COMPETITION COMMISSION OF INDIA

Case No. 05 of 2022

In Re:

Swapan Dey **Informant**
Ushumpur Shibir No. 2, Battala Agarpara,
North 24 Prgns, West Bengal
Kolkata - 700109

And

Vifor International (AG) **Opposite Party**
Rechenstrasse 37,
CH-9001 ST. Gallen, Switzerland

Also, at:

Vifor Pharma Management Ltd.,
Flughofstrasse 61, P.O. Box,
CH 8152, Glattbrugg

CORAM:

Mr. Ashok Kumar Gupta
Chairperson

Ms. Sangeeta Verma
Member

Mr. Bhagwant Singh Bishnoi
Member

Order under Section 26 (2) of the Competition Act, 2002

1. The present information has been filed under Section 19(1)(a) of the Competition Act, 2002 ('**Act**') by Mr. Swapan Dey ('**Informant**') against Vifor International (AG) **('Opposite Party'/ 'Vifor'**) alleging contravention of the provisions of Section 3(4) and Section 4 of the Competition Act, 2002.

Facts, as stated in the Information

2. Vifor International (AG) is stated to be the third largest Swiss pharmaceutical company and a global leader in the treatment of iron deficiency. As per its annual report 2020, Vifor has been a pioneer in the development of iron-based products and has established itself as a global leader in the treatment of iron deficiency and iron deficiency anaemia. Vifor attained global leading position by developing a molecule known as Ferric Carboxymaltose ('FCM') which is the active pharmaceutical ingredient ('API') used for manufacturing injectables for treatment of iron deficiency anaemia. As per the information, Vifor got approval for commercialising FCM molecule from the Indian Regulatory Authorities in February, 2011.

3. FCM is an injectable used for treatment of iron deficiency/anaemia which is a condition marked by low levels of haemoglobin in the blood. Iron is a fundamental mineral needed to produce haemoglobin, a protein in red blood cells that carries oxygen around the body, and a key element of energy metabolism. Human cells require iron in order to convert energy from food, and low iron means less energy can be produced. If iron levels fall too low and are not repleted, the body is unable to produce adequate amounts of haemoglobin and healthy red blood cells. Iron deficiency and iron deficiency anaemia affects primarily those suffering from chronic diseases such as chronic heart failure, chronic kidney disease (CKD) and inflammatory bowel diseases, among other. Women of reproductive age, and those who are pregnant or have recently given birth, are especially susceptible.

4. It is stated in the information that there are two hematinic methods for treatment of anaemia *i.e.*, Oral and Injectable. Oral is the therapeutic treatment which is used for non-serious cases. However, in serious cases such as CKD, Trauma, chronic heart failure, gynaecological emergencies, *inter alia*, injectable are necessary. Further, there are primarily two types of injectables available in the relevant market for treatment of iron deficiency anaemia in India, being Iron Sucrose and Ferric Carboxymaltose (FCM). As per the Informant, Iron Sucrose and FCM are not substitutable owing to several reasons. Iron Sucrose is a conventional injectable with hyper-sensitive side effects on serious CKD patients. Whereas, FCM is an advanced injectable with no to mild side effects. Further, Informant added that the Ministry

of Health and Family Welfare (MoHFW) in its training tool kit published under Anaemia Mukt Bharat, has recommended the use of Iron Sucrose in moderate cases and FCM in severe anaemia cases.

5. The Informant has submitted various studies to show that iron injectable containing FCM are better in terms of safety and efficacy than Iron Sucrose because of higher restoration of iron stores, higher elevation of haemoglobin level. Also, FCM have lesser adverse/hypersensitive reactions and higher maximum permissible dose of upto 1000 mg iron in case of FCM as compared to 200-500 mg iron in case of Iron Sucrose in single dose leading to convenience for patients in terms of lesser number of visits by a patient for a therapy.

6. The Informant also commented on the consumer preference and added that a patient suffering from anaemia would prefer an iron injectable which has lesser side effects. However, because of the huge difference in price, FCM injectables are not affordable and hence cannot be substituted with Iron Sucrose by consumers, at large.

7. In relation to price, the Informant added that the Iron Sucrose injectables are priced between ₹200/- to ₹300/- for 100mg/5ml, whereas FCM injectables are priced above ₹3,000/- for 500mg/10ml. The Informant further stated that FCM injectables are unaffordable by a common man, which is also evident from the observation of the core-committee constituted for revision of National List of Essential Medicines (NLEM) in the year 2015 where it is mentioned that "*Ferric carboxymaltose has the least safety concern and can deliver the maximum amount of iron. Ferric carboxymaltose is however, very expensive and hence it does not justify inclusion."*

8. Based on aforesaid characteristic differences, consumer preference and prices, the Informant has stated that iron sucrose fall in different relevant product markets and proposed that the relevant product market in the present case be '*market for Injectables containing FCM for treatment of anaemia as hematinic injection*'.

9. With respect to the relevant geographic market, the Informant has submitted that the conditions of competition are homogenous in the whole of '*India*' and also distinguishable from the neighbouring area. Finally, the Informant submitted that the relevant market may be delineated as '*market for Injectables containing FCM for treatment of anaemia as hematinic injection in India'.*

10. As per the Informant, Vifor has attained a dominant position in the relevant market and it has been abusing its dominant position by perpetrating its pre-determined anti-competitive business strategy in the Indian market with a view to limit/restrict product and distribution of the relevant product; extract patients/consumers surplus by unfair and discriminatory pricing; foreclose competition in the entire pharmaceutical supply chain through de-facto exclusive agreement and refusal to deal; and to maintain/protect its monopoly in the downstream market.

11. The Informant has alleged that Vifor is maintaining control over the entire pharmaceutical supply chain/downstream market by executing a *de facto exclusive* licensing agreement with Emcure Pharmaceutical Ltd ('Emcure') for manufacturing of injectables containing FCM molecule in India under the trade name 'Encicarb' in the year 2012; and *de facto exclusive licensing* agreement with Lupin Ltd. ('Lupin') for importation and distribution of the Ferric Carboxymaltose Injections named Ferinject (manufactured in Switzerland) in India in the year 2014 and violated the provisions of Section 3(4) of the Act.

