

Political Economy of India's Engagement with the WTO: An Analysis in the Context of Amendment of India's Patents Act

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Abstract:

Many developing countries like India were forced to take on commitments under TRIPS agreement due to the principle of 'either take it all leave all' during the Uruguay Round of trade negotiations. It was feared that strengthening of the IPR regime would lead to rise in medicine prices and would adversely affect not only the access to medicine issues but the very existence of the generic pharma industry in India which was the sole source of good quality cheap medicines in India and other developing countries. However, the policy makers during the early years of this decade seemed to have come to the realization, which is reflected in the Bill introduced in the Parliament of India for the amendment of the Patents Act 1970, that strengthening of the IPR regime is good for the country and did not bother to exercise the freedom to incorporate TRIPS flexibilities into the Act. But the Government had to face various hurdles in the form of resistance from left parties and civil society groups while amending the Act and was forced to incorporate substantial changes to the provisions – narrowing the scope of patentability to prevent evergreening, strengthening the CL provisions, facilitating export of medicines produced under CL, strengthening the pre-grant opposition provisions and protecting the production of generics of the 'mail-box' patented medicines - in the Bill amending the Patents Act.

The Background

At the Ministerial conference held at Marrakesh in 1994, the Government of India (GoI) ratified the Final Act of 1986-1994 Uruguay Round of trade negotiations establishing the WTO and it became obligatory for India to implement various Agreements incorporated in the Final Act. TRIPS Agreement, an important agreement of the WTO covering various forms of IPRs, had to be implemented by amending various IPR laws of the country. The IPR laws covered by TRIPS relate to:

- (a) Copyrights and related rights
- (b) Trademarks
- (c) Geographical Indications
- (d) Industrial Designs
- (e) Patents (also includes sui generis protection for plant varieties)

- (f) Layout Designs of Integrated Circuits
- (g) Protection of Undisclosed Information.

While the Members are obliged to enforce the minimum standards of IPR protection prescribed by the Agreement, they have the leeway in framing the working of IPR provisions such as scope of patentability, compulsory licensing provisions, etc. All the laws on IPRs in India except Patents have been amended without much debate in the Parliament or protests from the public¹. Amendment of the Patents Act 1970 has been crucial issue especially for the general public and the pharmaceutical industry (NWGPL, 2003). It was feared that the implementation of product patent rights in pharmaceuticals would give monopoly rights to the innovators of new medicines for a period of 20 years, resulting in sharp increase in the price of medicines. The new patent regime under the TRIPS was also perceived as a threat to the sustenance of Indian generic pharmaceutical industry, which supplied cheap and quality medicines to patients in India as well as foreign countries. This industry, which has thrived under the process patent regime under the Patents Act 1970, would no longer be able to continue with their modus operandi of reverse engineering and continue the production of cheap medicines. Thus, amending the Patents Act of 1970 was the most important hurdle in making Indian IPR system, TRIPS compliant.

TRIPS Agreement provided some transitional arrangements to developing country Members. Though the provisions of the Agreements are expected to be in force by 1st January 1996, developing countries which had process patent regimes were given time, if they wanted, to extend the period for further four years, i.e., till 1st January 2000². However, the Agreement required these Members to make provisions for receiving patent applications³. And for developing countries which are obliged to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of the Agreement, i.e., 1st January 1996, could delay the application of the provisions for an additional period of five years, i.e., till 1st January 2005. India was having process patent regime in pharmaceuticals and agro-chemicals and had the time till 1st January 2005 to extend product patent rights in pharmaceuticals and agro-chemical products, though in other areas it had to meet its obligations by 1st January 2000.

¹ There have been concerns expressed from various corners (industry association-Indian Pharmaceutical Alliance, CSOs, Health Activists, Academics, etc.) in the case of protection of pharmaceutical test data. GoI appointed an inter-ministerial Committee to study the issue and the Committee submitted its report in 2007. GoI is yet to take an official decision on the issue.

² Article 65.2 of TRIPS Agreement.

³ Article 70.8 of TRIPS Agreement.

