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Injunctions: Impact on Access to Medicines in India

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Introduction

With a population touching 140 crores (1.4 billion), health insurance penetration is still very poor in India and thus a large proportion of medical expenses are borne by citizens from their own pockets. For the year 2018, the World Health Organization (WHO) estimates[1] that out-of-pocket (OOP) health expenditure is 62.67% of total healthcare expenditure. Approximately 7% of Indians fall below the poverty line[2] just because of indebtedness due to health expenditure.

An important factor that impacts access to affordable pharmaceuticals and healthcare for common citizens in a country is the Intellectual Property (IP) regime of the country. Patent owners charge monopoly prices for their products. High prices coupled with low insurance prevalence and large OOP expenditure are a clear burden for a large segment of India's population.

In the context of accessing medicines, patents pose a predominant barrier, as the patentee gets a market monopoly on the medicine, is free to set an exorbitant price and can foreclose competition from the generic companies. Thus, patents give a patentee the right to stop another person from making, using, selling or offering for sale a patented product without his/her express permission[3] during the patent term.

However, in India, generic pharmaceutical companies *launch at risk* certain patented medicines and face the infringement suit by the patentee/patent holder. Patent infringement remedies such as injunctions and claims for damages are part of the patent enforcement proceeding in India. Injunctions issued in pharmaceutical patent infringement suits can become a hurdle to medicine access and hence should be issued keeping in view both access-related ground realities and legal principles.

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1 https://data.worldbank.org/indicator/SH.XPD.OOPC.CH.ZS?locations=IN
2 https://www.downtoearth.org.in/dte-infographics/india_s_health_crisis/index.html
3 Section 48 of the Patents Act, 1970.

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This paper examines the impact of injunctions in pharmaceutical patent litigations on public health due to the high costs of patented medicines, analyses the legal principles in granting injunctions, traces the existing trend in judicial precedents in patent infringement suits and cautions against the grant of injunctions.

Understanding the judicial process applicable to patent litigation proceedings

Indian law allows a generic pharmaceutical company to develop generic versions of a patented product during the patent term for the purpose of securing regulatory approval (commonly known as the 'Bolar exception')[4] to enable generic pharmaceutical companies to launch 'generic' products as soon as the underlying patent expires. A generic company may however decide to launch a generic version of the patented product 'at risk' without express approval from the patentee and prior to patent expiry.

Indian generic companies are adept at understanding the nuances of pharmaceutical patents and validity of such patents, and the risks and benefits associated with challenging such patents. In recent years, multiple generic companies have been attempting at launching or have launched products 'at risk' and this has led to a huge increase in the number of pharmaceutical patent infringement suits/litigations.

Patent litigation proceedings and remedies available

A patentee enforces its rights against a generic company's 'unlicensed'/'at risk launch' of its patented product by filing a 'civil suit'. Infringement suits, being civil suits, are governed by the Civil Procedure Code, 1908 (CPC). These suits are tried before a court with appropriate jurisdiction and have a single judge in the first instance, and provisions related to civil appeals etc. would also apply. After the passing of the Commercial Courts Act, 2015, a patent infringement suit is tagged as a 'commercial matter'. Such tagging would theoretically allow faster movement of the suit proceedings as 'commercial matter' proceedings have separate courts/judges adjudicating the matter and strict timelines for parties to file documents. In a patent infringement suit, a Court can[5] grant a permanent injunction and either damages or an account of profits from the infringer as final relief to a patentee. Additional final relief may include seizure and destruction of infringing goods.

Types of interim injunctions and their status as relief

During the pendency of a patent infringement suit, the Court may grant interim relief[6] to the patentee. Such relief is in the form of an '*interim*' injunction that operates during the pendency of the suit and it restrains the defendant from making/using/selling the patented invention during the pendency of the suit. *Ad-interim* injunctions are temporary in nature and usually given on the first day of hearing of the infringement suit. These usually do not contain a detailed rationale from the Court. Then comes an *interim* injunction. This interim injunction normally has a detailed rationale from the Court. Grant of an interim injunction is at the discretion of the Court and it is not a matter of patentee's right. For instance, the grant of injunction in favour of Bristol Meyers and Squibb (BMS) stopped the entry of the

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4 This right is covered under section 107A of the Patents Act 1970: '*Certain acts not to be considered as infringement*
For the purposes of this Act,—
(a) any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably related to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product;...'