12. It is stated that Vifor got approval for commercialising FCM molecule from the Indian Regulatory Authorities in February 2011 and during the same year *i.e.*, in 2011, Vifor granted *de facto* exclusive rights to Emcure for production of injectables containing FCM molecule in India under the trade name 'Encicarb' in the year 2012. Thereafter, in 2014, Vifor granted *de facto* exclusive distribution licensing agreement to Lupin for importation and distribution of Ferinject (manufactured in Switzerland) in the Indian market. Vifor, as per the Informant, wilfully chose Emcure and Lupin as its licensees to access their vast distribution channels which could easily enable Vifor to establish its monopoly in the Indian market. It is submitted that facts relating to *de facto* exclusive agreement entered by Vifor

have been ushered from the declaration so provided by Vifor to the Patent Office in the Form 27 which has been annexed with the Information.

13. In the year 2015, Lupin and Emcure started marketing the relevant product under different brand/trade names. For instance, Lupin started distributing the relevant product under the trade names 'Ferinject' and 'Revofer' whereas, Emcure started manufacturing and selling the relevant product under the brand/trade names namely, 'Encicarb', 'Ferium' and 'Orofer'. Further, the Informant added that as per the information available on the website of Controller General of Patents Design & Trade Marks, the trade names Ferinject and Revofer are owned by Vifor whereas, Orofer and Ferium were owned by Vifor but later, for reasons best known to Vifor, were withdrawn by it.

14. The Informant argued that though the relevant product is being sold in the Indian market under different trade/brand names by the licensees, they are all under the control of licensor *i.e.*, Vifor International. These brands have been launched by Vifor to create artificial product differentiation. There is no inter or intra brand competition between Emcure and Lupin as these licensees have been granted rights to operate on a different level of supply chain. Further, Lupin is only an importer and distributor of FCM injectables which are manufactured outside the relevant market. Whereas, Emcure is producing the relevant product within the relevant market. Even otherwise, it is practically implausible for the licensor such as Vifor to allow its licensees to compete with it for the relevant product in the relevant market.

15. The Informant has alleged contravention of Section 3(4) as well as Section 4 of the Act. Under Section 3(4), the Informant has stated that Vifor's conduct entails 'refusal to deal' with an aim to foreclose price and non-price competition in the entire pharmaceutical supply chain/downstream market. The Informant has added that one of the Indian manufacturers, *i.e.* West Bengal Chemical Industries Limited (WBCIL), approached Vifor for voluntary license to use FCM molecule to manufacture and market the relevant product in the Indian market at affordable prices to the patients/consumers, but Vifor passively refused to deal with such manufacturer by not taking any action in response to the request. Relying on the

'*Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings*', the Informant has averred that it is not necessary that there shall be an actual refusal, even a constructive refusal on the part of dominant enterprise is sufficient to establish refusal to deal. The Informant has added that FCM molecule is an active pharmaceutical ingredient which is objectively necessary for manufacturing the relevant product and by refusing to grant license to use FCM molecule, Vifor successfully eliminated the possibility of production of the relevant product at lower prices, thus, resulting in harm to consumers. Thus, Informant has submitted that Vifor has violated and continues to violate Section 3(4)(d) of the Act.

16. As regards Section 4, the Informant has submitted that Vifor is dominant in the relevant market, *i.e.* '*market for Injectables containing FCM for treatment of anaemia as hematinic injection in India*' and has alleged abuse/contravention on various grounds. It is stated that by granting license to just one manufacturer, Vifor has restricted the production and supply of the relevant product in the relevant market and kept the demand of the FCM injectables high enabling it to charge higher prices from the consumers/patients. Thus, Vifor has restricted the production and supply of the relevant product by limiting and restricting the number of manufacturers through *de facto* exclusive licensing agreements and refusal to deal, thereby contravening Section 4(2)(b)(i) of the Act.

17. The Informant has further alleged that Vifor charges unfair and discriminatory prices and submitted that the whole purpose of maintaining monopoly by Vifor is aimed at charging such unfair prices from the consumers/patients by avoiding any price and non-price competition in the downstream market from other manufacturers, wholesalers and retailers. The maximum retail price at which the FCM injectables under different brand names are being sold by Vifor's licensees to the consumers ranges between ₹3,045/- to ₹3,349/-. The Informant has submitted that the price of FCM injection is very low in the countries who are not the signatories of Patent Cooperation Treaty (PCT). In this regard, the Informant has submitted a copy of bill generated in Bangladesh (a non-PCT country) where the price of FCM injection is only 700 Taka (approx. ₹606/-). The Informant has further stated that one of the market participants *i.e.*, La Renon Healthcare Pvt Ltd (LaRenon) is selling the FCM

injectable in some parts of the relevant geographic market under the brand name Larinject at the maximum retail price of ₹1,740/-.

18. Further, the Informant has stated that for the patients with Chronic Kidney Disease, it is very common for them to develop anaemia and because of this, almost every patient is administered with iron injections. However, they have options either to choose Iron Sucrose injectables or FCM injectables for the therapy. But, because the FCM injectables are priced multiple times higher than Iron Sucrose, patients coming from economically weaker background, *inter alia*, are deprived of safer and efficient iron injectables.

19. The Informant has also compared the properties of Iron Sucrose and FCM and mentioned that both of them belongs to the same family of carbohydrates and for this reason, the input cost/cost of production incurred for manufacturing injectable containing Iron Sucrose or FCM is almost similar. However, there is a huge difference between the price at which Iron Sucrose injectables and FCM injectables are being sold in the retail market. The average price of Iron Sucrose injections is between ₹190- ₹310. The Informant has added that Vifor has only changed the molecular structure/shape of the carbohydrate to improve the side effect profile of the FCM injectables in comparison with Iron Sucrose injectables. For such a change, Vifor has been allegedly imposing and continues to impose excessive price for FCM injectables from the consumers/patients, indirectly through its licensees. Such unfair pricing does not have any economic justification in terms of cost of production but is only a result of abuse of monopoly position by Vifor.