India complied with its obligations under the TRIPS Agreement in three steps. The first step was the Patents (Amendment) Act of 1999, which provided for receiving of patent applications (mail-box applications) and for exclusive marketing rights⁴. The Patents (Amendment) Act 2002 introduced comprehensive amendments to bring together various provisions of the Patents Act 1970 into conformity with the TRIPS Agreement⁵. For the third and most important amendment aimed at introducing product patent rights along with already existed process patent rights in pharmaceuticals and agro-chemicals, a Bill amending the Patents Act was introduced in 2003 by the National Democratic Alliance (NDA) government led by the Bharatiya Janata Party (BJP). The Bill lapsed owing to a change in government at the centre and the consequent dissolution of the Lok Sabha. The new Congress-led UPA coalition government, established with the external support of left parties, pushed the 2003 Bill to amend the Patents Act so as to meet the TRIPS time line of 1st January 2005⁶. But the UPA could not gather the necessary support particularly owing to the disagreement of left parties on the provisions of the Bill and hence passed as a Presidential Ordinance on 26th December 2004 to meet the deadline. The government had six months to codify this Ordinance by obtaining the approval of the Parliament. The Government in March 2005 introduced a substantially revised Bill which was passed in the Parliament and became the Patents (Amendment) Act, 2005. The modifications to the Ordinance were not incorporated voluntarily by the Government but were the outcome of a hard bargain that the civil society groups and left political parties had with the Government. This paper is an analysis of the out come of this bargain and the process of co-ordination among the national and international civil society groups and with the political parties.

Salient Features of the Patents Act of India

High Criteria for Patentability:

There were serious concerns that a broad definition of what is patentable would lead to 'evergreening' of patents, that is the continuation of patent rights beyond the stipulated

⁴ An ordinance was issued on 31st December 1994 amending the Patents Act 1970 to introduce the mail-box provisions. But the amendment was not passed by the Parliament. The United States dragged India into a dispute in the WTO (WT/DS50) on the failure of providing mail-box facility where the decision went against India. Exclusive Marketing Rights brought with them a five-year, patent-like monopoly for products covered by the product patent applications made under the mailbox system. The company securing an exclusive marketing right has the exclusive right to sell or distribute the article or substance covered in a patent application in a country.

⁵ It introduced 64 amendments (Basheer 2005).

⁶ For details see Basheer (2003) and 'Brief History of National Working Group on Patent Laws: Activities During Past 20 Years', report by B K Keayla, Convener of NWGPL, 2008

20 years by acquiring patents on small changes made to the original invention. The third amendment restricted the chances of 'evergreening' by defining pharmaceutical substance and clarifying what is meant by an 'invention' and 'inventive step', which is the most important criterion determining the patentability of a subject matter. Indian Patents Act now defines new invention and inventive step as

"New invention means any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e. the subject matter has not fallen in public domain or that it does not form part of the state of the art" (Section 2.L) and "inventive step means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art" (Section 2Ja).

Whereas in the ordinance "invention" and "inventive step" were defined as

"invention means a new product or process involving an inventive step and capable of industrial application" (Section 2.J) and "inventive step means a feature that makes the invention not obvious to a person skilled in the art" (Section 2.Ja).

The scope of patentability has also been restricted by defining inventions that are not patentable. Section 3 of the Patents Act is on inventions not patentable. Section 3(d) is noteworthy. It reads inventions are not patentable if ;

"the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. Explanation.—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy".

Whereas section 3(d) in the Ordinance was ambiguous. It read that "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 new product or employs at least one new reactant”.

This section has been a powerful instrument in preventing frivolous patents, often inviting the ire of pharma MNCs. Novartis’ case in India would be the best pointer in exposing how effective is this section in preventing frivolous patents. Novartis had applied for patents though the ‘mailbox’ for crystalline form of ‘imatinib mesylate’, for the treatment of chronic myeloid leukaemia. This molecule in original form has been patented in 1992 in Switzerland and subsequently in other countries. The original molecule is not patentable in India as there is prior publication of the invention in pre-1995 period and hence the company has sought for patent on the crystalline form. In 2003 Novartis secured an Exclusive Marketing Right for its drug Glivec (Imatinib mesylate) and obtained injunctions against Natco, the only producer of generic version Glivec and against six other potential manufacturers of the generic version of Glivec. However, amendment of Section 3(d) in 2005 using TRIPS flexibilities prevented patenting of ‘salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives’ of already known substance unless they significantly enhance the efficacy of the already existing substance. After the 2005 amendment, generic companies and patient groups challenged the patent over Imatinib mesylate on various grounds and the Patents Office rejected Novartis’ patent application on beta crystalline salt of Imatinib mesylate in January 2006. Pharma majors with their advanced technical capabilities are able to incorporate incremental innovations to the original invention and thus able to prolong the life of patent even after the expiry of original patent.

