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* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

% *Date of Decision: 24th July, 2023*

\+ CS(COMM) 261/2021

VIFOR INTERNATIONAL LTD & ANR. ..... Plaintiffs

Through: Mr. Pravin Anand, Ms. Vaishali Mittal, Mr. Rohin Koolwal and Mr. Hersh Desai, Advocates.

versus

MSN LABORATORIES PRIVATE LIMITED & ANR.

..... Defendants

Through: Mr. J. Sai Deepak, Mr. G. Nataraj, Mr. Avinash K. Sharma, Mr. Ankur Vyas, Mr. Shashikant Yadav, Ms. Harshita Agarwal, Ms. Garima Joshi and Mr. Rahul Bhujbal, Advocates.

\+ CS(COMM) 265/2021

VIFOR INTERNATIONAL LTD & ANR ..... Plaintiffs

Through: Mr. Pravin Anand, Ms. Vaishali Mittal, Mr. Rohin Koolwal and Mr. Hersh Desai, Advocates.

versus

DR REDDYS LABORATORIES LIMITED ..... Defendant

Through: Mr. J. Sai Deepak, Mr. G. Nataraj, Mr. Avinash K. Sharma, Mr. Ankur Vyas, Mr. Shashikant Yadav, Ms. Harshita Agarwal, Ms. Garima Joshi and Mr. Rahul Bhujbal, Advocates.

\+ CS(COMM) 448/2022

VIFOR INTERNATIONAL LTD & ANR. ..... Plaintiffs

Through: Mr. Pravin Anand, Ms. Vaishali Mittal, Mr. Rohin Koolwal and Mr. Hersh Desai, Advocates.

versus

CORONA REMEDIES
PRIVATE LIMITED & ANR. ..... Defendants
Through: Ms. Rajeshwari H. and Mr. Tahir A.J., Advocates.

\+ CS(COMM) 450/2022

VIRCHOW BIOTECH PVT LTD & ANR. ..... Plaintiffs
Through: Ms. Rajeshwari H. and Mr. Tahir A.J., Advocates.

versus

VIFOR INTERNATIONAL LTD & ANR. ..... Defendants
Through: Mr. Pravin Anand, Ms. Vaishali Mittal, Mr. Rohin Koolwal and Mr. Hersh Desai, Advocates.

CORAM:
HON'BLE MS. JUSTICE JYOTI SINGH

JUDGEMENT

JYOTI SINGH, J.

I.A. 7037/2021 (under Order XXXIX Rules 1 and 2 CPC, by Plaintiffs) in CS(COMM) 261/2021,
I.A. 7138/2021 (under Order XXXIX Rules 1 and 2 CPC, by Plaintiffs) in CS(COMM) 265/2021
I.A. 10144/2022 (under Order XXXIX Rules 1 and 2 CPC, by Plaintiffs) in CS(COMM) 448/2022, and
I.A. 10180/2022 (under Order XXXIX Rules 1 and 2 CPC, by Plaintiffs) in CS(COMM) 450/2022

1. This judgment will dispose of I.A. 7037/2021 (under Order XXXIX Rules 1 and 2 CPC) in CS(COMM) 261/2021, I.A. 7138/2021 (under Order XXXIX Rules 1 and 2 CPC) in CS(COMM) 265/2021 and I.A. 10144/2022 (under Order XXXIX Rules 1 and 2 CPC) in

CS(COMM) 448/2022. These applications have been filed by Vifor (International) Limited, Patentee and Emcure Pharmaceuticals Ltd., a License Holder. For the ease of reference, Plaintiffs hereinafter are referred to as "Vifor". These suits have been instituted by Vifor against the Defendants i.e. (i) MSN Laboratories Private Limited and (ii) MSN Life Sciences Pvt. Ltd. (hereinafter collectively referred to as "MSN") in CS(COMM) 261/2021; Dr. Reddy's Laboratories Limited (hereinafter referred to as "DRL") in CS(COMM) 265/2021; and (i) Corona Remedies Private Limited and (ii) Virchow Biotech Private Limited (hereinafter referred to as "CRPL and VBPL") in CS(COMM) 448/2022. I.A. 10180/2022 (under Order XXXIX Rules 1 and 2 CPC) in CS(COMM) 450/2022 has been filed by CRPL and VBPL against Vifor (International) Ltd. and Vifor Pharma Pvt. Ltd., seeking interim injunction restraining the Defendants from threatening and hampering the business of CRPL and VBPL, in any manner whatsoever or by taking any coercive action, whether regulatory or legal, against the Plaintiffs therein, in respect of the suit patent.

2. As a prelude to the applications, it may be mentioned that Vifor asserts its right in the Suit Patent No.221536 titled *'Water Soluble Iron Carbohydrate Complex and A Process For Producing Water Soluble Iron Carbohydrate Complex'*, (hereinafter referred to as "IN'536"), relating to FERRIC CARBOXYMALTOSE (hereinafter referred to as "FCM"). Since all the suits pertain to alleged infringement and invalidity of IN'536 and the legal issues are inextricably linked, the aforementioned applications are being decided by a common judgment.

FACTS SET OUT IN THE PLAINT IN CS(COMM) 261/2021:

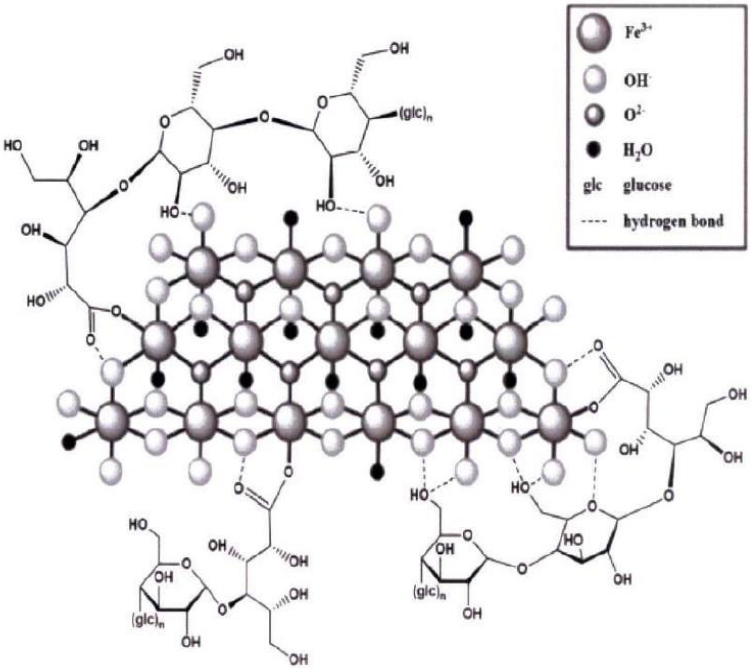
3. Plaintiff No. 1, Vifor (International) Ltd. is a company incorporated in 1991 under the laws of Switzerland and its registered office is in Switzerland. Plaintiff No.2, Emcure Pharmaceuticals Ltd. is a company incorporated under the Companies Act, 1956 with its registered office in Pune, Maharashtra. Plaintiff No. 1 has entered into a non-exclusive Licence Agreement dated 25.01.2012 with Plaintiff No.2 with an aim of commercializing invention of IN'536 under the brand name Encicarb (now also sold under the brand names Ferium and Orofer FCM) in India.

4. Plaintiff No. 1 is a part of Vifor Pharma Group of Companies founded in the year 2008, whereby Vifor and other entities, which formed part of erstwhile Galenica Group of Companies established in 1927 in Switzerland, were integrated to form Vifor Pharma Group of Companies, a standalone global speciality pharmaceutical company. Plaintiff No. 1 is involved in researching, developing, producing, and marketing its own pharmaceutical products and as part of Vifor Group of Companies focusses on finding new pharmaceutical solutions in addition to entering into licences with local pharmaceutical companies in several jurisdictions for manufacturing and marketing its patented products. Vifor claims to be a global leader in treatments for iron deficiency and iron deficiency anaemia, nephrology and cardio-renal therapies.

5. As a backdrop to FCM, it is averred that Plaintiff No. 1's invention is used for intravenous treatment of iron deficiency and iron deficiency anaemia, when oral iron preparations are ineffective or cannot be used. Prior to the invention of FCM, there existed a need for an intravenous iron therapy which is non-toxic, easily administrable in variety of clinical

conditions, capable of being quickly sterilized. Known parenterally applicable iron preparations based on sucrose and dextran were stable at temperatures up to 100ºC only, which made sterilization difficult and thus it was necessary to develop an iron-preparation which was free of the earlier adverse effects noticed in other treatments in the prior art, such as dextran-based complexes that were capable of inducing dangerous anaphylactic shocks.

6. FCM addresses all these needs and is the first non-dextran iron complex with high intravenous iron dosing and high rate of administration, with additional manifold advantages such as advanced stability, easy sterilization, reduced toxicity, parenteral application etc. The water soluble complex makes high dosing up to 1000 mg iron possible and can be administered by intravenous injection within less than 15 minutes. A graphical representation of the structure of FCM is as follows:-



7. World Health Organization ('WHO') has assigned the International Nonproprietary Name ('INN') FERRIC CARBOXYMALTOSE to Plaintiff No. 1's invention claimed in Claim 1 of IN'536 and the same has also been adopted by US Adopted Names Council ('USAN Council'). FCM was first approved for use and marketing in other countries in 2007 and received regulatory approval in India in 2011 and has been commercialized by Emcure Pharmaceuticals Ltd./Plaintiff No. 2 under Vifor's/Plaintiff No.1's licence.

8. IN'536 relates to *"Water Soluble Iron Carbohydrate Complex and A Process For Producing Water Soluble Iron Carbohydrate Complex"*, which is a novel water soluble iron carbohydrate of complex of iron and oxidation product of one or more maltodextrins. The bibliographic details of IN'536 are as follows:-

Patent Application No.	947/KOLNP/2005
Title of the Invention	Water soluble iron carbohydrate complex and a process for producing water soluble iron carbohydrate complex
Date of Filing	24th May, 2005
International filing date	20th October 2003 (filed as PCT/EP2003/011596, published as WO/2004/037865)
Date of publication (Section 11A)	22nd September, 2005
Date of priority	23rd October, 2002 (DE 10249551.1)
Date of grant	25th June, 2008
Date of publication of grant (Section 43)	27th June, 2008
Date of Expiry	20th October 2023

9. It is stated by Vifor that Claim 1 of IN'536 is a product claim for FCM and can also be described as 'product-by-process' claim pursuant to a common practice in claim drafting. The process elements are used to describe the end product which forms the subject matter of the claim and are not limiting and therefore, Claim 1 is a product *per se* claim even if the same is prepared using an alternate process. In essence, IN'536 claims 'a product' (Claims 1, 7-9) and 'a process for preparing the product' claimed in Claim 1 (Claims 2-6). IN'536 comprises of an independent product Claim 1 in addition to dependent claims, some of which are directed to the process to prepare the product, which does not limit the claim to mandate the use of the process. As per practice guidelines followed by Indian Patent Office ('IPO') in prosecuting patent applications pertaining to 'product-by-process' claim, the claim should disclose a novel and inventive product and patentability in such a claim cannot depend upon novelty and un-obviousness of the process limitation alone.

10. Plaintiff No. 1 has regularly filed statements under Form-27 in compliance with Section 146(2) of the Patents Act, 1970 (hereinafter referred to as '1970 Act') read with Rule 131(1) of the Patents Rules, 2003 (hereinafter referred to as '2003 Rules') before IPO, indicating the working of IN'536 in India. Details of sales of FCM of Vifor in India for the years 2017-19 are as follows:-

S. NO.	CALENDAR YEAR	NET SALES VALUE IN INR
1.	2019	2,14,13,20,375
2.	2018	1,67,16,27,753
3.	2017	1,34,92,76,588
TOTAL		5,16,22,24,716

11. Global sales figures of FCM products of Plaintiff No. 1 including the sales in India of FCM products under its brands Ferinject, Injectafer, Revofer etc. are as under:-

YEAR	NET SALE REVENUE IN USD (APPROX)	SALES OF UNITS (APPROX IN 100MG IRON EQUIVALENTS)
2018	542,000,000	31,000,000
2017	445,000,000	22,000,000
2016	347,000,000	18,000,000
2015	246,000,000	12,000,000
2014	196,000,000	8,000,000
2013	170,000,000	7,000,000
2012	135,000,000	5,000,000
2011	90,000,000	3,300,00
2010	60,000,000	2,500,000
2009	30,000,000	1,500,000
2008	7,000,000	800,000

12. Plaintiff No. 1 has been extremely vigilant in protecting its rights in IN'536 and has filed numerous suits claiming infringement before this Court and has successfully obtained interim injunctions against several third parties, details of which are mentioned in the plaint. Plaintiff No. 1's rights in corresponding patent in Pakistan have also been recognized by way of interim orders. Plaintiff No. 1 along with its US Licensee for FCM has initiated Abbreviated New Drug Application ('ANDA') litigations against Mylan Laboratories Ltd. in June, 2019 before the US District Court for the District of New Jersey. It is also averred that a revocation petition against the suit patent was filed by La Renon Healthcare in July, 2017, however, the same was withdrawn in favour of a counter claim preferred by the said entity in a suit for infringement filed by Plaintiff No. 1.

13. During routine online surveillance, in or around December, 2020, Vifor discovered that MSN intended to launch a generic infringing version of FCM under the brand name FEINJ and had initiated advertisements on their website *albeit* the product FEINJ was no longer shown in the list available on the website when the plaint was filed. Online investigation further revealed that Defendant No.1/MSN Laboratories Pvt. Ltd. filed Indian Patent Application bearing No.201841012945, published on 11.10.2019, pertaining to a *"Process for the preparation of Iron [III] Carboxymaltose complex"*, which reflects that Defendant No.1 admits that US'109 patent, which is counterpart of IN'536, discloses FCM and Defendant No.1 is aware that FCM is marketed by Vifor under brand name Ferinject. Additionally, Vifor has also come across a document generated by Telangana State Pollution Control Board, describing the proposed expansion plan of Defendants' manufacturing facilities with express admissions and proposed manufacture of FCM, as also the fact that Defendants have applied for registration of the mark FEINJ with the Trade Marks Registry in July, 2020. Several import-export records have also come to the notice of Vifor pointing to instances of import of FCM by MSN. On this ground, Vifor alleges infringement of the product claimed i.e. Claim 1 of IN'536 as well as of the process claimed in Claims 2-6.

ADDITIONAL/DIFFERENT FACTS SET OUT IN THE PLAINT IN CS(COMM) 265/2021:

14. In the middle of May, 2021, while conducting routine market surveillance, Vifor came across records which identified several instances of import-export of FCM by DRL for the period 2017-2021 and further online search revealed evidence indicating that DRL was already engaged in manufacture of FCM and was likely to launch a generic infringing

version of FCM. Advertisements and offers for sale of the infringing product were made on DRL's official website, permitting potential customers to submit inquiries, including sales inquiries. Listing on DRL's website clearly identifies Vifor's patented products by its INN, identifies the 'Innovator Brand' to be INJECTAFER, i.e. Plaintiff No.1's FCM product commercialized in USA and mentions the status of the Defendant's/DRL's product as being under development. The said listing even mentions the older erroneous CAS number mistakenly assigned to FCM, which was later corrected. Vifor also discovered documents such as a catalogue uploaded on a third-party website issued in 2021 by DRL, listing its various Active Pharmaceutical Ingredients ('APIs') products, application to Andhra Pradesh Pollution Control Board seeking 'Consent for Establishment' for Change of Product Mix, all of which enforces the belief of Vifor that DRL is intending to launch the infringing product and commercialize the same.

ADDITIONAL/DIFFERENT FACTS SET OUT IN THE PLAINT IN CS(COMM) 448/2022:

15. Defendants are Indian Companies involved in manufacture, sale and export *inter alia* of pharmaceuticals i.e. APIs and finished, mostly generic drugs across diverse therapeutic areas, in India and abroad. Vifor was informed by the Defendants vide letter dated 17.06.2022 that they were manufacturing FCM and claimed that their process was novel and therefore, the product was not infringing IN'536 as also that patent application filed by Defendant No.2/VBPL seeking Indian Patent was pending before the IPO and the product had been launched on 01.06.2022.

16. It is averred that Defendants were conspicuously silent on the brand names under which they had launched the impugned product and

details of the connection between Defendants and their respective roles were missing. Defendants also failed to disclose the earliest date of manufacture/sale/import and/or quantum of manufacture or sale of the impugned product and the modes of sale. However, despite the missing details, Vifor has no doubt that Defendants were commercializing FCM and thereby infringing IN'536.

