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Implementation of TRIPS Flexibilities and Injunctions: A Case Study of India

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**IMPLEMENTATION OF TRIPS FLEXIBILITIES AND
INJUNCTIONS: A CASE STUDY OF INDIA**

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SOUTH CENTRE

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ABSTRACT

The proponents of intellectual property (IP) have increasingly utilized injunctions with indiscriminate propensity as a strategic tool for IP enforcement, resulting in adverse socio-economic implications, including the enjoyment of human rights. This trend has eclipsed the flexibilities provided in the Doha Declaration on the TRIPS Agreement and Public Health. Although a substantial volume of the literature focuses on the flexibilities of compulsory license or scope of patentability, little attention has been given to the flexibilities related to IP enforcement. Discussing the implications of IP enforcement on public interest, the paper examines the gaps in the articulation of flexibilities of intellectual property rights (IPRs) enforcement, with special reference to injunctions in India. It examines how far the courts consider the implications on the enjoyment of fundamental rights while granting injunctions on patents. This paper argues that the Indian courts have deviated from the cautious approach provisioned under the TRIPS flexibilities that allows the courts to consider the public interest aspect and human rights implications while granting injunctions in patent litigation. Moreover, it asserts that the courts should exercise prudence in granting injunctive relief in cases involving patent infringement, and take into account the potential impact of such relief on the exercise of human rights. This suggests a need for a careful examination of the potential implications of injunctive remedies in such cases.

Los defensores de la propiedad intelectual (PI) han utilizado cada vez más las medidas cautelares de manera indiscriminada como herramienta estratégica para la observancia de la PI, lo que ha tenido consecuencias socioeconómicas adversas, incluido sobre el disfrute de los derechos humanos. Esta tendencia ha eclipsado las flexibilidades previstas en la Declaración de Doha relativa al Acuerdo sobre los ADPIC y la Salud Pública. Aunque un volumen considerable de la bibliografía se centra en las flexibilidades tales como las licencias obligatorias o el alcance de la patentabilidad, se ha prestado poca atención a las flexibilidades relacionadas con la observancia de la PI. Al analizar las implicaciones de la observancia de la PI en el interés público, el documento examina las lagunas existentes en la articulación de las flexibilidades de la observancia de los derechos de propiedad intelectual (DPI), con especial referencia a los mandamientos judiciales en la India. Se examina hasta qué punto los tribunales tienen en cuenta las implicaciones sobre el disfrute de los derechos fundamentales a la hora de conceder mandamientos judiciales sobre patentes. Este documento sostiene que los tribunales indios se han desviado del enfoque cauteloso previsto en las flexibilidades del ADPIC, que permite a los tribunales considerar el aspecto del interés público y las implicaciones para los derechos humanos a la hora de conceder medidas cautelares en litigios sobre patentes. Además, afirma que los tribunales deben actuar con prudencia a la hora de conceder medidas cautelares en casos de infracción de patentes, y tener en cuenta el impacto potencial de dichas medidas en el ejercicio de los derechos humanos. Esto sugiere la necesidad de un examen cuidadoso de las implicaciones potenciales de las medidas cautelares en tales casos.

Les promoteurs de la propriété intellectuelle ont de plus en plus recours aux injonctions de manière indiscriminée comme outil stratégique pour faire respecter les droits de propriété intellectuelle, ce qui a des conséquences socio-économiques négatives, y compris pour la jouissance des droits de l'homme. Cette tendance a éclipé les flexibilités prévues dans la déclaration de Doha sur l'accord sur les ADPIC et la santé publique. Bien qu'une grande partie de la littérature se concentre sur les flexibilités relatives aux licences obligatoires ou à l'étendue de la brevetabilité, peu d'attention a été accordée aux flexibilités liées aux moyens de faire respecter les droits de propriété intellectuelle. En discutant des conséquences des

moyens de faire respecter les droits de propriété intellectuelle sur l'intérêt public, le document examine les lacunes dans la mise en œuvre des flexibilités liées aux moyens de faire respecter les droits de propriété intellectuelle, avec une référence particulière aux injonctions en Inde. Il examine dans quelle mesure les tribunaux prennent en compte les implications sur la jouissance des droits fondamentaux lorsqu'ils accordent des injonctions sur les brevets. Ce document affirme que les tribunaux indiens se sont écartés de l'approche prudente prévue par les flexibilités de l'Accord sur les ADPIC qui permet aux tribunaux de prendre en compte l'aspect de l'intérêt public et les implications en matière de droits de l'homme lorsqu'ils accordent des injonctions dans le cadre de litiges relatifs aux brevets. En outre, elle affirme que les tribunaux devraient faire preuve de prudence lorsqu'ils accordent des injonctions dans des affaires de violation de brevet et tenir compte de l'impact potentiel de ces injonctions sur l'exercice des droits de l'homme. Cela suggère la nécessité d'un examen minutieux des implications potentielles des mesures d'injonction dans de tels cas.

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INTRODUCTION

There are increasing concerns with regard to the implementation of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities in respect of injunctions. While setting standards for intellectual property (IP) protection and enforcement, TRIPS provides for flexibilities, such as compulsory licensing (CL), government use, and limitations and exceptions to patent rights, that allow member countries to adopt measures to safeguard the public interest. TRIPS also has provisions for provisional and permanent injunctions as an enforcement tool to protect IPRs.

It is important to achieve the right balance between safeguarding intellectual property rights enforcement and addressing public health concerns and human rights. The implementation of TRIPS flexibilities regarding enforcement, especially through injunctions, requires a nuanced approach in terms of IP law and policy.

The term “enforce” means to execute a particular law, writ, judgment, or the collection of a debt or fine. In the context of IPRs, it means to prevent or procure a remedy for the infringement of the rights conferred. An infringement of IPRs happens when certain uses of IPRs, which fall within the exclusive rights of the IP holder, are performed by third parties without the authorization of the right holder or the competent authority such as through CLs. Generally, the exclusive rights of the IP holder can be enforced through civil remedy for infringement viz., injunctions and damages, including in the case of patents.

The paper examines the gaps in the articulation of flexibilities on enforcement of IP rights in the context of patents, with a special reference to injunctions in India. It argues that courts need to consider the public interest, especially human rights implications, while granting injunctions in patent litigation. Further, it also examines the question whether the flexibilities in the TRIPS Agreement allow such considerations while granting injunctions.

In the first section, the paper discusses the implications of IP enforcement on public interest. While the nature of the TRIPS Agreement and its flexibilities in IP enforcement related to injunctions are examined in the second section, the practices of granting injunctions in India, including the judicial trends reflecting the use of the flexibilities under the TRIPS are analyzed in the third section. The final section concludes the discussion with recommendations.

I. PUBLIC INTEREST AND PATENT ENFORCEMENT

The TRIPS Agreement provides patent holders the exclusive right to prevent third parties from the act of making, using, offering for sale, selling, or importing of the patented product (or a product directly obtained by a patented process) or using a patented process without their consent.² Patent holders can generally enforce these exclusive rights by filing a civil suit for patent infringement.³ Generally, the judicial authorities may grant two types of remedies. First, a permanent injunction to prevent the infringer from using the patented invention. Second, damages to compensate for the loss suffered by the patent holder. Apart from these two remedies, the court may also order the goods and materials and implements used for making them to be seized, forfeited, or destroyed, as it deems fit under the circumstances of the case without payment of any compensation.

Injunctions are considered an effective remedy against patent infringement. Injunctive remedies are restraining orders to the infringer to prevent the continuing act of infringement. Courts may grant a permanent injunction as a remedy at the end of the suit after establishing the infringement through the trial.

