

# Intellectual Property(IP) Remedies and TRIPS Flexibilities with Special Reference to Damages and Injunctions.

<sup>1</sup>Shirin Syed, <sup>2</sup>Dr. Sajeda Sultana J. Shaikh

<sup>1</sup> Ph.D. Candidate, <sup>2</sup>Assistant Professor, Dr. Babasaheb Ambedkar Memorial College of Law. Deopur. Dhule.

<sup>1</sup> Kavayitri Bahinabai Chaudhari North Maharashtra University, Jalgaon, Maharashtra, India.

## **Abstract:**

It was argued/complained by developed countries that earlier agreements like Paris and Berne conventions that it lacked effective enforcement and remedial measures for intellectual property rights, particularly in developing countries. The establishment of detailed rules on enforcement of IPRs was advocated in GATT negotiations by the USA and EC, they, in their independent submissions, reflecting the views of the business community advocated for stricter enforcement and liberal remedies to the IP owner in case of infringement. Adequate standards of IPR protection, they argued, were of little value if the conferred rights could not be effectively enforced.

As a result of this, TRIPS deals not with the availability of rights, but also with stricter enforcement and remedies. While most IP experts have focused on TRIPS flexibilities in Parts I and II and VI, the provisions in Part III on enforcement are quite important. Exceptions and limitations can be implemented as limitations on remedies to rights, including in particular limits on damages or injunctions.

The enforcement and maintenance provisions incorporated in the final version of TRIPS are influenced or to say identical to those in the Brussels Draft. This incorporation of interests of the developed nations has far reaching implications for the developing countries due to significant differences in the enforcement rules and remedies existed in the socio economic and legal systems (national laws) as they lacked the infrastructure and resources to apply these 'higher standards' for the enforcement of remedies.

Due to the wide differences that existed in national laws with regard to enforcement rules, Part III of TRIPS does not attempt to harmonize such rules but to establish general standards to be implemented according to the method determined by each Member, in line with the general principle set forth in Article 1.1

Article 41.1 introduces the need for balancing the interest of title-holders, alleged infringers and the public interest. It also requires Members to take action to avoid abuses of enforcement procedures. Such abuses may equally create barriers to legitimate trade or impose other burdens on the public or competitors. For instance, there is evidence of "strategic litigation" by large companies (often based on weak or invalid titles) targeted at small and medium companies which cannot bear the high costs and lengthy procedures involved in IPR litigation. Article 41.2 prescribes a rather general but important obligation: procedures concerning the enforcement of IPRs must be "fair and equitable". It then indicates, although vaguely, undesirable elements that could presumably make a procedure unfair or inequitable, based on complexity, costs, time-limits and duration.

Article 44 deals with injunctions to be adopted when an infringement has been established. It also follows the "judicial authorities shall have the authority" formulation, in this case to order a party to desist from an infringement. It provides an important exception where infringing matter is innocently acquired, Members are free to refuse an injunction and allow the bona fide acquirer to use or further dispose of the infringing subject matter. Article 44.2 explicitly excludes the granting of injunctions for cases of government use and compulsory licenses and Members have considerable leeway to determine "adequate" compensation.

Article 45.1, dealing with the damages, requires the judicial authorities to have the power to order the infringer to pay the right holder damages adequate to compensate for the injury the right holder has suffered. However, an infringer who did not know, or had no reasonable grounds to know, that he engaged in infringing activity is not required to pay damages, whatever the nature of his offence. Article 45.2 indicates that damages apply even where the infringer did not knowingly, or had no reasonable grounds to know s/he did, engage in infringing activity. But this extensive remedies need not necessarily be fulfilled by the Member state. Hence, a Member may provide for the recovery of profits or pre-established damages but limit these measures to culpable and negligent infringers only.

