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India's Use of Patent Opposition Mechanism as an Access to Drugs Strategy: An Empirical Analysis

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Global public health has emerged as a formidable challenge in modern times. India's patent opposition model shows how this legitimate safeguard can be used to alleviatesome of the burden on global health systems by improving access to affordable health technologies. India smartly linked its patentability threshold provisions, Sections 3(d) and 2(ja) of The Patents Act, 1970 (amended in 2005), with its procedural safeguard of patent opposition.This paper presents empirical data on the use of patent opposition procedures in India. The three-step method is adopted to statistically evaluate the practical use of India's patent opposition proceedings.Statistical data is collected on 249 patent opposition cases from IP India's official websiteto answer and analyse around 150 questions designed to highlight overall trends in the use of the Indian patent opposition mechanism. This paper summarizes the important findings of the statistical data. The main finding of this study is that India's well-thought-out patent opposition model has remained under-utilised, especially by non-corporate entities.

Keywords: Access to Medicines, India, Patent Opposition, Public Health, Section 3(d), TRIPS Flexibilities

India is a big developing country with a population of more than 1.4 billion. A vast majority of the Indian population cannot afford brand-name patented drugs. The annual income of an average Indian is too low to afford certain life-saving patented drugs because the annual cost of medicine is more than thirty times higher than the annual income of an average citizen.[1] India had excluded pharmaceutical drugs from patent protection prior to signing the World Trade Organization's Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. After signing up for TRIPS in 1995, India had to amend its patent laws because implementing TRIPS is a mandatory requirement for WTO membership.[2] The TRIPS Agreement was unprecedented because it not only provided for stringent patent protection for innovations in all fields of technology[3] for a period of 20 years from the date of filing[4] but also had teeth because of its enforcement[5] and dispute settlement[6] provisions for the effective implementation of the agreed minimum standards.[7]

The TRIPS Agreement did not provide any specific guidelines on patent opposition proceedings. It, however, prescribed some general procedural requirements that may be applicable to opposition procedures.[8] Article 62 (2) of the TRIPS Agreement requires the Member States to make sure that the procedures for grant or registration of intellectual property (IP) rights do not cause 'unwarranted curtailment of the period of protection'.[9] General obligations concerning safeguards against the abuse of IP rights have been provided in Article 62 (4) of the TRIPS Agreement. Under Article 41 (2) of the TRIPS Agreement, member countries have been directed to adopt fair and equitable procedures that are 'not unnecessarily complicated or costly' and that do not 'entail unreasonable time-limits or unwarranted delays'.[10]

As a developing country, India was provided with a grace period up to January 1, 2005, for TRIPS compliance.[11] Since 2005, India has provided a detailed legislative framework for both pre-grant and post-grant patent opposition to fully avail itself of the procedural flexibility provided under TRIPS. India not only provided the patent opposition safeguard in its patent laws but also made combined use of other TRIPS flexibilities to make this safeguard more effective. One of the grounds for invoking patent opposition proceedings in India, under Sections 25(1)(f) and 25(2)(f), is that 'the subject of any claim of the complete specification is not an invention within the meaning of this Act, or is not patentable

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under this Act'.[12] This ground of patent opposition links the Indian opposition proceedings with s 3(d) which provides a notable exception to patentability in India. Section 3(d) excludes trivial modifications of known substances from patent eligibility in India unless they satisfy the condition of 'enhanced efficacy'.[13] Moreover, under Sections 25(1)(e) and 25(2)(e), patents can be opposed on the grounds of obviousness or lack of inventive step.This ground of patent opposition links the Indian opposition proceedings with Section 2(ja) which defines the inventive step and adds additional requirements of 'technical advance' and 'economic significance' to the inventive step threshold. Sections 3(d) and 2(ja) are, therefore, a very important component of the Indian patent opposition proceedings.[14] This nexus of two distinct TRIPS flexibilities is a distinctive feature of the Indian patent opposition model.

India used its procedural mechanisms of patent opposition to reinforce its heightened patentability requirements. This study argues that India's patent opposition model was well-thought-out, and it had public health goals. The commitment to public health is included in India's public policy objectives because the government of India has a primary constitutional obligation to provide the right to health to its citizens under Article 47 of the Constitution of India. Article 47 stipulates that *'[t]he State shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties and, in particular, the State shall endeavour to bring about prohibition of the consumption except for medicinal purposes of intoxicating drinks and of drugs which are injurious to health (Emphasis added)*'. One of the key objectives of designing this model was to improve the availability of cheap generic versions of drugs in order to meet India's constitutional obligation of providing good healthcare to citizens. This empirical study evaluates the practical use of this purposefully designed patent opposition model.

India's Opposition Proceedings to Oppose Drug Patents

Out of a total of 249 patent opposition cases evaluated in this study, 166 were successful with a success rate of 66.67%. 160 out of a total of 249 patent oppositions were drug patent oppositions (Fig. 1). It means that 64.26% of the oppositions were drug patent oppositions. The data shows that 89 other (non-drug) patents were opposed in India which