Opposition to Grant of Patents:

The Patents Act provides for pre-grant⁷ and post-grant⁸ opposition to the grant of patents. There are 11 grounds under which any entity can register opposition to the grant of a patent. Though the Ordinance has also provided for the opposition of grant of patent, it made the pre-grant opposition weak as the grounds on which opposition can be made were restricted to mere two. After the amendment, the all the 11 grounds for the post grant opposition were made grounds for pre-grant opposition as well. (Section)

⁷ where an application for a patent has been published but a patent has not been granted

⁸ any time after the grant of patent but before the expiry of a period of one year from the date of publication of grant of a patent

The recent rejection of Gilead's patent application for 'tenofovir', an antiretroviral drug, is a very good example of how useful is the pre-grant opposition provision in preventing frivolous patents, especially from a public health perspective. This drug has been patented by Gilead Science (valid till 2018) and was licensed Indian pharmaceutical companies for the production and marketing. However, the patent holder in the recent past sought to obtain a patent in India for the medicine and this move had been immediately met with large-scale opposition and ire from activist groups and associations such as The Indian Network for People Living with HIV and the Delhi Network of Positive People, who were quick to file pre-grant oppositions against said application. The major legal ground of opposition has been that tenofovir is created by the addition of a salt (fumaric acid) to an existing compound (tenofovir disoproxil) and should therefore be granted no patent. Granting of patents would have eliminated the competitive producers and escalated the cost of drug in India. In developed countries, the drug costs \$5,718 per patient per year, while Cipla has been marketing a generic version called Tenvir, at a cost of \$700 per person per year in India. The Patent office of India rejected the patent application on grounds of violations of Section 3(d).

Fixed the negotiation period for the CL to be 6 months:

Compulsory licensing, which allows third parties to produce and market patented medicines on certain grounds and the Government to override patent rights in situations of national emergency or other circumstances of extreme urgency or for public non-commercial purposes, was another issue of concern. In the case of a third party, it was required before making an application to the Controller of Patents for compulsory license, to enter into negotiations with the patent holder for a license on reasonable terms and conditions and such efforts have not been successful within a reasonable period. But, the Ordinance did not specify what is the reasonable period within which such negotiations should be completed, resulting in widespread concerns that compulsory licenses may take too long and thus defeat the whole purpose of the vary provision. The third amendment addressed this concern by specifying that the reasonable time period is six months.

Compulsory licensing for export:

The other issue in this context was the export of medicines from India produced under compulsorily license to other countries which do not have manufacturing capacities. The TRIPS Agreement (Article 31.f) originally provided that compulsory license can be used predominantly for the supply of the domestic market of the Member authorizing such

license. This required domestic manufacturing capacity as a pre-requirement for the exercise of compulsory license and a number of developing and least developed countries raised this matter in the WTO ministerial and the Doha Declaration clarified that countries without sufficient or no manufacturing capacities can import from any country which has issued a compulsory license. Import from India of medicines produced under compulsory license was a major concern for the health activists and governments in developing countries because these countries benefit from import of cheap and good quality medicines from India. The ordinance had provided that patented drugs, which are produced through compulsory licenses in the country, can be exported to developing countries with in insufficient or no manufacturing capacity subject to the condition that the importing country grants a compulsory license. Globally this clause had attracted widespread criticism owing to the procedural hurdles for such countries to grant compulsory license. The third amendment clarified that the country can import from India if ‘provided compulsory license has been granted by such country or such country has by notification or otherwise allowed importation of the patented pharmaceutical product from India’.

The Ordinance provided ‘Compulsory license shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory license has been granted by such country’ (Section 92.A(1)). This section has been amended as “ compulsory license shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory license has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India”.

The term ‘shall’ implies that compulsory license will be granted automatically without separate scrutiny or procedural requirements in India. In addition, section 90 also allows the export of medicines that are produced under compulsory license for the supply within India to countries where an export market exists that is not being supplied or developed (Hoen 2009).