However, courts can also grant interim injunctions prior to the conclusion of the trial to prevent a continuing infringement and to maintain the status quo. An interim injunction, also known as preliminary/provisional injunction, is a temporary remedy used mainly for immediate relief. It is invoked to preserve the subject matter in its existing condition and prevent dissolution of the plaintiff's rights. Interim injunctions are either not conclusive as to the rights of the parties or they do not determine the merits of a case. They seek to prevent further injury, and irreparable harm or injustice until such time as the rights of the parties can be ultimately settled. Interim injunctions are also granted to prevent a perceived threat. Generally, in common law, the different types of interim injunctions are as follows:

1. *Inter partes* injunction: The court will hear both sides' arguments, the respondent is notified that the application for an injunction has been made, and when and where it will be heard.
2. *Ex parte* injunctions:⁴ The court will only grant an injunction on such an application if there are good reasons for not giving the respondent any notice (e.g., the matter is so urgent that the applicant approaches the court citing ongoing infringement of the patent and is only granted where it is not possible or not appropriate to give the other party proper notice).
3. *Quia timet* injunctions: Originating from the English equity courts, *quia timet* injunctions refer to a particular type of *ex parte* injunction, where the injunction is granted based on an imminent apprehension or fear of possible future infringement. While granting *quia timet* injunctions courts look into three elements viz. proof of

² Article 28

Rights Conferred

1. A patent shall confer on its owner the following exclusive rights:

- (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing⁽⁶⁾ for these purposes that product;
- (b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

³ Some countries also allow criminal procedures in cases of patent infringement.

⁴ Latin for "one-sided" (i.e., where the judge mainly bases his decision on the assertions of the plaintiff, if these appear substantiated. Details vary according to domestic laws.). The reason for this procedure is that the court has to act quickly, due to the danger of irreparable harm or a possible destruction of evidence.

imminent danger; proof that the threatened injury will be practically irreparable; and proof that whenever injurious circumstances ensue, it will be impossible to protect plaintiff's interests, and if relief is denied proof of damage is substantial and could cause irreparable injury to the right holders.⁵

While commonly used to remedy trademark infringement, these types of injunctions have also been issued in many jurisdictions in patent infringement cases, including relating to pharmaceutical patents.⁶

In India, while granting interim injunctive remedies, the judicial authorities form their opinion on the three pillars on which rest the foundation of any order of injunction. This three-step test, originally used in the American Cyanamid case⁷ by the UK House of Lords, lays down certain standards for the grant of injunctive relief. They are: a) existence of a *prima facie* case; b) the balance of convenience; and c) the probability of irreparable injury.⁸ The granting of injunctions is done on a case-by-case basis, taking into account the specific facts and circumstances, with relief remaining flexible.⁹

a) *Prima facie* case:

The court, at the initial stage, cannot insist upon a foolproof case warranting an eventual decree. Generally, it looks at whether there is a *prima facie* case, which warrants an interim injunction. The important factor to be considered in the determination of this requirement is that the plaintiff's claim is not frivolous or vexatious.¹⁰ The standard generally followed is the chance of the plaintiff to win the case. However, the level of assessment was diluted in the

⁵ See, *Graigola Merthyr Co Ltd v. Swansea Corporation*: CA 1928 (In this case mine owners sought an injunction to prevent the local authority filling its reservoir, alleging that it would flood their adjacent mine-shafts. The court granted the injunction in anticipation of the threatened action of refilling the reservoir. Lord Hanworth MR said: "When the Court has before it evidence sufficient to establish that an injury will be done if there is no intervention by the Court – it will act at once, and protect the rights of the party who is in fear, and thus supply the need of what has been termed protective justice principle." A *quia timet* action is not based upon hypothetical facts for the decision of an abstract question. When the court has before it evidence sufficient to establish that an injury will be done if there is no intervention by the court – it will act at once, and protect the rights of the party who is in fear, and thus supply the need of what has been termed protective justice".

⁶ Joshua D. Sarnoff (2020), TRIPS Flexibilities on Patent Enforcement: Lessons from Some Developed Countries Relating to Pharmaceutical Patent Protection, Research Paper No.119 (South Centre, Geneva), *SSRN Electronic Journal*, https://www.southcentre.int/wp-content/uploads/2020/10/RP-119_reduced.pdf, accessed on 12 April 2022.

⁷ *American Cyanamid Co v. Ethicon Ltd* [1975] AC 396 (The court developed a three-step test to establish whether an applicant's case merited the granting of an interlocutory injunction: 1) there is a serious question to be tried; 2) he will suffer irreparable injury if refused the interlocutory relief; and 3) the balance of inconvenience resulting from granting or denying the interlocutory relief lies with him rather than with the respondent.

⁸ The Supreme Court in *Shanti Kumar Panda v. Shakuntala Devi*, where the court held thus: "At the stage of passing an interlocutory order such as on an application for the grant of ad interim injunction under Rule 1 or 2 of Order 39 of the CPC, the competent Court shall have to form its opinion on the availability of a *prima facie* case, the balance of convenience and the irreparable injury". See also, In *Gujarat Bottling Co. Ltd. v. Coca Cola Company and Others*, 1995(5) SCC 545, (wherein it was held that it is a settled principle of law that in a suit where there is a no permanent injunction sought for, in the final analysis, ordinarily a temporary injunction cannot be granted. Grant of temporary injunction is governed by three basic principles, i.e. *prima facie* case; balance of convenience; and irreparable injury, which are required to be considered in a proper perspective in the facts and circumstances of a particular case.). But it may not be appropriate for any court to hold a mini trial at the stage of grant of temporary injunction (Vide *S.M. Dyechem Ltd. v. M/s. Cadbury (India) Ltd.*, AIR 2000 SC 2114; The Hon'ble Supreme Court in *Manohar Lal Chopra v. Rai Bahadur Rao Raja Seth Hira Lal*, AIR 1962 SC 527 held that the civil court has a power to grant interim injunction in exercise of its inherent jurisdiction even if the case does not fall within the ambit of provisions of Order 39 Code of Civil Procedure.

⁹ *Colgate Palmolive (India) Ltd. v. Hindustan Lever Ltd.*, AIR 1999 SC 3105.

¹⁰ *Gujarat Electricity Board, Gandhinagar v. Maheshkumar and Co., Ahmedabad* (1995(5) SCC 545,) wherein it was held that "Prima facie case" means that the Court should be satisfied that there is a serious question to be tried at the hearing, and there is a probability of Plaintiff obtaining the relief at the conclusion of the trial on the basis of the material placed before the Court. See also, *Marin Burn Ltd. v. R.N. Banerjee* 1958-I L.L.J. 247

American Cyanamid case for establishing the *prima facie* case.¹¹ Prior to this case, courts used to examine the chance of the plaintiff to win the case in a trial, and if the assessment shows that the plaintiff has the chance to win, then the *prima facie* case is to decide in favor of the plaintiff. It is a time-consuming exercise in a way to carry out a mini trial before the final trial. In the American Cyanamid case, the district judge spent three days deciding on the *prima facie* case. Similarly, the court of appeal spent eight days. Thus, the House of Lords diluted the level of scrutiny in establishing the *prima facie* case in the American Cyanamid case, stating:

“Your Lordships should in my view take this opportunity of declaring that there is no such rule. The use of such expressions as “a probability,” “a prima facie case,” or “a strong prima facie case” in the context of the exercise of a discretionary power to grant an interlocutory injunction leads to confusion as to the object sought to be achieved by this form of temporary relief. The court no doubt must be satisfied that the claim is not frivolous or vexatious, in other words, that there is a serious question to be tried.”

