

## The Delhi High Court elucidates the law on product by process claims in a patent

The Delhi High Court in a landmark judgment in patent law has set the legal position on the interpretation of scope of “product by process” claims and on patent claim construction in general under Indian law “The court has held that patent protection under product by process claims would extend to the product per se, regardless of the which process is used for its manufacture, provided that the product itself is novel and inventive”. The Division Bench vide its 188-page order dated 7<sup>th</sup> February 2024 in FAO (OS) (COMM) Nos. 159-161/2023 allowed the appeals filed by Vifor (International) Ltd. (**Vifor**) and set aside the order of a Ld. Single Judge of the Delhi High Court denying Vifor an injunction against three prominent generic pharmaceutical manufacturers engaged in the marketing and sale of Vifor’s blockbuster therapy for the intravenous treatment of iron deficiency anemia, known as Ferric Carboxymaltose (**FCM**), which is protected under its Indian patent No. 221536 (**the FCM patent**).

### Product by Process claims

A patent claim in an Indian patent can be construed as granting protection over either a product or a process. Product by process claims in a patent are a subspecies of product claims, whereby the novel and inventive product for which protection is claimed cannot be described feasibly using product characteristics alone and this necessitates use of process terms to describe the product for which protection is being claimed. The subject matter claimed is still a novel and inventive product – however it is described through the means of a process which may be used to make said product.

### The *lis* in brief

The FCM patent consisted of claims claiming protection over both a product (including *inter alia* FCM) as well as



claims seeking to protect the process developed by Vifor to make said product. However, the main independent claim was a claim for a product drafted in the product by process style, and which therefore included certain process terms to describe the end result, i.e. the product. Vifor had successfully enforced the FCM patent against a large number of generics in the past who had launched or sought to launch a generic version of FCM in India.

In 2021, Vifor sued MSN Laboratories (**MSN**) and Dr. Reddy’s Laboratories (**DRL**) when they sought to launch generic versions of FCM with each claiming that the process used for manufacturing FCM, in particular the oxidizing agent used therein, was different from that identified in the FCM patent claims, and thus they were not infringing. In 2022, another generic manufacturer Corona Remedies (**Corona**) launched a generic version of FCM, claiming it to be a different product altogether on the basis that their

manufacturing process used different starting materials than those identified in Vifor's process, which prompted Vifor to file a suit for patent infringement.

## Impugned Order

The Ld. Single Judge in an order dated 24<sup>th</sup> July 2023 had issued a detailed order *inter alia* interpreting product by process claims to be limited by the process terms used therein. It was held that protection under such a claim would extend only to a product which had been made used the specific process described in the claim. The defendants were thus held not to be infringing the FCM patent as each of them had claimed to be using a process for the preparation of FCM different from the process identified specifically in claim 1 thereof.

## The Decision in the Appeal

The Appellate Court has issued a detailed and nuanced judgment, analyzing each and every aspect of the impugned order, and addressing all submissions advanced by the parties before it, finding primarily as follows:

- 1. Re: whether interference is warranted:** The legal position as enunciated by the learned Single Judge suffers from patent and manifest illegalities and thus clearly warrants interference in appeal.
- 2. Re: the errors in the impugned order:** The foundational and conceptual mistake in the Ld. Single Judge's understanding is that there is a distinction between a "product by process claim" and a "pure product claim". The Single Judge's view, that product-by-process claims are limited to a product obtained through a specific process feature, fails to correctly appreciate that product-by-process claims are established and recognized in cases where products resist definition except by resort to process terms. This is particularly so, since the novelty of FCM appears to have been uncontested before the Ld. Single Judge. This is particularly so, since the novelty of FCM appears to have been uncontested before the Ld. Single Judge.
- 3. Re: product by process claims:**
  - a. A product by process claim is an amalgam which straddles the boundaries between products and process patents *per se*.