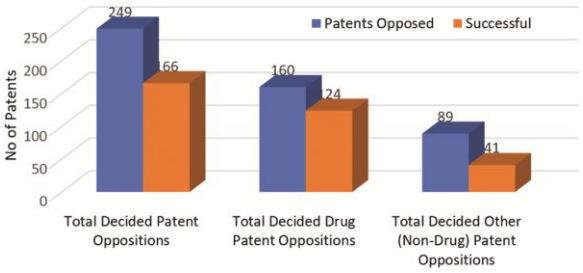

Fig. 1— Overview of success rate

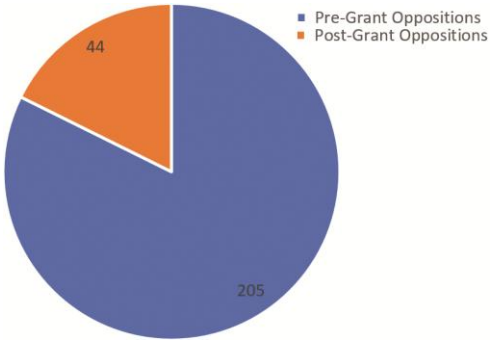

Fig. 2 — Number of pre-grant and post-grant oppositions

accounted for 35.74% of the total oppositions. The drug patents were, therefore, opposed more often as compared to other (non-drug) patents in India. As regards the success ratio, out of 89 other (non-drug) patent oppositions 41 were successful at a rate of 46.07%. On the other hand, out of 160 drug patent oppositions, 124 were successful at a rate of 77.50%. The success rate in drug patent oppositions is therefore distinctively higher as compared to other (non-drug) patent oppositions.

Pre-Grant and Post-Grant Opposition Proceedings

The phrase patent opposition is not defined under national patent laws or international treaties. It has been noted by the Médecins Sans Frontières that patent opposition is a general term to refer to the ways in which it is possible to challenge the validity of a patent – both during the period when a patent is being reviewed (pre-grant opposition), and after the patent has been granted (post-grant opposition).[15]

205 out of a total of 249 patent oppositions were pre-grant oppositions whereas only 44 were post-grant oppositions (Fig. 2). Pre-grant opposition proceedings have been used fourfold more often than post-grant opposition proceedings. This remarkably high use of pre-grant opposition as compared to post-grant opposition supports the argument that pre-grant opposition proceedings are procedurally convenient and cost-efficient.

As regards the success ratio, 137 out of 205 pre-grant oppositions were successful with a success rate of 66.83% (Fig. 3). On the other hand, 29 out of 44 post-grant oppositions were successful with a success rate of 65.91%. It can be noted that both pre-grant and post-grant oppositions have been almost equally successful in terms of the overall results of the opposition proceedings.

37 patent applications were abandoned as a result of patent opposition proceedings (Fig. 4). It can be noted that 29 out of these 37 abandoned applications were drug patent applications. The data, therefore, shows that drug patent applications were abandoned four times more often than other (non-drug) patent applications as a result of pre-grant opposition proceedings. This finding supports the argument that pre-grant opposition proceedings are more effective as compared to post-grant opposition proceedings in challenging the validity of questionable patents and in preventing such patents from being granted in the first place.

Linking Higher Substantive Standards with Opposition Proceedings

In designing its patent opposition model, India linked the higher substantive standards with the procedural safeguard of patent opposition.[16] Under Section 3(d) of The Patents Act 1970(amended in 2005), India set out higher patentability standards because of the requirement of enhanced efficacy.[17] Under Section 2(ja) of the Act, India also required technical advance and economic significance of the invention in order to meet the inventive step criteria.[18] Sections 25(1)(f)/25(2)(f) and 25(1)(e)/ 25(2)(e) link the Indian opposition proceedings with India's unique substantive threshold provisions like Section 3(d) and Section 2(ja).

Section 25(1)(e)/ Section 25(2)(e) provides the most commonly invoked ground of opposition whereas Section 25(1)(f)/ Section 25(2)(f) provides the second most commonly invoked ground of opposition in India both in overall oppositions as well as in pre-grant and post-grant oppositions (Fig. 5). However, in drug patent oppositions, Section 25(1)(f)/ Section 25(2)(f) provides the most commonly invoked ground of opposition whereas Section 25(1)(e)/ Section 25(2)(e) provides the second most commonly invoked ground of opposition (Fig. 6).

Section 25(1)(f)/ Section 25(2)(f) provides the most successful ground of opposition in India at a success rate of 47.24% whereas Section 25(1)(e)/Section 25(2)(e) provides the second most successful ground of opposition at a success rate of 44.65% (Fig. 7). In the case of drug patent oppositions, again Section 25(1)(f)/ Section 25(2)(f) provides the most successful ground of opposition in India at a success rate of 58.99% whereas Section 25(1)(e)/Section