Politicians, UN officials and international NGOs called on Indian policy makers to take into account India’s responsibility as a supplier of affordable medicines. A New York Times editorial called upon the Indian Parliament to ensure that India could continue to

play its role as leading supplier of low-cost medicines and to ensure that the amended patent law protected India's ability to make AIDS medicines available. This editorial received serious attention in India and was read out in the parliament during the debate on the Patents Act in March 2005⁹.

Production of generic versions of 'mail-box' patented drugs:

Possibly the biggest concern expressed after the Ordinance was on the continued production of drugs for which applications were pending in the mail-box. It was apprehended that generic medicines that are already produced and marketed in India for which patent application are pending in the mail-box, would go off the market once the patent is granted, leading to a quantum jump in drug prices. The Glivec case, the anti-cancer drug (Imatinib mesylate) for which the Swiss MNC Novartis obtained exclusive marketing rights in 2003 would be the best pointer to the concerns on the drug price. The price of Glivec was more than 10 times higher than that of its generic counterparts: Novartis charged Rs 130000 per person for one month whereas the price of Indian generic equivalents was Rs 10000 per person for one month¹⁰. These generic drugs going off the market would mean that patients have no other choice but to buy highly expensive patented medicines or continue with the disease without taking required medication. The third amendment clarified that those Indian companies already producing medicines for which applications are filed in the mail-box can continue to produce them even after patent is granted to the drug, after paying a royalty to the patent owner.

Section 11.A.7 provided for the continued manufacture of drugs with application in the mailbox. Mailbox was an arrangement mandated by the TRIPS agreement for those countries availed the transitional period of 10 years. The applications in the mail box would be examined only after 1st January 2005. India incorporated this provision into its Patents Act through the amendment in 1999. Many Indian companies started producing medicines for which applications were filed in the mailbox as it was legally permissible to do so. It was apprehended that after the final amendment of the Patents Act to allow for product patents from 2005, drugs which are produced by Indian companies and for which applications are pending in mail box would go off the market once patents are granted. But the final amendment provided that

“patent holder shall only be entitled to receive reasonable royalty from such enterprises which have made significant investment and were producing and marketing the concerned product prior to the 1st day of January, 2005 and which continue to

⁹ For details see Hoen (2009)

¹⁰ See <http://www.centad.org/download/centad%20Oct%202007%20Hyd.pdf>, accessed on 27th October 2008.

manufacture the product covered by the patent on the date of grant of the patent and no infringement proceedings shall be instituted against such enterprise”.

Even if an application in the mail box is granted patent rights, those generic firms producing that drug will not be prevented from doing so. If there are Indian producers, the incentive of foreign firms to import that drug into India will be less due to the cost advantage that Indian firms are having.

How did these flexibilities get incorporated into the Patents Act?

The GoI, in the early years of this decade did not seem to be keen on exerting the flexibilities available under the TRIPS agreement. Provisions in the 2003 Bill and the Ordinance are clear evidences for this. The TRIPS flexibilities were got incorporated into the Act only because of the pressure from left political parties and civil society groups. When the 2003 bill was introduced by the NDA led by the BJP, which had a very broad patentability criteria, weak pre-grant opposition, weak compulsory license regime, restrictions on the export of drugs produced under compulsory license and no provision for the protection of generics of ‘mail-box’ patented medicines the then major opposition party, the Congress party, did not offer any resistance in the Parliament. It was only the small group of left parties who opposed the bill despite the fact that they did not have adequate number of Members in the Parliament to prevent the Bill. However, the Bill lapsed owing to a change of Government at the Centre. The new UPA Government led by the Congress party took up the same Bill which the NDA presented and introduced in the Parliament for the amendment of the Patents Act. However, by this time, the mood in the NDA camp had changed due to political concerns and not because of the desire to bring in the TRIPS flexibilities into the Bill, and opposed the Bill in the Parliament. For the UPA, it had become impossible to get the amendment done without the support of the left parties. In order to secure the support of left parties, the UPA had to make substantial changes in the Bill. In the mean time, the UPA passed an Ordinance with the 2003 Bill to meet the time line of 1st January 2005 for the full implementation of the TRIPS Agreement.