20. Further, the Informant has contended that Licensee of Vifor (Emcure) had supplied the FCM Injectables to various public procurer at a price which is almost half the price at which the FCM injectables are being sold to the consumers in the open/retail market. The Informant has submitted BOQ of the 2 e-tenders, floated by two State Governments (Orissa and Assam), where the price quoted by Emcure and Lupin for FCM was ₹1,419/- and ₹1,477/- (excluding GST) and ₹1,460/- and ₹1,515/- (excluding GST). The Informant has alleged that charging different price from consumers for the same product and quantity amounts to price discrimination and if the FCM injectables can be sold to public procurers at a price of

₹1,419/- or ₹1,460/- (500mg/ 10ml, excluding GST), it can definitely be sold to the consumers/patients in the retail market at similar prices. Thus, the Informant has alleged that Vifor has violated Section 4(2)(a)(ii) of the Act.

21. Finally, the Informant has alleged that Vifor has not just distorted competition in one stage of the supply chain but has eliminated competition in the entire supply chain of the relevant product. Vifor protected and continues to protect the downstream market so as to foreclose the possibility of introduction of generics into the relevant market as the entry of generics in the relevant market would exert competitive pressure on Vifor and its licensees. The Informant has alleged that Vifor is contravening Section 4(2)(e) of the Act, and delineated the upstream market as '*market for license to use ferric Carboxymaltose molecule in India*' and the downstream market as '*market for production, distribution and retail sale of FCM injectables in India*'. The Informant has further added that by leveraging monopoly position; engaging in *de facto* exclusive licensing agreement; and by refusal to deal in the upstream market, Vifor has protected its market position and its licensees from price and non-price competition from the other manufacturers, distributors and retailers in the downstream market. Apart from resorting to anti-competitive business strategies, Vifor has also been resorting to litigation to cause legal hinderance for manufacturers/competitors/potential entrants with the sole intention of preventing launch and/or market penetration of other similar manufacturers trying to enter the market. Also, La Renon is the only manufacturer who was able to enter the relevant market in the year 2019 by filing a suit against Vifor International. La Renon had sought for protection under Section 105 of the Patent Act. The details of some of the litigations initiated by Vifor in the Hon'ble Delhi High Court have also been disclosed by the Informant.

22. The Informant has also presented a counter factual analysis and submitted that even by granting license to multiple manufacturers, Vifor would still have been able to maintain its monopoly profit in the form of License fee. Since the License fee charged by Vifor from multiple manufacturers would have been constant, the manufacturers would have competed on the variable component of the cost of production with each other. Further, production of FCM injectables by multiple manufacturers would have resulted in adequate and sometimes

excessive supply of FCM injectables in the relevant market which could have resulted in reduction in price and finally, grant of license to multiple manufacturers would have given impetus to the competition in the entire pharmaceutical supply chain *i.e.*, manufacturers, distributors/wholesalers and retailers in the relevant market.

23. Further, the Informant has submitted that Vifor International, being a monopolist has a special responsibility under competition law to act fairly in the relevant market. Vifor is under obligation not to devise business strategies and conduct its business in a way that distorts or eliminate competition in the relevant market.

24. Along with the Information, the Informant had also submitted an application dated 06.01.2022, wherein the Informant had stated that he was the CEO of the hospital which was approached by various patients seeking help with regard to high prices of FCM injectables. In the said application, the Informant had also annexed affidavits and letters of the patients along with the declaration of the doctors which are indicative that *firstly*, FCM is not substitutable with other iron injectables and *secondly* the prices are high for FCM. Such documents according to Informant also indicates that some of the doctors had to prescribe iron sucrose because of the unaffordability of FCM by their patients and such patients had to suffer adverse consequences. Further, the Informant also annexed various general complaints addressed to Commission during 2021 stating the high prices of FCM injectables. The Informant had sought confidentiality over the information contained in the said application, along with confidentiality *qua* the name of the Indian manufacturer (*i.e.* WBCIL) who approached Vifor for license but was not given the said license by Vifor stating that this Indian manufacturer has been granted product-by-process patent on an improved form of FCM recently and it is formulating a business plan to commercialize FCM injectables on a large scale in future and if these facts are disclosed, then Vifor, in retaliation, would resort to methods other than fair competition to prevent/delay the launch of FCM injectables in the relevant market. Further, the Informant had also sought confidentiality over its identity. However, later, *vide* application dated 12.09.2022, the Informant requested for withdrawal of the said confidentiality, which was accepted by the Commission *vide* order dated 14.09.2022 and the confidential facts, Information and documents over which

confidentiality was sought earlier was decided to be treated as non-confidential for all further purposes.

25. Based on the facts stated in the Information, the Informant prayed for correction in the relevant market which was allegedly distorted by Vifor through its anti-competitive conduct and for protection of the interest of consumers who otherwise are being harmed by Vifor through imposition of unfair and discriminatory price of the relevant product.

26. On 15.02.2022, the Commission considered the Information and decided to seek para-wise comments/reply from Vifor International AG ('Vifor') on the Information filed in addition to response on certain queries highlighted in the order dated 15.02.2022. Vifor was directed to file the above, within 4 weeks of the receipt of the Commission's order. However, no response was received within the stipulated time.

27. On 29.03.2022, the Commission considered the matter and decided to grant another opportunity to Vifor to file its comments/response as was directed *vide* order dated 15.02.2022. Vifor was accordingly directed to file the same within 4 weeks of the receipt of this order.

28. On 21.04.2022, Vifor filed an application seeking extension of time by 8 weeks to file requisite documents and relevant data/information. In its application, Vifor has stated that in light of the persisting COVID-19 situation in Europe and elsewhere, its present office is working under limited capacity and therefore the relevant documents as requested by the Commission are currently not easily accessible. It also mentioned that the nature of information required to be filed by it will be voluminous.

29. *Vide* order dated 26.04.2022, the Commission considered the aforesaid application filed by Vifor and decided to grant an additional time of 4 weeks from the receipt of this order to file its reply/comments, as sought *vide* order dated 15.02.2022. This timeline was further extended by 2 weeks on a request made by Vifor again *vide* email dated 28.04.2022.