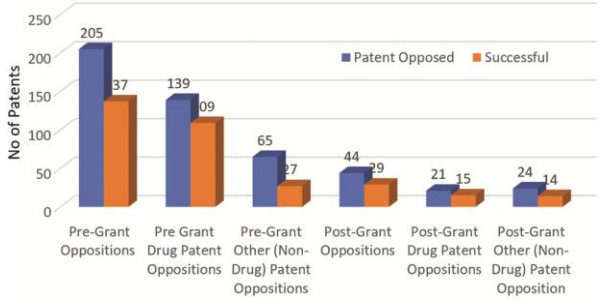

Fig. 3 — Success rate in pre-grant and post-grant oppositions

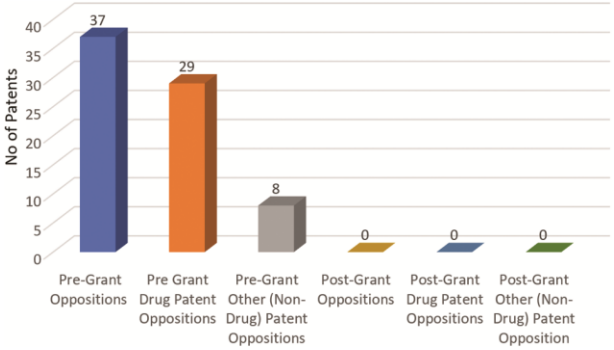

Fig. 4 — Patent applications abandoned

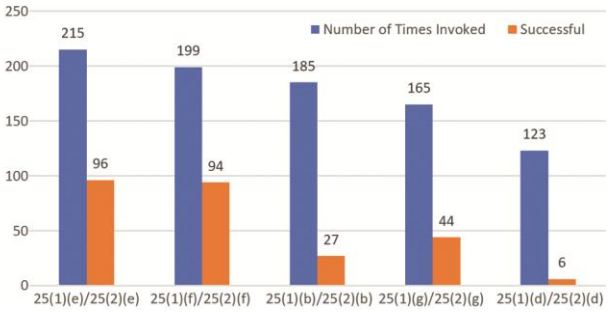

Fig. 5 —Most common grounds of patent opposition

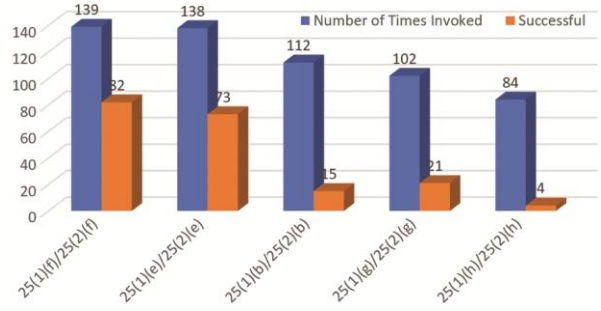

Fig. 6 — Most common grounds in drug patent oppositions

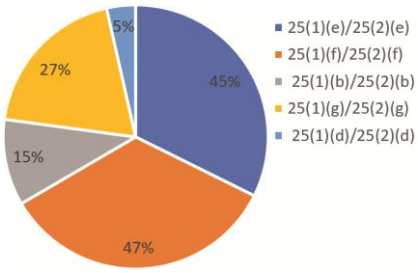

Fig. 7 — Most successful grounds of patent opposition

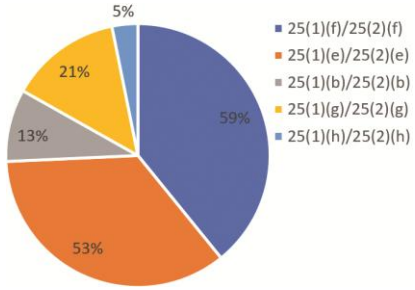

Fig. 8 — Most successful grounds in drug patent oppositions

25(2)(e) provides the second most successful ground of opposition at a success rate of 52.90% (Fig. 8).

Section 3(d) was invoked 116 times in patent opposition proceedings in India out of which 76 times the opposition proceedings resulted in a positive outcome at a success rate of 65.52% (Fig. 9). It is important to note that out of 116 times, Section 3(d) was invoked 108 times in drug patent oppositions. Over 93% times in its total use, Section 3(d) has been invoked in drug patent opposition proceedings which supports the argument that this provision was specifically designed to combat weak patents in the pharmaceutical industry. It is further noted that out of 108 times use in drug patent oppositions, Section 3(d) was used 95 times in pre-grant drug patent oppositions and 13 times in post-grant opposition proceedings. The provision, therefore, played an effective role in challenging the grant of questionable patents at the initial stage. The significance of Section 3(d) in the Indian patent opposition proceedings cannot be denied. It is pertinent to note that 64 patent applications were rejected in India due to the use of this provision in pre-grant opposition proceedings while 10 granted patents were revoked due to the use of this provision in post-grant opposition proceedings.

Section 2(ja) was invoked 150 times in patent opposition proceedings in India out of which 57 times the opposition proceedings resulted in a positive outcome at a success rate of 38% (Fig. 10). It is important to note that out of 150 times, Section 2(ja) was invoked 103 times in drug patent oppositions.

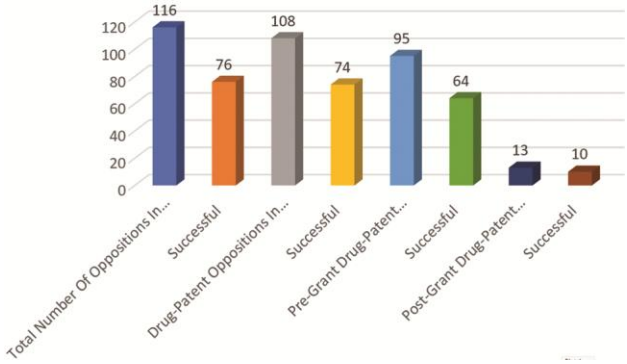

Fig. 9 — Role of Section 3(d) in opposition proceedings

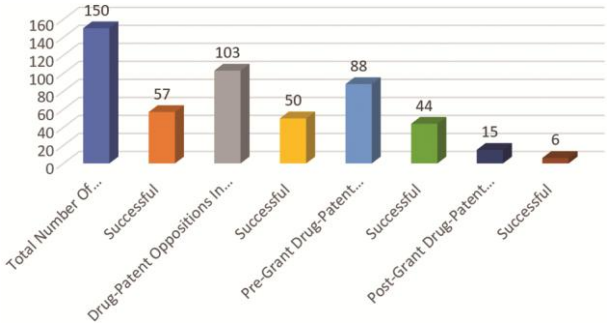

Fig. 10 — Role of Section 2(ja) in opposition proceedings

Nearly 70% times in its total use, Section 2(ja) has been invoked in drug patent opposition proceedings which supports the argument that this provision plays a pivotal role in combating weak patents in general and questionable patents in the pharmaceutical industry in particular. It is further noted that out of 103 times use in drug patent oppositions, Section 2(ja) was used 88 times in pre-grant drug patent oppositions and 15 times in post-grant opposition proceedings. The provision, therefore, played an effective role in challenging the grant of questionable patents at the initial stage. It is pertinent to note that 44 patent applications were rejected in India due to the use of this provision in pre-grant opposition proceedings while 6 granted patents were revoked due to the use of this provision in post-grant opposition proceedings.