Hence, the court held that the plaintiff is required to demonstrate before the court that there are serious issues to be tried and it is not frivolous or vexatious. Further, it advised trying to resolve conflicts of evidence on affidavit as to facts on which the claims of either party may ultimately depend, and not to decide difficult questions before the conclusion of the trial as they call for detailed argument and mature considerations. This approach lowered the scrutiny of the *prima facie* and led courts in many countries to consider the existence of a patent as a proof for a *prima facie* case.¹² It makes the court presume the validity of the patent without looking at the merits of the patent in question.

b) Irreparable injury:

This means the continuing injury emanating from the infringement of exclusive rights cannot be adequately remedied by damages. The remedy of damages would be inadequate if the compensation ultimately payable would not effectively keep the patent holder in the same position as it was before the injunction was refused.¹³ The question arises whether an infringement of a patent results in an irreparable injury when it can be compensated through damage.¹⁴ Courts need to look at the functioning of the industry in general and the exact role of the patent in question in the product market to find out whether there is an irreparable loss

¹¹ American Cyanamid Co. and Ethicon Ltd. 1974 Nov. 12, 13, 14; 1975 Feb. 5. The House of Lords held that: “Your Lordships should in my view take this opportunity of declaring that there is no such rule. The use of such expressions as “a probability,” “a prima facie case,” or “a strong prima facie case” in the context of the exercise of a discretionary power to grant an interlocutory injunction leads to confusion as to the object sought to be achieved by this form of temporary relief. The court no doubt must be satisfied that the claim is not frivolous or vexatious, in other words, that there is a serious question to be tried.”

¹² See Basheer, Shamnad, Sanklecha, Jay and Gowda, Prakruthi (2014), “Pharmaceutical Patent Enforcement: A Developmental Perspective”, Available at SSRN: <https://ssrn.com/abstract=2535763> or <http://dx.doi.org/10.2139/ssrn.2535763> (the authors primarily suggest that “developing countries such as India should embrace the more rigorous “relative assessment” threshold, as opposed to the lower triable issue standard.”; See also Joshua D. Sarnoff, Bilcare, KSR (2007), “Presumptions of Validity, Preliminary Relief, and Obviousness in Patent Law”, SSRN *Electronic Journal*, <http://www.cardozoelj.com/wp-content/uploads/Journal%20Issues/Volume%2025/Issue%203/Sarnoff.pdf> (last visited 5 April 2022) The author notes that it will be critically important for courts to recognize that there is no presumption against challenging validity. To the contrary public policy favors bringing such challenges and considering evidence of invalidity even in preliminary relief contexts.

¹³ *Orissa State Commercial Transport Corporation Ltd. v. Satyanarayan Singh* (1974) 40 Cut LT 336.

¹⁴ This becomes very relevant in the case of patent infringement involving Standard Essential Patents (SEP), where the patent holder is ready to license the patent at a higher royalty. In this case, the patent holder is ready to license, and the dispute is on the rate of royalty for using the patents in smart phones. In this case, an interim royalty is an effective option than an interim injunction. However, the Delhi High Court granted interim injunction only when there was refusal to pay the interim royalty. The Court does not follow the same approach in pharmaceutical patent infringement cases.

See also in *Merck Sharp and Dohme v. Glenmark Pharmaceuticals* (the Delhi High Court found irreparable injury even when it can be compensated monetarily).

to the patent holder. It is important that the courts look at the quantum of loss in monetary terms so that they can examine whether such loss can be compensated through other remedies such as interim royalty or damages.

c) Balance of convenience:

Courts should exercise sound judicial discretion while granting or refusing an interim injunction. It should find and compare substantial amounts of mischief or injury, which is likely to be caused to the parties, in case when the injunction is refused vis-à-vis in case an injunction is granted. After contemplating the likelihood of injury, if the court considers that the status quo should be maintained on the subject matter during the pendency of the suit, an interim injunction would be issued for the same.^{15,16}

In patent cases, making such a judgment is not so straightforward. One situation where such an assessment is possible is where the defendant has unsuccessfully challenged the patent in question using the pre- or post-grant opposition procedure and there is no fresh ground for opposition. It is also worth noting that many times courts do not spell out their reasoning on balance of convenience. However, in a patent infringement litigation, courts may need to look into many factors such as whether the patent is being worked in the country or the patented product or technology is available in the country.¹⁷ Further, courts should look into the implications of injunctions not only on the defendant, but also on the larger public.

The three-step test does not provide a straight-jacket formula with regard to application of the test. Courts need to analyze various merits of the case on a case-to-case basis before granting interim injunctions, and that is where the problem arises.

A. Public Interest and Injunctions

Although an injunction is a means of enforcement of patent rights, which are primarily private in nature, there remains the possibilities of involvement of public interest considerations, particularly in cases where the patent dispute in question is related to medicines. For example, if an interim injunction is granted against a generic manufacturer who is marketing the drug at a much lower price than the patentee, the public who were relying only on the cheaper generic medicine would be deprived of access to it in case of grant of an injunction. This would harm the public interest. Hence, courts have to take into account the implications of such injunctions not only on the defendant, but also on the larger public. They ought to consider the

¹⁵ *Dalpat Kumar v. Prahlad Singh* AIR 1993 SC 276.

¹⁶ *Anwar Elahi v. Vinod Misra and Anr.* 1995 IVAD Delhi 576, 60 (1995) DLT 752, 1995 (35) DRJ 341; In *Bikash Chandra Deb v. Vijaya Minerals Pvt. Ltd.*: 2005 (1) CHN 582, the Hon'ble Calcutta High Court observed that issue of balance of convenience, it is to be noted that the Court shall lean in favor of introduction of the concept of balance of convenience, but does not mean and imply that the balance would be on one side and not in favor of the other. There must be proper balance between the parties and the balance 1995 (35) DRJ 341; In *Bikash Chandra Deb v. Vijaya Minerals Pvt. Ltd.*: 2005 (1) CHN 582, the Hon'ble Calcutta High Court observed that issue of balance of convenience, it is to be noted that the Court shall lean in favor of introduction of the concept of balance of convenience, but does not mean and imply that the balance would be on one side and not in favour of the other. There must be proper balance between the parties and the balance cannot be a one-sided affair. In *Antaryami Dalabehera v. Bishnu Charan Dalabehera*: 2002 I OLR 531, at this point, it was held that balance of convenience, which means, comparative mischief for inconvenience to the parties. The inconvenience to the petitioner, if temporary Injunction is refused, would be balanced, and compared with that of the opposite party, if it is granted. In the case of *Orissa State Commercial Transport Corporation Ltd. v. Satyanarayan Singh*, (1974) 40 Cut LT 336, observed: 'Balance of convenience' means the comparative mischief or inconvenience to the parties. The inconvenience to the plaintiff if temporary injunction is refused would be balanced and compared with that to the defendant if it is granted. If the scale of inconvenience leans to the side of the plaintiff, then alone interlocutory injunction should be granted.

¹⁷ Indian courts have held that whether there is an actual commercial working/exploitation of invention in India is a key consideration for assessing interim injunction. See Sandeep K. Rathod, "Injunctions: Impact on Access to Medicines in India", TWN Briefing Paper, October 2022. Available from https://www.twn.my/title2/briefing_papers/twn/Injunctions%20TWNBP%20Oct%202022%20Rathod.pdf.

convenience of the plaintiff against the convenience of the defendant and the public. If the court believes that refusing interim injunctions would cause greater or more inconvenience to the plaintiff, it may grant interim injunction; and if the court finds that greater inconvenience will be caused to the defendant and the public, it should refuse the relief.