30. On 09.06.2022, Vifor filed its preliminary response to the Information filed by the Informant making certain preliminary objections/submissions. It *inter alia* stated that it is an international company registered in Switzerland with no registered office/place of business in India and, thus, should have been served using proper diplomatic channels of service. Vifor also challenged the jurisdiction of the Commission and raised several preliminary objections. It was stated that the service of orders by the Commission upon Vifor does not constitute proper service as the same is in violation of Hague Convention and also the principles of International Law in so far as Switzerland is concerned. Further, Vifor had alleged that the Commission's direction for provision of information including certain documents are illegal under Swiss Law and may expose Vifor's officers to the risk of criminal liability under Article 271 of Swiss Criminal code, if they provide the requested information. Only Swiss authorities may apply coercive measures on Swiss territory as part of their judicial sovereignty.

31. Vifor also challenged the jurisdiction of the Commission to entertain the present matter which should ideally been looked at by the Patents authority. It had been stated that the Commission does not have expertise nor competence to decide a matter falling within domain of Patent Law. Vifor has been granted a registered patent under the Patents Act in India and no person has any right without Vifor's consent from making, using, selling, offering for sale and importing the product. Its patent is not an SEP and therefore, FRAND terms are not applicable. The Informant, by filing the information with the Commission, has tried to curtail Vifor's right under Patent Act and also tried to create a regulatory conflict between patent law and competition law.

32. It was further averred that Section 3(5) of the Act, has exempted the Commission from entering into the domain of the Patent Act. The Informant could have approached Controller of Patents for grant of compulsory licenses under Section 84 of the Patent Act. As per judgment of Hon'ble Supreme Court in *Competition Commission of India vs Bharti Airtel Limited and Others (Civil Appeal Nos 11844-1145)*, the Commission's jurisdiction is sequential. The Informant has failed to exercise its option to seek a compulsory license under the Patents Act. The patent with respect to FCM was granted to Vifor on 25.06.2008 and the

statutory period of 3 years after which a compulsory license may be applied for by any willing party, expired on 24.06.2011. The Commission cannot adjudicate on the decision of Central Government to include or not include a specific medicine under National List of Essential Medicines, 2015. Also, in case of FCM patent, no pre-grant or post grant opposition was filed by any person much less the Informant. Further, the patent has been granted in 57 jurisdictions of the world.

33. Vifor also stated that the Information is tainted with malafide and is an abuse of process and suffers from procedural irregularities. The Informant has claimed that Vifor has *de facto* exclusive agreement with its licensees *viz.*, Emcure having 3 brands being Encicarb, Orofer and Ferium and Lupin (distributor of 2 of Vifor's brands namely Ferinject and Revofer. As per publicly available information, Vifor's licensee Emcure freely competes with Vifor's distributor Lupin in India through their own products *i.e.*, Encicarb, Orofer and Ferium. Vifor's FCM patent is due to pass into public domain on 21.10.2023 upon expiry of 20 years. The Informant has many remedies under Patent Law but, in the face of existence of Section 3(5) of the Act, is opting for remedies under competition law.

34. Vifor also submitted that it intends to fully cooperate with the Commission within the fold of what is legally permissible and is filing the preliminary objections without submitting to the jurisdiction of Commission. Vifor also requested for an oral hearing to put forth the aforesaid preliminary objections.

35. The Commission considered the aforesaid preliminary objections of Vifor in its ordinary meeting held on 13.07.2022 and decided to give a last opportunity to Vifor to furnish information as sought by the Commission in its earlier order dated 15.02.2022, within a period of two weeks of the receipt of the Commission's order dated 13.07.2022. The Commission also decided that upon non-receipt of the information/documents from Vifor as directed, within the stipulated time, the Commission shall thereafter proceed with the matter based on the information/documents available on record.

36. Instead of filing a response to the Commission, Vifor filed a writ petition being W.P. No. 11263 of 2022 before the Hon'ble High Court of Delhi. The Hon'ble High Court disposed of the said petition and, *vide* order dated 28.07.2022, *inter-alia* directed Vifor to raise its contentions before the Commission, which shall dispose of the same in accordance with law. Pursuant to the directions of the Hon'ble High Court, Vifor submitted a comprehensive preliminary objection cum response on merits dated 08.09.2022 in confidential as well as non-confidential version. A copy of the same was also served on the Informant.

37. In the preliminary objection cum-response on merits dated 08.09.2022, Vifor has *inter-alia* stated that an anonymous information has been filed to mislead the Commission and seeking it to intervene in an Information over which the Commission has no jurisdiction as the issues are covered entirely by the Patent Act 1870. It was also stated that Vifor is not clear as to how the Informant has received Information regarding Vifor's commercial discussions with an unnamed party. Vifor also submitted that it is not obligated to deal with all those who approach it. The request received by Vifor from Sun Pharmaceutical Limited of 30.12.2021 and another one through an independent lawyer of 09.01.2022 were not supported by any detailed business plans. Also, the timing of the filing of the Information is in close range to the aforesaid requests and this indicates the possibility of the Information having being filed with oblique motives. The successful record of enforcement of its patent before the Hon'ble High Court of Delhi, is proof of its *bonafide.*

38. Vifor further stated that the delineation of the relevant product market as contained in the Information is not correct. Even if in a few cases with regard to certain critical drugs (for example in the cancer area), a narrow product market at the molecule level has been defined, the same was because the products at issue had unique properties and no meaningful substitutes. There is no precedent dealing with Iron Deficiency (ID)/ Iron deficiencies anaemia (IDA) products in India. Even in some cases in Europe relating to ID products, though a precise relevant market has not been defined, yet the competition authorities have not even remotely suggested that FCM molecule could plausibly constitute a relevant product market in itself. Iron products are grouped within a class comprising of oral irons and IV irons with the same therapeutic outcome. Some of these medicines comprise

Dexorange, Orifer-Xt, Tonoferion, R.B. Tone and Livogen and in IV (Orofer-S, Jectocos Plus, Imferon and Hemfer) iron products, which are widely available off patent and freely commercialised by numerous companies. These products are functional substitutes to FCM and exert significant competitive constraint on FCM. Even health care professionals substitute oral and IV irons based on a case by case holistic and complex clinical judgement. In some disease cases, health care professional could start with oral iron followed by analysis of blood parameters and switch to IV iron. In case of other diseases causing excessive blood loss or due to surgery or accident, IV therapy may be initiated to replenish iron stores speedily, and with stability, patient may be given a maintenance dose with oral iron. So, there is significant interchangeability between oral and IV irons. There is no one time choice as patients may be switched back and forth between two therapies. Further, certain studies have indicated that oral iron can in specific instances, replenish iron stores similar to IV irons and there is no conclusive body of evidence demonstrating general efficacy and superiority of IV irons over oral irons. In so far as the safety/tolerability profile is concerned, there is nothing to establish that one is better than the other and it is ultimately patient specific. Even cost of care of ID/IDA is not materially different between oral and IV iron therapies, when seen that absorption rate of oral iron is lesser and therefore more dosage is required over a period of time, and thus the cost of oral iron is not less than IV iron.