5 Reliefs to the patentee are covered by section 108 of the Patents Act 1970:
'*Reliefs in a suit for infringement*
(1) The reliefs which a court may grant in any suit for infringement include an injunction (subject to such terms, if any, as the court thinks fit) and, at the option of the plaintiff, either damages or an account of profits.
(2) The court may also order that the goods which are found to be infringing and materials and implements, the predominant use of which is in the creation of infringing goods shall be seized, forfeited or destroyed, as the court deems fit under the circumstances of the case without payment of any compensation.'

6 Interim injunctive relief is granted pursuant to 'Order XXXIX, Rule 2 of the Civil Procedure Code'

affordable low-cost generic version of the anti-cancer drug dasatinib which was being sold at a higher price. A course of treatment with 100 mg tablets of dasatinib per month was priced at Rs 1,67,000 while the price offered by the generics was Rs. 8900/-.[7] Alternatively, the Court may allow the defendant to continue such actions upon provision of security or maintaining accounts till the infringement suit is finally decided.

Injunctions and impact on access to medicines

Completion of trial proceedings takes a very long time in India due to the very high number of legal proceedings[8]. Hence whenever a patentee sees an 'at risk' launch by a generic company, it will file the infringement suit immediately and attempt to secure the interim injunction at the start of the trial itself. The delay in adjudication has resulted in patentees putting a strong emphasis on and large resources for securing interim injunctions. Most patent suits lose traction after the interim relief stage.

The grant of such interim injunctions and slow pace of judicial proceedings adversely impact generic companies as they are then stopped from selling any additional product till the final adjudication of the suit (even when these companies have originally weighed the strengths and weaknesses of the underlying patent and associated costs and are ready to take the associated commercial and legal risks). These injunctions thus prevent the generic company from being present in the market, even when they would have assessed the potential impact of a negative outcome of the suit or genuinely believe that the underlying patent is without merit. A WHO, WTO (World Trade Organization) and WIPO (World Intellectual Property Organization) trilateral document[9] notes:

> *'Litigation proceedings initiated by patent holders can constitute a deterrent to market entry of generics irrespective of the final outcome. Courts may grant preliminary injunctions in favour of patent holders while litigation is pending and before the ultimate determination of the validity of patents is made.'*

Interim injunctions also impact patients as they are denied a lower-priced generic pharmaceutical product during the pendency of the suit proceedings. This is the most important negative consequence of interim injunctions since the patients are prevented from choosing the lower-priced option and are solely dependent on the patentee's monopoly-priced product.

Legal background on principles for interim injunctions

Interim injunctions, being discretionary reliefs, are granted on grounds of equity. The Supreme Court of India, in the case of *Wander v. Antox*[10], while categorically noting that the interim injunction remedy is both **temporary** and **discretionary** has mentioned the following principles while considering interim injunctions in IP disputes:

a) Interim injunctions are to be issued when the plaintiff cannot be adequately compensated by monetary damages;
b) Courts must consider aspects of 'balance of convenience' and '*prima-facie* case of parties'.

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7 As per price quoted in judgement in Bristol-Myers Squibb Company & Ors. Vs. Mr. J D Joshi & Anr. [CS(OS) 2303/2009]; Bristol-Myers Squibb Company & Ors. Vs. Mr. D Shah & Anr. [CS(OS) 679/2013]

8 As of August 2019, approx. 35 million cases were pending across various Courts in India. See https://www.prsindia.org/theprsblog/examining-pendency-cases-judiciary

9 '*Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade*' 2nd Edition, pg. 272. See https://www.wto.org/english/res_e/booksp_e/pamtiwhowipowtoweb13_e.pdf