India's Patent Opposition Proceedings to Challenge Foreign Patents

A total of 161 patents filed by foreign patent applicants were opposed out of which 132 oppositions were to drug patents filed by foreign applicants (Fig. 11). It means that 82 % of the total oppositions to foreigners' patents were oppositions to drug patents. Out of these 132 oppositions to foreigners' drug patents, 104 were successful at a success rate of 78.79 %. The success rate in oppositions to other

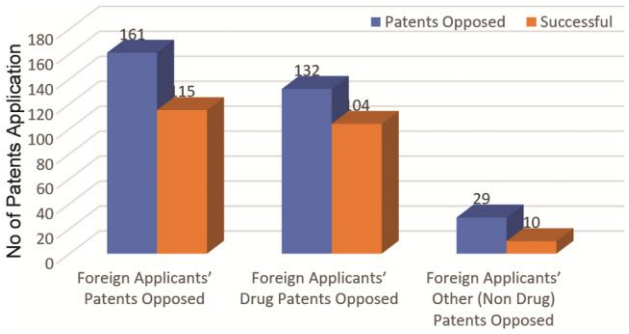

Fig. 11— Oppositions to foreign patent applications

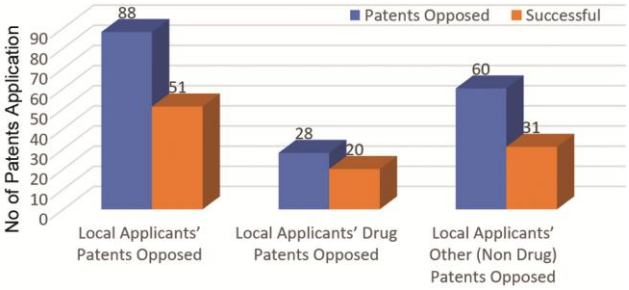

Fig. 12 — Oppositions to Local Patent Applications

(non-drug) patents filed by foreign patent applicants was remarkably low at 34.48%. On the other hand, a total of 88 patents filed by local applicants were opposed out of which 28 oppositions were to drug patents filed by local applicants (Fig. 12).This means that 31.82 % of the total oppositions to patents filed by locals were oppositions to drug patents. Out of these 28 oppositions to locals' drug patents, 20 were successful at a success rate of 71.43 %. It can be noted that patents filed by foreigners were opposed considerably more often as compared to patents filed by local opponents. The ratio of opposed drug patents is distinctively high in the case of foreigners' patents as compared to locals' patents. The success rate is slightly higher in the case of opposition to foreigners' patents as compared to locals' patents.

228 patent oppositions decided in India were filed by local opponents and only 17 oppositions were filed by foreign opponents (Fig. 13). It means that over 90 % of the total oppositions were filed by local opponents. The data shows that 155 out of 228 patent oppositions filed by local opponents were successful at a success rate of 67.98 %. On the other hand, only 3 out of 17 patent oppositions filed by foreign opponents were successful at a nominal success rate of 17.65 % (Fig. 14).The success rate was even higher at 78.67 % in the case of drug patent oppositions filed by local opponents.