39. It was further stated that there is no universal factor that would dictate the choice of an iron product or a particular therapy. The choice is always holistic and complex, based on parameters like severity of ID/IDA, patient population, type of diseases, level and timing of needed HB level increase, underlying disease state of the patient, patient specific health status, safety risks, physician's education, patient's preferences, convenience, access to therapy and cost *etc*. There parameters show that oral and IV irons are interchangeable. Even the scientific studies demonstrate significant interchangeably between oral and IV iron. Thus, the relevant product market would comprise both oral and IV iron for treatment of ID/IDA and relevant geographic market would be whole of India. When the relevant market comprises both oral and IV irons for treatment of ID/IDA in India, Vifor's FCM share through Emcure and Lupin would be below 1%. Vifor does not have any affiliated presence or direct operations in India and the only link it has in the country is based on outside

contractual arrangements with the aforesaid two companies through a non-exclusive distribution and promotion agreement that allows Lupin Ltd. to import, market, distribute and use in India FCM manufactured by Vifor and a non-exclusive patent licencing agreement that allows Emcure to manufacture and sell in India. Both these companies are independent and unconnected to Vifor and therefore do not form a group or enterprise with Vifor in India for the purposes of Section 4 of the Act. Emcure and Lupin set and follow their own commercial plan that is not driven by FCM (or by Vifor) but reflects their overall product portfolio. Further, Vifor does not dictate any commercial strategy or set or influence pricing policy in India, which can be construed as Resale price maintenance (RPM). Thus, there is no reasonable basis to attribute Emcure and Lupin's FCM sales in India to Vifor. Further, even if such FCM sales of these companies (under an extremely conservative approach) is attributed to Vifor, yet in the properly defined market for oral and IV iron for treatment of ID /IDA in India, its share would be below 1%. Without prejudice to the relevant market so delineated (comprising of oral and IV irons), Vifor's FCM share through Emcure and Lupin in a putative IV iron segment in India would be below 10%. Thus, Vifor cannot be said to have a dominant position in India as per Section 4 of the Act or having a substantial market power as per Section 3(4) of the Act.

40. The contentions of the Informant that non injectables containing FCM are better in terms of safety and efficacy than iron sucrose and therefore in different product markets is not correct. On the contrary, both products have similar safety profile. The Informant has alleged huge difference in cost between FCM and Iron Sucrose (IS) namely Rs. 200/ to Rs. 300/ for 100mg/5ml of IS compared to above Rs. 3000/ for 500 mg/10ml of FCM. These prices are the MRP of FCM's, which includes wholesaler and retailer margins, which are independently set by these channels, without any control or influence of Emcure, Lupin or Vifor. The starting point for companies cannot be FCM MRP but FCM prices actually charged by Emcure and Lupin to wholesales/retailers. Also, Lupin and Emcure prices reflect a 500mg dose while the referenced IS similar reflect a 100mg dose. There is fivefold difference in the dosage. Further, IS requires a higher number of cumulative doses compared to FCM. The overall treatment cost is thus, higher and includes direct non-medical cost like

transportation of patient. Certain studies indicate that cost of treating ID with FCM is lesser than with IS.

41. Vifor also stated that the Informant has failed to demonstrate that Vifor has imposed unreasonable conditions in relation to its patent FCM product that would justify withholding of the benefit of Section 3(5) of the Act.

42. Vifor's contractual framework in India is legitimate and justified. Pursuant to extensive and costly R & D efforts, Vifor obtained certain exclusive and time limited rights under the Patent Act which includes exclusive right to decide upon commercial exploitation of FCM and to prevent unauthorised third parties from manufacturing, using, offering for sale, selling or importing FCM in India. Therefore, without an order from Controller of Patents, Vifor is under no obligation to allow any third party to use, manufacture, sale or import FCM, be it via a licensing, distribution or any other arrangement. In these circumstances, Vifor's willingness to grant a non-exclusive manufacturing license to Emcure and a non-exclusive distribution agreement with Lupin is inherently pro-competitive as Vifor shares its technology and product with local players without being obliged to do so at all. This is in consonance with the order of the Commission in Case No. 18 of 2021 (Hiveloop Technology Pvt. Ltd and Britannia Industries Ltd.) that a company is free to choose its trading partner as long as it does not impact the fair function of the markets.

43. It was further averred that the Informant is attempting to interfere with Vifor's legitimate business arrangements through a putative application of the duty to deal doctrine, but such doctrine is not applicable as Vifor does not possess substantial market power in India. Further, this theory is ill-fitted to distribution arrangements and to companies that are not vertically integrated as declining to contract in that context does not give rise to material economic harm. Also, there is no reasonable basis to consider FCM to constitute an essential facility which is fundamental to apply the said theory. There is no precedent in India or US or in Europe that a pharmaceutical product is an essential facility. FCM is sold in India from two independent suppliers under five different brands. Further, an FCM similar is sold by La Renon and additional FCM similars are expected to enter the market in the short term

following the expiry of the FCM patent in 2023. There are numerous other oral and IV iron alternative to FCM in India and the Indian authorities explicitly excludes FCM even from the 2015 National List of Essential Medicines (NLEM). Also, FCM cannot be put in the category of Standard Essential Patents (SEPs).