10 *Wander Ltd. And Anr. vs Antox India*, 1990 Supp (1) SCC 727, refer to para 5, available at: https://indiankanoon.org/doc/330608/

These factors are similar to the principles laid down in the English case of American Cyanamid[11]. The above factors and their application to the pharmaceutical patent litigation context are explained as follows:

1. Likelihood of suffering an irreparable injury if the defendant's action is not injuncted: Whether the plaintiff would suffer an irreparable injury if the defendant is not injuncted – is an enquiry that the Judge must make initially. Mere hypothetical scenarios for untold, fantastic future losses cannot and should not be the basis for requesting an injunction. An injunction should not be granted as a matter of course. If monetary damages can be adequate remedy for protecting the plaintiff, then an injunction is not warranted. An injunction can be refused where the patentee can be adequately compensated in terms of money or the court can sufficiently protect the interests of the patentee by passing certain other directions[12].

Generic companies launch competing products after securing appropriate regulatory permissions and have adequate financial resources to pay financial damages at the end of the proceedings. At the same time, patentees can be adequately compensated by damages and such damages can be secured via secured deposits by the generic company in the Court. Based on this factor alone, Judges should consider granting interim injunctions only as an exceptional relief since normal relief via damages is adequate.

2. Balance of convenience: The Judge has to look at which party has already taken steps to market or who will suffer most by issuance/non-issuance of an injunction. For instance, the Judge will look at whether the defendant has launched his product or not or has taken steps to launch the product etc. Balance of convenience can be ascertained by examining the launch of product by the generic company. If the generic company has launched its product, an injunction should be avoided. This is a fact-based criterion and will need to be examined as of the date of hearing.

3. Presence of a *prima-facie* case: This is also a matter of initial enquiry by the Judge and an injunction is to be granted only when the patentee is able to present a credible, clear and *prima-facie* case. In India, there is no presumption of validity of a patent.[13] It is an established principle that an interim injunction cannot be granted if the validity of patent is itself in question. The Judge should consider granted claims of the patent on one side and on the other side, the defendant must be able to present a credible challenge to the validity of the patent. Such a challenge could be in the form of a revocation/opposition already filed or cogent invalidity arguments presented by the generic company.

Special principles for assessing interim injunction in pharmaceutical patent cases

In patent infringement/injunction suits, the working/non-working of the patent is an important factor which is considered for the grant of an interim injunction. The Courts have held that whether there is an actual commercial working/exploitation of invention in India is a key consideration[14]. Apart from the above factors, Indian Courts[15] have brought in a fourth and independent factor in the case of pharmaceutical patents, while considering the issuance of interim injunctions. This factor was also discussed in the US Supreme Court ruling in EBay[16].

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11 *American Cyanamid v. Ethicon Limited*, [1975] 1 All ER 504, available at: http://www.bailii.org/uk/cases/UKHL/1975/1.html

12 *Vringo Infrastructure v. Indiamart Intermesh*, (60) PTC 437 (DEL), available at https://indiankanoon.org/doc/170975121/

13 The Indian Patents Act, 1970, Section 13(4) provides that mere grant of the patent is not a sufficient ground for validity of patent.

14 *Franz Xaver Huemer v. New Yash Engineers* [AIR 1997 Delhi 79]: The plaintiff who has registered patents in India in 1984 but has not used them in India cannot, in equity, seek temporary injunction against the respondent, available at: https://indiankanoon.org/doc/254672/

15 *F. Hoffmann La Roche v. Cipla*, MIPR 2008 (2) 35, available at: https://indiankanoon.org/doc/64813/

16 *eBay v. Merc Exchange*, 547 US 388 (2006)

This fourth factor is consideration of '*public interest*' when looking at an injunction for a patent covering a life-saving drug. In a suit covering the Erlotinib drug patent (Roche product, under the brand Tarceva), the Delhi High Court, in March 2008, specifically held:

> '(para 85) … *Another way of viewing it is that if the injunction in the case of a life saving drug were to be granted, the Court would in effect be stifling Article 21 so far as those would have or could have access to Erlocip are concerned.*
> …
> (para 86) … *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 life saving drug, the balance has to be tilted in favor of the latter.'*