COMMON CONTENTIONS ON BEHALF OF VIFOR:

17. IN'536 distinctly claims: (a) 'a product' (along with its medicament), in Claims 1 and 7-9; and (b) 'a process' for preparing the said product claimed in Claim 1 (Claims 2-6). A plain reading of complete specification of the patent reflects that the title, description and the claims of the patent itself cover both, i.e. product and process. The intent of the Patentee was to protect the product as well as the processes of preparing the same. The main independent claim of IN'536, Claim 1, is a product claim for FCM which pursuant to a common practice in claim drafting is more appropriately described by reference to the product which results by following an illustrative process, though other processes could also lead to the same product. Therefore, the product claim of IN'536 covers the product, howsoever made. Process elements are used as an aid to help describe the end product, which forms the subject matter of the claim, but these process elements are not limiting and thus what is claimed is the product, irrespective of the process used for its manufacture. Claim 1 is an independent product claim and most of the dependent claims are directed towards the process to prepare the product in Claim 1. On the filing date of the application in 2003, it was not easy for the applicant to describe the product pertaining to its structural characteristics in entirety and while the process terms used in Claim 1 to

describe the product do represent the exemplary process to prepare FCM, it does not limit the claim to mandate the use of the said process and covers the product *per se* regardless of the process used for its preparation.

18. This stand of the Vifor, finds support in the practice guidelines followed by IPO in prosecuting patent applications pertaining to 'product-by-process' claims, as per which the said claim should disclose a novel and inventive product and patentability cannot depend on novelty and un-obviousness of the process limitation alone. Therefore, the fact that IN'536, containing a claim in the 'product-by-process' format, has been granted in India is evidence of the novelty, inventiveness and the patentability of the product claimed therein, independent of process limitations. Section 2(1)(j) of 1970 Act defines "Invention" *'to mean a new product or process involving an inventive step and capable of industrial application'* and the Constitutional Bench of the Supreme Court in ***Punjab Land Development and Reclamation Corporation Ltd., Chandigarh v. Presiding Officer, Labour Court, Chandigarh and Others, (1990) 3 SCC 682,*** has held that the word "means" suggests an exhaustive definition and thus no other meaning can be assigned thereto. Reliance was also placed on the judgment in ***D.A.V. College Trust and Management Society and Others v. Director of Public Instructions and Others, (2019) 9 SCC 185,*** for the same proposition. Therefore, going by the plain reading of the definition of invention, it is clear that the 1970 Act recognises only "product" and "process" as capable of being patentable subject matter and no third category, as alleged by the Defendants i.e. 'product-by-process', has a statutory recognition. This is fortified by a reading of Section 48 of the 1970 Act, where the

Legislature has not used the expression 'product-by-process' and it is trite that Courts cannot add words in a statute as legislation is not the Court's domain.

19. Order passed by European Patent Office ('EPO') Opposition Division on 14.09.2016 in respect of the division application of the EU Patent corresponding to IN'536 makes it abundantly clear that protection to Vifor in the independent claim was for the new product *per se*. Pertinently, opposition was filed challenging the divisional patent EP 2287204 on the ground that scope of its claims extended beyond the content of its parent application. EPO Opposition Board rejected the opposition proceedings and noted that *"...The Opposition Division finds that claim 1 as granted does not extend beyond the content of the application as filed. In the original claim 1 from the parental application (D26) the expression "obtainable from" is used. This expression shows clearly that the subject-matter of the claim and the application is not only a water-soluble iron-carbohydrate-complex obtained but the process described in original claim 1, but also water-soluble iron-carbohydrate-complexes, which have the same essential features (a weight average molecular weight Mw of 80 kDa to 400 kDa and a ligand from oxidation products from maltodextrin) but can be obtained by other processes...."* and "*.... The process for the production of the complex is not substantial for the invention; the application of the oxidation product of a maltodextrin as ligand and the weight average Mw of the complex are the essential features of the invention...."* Although appeal was preferred against the decision of EPO Opposition Board, but the same was withdrawn and the order has attained finality. Therefore, the invention is the product itself and not merely the way of making FCM, as stated on

oath by Sir Robin Jacob in his affidavit including his cross examination in another suit being CS(COMM) 1680/2016 titled ***'Vifor (International) Ltd. v. Suven Life Sciences Ltd.'.***

20. In certain cases where the molecular composition of the invented product is large or complex such that it cannot be accurately described in the conventional sense using formula or chemical structure, the only way to describe the product is through the exemplary process of preparation of the product. This is evident from WHO's publication of the INN for FCM, which reflects the presence of several variables in the chemical formula indicating its complexity. The said chemical formula is set out below:-

$$FeIII_w([C_6H_{10}O_5]_aC_6H_{11}O_7)x(OH)_yO_z.nH_2O$$

21. By virtue of provision of Section 48 of the 1970 Act, upon grant of IN'536, Vifor has acquired exclusive right to prevent third parties, who do not have its consent, from using, making, offering for sale or importing and selling the product FCM, which is protected by IN'536 or the product obtained directly from the process protected by IN'536 in India. FCM is a product covered directly under IN'536 and has definite and unique characteristic features, such as average molecular weight between 80 kDa and 400 kDa and manufacture by any unauthorised entity of a product which exhibits the same characteristics, would amount to infringement of IN'536, by virtue of Section 48 of the 1970 Act. Defendant No.1/MSN in CS(COMM) 261/2021 is manufacturing the product FCM protected by IN'536, which is evident from its Patent Application No.201841012945. MSN's patent application mentions US patent corresponding to IN'536 as the earliest literature where FCM was disclosed and MSN has also sought approval from Indian Authorities for

building capacity to manufacture large quantities of FCM. Evidently, this is being undertaken with the aim of launching an infringing version of FCM in the near future, *albeit* Vifor has already filed pre-grant opposition to the patent application of MSN. As can be seen from the website of the Defendant, MSN's product under the brand FEINJ is FCM, a water-soluble iron carbohydrate complex with a molecular weight of approximately 150 kDa, which is between 80 kDa and 400 kDa.

22. INN FCM has been assigned by WHO to Vifor's invention in Claim 1 and the same has also been adopted by USAN Council. INN is given to a new and unique product and 'Ferric Carboxymaltose' is inextricably linked with the actual complex which is subject matter of IN'536. The INN, USAN names and CA Index name all directly correspond to the structure of Ferric Carboxymaltose recognizing it to be a complex of polynuclear iron (III) hydroxide core with oxidized maltodextrin as the carbohydrate ligand. If the claim of the Defendants is correct that they do not use maltodextrin, then they cannot be permitted to refer to their product as FCM.

23. Vifor's US Patent 'US 7612109', which corresponds to IN'536 has been listed in the US Food and Drug Administration's ('US FDA') Orange Book as the "DS" or "Drug substance" which covers FCM. Process patents, i.e. those patents which have no claim over a product cannot be enlisted in the US FDA Orange Book.

24. Regulatory approval for manufacture of FCM as "new drug" in India was awarded in favour of Plaintiff No.2/Emcure Pharmaceutical Limited on 11.02.2011, which has been marketing the patented invention since March, 2011 and second regulatory approval was thereafter granted in October, 2013, pursuant to which Vifor began commercializing its

FCM product in India under its brand Ferinject. Commercial success of Vifor's product is evident from the various Form-27 filings made in compliance with Section 146(2) of the 1970 Act read with Rule 131(1) of the 2003 Rules. Net sales of FCM in India for the period 2017-21 are close to Rs.650 Crores.

25. Strength of IN'536 is evident from the fact that patents corresponding to the suit patent have been granted in favour of Vifor in 57 jurisdictions globally including in major patent jurisdictions, such as US and EU. IN'536 is a valid and subsisting patent in the 19th year of its term spanning 20 years from 20.10.2003 in India and no pre-grant or post-grant opposition was filed challenging the suit patent.

26. Vifor has been consistently proactive and vigilant in protecting its rights and interests in IN'536 and several suits claiming infringement of the patent have been filed in this Court where interim injunctions have been granted against many third parties. Tabular representation of various suits filed by Vifor and the orders, both interim and final granted in those suits, as extracted in the plaint in CS(COMM) 448/2022 is given hereunder for ready reference:-

S. NO.	PARTICULARS OF THE MATTER	STATUS	ORDER DATE	ORDERS
1.	CS(OS) 2282/2011 VIFOR (INTERNATIONAL) LTD. VS. D. MOHAN RAO & ORS. (SYMED LABS)	Disposed of	16.09.2011	Interim Injunction
			09.09.2015	Disposed of (Undertaking)
2.	CS(OS) 4005/2014 VIFOR (INTERNATIONAL) LTD. VS. MOHAN RAM & ANR. (MAXYCON HEALTH CARE PVT. LTD.)	Disposed of	22.12.2014	Interim Injunction
			12.04.2018	Decreed (Permanent Injunction and Damages)

	[Later CS(COMM) 712/2018 VIFOR (INTERNATIONAL) LTD. & ANR. VS. MAXYCON HEALTH CARE PRIVATE LIMITED & OTHERS]			
3.	CS(OS) 4038/2014 VIFOR (INTERNATIONAL) LTD. VS. NIKUNJ GOSWAMI & ANR.	Disposed of	24.12.2014 03.09.2015	Interim Injunction Settlement
4.	CS(OS) 1179/2015 VIFOR (INTERNATIONAL) LTD. VS. SURENDER KUMAR TANEJA & ORS. (INTAS PHARMACEUTICALS LTD.)	Disposed of	29.04.2015 23.11.2015	Interim Injunction Decreed (Permanent Injunction)
5.	CS(OS) 1489/2015 VIFOR (INTERNATIONAL) LTD. VS. SANJAY PATEL & ANR. (NIKSAN PHARMACEUTICAL)	Disposed of	21.05.2015 06.10.2016	Interim Injunction Settlement
6.	CS(OS) 1488/2015 VIFOR (INTERNATIONAL) LTD. VS. GAGAN SINGH & ANR. (AVANSCURE PHARMACEUTICALS PRIVATE LIMITED)	Disposed of	21.05.2015 10.04.2018	Interim Injunction Decreed (Undertaking)
7.	CS(OS) 4083/2014 VIFOR (INTERNATIONAL) LTD. VS. MR. DHARMENDRA VORA & ANR. (EXIM PHARMA)	Disposed of	29.07.2015 07.11.2017	Interim Injunction Decreed (Permanent Injunction and Damages)

8.	CS(COMM) 1548/2016 VIFOR (INTERNATIONAL) LTD. VS. MR. G. SANU NAIR & ORS. (NEOFALCON LIFE SCIENCES AND HEALTH BIOTECH LIMITED)	Disposed of	24.11.2016	Interim Injunction
			18.01.2018	Settlement
9.	FAO(OS) (COMM) 146/2016 VIFOR (INTERNATIONAL) LIMITED VS. UDEET JEEGUL BANKER & ORS. (MANUS AKTEEVA BIOPHARMA)	Disposed of (both suit and appeal)	23.12.2016	Interim Injunction
			12.01.2017	Decreed (Undertaking)
10.	CS(COMM) 214/2017 VIFOR (INTERNATIONAL) LTD. VS. MR. VISHAL N. JAJODIA & ORS. (SWATI SPENTOSE AND ALCON BIOLIFESCIENCES)	Disposed of	21.03.2017	Interim Injunction
			15.09.2017	Settlement
11.	CS(COMM) 417/2017 VIFOR (INTERNATIONAL) LTD. VS. JIGEN BIPINCHANDRA SHAH & ANR. (JIGS CHEMICALS)	Disposed of	31.05.2017	Interim Injunction
			09.05.2018	Interim Injunction
			20.12.2018	Decreed (Undertaking)
12.	CS(OS) 4079/2014 VIFOR (INTERNATIONAL) LTD. VS. SUNILA RAIZADA & ANR. (PUNEET PHARMACEUTICALS)	Disposed of	24.12.2014	Interim Injunction
			23.04.2015	Settlement
13.	CS(COMM) 1680/2016 VIFOR (INTERNATIONAL) LTD. VS. SUVEN LIFE SCIENCES LTD.	Pending-trial ongoing	23.12.2016	Defendant ordered to be bound by the undertaking given under

				S107A of the Patents Act
			19.11.2018	Defendant agreed to be bound by the undertaking dated 23.12.2016 to be continued till the disposal of the suit
14.	CS(COMM) 1206/2015 VIFOR (INTERNATIONAL) LTD. VS. MR. PANKAJ RAMANBHAI PATEL & ANR. (ZYDUS CADILA)	Pending-trial ongoing	16.09.2015	Interim Injunction
15.	CS(COMM) 565/2017 VIFOR (INTERNATIONAL) LTD. VS. MANASI MEHTA & ORS. (LA RENON HEALTHCARE)	Pending-trial ongoing	31.07.2019 (framing issues)	No injunction order as suit for non-infringement already filed prior to suit for infringement – issues framed and parties directed to expedited trial. Interim Application still pending.
16.	CS(COMM) 261/2021 VIFOR (INTERNATIONAL) LTD. & ANR. VS. MSN LABORATORIES PVT. LTD. & ANR.	Pending-recently filed	01.06.2021	Undertaking not to infringe
17.	CS(COMM) 264/2021 VIFOR (INTERNATIONAL) LTD. & ANR. VS. UNIJULES LIFE SCIENCES LTD. & ANR.	Disposed of	02.06.2021	Interim Injunction
			11.03.2022	Settlement

18.	CS(COMM) 265/2021 VIFOR (INTERNATIONAL) LTD. & ANR. VS. DR. REDDY'S LABORATORIES LTD.	Pending-recently filed	02.06.2021	Undertaking not to infringe
19.	CS(COMM) 335/2021 VIFOR (INTERNATIONAL) LTD. & ANR. VS. ALEMBIC PHARMACEUTICAL LTD.	Disposed of	28.07.2021	Undertaking not to infringe
			26.11.2021	Settlement
20.	CS(COMM) 210/2022 VIFOR (INTERNATIONAL) LTD. & ANR. VS. HETERO HEALTHCARE LIMITED & ANR.	Pending-recently filed	05.04.2022	Interim Injunction

27. Grant of several interim injunctions in favour of Vifor pertaining to FCM not only indicates the strength of IN'536 but also shows a consistent view of different Courts in favour of protecting Vifor's rights in the suit patent. Judicial propriety demands that even in these suits, interim injunctions be granted/continued to maintain uniformity in judicial orders with respect to the same suit patent. In fact, in ***Vifor (International) Limited v. Udeet Jeegul Banker & Ors., FAO(OS) (COMM) 146/2016,*** a Division Bench of this Court on 23.12.2016 has granted interim injunction in favour of Vifor.

ABOUT THE DEFENDANTS IN CS(COMM) 261/2021:

28. MSN Laboratories Limited/Defendant No.1 is a 17-year-old leading healthcare company based out of Hyderabad and MSN Life Sciences Pvt. Ltd./Defendant No.2 is a research-based sister entity of Defendant No.1 and both are part of MSN Group of Companies. Defendant No.1 has 9 APIs and 5 finished dosage facilities globally,

including in India, with more than 650 National and International Patents (including applications), a product portfolio featuring over 350 APIs, 250 formulations covering over 35 major therapies in its portfolio.

ABOUT THE DEFENDANT IN CS(COMM) 265/2021:

29. Dr. Reddy's Laboratories Ltd./Defendant is a 37-year-old healthcare company based out of Hyderabad and is a leading pharmaceutical company manufacturing over 190 medications and over 60 APIs for diagnostic kits, critical care and biotechnology products across the globe, including India. Defendant boasts of 7 FDA plants producing APIs in India and 7 FDA-inspected and ISO 9001 (Quality) and ISO 14001 (Environmental Management) certified plants making patient-ready medications, 5 of them in India and 2 in UK.

COMMON CONTENTIONS ON BEHALF OF THE DEFENDANTS IN CS(COMM) 261/2021 AND 265/2021:

30. Paragraph 2 on page 1 of IN'536 identifies certain prior art iron deficiency treatments and stipulates that both oral and parenteral formulations were known, as also that iron carbohydrate complexes were known. The three prior art complexes identified are iron carbohydrate, iron-dextran, iron-pullulans or water soluble iron (III) hydroxide sucrose complex. Problems of the prior art identified in IN'536 are all process related, i.e. such prior art complexes are difficult to obtain and require production under pressure and high temperature and involve a hydrogenation step. The next two paragraphs are instructive of Vifor's own perception of the invention it sought to patent. Paragraph 3 on page 1 stipulates "*problem to be solved*" i.e. to provide a parenteral iron formulation which could be easily sterilized and was stable at high temperatures with a further property of reduction of toxicity and prevention of anaphylactic shocks associated with dextran-based

formulations, enabling application at high dosage rates. Despite the claimed objective, the description is silent on head-to-head comparison in this context between iron-dextran and FCM and there is no disclosure whatsoever as to the nature and character of prior art iron-carbohydrate complexes and the problems which are overcome by FCM.

31. First paragraph on page 2 of IN'536 reflects that the problem(s) identified in previous paragraphs is solved only by an iron (III) carbohydrate complex, which is obtainable using the oxidation products of maltodextrin and the only oxidation route identified is using aqueous hypochlorite. However, what is significant is that: (a) while the written description states that a TEMPO system can also be used, the examples only refer to hypochlorite; (b) the written description identifies only advantages in terms of sterilization and while there is a reference to purported LD50 values to show reduction in toxicity, there is no example which sets out how this was measured; and (c) critically, the weight average molecular weight feature of the product obtained via a route involving oxidation of maltodextrins is stipulated as being within prior art ranges of 80kDa to 400 kDa, thus, showing that this product feature was also in the prior art.