44. It was further submitted that there is nothing to indicate that the distribution agreement is exclusive. Nothing prohibits Vifor from appointing additional distributors in India. There is significant intra brand and inter-brand competition in iron products in India. There is nothing to indicate that FCM prices independently set by Emcure and Lupin in their sole discretion are anyway excessive or discriminatory. Further, the Commission has recognised that determining whether a price is excessive is an uncertain and difficult task. The Informant's comparison of FCM MRP prices in India with Bangladesh is flawed as Bangladesh is not part of relevant geographic market and thus will not be reflective of different consumption habits and other economic and socio-cultural factors. Also, the product sold in Bangladesh is not FCM, but an FCM similar. In line with Vifor's social responsibility approach, Vifor does not patent FCM in the Least Developed Countries as defined by the WTO, which includes Bangladesh. Similarly, Informant's comparison with La Renons' prices in India is flawed as La Rino does not sell FCM, but an attempted FCM 'similar' and there is no evidence of any clinical equivalence between FCM and Le Renons' similar and there is no reasonable basis to compare their prices. In any case, the residual price difference between FCM prices actually, charged by Lupin/ Emcure and prices charged by La Renon is not manifestly excessive or arbitrary so as to warrant any unprecedented pricing intervention by the Commission in pharmaceutical sector in India. Further, the Informant's comparison of FCM price sold in the market with prices in public tenders is flawed as there are material differences between the procurement and retail sale. Tenders involve significant volume commitments, are supplied for a longer duration, involve direct supplies, by passing wholesalers and retailers and avoiding their margins and they do not require significant FCM related educational and marketing spends, which is incurred by Emcure and Lupin at retail level. Further, the residual price difference between Lupin/Emcure actual retail and tender prices is not manifestly excessive and arbitrary so as to warrant an unprecedented pricing intervention in the pharmaceutical sector in India.

45. Based on the aforesaid submissions, Vifor has requested for an opportunity of oral hearing and *inter-alia* sought prayer from the Commission in the nature of declaration that no *prima facie* case has been established by the Informant and seeking closure of proceedings under Section 26(2) of the Act as also initiation of action against Informant for suppression of relevant facts under Section 45 of the Act, and that Informant pay legal costs to Vifor for filing frivolous and vexatious information before the Commission.

46. Subsequent to filing the aforesaid submissions, Vifor also filed a letter dated 10.10.2022, seeking to bring on record some facts and instances of alleged suppression and misrepresentation by the Informant. These facts *inter-alia* pertained to one West Bengal Chemical Industries Ltd. (WBCIL) allegedly having infringed the patent of Vifor, by obtaining its own product-by-process patent in the year 2017, from the patent authority in India. As per the records filed along with the letter, there are *inter-se* suits between Vifor and WBCIL relating to the said patent filed in 2022 (post filing of Information) which are pending adjudication before the Hon'ble Delhi High Court. It was contended by Vifor that the Informant has failed to disclose these facts to the Commission and the suppression came to Vifor's notice only when the identity of the Informant was revealed by the Commission *vide* order dated 14.09.2022.

47. In response to the submissions filed by Vifor, the Informant filed response dated 23.06.2022 and 11.10.2022. In its response dated 23.06.2022, the Informant *inter-alia* stated that Vifor has made vague submissions regarding competition between Emcure and Lupin without submitting the Licensing Agreements with them which could have helped the Commission to understand and decide the present matter.

48. As regards the objection to jurisdiction, the Informant has relied upon the Delhi High Court's order in W.P.(C) 464/2014 titled as '*Telefonaktiebolaget Lm Ericsson Vs. Competition Commission of India & Anr.*', whereby the Hon'ble High Court categorically stated that '*there is no irreconcilable repugnancy or conflict between the Competition Act and the Patents Act. And, in absence of any irreconcilable conflict between the two legislations, the jurisdiction of CCI to entertain complaints for abuse of dominance in respect of patent rights*

cannot be ousted.' Further, reliance has also been placed on decision in '*Monsanto Holdings Pvt. Ltd. and Ors. vs. Competition Commission of India & Ors. [W.P (C) 1776/2016]*, wherein, the Hon'ble Delhi High Court, while upholding Ericsson's observation, stated that '*[….] the jurisdiction of the CCI to entertain complaints regarding abuse of dominance in respect to patent rights could not be excluded*.'

49. As regards the supremacy of sectoral regulators and reliance of Vifor on *Star India* Judgement and *Bharti Airtel* Judgment, the Informant stated that the ratio of those judgments does not apply to this case as the facts in those matters were completely different from the present matter. In those cases, there were certain facts which were already in dispute/controversy before the sectoral regulators which were to be decided first before the Commission could proceed in terms of Section 26(1) of the Competition Act. Since no such factual dispute is pending with any other authority/regulator, the reliance of Vifor on those case laws is misplaced. The Informant has further cited the observations of the Hon'ble Delhi High Court in *Monsanto* matter wherein the Hon'ble Court has held that '*the decision of the Supreme Court in Bharti Airtel Ltd. (supra) is certainly not an authority for the proposition that wherever there is a statutory regulator, the complaint must be first brought before the Regulator and examination of a complaint by the CCI is contingent on the findings of the Regulator*.'

50. As regards the exclusion under Section 3(5) of the Act, the Informant has stated that Section 3(5) provides right to a person to restrain any infringement of, or to impose reasonable conditions, as may be necessary for protection of his rights conferred upon him under Patent Act, 1970, *inter alia* and Vifor cannot claim such exception/exemption unless it brings the license agreement(s) entered with the Indian companies on record. Thus, it is not possible for the Commission to determine whether the terms of an agreement are reasonable or not, unless Vifor brings on record the license agreement(s) it had entered into with Emcure and Lupin.

51. As regards Article 271 of the Swiss Criminal Code, the Informant has submitted that Vifor has failed to explain how providing information and documents to the Commission would

expose Vifor and its representative to the risk of criminal liability under Article 271 of the Swiss Criminal Code. Vifor or its officers or directors can only be held liable under Article 271 of SCC, when they carry out an activity on behalf of foreign state when the responsibility of such activity is with the public authority or public official of Swiss Government. This, as per the Informant, is not the case in the present matter.

52. The Informant further brought to notice that the EU Commission /DG Comp has formally opened an antitrust investigation against Vifor to assess whether Vifor Pharma restricted competition by illegally disparaging its closest and potentially only competitor in Europe in the market for intravenous iron treatment. The said conduct has been stated to be aimed at hindering competition against Vifor's blockbuster high-dose intravenous iron treatment medicine, 'Ferinject', which is stated to be the relevant product in the present case.