It must be noted that the Judge examined the standard factors for injunction and then looked at 'public interest' as an independent assessment. This ruling was taken to appeal and the Appeal Court, in April 2009, also approved[17] the rationale. The Appeal Court also kept the 'public interest' prong independent of the other prongs and noted:

> *'(para 85) … the public interest in greater public access to a life saving drug will have to outweigh the public interest in granting an injunction to the plaintiffs.*'

The Single Bench, in this case, had in the context of 'irreparable financial harm' versus public interest, noted:

> *'86. … 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 life saving drug, the balance has to be tilted in favor of the latter. The damage or injury that would occur to the plaintiff in such 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 restituted in monetary terms, is not only uncompensatable, it is irreparable. Thus, irreparable injury would be caused if the injunction sought for is granted.'*[18]

Thus, independent of the 'access to drug' policy argument from a public interest perspective, the Appeal Court looked at the irreparable harm prong within a framework of damages being compensable in monetary terms and ruled against the grant of injunction. It reinforced the position that if damages are adequate compensation, then an interim injunction should not be the primary response. However, later while adjudicating an injunction application relating to the anti-cancer drug Dasatinib, the Delhi High Court held that '*the plea of public interest may be invoked once the Court would find that prima-facie the case of credible defence is made out. In the present case, the defendants have not made any representation to the Central Government by raising the plea of public interest, expensive drug and fully non-availability of the drug in question to the patients, nor has the Government exercised its discretion under Section 66 of the Act.*'[19] This indicated a change in the approach of the judiciary towards pharmaceutical patent injunctions and public interest.

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17 *F. Hoffmann La Roche v. Cipla*, (40) PTC 125, available at https://indiankanoon.org/doc/131401110/

18 *F.Hoffmann-La Roche Ltd. & Anr. Vs. Cipla Ltd 2008* (37) PTC 71 (Del.), available at: https://indiankanoon.org/doc/64813/

19 Bristol-Myers Squibb Company & Ors. Vs. Mr. J D Joshi & Anr. [CS(OS) 2303/2009]; Bristol-Myers Squibb Company & Ors. Vs. Mr. D Shah & Anr. [CS(OS) 679/2013]

Erlotinib temporary injunction case

The earliest high-profile pharmaceutical product patent litigation that focused around principles was the Erlotinib litigation between the patentee Roche and the generic company Cipla.

Roche secured Indian patent IN196774 in early 2007 that covered the product Erlotinib Hydrochloride – the cancer medicine sold as Tarceva. Cipla launched an 'at risk' generic version of this drug in December 2007 at a third of Roche's price. Roche immediately filed a patent infringement suit against Cipla at the Delhi High Court and sought an injunction as interim relief.

In a detailed judgment issued in March 2008, J. Bhat of the Delhi High Court refused an interim injunction to Roche. The Court noted that it must be mindful '*of the right of the general public to access life saving drugs which are available and for which such access would be denied if the injunction were granted*'.

This case was appealed and the Appeal Court also refused an interim injunction. The generic product continued to be available in the market during the course of the litigation.

However, there have been multiple later cases where patent holders have been able to secure injunctions against generic companies. For instance, in early 2015, Novartis was able to secure an injunction for its patented drug Indacaterol, with the Court noting that where the patent was *prima facie* valid and infringement was established with no credible defence, public interest cannot be a valid consideration for not granting an injunction. This was after Cipla launched a generic version in November 2014.

So, the Courts have moved between granting and refusing injunctions in pharmaceutical patent infringement cases, over the years. This impacts early access to generic drugs – even when the generic company is ready to take the commercial risk of patent infringement.

Later attempt to restate the framework and grant injunctions

In an April 2013 decision[20], the Delhi High Court initially refused an injunction to Merck against Glenmark, which had launched an 'at risk' version of Merck's patented Sitagliptin molecule, during the term of the patent. Public interest was not specifically cited as a reason for refusal of the injunction.

