 million people worldwide who needed ARVs in 2003, fewer than 8% were receiving them. There has been relative success in improving access to ARVs by countries like India and Brazil but it is vital that the second line treatment of HIV becomes cheaper and more accessible. Apart from HIV many millions of people still cannot access existing vaccines and drugs for TB, malaria, cancer, and for the few neglected diseases medicines that exist. Price constitutes a very important dimension of drug access. Novartis defense of its cancer-drug patent today will undermine access to medicines for HIV/AIDS, for heart disease, for diabetes, in fact for every new medicine needed by the poor in developing and poorer countries.

The patent monopoly system functions particularly poorly for pharmaceuticals. Since pharmaceutical products are vitally linked to preservation of life it cannot be treated like other consumer products. Intellectual property rights, as a reward system, accords similar status and value to software and medical drugs. In pharmaceuticals patents have the potential to lead to

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misdirected innovation and marketing and to inaccessible high prices. The underlying assumption behind patents is that there is a kind of trade-off between high prices and innovation. The assumption is that if people are willing to pay high prices for a product, it indicates that the product is a valuable innovation. This links up the value of a product to its monetary demand and not the actual demand which stems from the gap between disease and drugs. In other words innovation is frequently driven by the monetary value of the demand and not by its social value. This is the reason many diseases have been termed 'neglected', for research gaps, and for drug availability and accessibility gaps. While they all have multiple contributing factors, patents constitute a vital connection.

CONCLUSION

As a signatory to the TRIPS agreement, there is little room for maneuverability with introduction of product patent in pharmaceuticals in India. It is however vital that the patent safeguards are interpreted in a manner that prevent a compromise on the fundamental right to health or endanger the right to access medicines at an affordable price, as was done by the Chennai High Court in August 2007.

In January 2006, the Patent Controller in Chennai, in a landmark decision, refused to grant Novartis a patent, agreeing with the contentions of the CPAA and generic companies that the subject application lacked novelty, was obvious, and was unpatentable under section 3(d) of the Act. The patent rejection meant that generic companies could manufacture and market their drug, both in India and abroad, who make available the generic imatinib mesylate priced at less than one-tenth the price that Novartis was charging. In their closing remarks on the 3rd case Justices Prabha Sridevan and R.Balasubramanian of the Chennai High Court said: “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 drugs and to discharge the constitutional obligation of providing good health care to its citizens.” The ramifications of this case are wide: they extend beyond India, beyond the drug Glivec, bringing the ethics of patenting of medical drugs into focus and questioning the fundamental basis of intellectual property rights in medical field. It also brings into focus the need to adopt a system of priority in adjudicating claims between two sometimes competing rights viz the right to health and life and the right to intellectual property.

The judgment is significant for three reasons, from the immediate to the larger. First it ensures the availability of cheaper versions of Glivec to CML patients. Aid organizations and patient groups
say, the consequences would have been severe. First, it would have prevented Indian companies from making available generic medicines for leukaemia at roughly one tenth of the Rs.1,25,000 a month that Novartis charges for Gleevec. "We fought for patients' rights and we are greatly relieved that the court has ruled in our favour and recognised that patients, more than patents, need protecting," said Y.K. Sapru, founder and chairman of the CPAA.

Secondly, it sets a precedent for similar grounds of conflict between an Indian manufactured generic drug generic and the patented ones which have been incrementally improved for a 're-patent' and whose 'enhanced efficacy' is not clearly demonstrable. What stands threatened by the Novartis case are the drugs which are not truly innovative.82

Take the case for the patent filing made by Abbott Laboratories Inc. for Aluvia, an anti-HIV drug. Pre grant oppositions have already been filed in the US on grounds that it a similar version of an old drug. Indian patient groups say they are also contemplating following the example set by Initiative for Medicines, Access & Knowledge (I-MAK), which announced its filing in the Mumbai Patent Office, on Thursday. Meanwhile, Indian generic drug maker Cipla Ltd claims it, too, might fight the Abbott patent filing. Sold under the brand name Aluvia by Abbott, the drug is a combination of lopinavir and ritonavir drugs, Aluvia is similar to its original version, Kaltera which has the same drug combination but is in the form of soft gel capsules and not tablets like Kaltera. Roughly 93,000 AIDS patients in India are on antiretroviral therapy and a tenth of them are estimated to require drugs similar to Aluvia.83 Lawyers Collective, a group of advocates engaged in public health and drug access issues, is challenging the grant of patents to several HIV drugs such as Merck's Efavirenz, Gilead Science's Tenofovir and Amprenavir, and also Roche's hepatitis drug Pegasys, contesting the incremental innovation claimed by the applicants, the site reports. The group has filed 15 pre-grant oppositions against patent applications, says Anand