An analysis of the above TRIPS provisions indicates that while many provisions were weakened and some measures were left at the discretion of the Members, the USA and the EC largely imposed their own conception of the subject. The extent to which the legitimate interests for using the flexibilities by developing countries

receives due attention in the course of implementing IP remedies is a matter of debate. It is to be looked upon how far the developing nations can utilize the flexibilities under TRIPS in order to move away from stricter implementation of IP remedies (and enforcement).

**Keywords:** Intellectual Property, TRIPS Flexibilities, Enforcement, Injunctions, Patents.

## I. Introduction:

The development and implementation of IPR laws involves balancing the interests of the public in access to information and technology, and the interests of those creating new works and inventions in securing return on their investments.

It is often possible to expand the protection of private right holders and increase their investment returns, but this expansion of rights may have an adverse impact on the welfare of a wider public. The objective of IPR laws is not to provide the maximum possible return to right holders, but to strike the proper balance of private and public interests.

As early on as the Uruguay Round Negotiations, which ultimately led to the adoption of the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) as part of the World Trade Organization (WTO). As a result, the standards of international patent protection heightened and restricted the access to essential medicines especially in developing countries.

Developing countries, including those with pharmaceutical production capabilities such as India and Brazil, could no longer reverse-engineer patented products, as their domestic laws had to be made TRIPS-compliant by 2005. This restriction on vital public health interests was raised by the developing country members of WTO and demanded of removal of the existing constraints on public health policies. This issue formed an essential element of the deal to launch the Doha round of trade negotiations and opportune political environment successfully culminated in Doha Ministerial Declaration on the TRIPS Agreement and Public Health<sup>1</sup> in 2001. This Declaration was a significant breakthrough confirming the flexibilities under TRIPS Agreement and affirmed “the right to determine what constitutes a national emergency or other circumstances of extreme urgency” (para. 3, lit. b and c). Thus, a balanced interpretation of TRIPS complementing and supporting these international initiatives. Brazil and India were on the forefront leading multilateral efforts towards shaping the global health regime and enacting domestic legislation seeking to maximize flexibilities under TRIPS.

## II. TRIPS provisions on enforcement and flexibilities:

An important element of flexibility was recognized under the preamble<sup>2</sup> of TRIPS that enforcement measures may take into account differences in national legal systems, it also refers to intellectual property rights as “private rights.”<sup>3</sup> Most likely, the reference to IPRs as private rights was inserted in the preamble because of the unique characteristic of TRIPS in regulating national laws governing privately held interests (e.g., patents), in specifying remedies that are to be provided under national law for protecting such interests, and in clarifying that governments would not be responsible for policing IPR infringements on behalf of private right holders.<sup>4</sup>

It further recognizes the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives. It is emphasized in the preamble itself the need for “maximum flexibility”<sup>5</sup> in favor of least developed countries

Article 1<sup>6</sup> of the TRIPS Agreement makes it clear that Members are not obliged to adopt more extensive than TRIPS Agreement standards (TRIPS-plus). And each member is free to determine whether it will apply the

<sup>1</sup> World Trade Organization, Declaration on the TRIPS Agreement and Public Health, 20 November 2001, WT/MIN(01)/DEC/2 [hereinafter the Doha Declaration].

<sup>2</sup> Subparagraph (c) of TRIPS preamble.

<sup>3</sup> Fourth clause of the TRIPS preamble.

<sup>4</sup> UNCTAD-ICTSD. 2005. Resource Book on TRIPS and Development. Cambridge University Press, New York. pp.11.

<sup>5</sup> Sixth clause of the TRIPS preamble.

<sup>6</sup> General Provisions and Basic Principles

Agreement directly, and that will depend on its legal system and practice. Therefore, it acknowledges the flexibility inherent in the express text of the TRIPS Agreement and intellectual property law more generally, authorizing each Member to implement the rules in the manner most appropriate for itself, provided that implementation is in accord with the terms of the agreement. It acknowledges that IPR protection will vary among Members, and that Members maintain flexibility in implementing TRIPS.