Injunctions emerged as a remedy in the context of tangible properties. However, in the case of patents, a fine balance of the public and private interests involved need to be maintained. Since a patent functions as a monopoly in the market, an injunction erroneously granted by the court would further monopolize it at the cost of the public interest. Moreover, as the patent documents are techno-legal in nature, it is an arduous task to reach a conclusion in determining the infringement of a patent without a proper trial. Hence, granting an interim injunction without undergoing thorough examination of the claims could result in unjust enrichment for the patent holder and harmful for the public at large as in the case of medicines. Further, it is also well documented that the patent office sometimes commits mistakes while granting patents and often grants patents contrary to the provisions of domestic patent laws.¹⁸ Therefore, interim injunctions in patent infringement proceedings should be considered with skepticism.

Another concern is that the exceptional remedy of an interim injunction can be strategically misused by the patent holder to buy time in order to enjoy an unjust monopoly. This is worrisome as there is high pendency of litigation in India.¹⁹ The judiciary is pressured to offer quick remedies, and interim injunctions are sought citing delay in the trial. As a result, the interim injunction in practice becomes a permanent injunction and delays justice to the defendant because after obtaining an interim injunction the plaintiff may not be interested in expediting the trial to reach a final verdict. This becomes worse when there is the absence of a timeline for the conclusion of the litigation.

One could argue that the enforcement of patents through injunction is designed for the promotion of general welfare in a democratic society in accordance with Article 4 of the International Covenant on Economic Social and Cultural Rights (ICESCR).²⁰ However, this argument may not hold true when such injunctions affect the enjoyment of the right to health or right to science.

The obligations laid down in Article 4 of the ICESCR clearly state that “*the State may subject such rights only to such limitations as are determined by law only in so far as this may be compatible with the nature of these rights and solely for the purpose of promoting the general welfare in a democratic society*”. Moreover, in line with Article 5 such limitations must be proportional, i.e., the least restrictive alternatives must be adopted where several types of limitations are available. Even where such limitations on grounds of protecting public health are basically permitted, they should be of limited duration and subject to review.²¹ This makes

¹⁸ Ali, Feroz, Rajagopal, Sudarsan, Raman, VS, and John, Roshan (2018), *Pharmaceutical Patent Grants in India: How Our Safeguards against Evergreening have Failed, and Why the System must be Reformed*, <https://accessibsa.org/media/2018/04/Pharmaceutical-Patent-Grants-in-India.pdf>, accessed on 11 January 2022.

¹⁹ India has one of the world’s lowest ratios of judges to population in the world, with only 13 judges for every million people, compared with 50 in developed nations. As a result, scores of cases are heard every day, which leads to a large number of adjournments, judges passing cases between them, and increasingly long queues of people waiting outside courtrooms on the off-chance that their case is heard. <https://www.theguardian.com/world/2016/may/05/indias-long-wait-for-justice-27-million-court-cases-trapped-in-a-legal-logjam> (last visited Apr 10, 2022). See National Judicial Data Grid, njdg.ecourts.gov.in (2022), <https://njdg.ecourts.gov.in/njdgnew/> (last visited Feb 8, 2022).

²⁰ Article 4 of the International Covenant on Economic Social and Cultural Rights (ICESCR) states: The States Parties to the present Covenant recognize that, in the enjoyment of those rights provided by the State in conformity with the present Covenant, the State may subject such rights only to such limitations as are determined by law only in so far as this may be compatible with the nature of these rights and solely for the purpose of promoting the general welfare in a democratic society.

²¹ Article 5 of the International Covenant on Economic Social and Cultural Rights (ICESCR) states: “1. Nothing in the present Covenant may be interpreted as implying for any State, group or person any right to engage in any

it clear that obligations from various international agreements like the TRIPS Agreement or even domestic law cannot be cited as justification for the derogation of rights guaranteed under ICESCR. Thus, measures like an injunction, which could be justified as a tool for the promotion of general welfare in a democratic society, could not restrict the enjoyment of rights under ICESCR.²²

Interpreting on similar lines, the High Court of Kenya held certain provisions of the anti-counterfeit legislation as unconstitutional and made the following observation:

“While such intellectual property rights should be protected, where there is the likelihood, as in this case, that their protection will put in jeopardy fundamental rights such as the right to life of others, I take the view that they must give way to the fundamental rights of citizens in the position of the petitioners.”²³

In India, the Delhi High Court contemplated on public interest in the *Roche v. Cipla* case, where both the Single and the Division Benches rejected the plea for an interim injunction citing the impact of such an injunction on access to medicines. While refusing interim injunction in *Roche v Cipla*, the court stated that:

[T]he Court cannot be unmindful of the right of the general public to access lifesaving drugs which are available and for which such access would be denied if the injunction were granted ... The degree of harm in such eventuality is absolute; the chances of improvement of life expectancy; even chances of recovery in some cases would be snuffed out altogether, if [an] injunction [were to be] granted ... Another way of viewing it is that if the injunction in the case of a lifesaving drug were to be granted, the Court would in effect be stifling Article 21 [of the Indian Constitution, which provides for the right to life and which forms the bedrock of the right to health in India] so far as those [who] would have or could have access to Erlecip are concerned.

The Court further noted that:

“This Court is of the opinion that as between the two competing public interests, that is, the public interest in granting an injunction to affirm a patent during the pendency of an infringement action, as opposed to the public interest in access for the people to a lifesaving drug, the balance has to be tilted in favor of the latter. The damage or injury that would occur to the plaintiff in such a case is capable of assessment in monetary terms. However, the injury to the public which would be deprived of the defendant's product, which may lead to shortening of lives of several unknown persons, who are not parties to the suit, and which damage cannot be resituated in monetary terms, is not only uncompensable, it is irreparable”.

activity or to perform any act aimed at the destruction of any of the rights or freedoms recognized herein, or at their limitation to a greater extent than is provided for in the present Covenant. 2. No restriction upon or derogation from any of the fundamental human rights recognized or existing in any country in virtue of law, conventions, regulations, or custom shall be admitted on the pretext that the present Covenant does not recognize such rights or that it recognizes them to a lesser extent.”

²² The Committee has inter alia in General Comment 14, para. 28 reiterated the restrictive situations in which such limitations may be employed. For example, restricts the movement of, or incarcerates, persons with transmissible diseases such as HIV/AIDS, refuses to allow doctors to treat persons believed to be opposed to a Government, or fails to provide immunization against the community's major infectious diseases, on grounds such as national security or the preservation of public order, has the burden of justifying such serious measures in relation to each of the elements identified in article. See, Oke, Emmanuel Kolawole (2022), "The Right to Health in Pharmaceutical Patent Disputes", South Centre. https://www.southcentre.int/wp-content/uploads/2022/02/RP-145-The-Right-to-Health-in-Pharmaceutical-Patent-Disputes_EN.pdf, accessed on 9 April 2022.

²³ "Republic of Kenya in the High Court of Kenya at Nairobi. Petition No. 409 of 2009 Patricia Asero and the Attorney General", 2009, <https://www.cehurd.org/publications/download-info/petition-no-409-of-2009-patricia-asero-ochieng-maurine-atieno-joseph-munyi-the-aids-law-project-v-the-attorney-general/>. Accessed on 7 July 2020, para 86.

During the appeal the patent holder argued on the following grounds:

As per the CL provisions of the Indian Patents Act,²⁴ the three years' cooling period enables the patent holder to recoup the research and development (R&D) cost, and therefore the court should not override the legislative intent and the court should not interfere on affordability. Since the statutory monopoly is granted under the Patents Act, it is to be considered as a public interest.