Merck appealed the refusal and the Appeal Court granted an injunction to Merck in March 2015 by creating a distinction between lifestyle disorders and life-threatening diseases[21] without acknowledging the reality that managing lifestyle disorders like diabetes also requires financial resources due to the chronic nature of the disease and India's large diabetes burden.

In examining the public interest angle, the Sitagliptin Appeal Court held:

> *'85. ... whether the Court can overlook the public interest in maintaining the integrity of the patent system itself, so that a legitimate monopoly is not distorted. ...*
> *The Court must be mindful – especially in a case where a strong case of infringement is established, as here – there is an interest in enforcing the Act. It may be argued that despite this no injunction should be granted since all damages from loss of sales can be compensated monetarily ultimately if the patentee prevails. This argument though appealing, is to be rejected because a closer look at the market forces reveal that the damage can in some cases be irreparable.'*

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20 *Merck Sharp and Dohme Crop. v. Glenmark Pharmaceuticals*, CS(OS) 586/2013, available at: https://indiankanoon.org/doc/29163838/

21 *Merck Sharp and Dohme Crop. v. Glenmark Pharmaceuticals*, FAO (OS) 190/2013, para 84, available at: https://indiankanoon.org/doc/41495724/

The Appeal Court, without discussing how the harm was actually irreparable, injuncted Glenmark with a limited right to sell its existing stock.

Shortly thereafter, the April 2015 decision[22] concerning Novartis' drug Indacaterol also attempted to rewrite the Erlotinib ruling by specifically linking the 'public interest' prong with a 'credible challenge' while not keeping the enquiry separate and also relooked at the issue of compensable damages. The Court's order states:

> '*88. Therefore to say that public interest is a complete exception to the patent would not be correct as otherwise the rights granted by the sovereign towards monopoly would be undermined by too broadly interpreting the public interest.*
> ...
> *119. It is necessary to draw a fine distinction between the cases relating to patent infringement wherein there exists plausible ground of the invalidity of the patent coupled with the outweighing public interest enabling the court to refuse the injunction on all these grounds collectively vis-a-vis the cases where the patents are otherwise valid and there exists no plausible ground of the invalidity yet for serving the private commercial interests, the private defendant raises the ground of the public interests in order to harbour the infringing activities and attempts to make invention public which may have certain level of tenability in its plea depending upon the fact finding as to the correctness and veracity of the plea and other attendant circumstances.*'

Cipla appealed against this injunction and the Appeal Court, in March 2017, continued[23] with the injunction. The Appeal Court based its Order around the point that the defendant had not made out any credible challenge to the patent and that the needs of public were being met.

Problems with Sitagliptin and Indacaterol rulings

The Sitagliptin and Indacaterol rulings are not a completely fair application of the 2009 Erlotinib Appeal Bench ruling.

a) These rulings tend to make public interest a less important factor by linking it to other factors like irreparable harm or credible challenge – something that is not warranted. Independent observers have also written[24]:
'*...public interest, as it stands today in the Indian jurisprudence, is an etiolated principle in theory as well as in practice, and rendered subservient to the satisfaction of the three-factor test and/or the 'credible challenge' test. ...*
public interest cannot be subservient to patent rights either. It therefore should have a greater role to play in deciding patent disputes in India, at least in the domain of pharmaceutical patents.'

b) In these rulings, Courts came out with a distinction between 'life saving' drug (for diseases like cancer) and non-life saving drug (for lifestyle/less serious diseases like diabetes or chronic obstructive pulmonary disease (COPD)) while analysing the grant of injunction and brought in 'substitutability' of existing medicines.
For instance, the Indacaterol Court stated:
'*(25) ... We may also point out that apart from INDACATEROL, there are other drugs which deal with the management of COPD which are also available in the Indian market. INDACATEROL also does not fall in the category of a life saving drug, such as a cancer medicine. We have also noted the submission made on behalf of the respondents that sufficient quantities are being imported into India in order to serve the needs of the COPD patients.*'