The left parties, i.e., CPI(M), CPI, Forward Block and RSP said “the left parties have been consistently of the view that TRIPS was and continues to be an iniquitous agreement balanced heavily in favour of multinational corporations” (People’s Democracy, 2005). The interventions that these parties made were based on this perspective. The left parties intervened in a major way in the third amendment of the Patents Act.

There were eight areas where the left parties wanted the Government to review the provisions in the Ordinance. The eight areas are: (1) patentability criteria, (2) pre-grant opposition to patent applications, (3) compulsory licensing provision, (4) export of drugs produced under compulsory license, (5) production of drugs for which applications were pending in the mail-Box, (6) patenting of software, (7) exclusion of micro-organisms from patenting, and (8) defining what is a new chemical entity (people's Democracy, 2005). All their demands except the exclusion of micro-organisms from patenting and defining what is a new chemical entity were met to appease the left parties and in these two areas, an expert committee was to set up. A case in point is the 'inventive step' clause, which was copied verbatim with an addition of just two words from the list of recommendations by the CPI(M), which in turn appears to be based on a report by a prominent civil society initiative – the National Working Group on Patent Law (NWGPL). The recommendations sent by CPI(M)¹¹ to GoI defined an inventive step as “a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance and that makes the invention not obvious to a person skilled in the art” and the CPIM has copied this verbatim from the Report of the Fourth Peoples' Commission on Review of Legislations Amending Patents Act 1970, commissioned by NWGPL¹².

The civil society groups like the NWGPL, Medicines Sans Frontiers (MSF), Gene Campaign, etc. have been a decisive force in the formulation of WTO consistent domestic policies from a perspective of protecting the interests of the people of the country. These organizations though do not have any official representation, act as pressure groups. The role played by the civil society groups especially the NWGPL during the final amendment of Patents Act is praise worthy and would be the best example of civil society groups successfully pressurizing the government to review its stance.

The NWGPL, which is a network of 12 organizations¹³, began its work on WTO issues as early as 1988 during the mid-term review of Uruguay Round negotiations. The positive

¹¹ Communist Party of India (Marxist), Left Parties on Amendments to the Indian Patent Act, at http://www.cpim.org/upa/2004_patents.pdf, accessed on 11th October 2008.

¹² Report of the Fourth People's Commission on Review of Legislations Amending Patents Act 1970, at <http://www.who.int/entity/intellectualproperty/documents/Report4thCommission.pdf>, accessed on 11th October 2008.

¹³ The 12 organizations are: (a) Public Interest, Legal Support and Research Centre, (b) CSIR Scientific Workers Association, (c) Delhi Science Forum, (d) Academy of Young Scientists, (e) Consumers' Forum, (f) National Confederation of Officers' Association of Public Sector Undertakings, (g) Forum of Financial Writers, (h) All India Drug Action Network, (i) Forum for Preservation on Indian Patents Law, (j) National

impact of the Patents Act 1970 was widely visible at this time as India had a vibrant generic pharmaceutical industry which brought down the prices of medicines in India from one of the highest in the world¹⁴ to one of the lowest in the world in a matter of few decades. The Ayyangar Committee Report and the Report of the Patents Enquiry Committee which formed the basis of the Patents Act 1970 had already generated a lively discussion in India and other developing countries about the merits of the process patent regime. So it was quite natural for the people working in this area to come together in a group to convince the government on the importance of continuing with the Patents Act 1970. NWGPL held that India should continue with protecting the processes and not the products and there should be a strong compulsory license system (Dhar and Murali, 2007).

The NWGPL established Peoples' Commissions, members of which constituted eminent personalities from diverse fields in the country like bureaucracy, academics, industry, law, etc., to study various facets of new patent regime and come out with reports. The Fourth Peoples' Commission established in 2003 to study the provisions of the '2003 Bill' with I.K Gujral, former Prime Minister of India as Chairman and Prof. Yaspal, former chairman of University Grants Commission, Prof. Muchkund Dubey, former Foreign Secretary, B.L Das, former India's ambassador to GATT, Dr. Yusuf Hamied, Chairman and MD Cipla, S.P Shukla, former member, Planning Commission, Prof. Prabhat Patnaik, Professor in Jawaharlal Nehru University, Dr. Rajeev Dhavan, senior advocate at supreme court of India and Prof. Ashok Parthasarathi, former secretary of GoI as members and B.K Keayla, former commissioner of payments as convener submitted its report in October 2004. The Recommendations of the Commission became the breeding ground for the protests from various corners when the UPA attempted to introduce the final amendment Bill in December 2004.