32. Scope of Claim 1 read in light of the said written description and the 1970 Act, very clearly involves a step of oxidation of maltodextrin using aqueous hypochlorite in alkaline pH range as an essential and inextricable part. Given the admissions of the fact that iron carbohydrate complexes were already known, failure or deliberate concealment by Vifor to identify such complexes and any disadvantages associated therewith, the only conclusion that can be drawn is that the purported invention resided in preparing iron carbohydrate complexes, where the

step of oxidation of maltodextrin(s) is essential to the alleged novelty and inventive step.

33. Contrary to the stand of Vifor, scope of Claim 1 of IN'536 is limited to a product obtained by or through the specific process provided therein i.e. oxidation of maltodextrin using aqueous hypochlorite and it does not cover any or all processes that may be used to obtain FCM, or any or all processes for oxidation of maltodextrin. This stand of the Defendants is fortified by the terminal disclaimer filed in US Patent Application 17/132652 which claims an iron (III) carbohydrate complex 'obtained by' oxidation of maltodextrins, based *inter alia* on US'109 as well as abandonment of US Patent Application 12/581212, a divisional application out of US'109. In the said divisional application US'212, the claims were originally identical to Claims of IN'536 and were amended based on objections to claims for a product *per se* without any limitation of the process feature on account of being non-responsive and not enabled and were therefore abandoned. Significantly, in the opposition filed by Vifor in February, 2020 to IN 3474/CHE/2013, it admits in multiple places that claim 1 of IN'536 is a process claim. Additionally, in a response filed by Vifor in EP Application 03769422.1, granted as EP1554315B1 (hereinafter referred to as EP'315), it was expressly stated that invention of Claim 1 of EP'315 is different from the cited prior art which taught oxidation of dextrin and dextran on the ground that EP'315 uses alkali material, i.e., aqueous hypochlorite. This clearly amounts to an admission that this is the only feature which distinguishes the product-by-process claim from the prior art and shows that step of oxidation of maltodextrins using aqueous hypochlorite in alkaline pH range is essential and critical to determination of the scope of Claim 1 of EP'315

and the same language is found in IN'536 in Claim 1 in India as well. In a nutshell, the argument is that use of the expression 'obtainable from' in Claim 1 makes no difference as the holistic reading of the Claim shows that Vifor had consciously restricted the product claimed to a specific process detailed therein and cannot claim monopoly outside the said process.

34. Since Claim 1 is a 'product-by-process' claim, use of different process by the Defendants to produce FCM cannot amount to infringement, as alleged. Defendants have arrived at a process, which is different from the process of Vifor and therefore cannot be accused of infringing Claims 1 and 2 of IN'536. The process employed by Defendants for manufacture of FCM involves replacement of maltodextrin-oxidising agent i.e. Oxone in place of aqueous hypochlorite used by Vifor. The chemical and the physical properties of Oxone and sodium hypochlorite are distinct and different and this difference gives an edge to the Defendants in terms of avoiding formation of undesired chlorinated by-products, inorganic impurities such as metal bromides, chlorides and carbonates, which impact the yield and purity of iron (III) Carboxymaltose, problems inherent in Vifor's process. Therefore, Defendants' process to produce FCM is different and hence, non-infringing.

CONTENTIONS ON BEHALF OF THE DEFENDANTS IN CS(COMM) 448/2022

35. No case for infringement is made out and no interim orders are therefore required to be passed by this Court. It is settled law that there are two steps for the purpose of determining infringement of a patent: (a) claim construction which involves determining the scope and meaning of the claims; and (b) comparing the claims as construed of the suit

patent, with Defendant's product/process. ***[Ref. F. Hoffmann-La Roche Ltd. & Anr. v. Cipla Ltd., 2015 SCC OnLine Del 13619]***. By applying the test laid down by this Court in ***Sotefin SA v. Indraprastha Cancer Society and Research Centre and Others, 2022 SCC OnLine Del 516***, the essential elements of the claims of the suit patent must be identified and infringement is made out only if "all elements of the claim are present in the impugned product". To the same effect is the decision of this Court in ***Nokia Corporation v. Bharat Bhogilal Patel, CS(OS) 3071/2011, dated 28.05.2014.***

36. In the present case, upon claim construction of IN'536, it is obvious that the novelty of the suit patent resides in the use of maltodextrin as a carbohydrate shell to trap iron ions whereas Defendants use starch hydrolysate as the starting material *albeit* the oxidising agent is aqueous hypochlorite. Starch hydrolysate is a broken starch having Dextron Equivalent ('DE') value greater than 25 and thus it is irrelevant whether the claims are construed as product or product-by-process.

37. During prosecution of IN'536, when prior art pertaining to iron carbohydrate complex was cited (HPCAPLUS 1960:117732/ US3,086,009-), by IPO, Vifor had specifically stated that its product was novel on account of use of 'oxidised maltodextrin', a specific type of carbohydrate in the process and is thus bound by the said stand and cannot take a contrary position. For the proposition that a party cannot be permitted to take contradictory stand, reliance was placed on the judgment of the Supreme Court in ***Union of India and Others v. N. Murugesan and Others, (2022) 2 SCC 25.***

38. Claims of IN'536 are not product claims but are simply a product derived from a specific process, which are nothing but 'product-by-

process' claims. In 'product-by-process' claims, the claims are deemed to be novel and inventive because of the characteristic features imparted by the process to the product. The claims are never construed as product claims *per se* but are inextricably tied to the process of which they are the outcome/result. The argument that in a 'product-by-process' claim, one should read the claim as a product claim, was specifically rejected by the UK Patents Court in ***Hospira UL Limited v. Genentech Inc., [2014] EWHC 3857 (Pat)*** as follows:-

> *"143. However a question not focused upon by Lord Hoffmann in Kirin- Amgen is whether the rule that the process feature is irrelevant for novelty is a rule of law of novelty or a rule of mandatory claim interpretation. To be novel, a claim of erythropoietin made by the expression of a gene in a host cell had to be different from known urinary erythropoietin. But assuming that the claim was novel, was it infringed by erythropoietin which had not been made by the expression of a gene in a host cell?*
>
> *144. Now the House of Lords also decided that the defendant's rEPO did not infringe the patent because it was not the product of the expression of a gene in a host cell (see paragraphs 13 onwards, ending at paragraph 85 which finds no infringement of any claim). Thus Lord Hoffmann was applying the process feature as a relevant limitation which was not satisfied for the purposes of (non-)infringement but ignoring it for the purposes of novelty. That can only be on the basis that the product by process rule is a rule of novelty law, not claim construction."*

39. In a 'product-by-process' claim, infringement can only lie where the product is prepared by the process of the claim in the suit patent and therefore, in order to establish infringement, Vifor will have to make out a case that the process of the Defendants is identical to the process claimed in IN'536, which it has failed to prove, even *prima facie.* ***[Ref.: Hospira UL Limited (supra)*** and ***Terrel on the Law of Patent, 18th Ed., Chapter 9, Section 8]***.

40. There are stark differences in the process used by the rival parties. Defendants' product is made of iron (FE) at the centre with starch as

carbohydrate shell and is prepared from hydrolysed starch where DE value of the said starch is always higher than 20, which is never the case with maltodextrin used by Vifor as described in the claims. Where process/product of the Defendant is different, precedent shows that Courts have invariably declined interim injunctions.

41. Significantly, Vifor has realized that iron complexes based on starch are not covered by the claims of US'109, equivalent to IN'536, where the patent is for a starch-based Iron Carbohydrate Complex, being US'564, else, there was no need to file for an additional patent for a starch-based Iron Carbohydrate Complex.

42. Vifor's product is nothing but an Iron Carbohydrate Complex and this product is known by several names in the industry such as Iron (III) Hydroxide-Polymaltose, Ferric Polymaltose, Ferro maltose, Ferrum Polymaltose, Iron Carboxymaltose, Ferric Carboxymaltose, Iron Dextri-maltose and Iron Polymaltose and therefore, no monopoly can be claimed on the name 'Ferric Carboxymaltose'. WHO specifically states that INNs are generic names and public property for use by everyone in the industry. In fact, these are names which are for the purpose of ease and convenience, given to a pharmaceutical substance. Section 13(b) of the Trade Marks Act, 1999 bars anyone from claiming proprietary rights in an INN. Therefore, any product that has iron ions and a carbohydrate shell shall fall under the category of Ferric Carboxymaltose. In any event, nomenclature of the product is not relevant and what is relevant is the claim construction. In ***Kirin-Amgen Inc. and Others v. Hoechst Marion Roussel Limited and Others***, ***[2004] UKHL 46,*** product of the Defendant was called 'Erythropoietin", yet the Court found that the product did not infringe the claims of Plaintiff's patent as the process used by the

Defendant was different from the recombinant method of the Plaintiff. In ***Hospira UL Limited (supra),*** both parties made the same product using INN 'Trastuzumab', yet declaration of non-infringement was given by the Court as the Defendant's product fell outside the claim limitations. Most importantly, Defendant has already launched its product Fur FCM in June, 2020 and therefore, even as per the settled law on balance of convenience, no interim injunction should be granted in favour of Vifor.

REJOINDER ON BEHALF OF VIFOR:

43. Defence of the Defendants against infringement of product under Claim 1 of IN'536 that the process used by the Defendants is different inasmuch as they are using a different oxidizing agent i.e. Oxone/ Hydrogen Peroxide or starting material, is wholly misplaced. The three essential elements of Claim 1 of IN'536 are iron carbohydrate complex having (i) an iron (III) core; (ii) an average molecular weight in the range of 80 kDa-400 kDa; and (iii) using oxidized maltodextrin as ligand. All the Defendants' products contain each of the three essential elements of IN'536. In ***Sotefin SA (supra),*** this Court has held that in order to show infringement, Plaintiff only needs to show that essential elements of the asserted claim are found in the impugned product. Defendants admit that their iron (III) complex has an average molecular weight within 80 kDa-400 kDa and uses oxidized maltodextrin as a ligand and difference in oxidizing agent which is the basic argument of the Defendants, is not an essential element of Claim 1.

44. The complete specification of IN'536 mentions that there are several possible oxidizing agents that can be used to oxidize the maltodextrins and therefore, the claim is essentially directed to FCM

irrespective of the process used to produce FCM. In ***Novartis AG v. Union of India and Others, (2013) 6 SCC 1***, the Supreme Court observed that if a drug manufacturer refers to its product by a particular name on the packaging or the product insert, it will be deemed to be referring to that very product and no other. In the present case, Defendants are admittedly manufacturing the product with INN FCM.

45. Defendants' reliance on majority decision in ***Abbott Laboratories v. Sandoz, Inc., 566 F.3d 1282,*** is misplaced as the decision represents a change in US law which is apparent from a reading of the dissenting opinions as also certain sections in the majority opinion, which establishes a strict bright-line rule for interpretation of product-by-process claims under US law. Majority seeks to justify its view in light of perceived inconsistency and need for clarification of US law on the subject, however, two dissenting opinions must be considered by this Court as equally persuasive. Even otherwise, while this change in US still stands, it is not the law in India or UK and EU or other common law jurisdictions. Position under UK/EU law has been clarified further in ***Hospira UL Limited (supra)*** where, while commenting upon ***Kirin-Amgen (supra)***, it is held that position in ***Hospira UL Limited (supra)*** with respect to claim interpretation for the purpose of infringement of a claim directed to a new product is *ad idem* with ***Kirin-Amgen (supra).*** In paragraph 147(i) in ***Hospira UL Limited (supra)***, Justice Birss recognises that when a claim relates to a product identical to an old product, use of the word 'obtainable' is no different than 'obtained' and this is a rule of law of novelty, however, when dealing with a new product, scope of a claim which uses the word 'obtainable' would be different from a claim using the term 'obtained'.

46. In the present case, it is clear that FCM is a new product and the language used 'obtainable from' does not restrict its scope to any particular process. Sir Robin Jacob has explained how the term product-by-process has evolved from the situation existing pre-1977 in UK when it referred to old products manufactured by new processes and were used to bestow protection upon a patentee where product is manufactured using the said process in an overseas land and brought into the country where the dispute arose. This was corrected by Legislation i.e. European Patent Convention and reflected in the new UK law, The Patents Act, 1977 and in India in Section 48(2) of 1970 Act. The expression now simply refers to a claim where a molecule, which is so large and complex, that it is impossible to define with precision, is defined by reference to one possible process that may be followed to make it but this process is not the only process and any other process may also produce the same product. Therefore, one cannot escape the liability of infringement of a product claim merely by claiming that they have a distinct/different process.

ANALYSIS AND FINDINGS:

The Patent Bargain

47. Before embarking on the journey of examining the rival claims of the parties to the *lis* pertaining to patent infringement, it would be profitable to have a close look on the *raison d'etre* behind grant of patents in India. In this context, I may allude to *'A Report on the Revision of the Law in India relating to Patents for Inventions'* known as the Ayyangar Committee Report. In the said report, under the heading *"Rewarding inventors by patent grant"*, it is stated that the patent system of rewarding inventions is based on the ethos that grant of monopoly will

automatically secure to an inventor a reward which is commensurate with the value of his invention, i.e., if invention is good, inventor should be able to exploit or sell his patent and make profit while if the invention is useless, he receives nothing.

48. Further, in the said report, it has been emphasized that patent monopoly must be used for the purpose for which it is granted. The report refers to an observation of Michel on Principle National Patent System, Vol. I, page 15, that "*Patent systems are not created in the interest of the inventor but in the interest of national economy. The rules and regulations of the patent systems are not governed by civil or common law but by political economy.*" It is further stated "s*everal theories have been put forward as regards the consideration or the quid pro quo which society receives in return for the grant of the monopoly. In the earliest law on the subject of the grant of patents in the United Kingdom, the consideration received by society as justifying the grant of monopoly was stated to be the introduction of a new manufacture within the country. At a later date it was stated that the consideration consisted in the disclosure to the public of the invention which they were at liberty to use at the expiry of the period of monopoly.*"

49. Paragraph 17 of the report captures the observations of the Swan Committee that patent system is based on the theory that opportunity of acquiring exclusive rights in an invention stimulates technical progress and this is achieved in four ways as follows:-

(i) encourages research and invention;

(ii) induces an inventor to disclose his discoveries instead of keeping them as a trade secret;

(iii) offers reward for expenses incurred in developing inventions to a stage at which they are commercially practicable; and

(iv) provides an inducement to invest capital in new lines of production which may not appear profitable if competing producers embarked on them simultaneously.

50. From a reading of the report, it emerges that the ethos of the patent system works on a *quid pro quo* where the inventor is rewarded for his invention and in return, he is required to disclose what he has invented in public interest. In light of the report, one can safely state that the foundation of the patent system is on an edifice of "bargaining" and "public interest" which means that in exchange for the monopoly rights over the inventions disclosed, the patentee gets a protection over the invention for a limited term and in turn public stands to benefit by the disclosure of newer technologies.

51. It needs no emphasis that the subject matter of an invention for which protection is sought is defined by the claims. Section 10(4) of the 1970 Act provides the mandatory requisites for the contents of a complete specification of the patent application. Section 10(4) is extracted hereunder for ready reference:-

> *"**10. Contents of specifications**. –*
>
> *(4) Every complete specification shall—*
>
> *(a) fully and particularly describe the invention and its operation or use **and the method by which it is to be performed**;*
>
> *(b) disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection; and*
>
> *(c) end with a claim or **claims defining the scope of the invention for which protection is claimed**;*
>
> *(d) be accompanied by an abstract to provide technical information on the invention. "*
>
> *(emphasis supplied)*

52. A reading of Section 10(4)(a) leads to an inevitable conclusion that when a complete specification is filed to describe the invention, it is implicit that the applicant has fully and particularly described not only the invention and its operation but also the use and "method" by which it is to be performed and the monopoly on grant of patent is limited to the scope as defined by the claims. In this context, I may refer to the judgment of the Supreme Court in ***Novartis AG (supra)***, wherein it was emphasized that the scope of monopoly rights granted by means of a patent are in exchange for the disclosure of the invention and the scope cannot travel beyond the disclosure as that would negate the fundamental rule underlying the grant of patent. Relevant passage from ***Novartis AG (supra)*** is as follows:-

> *"118. The submissions of Mr Andhyarujina and Mr Subramanium are based on making a distinction between the coverage or claim in a patent and the disclosure made therein. The submissions on behalf of the appellant can be summed up by saying that the boundary laid out by the claim for coverage is permissible to be much wider than the disclosure/enablement/teaching in a patent.*
>
> *119. The dichotomy that is sought to be drawn between coverage or claim on the one hand and disclosure or enablement or teaching in a patent on the other hand, seems to strike at the very root of the rationale of the law of patent.* ***Under the scheme of patent, a monopoly is granted to a private individual in exchange of the invention being made public so that, at the end of the patent term, the invention may belong to the people at large who may be benefited by it****. To say that the coverage in a patent might go much beyond the disclosure thus seem to negate the fundamental rule underlying the grant of patents."*
>
> *(emphasis supplied)*

53. In the aforesaid judgment, the Supreme Court expressed a concern that the law of patent should not develop such that the scope of the patent is determined not on the intrinsic worth of the invention but by artful

drafting of the claims by skilful lawyers. Relevant paragraph is as follows:-

> "*134. .... We certainly do not wish the law of patent in this country to develop on lines where there may be a vast gap between the coverage and the disclosure under the patent; where the scope of the patent is determined not on the intrinsic worth of the invention but by the artful drafting of its claims by skillful lawyers, and where patents are traded as a commodity not for production and marketing of the patented products but to search for someone who may be sued for infringement of the patent."*
>
> *(emphasis supplied)*

Nature of the patent:

54. Broadly two issues raised by Vifor can be captured as: (i) statutory regime in Indian jurisdiction does not recognise product-by-process patent; and (ii) even though described by a process, Claim 1 of Vifor is a product claim and therefore, irrespective of the process adopted by the Defendants, production of FCM would infringe IN'536.