Article 7<sup>7</sup> and 8<sup>8</sup> of TRIPS set forth the objectives and principles, establish a balancing of interests at the multilateral level to substitute for the balancing traditionally undertaken at the national level.<sup>9</sup>

IPRs have been designed to benefit society by providing incentives to introduce new inventions and creations.<sup>10</sup> Article 7 makes it clear that IPRs are not an end in themselves. It sets out the objectives that member countries should be able to reach through the protection and enforcement of such rights. In introducing IPR protection, countries should frame the applicable rules so as to promote technological innovation and the transfer and dissemination of technology “in a manner conducive to social and economic welfare”. In countries who lack innovative activities and scientific and technological capabilities, IPR cannot promote innovation. In this situation, mutual advantage of producers and users of technological knowledge is significant, since developing countries are largely users of technologies produced abroad. Article 7 provides guidance for the interpreter of the Agreement, emphasizing that it is designed to strike a balance among desirable objectives whereas Article 8 which is to be read as statement of TRIPS interpretative principle which advises that Members were expected to have the discretion to adopt internal measures they consider necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development.

Article 41.1<sup>11</sup> introduces the need for balancing the interest of title-holders, alleged infringers and the public interest:

*“procedures shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse”.*

---

## Article 1

### Nature and Scope of Obligations

1. 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. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.

<sup>7</sup>The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

<sup>8</sup>1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

<sup>9</sup>UNCTAD-ICTSD.2005 Resource Book on TRIPS and Development. Cambridge University Press, New York.pp.119.

<sup>10</sup>Correa, Carlos,2003. Formulating Effective Pro-Development National Intellectual Property Policies, Trading in Knowledge. Bellmann, C., Dutfield, G. and Melendez -Ortiz, R., London. Earth scan: 9, 209.

<sup>11</sup>Members shall ensure that enforcement procedures as specified in this Part are available under their law so as to permit effective action against any act of infringement of intellectual property rights covered by this Agreement, including expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements. These procedures shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse.

Thus Article 41 ensures that in adopting and applying enforcement procedures Members must ensure that legitimate trade is not jeopardized, for instance, by injunctive measures adopted without sufficient justification.

Article 41.2<sup>12</sup> It prescribes a rather general but important obligation: procedures concerning the enforcement of IPRs must be “fair and equitable” indicating undesirable elements that could presumably make a procedure unfair or inequitable, based on complexity, costs, time-limits and duration.

Article 41.5<sup>13</sup> makes it clear that Members are not obliged to establish a special court to deal with intellectual property issues, nor to allocate special funds to this area. An important exception to the rule established in Article 44.1 is that Members are not obliged to accord judges the authority to grant injunctions in respect of protected subject matter acquired or ordered by a person prior to knowing or having reasonable grounds to know that dealing in such subject matter would entail the infringement of an intellectual property right.<sup>66</sup> This means that where infringing matter is innocently acquired, Members are free to refuse an injunction and allow the *bona fide* acquirer to use or further dispose of the infringing subject matter.<sup>67</sup>

Article 44.2 explicitly excludes the granting of injunctions for cases of government use<sup>69</sup> and other uses permitted by the government without the authorization of the right holder, such as compulsory licenses.<sup>70</sup> This provision makes it clear that the title holder cannot prevent in these cases the exploitation of the respective subject matter, and that his sole right would be to claim payment of a remuneration in accordance with subparagraph (h) of Article 31.<sup>71</sup>

### III. TRIPS flexibilities in US and Indian context:

Interim injunctions are procedural relief granted under Code of Civil Procedure 1908<sup>14</sup> The object of granting such relief is to protect the plaintiff against the injury by violation of his rights for which he could not adequately be compensated in damages recoverable in the action if the uncertainty were resolved in his favour at the trial.<sup>15</sup> This remedy is both temporary and discretionary.

With this backdrop, ....