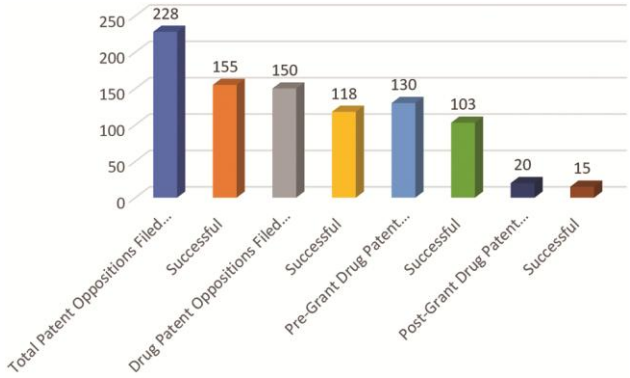

Fig. 13 — Oppositions filed by local opponents

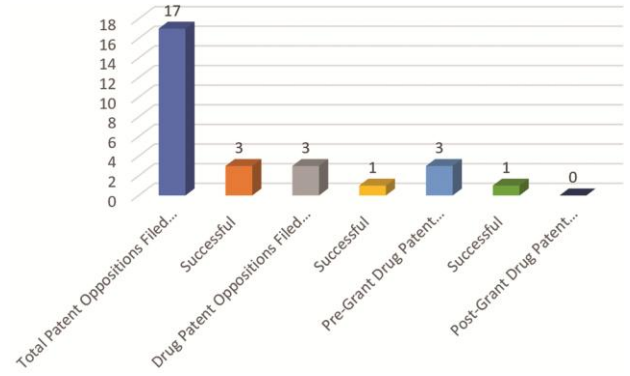

Fig. 14 — Oppositions filed by foreign opponents

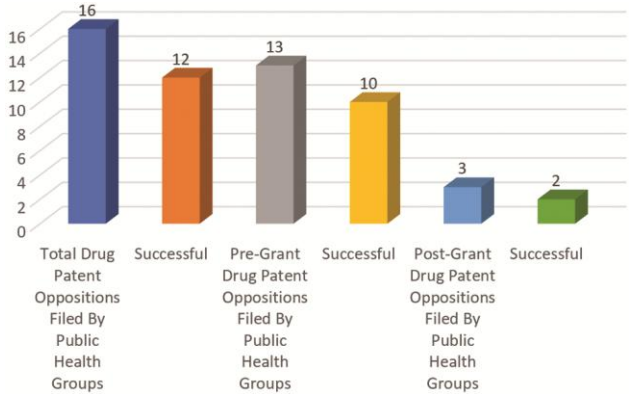

Fig. 15 — Oppositions filed by public health groups

Participation of Civil Society Organizations

Only 16 drug patent oppositions filed by public health groups were decided out of which 12 oppositions were successful at a rate of 75 % (Fig. 15). On the other hand, 123 drug patent oppositions filed by generic manufacturers were decided out of which 94 oppositions were successful at a rate of 76.42 % (Fig. 16). It can be noted that there was not much difference in success rate in oppositions filed by public health groups and generic manufacturers. Out

of 16 drug patent oppositions filed by public health groups, 13 were pre-grant oppositions. On the other hand, out of 123 drug patent oppositions filed by generic manufacturers, 107 were pre-grant oppositions.

It is clear from the above statistics that the participation of civil society organizations in the Indian patent opposition proceedings has been nominal. Mainly, corporations have used the Indian opposition proceedings but the decisions of corporations to challenge patents are not motivated by the public interest considerations. Civil society organizations are best suited to represent the public interest in the patent system and their participation in the patent system should be central, not as an exception.It is, however, important to note that patent oppositions filed by public health groups targeted some of the most valuable patents covering medically more important products.

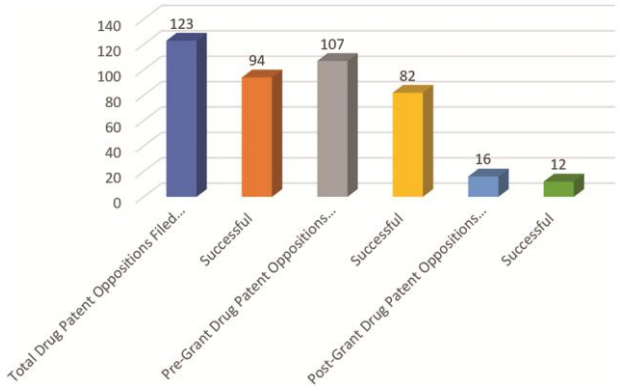

Fig. 16 — Oppositions filed by generic manufacturers

Though less in number, in terms of health impact patent oppositions filed by public health groups have been more significant because in most of the cases they targeted exceptionally important blockbuster drugs that subsequently became widely used globally (Table 1). HIV/ AIDS and chronic hepatitis B virus (HBV) are serious public health problems because of their worldwide distribution. HIV/ AIDS and HBV

Table 1 — Health impact of successful oppositions by public health groups

Product/ Application no.	Opponent(s)	Health impact
Boehringer Ingelheim's Nevirapine (Viramune) 2485/DEL/1998 (US5366972)	Indian Network for People Living with HIV/AIDS;Positive Women's Network	Nevirapine is a potent and easy-to-take HIV/AIDS antiretroviral drug.[19] It is one of the non-nucleoside reverse transcriptase inhibitors that stop the virus from replicating itself in the body.[20] It is a highly specific inhibitor of the reverse transcriptase of HIV-1.[21] It is also used alone or in combination with other antiretroviral agents for the prevention of mother-to-child transmission of HIV.[22] Nevirapine is relatively cheaper as compared to other anchor drugs. As a result of successful patent opposition, Indian generic manufacturers Cipla Ltd., Aurobindo Pharma, and Hetero Drugs manufacture even cheaper fixed-dose formulations of nevirapine.[21]
Gilead Sciences' Tenofovir Disoproxil Fumarate (Viread/ Truvada/ Atripla) 896/DEL/2002 (Divisional application out of parent application 2174/DEL/1998) (WO/1999/005150)	Indian Network of People Living with HIV/AIDS (INP+); Delhi Network of Positive People (DNP+); Intermed Labs Pvt. Ltd., India	Tenofovir Disoproxil Fumarate (TDF) is effective against all clades of the human immunodeficiency virus (HIV-1 and -2).[21]It is one of the nucleoside/ nucleotide reverse transcriptase inhibitors that interrupt the life cycle of HIV and prevent HIV from replicating in the body.[20] TDF is a high-potency antiviral agent.[23] It has been well tolerated in clinical trials and it is associated with morefavourable lipid profiles and has not been associated with mitochondrial toxicity attributed to other nucleoside analogues.[24] In combination with Efavirenz and Emtricitabine, TDF forms a complete HIV regimen branded as Atripla.[25] It is a big step forward from the burdensome multi-pill drug HIV regimens.[20] Taking multiple pills per day used to be a cumbersome option for HIV/AIDS patients. Atripla, the single-pill therapy, provides a much more effective and streamlined medication routine. It improves patient adherence by making it easier for HIV/AIDS patients to follow a feasible treatment plan with a substantially reduced pill burden. TDF is active against hepatitis B virus (HBV).[21] TDF is one of the most efficacious therapies in the suppression of HBV DNA.[21] HBV is a leading cause of chronic liver disease.[26] TDF therapy can reverse liver function and improve liver histology.[21] The efficacy of TDF as a rescue therapy is well-established and international guidelines recommend that TDF be included in the antiretroviral therapy regimen of all HIV-HBV co-infected individuals.[21] TDF has been included in the WHO guidelines as a part of a first-line regimen.[21]
Gilead Sciences' Tenofovir Disoproxil Fumarate (Viread/ Truvada/ Atripla) 2076/DEL/1997 (WO/1998/004569)	Indian Network of People Living with HIV/AIDS (INP+); Delhi Network of Positive People (DNP+);Cipla Ltd., India; Intermed Labs Pvt. Ltd., India	

(*Contd*.)