55. Addressing the first issue first, reference be made to the *'Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals*' issued by the Office of the Controller General of Patents, Designs and Trademarks in October, 2014, more particularly, paragraph 7 thereof, wherein there is a reference to an IPAB order in the ***Research Foundation of State University of New York v. Assistant Controller of Patents, [OA/11/2009/PT/DEL].*** These Guidelines indicate that the Patent Office in India recognises the existence of product-by-process claims and this concept is not alien to the patent jurisdiction in India, else it would not have laid down the pre-requisites for assessment of novelty for product-by-process claims. Patentability of product-by-process claim depends upon the product itself if it does not depend upon the method of production, which highlights that process terms in such claims are limitations and not additional features of the product

concerned though it must be stated that assessment of novelty and the assessment of infringement are separate exercises and cannot be equated. Relevant part of paragraph 7 of the Guidelines is extracted hereunder:-

> *"7. Assessment of Novelty:*
>
> *xxx xxx xxx xxx*
>
> *7.9 Product-by-process claims:*
>
> *A claim to a product obtained or produced by a process is anticipated by any prior disclosure of that particular product per se, regardless of its method of production. In a product-by-process claim, by using only process terms, the applicant seeks rights to a product, not a process. The IPAB held in ORDER No. 200/2012 ".....**product-by-process claims** must also define a novel and unobvious product, and that its patentability cannot depend on the novelty and unobviousness of the **process limitations alone**. Therefore, the patentability of a product by process claim is based on the product itself if it does not depend on the method of production. In other words, if the product-by-process claim is the same as or obvious from a prior product, the claim is un-patentable even if the prior art product was made by a different process. Accordingly the product by process claim must define a novel and unobvious product and the patentability in such claim cannot depend on the novelty and un-obviousness of the process limitation alone.""*
>
> *(emphasis supplied)*

56. Consistent stand adopted on behalf of Vifor during the arguments that the concept of 'product-by-process' claim is unknown to the statute and practice of 'patents' in India also stands negated by the observations of the Co-ordinate Bench of this Court in ***Nippon A&L Inc. v. Controller of Patents, 2022 SCC OnLine Del 1909,*** *albeit* in the context of amendment of product-by-process claim to a pure process claim. Observations of the Court in paragraphs 36 and 37 of the judgment support the case of the Defendants that 'product-by-process' claims are known and accepted in the patent law jurisprudence in India. Relevant paragraphs are as follows:-

> *"**36.** Due to the objections raised by the Patent Office that there was no clarity as to whether the patent was for a product or for a process, the Appellant chose to restrict the patent to the 'process'*

alone. In fact, the objections raised by the Patent Office in the FER and the hearing notices themselves make it adequately clear that the patent as originally filed also had process/method claims. The language used in the objections shows that the claims as originally filed were sought for "product or process". Thus, for the Patent Office to now say that there were no process claims in the original claims and that the method claims are not supported by the description would be contrary to what is stated in the FER and the subsequent objections which were raised. The objection of the Patent Office was that the there was no clarity in the application of the Appellant as to whether the monopoly was sought for a product or for a process. In the face of such an objection, the Appellant has sought to limit the claims to the method i.e., the process, to its own detriment. By so amending the claims, the Appellant loses the claim of exclusivity for the copolymer latex as a product.

37. *It is common understanding in the field of patents that product claims are much broader claims then process claims. A product claim, if granted, confers a monopoly on the patentee for the product itself, irrespective of the process by which the said product could have been made. However, in the case of a process claim, the exclusivity or the monopoly is restricted to the manner/method by which a particular product is manufactured and if the same product is manufactured or achieved through a different process/method, the exclusivity of the patentee cannot usually extend to such different process or to the product manufactured by the different process.* ***When there are 'product by process' claims, however, the extent of monopoly depends upon the reading of the claims in each case.*** *In the present case, the amendment of the claims from 'product by process claims ', wherein the copolymer latex has various features and can be manufactured by the process described in the specification, to merely the process of manufacturing the copolymer latex is clearly a step down for the patentee."*

(emphasis supplied)

57. Learned counsel for Vifor had also taken the Court to the provisions of Sections 2(1)(j) and 48 of the 1970 Act in the endeavour to highlight the alleged absence of 'product-by-process' patent and it was urged that the legislative scheme knows only of 'product' and 'process' patents. To my mind, this argument is based on an incorrect reading of the provisions and in this context it would suffice to refer to the judgment of the House of Lords in ***Kirin-Amgen (supra).*** This judgment is especially relevant on account of similitude of facts and the statutory

provisions considered in the said case, which are *pari materia* to Section 48 of 1970 Act. Before proceeding further, I may extract few passages from ***Kirin-Amgen (supra)***, as follows:-

> *"86. TKT appeals against the rejection by both the judge and the Court of Appeal of its challenge to claim 26 on the ground of anticipation. This raises a point of principle about what counts as a new product.*
>
> *87. Section 1(1)(a) of the Act says that a patent may be granted only for an invention which is new and section 2(1) says that an invention shall be taken to be new if it does not form part of the state of the art. The Act assumes that any invention will be either a product or a process (see the definition of infringement in section 60.) Claim 26 is to a product, namely a polypeptide which is the expression in a host cell of a DNA sequence in accordance with claim 1. Such a product is EPO and the question is whether it is new or the same as the EPO which was already part of the state of the art, namely the uEPO which Miyake and others had purified from urine.*
>
> *88. The practice in the United Kingdom under the Patents Act 1949 and earlier was to treat the fact that a product was made by a new process as sufficient to distinguish it from an identical product which was already part of the state of the art. This was not particularly logical, because the history of how a product was made is not an attribute which it carries around and makes it something new. It was still the same product, even if made in a different way. But the English practice had practical advantages when the extent of protection conferred by a patent was undefined (as it was until 1977) and it was assumed that a process claim could be infringed only by using that process in the United Kingdom. A product-by-process claim had the advantage of enabling the inventor of a new process to pursue not only the manufacturer who infringed his claim to the process but also, by virtue of the separate "product-by-process" claim, anyone who dealt in a product which had been made by that process. That was particularly useful in the case of the importation of a product made by someone outside the jurisdiction by a process which would have infringed the process claim if it had been made in this country.*
>
> ***89. The EPC, however, contains a provision which allows a patentee to rely directly on his process claim to allege infringement of a product made (whether within the jurisdiction or abroad) by that process. This is article 64(2) (given effect in United Kingdom domestic law by section 60(1)(c) of the Act):***

> ***"If the subject-matter of the European patent is a process, the protection conferred by the patent shall extend to the products directly obtained by such process."***

90. This provision largely removes the practical argument for allowing product-by-process claims. The European Patent Office has therefore been able to accept the logical argument that a new process is not enough to make the product new. It will not ordinarily accept a "product-by-process" claim. ***A patentee who wishes to complain of dealings in a product made by his patented process must rely on his process claim and article 64(2).*** *The principle is clearly stated by the Technical Board of Appeal in International Flavors & Fragrances Inc [1984] OJ EPO 309, in which the United Kingdom was singled out as the only Member State of the EPC which accepted product-by-process claims.*

91. The only case in which the EPO will accept a claim to a product defined in terms of its process of manufacture is when the product is new in the sense of being different from any existing product in the state of the art but the difference cannot be described in chemical or physical terms. As the Board said in International Flavors (at paragraph 8):

> *"This may well be the only way to define certain natural products or macromolecular materials of unidentified or complex composition which have not yet been defined structurally."*

92. When the application for the patent in suit was made to the EPO, both claims 19 and 26 were product claims in which the product was described wholly or partly in terms of the way it was made. In the case of claim 19, it was a claim to EPO which was (a) in the form of Table VI ("or any allelic variant or derivative thereof") and (b) "the product of ... expression of an exogenous DNA sequence". The Technical Board found on the evidence that EPO which complied with these descriptions would not necessarily be different from uEPO and therefore rejected the claim. Amgen were therefore put to finding some distinction between the patented EPO and uEPO. They amended the claim by adding the words "and which has higher molecular weight by SDS-PAGE from erythropoietin isolated from urinary sources." I shall come back to the sufficiency of such a claim but there is no doubt that the product would, by definition, be different from uEPO.

93. In the case of claim 26, the EPO was defined as the product of the expression, in a eucaryotic host of a DNA sequence according to claim 1. This is verbally different from the definition in claim 19, which applies to the expression of any exogenous DNA sequence, although whether this makes any practical difference is another matter. The Technical Board found on the evidence that expression in a eucaryotic host?

"will ensure glycosylation of the product, thus distinguishing it from the prior art."

94. The Board went on to say:

"The Board is on the evidence prepared to presume that the limitation to the polypeptide being a product makeable using the DNA of Claim 1 is a technical feature which ensures that it has a glycosylation pattern different from the known uEPO."

95. I must confess to being a little puzzled by these findings. It is unclear to me whether the technical feature which ensured novelty was the use of a eucaryotic host cell (as the first quotation above suggests) or whether it was the use of DNA according to claim 1 (as the second quotation suggests). It is true that glycosylation occurs only in eucaryotic cells, but that is no distinction from the prior art because human cells are eucaryotic. Likewise, the DNA of Claim 1 was alleged to be the human EPO gene as sequenced by Dr Lin. Nor can I quite understand why the Board arrived at a different conclusion in respect of the facts relevant to claim 19. But for present purposes none of this matters: the decision of the Board on claim 26 was based upon a finding of fact that it was necessarily different from uEPO.

96. Neuberger J, on the other hand, found as a fact that there was no difference between uEPO and EPO made according to claim 26. He drew no distinction between EPO made in accordance with claim 19 and EPO made in accordance with claim 26, calling them both recombinant EPO ("rEPO"). He found (at paragraphs 545 to 557) that there was no necessary distinction between rEPO and uEPO. It seems clear that if the European Patent Office had made similar findings of fact, it would have rejected claim 26. So TKT say that Neuberger J ought to have held it had been anticipated.

97. Both the judge and the Court of Appeal rejected this argument as a matter of law, and for similar reasons. In the Court of Appeal, Aldous LJ said:

"The [Technical] Board [of the EPO] accepted that it is permissible to have a claim to a product defined in terms of a process of manufacture, but state that such claims should only be granted in cases when the product cannot be satisfactorily defined by reference to its composition, structure or other testable parameter. That is a rule of practice which is not the concern of the national courts."

98. That is, I must respectfully say, an incomplete statement of the position of the Board. The first requirement is that the product must be new and that a difference in the method of manufacturing an identical product does not make it new. ***It is only if the product is different but the difference cannot in practice be satisfactorily defined by reference to its composition etc that a definition by***

process of manufacture is allowed. The latter may be a rule of practice but the proposition that an identical product made by a new process does not count as new is in my opinion a proposition of law. It cannot be new in law but not new for the purposes of the practice of the Office.

99. Aldous LJ then went on to say "it seems that the Office concluded that claim 26 fell within the type of case where the product could not be satisfactorily defined by its features." That is true, but again incomplete. The important point is that the Office found that rEPO according to claim 26 was a new product because its glycosolation pattern would necessarily be different from that of uEPO. Once this finding of fact was removed, there was no basis for allowing claim 26.

100. Aldous LJ also relied upon article 64(2) as being consistent with a product-by-process claim. But in my opinion it leads to exactly the opposite conclusion and the Technical Board in International Flavors so held. The point of article 64(2) is to extend the protection afforded by a process claim to a product directly made by that process and to make it unnecessary to claim the product defined by reference to the process.

101. I think it is important that the United Kingdom should apply the same law as the EPO and the other Member States when deciding what counts as new for the purposes of the EPC: compare Merrell Dow Pharmaceuticals Inc v H.N. Norton & Co Ltd [1996] RPC 76, 82. It is true that this means a change in a practice which has existed for many years. But the difference is unlikely to be of great practical importance because a patentee can rely instead on the process claim and article 64(2). It would be most unfortunate if we were to uphold the validity of a patent which would on identical facts have been revoked in opposition proceedings in the EPO. I would therefore allow this part of the appeal and declare claim 26 invalid on the ground of anticipation."

(emphasis supplied)

58. To continue further, reference be made to the decision of the Technical Board of Appeal of the European Patent Convention in ***T 0150/82*** titled ***International Flavors & Fragrances Inc, [1984] O.J. EPO 309***, which has also been referred to in ***Kirin-Amgen (supra)*** and considered by the Court. It is pertinent to note that in ***International Flavors & Fragrances Inc (supra),*** the specific contention that protection provided by product-by-process claim would be equal to that

enjoyed by the product *per se*, with no restriction on the method of its preparation, was categorically rejected. Relevant extracts from the said decision are as follows:

> *"7. Inventions fall either into the category of products, e.g. articles, devices or materials, or of processes, e.g. methods of preparing product, or using an article, or obtaining a result. Nevertheless, the invention defined in the claims for products or for processes must all be novel, inventive and industrially applicable according to Article 52(1). Whilst a process may well be novel and deserves full protection in view of its inventiveness, the same may not be true for its product if that is known or obvious in the light of the state of the art. Notwithstanding this, the special protection provided by Article 64 (2) EPC extends even to products which are not themselves inventions. According to the submissions of the appellants, the protection provided by "product-by-process" claims should go beyond the limits of "direct products" in Article 64(2) and ought to be equal to that enjoyed by products which are claimed per se, with no restriction to the details of their preparation. This, irrespective of the fact that the product protected in this manner may not represent an invention at all, as such.*
>
> *8. The Guidelines for Examination in the EPO (C. III. 4.7b) allows claims for products defined in terms of a process of manufacture provided the products themselves fulfil the requirements for patentability. This may well be the only way to define certain natural products or macromolecular materials, of unidentified or complex composition which have not yet been defined structurally. Nevertheless before such claims are allowable their patentability as products must be established since such definition is in lieu of the normal definition by structure.*
>
> *9. The appellants referred to German law in this respect and alleged that product-by-process claims had also been validly granted in cases where the product itself was not patentable. The evidence submitted in this respect by Dr. Goddar refers to Benkard 7. Ed. page 353 and 355. It is clear that the statements there relate to the question of direct product protection for processes under $9 (2) (3) of the Patent Law which is analogous to Article 64(2) EPC. It is apparent that the submitted Opinion is silent about the more relevant entries in the same textbook (e.g. Benkard, 7. Ed. $1.14 on page 124, 86 on pages 158 and 159, and 88 (dc) on page 159) where it is clearly indicated that a claim to a patentable product is allowable as long as neither the structure nor the physical characteristics of the material are known. This is based on the appropriate decisions of the Supreme Court and the Federal Patent Court ("Trioxan" B1PMZ, 1971, 73, pp. 374-33; BPatGE- 20, pp. 20-25, 1 BGHZ 57.1.). There is no suggestion in the attached*

documents that unpatentable products could be expressly claimed in this manner.

10. An earlier decision of the Board already established that "the effect of a process manifests itself in the result, i.e. in the product in chemical cases, together with all its internal characteristics and the consequence of its origin, e.g. quality, yield and economic value". ("Gelation/Exxon" T 119/82, 12.12.1983). Although problems may be recognised in processes known in the state of the art which are then removed by appropriate modifications or by an altogether different approach, the effect of such measures en route ultimately manifests itself in the technical and economic characteristics of the product, the real purpose of the exercise. ***Whilst some features of such end-effects may be drawn into the definition of the process for reasons of clarity and of conciseness, the product is in consequence of the invention, without being the invention itself, which is rather the novel interaction represented by the process in such cases. Any attempt to claim the in itself non-inventive product by means of product-by-process claims is claiming the mere effects instead****. Whilst reliance on the provisions on Article 64(2) EPC may nevertheless provide protection beyond the invention in processes leading to known or patentable products alike, this should not be afforded for both kinds of product themselves on the same footing, irrespective of their character. This must therefore be rejected as unjustified and contrary to the requirements of Article 52(1) and 84 EPC. The Board takes the view that in order to minimise uncertainty, the form for a claim to a patentable product as such defined in terms of a process of manufacture (i.e. "product-by- process claims"), should be reserved for cases where the product cannot be satisfactorily defined by reference to its composition, structure or some other testable parameters.*

11. The Board has seriously considered the well known fact that both "omnibus" and "product-by-process" claims were commonly admitted in the United Kingdom, one of the member states of the Convention. Nevertheless, it is also important to note that in no other member state have they gained acceptance beyond a manner of claiming structurally undefinable product inventions, and there appears to be no room under the Articles or Rules of the Convention to admit such claims on the basis of practice in a single Contracting State. Since the appeal is unsuccessful as regards the issues under consideration, the refund of the appeal fee must be rejected."