53. In addition to the above, the Informant submitted a rejoinder dated 11.10.2022 in response to the submissions dated 08.09.2022 filed by Vifor. In its rejoinder, the Informant has *inter alia* submitted that Vifor has used deceptive tactics to gain time for filing its reply before the Commission, that Article 271 of the Swiss Criminal Code has no applicability to the present matter and that Vifor has made incorrect, contrary and wrong submissions to mislead the Commission. On the aspect of delineation of the relevant market, the Informant has contended that there is no bar in the competition law to define relevant product market in pharmaceutical industry at molecule level. The Commission in *Bicon Limited and Anr. vs. F. Hoffmann-La-Roche AG, Case No. 68 of 2016* had delineated the relevant product market at the molecular level. The Informant has also disputed the reliance placed upon by Vifor in certain cases decided by the European Commission, stating that decision pertained to merger case and a relevant product market as defined under an *ex-ante* analysis cannot be applicable in respect of an *ex-post* analysis. The Informant also stated that submissions of Vifor that "relevant product market" should include oral and IV irons based on ATC-3 classification is only partially correct as ATC-3 classification can only be used as a starting point to define a relevant product market and is neither conclusive nor binding on the Commission. The Informant thus stated that oral and IV irons cannot be considered substitutable to each other and even the Anemia Mukt Bharat operational Guidelines nowhere states that oral and IV

irons be used interchangeably. Also, while determining a particular treatment even doctors give due regard to the affordability of a medicine/drug/injectable by a patient. Health care professionals would not recommend FCM to a patient who cannot afford high price of it. The price of FCM is multiple times higher than Iron sucrose and thus, FCM is not substitutable with Iron sucrose.

54. The Informant contended that Vifor has violated Section 3(4) of the Act. Further, the Informant submitted that it has never stated that Vifor has a duty to deal with all interested parties or that it is obliged to give license to all interested or that Vifor should have granted licenses to a considerable number of Indian manufacturers. While Gilead Sciences Inc. granted non-exclusive voluntary licenses to 10 Indians manufacturers for production and distribution of medicines used for treatment of HIV infection, Vifor has granted only one *de facto* exclusive license to Emcure for production and distribution of the relevant product in India. The Informant also attacked Vifor's stand that it is under no obligation to allow any third party to use, by stating that such a position is contrary to Section 83 of the Patents Act, 1970.

55. The Informant has submitted that Vifor is an enterprise as defined under the Act and which includes the term 'person' to mean a body corporate incorporated by or under the laws of a country outside India. Further, the Commission has extraterritorial jurisdiction under Section 32 of the Act to inquire against any party or enterprise abusing its dominant position, based outside India.

56. With respect to the allegations of abuse under Section 4 of the Act, the Informant has stated that it is not the case of the Informant that Vifor is obliged to give license to all interested parties, rather Vifor should grant license to a considerable number of Indian manufacturers in accordance with its business strategy so that the production and distribution of the relevant product in India is controlled by market forces of demand and supply and not by Vifor holding a dominant position. Vifor has granted *de facto* exclusive license to a single manufacturer to show apparent compliance of Section 83(b) of the Patents Act. Vifor is under obligation to disclose in Form 27 that the patented invention is being manufactured in

India or not. Approximately 25% of the net sales of relevant product since 2014 till 2019 is being imported into India by Lupin and India is having 3rd largest pharmaceutical Industry with adequate manufacturing capacity and there is no need to import the relevant product unless article scarcity is created within India.

57. The Informant also submitted that Vifor is misleading the Commission by stating that Vifor does not set or influence FCM prices in India and FCM prices are independently set by Emcure and Lupin. The Informant stated that price of Ferinject and Revofer (imported and distributed by Lupin) is similar to the price of Emcicarb, Orofer and Ferium (manufactured and distributed by Emcure) in India. It is irrational, impractical and unrealistic to believe that a licensor such as Vifor would allow a license like Emcure to compete with the original product of Vifor (Ferinject). On the aspect of price of product, the Informant submitted that Vifor has failed to bring on record the total cost that is incurred to produce one unit of relevant product so as to show that Vifor is charging through its licensee is not unfair or excessive. It was also submitted that discount should not be considered while forming an opinion regarding imposition of unfair/excessive pricing on consumers. Also, the definition of price given under Section 2 (o) of the Act does not include 'discount' in its ambit. Neither the competition law nor patent law expressly allows a patentee to charge high/excessive/unfair prices for its patented product. Rather, the patentee is under an obligation to commercialise the patented product to the fullest extent at reasonable affordable prices as per Section 83 of the Patents Act. The Informant has also contended that FCM injections sold by Vifor to public procurer is only 0.05% of what is sold in the retail market, yet Vifor has stated that reduction in price of FCM injections to public procurer as compared to retail consumers was due to significant volume commitments.

58. Thus, based on the above, the Informant has submitted that Vifor has engaged in *de facto* exclusive licensing agreements and there is evidence on received that Vifor refused to deal with Indian manufacturer to grant licenses for the relevant product in violation of Section 3(4) of the Act. Also, Vifor has violated the provisions of Section 4 of the Act and therefore Commission may direct to DG to cause investigation against Vifor.

Observations and Analysis of the Commission

59. The Commission has considered the Information and the written submissions made by the parties. The Commission, at the outset, observes that Vifor has raised two preliminary objections, *albeit* both related to jurisdiction of the Commission, which the Commission proposes to deal with, before dealing with the present matter on merits.

60. Vifor has argued *firstly* that the Commission's direction for provision of information including certain documents is illegal under Swiss Law and may expose Vifor's officers to the risk of criminal liability under Article 271 of Swiss Criminal code, if they provide the requested information. As per Vifor, only Swiss authorities may apply coercive measures on Swiss territory as part of their judicial sovereignty; and *secondly* that having regard to Section 3(5) of the Act, the Commission is exempted from entering into the domain of the Patent Act and the issues raised relating to compulsory licensing of patents would fall within the domain of the patent controller. This objection has been sought to be amplified further by the submission that there is primacy of the Patents Act in matters of patent licensing and Commission cannot assume jurisdiction, much less when a Standard Essential Patent (SEP) is not involved. Vifor also submitted that it has a statutorily guaranteed right under the Patents Act and is liable to enforce the same to maximum extent permissible under the law. While no remedy is available to the Informant under the Competition Act, it has also failed to exercise its option to seek a compulsory license under the Patents Act.