Gilead Sciences' Tenofovir Disoproxil Fumarate (Viread/ Truvada/ Atripla) 1135/DEL/2007 (Divisional application out of parent application 896/DEL/2002)	Delhi Network of Positive People (DNP+)	Keeping in view the importance of TDF, MSF strongly supported the Indian opponents.[27] As a result of successful patent opposition, TDF is marketed by Indian generic manufacturer Cipla Ltd. as Cipla-tenofovir-300 and by Dr Reddy's laboratories as Reviro.[21]
Abbott Laboratories' Lopinavir-Ritonavir (Kaletra) 339/MUMNP/2006 (WO/2000/04016)	Initiative for Medicines, Access & Knowledge (I-MAK), Delhi; Cipla Ltd. India; Osaka Pvt. Ltd.; Matrix Lab Ltd.	Lopinavir-ritonavir is an HIV/AIDS drug. Lopinavir is an HIV-1 specific protease inhibitor (PI) that is co-formulated with ritonavir.[21] Ritonavir is a potent inhibitor of hepatic cytochrome P-450 3A4 isoenzyme.[21] Ritonavir decreases metabolism and increases plasma levels of lopinavir.[21] Co-formulated lopinavir-ritonavir takes advantage of ritonavir boosting and is characterized by a high genetic barrier to resistance.[28] Lopinavir-ritonavir's heat stability, which results in an elimination of the refrigeration requirement, distinguishes it from the other PIs.[28] In the USA, lopinavir-ritonavir is a preferred first-line agent in children as young as 14 days.[21]According to global guidelines, lopinavir-ritonavir is a preferred first-line agent for children up to 3 years of age.[21] Despite successful patent opposition, it took a long time for generic manufacturers to introduce an equivalent product for a lower price. Finally, in January 2017, Lannett Co. Inc. launched a generic version of theKaletra oral solution.[21]
Abbot Laboratories' Lopinavir-Ritonavir (Kaletra) 6733/DELNP/2007 (WO/2000/04016)	President, Delhi Network of Positive People; Mylan Laboratories Ltd., India	
Abbott Laboratories' Lopinavir-Ritonavir (Kaletra) IN/PCT/2001/ 01312/MUM	I-MAK; Delhi Network of Positive People (DNP+); Indian Network of People Living with HIV/AIDS (INP+)	
GSK's Abacavir (Ziagen) 872/CAL/1998 (WO/1998/52949)	The Indian Network for People Living with HIV/AIDS ("INP+")	Abacavir is a specific inhibitor of the reverse transcriptase of HIV-1.[21] It also has limited activity against the reverse transcriptase of hepatitis B.[21] Because of high water solubility, abacavir has an excellent bioavailability profile compared with many other drugs within the same class.[21] As a result of successful patent opposition, generic forms of abacavir are manufactured and made available at a lower price by various generic manufacturers like Cipla Ltd., Meditab Specialities, and Hetero Drugs.[21]
Novartis International AG's Atazanavir (Reyataz) 805/MAS/1997 (WO/1997/40029)	Indian Network for People Living with HIV/AIDS ("INP+"); Karnataka Network of People Living with HIV/AIDS ("KNP+")	Atazanavir is an HIV/AIDS drug with a distinct resistance profile.[29] It prevents the formation of mature virions in HIV-1 infected cells.[30] As a result, immature virions are formed that are unable to infect new cells.[21] Atazanavir is generally well tolerated and more potent than other PIs against a variety of strains of HIV-1.[29] Successful patent opposition created an opportunity for generic entry of Atazanavir. Generic versions of atazanavir are produced by several generic drug companies in India like Cipla Ltd., Mylan, Emcure, Hetero Drugs, and others.
GSK's Amprenavir (Agenerase) 727/DEL/1997	1 Uttar Pradesh Network of Positive People ("UPNP+"); Indian Network of Positive People ("INP+")	Amprenavirprevents the formation of infectious HIV-1 virions.[31] It offers the convenience of twice-daily administration with no food-timing or fluid restrictions.[21] Amprenavir is rapidly absorbed after oral administration.[31]
GSK's Zidovudine(Retrovir)	Indian Network of People Living with HIV/AIDS (INP+);	Zidovudine is a potent inhibitor of the HIV reverse transcriptase.[21] Moreover, zidovudine triphosphate has been reported to inhibit the DNA polymerase of the human hepatitis B virus.[21]