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82 For a view that the majority of research conducted by industry is for higher-priced and similar versions of existing medicines ('me-too' medicines with little added therapeutic benefit), or monopoly extensions for new uses of old medicines, See H. Mintzberg, "Patent Nonsense: Evidence tells of an industry out of social control," Canadian Medical Association Journal 175 (4), 15 August 2006, www.cmaj.ca/cgi/content/full/175/4/374. These medicines are rarely innovative: only 15 per cent of the new drug applications approved by the US Food and Drug Administration (FDA) from 1989 to 2000 were identified as clinical improvements over products already on the market.[ National Institute for health Care Management, 'Changing patterns of pharmaceutical innovation', May 2000. See http://www.nihcm.org/finalweb/innovations.pdf. For a comparison of New Molecular entities inventions (NMEs) with incrementally modified drugs (IMDs) see, "Changing Patterns of Pharmaceutical Innovation," A research report by The National Institute for Health Care Management Research and Educational Foundation. May, 2002

Grover, project director of the HIV/AIDS unit at the lawyers' group. Of the 7000 applications pending in the 'mailbox' around 2000 drugs come under section 3d, which Novartis wanted deleted from patent laws. There are 150 pre-grant oppositions which are likely to be affected by the Glivec ruling. Prominent among these 150 "pre-grant" oppositions are some that involve an AstraZeneca's lung cancer drug and a cholesterol-lowering med; a Pfizer treatment for fungal infections; Roche's Tamiflu bird flu med, and Eli Lilly's erectile dysfunction drug. Pre-grant opposition allows a company or individual to oppose claims in a patent application before its granted.

This case thus has huge implications for the supply of affordable medicines not just in India but in African countries and other parts of the developing world that rely on medicines exported from India. The ramifications of this case are wide. As Sarah Middleton evocatively writes: "For the 32 million people in India suffering from diabetes, for the 36 million with coronary heart disease, the 5.2 million living with HIV, the 3.3 million with TB (tuberculosis), the 1.2 million with malaria, the 25,000 people diagnosed each year with chronic myeloid leukaemia, and for the government agencies, hospitals, non-governmental organizations (NGOs) and patient groups distributing medicines, the Madras High Court's August 6 rejection of Swiss pharmaceutical giant Novartis' challenge to the Indian government is significant". Dr. Tido von Schoen-Angerer, director of the MSF Campaign for Access to Essential Medicines, in a statement from Geneva said: "This is a huge relief for millions of patients and doctors in developing countries who depend on affordable medicines from India," As mentioned earlier, agencies such as the United Nations Children's Fund (UNICEF) rely heavily on importing drugs manufactured in India; Indian companies supply 84 per cent of the antiretrovirals that MSF prescribes worldwide.

There is a third and a larger issue under consideration here, namely the relationship between intellectual property, the proprietary knowledge system that it advances, and public health. Access to drugs is one of the components of the human right to health and one that is closely linked to patenting of drugs. In this context, the relevant human right agreed in the International Covenant on Economic, Social and Cultural Rights (article 12.1) is "the right of everyone to the

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84 http://www.lawyerscollective.org/amte/Patent_Oppositions/introduction.asp
85 "Industry Hails Novartis Decision," Times of India (8 Aug, 2007)
88 Ibid
enjoyment of the highest attainable standard of physical and mental health” 89 This language reflects the overarching objective in WHO’s Constitution, which is “the attainment by all peoples of the highest possible level of health”. Governments’ obligations are to be based on the progressive realization of the latter. The notion of progressive realization is an essential part of the discourse on social and economic rights, because it acknowledges the inevitability of resource limitations on governments and other actors.

Outlining the implications of the Right to Health the CIPIH Report (p,10) states: “The right to health contains both freedoms and entitlements. The freedoms include the right to control one’s health and body. The entitlements include the right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health. Moreover, the Committee emphasizes that it is incumbent on States and “other actors in a position to assist” to provide international assistance and cooperation, especially economic and technical, to enable developing countries to fulfill their obligations under the Covenant. Although the General Comments of the Committee do not have legally binding effect, they are considered authoritative guidance on clarifying the contents of rights and obligations enshrined in the Covenant. They therefore constitute an important foundation for arguments that treat access to essential treatments, preventives and diagnostics as a right, and entail particular obligations on States. Access to these products is, therefore, a legitimate and core component of the right to health, as is the right to benefit from the fruits of scientific progress.

Intellectual property as a right, it can be inferred, is only a means to an end, the end being that the people in general benefit from the fruits of scientific progress. Patents have the potential to improve access by providing incentives for the development of new drugs and at the same time restrict access by pricing its drugs high in order to cover its input costs. Eventually whether they become an instrument in restricting access or improving access largely depends on the precedence granted to intellectual property rights when the conflict with other rights like the right to health.. Both health rights and intellectual property rights have been accorded the status of human rights in the UN covenants.90 Tensions inevitably arise in securing universal human rights as particular rights for particular persons in particular contexts. This tension specifically arises in case of those human rights, viz knowledge rights, which have strong contextual variations and

90 Health as a human right: Universal Declaration of Human Rights, Article 25; ESCR Covenant, Article 12; Intellectual property as a human right: Article 15(1) of the ESCR covenant; Article 27(2), Universal Declaration of Human Rights, 1948.
interpretations. When two human rights conflict, as in the Glivec case between health rights and intellectual property rights, grounds of adjudication need to be devised.