#### United States Supreme Court’s Decision in eBay.

The United States Supreme Court issued its decision in *eBay Inc. v. Merc Exchange, L.L.C.* in 2006. The decision addressed the circumstances under which a permanent injunction can issue to remedy the infringement of a valid patent.

Prior to this decision, the US appellate court with exclusive jurisdiction over patent appeals consistently held that a permanent injunction should issue as a matter of course if a valid patent is found infringed.<sup>16</sup>

The court recognized only ‘rare instances’ in which an injunction should not issue, such as when the patentee’s failure to practice frustrates an important public health need for the invention.<sup>17</sup>

<sup>12</sup>Procedures concerning the enforcement of intellectual property rights shall be fair and equitable. They shall not be unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays.

<sup>13</sup>It is understood that this Part does not create any obligation to put in place a judicial system for the enforcement of intellectual property rights distinct from that for the enforcement of law in general, nor does it affect the capacity of Members to enforce their law in general. Nothing in this Part creates any obligation with respect to the distribution of resources as between enforcement of intellectual property rights and the enforcement of law in general.

<sup>14</sup>Order XXXIX (Temporary Injunctions and Interlocutory Orders), section 2. A copy of the statute is available at: <[http://ecourts.gov.in/sites/default/files/The%20Code%20of%20Civil%20Procedure\\_0\\_0.pdf](http://ecourts.gov.in/sites/default/files/The%20Code%20of%20Civil%20Procedure_0_0.pdf)>

<sup>15</sup> *Wander v. Antox*, 1990 Supp (1) SCC 727

<sup>16</sup>See, e.g., *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1246–7 (Fed. Cir. 1989).

<sup>17</sup> see *Rite- Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1547–8 (Fed. Cir. 1995) (en banc); *Vitamin Technologists, Inc. v. Wisconsin Alumni Research Found.*, 146 F.2d 941, 944–5 (9th Cir. 1945) (finding that public interest warranted refusal of injunction on irradiation of oleomargarine); *City of Milwaukee v. Activated Sludge, Inc.*, 69 F.2d 577, 593 (7th Cir. 1934) (denying a permanent injunction against city operation of sewage disposal plant because of public health danger).



The eBay Inc. v. Merc Exchange, L.L.C. Decision,<sup>18</sup> the Court rejected the conclusion that all patentees who are both willing to license and are not commercially practicing their patents should not be awarded injunctions.

The court in eBay case denied any necessary legal entitlement to an injunction and restored their flexibility to deny injunctive relief.

These decisions to deny injunctions to stop infringement reflect the roots of injunctive relief in equity, demonstrating its flexibility and its sensitivity to the factual context and the positions of the parties in achieving substantive justice.<sup>19</sup>

Therefore, TRIPS Members retain substantial discretion to determine their legislative policies and to delegate policy discretion to their judges to decide whether, when and how to grant preliminary and permanent injunctive relief, as well as to award damages that authorise continued infringing activity.

The body of case law that is being developed in the United States through the discretionary judgments of trial judges may be instructive to other developed and to developing countries in assessing whether, when and how to grant prospective injunctive relief. This is true even if legislators and judges in those countries choose to exercise their policy discretion differently from judges in the United States. To the extent that social conditions or policy preferences differ from those in the United States, legislators or judges in other countries may choose to specify different conditions under which injunctive relief should be granted.<sup>20</sup>

In the Indian context, there are instances of using this flexibility incorporated in its patent laws such as, Roche, OSI and Pfizer had filed a suit against Cipla before the Delhi High Court claiming that “Erlolcip”, a generic anti cancer drug by Cipla corresponding to Roche’s originator drug, “Taraceva” violates Indian patent. Both drugs are based on “Elrotinib Hydrochloride”. a compound now known to exist in several polymorphic forms. In the trial Court, the Single Judge Justice Ravindra

Bhat declined to grant a temporary injunction on the ground of “public interest”; holding that the lower priced generic version of Cipla would enable “more access” to this life saving drug in India.<sup>21</sup>

While ruling in favour of Cipla, the court noted:

- i) that Cipla’s product does not infringe the Roche patent
- ii) that even if it did, there was a serious doubt cast on the validity of the patent
- iii) that even if the above two issues were to be held in favour of Roche, the injunction would not still issue, owing to the “public interest” factor.