(emphasis supplied)

59. Decisions in ***Kirin-Amgen (supra)*** and ***International Flavors & Fragrances Inc (supra)***, are relevant as Section 48(2) of the 1970 Act is *pari materia* to Section 60(1)(c) of the UK Patents Act, 1977 and Article

64(2) of the European Patent Convention, which can be seen from the comparative table below:-

Section 48(b) - India	Section 60(1)(c) - UK	Article 64(2) – EPC
(b) where the subject matter of the patent is a process, the exclusive right to prevent third parties, who do not have his consent, from the act of using that process, and from the act of using, offering for sale, selling or importing for those purposes ***the product obtained directly by that process in India****.*	*(c) where the invention is a process, he disposes of, offers to dispose of, uses or imports any* ***product obtained directly by means of that process*** *or keeps any such product whether for disposal or otherwise.*	*(2) If the subject-matter of the European patent is a process, the protection conferred by the patent shall extend to the* ***products directly obtained by such process****.*

60. Coming now to the second issue which directly concerns IN'536. Before moving to claim construction, it would aid to look at definitions in Black's Law Dictionary, 8th Ed., wherein 'product claim' is defined as "*a patent claim that covers the structure, apparatus or composition of a product"* while 'process claim' is defined as "*a patent claim that describes by steps what is done to the subject matter usually a substance in order to achieve a useful result."* 'Product-by-process claim' is defined as "*a patent claim defining a product through the process by which it is made".* It is not Vifor's claim that IN'536 is a process claim. To be categorised as a product claim, a product must be described by its composition and structure, both physical and chemical and not limited by a process. Claim 1 does not fit into the definition of 'product claim' and the limitations on obtaining FCM by a specified process defined in the said claim aligns it with a 'product-by-process claim'. The reasons for this conclusion are adverted to in the later part of the judgment. Insistence of Vifor to treat Claim 1 as a product claim would, in fact, trigger issues

of clarity and sufficiency of disclosure and will be hit by non-compliance of Section 10(5) of the 1970 Act, besides reducing the process terms to a dead letter, even when the process steps are the essence of the claims, both in quantitative and qualitative terms. Be it ingeminated that in an another suit being CS(OS) 1206/2015 filed by Vifor, Court permitted the Defendants to manufacture the water soluble iron carbohydrate complex using a different process which did not infringe the patent of the Plaintiff and this, in my view, recognizes that IN'536 is a product-by-process patent, else the Court would have injuncted the Defendants, since in a product patent the process is irrelevant. Relevant extract of the order dated 16.09.2015 is as follows:

> *"It may be noted that once the plaintiff has a registered patent, defendants cannot use the subject matter of the patent and can only use a process of manufacture which does not infringe the patent of the plaintiff for manufacture of the water-soluble iron carbohydrate complex. It may be noted that learned senior counsel for the defendants states that defendants are not and do not intend to violate the plaintiff's patent and the defendants claim to be using a different process which is not the subject matter of plaintiff's patent."*
>
> *(emphasis supplied)*

Claim Construction:

61. The next question that posits is 'why claim construction?'. As per Section 10 of the 1970 Act, claims define the scope of the patent and that in turn defines not just the boundaries of coverage of the invention, but also plays a pivotal role in determining the economic value of a patent. The broader the scope of invention, the larger the number of competing products or processes that will infringe the patent and consequently, larger would be its economic value. Subject to other provisions of the 1970 Act, grant of patent under the Act confers upon the patentee the exclusive right to prevent third parties from making, using, selling, importing or offering to sell, without the consent of the patentee, the

patented product and where the subject matter of the patent is a process, from using the said process. Therefore, when the patentee sues the alleged infringer, patentee will endeavour to establish that the infringer's product/process is within the scope of the patent of the patentee while the accused infringer will seek to carve out its product/process from the scope of the patented claims. Either way, the decision would have to be predicated on construing the claims and therefore the real challenge for adjudicating the claim of infringement of a patent will be to construe the scope of the claims. In the present case, since Defendants plead non-infringement of IN'536 predicating their case on difference in the respective processes, without prejudice to the argument of invalidity, it becomes imperative to construe the claims of Vifor in order to ascertain the actual scope of the claimed invention.

62. Before entering into the exercise of claim construction, it would be beneficial to refer to the following three components, which form part of a patent claim:

(i) A 'preamble': setting forth a general description of the invention, which may also identify the category of invention and also the purpose of the invention;

(ii) A 'transitional phrase': specifying whether the preamble is restricted only to the components mentioned or if the claim covers products or processes that include more elements; and

(iii) The 'body of the claim': reciting the limitations of the claim and the relationship between the different limitations.

63. Process of determining if a product/process infringes the patented product/process involves two primary steps. First step in this determination is to construe the language of the claim to define the legal

scope of the claim. The next step involves comparison of the rival product/process to ascertain if the alleged infringer's product/process has trespassed the boundaries of the scope of patented claims, either literally, in terms of the text of the claims or in accordance with the concept of equivalents. It is only where the limitations of the scope of claims are trespassed, can the patentee complain of infringement.

64. Principles of claim construction have been elucidated in the judgment in ***F. Hoffmann-La Roche Ltd. & Anr. (supra),*** wherein relying on ***Herbert Markman v. Westview***, ***52 F.3d 967,*** the Division Bench of this Court held that infringement analysis of a patent involves two steps: (a) determining the meaning, scope and ambit of the suit patent claims; and (b) comparing the construed claims with the allegedly infringing product/process. The principles culled out are as follows:-

> ***"67.*** *For the above conspectus, pithily put, principles of claim construction could be summarized as under:-*
>
> *(i)* ***Claims define the territory or scope of protection*** *(Section 10(4) (c) of the Patents Act, 1970.*
>
> *(ii) There is no limit to the number of claims except that after ten claims there is an additional fee per claim (1st Schedule of the Act).*
>
> *(iii) Claims can be independent or dependent.*
>
> *(iv) The broad structure of set of claims is an inverted pyramid with the broadest at the top and the narrowest at the bottom (Manual of Patents Office - Practice and procedure).*
>
> *(v) Patent laws of various countries lay down rules for drafting of claims and these rules are used by Courts while interpreting claims.*
>
> *(vi) One rule is that claims are a single sentence defining an invention or an inventive concept.*
>
> *(vii) Different claims define different embodiments of same inventive concept.*
>
> *(viii) The first claim is a parent or mother claim while remaining claims are referred to as subsidiary claims.*
>
> *(ix) If subsidiary claims contain an independent inventive concept different from the main claim then the Patent office will insist on the filing of a divisional application.*

(x) Subject matter of claims can be product, substances, apparatus or articles; alternatively methods or process for producing said products etc. They may be formulations, mixtures of various substance including recipes. Dosage regimes or in some countries methods of use or treatment may also be claimed.

(xi) Where claims are 'dependent' it incorporates by reference 'everything in the parent claim, and adds some further statement, limitations or restrictions'. (Landis on Mechanics of Patent Claim Drafting).

(xii) Where claims are 'independent' although relating to the same inventive concept this implies that the 'independent claim stands alone, includes all its necessary limitations, and is not dependent upon and does not include limitations from any other claim to make it complete .... An independent Claim can be the broadest scope claim. It has fewer limitations than any dependent claim which is dependent upon it'. (Landis on Mechanics of Patent Claim Drafting)

(xiii) For someone wishing to invalidate a patent the said person must invalidate each claim separately and independently as it is quite likely that some claims may be valid even while some are invalid.

(xiv) At the beginning of an infringement action the Courts in the United States conduct what is known as a 'Markman hearing' to define the scope of the claims or to throw light on certain ambiguous terms used in the claims. Although this is not technically done in India but functionally most Judges will resort to a similar exercise in trying to understand the scope and meaning of the claims including its terms."

(emphasis supplied)

65. Claims of Vifor are to be construed in light of the aforesaid principles to understand their scope and limitations and for this analysis, the Claims are extracted hereunder for ready reference:-

"<u>WE CLAIM</u>

1. Water soluble iron carbohydrate complexes obtainable from an aqueous solution of iron (III) salt and an aqueous solution of the oxidation product of one or more maltrodextrins using an aqueous hypochlorite solution at a pH-value within the alkaline range, where, when one maltodextrin is applied, its dextrose equivalent lies between 5 and 20, and when a mixture of several maltodextrins is applied, the dextrose equivalent of the mixture lies between 5 and 20 and the dextrose equivalent of each individual maltodextrin contained in the mixture lies between 2 and 40, wherein the obtained

iron complexes have an average molecular weight of 80 kDa to 400 kDa.

2. A process for producing an iron carbohydrate complex as claimed in Claim 1, wherein one or more maltrodextrins are oxidized in an aqueous solution at an alkaline pH-value using an aqueous hypochlorite solution and the obtained solution is reacted with an aqueous solution of an iron (III) salt, wherein, when one maltodextrin is applied, its dextrose equivalent lies between 5 and 20, and when a mixture of several maltodextrins is applied, the dextrose equivalent of the mixture lies between 5 and 20 and the dextrose equivalent of each individual maltodextrins contained in the mixtures lies between 2 and 40.

3. A process as claimed in claim 2, wherein the oxidation of the maltodextrin or the maltodextrins is carried out in the presence of bromide ions.

4. A process as claimed in claim 2 or 3, wherein the iron (III) chloride is used as the iron (III) salt.

5. A process as claimed in claims 2, 3 or 4, wherein the oxidized maltrodextrin and the iron (III) salt are mixed to form an aqueous solution having a pH-value so low that no hydrolysis of the iron (III) salt occurs, whereafter the pH is raised to 5 to 12 by the addition of a base.

6. A process as claimed in any of claims 3 to 5, wherein the reaction is carried out at a temperature of 15°C up to boiling point for 15 minutes up to several hours.

7. A medicament containing an aqueous solution of an iron carbohydrate complex as claimed in claim 1 or 2 or obtained in accordance with any of claims 3 to 6.

8. A medicament as claimed in claim 7 formulated for parenteral or oral application.

9. Water-soluble iron carbohydrate complex as claimed in claim 1 for therapy or prophylaxis of iron deficiency."

66. As captured above, preamble of Claim 1 recites 'water-soluble iron carbohydrate complexes' and 'obtainable from' is the transition phrase. The limitations to the preamble are expressed in the form of process terms. The process is limited by the requirement of using an aqueous solution of iron (III) salt and an aqueous solution of oxidation product of one or more maltodextrins using an aqueous hypochlorite solution at a pH-value within the alkaline range. This process is further limited by

specifying that where one maltodextrin is applied, its DE value lies between 5 and 20 and when a mixture of several maltodextrins is applied, DE value of the mixture lies between 5 and 20 and the DE value of each individual maltodextrin contained in the mixture lies between 2 and 40. The process so claimed results in iron carbohydrate complexes with a defined average molecular weight between the range 80 kDa to 400 kDa.

67. Claim 1 thus refers to the product followed by description of the sequence of using aqueous solution of oxidation product of one or more maltodextrins in an alkaline pH in the presence of a specified oxidising agent i.e. aqueous hypochlorite solution, where the end product i.e. iron carbohydrate complexes have a defined average molecular weight and the limitation to the product by the process is *prima facie* evident. Stand of Vifor that the claim as drafted is a product claim and/or that even with the limitation of the process, the claim leads to a product claim only, would render the description of the claim with a detailed and a specific process meaningless and *otiose.* Therefore, *prima facie* IN'536 is a product-by-process claim and monopoly will be limited to the product obtained by the specific process in the claims, going by the first principles delineated in ***F. Hoffmann-La Roche Ltd. & Anr. (supra),*** that claims define the territory or scope of protection.

68. Great emphasis was laid by Mr. Anand on the expression *'obtainable from'* in Claim 1 to argue that what has been described as a process is only one of the many ways in which FCM can be produced and this claim cannot be construed as limiting the product by the process prescribed. In a nutshell, according to him, the process being irrelevant, no matter the variation in the process adopted by the Defendants, once it is shown that Defendants produce FCM, by whichever process, they

infringe IN'536. This contention merits rejection. Product-by-process claims were subject matter of consideration by the UK Patents Court in ***Hospira UL Limited (supra),*** where the Court also considered the thin line of distinction between: (a) product 'obtained by' a process; and (b) a product 'obtainable by' a process and relevant paragraphs are as under:-

> *"125. Product by process claims are tricky. Before coming to the House of Lords in Kirin Amgen there are some background matters to deal with.*
>
> *126. One of the key problems which a system of patents for inventions has to handle is how to legislate for future inventive (non-obvious) developments. By definition they are often hard to foresee. One way this is done is to give inventors more or less complete freedom in the drafting of their patent applications. They can define the invention in a claim in any way and using any language they like so long as the definition is clear to a person skilled in the art and the invention satisfies various other criteria.*
>
> *127. Most inventions are either products or processes and it has proved possible for the law to define acts of infringement by reference to these different kinds of inventions. Section 60 of the Patents Act 1977 does just this. It is based on the Community Patent Convention (CPC) rather than the EPC. The way s60(1) is drafted one might assume that an invention must be either a product or a process. There is no such rule. By and large the system works but there can be difficulties. A well known example is a new pharmaceutical use of an old drug which gives rise to Swiss style claims. Infringement of these claims is often argued only under s60(2) (infringement by supplying means essential) which avoids the problem of deciding whether it is a product or a process.*
>
> *128. Another kind of claim which straddles the boundary between products and processes is a product by process claim. As a matter of language there are two kinds: (1) a product "obtained by" a process, and (2) a product "obtainable by" a process.* ***At least at first sight*** *they are different.*
>
> *129. At first sight the scope of a claim to a product "obtained by" a process would be only to products which had actually been made by the process. There might be problems of proof in an infringement case or for novelty but conceptually there is no difficulty. If no products had ever been made that way in the past, then the claim would be novel.* ***The fact that such products are physically entirely identical to products made in the past would not alter the fact that no product made by that process had been made available to the public before. They would only be infringed by products actually***

made by the relevant process. This was the view taken of product by process claims in the Court of Appeal in Kirin Amgen ([2002] EWCA Civ 1096, [2003] RPC 3).

130. There can be clarity problems, particularly if the process conditions are not specified carefully, but in the past there was good reason to have such claims. Before s60(1)(c) was enacted (based on the CPC and Art 64(2) EPC) it was not clear that a process claim was infringed by selling a product of the process. Even today there may still be a motive for seeking such a claim because the inventor wishes to catch a product made by a process but not directly so (but query if that leads into problems of the "tin whistle on a ship" variety). On the other hand some "obtained by" claims may well be regarded as abusive in simply being an attempt to re-patent an old thing by reference to a spurious change in process conditions.

131. Turning to "obtainable by" claims, they are no panacea and present their own conceptual difficulties. The point of such a claim is to cover a product which was not made by the defined process but could have been. One might ask how a product which was in fact made one way could ever have been made a different way. What the process language in these kinds of claims is really intended to be referring to is a particular characteristic or characteristics of the product. So in the Johnson Matthey case cited in argument (T956/04) the patentee wanted to define the product (a catalyst) by reference to the size distribution of crystallites. The information in the patent would allow them to specify actual values for other characteristics (such as preferred amounts of cobalt) but the only way to define the product by reference to the characteristic of crystallite size distribution was by reference to the process conditions which produced that particular distribution.

132. In other words what the patentee was trying to do was claim a product irrespective of how it was made but with a particular characteristic which is the same characteristic which results from using a given process. If it is clear what the characteristic is and is true that in fact process conditions can be specified which do produce the given characteristic then one can see why this makes sense. Claim 1 in Johnson Matthey used the "obtainable by" language.

133. So "obtainable by" claims create an additional potential problem of clarity over and above the "obtained by" claims. Unless the claim specifies the characteristic being referred to, how is the skilled reader to know which characteristic is being referred to?

134. The view taken by the EPO in the 1980s (see e.g. IFF / Claim Categories T150/82 and later cases T248/85 and T219/83) was firmly against the idea that an old thing could be patented using product by process language. The EPO held that defining a product by the process by which it was made could not confer novelty on a

> *product which was known per se. The product itself had to be novel. In effect in these cases the EPO was deciding to treat "obtained by" claims and "obtainable by" claims in the same way, at least for its purposes, i.e. for validity. Regardless of the claim wording, all claims were treated as if they meant "obtainable by". If the process conferred a particular characteristic on the product then one could take that characteristic into account. But if not, then the process feature made no difference and the product was not different from the prior art. The product would lack novelty.*
>
> *135. The EPO's approach to overt product by process claims today is settled. They will be permitted (and only permitted) if there is no other way of defining the product open to the patentee. This is a decision based on policy. Such claims present clarity problems and are best avoided but if there is no alternative way of defining the characteristic in question, then they will be permitted."*
>
> *(emphasis supplied)*

69. Reference may be made in this regard to *'Chisum on Patents: A Treatise on the Law of Patentability, Validity and Infringement'* by Donald Chisum, wherein a product-by-process claim has been defined as one in which the product is defined at least in part in terms of the method or process by which it is made. This definition has been referred to by the Court of Appeals for the Federal Circuit of the United States in ***Atlantic Thermoplastics Co., Inc. v. Faytex Corporation, 970 F.2d 834***.