The report of the Fourth Peoples' Commission has dealt with each of the important provisions of the proposed Patents (Amendment) Bill and made concrete recommendations for the consideration by the GoI. The report clearly states the objective of the exercise. It says:

“... we must ensure that the exercise of making our Patent Act WTO – compliant does not end up contravening or jeopardizing the fundamental rights that the Constitution guarantees to our people....A sound and balanced national patent system is of crucial importance for the autonomous development of any economy

Campaign Committee on Drug Policy, (k) All India Lawyers Union, and (l) Indian Drug Manufacturers Association.

¹⁴ The United States' Senate Committee on Drug Prices, the 'Kefauver Committee' reported in 1962 that 'in drugs, India ranks amongst the highest priced nations of the world'.

and for meeting public demand for drugs, pharmaceuticals and other essential commodities. It is, therefore, extremely important that every provision of the amending Bill should be formulated with utmost care and attention and with clarity and precision” (pages 6,14).

The recommendations of the Peoples’ Commission were spread into six broad areas; most of them were raised also by the left parties. The major issues raised by the commission were: (a) Scope and Patentability, (b) Compulsory licensing, in order to enable the domestic enterprises to ensure abundant availability at competitive prices, of pharmaceuticals and other products covered by the patent regime, (c) The terms of patent i.e. period of patent and licenses, (d) Royalty parameters, (e) Export of patented products; and (f) Pre-grant opposition to patent claims. Most of these recommendations were accepted by the GoI, as we have seen earlier in this section. One specific issue which the Commission raised was to limit the reasonable period after which the applicant can approach the Controller of Patents for compulsory license to 150 days¹⁵. The third amendment clarified it by saying that “reasonable period shall be construed as a period not ordinarily exceeding a period of six months”. A brief analysis of the working of NWGPL, which is given below, would show the efforts of the Group in sensitizing the policy makers and concerned stakeholders the method adopted by them for the sensitization.

When the NWGPL was formed, the first task they undertook was to evolve some kind of a program. They focused on sensitizing the people on the impact of changes in the patent law by organizing national and international conferences. The first national seminar organized by the group in 1998 was attended by eminent scientists, jurists, economists, technocrats, industrialists, journalists, representatives of government and various organizations. A clear cut position got established with the unanimous adoption of a resolution in the concluding session of this conference which was addressed by K R Narayanan, then Minister of State for Science and Technology, P N Haksar, former vice Chairman, Planning Commission, Justice V R Krishna Iyer and Justice D A Desai, former judges of Supreme Court, Dr Surendra Patel, world known economist and senior scientists like Dr Nitya Anand. The resolution became the basis for the national campaign against change to the patent law¹⁶. After the seminar, representatives of the Group led by Justice V R Krishna Iyer met then Prime Minister Chandra Shekhar to appraise him of

¹⁵ See page 27 NWGPL (2004).

¹⁶ See ‘Brief History of National Working Group on Patent Laws: Activities during Past 20 Years, report by B K Keayla, Convener of NWGPL, 2008.

their serious concern and the need to protect the national interest during the GATT negotiations. In 1993, an International Conference on Patents Regime proposed in the Uruguay Round of GATT negotiations was organized by NWGPL jointly with ALIFAR (Asociación Latinoamericana de la Industria Farmacéutica or the Latin American association of the pharmaceutical industry) of South America, Canadian Drug manufacturers Association and IDMA. New Delhi Declaration and New Delhi Statement were issued, which became landmark documents for further campaign. Arising out of this conference, a delegation of these industries associations was led by NWGPL to Geneva and met the officials at GATT.