2044/CAL/1997 (WO/1998/18477)	Manipur Network of Positive People (MNP+)	Because of successful patent opposition, cheaper generic forms of zidovudine are produced by various generic manufacturing companies in India including Cipla Ltd., Aurobindo Pharma, Sun Pharma Laboratories, and Hetero Drugs.[21]
F. Hoffmann-La Roche Ltd.'s Valganciclovir (Valcyte) 959/MAS/1995 (207232) (Post-grant opposition)	Delhi Network of Positive People; Indian Network of People living with HIV/AIDS; Ranbaxy; Cipla Ltd.; Bakul Pharma; Matrix Labs.	Ganciclovir is the standard or principal anti-cytomegalovirus (CMV) drug.[32] It has activity against most herpesviruses and certain other DNA viruses, but its oral absorption is very poor.[21] Valganciclovir is a stable prodrug form of ganciclovir with improved oral absorption.[21] It is effective for the treatment of AIDS-related CMV retinitis.[33]It is particularly effective for the treatment of CMV infection and disease in high-risk solid organ transplant recipients.[33] The simple and convenient once-daily valganciclovir regimen offers the potential for improved patient compliance.[33]

drugs targeted by public health groups or patient advocacy groups in their patent oppositions are, therefore, some of the most important drugs that are desperately needed to address global public health issues. Affordable access to generic versions of products like *Tenofovir Disoproxil Fumarate (Viread/ Truvada/ Atripla), Lopinavir-Ritonavir (Kaletra), Atazanavir (Reyataz), Abacavir (Ziagen), and Zidovudine (Retrovir)* is crucial to global public health. Successful patent oppositions filed by public health groups created opportunities for generic drug companies to introduce cheaper generic versions of these patented drugs legally.

Table 1 supports one of the key arguments of this study that community involvement in the patent system should be central. Civil society organizations should be the main driving force behind patent invalidation challenges. Public interest groups should deter the grant of low-quality patents by acting as watchdogs. Community organizations represent the public interest and their decisions to challenge patent validity are motivated by public health considerations. This is the reason why the outcome of patent validity challenges brought by community organizations affects the public at large.

Lack of Speed Efficiency

The total time incurred in 185 pre-grant patent opposition proceedings was 187373 days. The average time incurred in 185 pre-grant patent opposition proceedings was 1012.83 days (round figured to 1013 days). The average time in years was 2 years 9 months and 13 days (Table 2). The total time incurred in 35 post-grant patent opposition proceedings was 48552 days. The average time incurred in 35 post-grant patent opposition proceedings was 1387.2 days (round figured to 1387 days). The average time in years was 3 years 9 months and 22 days. Moreover, the data shows that the average time incurred in pre-grant drug patent opposition proceedings in India was 2 years7 months while average time incurred in post-grant drug patent opposition proceedings in India was 3 years 4 months and 7 days.

Table 2 — Average time incurred in patent opposition proceedings

Category	Years	Months	Days
Pre-Grant Opposition	2	9	13
Post-Grant Opposition	3	9	22

In a dozen instances, India's pre-grant opposition proceedings took six or more than six years (Table 3). The reason to select these patent applications is to highlight the inordinate delay in disposing of these patent oppositions.In seven instances, India's post-grant opposition proceedings took six or more than six years (Table 4). These applications stand out in the broader dataset as prominent instances of the least time-efficient proceedings.

It can be clearly noted that on average both pre- and post-grant opposition proceedings in India took more than the desired timeframe of 9 months for pre-grant and 12 months for post-grant proceedings. The substantial delay caused by opposition proceedings can be a contributing factor to the low rate of patent opposition in India.

There can be a number of contributing factors to the delay in the disposal of patent opposition proceedings in India. Several key terms are not defined in the Act. Section 3(d) requires 'enhanced efficacy', but this phrase is not defined in the Act or patent office guidelines. There has been a lengthy discussion around what constitutes 'enhanced efficacy' resulting in significant delays.[34] Section 2(ja) requires 'technical advance' and 'economic significance' of the invention. Both these phrases are not defined in the Act or guidelines. Moreover, there is a lack of clarity regarding the date of grant of a patent. Issues related to the date of grant of a patent have been raised several times.[35-39] Furthermore, despite dealing with the fast-growing rate of patent filings in India, the Indian Patent Office is

Table 3 — Instances of pre-grant oppositions taking six or more years

Patent application no.	Date of filing opposition	Date of decision	Time incurred		
			Years	Months	Days
1008/CHE/2006	02/11/2007	09/06/2015	7	7	4
3450/CHENP/2007	25/02/2009	28/06/2016	7	4	3
5435/DELNP/2005	17/07/2008	21/09/2015	7	2	4
2664/KOLNP/2007	29/08/2008	02/11/2015	7	2	4
1784/DEL/2006	29/03/2010	02/06/2017	7	2	4
3140/KOLNP/2007	05/07/2008	25/08/2015	7	1	20
5440/CHENP/2009	06/05/2010	09/05/2017	7	0	3
4572/CHENP/2006	08/09/2008	01/06/2015	6	8	24
1219/DEL/2004	21/12/2006	20/06/2013	6	5	30
752/MUM/2004	21/07/2008	31/12/2014	6	5	10
674/CHE/2005	26/03/2010	11/08/2016	6	4	16
651/KOLNP/2007	31/03/2009	19/06/2015	6	2	19

Table 4 — Instances of Post-grant oppositions taking six or more years

Patent application no.	Date of filing opposition	Date of decision	Time incurred		
			Years	Months	Days
178/MUM/2004	23/04/2007	06/11/2015	8	6	14
447/DEL/2006	09/04/2009	28/11/2016	7	7	19
IN/PCT/2001/00992/DEL	23/04/2009	29/11/2016	7	7	6
2653/DEL/2006	10/08/2009	25/01/2017	7	5	15
887/MUM/2005	25/08/2009	04/01/2016	6	4	10
1317/MUM/2003	28/03/2008	24/06/2014	6	2	27
212/MUM/2003	11/07/2008	25/08/2014	6	1	14