70. Contention of Vifor that Claim 1 of IN'536 is a product claim, is also not supported by the complete specification of the suit patent, which by its plain reading points to the contrary and relevant portion is as follows:-

> *"The problem to be solved by the present invention is to provide an iron preparation which is especially to be applied parenterally and which can easily be sterilized; the known parenterally applicable preparations on the basis of sucrose and dextran were only stable at temperatures up to 100° C., which made sterilisation difficult. Further, the preparation to be provided by the invention shall have reduced toxicity and shall avoid dangerous anaphylactic shocks which can be induced by dextran. Also, the stability of the complexes of the preparation shall be high in order to enable a high applicable dosage and a high rate of application. Furthermore, the iron*

preparation is to be producible from easily obtainable starting products and without great effort.

xxx xxx xxx

In accordance with the present invention ***the problem can be solved by providing iron (III) carbohydrate complexes on the basis of the oxidation products of maltodextrins****. Therefore, an object of the present invention are water soluble iron carbohydrate complexes which are obtainable from an aqueous solution of an iron (III) salt and an aqueous solution of the oxidation product of one or more maltodextrins, using an aqueous hypochlorite solution at an alkaline pH-value of e.g. 8 to 12 where, when one maltodextrin is applied, its dextrose equivalent lies between 5 and 20, and when a mixture of several maltodextrins is applied, the dextrose equivalent of the mixture lies between 5 and 20 and the dextrose equivalent of each individual maltodextrin contained in the mixture lies between 2 and 40.*

A further object of the present invention is a process for producing the iron carbohydrate complexes according to the invention wherein one or more maltodextrins are oxidized in an aqueous solution at an alkaline pH-value of e.g. 8 to 12 using an aqueous hypochlorite solution and reacting the obtained solution with an aqueous solution of an iron (III) salt where, when one maltodextrin is applied, its dextrose equivalent lies between 5 and 20, and when a mixture of several maltodextrins is applied, the dextrose equivalent of the mixture lies between 5 and 20 and the dextrose equivalent of each individual maltodextrin contained in the mixture lies between 2 and 40."

(emphasis supplied)

71. As rightly contended by the Defendants, there is an admission by Vifor that use of iron carbohydrate complexes is known and a water-soluble iron (III) hydroxide sucrose complex is a frequently and successfully used preparation. It is stated that the problem to be solved by the present invention is to provide an iron preparation which is especially to be applied parenterally and can be easily sterilized as the known parenterally applicable preparations on the basis of sucrose and dextran were only stable at temperatures up to 100°C, which made sterilization difficult. It is categorically asseverated in the complete specification that present invention is a process for producing iron carbohydrate complexes

wherein one or more ‘maltodextrins’ are oxidized in an aqueous solution at an alkaline ‘pH’ using ‘aqueous hypochlorite solution’ and further that when one maltodextrin is applied, the DE value is between 5 and 20 and when mixture of several maltodextrin is applied, the DE value of the mixture lies between 5 and 20 and the DE value of each individual maltodextrin contained in the mixture lies between 2 and 40. Given the admission of Vifor in the complete specification that iron carbohydrate complexes were already known, the only *prima facie* conclusion that this Court can reach is that the purported invention resides in preparing iron carbohydrate complexes with maltodextrin as the starting material and/or the step of oxidation using the specified oxidizing agent i.e. aqueous hypochlorite solution. In fact, what Vifor overlooks in making the submission that the process is inconsequential, is that the characteristic properties that it claims in FCM, distinguished from the prior art, are a direct result of the process used by Vifor, an admission that it makes during the prosecution of the patent application and is glaringly evident in the complete specification. Therefore, the scope of Claim 1 of IN’536 is limited to a product obtained through a specific process feature identified therein and cannot cover any and all processes that may be used by a third party to produce FCM and it is thus held that Claim 1 is a product-by-process claim and not a pure product claim.

72. The stand now taken by Vifor claiming that Claim 1 is a product claim, though ingenious, is further dented by a close look at the prosecution history of IN’536. During these proceedings, the Assistant Controller of Patents and Designs had in the First Examination Report (‘FER’) dated 10.12.2007 raised an objection to the Patent application of Vifor on the ground that the claimed invention was not novel under

Section 2(1)(j) of the 1970 Act, citing 5 prior art documents. In response to the FER vide letter dated 19.12.2007, Vifor had limited the invention to iron (III) complexes, having an average molecular weight of 80 kDa to 400 kDa and stated that the essence of invention resided in appropriately selecting suitable maltodextrins, having specific Dextrose Equivalent as defined in the claims and oxidizing them stereoselectively and regioselectively at the terminal aldehyde group and then by reacting them with iron (III) salts, as a result of which iron (III)-oxidized maltodextrin complexes are obtained, which are polynuclear complexes, having a specific high average molecular weight. The maltodextrins and the oxidation process are known, but the new feature of the present invention is that the obtained iron complexes are very stable to heat, have a very low toxicity, a low risk of anaphylactic shock and thus can be sterilized by heating and used for injection in very high doses. With this in the backdrop, it cannot be argued by Vifor, at this stage, that Claim 1 for preparation of 'water-soluble iron carbohydrate complexes' was not limited by the process defined therein.

73. No party can be permitted to approbate and reprobate at the same time and the prosecution history estoppel becomes pronounced on account of the fact that the patent was obtained by representing that the novel properties in the product were attributable to characteristic features of the process mentioned therein. There is wealth of judicial precedents, both in India and abroad, where prosecution history estoppel has been a well recognized parameter to adjudicate issues pertaining to patents, particularly, at the stage of grant of interim injunctions, which is a discretionary relief and one of the factors that goes into the decision-making process is the conduct of the party seeking equitable relief.

United States Court of Appeals for the Federal Circuit in ***Pharma Tech Solutions, Inc., Decision IT Corp. v. Lifescan, Inc., Lifescan Scotland, Ltd., decided on 22.11.2019,*** emphasized on the importance of prosecution history in the context of infringement analysis and the principle is well recognized by this Court in ***Astrazeneca AB and Ors. v. Intas Pharmaceuticals Ltd. and Ors.***, ***2021 SCC OnLine Del 3746*** and ***FMC Corporation and Others v. GSP Crop Science Private Limited***, ***2022 SCC OnLine Del 3784***.

74. Court has also taken note of the submission of the Defendants that in the opposition filed by Vifor in February, 2020 to a patent application of a third party bearing No. 3474/CHE/2013, it has been stated at multiple places that Claim 1 of IN'536 relates to a process claim. Additionally, in a response filed by Vifor in the EP Application 03769422.1, granted as EP'315, it was expressly stated that invention of Claim 1 of EP'315 is different from the cited prior arts which taught oxidation of dextrin and dextran on the ground that EP'315 uses alkali material, i.e., aqueous hypochlorite. These facts are pointers of the inconsistency of Vifor's stand in different matters and applications. *Prima facie,* this amounts to a tacit admission that the step of oxidation of maltodextrins using aqueous hypochlorite in alkaline pH range is essential and critical to determination of the scope of Claim 1 of EP'315 and IN'536 and is the distinguishing feature.

INFRINGEMENT ANALYSIS:

75. The next issue that needs determination at this stage is the scope of infringement of a product-by-process claim. In this context, a reference may profitably be made to the observations in ***Atlantic Thermoplastics Co., Inc. (supra),*** from where guidance can be taken on construction of a

claim in the context of both infringement and validity of a product-by-process claim. It was observed that the infringement rule focusses on the process as a limitation and is usually deemed infringed only by a product made by the same process. Relevant passages are as follows:-

> *"[47] After stating this rule for claim construction, the Supreme Court offered an alternative "view of the case." BASF, 111 U.S. at 311, 4 S.Ct. at 464. BASF's artificial alizarine was an "old article." Id. In the words of the Supreme Court, "While a new process for producing it was patentable, the product itself could not be patented, even though it was a product made artificially for the first time." Id.; see also The Wood-Paper Patent, MANU/USSC/0223/1874 : 90 U.S. 566, 596, 23 L.Ed. 31 (1874). In other words, a patent applicant could not obtain exclusive rights to a product in the prior art by adding a process limitation to the product claim. A new process, although eligible for a process patent, could not capture exclusive rights to a product already in the prior art. Therefore, BASF could have claimed a new process for making artificial alizarine, but it had no rights to claim the product.[fn7]*
>
> *[48] Thus, in BASF, the Supreme Court addressed both infringement and validity (in terms of patentability) of product claims containing process limitations. In judging infringement, the Court treated the process terms as limitations on the patentee's exclusive rights. In assessing validity in terms of patentability, the Court forbade an applicant from claiming an old product by merely adding a new process. The infringement rule focused on the process as a limitation; the other rule focused on the product with less regard for the process limits. A decision from the Patent Office, for instance, cited BASF twice - once for an infringement rule and once for a patentability rule. Ex parte Fesenmeier, 1922 C.D. 18, 302 Off. Gaz. Pat. Office 199 (1922).*
>
> *[49] In Plummer v. Sargent, MANU/USSC/0234/1887 : 120 U.S. 442, 7 S.Ct. 640, 30 L.Ed. 737 (1887), the Supreme Court reviewed two patents. One claimed an improved process for bronzing or coloring iron; another claimed the product of that process. Id. at 443, 7 S.Ct. at 641. After reviewing the prior art and descriptions of both patents, the Court stated:*
>
> > *[I]t may be assumed that the new article of manufacture called Tucker bronze is a product which results from the use of the process described in the patent, and not one which may be produced in any other way. So that, whatever likeness may appear between the product of the process described in the patent and the article made by the defendants, their identity is not established unless it is shown that they are made by the same process.*

xxxx xxxx xxxx xxxx

[52] General Elec., 304 U.S. at 373, 58 S.Ct. at 904 (footnote omitted). At that point, the Court quoted from BASF: "nothing can be held to infringe the patent which is not made by that process." Id. at 373-74, 58 S.Ct. at 904.

[53] Thus, the Supreme Court stated in a line of cases that the infringement inquiry for product claims with process limitations focuses on whether the accused product was made by the claimed process or its equivalent. In reviewing for infringement, the regional circuits followed the rule that the process limits a product-by-process claim. For instance, in Hide-Ite Leather v. Fiber Products, 226 F. 34 (1st Cir. 1915), the United States Court of Appeals for the First Circuit affirmed the trial court's non-infringement holding because the accused product was not made by the claimed process or its equivalent. The First Circuit stated:

> *It is also a well-recognized rule that, although a product has definite characteristics by which it may be identified apart from the process, still, if in a claim for the product it is not so described, but is set forth in the terms of the process, nothing can be held to infringe the claim which is not made by the process.*

xxxx xxxx xxxx xxxx

[55] In Parke, Davis & Co. v. American Cyanamid Co., MANU/FEST/0135/1953 : 207 F.2d 571, 572, 99 USPQ 237, 238 (6th Cir. 1953), the patentee's product claim included a process limitation: "said acid being the acid derived by autolysis of mammalian liver tissue." The Sixth Circuit determined that a synthetic folic acid process did not infringe the claimed extraction process. Id. Likewise, the Seventh Circuit in National Carbon Co. v. Western Shade Cloth Co., MANU/FEVT/0217/1937 : 93 F.2d 94, 97 (7th Cir. 1937), cert. denied, MANU/USSC/0010/1938 : 304 U.S. 570, 58 S.Ct. 1039, 82 L.Ed. 1535 (1938), stated: "It has been said that a claim for a product produced by any process which will produce a like result covers the product only when made by equivalent processes." Indeed sister circuits that examined the standard for infringement of product-by-process claims uniformly followed the Supreme Court's lead.

xxxx xxxx xxxx xxxx

[57] 2 D. Chisum, Patents § 8.05 (1991) (footnotes omitted).[fn8] Lipscomb's Walker on Patents states:

> *A claim to a product by a specific process is not infringed by the same product made by a different process.*

[58] 3 E. Lipscomb III, Lipscomb's Walker on Patents § 11:19 (3d ed. 1985). Another legal text states:

> *Product-by-process claims are usually deemed infringed only by a product made by the same process.*
>
> *[59] 1 Iver P. Cooper, Biotechnology and the Law § 5B.05[2] (1991). Finally, one treatise concludes:*
>
> > *There is considerable case authority supporting th[e] position [that product-by-process claims cover only products made by the process specified in the claim] including a nineteenth century Supreme Court decision.*
> >
> > *[This precedent represents] a hundred years of prior law. . . .”*

76. In this context, I may allude to Terrell on Law of Patents, 18th Ed., Chapter-9, Section 8 wherein it is stated:

> “*9-307: Accordingly, in the context of infringement, where a product is said to be “obtained by process X” it must have been actually obtained by the process in order to infringe. However, when it comes to validity (specifically novelty), the wording “obtained by” does not exclude prior art material which is physically the same, even though it has not been obtained by the process claimed. In this respect therefore, though stated as a rule of novelty, the rule construes the words “obtained by” differently in the context of validity and infringement*.”

77. Reference may also be made in this regard to certain passages from the judgment in ***Hospira UL Limited (supra)*** as follows:

> *“145. The result is that a product not made by the claimed process has been found not to infringe because it was not made by the claimed process while another product not made by the process has been found to render the claim lacking novelty despite the fact it was not made by the process. This is a little paradoxical but it shows the difficulties one can get into with product by process claims. A further puzzle is the following. What if, in Kirin-Amgen, the prior art uEPO had not been disclosed so as to be relevant for novelty but was something which was obvious? Presumably it would make the claim obvious for the same reason?*
>
> *xxxx xxxx xxxx*
>
> *148. The claim is to a "lyophilised mixture". As a matter of language and applying the principles I have just discussed, that is limited to something which has actually been made by yophilisation. It does not say "obtainable by" lyophilisation, it is a claim to a product "obtained by" lyophilisation. Air dried material which had never been lyophilised might anticipate the claim (but none is suggested to) but it could never infringe.*
>
> *149. The problem is caused by the way the claim is drafted in using "obtainable by" language but not specifying what characteristic the*

process feature is supposed to define. Nevertheless Hospira's submission that the result is that the process *feature imposes no limit at all goes too far*."

78. In ***Abbott Laboratories (supra),*** observations to the same effect have been made and the relevant passages are set out below:-

> *"This court's sister circuits also followed the general rule that the defining process terms limit product-by-process claims. See, e.g., Hide-Ite Leather v. Fiber Prods., 226 F. 34, 36 (1st Cir. 1915) ("It is also a well-recognized rule that, although a product has definite characteristics by which it may be identified apart from the process, still, if in a claim for the product it is not so described, but is set forth in the terms of the process, nothing can be held to infringe the claim which is not made by the process."); Paeco, Inc. v. Applied Moldings, Inc., 562 F.2d 870, 876 (3d Cir. 1977) ("A patent granted on a product claim describing one process grants no monopoly as to identical products manufactured by a different process."). Indeed, this court itself had articulated that rule: "For this reason, even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself." In re Thorpe, 177 F.2d 695, 697 (Fed. Cir. 1985)*
>
> *The Supreme Court has long emphasized the limiting requirement of process steps in product-by-process claims. In BASF, the Court considered a patent relating to artificial alizarine. Specifically, the patent claimed "[a]rtificial alizarine, produced from anthracine or its derivatives by either of the methods herein described, or by any other method which will produce a like result." 111 U.S. at 296, 4 S.Ct. 455 (quoting U.S. Patent Reissue No. RE 4,321). In turn, the specification generally described a method for making artificial alizarine involving anthracine or its derivatives. Alizarine had been in use for thousands of years as a red textile dye, traditionally extracted from madder root. Pure alizarine has the chemical formula C14H804, but "artificial alizarines" available in the market at the time of the litigation varied from almost completely pure alizarine, to combinations of alizarine and anthrapurpurine, to pure purpurine containing no alizarine whatsoever. Id. at 309-10, 4 S.Ct. 455. The defendant's product contained approximately sixty percent anthrapurpurine. Thus both alizarine and artificial alizarines were known in the prior art. The Supreme Court clearly articulated some of the scope and validity problems that arise when process limitations of product-by-process claims are ignored:*
>
> > *[The defendant's product] is claimed by the plaintiff to be the artificial alizarine described in No. 4,321, and to be physically, chemically, and in coloring properties similar to that. But what that is is not defined in No. 4,321, except that it is the product of the process described in No. 4,321. Therefore, unless it is shown that the process of No. 4,321 was followed to produce the defendant's article, or unless it is shown that that article could not be produced by any other process, the defendant's article cannot be*

> *identified as the product of the process of No. 4,321. Nothing of the kind is shown.*
> * * *
> *If the words of the claim are to be construed to cover all artificial alizarine, whatever its ingredients, produced from anthracine or its derivatives by methods invented since Graebe and Liebermann invented the bromine process, we then have a patent for a product or composition' of matter which gives no information as to how it is to be identified. Every patent for a product or composition of matter must identify it so that it can be recognized aside from the description of the process for making it, or else nothing can be held to infringe the patent which is not made by that process.*
> *(emphasis supplied)*

79. Therefore, there is merit in the contention of the Defendants that if they are able to successfully establish that their product FCM is made by a different process, Defendants cannot be accused of infringement.