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22 *Novartis Ag. v/s Cipla*, CS(OS) 3812/2014, available at: https://indiankanoon.org/doc/131401110/

23 *Cipla Ltd. v. Novartis Ag.*, FAO(OS) 21/2015, available at: https://indiankanoon.org/doc/56225903/

24 Views expressed by Victor Vaibhav Tandon and Devvrat Joshi (Patent Attorneys), available at: https://spicyip.com/2020/11/back-to-the-drawing-board-indian-courts-tryst-with-public-interest-principle-in-pharmaceutical-patent-infringement.html

Such distinction is artificial as it does not exist in the patent statute and is not beneficial to patients. There is no separate examination for patents for life-saving drugs versus patents for drugs of lifestyle diseases – all claims are examined in a like manner and get a patent. The Constitution and the earlier Supreme Court cases discussing health generally and the Erlotinib 2009 ruling also did not make any such a distinction. From a patient's perspective, removing 'chronic' use drugs or drugs for lifestyle diseases from the ambit of refusing an injunction under the public interest perspective becomes financially draining on the patient. Considering the disease burden of conditions likes diabetes and hypertension, the ambit of interim injunction on public interest for drugs in the 'chronic' use category must be expanded.

c) Additionally, the Sitagliptin Court mentioned that damages would not be adequate while the Indacaterol Court did not examine the issue of why financial damages would be inadequate compensation at all. The damages discussion in both cases never mentioned why a patentee who ultimately was seeking financial damages could not be adequately compensated in money terms.

The challenge of the *quia-timet* injunction

Another problem that has surfaced in the last decade or so is the filing for and consequent issuance of a '*quia-timet*' injunction order. Legally, an interim injunction proceeding is to secure the rights/*status quo* of the patentee, during the continuance of trial proceedings. A *quia-timet* injunction request is based on a fear of possible future injury and therefore based on a mere threat of an infringing act[25]. That is, such injunction proceeding is initiated even before a generic company has actually launched a product 'at risk'. This injunction request is 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 and the patentee seeks to stop an 'imminent' launch. The patentee argues that such a launch would forever change the market dynamics, negatively affecting the patentee.

Patentees targeting business partners – the 'chilling effect'

Over the years, patentees have gone beyond filing suits against generic companies and have also targeted their distribution partners. Recently a patentee (Astra), after securing an injunction against the generic pharmaceutical company (Natco) for patent related to the drug Dapagliflozin, also filed independent suits against its distributors and secured injunctions against such distributors. This effectively froze all sales of the product – specifically what was already in distribution prior to the injunction on the company. These aggressive tactics have a chilling effect and seek to make generic companies rethink their 'at risk' launch plans.[26]

Interim and *quia-timet* injunctions in pharmaceutical cases: some examples

The Supreme Court has taken an expansive view on public health and right to life and the Courts in pharmaceutical patent matters have held that 'public interest in access to a life-saving drug' is an important consideration in refusal of an interim injunction for a pharmaceutical patent. However, later Courts have routinely granted injunctions to the patentees – in apparent disregard of the Erlotinib ruling. This trend goes against the conscious position taken by the Erlotinib Court and negatively impacts access to drugs.

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[25] See Aparajita Lath, 'Analysing the Pitfalls of Indian Patent Injunctions based on Fear of Infringement', *Journal of Intellectual Property Rights Vol. 19*, July 2014, pp. 253-259.

[26] However, in 2021, in a series of cases relating to Dapagliflozin, the Court refused to grant an interim injunction, because the generic companies were able to establish a serious challenge to the validity of the patent.

Courts have granted interim and *quia-timet* injunctions in the following cases.