It is the contention of the chapter that some human rights may be universal in a strong sense, i.e., they apply in more or less the same way to all people everywhere. Such is the case with health as a human right. The right to health implies freedom from disease in way that it does not debilitate or terminate one's life. It not only has a universality of application but also links with the right to life which, in the history of Liberal theory of rights, has perhaps the highest lexical priority. Intellectual property rights as human rights are universal in a weaker sense. Core normative considerations and fundamental cultural diversities in the construction and dissemination of knowledge, limits applicability to all people everywhere in a similar manner. Of course even human rights that are universal in the strong sense, like health rights, will often require context-dependent interpretation. This will happen, for example, when a context either generates a conflict between the two rights in question or makes inadequate standard institutional efforts at securing some particular right. Between health rights and intellectual property rights, a priority may have been granted by the international covenants to health rights. In fact, the UN Committee on Economic, Social and Cultural Rights has specifically indicated in the case of the right to health that states should not agree to measures that are manifestly incompatible with their previous international legal obligations. However, the institutional efforts to secure health rights have been rather weak in the face of institutionalization of intellectual property protection. Health as a human right has only received the first level of articulation in various declarations and international covenants. They are more a statement of intent than institutional provisions and at best a broad framework within which health policies should fall. Identifying human rights violations and adjudicating human rights claims, however, are incomplete unless and until human rights are enforced. While enforcement mechanisms are in place with respect to intellectual property, such is not the case with health rights. It is highly dependent on the ability, will and capability of individual states to enforce mechanisms while being compliant with TRIPS. The Glivec case clearly showed that non-compliance of a legislated 3d with TRIPS was a key complaint of the petitioner, Novartis. The implication was that TRIPS has few obligations

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91 See Committee on Economic, Social and Cultural Rights, General Comment No 14, 'The right to the highest attainable standard of health', UN Doc E/C 12/2000/4 (2000). www.ielrc.org. The CIPIH report, in its preface clearly prioritizes health rights over intellectual property: "...we quickly concluded that innovation was pointless in the absence of favourable conditions for poor people in developing countries to access existing, as well as new, products. The price of medicines is an important factor in determining access...See, Public health, innovation and intellectual property rights. Report of CIPIH. See esp. Preface, sections 4.10; 4.16, p. 139
towards health issues and concerns of developing countries, fewer than those endorsed by international covenants and institutions and by the Doha declaration of TRIPS.

Public health and access to medicines have been singled out as major issues needing special attention in TRIPS implementation at Doha. This indicates that health care and health care products need to be treated differently from other products. Says Ellen t’Hoen, “By giving countries broad discretion in deciding how to counter the negative effects of TRIPS, the Doha Declaration may stand for the proposition that public health concerns outweigh full protection of intellectual property. TRIPS emphasizes a property rights approach whereby private "owners" of the inventions can restrict access on the basis of commercial considerations.” 92

The global extension of intellectual property rights, especially with respect to patents, and the enhanced powers conferred on titleholders have raised concerns about the extent to which the fundamentally commercial interests protected by intellectual property rights may be given primacy over other interests of society’s, such as those relating to public health, farmers’ rights and consumer protection.

Medical patents constitute an important case study within the broader field of intellectual property rights because this constitutes an area where the industry is highly dependent on patents. On of the perceived advantages is that it gives an incentive to the private sector for undertaking research and innovation of medicines and pharmaceutical products.93 However the utility of intellectual property protection, even if that were to be its most powerful defense, cannot be judged in terms of the innovation generated. Innovation is a means to an end: the end utility being the well being of the people. If a bulk of the people, i.e., a third of the world’s population does not have access to basic drugs, 94 then clearly innovation is not meeting its desired objectives.

The key question is whether medical patents necessarily conflict with the realization of health as a human right. The answer is that there is strong potential for the conflict in countries where a large population is already unable to access existing medicines because they can’t afford them. 95 Patents increase the threshold of accessibility and reduce the number of people who can afford them. Denial of access is denial of the right to health. TRIPS does not provide much guidance

93 Debates related to patents and innovation have been discussed in chapter 3
concerning its links with other rights. TRIPs was adopted as a stand-alone agreement which makes no mention of the impacts it can have, for instance, in the field of health. Examples from South Africa, Brazil, and more recently India indicate that TRIPS cannot be implemented in isolation. There are a number of other international obligations, in particular in the field of health as a human right. Intellectual property rights coexist with them with a great degree of unease and context dependent interpretations.