<sup>18</sup>The eBay case involved eBay, Inc., which owns and operates an Internet website that allows buyers and sellers to search for goods and to purchase them by participating in live auctions or by buying them at a fixed price. The technology at issue in the case was the fixed-price purchasing feature of eBay’s website. Merc Exchange, L.L.C. alleged that eBay infringed three of Merc Exchange’s patents. After a jury trial, eBay was found liable for wilfully and directly infringing one of Merc Exchange’s patents and Merc Exchange was awarded \$ 10.5 million.

In a unanimous opinion, the Supreme Court rejected the Federal Circuit’s general rule and held that courts must apply the well-established, general four factor test for determining whether a permanent injunction should issue, the plaintiff must demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.’

<sup>19</sup> Li, Xuan & Correa, Carlos(editors),2009. Intellectual Property Enforcement International Perspectives, Edward Elgar Publishing Limited,Cheltenham, UK • Northampton, MA, USA,2009.pp106.

<sup>20</sup>ibid

<sup>21</sup>The trial Court decision has been reported as Hoffman La-Roche v. Cipla Ltd., 148 (2008) DLT 598).

#### IV. Enforcement of injunctive relief:

But, during the course of time there are some instances of (mis)using injunctions as tool for enforcing IP and patents in particular in India. Pharma patentees get injunctions quickly and have been successful in preventing launch of generic versions of their patented products(s). An overwhelmingly majority of injunction requests are filed as ex-parte and are quia-timetd in nature. The reason for this is because ex-parte facilitates the patentee to seek interim injunction without informing the defendant, in advance, of such a request. This means that the defendant, in all likelihood, will not be able to present his defence before the issuance of the injunction and will have to present his case only after the injunction has been served on him. *Quia timet* requests are injunction requests that are filed in advance of any actual wrongful act having been committed, as the patentee believes that an infringement is threatened or imminent but has not yet actually occurred. Consequently, patentees were able to take the safe route of injunctions to prevent their competitors marketing their patented product(s).

One such example is in Bristol-Myers Squibb vs. BDR Pharma case (hereafter referred as BMS' case)<sup>22</sup> the Delhi High Court upheld BMS' patent for anti-cancer drug Dasatinib. BMS filed a suit for a qua timet injunction against BDR as it suspected that BDR was planning on marketing Dasatinib, based on the fact that the latter had applied to the DCGI for the requisite approvals. BDR also argued that the drug in question is important in the treatment of Leukaemia and is exorbitantly priced at Rs.1,67,000 for a month's course, putting it outside the reach of the majority of the Indian population. Therefore, they argued, in infringement proceedings, the public interest lies in avoiding interim injunctions and granting other reliefs such as royalties, so that patients may benefit from cheaper drugs in the market. The Court held that where there the patent is prima facie valid and infringement is established with no credible defence, public interest cannot be a valid consideration for not granting an injunction. Consequently, a generic version of Dasatinib was present in market for a very short while before the patent injunction came through.

Likewise, the Swedish telecom giant mobile company secured injunctions against its major competitors like Lava, Xiaomi, Intex and Micromax and eventually restricting them from importing, exporting, manufacturing, and selling any mobile phones that use Ericsson's patents and technology.

