

# News

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## "Clearing the way": A medicine that can save lives in ongoing patent lawsuit injunction battles?



A thorough explanation and analysis of the patent law "Clearing the way" principle using resolved generics cases from the pharmaceutical sector.

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## Overview

Assume that a pharmaceutical company (referred to as the "innovator" for this purpose) has a statutory term to hold the patent for a vital drug. During this time, the innovator has also acquired a number of other nearby patents (referred to as the "species patent(s)"), the statutory term of which will undoubtedly outlive the statutory term of the original genus patent.

Competitors may try to introduce generic versions of the drug (referred to as "generics") when the genus patent is about to expire, and occasionally even before, on the grounds that the innovator's genus patent (and any applicable species patents) are invalid; if the genus patent has already expired, the generics may launch their generic product on the grounds that the species patent(s) are invalid.

Fundamental to patent jurisprudence is the fact that a patent's validity must be independently assessed when challenged by an opponent, and that a patent's validity is not presumed to exist simply because it was granted in compliance with the legislative procedure.

In the event that the innovator requests a civil court injunction to prevent the generic from releasing its generic product, the judge must make a preliminary determination about the validity or invalidity of the patent on which the injunction is based after being deluged with evidence both in favor of and against the issuance of the injunction.

This article will continue to use the example of generics in the pharmaceutical industry as a convenient device, in accordance with the cases that have found fit to invoke the concept. Generally speaking, the concept of "clearing the way" has evolved in English law as one of the factors to be considered for evaluating whether a potential infringer of a pharmaceutical patent ought to be enjoined. There are indications that this concept is becoming an increasingly common point of contention in Indian pharmaceutical patent litigation.

Simply put, the **"clearing the way"** principle mandates that a company that launches a product (**typically a generic in the pharmaceutical industry**) knowing that another company has obtained a patent that may be arguably infringed by the launch of its product must first challenge that patent by applying to revoke the innovator's patent or by starting proceedings for a declaration of non-infringement. If it does not, it may face an injunction [see Section 64 (1) and Section 105 of the Indian Patents Act, 1970, as amended].

Because it initially seems to provide the sense of a legal obligation to initiate proceedings and an implied presumption of validity of the patent awarded to the innovator, this warrants more investigation.

## Background

In *SmithKline Beecham plc v. Generics (UK) Limited*, reported at [2001] 10 WLUK 610 ("SmithKline Case"), Jacob J. may have developed the principle of "clearing the way" for the first time. The judge found that although both the innovator and the generic would suffer irreparable harm in either case, the generic knew that litigation was inevitable and could have resolved the entire dispute by taking appropriate legal steps before launching its generic product by "clearing the way." The generic was then forced to bear the consequences of an injunction.

Even recently, the Court of Appeal in England upheld the "clearing the way" approach in the *AstraZeneca AB v. Glenmark Pharmaceuticals Europe Limited* case, which was dubbed the "**Dapagliflozin Case**" after the medicine in question and was reported at [2025] EWCA Civ 480.

In the 2015 case of *Merck Sharp and Dohme Corporation and others v. Glenmark Pharmaceuticals Limited*, reported at 63) PTC 257 [Del][DB] (**the "Merck Case"**), a Division Bench of the Delhi High Court also found this line of reasoning to be persuasive, and it was subsequently incorporated into Indian law.

The Delhi High Court's Division Bench examined the "clearing the way" principle as one of six equitable principles that influence the issuance of an injunction in cases involving patent infringement. The Division Bench reasoned that, even after the grant, the generic in this case

was aware of a potential challenge to its own launch of a potentially (or allegedly) infringing product, and that the fact that the generic went ahead and launched its product in these circumstances without requesting revocation or negotiation is undoubtedly "a relevant factor" at the stage of issuing an injunction.

The Delhi High Court's Division Bench's ruling is still regarded as authoritative, even though the Supreme Court later changed the terms of the injunction it had granted [See *Glenmark Pharmaceuticals Limited. v. Merck Sharp and Dohme Corporation and others*, reported at (2015) 6 SCC 807].

The following five propositions about this principle should help to clarify how Indian courts might apply it as this jurisprudence develops. Based on practical experience, it is likely that this principle will be the subject of significant contestation in patent litigation (particularly with regard to pharmaceutical patents) in Indian courts.

## **Five claims on "clearing the way"**

First, it is helpful to clarify what this principle is not. According to the Court of Appeal, in *SmithKline Beecham v. Apotex Europe Limited*, reported at [2003] FSR 31, at paragraph 39 (Aldous LJ), *Merck Sharp and Dohme Corporation and others v. Glenmark Pharmaceuticals Limited*, reported at 2015 (63) PTC 257 [Del][DB] at paragraph 87, there is no positive or substantive duty on the part of the generic (or the company launching a new product that may be potentially or allegedly infringing) to pursue legal action.

It is evident from the rulings of both English and Indian courts that the failure to initiate proceedings is merely a factor (albeit a very important one) in the exercise of discretion to grant an injunction. For example, the generic or the company launching a new product cannot be made to pay damages for it. This is not a

"breach" of any law that sounds in any remedy.

Second, the **"clearing the way"** principle, even as a factor in that discretionary exercise, does not alter the traditional test for the granting of an injunction, which remains: (i) a prima facie case, (ii) irreparable injury, and (iii) balance of convenience. It merely streamlines the process of evaluating one of these limbs, the balance of convenience.