Since the Essential Commodities Act (ECA) applies to pharmaceuticals through Drug Price Control (DPC), the eBay decision should not be applied here, because of the absence of any legislation like ECA provisions.

The Division Bench held that:

“In a country like India where the question of general public access to life saving drugs assumes great significance, the adverse impact on such access which the grant of injunction in a case like the instant one is likely to have, would have to be accounted for. Erlocip is the Indian equivalent produced by the defendant in India as a generic drug manufacturer. It is priced at Rs.1600 per tablet. Even if this does not make it inexpensive, the question of greater availability of such drugs in the market assumes significance”.

Further on the application of the e-Bay ratio,²⁵ the court stated that:

“Given the nature of the drug, in the instant case, which admittedly is a lifesaving one, the fourth test identified in eBay that the grant of an injunction should not result in the public interest being “disserved” would be relevant”.

This elucidates that the judicial enforcement of patents, especially through injunctions, can eliminate the competition hence compromising the access to affordable products, which are critical for the enjoyment of human rights. For instance, an injunction against a generic medicine for the infringement of patents can affect access to lifesaving medicines to thousands of people and also can affect the dissemination of technology or further R&D. Therefore, it is important for the judicial authorities to thoroughly examine the consequences of enforcement of patents on the enjoyment of human rights.

²⁴ Section 84 of The Patents Act, 1970

169 [84 Compulsory licenses -

(1) At any time after the expiration of three years from the date of the 170 [grant] of a patent, any person interested may make an application to the Controller for grant of compulsory license on patent on any of the following grounds, namely:

(a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or

(b) that the patented invention is not available to the public at a reasonably affordable price, or

(c) that the patented invention is not worked in the territory of India.

²⁵ *eBay v. MercExchange* (Supreme Court of the United States unanimously determined that an injunction should not be automatically issued based on a finding of patent infringement, but also that an injunction should not be denied simply on the basis that the plaintiff does not practice the patented invention. Instead, a federal court must still weigh what the Court described as the four-factor test traditionally used to determine if an injunction should be issued.) Also see Joshua D. Sarnoff, *supra* note 6.

II. TRIPS FLEXIBILITIES AND PATENT ENFORCEMENT

The Paris Convention included obligations regarding the enforcement of trademark rights with respect to infringing imports.²⁶ However, the TRIPS Agreement is the first multilateral instrument to regulate the internal administrative and judicial mechanisms that the members of the World Trade Organization (WTO) are obligated to maintain with respect to the application of a set of agreed upon legal rules. The enforcement provisions of TRIPS, which reflects the interests of the developed nations, have far reaching implications for developing countries; they may be incompatible with the socio-economic realities and problematic to be incorporated in the legal systems of these countries. Further, these countries lacked the infrastructure and resources to apply these “higher standards” for the enforcement of remedies. Member States are obliged to ensure that enforcement procedures are “fair and equitable”, and “not unnecessarily complicated or costly, or entail unreasonable time limits or unwarranted delays.”

TRIPS refers to IPRs as “private rights.”²⁷ This is inserted in the preamble, because of the unique characteristic of TRIPS in regulating national laws governing privately held interests such as patents and in specifying remedies that are to be provided under national laws for protecting such interests. This implies that governments will not be responsible for policing IPR infringements on behalf of private right holders.²⁸

Thus, an important element of flexibility was recognized under the preamble of TRIPS that enforcement measures may take into account differences in national legal systems. It further recognizes the underlying public policy objectives of national systems for the protection of IP, including developmental and technological objectives, and also emphasized in the preamble itself the need for “maximum flexibility” in favor of least developed countries.^{29, 30}

A. Nature of IP Enforcement Obligations

Article 1.1 makes it clear that Members are not obliged to adopt standards more extensive (TRIPS-plus) than those required by the TRIPS Agreement, and each member is free to determine how it will meet them, including whether its courts will apply the Agreement directly (or upon incorporation into the domestic law), depending on its legal system and practice.³¹ Therefore, it acknowledges the flexibility inherent in the TRIPS Agreement and IP law more generally, authorizing each WTO Member to implement the rules in the manner most appropriate for itself, provided that the implementation is in accord with the terms of the agreement. Article 1.1 acknowledges that IPR protection may vary among Members, and that they can maintain flexibility in implementing the TRIPS obligations. Most importantly, the preamble of the agreement notes the need to ensure that “measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade”.

²⁶ See Articles 9 &10 of the Paris Convention.

²⁷ Fourth clause of the TRIPS preamble. “WTO | Intellectual Property (TRIPS) - Agreement Text - Preamble”. https://www.wto.org/english/docs_e/legal_e/27-trips_02_e.htm, accessed on 7 June 2018.

²⁸ UNCTAD-ICTSD (2005), *Resource Book on TRIPS and Development*, Cambridge University Press, p. 11.

²⁹ Subparagraph (c) of TRIPS preamble. “WTO | Intellectual Property (TRIPS) - Agreement Text - Preamble”. https://www.wto.org/english/docs_e/legal_e/27-trips_02_e.htm, accessed on 7 June 2018.

³⁰ Sixth clause of the TRIPS preamble. “WTO | Intellectual Property (TRIPS) Agreement Text - Preamble”, https://www.wto.org/english/docs_e/legal_e/27-trips_02_e.htm, accessed on 7 June 2018.

³¹ “Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.”

It is important to read the TRIPS enforcement provisions in the light of the objective and purpose of the TRIPS Agreement mentioned in Article 7.³² It indicates that a balance must be struck between the rights and obligations of the right holder with regard to the protection and enforcement of IPRs. Intellectual property rights have been designed to benefit society by providing incentives to introduce new inventions and creations.³³ Thus, Article 7 makes it clear that IPRs are not an end in themselves and 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”. It also means that the enforcement of IPRs should take into account implications of enforcement measures on the promotion of technological innovation and to the transfer and dissemination of technology and the balance of rights and obligations. IPRs alone cannot promote innovation in countries which lack innovative activities and scientific and technological capabilities. In this situation, the mutual advantage of producers and users of technological knowledge is significant, as it is a matter of fact that developing countries are largely users of technologies produced abroad.

Article 8³⁴ confirms that Members 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. It also recognizes the right of Members to take measures to prevent the abuse of IPRs by right holders.

Hence, Articles 7³⁵ and 8³⁶ of TRIPS set forth objectives and principles, that aim at establishing a balancing of interests at the multilateral level to complement or substitute for the balancing undertaken at the national level.³⁷ They provide an express recognition of the public policy objectives that are fundamental to IP protection. Further, they not only recognize the goals of technological innovation and dissemination, but also acknowledge a wider public interest agenda in the Agreement, which has been reaffirmed in respect of access to medicines through the Doha Declaration on the TRIPS Agreement and Public Health.³⁸

³² “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.”

³³ Correa, Carlos (2003), “Formulating Effective Pro-Development National Intellectual Property Policies”, in C. Bellmann, G. Dutfield and R. Meléndez-Ortiz (eds.), *Trading in knowledge. Development perspectives on TRIPS, Trade and Sustainability*, Earthscan, London, p. 209.

³⁴ “Appropriate measures 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”.

³⁵ The protection and enforcement of IPRs 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.

³⁶ 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.

³⁷ *Resource Book on TRIPS and Development*. Cambridge University Press, 2005, p. 119.

³⁸ The Doha Declaration on the TRIPS Agreement and Public Health states: “We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose”.