INFRINGEMENT ANALYSIS IN CS(COMM) 448/2022

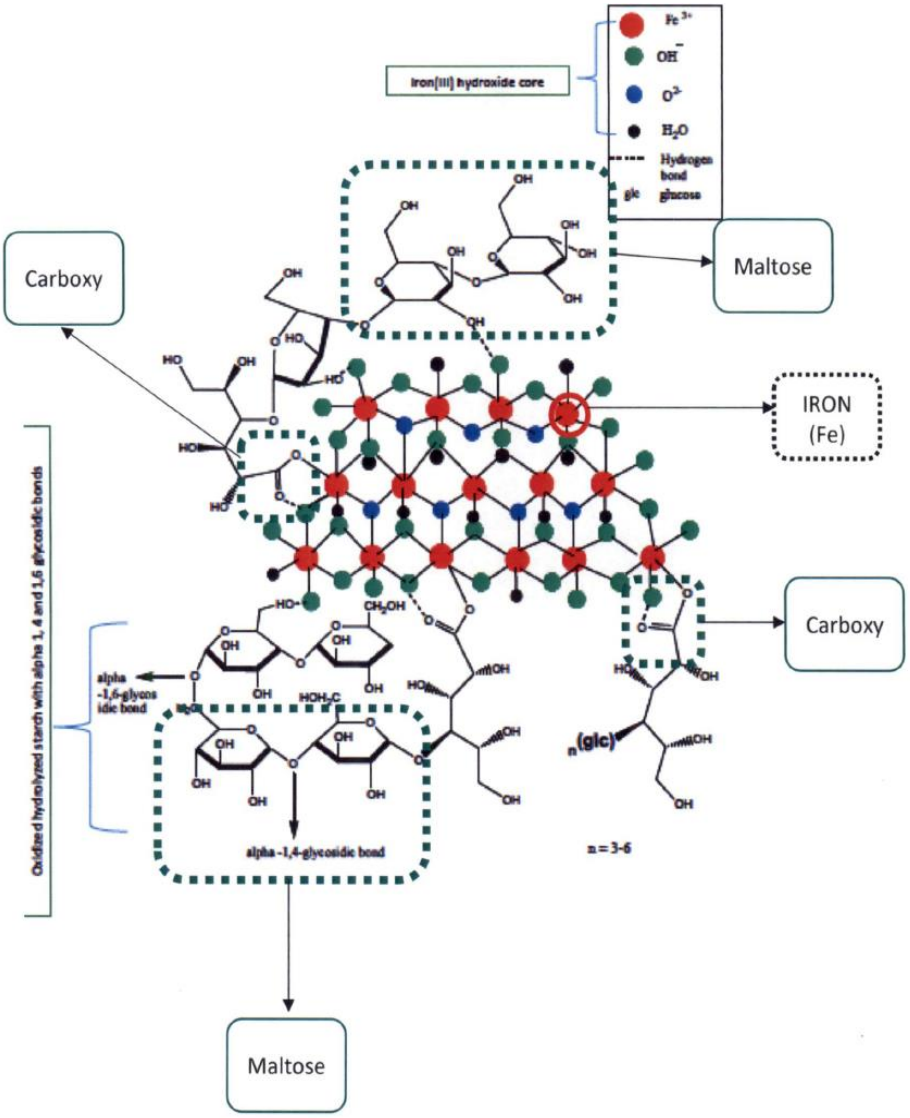
80. For an infringement analysis, a close look would be required on the rival processes. A comparative of Vifor's process and that of the Defendants is as follows:-

CLAIM OF IN'536	PRODUCT AND PROCESS OF DEFENDANT
We Claim 1. Water soluble iron carbohydrate complexes obtainable from: - an aqueous solution of iron (III) salt and an aqueous solution of the oxidation product of one or more maltodextrins - using an aqueous hypochlorite solution at a pH-value within the alkaline range, where, - when one maltodextrin is applied, its dextrose equivalent (DE) lies between 5 and 20, and - when a mixture of several maltodextrins is applied, the dextrose equivalent of the mixture lies between 5 and 20 and - the dextrose equivalent of each individual maltodextrin contained in the mixture lies between 2 and 40, wherein the obtained iron complexes have an average molecular weight of 80 kDa to 400 kDa.	Water soluble iron carbohydrate complex obtained from - aqueous solution of Iron (III) salt and aqueous solution of **oxidation product of starch hydrolysate of DE value >25;** - using aqueous hypochlorite solution at pH within acidic range wherein the obtained iron complexes have an average molecular weight of 100-120 kDa.

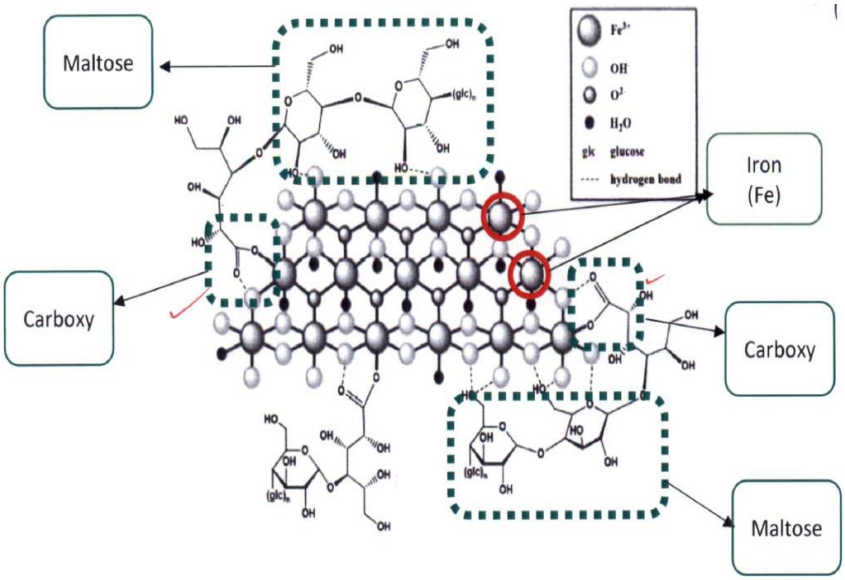
81. Schematically and diagrammatically, the two processes are depicted as follows:

Plaintiff's claim IN'536	Defendant's product
Ferric carboxy maltose obtained by a. Maltodextrin +sodium hypochlorite = oxidized maltodextrin b. reacting oxidized maltodextrin+iron salt ==== ferric carboxymaltose **Product: maltodextrin based ferric carboxymaltose**	Ferric carboxy-maltose obtained by a. Starch + acid = hyrolysed (broken up) starch (DE Value >20) b. Hydrolysed starch + sodium hypochlorite = **oxidized hydrolysed starch** reacting oxidized hydrolysed starch + iron salt = ferric carboxymaltose **Product: starch based ferric carboxymaltose**

MALTODEXTRIN BASED FCM (IN'536)



STARCH BASED FCM (VIRCHOW)



82. A reading of Claim-1 in IN'536 reveals that it claims water-soluble iron carbohydrate complexes obtainable from aqueous solution of iron (III) salt and aqueous solution of oxidation product of one or more maltodextrins using an aqueous hypochlorite solution at an alkaline pH. The process starts from maltodextrin as a starting material with DE value 2-20, which is then oxidized in the presence of sodium hypochlorite to obtain oxidized maltodextrin, which then reacts with iron (III) salt to obtain a maltodextrin-based iron complex. *Prima facie* the essence of Vifor's patent is a maltodextrin-based iron complex. In fact, it is Vifor's stated case that its product FCM is different from prior art which includes dextrin-based complexes since Vifor uses 'maltodextrin as the starting material' instead of any other carbohydrate. This position was clearly adopted by Vifor before the Controller of Patents during prosecution of IN'536. The essential features of IN'536 are: (a) iron (III) core; (b) oxidized maltodextrin having DE value between 2-20; (c) pH value within the alkaline range; (d) end product with average molecular weight

80-400 kDa; and (e) oxidation of maltodextrin is carried out using 'sodium hypochlorite' as oxidizing agent.

83. As for the Defendants, the process of obtaining FCM involves using hydrolysed starch by treatment with appropriate acid medium in acidic pH, followed by heating to result in a mixture of hydrolysed starch. The said mixture is then fractioned according to size and DE value, so that the purified fraction has weight average molecular weight between 1000-2000 Daltons and DE value between 25-28. Hydrolysed starch is further treated to obtain a dry product which is then reacted with sodium hypochlorite, sodium bromide and sodium hydroxide to yield an oxidized starch product. This is then reacted with ferric chloride at 95-100ºC to obtain iron dextrin-based product, which is thereafter filtered, purified and isolated. Therefore, Defendants use starch hydrolysate as a starting material for the reaction and importantly the DE value is greater than 20 as opposed to starting material of Vifor which is maltodextrin with DE value less than 20. The DE value claimed by the Defendants is supported by three Certificate of Analysis issued by Obvez Labs Pvt. Ltd. dated 14.01.2022 as well as three Test Reports by Sipra Labs Ltd. dated 16.06.2022. The DE value greater than 20 itself is indicative of absence of maltodextrins as a starting material in Defendants' process to obtain FCM.

84. To better understand the difference in the competing processes a little backdrop is required into various kinds of carbohydrates. Carbohydrates are biomolecules made up of carbon, hydrogen and oxygen arranged in different combinations and can be in the form of glucose, fructose, sucrose, maltodextrin, starch, lactose, dextrose, maltose etc. The difference in each one is the number of glucose units and the

resultant structure and function. Maltose, for instance, is a carbohydrate with two units of glucose and is a simple sugar. Carbohydrates are classified into a Monosaccharides (single glucose unit), Disaccharides and Polysaccharides. Maltodextrin and starch are both Polysaccharides. Maltodextrin $(C_6H_{10}O_5)n.H_2O$ is a polymer of saccharides comprising of glucose units primarily linked by **α**-1,4 glucosidic bonds. It is a complex biomolecule with several units of glucose arranged in series such that the entire chain has DE value 2-20. Starch on the other hand is far more complicated and is made up of several glucose units which are linked to each other by 1-4 and 1-6 linkages and is branched.

85. DE value is the dextrose equivalent i.e. a measure of amount of reducing sugar present in a sugar product, expressed as a percentage on a dry weight basis relative to dextrose. Vifor seriously contended that all maltodextrins need not have DE value of 5-20 and its claims cover DE value 2-40, to essentially highlight that difference in using maltodextrins or starch as starting materials, even if any, was inconsequential. This contention is not supported by scientific literature on the subject. J. N. BeMiller, *Dextrins,* Encyclopedia of Food Sciences and Nutrition (Second Edition) 2003, Pages 1773-1775 states that maltodextrins are products having DE values of less than 20, generally, DE 5-19. Syrup solids are those products of starch hydrolysis with DE value of more than 20 that are available as dry powders. DE value is inversely related to molecular weight i.e. degree of polymerization and is thus an indicator of the degree of hydrolysis. Maltodextrins and syrup solids are prepared in basically the same way as are starch-based glucose syrups, except that the process is stopped at an earlier stage to keep the DE value low and the difference arises on account of partial and complete hydrolysis.

86. Reference in this context may be made to a research paper titled "*Phase equilibria and gelation in gelatin/maltodextrin systems – Part I: gelation of individual components"* authored by Stefan Kasapis, et. al. published in Carbohydrate Polymers, Vol. 21, Issue 4, 1993, Pages 243-248, wherein the author notes that partial hydrolysis of starch to different extent of depolymerization yields a range of commercially useful products characterized according to their DE values which give the content of reducing end-groups relative to glucose as 100. It is brought out that DE value of 20 corresponds to degree of polymerization of 5 and hydrolysis product with DE above this value i.e. 20 are called 'glucose syrups', while those with lower DE value are called 'maltodextrins'. The distinction is not entirely arbitrary, since it corresponds roughly to the transition from freely-soluble, short oligomers to materials with a significant proportion of chains long enough to form thermally reversible gels.

87. Defendants have also drawn attention of the Court to a research article titled "*Feasibility Study for Determination of the Dextrose Equivalent (DE) of Starch Hydrolysis Products with Near-Infrared Spectroscopy (NIRS),* authored by Elizabeth Storz, et. al. published in Starch/Starke 56 (2004) 58-62. In the said article, maltodextrins have been defined as products with DE value less than 20 and products with DE value higher than 20 have been classified as 'glucose syrup'. The relevant extract is as under:

> *"Starch is an important raw material in the pharmaceutical and food industry. Apart from being applied in native or modified form, starch is used as the starting material for many diverse products. Partial enzymatic or acidic hydrolysis of starch leads to a mixture of glucose, maltose and oligosaccharides. Depending on the composition of the mixture two widely used products, namely maltodextrin and glucose syrup, are obtained. These products are characterized by the dextrose equivalent (DE) value. The DE is a*

> *measure of the extent of starch hydrolysis, which is expressed as the reducing power of the substance, i.e. glucose has a DE of 100 whereas starch at the other extreme has a DE of 0.* ***Maltodextrins are defined as products with a DE less than 20****, whereas products with a DE higher than 20 are classified as glucose syrups. It is important to know the extent of the starch hydrolysis, because several physical and functional characteristics vary according to the DE value. The solubility, sweetness, hygroscopicity and compressibility increase with increasing DE, whereas the viscosity and the inhibition of crystallization of syrups decrease as the DE increases. The caloric value is 17 kJ/g and independent of the DE value [1]."*
>
> *(Emphasis supplied)*

88. Court has also independently analysed the relevant scientific literature on this aspect. In this regard, I may allude to Chapter-7 of the book titled '*Carbohydrate Chemistry for Food Scientists (Third Edition)*' authored by Prof. James BeMiller, which deals with starches, wherein maltodextrin has been described as "*mixtures of oligosaccharides derived from starch (that is, they are maltooligosaccharides). Maltodextrins have average DE values in the approximate range 5-18. (By definition and regulation, the DE values of maltodextrin products is less than 20) [average degree of polymerization (DP) more than 5]"*. It is also revealed during the search that this book has been cited in as many as 956 publications which lends credence to the views expressed therein.

89. From a reading of the aforesaid research publications/articles, two conclusions *prima facie* emerge: (a) maltodextrin cannot have a DE value greater than 20; and (b) partial hydrolysis of starch to different extents of depolymerization yields different commercially useful products, characterized by their DE value and maltodextrins are formed with a DE value lower than 20 while those with DE value greater than 20 are glucose syrups. Pertinently, in the rejoinder arguments, submitted to the

Court through a written note, it is admitted by Vifor that maltodextrin with DE value above 20 is a glucose syrup. Holistically and cumulatively seen, the stand of the Defendants that the DE value of the product of starch hydrolysis being 25-27 is an indicator that the process does not use maltodextrin is *prima facie* correct and that of Vifor to the contrary cannot be accepted. It would be relevant at this stage to reiterate the stand of Vifor before the Controller of Patent during the prosecution of IN'536 that "*the essence of the present invention is that by appropriately selecting suitable maltodextrins having specific dextrose equivalent as defined in the claims*".

90. It is also interesting to note that having taken a position in response to the FER for obtaining a patent, limiting the claim to maltodextrins and a specific range of DE value, Vifor seeks to canvass to the contrary before this Court that DE value is irrelevant to Claim 1 and that no DE limitation is included in INN/USAN/CAS names for FCM. The stand of Vifor that even if Defendants used starch hydrolysis product of DE value 25-27, they are using maltodextrins, is thus contrary to scientific literature on the subject.

91. Additionally, it needs to be noted that Defendant No. 2/VBPL has been granted patent being IN402787 titled '*Efficient Process for the Synthesis of Iron (III) Carbohydrate Complexes'* for the process, which is a subject matter of the present suit and is alleged to be infringing by Vifor. While the Court is conscious of the legal position that there is no presumption of validity of a patent granted by the IPO, however, grant of patent does add strength to the argument of VBPL at least in the context of infringement and at this interim stage tilts the balance of convenience heavily in favour of the Defendants.

92. In view of the aforesaid, in my *prima facie* view, Defendants have succeeded at this stage in establishing that the process adopted by them to obtain FCM is outside the limits of the scope of IN'536 and it is held that the impugned process of CRPL and VBPL is non-infringing. It is pertinent to note that neither of the parties addressed arguments on the issue of validity of IN'536 and arguments for the purpose of interim injunction were confined to infringement analysis. Therefore, this Court is not adjudicating the issue of invalidity of IN'536 raised by the Defendants in the written statement and the same is left open for adjudication at the appropriate stage.