The ulterior purpose of restoring to *quia timet* actions which are merely speculative is to use injunctions as a weapon to curb otherwise legal activities and to assert dominance. It could also be aimed at cutting off legal and successful businesses of competitors.<sup>23</sup> It may also have a 'chilling effect' on other legitimate manufacturers. Moreover, a patent itself is a preventive legal tool as it allows the patentee to initiate action upon infringement. The scope of the process of this law is therefore curative. Seeking *quia timet* actions can be thus argued to be beyond the scope of relief contemplated by patent law.<sup>24</sup>

Though for a patentee it would be utopian to able to obtain injunctions based on mere fears, the legal system should not cater to such demands. Even if the threat of infringement materialises, the injury caused to the patentee may not be irreparable as he can be compensated for the same.<sup>25</sup>

Such wrongly granted injunctions harm not only competitors against whom they are granted, but also consumers who are forced to pay a monopoly price during the subsistence of the injunction/restraining order.

#### V. Conclusion.

India, with the high disease burden and poor per capita income, needs to pursue various measures incorporated in its statutes like the Indian Patents Act 1970, the fundamental rights and Directive Principles of State Policy enshrined in the Constitution on the lines of International Covenant on Economic, Social and Cultural Rights(ICESCR)<sup>26</sup>, flexibilities under TRIPS for improving affordable access to lifesaving patented medicines.

Overall, the Doha Declaration contributed greatly to confirming the flexibilities under TRIPS and clarified the legal situation as to their use for public health purposes. Although the developing US and Indian experience with injunctive relief after the eBay and Roche v Cipla is highly instructive, India and other developing countries may

<sup>22</sup> Bristol Myers Squibb Company & Ors v Mr. J D Joshi & And CS(OS) No. 2303/2009.

<sup>23</sup>Niki Tasha India Pvt Ltd v Faridabad Gas Gadgets Pvt Ltd, AIR 1985 Delhi 336.

<sup>24</sup> Lath, Aparajita, July 2014. "Analysing the Pitfalls of Indian Patent Injunctions based on Fear of Infringement", Journal of Intellectual Property Rights, Vol 19, p.257.

<sup>25</sup>Niki Tasha India Pvt Ltd v Faridabad Gas Gadgets Pvt Ltd, AIR 1985 Delhi 336.

<sup>26</sup> Shankar, Uday & Bindal, Saurabh, 2013. Constitutionalizing Intellectual Property. Satyam Law International, New Delhi. pp.10.

choose different approaches in light of the TRIPS Agreement's flexibilities, and thus may and do make different choices regarding the use of injunctions as tool of unreasonable enforcement of IP and protection for their patented products by IP owners. Further, India and other developing countries may point towards the flexibilities under TRIPS as unanimously admitted under Doha Declaration, to respond to recent pressures being applied in context of multilateral trade agreements to restrict such flexibility and policy discretion in regard to irrationally claimed injunctions against imaginary infringements.

## References:

- 1) Doha Declaration.
- 2) Constitution of India.
- 3) Indian Patents Act, 1970.
- 4) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).
- 5) UNCTAD-ICTSD. 2005. Resource Book on TRIPS and Development. Cambridge University Press, New York.
- 6) The Code of Civil Procedure, 1908.
- 7) Wander v. Antox, 1990 Supp (1) SCC 727.
- 8) Li, Xuan & Correa, Carlos (editors), 2009. Intellectual Property Enforcement International Perspectives, Edward Elgar Publishing Limited, Cheltenham, UK • Northampton, MA, USA, 2009
- 9) Hoffman La-Roche v. Cipla Ltd., 148 (2008) DLT 598.
- 10) Bristol Myers Squibb Company & Ors v Mr. J D Joshi & And CS(OS) No. 2303/2009.
- 11) Niki Tasha India Pvt Ltd v Faridabad Gas Gadgets Pvt Ltd, AIR 1985 Delhi 336.
- 12) Lath, Aparajita, July 2014. "Analyzing the Pitfalls of Indian Patent Injunctions based on Fear of Infringement", Journal of Intellectual Property Rights, Vol 19,
- 13) Shankar, Uday & Bindal, Saurabh, 2013. Constitutionalizing Intellectual Property. Satyam Law International, New Delhi.