The WTO panel reports in Canada – Pharmaceutical Patents and in the Australia – Tobacco Plain Packaging clarified that the provisions of Articles 7 and 8 play a fundamental role in the interpretation of substantive provisions contained in the TRIPS Agreement.³⁹

Articles 7 and 8 also have legal significance for the provisions on enforcement of the Agreement, as they can be read, in particular, as providing the courts ample discretion to deny injunctions as a remedy to patent infringement if there are adverse implications for the enjoyment of human rights such as right to health and right to science.

B. Flexibilities and Injunctions

The TRIPS Agreement has flexibilities with reference to injunctions. A close analysis of the relevant provisions of the Agreement reveals the following TRIPS-compliant flexibilities in the grant and implementation of injunctive relief:

1. Article 44 sets the norms for permanent injunctions. It creates an obligation on Member States to provide discretion to judicial authorities to order a party to desist from an infringement activity. It mentions the clear case of preventing the entry into channels of commerce in their jurisdiction of imported infringed goods immediately after the customs clearance of such goods.
 - a) However, under article 44.1 the WTO Members have the freedom to exempt from the scope of injunctions subject matter acquired or ordered prior to knowing or having reasonable grounds to know that dealing in such subject matter entails an infringement.⁴⁰ 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.⁴¹
 - b) Article 44.2 provides the freedom to Member States to deny the injunction remedy to disputes related to government use and limit the scope of remedy only to the quantum of compensation.
2. Article 50.1 obligates the Member States to provide the authority to the judiciary to order prompt provisional measures in the following two contexts. First, to prevent the infringement of IP from occurring or to prevent the entry of infringed goods in commercial channels. Second, to preserve the relevant evidence regarding the alleged infringement.
 - a) Article 50.2 is an obligation to provide judicial authorities with powers to grant injunctions *inaudita altera parte*⁴² in appropriate situations. It applies particularly in

³⁹ Australia – Plain Packaging (P), WT/DS435/R, WT/DS441/R, WT/DS458/R, WT/DS467/R, op. cit. 7.2402. (applying them as the guiding principles “Articles 7 and 8, together with the preamble of the TRIPS Agreement, set out general goals and principles underlying the TRIPS Agreement, which are to be borne in mind when specific provisions of the Agreement are being interpreted in their context and in light of the object and purpose of the Agreement”). As the panel in Canada – Pharmaceutical Patents observed in interpreting the terms of Article 30 of the TRIPS Agreement, “[b]oth the goals and the limitations stated in Articles 7 and 8.1 must obviously be borne in mind when doing so as well as those of other provisions of the TRIPS Agreement which indicate its object and purposes”).

⁴⁰ The US and EC original proposals did not contain this limitation. The Anell Draft as of 23 July 1990 read as follows: “1A. The judicial authorities shall have the authority to issue upon request an order that an infringement be refrained from or discontinued, irrespective of whether the defendant has acted with intent or negligence” (W/76).

⁴¹ According to Dratler, p. 1A–103, the exception operates like a “sort of compulsory license by refusing an injunction and remitting the claimant to a damage remedy”. See also Article 45, below.

⁴² Latin for “Without hearing the other Party”.

situations where any delay is likely to cause irreparable harm to the right holder or if there is a demonstrable risk of destruction of evidence.⁴³

b) Article 50.3 reflects the “check and balances” approach where the judicial authorities can demand from the applicant to provide any reasonably available evidence to satisfy themselves with a sufficient degree of certainty that the applicant is the right holder and provides the powers to seek the reasonable evidence from the applicant to show the right being infringed or that such infringement is imminent. The mere possibility of causing harm to the right holder would not be sufficient to ignore the defendant’s basic right to be heard before an injunction or other relief is granted. The judicial authorities also have the power to order the applicant to make a security deposit to prevent the abuse during the operation of provisional measures.

c) Article 50.4 mandates to issue notice to the affected party immediately after the execution of the measures; it provides safeguards to prevent the abuse of the *inaudita altera parte* procedure.

d) Article 50.5 provides discretion to the authorities in charge of the execution of provisional measures to seek information from the applicant about concerned goods.

e) Article 50.6 makes it mandatory to cancel any provisional measures upon the request of the defendant or order the provisional measures to cease to exist if the applicant fails to initiate proceedings on the merit of the case within a reasonable period.⁴⁴

f) Article 50.7 mandates the WTO Members to provide authority to the judicial authorities to order compensation to the defendant in the event of revocation or lapse of the provisional measures due to the act or omission of the applicant. Similarly, the defendant is also entitled to obtain compensation for finding lack of infringement or threat of infringement.

g) Article 50.8 provides that if any provisional measures are ordered through administrative procedures, then the procedures shall conform to principles set forth by the judiciary.

Articles 44 and 50 thus spell out the standards for the Member States while providing wide discretion to the judicial authorities to order a party to desist from an infringement activity and to grant (or not) enforcement measures. In other words, under Articles 44 and 50 there is no obligation to grant mandatory injunctions (permanent or interim) to remedy patent infringement. The only obligation is to provide the discretion to courts to grant injunctions and this does not prevent making it mandatory for courts to consider the implications of injunctions in the public interest, especially human rights.

The referred to Doha Declaration in paragraphs 4 and 5 clarified that Member States agree that the TRIPS Agreement does not and should not prevent measures to protect public health.⁴⁵ Further, in a resolution adopted in 2000, the Sub Commission on the Promotion and Protection of Human Rights (the Sub Commission) reminds all governments of the “primacy of human rights obligations over economic policies and agreements”.⁴⁶ Although not binding in nature, the statement definitely sets an agenda for addressing intellectual property rights issues within the UN human rights framework.⁴⁷ The Special Rapporteurs hold a strong view

⁴³ An example of this type of measure is the “Mareva” injunction allowed under common law to temporarily freeze the defendant’s assets (generally bank deposits) that are required to satisfy a judgment in order to prevent their dissipation or removal from the jurisdiction.

⁴⁴ This reasonable period can be determined by the judicial authorities, if the law of the land permits or should not exceed 20 working days or 31 calendar days, whichever is longer.

⁴⁵ ... [W]e reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose. ... [W]e affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all.

⁴⁶ UN Sub-Commission on the Promotion and Protection of Human Rights, “Resolution 2000/7. Intellectual Property Rights and Human Rights”, UN Doc. E/CN.4/SUB.2/RES/2000/7, para. 3.

⁴⁷ Helfer LR (2007), “Toward a Human Rights Framework for Intellectual Property”, *Univ Calif Davis Law Rev* 40 (3):971–1020.

that the primacy of international human rights law over all other regimes of international law is a basic and fundamental principle that should not be departed from.⁴⁸

Against this background, it is pertinent to investigate the trends in the application of the TRIPS-related flexibilities by the judiciary while adjudicating patent infringement suits involving public interest/human rights.

⁴⁸ UN Sub-Commission on the Promotion and Protection of Human Rights, "Preliminary Report Submitted by J. Oloka-Onyango and Deepika Udagama, in Accordance with Sub-Commission Resolution 1999/8 on Globalization and its Impact on the Full Enjoyment of Human Rights", UN Doc. E/CN.4/Sub.2/ 2000/13, para. 63.

III. JUDICIAL TRENDS

As mentioned, the TRIPS Agreement does not prescribe mandatory injunctions as a remedy but obligates Members to provide the authority to the judicial authorities to decide whether to grant injunction as a remedy. However, the Agreement does not provide any guidance to exercise discretion. In the absence of such guidance, Members have the freedom to provide for the applicable rules in their domestic legislation or through case law. Judiciary can use the objectives and principles of TRIPS as a guidance while exercising its discretion on injunctions. This section examines the judicial trends pertaining to injunctions for patent infringement in the US and India.