INFRINGEMENT ANALYSIS IN CS(COMM) 261/2021 AND CS(COMM) 265/2021:

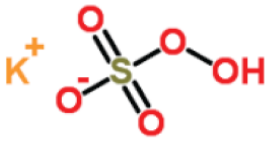
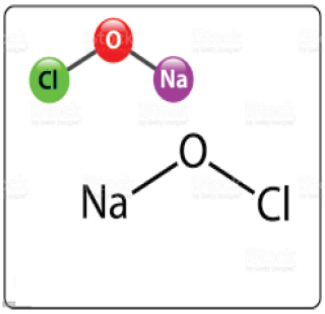
93. The prime argument of MSN and DRL against alleged infringement is that Vifor has limited Claim 1 by the process described therein i.e. "*water soluble iron carbohydrate complexes obtainable from an aqueous solution of iron (III) salt and an aqueous solution of the oxidation product of one or more maltodextrins using an aqueous hypochlorite solution at a pH-value within the alkaline range"* and since Defendants manufacture FCM by using an oxidizing agent Oxone, different from aqueous hypochlorite, used as oxidising agent by Vifor, the process is non-infringing and Vifor argues to the contrary. Therefore, insofar as the present suits are concerned, at the interim stage, arguments with respect to infringement are in a narrow compass i.e. to examine whether the use of a different oxidising agent by the Defendants can rescue them from the allegation of patent infringement.

94. Defendants have categorically stated in their respective written statements that in their process of manufacture, FCM is obtainable from an aqueous solution of iron (III) salt and aqueous solution of oxidation

product of one or more maltodextrins *albeit* by using 'Oxone' as an oxidising agent instead of 'aqueous hypochlorite' solution used by Vifor and the chemical and physical properties of Oxone and Sodium hypochlorite are distinct and different. The process being different from the product-by-process claim of Vifor, Defendants do not trespass into the scope of claim 1 of IN'536 and are not liable for patent infringement.

95. This Court has in the earlier part of the judgment already rendered a *prima facie* finding that Vifor's patent for production of FCM is a product-by-process patent and that Claim 1 is limited by the process described therein. Plain reading of Claim 1 reflects that monopoly was sought to be claimed on water soluble iron carbohydrate complexes which were obtainable from: (a) aqueous solution of iron (III) salt; and (b) aqueous solution of oxidation product of one or more maltodextrins "using an aqueous hypochlorite solution at a pH value within the alkaline range". It needs no reiteration that claims and specifications have to be carefully drafted and an applicant claiming a patent cannot transgress the boundaries of what is claimed at the time of instituting a suit for infringement. Vifor while drafting Claim 1 has consciously and knowingly restricted the scope of the claim for obtaining FCM by a process where aqueous hypochlorite is used as an oxidising agent, which is not the oxidising agent used by the Defendants. Therefore, it is not open to Vifor to go outside the limits of its claim and claim infringement against a party whose process is different.

96. Defendants are *prima facie* correct that the physical/chemical properties of Oxone and Sodium Hypochlorite are different and as a ready reckoner, the differences in the two are set out below in a tabular form, which also marks a difference in the two rival processes:

	Oxone [$KHSO_5$]	Sodium hypochlorite [NaOCl]
		
Cas Number	100058-23-8	14380-61-1
Na,e	Potassium peroxymonosulfate	Sodium hypochlorite
M. Wt.	152.2 g/mol	74.44 g/mol
Appearance	Off-white solid	Yellow solution
Oxidant	Sulfur containing oxidizing agent	Chlorine containing oxidizing agent

97. Be it noted that Defendants have highlighted the advantages of substituting Hypochlorite with Oxone on account of which undesired chlorinated by-products/inorganic impurities are not produced, which otherwise impact the yield and purity of iron (III) Carboxymaltose. In my *prima facie* view, the change of oxidizing agent is not insignificant or innocuous and the limitation of the process in Claim 1, carefully drafted, takes the process of the Defendants outside its scope and is *prima facie* non-infringing.

INTERIM ORDERS RELIED UPON BY VIFOR:

98. Mr. Anand had laboured to contend that several interim orders have been granted by different Courts with respect to FCM, which reflects the strength of IN'536 and for the sake of uniformity in judicial decisions, this Court must follow the same path and grant injunction against the Defendants. This argument cannot be accepted. Insofar as interim orders passed by the Co-ordinate Benches are concerned, the same are only persuasive and no order has been pointed out by Mr. Anand where the scope of IN'536 and infringement analysis has been

carried out. One of the orders relied upon by Vifor is an interim order of the Division Bench of this Court in FAO(OS)(COMM) 146/2016. A bare reading of the order shows that this was an appeal filed by Vifor primarily raising a grievance that the learned Single Judge was deferring the matter for decision on territorial jurisdiction despite there being several interim orders in the past granting interim injunctions by this Court, which was reflective of the fact that this Court has territorial jurisdiction. The Division Bench after noting that the learned Single Judge was yet to form an opinion on the issue of territorial jurisdiction and since with respect to the product in question, 10 suits had earlier been instituted in Delhi, wherein injunctions were granted, restrained the Respondents by ad-interim injunction but without going into the merits of the case.

99. It is pertinent to note here that some of the interim orders relied upon by Vifor, in fact, reflect a position contrary to what is urged before this Court or if I may say, is self contradictory. In CS(COMM) 1548/2016 while granting interim injunction in favour of Vifor on 24.11.2016, the Court recorded the submission of the Plaintiff: "*10. The counsel for the plaintiff further states that the subject patent is not a process patent but a 'product by process patent' i.e. the produce cannot be achieved without following the process in which the plaintiff has a patent and the patent is in the product as well as the process."* Similarly, in the order dated 07.11.2017 in CS(OS) 4083/2014, the Court has recorded the contention of the Plaintiff: *"……It is the contention of the Plaintiff that they are the registered proprietor of Indian Patent No. 221536 (hereinafter referred to as IN'536). It is contended that the patent in the suit is related to a 'product-by-process' invention which is a novel water soluble iron*

carbohydrate complex which is a complex of iron (ferric) and oxidation product of one or more maltodextrins and a process for making the same. It is contended that the invention is used for intravenous treatment of iron deficiency. The properties of the complex makes high dosing up to 1000 mg iron, which characteristics make the said invention the first non-dextran iron complex for high intravenous (I.V.) iron dosing."

100. In CS(OS) 1206/2015, the Court has in the order dated 16.09.2015 observed *"It may be noted that once the plaintiff has a registered patent, defendants cannot use the subject matter of the patent and can only use a process of manufacture which does not infringe the patent of the plaintiff for manufacture of the water-soluble iron carbohydrate complex. It may be noted that learned senior counsel for the defendants states that defendants are not and do not intend to violate the plaintiff's patent and the defendants claim to be using a different process which is not the subject matter of plaintiff's patent."*

101. Insofar as CS(COMM) 565/2017 is concerned, it is an admitted position by Vifor that no injunction was granted and after framing of the issues, parties were directed to expedite the trial. Pertinent it is to note that FCM of the Defendant therein i.e. La Renon Healthcare is presently being sold in the market. In view of the aforenoted facts, the interim orders cited by Vifor cannot come to its aid to argue that on account of judicial propriety, this Court should also grant an interim injunction.

AFFIDAVIT OF SIR ROBIN JACOB:

102. Insofar as the affidavit of Sir Robin Jacob, heavily relied upon by Vifor is concerned, suffice would it be to state that at this stage, no final conclusion can be drawn, particularly, in the absence of the statements made therein being tested in cross-examination by the Defendants in the

present case *albeit* this Court is mindful of the fact that the deponent of the affidavit has been cross-examined in a different suit being CS(COMM) 1680/2016 titled ***'Vifor (International) Ltd. v. Suven Life Sciences Ltd.'.*** However, I may deal with the submissions of Vifor pertaining to the affidavit for the purpose of taking a *prima-facie* view on the opinion rendered in the affidavit.

103. In the context of claim construction, it would be relevant to refer to the section of the affidavit which deals with "*General principles of patent claim construction*". Referring to Article 69 of the European Patent Convention ('EPC'), the author has opined on the scope of protection of claims as follows:

> *"6. Since that decision the UK Supreme Court has held that, pursuant to the amended Article 69 of the EPC and the amended Protocol to that Article, the extent of protection may go further than the product or process covered by the claims as construed by the Kirin-Amgen principle (protection will extend to include product or processes which differ immaterially from that which falls within the claim itself: Actavis v Lily [2017] UKSC 48). However I do not think the introduction into English law of a "doctrine of equivalents" has any relevance to the present problem."*

104. After having carefully perused Article 69 of EPC, in my *prima facie* view, this position is not wholly correct. For ready reference, Article 69 of the EPC is extracted as under:

> *"Article 69: Extent of protection*
>
> *(1) The **extent of the protection conferred by a European patent or a European patent application shall be determined by the claims**. Nevertheless, the description and drawings shall be used to interpret the claims.*
> *(2) For the period up to grant of the European patent, the extent of the protection conferred by the European patent application shall be determined by the claims contained in the application as published. However, the European patent as granted or as amended in opposition, limitation or revocation proceedings shall determine retroactively the protection conferred by the application, in so far as **such protection is not thereby extended**.*
>
> *(Emphasis supplied)*

105. Upon a bare perusal of Article 69(1), it is luminously clear that the extent of protection conferred by a patent or a patent application shall be determined by the claims and any *contra* position to state that actual scope of enforcement of the claims of a patent can extend beyond what is defined by the claims, cannot be accepted. Additionally, in the Indian context, the Supreme Court in ***Novartis AG (supra)***, has clearly held that coverage cannot go beyond what is disclosed in the complete specification of the patent application and therefore, the stand adopted in the affidavit, if accepted, would strike at the very root of Indian Patent law. In any event, the applicability of the decision of the UK Supreme Court in ***Actavis v. Lily, [2017] UKSC 48***, which concerned indirect infringement, is yet to be tested in the Indian context. In fact, for the sake of record, it may be noted that in ***Actavis (supra)***, emphasis has been laid on the limitations placed on a claim that a patentee chooses consciously at the time of drafting and filing the claims. In this context, I may highlight the relevant observation in ***Actavis (supra)***, which is as under:-

> *"110. Actavis additionally argue that it is irrational to hold that there could be indirect infringement because it would all depend on the solvent in which the Actavis product is dissolved, and, even if that solvent was saline, it would depend on the proportion of sodium ions and pemetrexed ions in the solution which would vary by reference to the weight of the patient. The fact that infringement may depend on the nature of solvent and the relative amounts of ions in the solution does not seem to me to be irrational. It is simply a result of the extent of the scope of protection afforded by the patent given that (as determined by the Court of Appeal) its claims are limited to pemetrexed disodium, which, when dissolved in water produces two sodium cations to every one pemetrexed anion."*
>
> *(Emphasis supplied)*

106. Seen holistically in the Indian context, this Court cannot overlook the legislative scheme reflected from the language of Section 10(4)(c) of 1970 Act which stipulates *"defining the scope of the invention for which*

protection is claimed" and is at complete variance with statutory scheme of UK Patents Act of 1949 which provides *"shall end with a claim or claims defining the scope of the invention claimed"*. No divergent view can be taken on this aspect in view of the legislative intent clearly evident from the provision of Section 10(4)(c) of the 1970 Act.

INN NAME:

107. Last but not the least, this Court must address the issue of INNs, canvassed by both sides painstakingly. The position adopted by Vifor is that no product other than FCM produced by the Plaintiff through the process under IN'536 can be given a nomenclature 'ferric carboxymaltose' and that INNs are given only for new products and not for old products or even processes. As a corollary, it was urged that if Defendants make anything different then they cannot call it FCM and if they produce the same product FCM, they infringe the suit patent. This conundrum can be best resolved by the position adopted by WHO in this regard, under whose aegis INNs are allotted and suffice would it be to refer to certain paragraphs of *'Guidance on the use of international nonproprietary names (INNs) for pharmaceutical substances. Geneva: World Health Organization; 2017',* which are as follows :

> *"1. General introduction*
>
> *The present document on the use of INNs is intended as a general explanation of the INN selection process. They have been developed for drug regulatory authorities for use in the marketing authorization/registration of products, drug manufacturers who are requesting new INNs and those using INNs, patent authorities/offices, trademark attorneys and trademark specialists, scientists, teachers, health professionals, as well as any person interested in nomenclature.*
>
> *1.1.General information on the INN system*
>
> ***An International Nonproprietary Name (INN) identifies a pharmaceutical substance or active pharmaceutical ingredient by a***

unique name that is globally recognized and is public property. A nonproprietary name is also known as a generic name*.*

xxx xxx xxx xxx

As unique names, INNs have to be distinctive in sound and spelling, and should not be liable to confusion with other names in common use. To make INNs universally available they are formally placed by WHO in the public domain, hence their designation as "nonproprietary". They can be used without any restriction whatsoever to identify pharmaceutical substances.

Another important feature of the INN system is that the names of pharmacologically-related substances demonstrate their relationship by using a common "stem". By the use of common stems the medical practitioner, the pharmacist, or anyone dealing with pharmaceutical products can recognize that the substance belongs to ***a group of substances having similar pharmacological activity*****.....**

The extent of INN utilization is expanding with the increase in the number of names. Its wide application and global recognition are also due to close collaboration in the process of INN selection with numerous national drug nomenclature bodies. The increasing coverage of the drug-name area by INN has led to the situation whereby the majority of pharmaceutical substances used today in medical practice are designated by an INN. The use of INN is already common in research and clinical documentation, while their importance is growing further due to expanding use of generic names for pharmaceutical products."

xxx xxx xxx xxx

2.2 Recommended INNs: The final stage of selection process is the recommended INN. Once a name has been published as recommended INN it will not normally be modified further and is ready for use in labeling, publications, on drug information. It will serve to identify the active pharmaceutical substance during its lifetime worldwide. ***Since the name is available in the public domain it may be used freely.*** *However it should not be registered as a trademark since this would prevent its use by other parties…..."*

(emphasis added)

108. From the aforesaid, it can be safely stated *albeit prima facie* that no monopoly can be claimed on INNs and in any event, INNs are irrelevant for infringement analysis. The contention that INNs are allotted for new

products, does not seem to be correct, as WHO does not enter into the exercise of novelty of a product while allotting INNs.

CONCLUSION

109. Going by the binding dictum of the Supreme Court in ***Novartis AG (supra)*** and the observations of the Ayyangar Committee Report, grant of patent is restricted to the disclosure in the complete specification. Once Claim 1 has been limited by a particular process, Vifor cannot assert a right to prevent a third party which uses a process/set of processes different and distinct from the claimed process of Vifor and claim infringement qua IN'536. In order to succeed in establishing its claim for infringement even at the *prima facie* stage, Vifor is required to show that the rival processes to manufacture FCM are identical, which burden Vifor has failed to discharge. Balance of convenience is in favour of the Defendants and against the Plaintiffs. Irreparable injury shall be caused to the Defendants and it would also be prejudicial to public interest, if the undertakings given by the Defendants not to market or launch FCM are continued in favour of Vifor in CS(COMM) Nos.261/2021 and 265/2021 or if an injunction is granted at this stage in CS(COMM) No.448/2022, in favour of Vifor.

KEY POINTS EMANATING FROM THE ABOVE DISCUSSION:

110. Securing patent protection in subject matter using product-by-process claim(s) is not unknown to Indian jurisdiction. Indian Patent Office has also recognized such claims in the "*Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals*".

111. Patent protection secured by product-by-process claim(s) is limited by the process by which the product is obtained. Therefore, monopoly cannot be claimed on the product as a whole which is the subject matter

of product-by-process claim(s). In any case, the scope of protection of claim(s) cannot be wider for infringement analysis than for patentability.

112. Maltodextrin is a starch derivative but has DE value less than 20. The extent of hydrolysis of starch determines the DE value and products with DE value higher than 20 are classified as glucose syrups.

RELIEF:

113. In view of the *prima facie* finding that impugned processes of the Defendants are non-infringing, Defendants are permitted to launch their product, i.e., FCM, with a caveat that Defendants shall not use a process/set of processes claimed under IN'536, which infringes the suit patent. Needless to state that before proceeding to launch the product in the market, Defendants shall take all requisite statutory approvals. Additionally, Defendants shall keep accounts of manufacture and sales of FCM and file the same on affidavits on half-yearly basis in this Court.

114. In view of the aforesaid, I.A. 7037/2021 in CS(COMM) 261/2021, I.A. 7138/2021 in CS(COMM) 265/2021 and I.A. 10144/2022 in CS(COMM) 448/2022 are dismissed and Defendants are absolved of their undertakings. Applications stand disposed of.

115. Before drawing the curtains, I may pen down the usual caveat that the observations and opinion of the Court in the present judgment is *prima facie* and will have no bearing on the final adjudication of the suits.

I.A. 10180/2022 (under Order XXXIX Rules 1 and 2 CPC, by Plaintiffs) in CS(COMM) 450/2022

116. In view of the order passed above in I.A. 10144/2022 in CS(COMM) 448/2022, no further order is required to be passed in the present application and the same is accordingly disposed of.

CS(COMM) 261/2021, CS(COMM) 265/2021, CS(COMM) 448/2022 and **CS(COMM) 450/2022**

117. List before the Roster Bench on 07.08.2023, subject to orders of Hon'ble Judge In-charge (Original Side).

JYOTI SINGH, J

JULY 24 , 2023/kks/shivam/ck