- b. It is necessarily directed to a novel and inventive product, which could not be fully described by its structure compelling the patent applicant to rely upon and refer to the process features to describe said product.
- c. Different tests of novelty and standards of claim construction cannot be applied at the stage of grant and while deciding infringement. It would amount to propagating a double standard and would be unjust to prune or whittle down the scope of product by process claims to the process alone for the purpose of determining infringement, even though at the time of grant it may have been understood as granting protection to a novel and inventive product.
- d. Section 48 (b) of the Patents Act embodies the phrase "*obtained directly by that process*", hinting towards a distinction between the scope and extent of protection that can be claimed in respect of process claims, and the "*obtainable by*" language embodied in the claim of the FCM patent which would appear to convey a descriptive process by which the claimed product could be manufactured or produced, even though that process in itself isn't the inventive or indispensable element. The claim language and the specification would have to be seen to determine whether protection extends to the product *per se* or not. The usage of "*obtainable by*" language, as in claim 1 of the FCM patent, is identical to what occurs in Section 48 (a) of our Act and extends to product claims *per se*, irrespective of the process of manufacture, provided that the product-by-process claim pertains to a product which is novel and inventive. Since FCM was not a known product, the FCM patent did indeed grant protection to FCM *per se*, and any entity manufacturing, selling or offering FCM for sale would have been infringing the product by process claim 1 of the FCM patent, irrespective of the process used for its manufacture.

## Conclusion

While the Division Bench has issued its judgment in an appeal against an order denying an interim injunction, which may not technically be binding for the final adjudication of any FCM patent infringement suits, it carefully lays down aspects of law which have not been enunciated in any decision of an Indian court till date and serves to bring

the legal position in India in line with the position in most other prominent jurisdictions. The judgment clearly notes the criticality of correctly laying down the legal position *qua* product by process claims and recognizes that it may affect not only the final adjudication of the underlying suits, but also all the other pending suits where Vifor has asserted the FCM patent against other third-parties who have raised similar pleas of non-infringement.

Furthermore, while the Appellate Court has not granted an interim injunction to Vifor on account of the expiry of the FCM patent in October 2023, it has taken a step towards the creation of a totally new form of deterrence in pharmaceutical patent infringement suits, by granting Vifor liberty to press its claim for deposit of percentage of sales made by the infringers in the respective suits.

The order holds immense potential to start a trend of Standard Essential-Patent style interim arrangements in pharma litigations, whereby infringers may be asked to deposit money in court *in lieu* of suffering an interim injunction. Aided by the provisions of the Delhi High Court's IPD Rules, any order that Vifor can secure pursuant to the instant appeal judgment can help create an avenue for other patentees to seek similar interim remedies against defendants in other pharma patent litigations, thus leveling the playing field and disincentivizing patent infringement to a large extent.

The judgment can be accessed form the following [link](#).

## Contributors:

**Swati Sharma**  
Partner (Head - Intellectual Property)

**Rohin Koolwal**  
Principal Associate

### Disclaimer

All information given in this alert has been compiled from credible, reliable sources. Although reasonable care has been taken to ensure that the information contained in this alert is true and accurate, such information is provided 'as is', without any warranty, express or implied as to the accuracy or completeness of any such information.

Cyril Amarchand Mangaldas shall not be liable for any losses incurred by any person from any use of this publication or its contents. This alert does not constitute legal or any other form of advice from Cyril Amarchand Mangaldas.

Should you have any queries in relation to the alert or on other areas of law, please feel free to contact us on [cam.publications@cyrilshroff.com](mailto:cam.publications@cyrilshroff.com)

**Cyril Amarchand Mangaldas**  
Advocates & Solicitors

**100<sup>+</sup>** years of legacy

**1000** Lawyers

**Over 170** Partners

Peninsula Chambers, Peninsula Corporate Park, GK Marg, Lower Parel, Mumbai 400 013, India  
T +91 22 2496 4455 E [cam.mumbai@cyrilshroff.com](mailto:cam.mumbai@cyrilshroff.com) W [www.cyrilshroff.com](http://www.cyrilshroff.com)  
Presence also in Delhi-NCR | Bengaluru | Ahmedabad | Hyderabad | Chennai | GIFT City | Singapore