A. *The eBay Case*

Until the late 1980s the US Court of Appeals for the Federal Circuit (Federal Circuit) routinely granted permanent injunctions under the established precedents and Section 283 of the US Patent Act to patent holders in infringement cases.⁴⁹ This trend took a new turn in 2006 when the US Supreme Court rejected the Federal Circuit decision in the *eBay v. MercExchange* case, which held that a patent holder is not presumably entitled to an injunctive relief on the grounds that the patent holder has successfully proved infringement and successfully defended against its invalidity. The Supreme Court placed the burden on the patent holder to establish their entitlement to this equitable remedy and laid down a four-factor test for the patent holder to establish: a) that they have suffered an irreparable injury; b) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; c) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and d) that the public interest would not be disserved by a permanent injunction.

Since the *eBay* decision, permanent and preliminary injunctions in the US patent infringement cases have been significantly less frequent.⁵⁰ In case of denial of a permanent injunction, courts would allow the infringer to continue the infringement against payment of a royalty to compensate the patent holder for the damages done to her as a result of the continuing infringement. This arrangement is more likely in the situation where the patent holder is a non-practicing entity (NPE), where it is reasonable to be compensated by the award of such royalties.

The US courts have examined the implications of granting injunctions with regard to public interest. If the injunction has adverse implications on public interest, then the court looks at other options to compensate the patent holder. It is agreed that, as a matter of principle, the public interest is a factor in determining the award or denial of injunctions.⁵¹

This approach in decisions denying injunctions to stop infringement reflects the roots of injunctive relief in equity, its flexibility and sensitivity to the factual context and the positions of the parties in achieving substantive justice.⁵² The US courts also considered the need to balance these factors in assessing the “public interest”.⁵³

⁴⁹ See, e.g., *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1246–7 (Fed. Cir. 1989).

⁵⁰ Joshua D. Sarnoff (2020), *supra* note 6.

⁵¹ Sandeep K. Rathod, *supra* note 17, p.5.

⁵² Li, Xuan (2009), *Intellectual Property Enforcement*, Elgar, p. 106; See, Joshua D. Sarnoff, *supra* note 6. (Observing that “But particularly for denials of injunctions, appellate judges often reverse district court denials. This may suggest that appellate court judges frequently substitute their own views of the equities for those of trial judges”).

⁵³ *Pfizer v. Teva*, 429 F.3d 1364 (Fed. Cir. 2005) and *Sanofi v. Apotex*, 488 F.Supp.2d 317 (S.D.N.Y. 2006).

US courts, time and again, have also realized the need for balancing the interests on both sides.⁵⁴ However, it is argued that the US court's attempt to attain such a balance is not very successful. One argument is that in case of infringement, the patentee is burdened with the assessment whether the grant of an interim injunction would go against public interest or the public interest would not be disserved by the grant of an injunction. However, this does not always hold true, for instance, in cases relating to the healthcare segment, the public interest factor is not a one-way road, as it is mostly assumed. As some scholars assert, ensuring affordable access to generic drugs and promoting innovation through patent enforcement are both important for public interest and requires a delicate balance⁵⁵ In the context of balancing the two interests above, the US courts seem to take the position that price differential alone is not a tipping point – the mere fact of the accused infringer selling at a lower price than the patentee alone is not enough to outweigh the interest in enforcing a valid patent.⁵⁶ However, other jurisdictions are free to consider the access to medicines as an element of public interest, while granting injunction following the reasoning of the eBay case.

WTO 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 authorize continued infringing activity. The body of case law that is being developed in the US through the discretionary judgments of trial judges may be instructive to other developed and developing countries in assessing whether, when and how to grant prospective injunctive relief. This is true even if legislators or judges in other countries choose to exercise their policy discretion differently from those in the US. They may choose to specify different conditions under which injunctive relief should be granted or refused to the extent that social conditions or policy preferences differ from those in the US.⁵⁷

B. The Indian Experience

Perceiving the potential danger of misusing the issuance of interim injunctions particularly *ex parte*, the Supreme Court of India developed certain guidelines.⁵⁸ Further, it termed the

⁵⁴ Delhi High Court in *Merck v. Glenmark*, citing *Bayer v. Cipla*, recognized the public interest element flowing in favor of grant of an injunction. The court emphasized the need to balance both these interests.

⁵⁵ Ramanujan, Adarsh (2018), "Understanding the Public Interest Element of the Injunction Analysis in Patent Infringement Cases", <https://spicyip.com/2018/05/understanding-the-public-interest-element-of-the-injunction-analysis-in-patent-infringement-cases.html>, accessed on 4 May 2019.

⁵⁶ Observations of the Federal Circuit in *Pfizer v. Teva*, 429 F.3d 1364 (Fed. Cir. 2005) and *Sanofi v. Apotex*, 488 F.Supp.2d 317 (S.D.N.Y. 2006).

⁵⁷ *Ibid.*

⁵⁸ The Supreme Court of India in a recent judgment, *Ramrameshwari Devi & Ors. v. Nirmala Devi & Ors.* 2011, has laid down positive guidelines for the grant of *ex parte* orders. The case involved a 40-year-old disputed property; the Appellants had continuously filed frivolous appeals before the courts even after the matter had been decided. Justice Dalveer Bhandari, the presiding judge, laid down the following guidelines, which the courts should adopt, in preventing such litigation and also cautioning courts on the grant of indiscriminate *ex parte* orders:

1. The Presiding Judge must exercise due care, caution, diligence and attention while framing the issues for the suit so as not to include issues already decided by other courts in violation of the principle of *res judicata*.
2. The trial judge must carefully scrutinize, check and verify the pleadings and the documents filed by the parties.
3. The court should order discovery and production of the documents at the earliest so as to focus on the main controversies of the case and arriving at the truth of the matter.
4. Courts should impose realistic costs on parties who engage in frivolous litigation. In our present system, courts do not impose penalties on the parties who prolong the suit. Thus, unscrupulous parties are incentivized to carry out a cost-benefit analysis between the likelihood of tiring the other party into settlement and prolonging the case to such an extent that the other party suffers. In the present case, the court imposed Rs. 2 lakhs as costs on the appellants for unnecessarily prolonging the dispute.
5. Courts must be very careful in imposing *ex parte* orders. If an injunction has been granted on the basis of

decision to grant an interim injunction as the discretion of the court and reaffirmed the test laid down by the House of Lords in the American Cyanamid case.⁵⁹ Apart from the three-step test for the grant of injunctive relief mentioned therein, courts may consider public interest implications of granting injunctions. The decision to grant an interim injunction is always considered as an exceptional remedy in the absence of alternative remedies such as damages.⁶⁰

Another concern is that the exceptional remedy of interim injunction can be misused by the plaintiff and delay the further proceedings, including the trials. The Indian Supreme Court has realized that due to high pendency and inordinate delay in litigation, quick remedies such as interim injunctions are sought by the patent holder.⁶¹ This has resulted in interim injunctions taking *de facto* the effect of a permanent injunction as the suits remain pending in the courts for years, delaying justice to the defendant.

Empirical evidence suggests, however, that Indian courts are granting interim injunctions including *ex parte* injunctions liberally. A survey of patent infringement suits between 2000 and 2016 reveals interlocutory injunctions in 36 out of 59 cases, which constitute 60 per cent. This shows that High Courts and district courts are paying little attention to the direction of the Supreme Court.⁶²

false pleadings or forged documents (which is very often the case in India) courts must impose costs on the litigants.