The second major initiative of the Group came in the wake of Dunkel Draft in December 2001. A Peoples' Commission on constitutional issues of Dunkel Draft Text with the Chairman and Members of former Judges of Supreme Court was established in November 1993. The Commission submitted a detailed report which was submitted to the Prime Minister and circulated extensively. The report had looked into the constitutional issues arising out of GoI holding negotiations in the Uruguay Round on agricultural issues without consulting the state governments. The group members approached a number of state governments and held discussion with them about the implications of Dunkel Draft Text. Some of the state governments – Tamil Nadu, Rajasthan and Orissa agreed to file petitions in the Supreme Court¹⁷. These petitions were drafted by Dr. Rajeev Dhavan, a member of NWGPL¹⁸.

NWGPL took the lead in establishing a Forum of Parliamentarians on patent law and WTO Issues in 1995. The core group of the forum included Dr. Murli Manohar Joshi as Convener and Dr. Ashok Mitra, A. B. Bardhan, Jaipal Reddy, George Fernandes and Prithviraj Chauhan as members and B. K. Keayla as convener, S. P. Shukla as forum advisor. NWGPL and the Parliamentarians Forum jointly organized an international Conference of Parliamentarians in 1996, attended by a number of Parliamentarians from South America, Pakistan, Bangladesh, Sri Lanka, Nepal, etc.

NWGPL established the second Peoples' Commission in 1998 to examine the transitional period obligations in the TRIPS agreement and implementation of the obligation in the TRIPS agreement and submitted its report of the government with recommendations. The Third Peoples' Commission was established during the course of introduction of second

¹⁷ In the course of time there were changes in the leadership in these state governments and the writ petitions were withdrawn.

¹⁸ Supra note 18.

amendment. A large number of experts and stakeholders numbering 25 appeared before the commission. The Commission has also received nine detailed papers from various experts, who could not personally appear before the Commission¹⁹. The Commission submitted its report in 2003 for the consideration of the Government and Members of Parliament. In December 2003 the Government introduced the final Patents (Amendment) Bill, prompting NWGPL to set up the Fourth Peoples' Commission on Review of Legislations Amending the Patents Act 1970. This Commission went into the depth of various amendments already carried out and the proposed amendments in the final amending Bill. In order to put their views upfront, NWGPL coordinated with the left parties, the king maker of UPA coalition government. S.P Shukla of NWPL acted as the coordinator with left parties during the course of third amendment to the Patents Act 1970²⁰.

We have already seen that there are commonalities in the contents of interventions of the left parties and NWGPL in the context of making Indian patent regime compatible to the WTO. These two groups were quite successful in exerting pressure on the government. What is more important is that there is a commonality in the ideology representing both these groups-the left parties and the NWGPL believed that the TRIPS agreement had sought to strengthen the monopoly position of multinational companies²¹. These two non-state actors led by a common ideology turned out to be the most important pressure group in directing India's relations with WTO in the area of IPRs.

Conclusion

The formulation of India's engagement with the WTO is not an easy task and it requires consensus building among various stakeholders including the civil society groups and small political parties. The implications of WTO agreements being vast and diverse for various segments of the society, India's policy towards the Organization has to take into consideration the concerns of all these segments. In the case of IPRs, it was feared that strengthening of it would adversely impact the survival of the Indian generic pharma industry and access to medicines and the Government of India was forced to take into account concerns raised by patient groups, public health groups and the pharma industry. With the emergence of the WTO, there is a globalization of the issues arising out of each of its Agreements and has subsequently resulted in the emergence of the globalization of

¹⁹ Supra note

²⁰ This point came out during my conversation with B K Keayla, convener of NWGPL.

²¹ See page 9 of NWGPL (2004) and Peoples Democracy (2005).

civil society groups and these groups exert their pressure through various channels such as the Parliament, media, judiciary, political parties, etc. Given the multitude of issues emerging from the global trading regime and the diversities within the country, India cannot formulate its external economic policies merely based on its economic reasoning but has to take into account the interests of the public well.

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Abbreviations

AoA	Agreement on Agriculture
DGFT	Director General of Foreign Trade
DoC	Department of Commerce
FDI	Foreign Direct Investment
GoI	Government of India
IDMA	Indian Drug Manufacturers Association
IPR	Intellectual Property Rights
MoCI	Ministry of Commerce and Industry
NWGPL	National Working Group on Patent Law
TPD	Trade Policy Division
TRIPS	Trade Related Aspects of Intellectual Property Rights
UPA	United Progressive Alliance
WTO	World Trade Organization