#	Molecule	Innovator and brand	Defendant/Other details
Patentees successful in getting an injunction <u>after</u> generic launch:			
1.	Dasatinib	Bristol Myers/Sprycel®	Natco Pharma Ltd. CS (OS) 2279/2009, Delhi High Court
2.	Sorafenib Tosylate	Bayer/Nexavar®	Cipla Ltd. CS (OS) 523/2010, Delhi High Court
3.	Sitagliptin Phosphate	Merck/Januvia®	Glenmark Pharma CS(OS) 586/2013, Delhi High Court
4.	Indacaterol Maleate	Novartis/Onbrez®	Cipla Ltd. CS(OS) 3812/2014, Delhi High Court
5.	Ticagrelor	Astra/Brilinta®	Dr. Reddy's CS(COMM) 792/2018, Delhi High Court
6.	Dapagliflozin	Astra/Farxiga®	Micro Labs. CS(COMM) 346/2020, Delhi High Court Natco Ltd. Natco originally escaped an injunction but was later injuncted through an injunction on its distributors CS(COMM)129/2020, Delhi High Court
7.	Valsartan Sacubitril	Novartis/Entresto®	Natco Ltd. CS(COMM) 62/2019, Delhi High Court
Patentees successful in preventing launch (i.e. *quia-timet* proceeding):			
1.	Dronedarone Hydrochloride	Sanofi/Multaq®	MSN Laboratories CS(OS) 1682/2010, Delhi High Court
2.	Rivaroxaban	Bayer/Xarelto®	MSN Laboratories CS(OS) 2433/2013, Delhi High Court
3.	Vildagliptin Hydrochloride	Novartis/Galvus®	Biocon Limited CS (OS) 891/2014, Delhi High Court
4.	Saxagliptin Hydrochloride	Astra/Onglyza®	Mr. A. V. Reddy (Lee Pharma) CS (OS) 2197/2015, Delhi High Court
5.	Diclofenac Injection	Troikaa/DynaparAQTM	CS(OS) 7/2012, Ahmedabad City Civil Court
6.	Ferric Carboxy Maltose	Vifor/Ferinject®	D. Mohan Rao CS(OS) 2282/2011, Delhi High Court
7.	Tofacitinib	Pfizer/Xeljanz®	Sun Pharma CS(Comm) OS 1154/2016, Delhi High Court
8.	Sunitinib Maleate	Pfizer/Sutent®	Cipla Ltd. CS(OS) 3429/2012, Delhi High Court
9.	Ticagrelor	Astra/Brilinta®	Micro Ltd. CS (Comm) 740/2018, Delhi High Court
10.	Abemaciclib	Lilly/Verzenio®	Natco Ltd. CS (Comm) 183/2020, Delhi High Court

The above representative data from Indian Courts unambiguously shows that injunctions impact access to cheaper pharmaceuticals for ordinary citizens and impact business plans of generic pharmaceutical companies even when such generic companies have adequate financial resources to pay financial damages and have taken such business decisions after detailed analysis. Thus, such injunctions deprive people of cheaper generic drugs even when a business is ready to bear the financial and legal risks.

Conclusions

- The *Wander v. Antox* and Erlotinib rulings were instructive in suggesting not to rush to grant interim injunctions in pharmaceutical patent cases, especially when financial damages are an appropriate relief.

- The public interest prong should be given important consideration while issuing interim injunctions in pharmaceutical patent cases.

- The dichotomy between life-saving drugs and drugs for lifestyle/chronic diseases for purposes of considering injunctions in patent infringement suits is unwarranted. The judiciary could consider expanding the 'public interest prong' beyond only life-saving drugs to all drugs, especially for chronic diseases or diseases affecting large patient populations.

- The judiciary needs to ensure that full benefits of the TRIPS flexibilities reach the common citizens especially when generic pharmaceutical companies are ready to take the commercial risks associated with such 'at risk' launches, by structuring interim and final orders that focus on financial compensation and damages rather than interim injunctions.

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He has a master's degree in law from India and a master's degree in law from the USA. He is a recipient of scholarships from WIPO-UNISA, the Japan Patent Office and the University of Washington. He is on the Editorial Board of the Journal of Generic Medicines *and regularly writes/speaks/teaches on pharmaceutical legal issues and access to medicines. In recent years, he has been an invited speaker at events organised by WIPO and the Max Planck Institute for Innovation and Competition. He also advises and trains various international civil society groups on policy matters related to intellectual property.*