6. Courts should give short notice to the defendants and hear both parties before passing *ex parte* interim orders since the experience has been that once granted these orders cause havoc and getting them modified is next to impossible.
7. In an exceptional case where the court has to grant an *ex parte* injunction it must record in the order that if the suit is dismissed the petitioner will have to pay full restitution, actual or realistic costs and mesne profits.
8. If *ex parte* order is granted, then all endeavors should be made to dispose the application for injunction as expeditiously as possible, preferably as soon as the defendant appears in court or another option available is, to limit the life of the *ex parte* order for a week so as to prevent any incentive of prolonging the matter on the plaintiff's part.

⁵⁹ *Gujarat Bottling v. Coca Cola* (1995) 5 SCC 545.

⁶⁰ In *Gujarat Bottling v. Coca Cola*, the Supreme Court of India explains the rationale behind the granting of injunction as follows:

“The decision whether or not to grant an interlocutory injunction has to be taken at a time when the existence of the legal right assailed by the plaintiff and its alleged violation are both contested and uncertain till they are established at the trial on evidence. Relief by way of interlocutory injunction is granted to mitigate the risk of injustice to the plaintiff during the period before that uncertainty could be resolved. The object of the interlocutory injunction is to protect the plaintiff against injury by violation of his right for which he could not be adequately compensated in damages recoverable in the action if the uncertainty were resolved in his favor at the trial. The need for such protection has, however, to be weighed against the corresponding need of the defendant to be protected against injury resulting from his having been prevented from exercising his own legal rights for which he could not be adequately compensated. The court must weigh one need against another and determine where the 'balance of convenience' lies. [see: *Wander Ltd. & Anr. v. Antox India P. Ltd.*, 1990 (suoo) Scc 727 at pp. 731–32]. In order to protect the defendant while granting an interlocutory injunction in his favor the Court can require the plaintiff to furnish an undertaking so that the defendant can be adequately compensated if the uncertainty were resolved in his favor at the trial.”

⁶¹ In *Bajaj Auto v. TVS Motors*, the Supreme Court, while ordering speedy trial, remarked that “experience has shown that in our country, suits relating to the matters of patents, trademarks and copyrights are pending for years and years and litigation is mainly fought between the parties about the temporary injunction. This is a very unsatisfactory state of affairs, and hence we had passed the above quoted order in the above-mentioned case to serve the ends of justice. *Bajaj Auto Ltd v. TVS Motor Company Ltd*”. The same judgment also recalled a previous judgment in *M/s. Shree Vardhman Rice & Gen Mills v. M/s Amar Singh Chawalwala Bajaj Auto Ltd v. TVS Motor Company Ltd*. In this judgment the Supreme Court stated the need for the speedy trial in IP infringement issues through day-to-day trial. It stated: “Without going into the merits of the controversy, we are of the opinion that the matters relating to trademarks, copyrights and patents should be finally decided very expeditiously by the Trial Court instead of merely granting or refusing to grant injunction. Experience shows that in the matters of trademarks, copyrights and patents, litigation is mainly fought between the parties about the temporary injunction and that goes on for years and years and the result is that the suit is hardly decided finally. This is not proper.”

⁶² Ramakrishna, Thammaiah (2017), "An India Perspective on Establishing a Prima-Facie Case in Patent Suits", *SSRN Electronic Journal*, p. 9. Elsevier BV, doi:10.2139/ssrn.3047057, accessed on 13 August 2019.

There are instances wherein the Delhi High Court granted interim injunctions even without establishing a *prima facie* case against the defendant. The orders are also silent on the other two tests viz. irreparable injury and balance of convenience. The single bench cited its own previous order to grant interim injunction while admitting that "At this stage, it is not possible to form an opinion, even *prima facie*".⁶³ These faulty interim orders were canceled by the division bench and insisted that the court should state its opinion on the three elements viz. *prima facie* case, irreparable damage and balance of convenience. The division bench stated:

"It is not possible to conceive an across-the-board blanket approach that would apply to all such cases, whereas as a matter of routine at the first hearing there would be a grant of injunction in favor of the Plaintiff. The decision in the application of interim injunction has to necessarily indicate the view of the Court on the three elements mentioned herein before and the additional features when it involves a case of alleged infringement of a patent, and in particular, a pharmaceutical patent".⁶⁴

The preceding discussion indicates that some Indian courts exhibit leniency in issuing interim injunctions in patent infringement litigation, often without conducting the requisite three-step mandatory tests. In one instance, while restraining the defendant, Justice Endlaw said: "this experimentation with interim orders in patent infringement suits is the need of the hour."⁶⁵ According to the court, it is not possible to form even a *prima facie* opinion at this stage. This experimentation, however, can result in setting dangerous precedents and disproportionate outcomes in patent infringement suits which can have adverse consequences in enjoyment of human rights and fundamental rights. If the injunction may adversely impact on public interest, then the court can look at other options to protect the interests of the patent holder.

⁶³ *Sterlite Technologies v. ZTT India Private* (CS [COMM] 314/2019, IA No. 8386/2019, IA No. 8389/2019 & IA No. 8390/2019).

⁶⁴ *Bayer Corporation v. Natco Pharma Ltd.*, (2013) Order No. 45 (India); Agarwal, Pankhuri (2019), "Delhi HC Division Bench Restores Sanctity of Three-Pronged Test for Interim Injunctions; Sets Aside Two Interim Injunction Orders Against Natco", <https://spicyip.com/2019/11/delhi-hc-division-bench-restores-sanctity-of-three-pronged-test-for-interim-injunctions-sets-aside-two-interim-injunction-orders-against-natco.html>, accessed on 6 April 2020.

⁶⁵ *Sterlite Technologies v. ZTT India Private* (CS [COMM] 314/2019, IA No. 8386/2019, IA No. 8389/2019 & IA No. 8390/2019); <https://www.thequint.com/news/hot-news/hc-stops-ztt-marketing-sterlite-tech-s-optical-fibre-patent#read-more>

IV. CONCLUSION

The US and Indian experiences with injunctive relief after the eBay and *Roche v. Cipla* cases are highly instructive. However, Indian courts deviated from the cautious approach, as expressed in the Roche case, and followed a liberal approach on injunctions. Instead of considering injunctions, especially interim injunctions, as a standard remedy, courts ought to consider the facts while granting injunctions. They must consider –as allowed by the flexibilities in the TRIPS Agreement– the human rights implications of patent enforcement, including the realization of the right to health. They should refrain from granting interim injunctions in patent infringement disputes as a general rule. As discussed above, the grant of interim injunctions in patent infringement cases can have adverse socio-economic implications, including the enjoyment of human rights, and therefore, courts must be cautious in considering their grant.

Interim injunctions are potent weapons in the enforcement arsenal of patent owners, especially pharmaceutical patent owners, which may harm generic competition and consequently the consumers. Hence, it is imperative to equip the judicial authorities, who wield discretionary powers, with explicit guidelines that facilitate a fair and equitable balancing of the patentee's interest in securing prompt and efficient enforcement of their rights, and the public interest in guarding against unwarranted injunctions.

The TRIPS Agreement provides sufficient policy space for the WTO Members to follow such cautious approach and mitigate the adverse effects of unwarranted injunctive relief on human rights while ensuring the exercise of patent owners' exclusive rights. Guidelines on the matter would facilitate a prudent exercise of discretionary powers and result in a just outcome. Furthermore, it is recommended that *ex parte* interim injunctions be categorically banned in the context of patent infringement cases relating to pharmaceuticals.

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