Table 5 — Rate of pre-grant opposition in India

Year	No. of pre-grant oppositions filed	No. of applications published	Patent opposition rate	No. of patents granted	Patent opposition rate
2005-06	155	23,398	0.66%	4,320	3.59%
2006-07	44	19,310	0.23%	7,539	0.58%
2007-08	64	60,506	0.11%	15,261	0.42%
2008-09	153	40,749	0.38%	16,061	0.95%
2009-10	160	34,305	0.47%	6,168	2.59%
2010-11	154	32,213	0.48%	7,509	2.05%
2011-12	193	27,753	0.70%	4,381	4.41%
2012-13	279	26,159	1.07%	4,126	6.76%
2013-14	309	31,413	0.98%	4,227	7.31%
2014-15	247	26,934	0.92%	5,978	4.13%
2015-16	290	41,752	0.69%	6,326	4.58%
2016-17	206	86,766	0.24%	9,847	2.09%
2017-18	260	46,899	0.55%	13,045	1.99%
2018-19	426	46,345	0.92%	15,283	2.79%
Total	2,940	544,502	0.54%	120,071	2.45%

Source: Annual Reports of IP India

understaffed and has a substantial backlog of pending patent applications.[40]

The statistical analysis of patent oppositions filed in India from 2005-2019 suggests that India's patent opposition procedures remained seriously under-utilized. The rate of patent opposition never exceeded 7.31 %. From 2006-2009, the opposition rate remained below 1 % (Table 5).The average opposition rate of 2.45 % is not encouraging and it raises serious questions about the effectiveness of the Indian patent opposition model in terms of achieving its intended goals.

Conclusion

This study supports India's use of patent opposition procedures as a pre-emptive safeguard. India has rightfully used the legitimate flexibility provided to

the WTO Member States to adopt patent opposition procedures in their national patent laws. India's use of its patent opposition safeguard as an access to drugs strategy offers hope to several other developing countries facing similar challenges in terms of affordable access to health technologies. Statistical analysis of 249 patent opposition cases in India suggests that the Indian patent opposition proceedings have been predominantly used to oppose drug patents and the success rate in drug patent opposition cases has been higher as compared to other (non-drug) patents. The data shows that 64.26 % of the oppositions were drug patent oppositions with a success rate of 77.50 %. On the other hand, in 35.74 % of cases other (non-drug) patents were opposed at a success rate of 46.07 %. These findings confirm that this legitimate safeguard can be used to alleviate, to some extent, the burden of expensive pharmaceutical drugs on global health systems by improving affordable access to essential medicines.

Empirical analysis suggests that in India pre-grant opposition proceedings have been used four times more often as compared to post-grant opposition. Out of a total of 249 patent opposition cases, 205 were pre-grant oppositions whereas only 44 were post-grant oppositions. These statistics support one of the central arguments of this study that India made the right choice by providing procedurally convenient and cost-efficient pre-grant opposition procedures. The statistics also support another central argument of this study that India made the right choice by linking its higher substantive threshold standards with its opposition proceedings under Sections 25(1)(f)/ 25(2)(f) and 25(1)(e)/25(2)(e). The data shows that Sections 25(1)(f)/25(2)(f) provides the most common and the most successful ground of drug patent opposition in India at a success rate of 58.99% whereas Sections 25(1)(e)/25(2)(e) provides the second most common and the second most successful ground of opposition at a success rate of 52.90%.

The data highlighted that the Indian opposition mechanism has not been used to its full potential.It rather remained seriously underused. The average rate of pre-grant opposition in India is low at only 2.39%. The Indian opposition model is less likely to help India achieve public health objectives or health-related Sustainable Development Goals (SDGs) if used at the current rate. The lack of time efficiency of Indian opposition proceedings might be one of the important reasons why the Indian model remained underused because slow and lengthy proceedings are less attractive to third parties. The data shows that the average time incurred in pre-grant oppositions was 2 years 9 months and 13 days while the average time incurred in post-grant patent oppositions was 3 years 9 months and 22 days. This average time is much higher than the desired or ideal timeframe for opposition proceedings.

Most importantly, the data highlighted that India's patent opposition mechanism was predominantly used by corporations while civil society organizations rarely participated in the system. Only 16 drug patent oppositions were filed by public health groups while 123 drug patent oppositions were filed by generic manufacturers. Though civil society organizations opposed some of the most important patents, these figures raise serious concerns about the public health rationale or objectives of the Indian opposition proceedings. Corporations are not defenders of the public interest as their decisions to oppose patents are motivated by private commercial interests. The engagement of civil society organizations is critical because their decisions to oppose patents are motivated by public interest considerations and they are best suited to represent and safeguard societal interests in the patent system.

India needs to adopt a community-based patent opposition model that empowers and procedurally enables communities to participate in the patent system as representatives of the public interest and shared values. In addition to conventional technical grounds of patent opposition - like lack of novelty or inventive step, insufficient disclosure, and grant of patent on ineligible subject matter – India should provide a special ground of patent opposition that can be invoked by community representatives to mount patent challenges focused on the public interest or public health as well as moral and ethical aspects of pending patent applications or granted patents. This additional ground will empower civil society organizations to raise larger public policy and public interest issues.

In order to improve speed efficiency, India needs to clearly define key substantive criteria in order to avoid unnecessary delays in patent opposition proceedings. Moreover, the procedural time limits of opposition proceedings in India should be restricted and pre-determined. The pre-grant and post-grant opposition proceedings should be completed within nine months and twelve months respectively. In

exceptional cases, the Controller may allow an extension of up to three months. Furthermore, India needs to increase the number of patent examiners for swift disposal of patent opposition proceedings. In 2016, the number of patent examiners in India increased by almost four-fold with the recruitment of 458 new patent examiners.[41]There is a need to hire many more patent examiners as it is estimated that patent filing has increased by ten times since 2016.[42]

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