Because Section 13(4) read with Section 107(1) of the Indian Patents Act, 1970 ("Patents Act") makes it clear that the grant of a patent does not create any presumption in favor of the validity of the patent, a generic's failure to "clear the way" can never result in establishing or inferring a "prima facie case" of infringement. The statute is, as a matter of policy, averse to presumptions about the prima facie validity of patents [See *Boehringer Ingelheim Pharma GMBH and Co v. Vee Excel Drugs and Pharmaceuticals Private Limited and Others* reported at 2023 SCC OnLine Del 1889, at paragraphs 37, 44 to 48].

According to Section 64 of the Patents Act, a defendant may challenge the patent's validity at any time, including after it has been granted. If the defendant can present a convincing argument against the patent, the injunction will be denied because the injunction-claimant will not be able to establish a prima facie case [See *M/s. Bishwanath Prasad Radhe Shyam v. Hindustan Metal Industries*, reported at (1979) 2 SCC 511, at paragraph 32; *TenXC Wireless INC and others v. Mobi Antenna Technologies (Shenzhen) Co. Limited.*, reported at 2011 DHC 5605].

If the failure to "clear the way" is ever found to be sufficient to satisfy the test of prima facie case for the grant of an injunction, it would indirectly defeat the policy of the statute that there can be no presumptions about the validity of the patent. This distinction is essential to ensure that no legal duty to commence proceedings is introduced in Indian patent jurisprudence through the backdoor, which would indirectly create an implied presumption of validity in favor of a granted patent.

Rather, only when evaluating the "balance of convenience" is it appropriate to take into account the defendant's failure to "clear the way" [see **Terrell on the Law of Patents (20th ed) at paragraphs 19-245, 19-246**].

This theoretical foundation is supported by an analysis of cases decided on the basis of the

"clearing the way" principle. In the original SmithKline Case, the generic's failure to "clear the way" was taken into consideration when evaluating the balance of convenience because the generic had already advanced into an advanced stage for launching its product; the judge only took this into consideration after concluding that the innovator had a prima facie case. Similarly, in EISAI Co. Limited and another v. Satish Reddy and others, reported at 2019 (79) PTC 568 [Del], the court found that the plaintiff-innovator had a prima facie case because the defendant-generic had not cleared the way prior to launch.

Therefore, a Plaintiff may only invoke a Defendant's failure to "clear the way" when assessing the "balance of convenience" between the parties, not when assessing (a) the prima facie case for the grant of an injunction and (b) the credibility of the Defendant's challenge to the validity of the patent.

AstraZeneca AB and others v. Torrent Pharmaceuticals Limited, reported at 2020 DHC 3270, is the best example of the implications of this distinction. The single judge in that case determined that, despite the fact that the plaintiff-innovator had the advantage of convenience due to the defendant-generic's failure to "clear the way," it was unable to obtain an injunction because it had failed to establish a prima facie case in the first place. This is the proper application of the "clearing the way" principle.

Third, "clearing the way" can in some situations be most usefully seen as a tiebreaker when the Court is unable to form a view on the prima facie test and irreparable harm, or that it finds that these factors are otherwise evenly balanced between the parties. However, the role of the principle of "clearing the way" as a tiebreaker is not small. In fact, as the Court of Appeal aptly pointed out in the Dapagliflozin Case, the distinctive feature of patent injunction cases in the pharmaceutical sector is that injury will be irreparable on either side: loss from inevitable price cutting is not easy to reverse for the innovator, and the loss of first-mover advantage is not easy to reverse for the generic. This means that often, the injunction will be decided based on "balance of convenience" as a more dominant factor, in which a Defendant's failure to "clear the way" will assume paramount significance. However, this proposition is nebulous. It must, therefore, be applied with extreme caution and in exceptional cases, perhaps only when any implication of the validity of the patent is an insignificant consideration for grant of injunction in the peculiar factual matrix of a case.

Fourth, incorporating "clearing the way" factors into the balance of convenience also broadens the scope of information that can be taken into account for a proper understanding of that principle. The cases demonstrate that "clearing the way" is a manifestation of the broader principle that a party's actions during litigation can result in inferences against it. This definition of "clearing the way" as a litigation management control device means that the investigation is not limited to demonstrating that a generic has announced the impending launch of a drug that it knew would raise challenges; even after launch, the generic may be able to request expedited trials to settle the issue prior to launch [See AstraZeneca AB v. Glenmark Pharmaceuticals Europe Limited, reported at [2025] EWCA Civ 480 at paragraph 88 (Arnold LJ)]. The general question is whether the generic has taken action to bind a trial judge's hands by creating an irreversible status quo.

Fifth, by knowing where it falls in the matrix of factors in the grant of injunction, we can create more specific conditions in the application of this principle. This article suggests that "clearing the way" factors should be subject to an overall reasonableness criterion: a defendant's failure to clear the way should only count against it if it was reasonable for it to take certain steps, which is typically the case when (i) the defendant is about to launch a competing generic; (ii) it knew that the innovator's patent had been in use for a long time, either without any successful challenge or has withstood unsuccessful challenge(s) by others; and (iii) it knew that a legal challenge by the innovator is very likely.

Furthermore, even if it is determined that it was reasonable for the generic to have "cleared the way" and that it did not, the investigation is not yet finished. The weight of other compelling factors may still weigh against the grant of an injunction [see, for example, Cephalon Inc. and others v. Orchid Europe Limited and another, reported at [2010] EWHC 2945 (Pat)]. The better option is for the generic or the company launching a new product to demonstrate that, even though it did not "clear the way," the balance of convenience still favors it.

## **In conclusion**

It is hoped that applying the five propositions above will result in more equitable outcomes. The "clearing the way" principle is a helpful tool to assess the balance of convenience. In a jurisdiction that struggles with severe case pendency, such tools are welcome. However, its

practicality cannot outrun the limits of principle.

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