61. The Commission shall deal with first things first. The Commission would like to place emphasis on the larger mandate conferred upon it as a market regulator as the "*sentinel on the qui vive*" drawing sustenance from the preamble to the Act and Section 18 thereof which casts a bounden duty to eliminate practices having an adverse effect on competition, protect the interests of consumers and ensure freedom of trade carried on by other participants in markets in India. While Vifor may submit that it does not have any office or operations in India, but in the view of the Commission, it will never lie in its mouth to say that it conducts no economic activities or reaps financial rewards within the territory of India. The fact that it enjoys a patent protection for its product granted under the patent regime in India and exploitation of this right *albiet* in a limited manner, through arrangements with two Indian

companies, one of whom imports and distributes its product in India and the other which manufactures and sells to consumers in India, under a licensing arrangement with it, is more relevant to the ascertainment of jurisdiction than the presence of physical office.

62. Dilating on the objection further, what is to be seen is not whether Vifor has any real or perceptible legal difficulty in so far as it has claimed it has under the Swiss law, but whether, when it conducts economic activities in India, under a legally valid contract, it can ask the Commission to act oblivious in respect of its conduct, which is alleged to be in contravention of the provisions of the Act by having an adverse impact on competition in the Indian markets and affecting the trade and consumers thereof. Going further, the Commission observes that provisions of Section 32 of the Act are explicit and extends the extra-territorial jurisdiction of the Commission, for acts taking place outside India, but having an effect on competition in India. It is within the jurisdiction of the Commission and it shall have powers to *inter alia* inquire and pass such corrective orders as it deems fit, into any agreements entered into outside India or if any party to the agreement is outside India, or an enterprise is abusing its dominant position outside India, which has or is likely to have AAEC on competition in the relevant market in India. Thus, what really matters is the effect on competition in India and not the disability, if any, under a foreign law. If an entity does business in India, it must act within the confines of competition law as applies to India and there is no escape from this provision. Curiously, the Commission notes that under both the agreements that Vifor has submitted, that it has with its Indian counterparts, permitting the latter to deal in its patent protected product in India, it has been mentioned that if any dispute arises under the agreements, then the substantive law governing such disputes shall be laws of England and the procedural law for arbitration shall be that of Singapore International Arbitration Centre. Thus, in respect of contractual matters with Indian parties, it chooses a particular mode of dispute resolution, which has neither an Indian or a Swiss connection, but when the Commission proceeds to seek information, in relation to certain allegations of anti-competitive conduct, at a preliminary stage, disabilities under Swiss law are brought to the fore.

63. The Commission also notes the submissions of the Informant as to what disabilities, if any, has been suffered either by Vifor and/or its officials pursuant to complying with the order of the Commission to submit the information/documents, post the intervention of the Hon'ble High Court of Delhi, which shows the deliberate attempt of Vifor to delay/stall the proceedings before the Commission.

64. Be that as it may, for the reasons recorded hereinabove, the Commission is constrained to reject the first objection taken by Vifor as being devoid of any legal merits and reiterates its jurisdiction as emanates from the provisions of the Act, to look into the matter applying the principles of competition law, as are attracted.

65. Now, the Commission shall deal with the second objection raised by Vifor, in relation to the lack of subject matter jurisdiction with the Commission to deal with the allegations contained in the Information filed as they fall within the exclusive domain of the Patents Act, and which has been exempted by Section 3(5) of the Act. With regard, to the exclusion of jurisdiction argument taken by Vifor, the Commission observes that Section 3(5) of the Act does not absolutely exclude the jurisdiction of the Commission, in matters falling under Section 3 of the Act. The very construct of Section 3(5) of the Act shows Competition Act having application over matters which involve existence of a right under any of the intellectual property rights' statutes mentioned therein. It rather allows the Commission to examine whether the alleged anti-competitive agreements, have some justifications in relation to protecting any intellectual property rights of any person as prescribed under Section 3(5) of the Act to restrain any infringement of such rights or to impose reasonable conditions, as may be necessary for protecting any of such rights. Such a determination of reasonability can be done, only when the Commission examines the condition within the overall contours of the Act. The wordings of Section 3(5) make it amply clear that jurisdiction of the Commission is not ousted in any manner, merely because the matter is also a subject matter of Patent Act or any other intellectually property law statute, as has been claimed by Vifor. Similarly, to contend that the Commission will have jurisdiction only in respect of examination of patent issue in context of SEPs and not others is also a very narrow and restrictive interpretation of the Commission's powers, without any legal or

factual basis. The Act does not make a distinction between SEPs and other patents and the artificial distinction being sought to be introduced by Vifor to suit its case is not tenable. Further no embargos have been noticed *qua* the powers of the Commission, in relation to IP protected rights, as is evident from the provisions of Section 3(5) of the Act, subject to the limitation that Commission has to, in appropriate cases, determine either the existence or non-existence of a right, flowing through an intellectual property held by the party or derived by it and the reasonability of the exercise of such right, when posed as a defense before it, in an allegation of violation of Section 3 of the Act. There is nothing that *ex facie* warrants the Commission to circumscribe its powers, in aid of exercise towards sustaining free and fairer market, when distortions can be induced through an anti-competitive conduct arising out of an intellectual property right, the use or non-use of which borders on unreasonableness.

66. The Commission further observes the following observations made by the Hon'ble Delhi High Court in the case of *Monsanto Holdings Private Ltd and Ors vs Competition Commission and Ors* (W.P.(C) 1776/2016 and CM Nos. 7606/2016, 12396/2016 & 16685/2016

> "*As is apparent from the plain language of sub-section (5) of Section 3 that nothing contained in Section 3 of the Competition Act would restrict the right of a person to restrain any infringement of his IPR or to impose reasonable conditions for protecting them. It recognizes that a person has a right to restrain infringement of IPR granted under the specified statutes and any agreement entered for the aforesaid purpose would fall outside rigors of Section 3 of the Competition Act. However, such rights are not unqualified. Only such agreements that are "necessary for protecting any of his rights which have been or may be conferred upon him under" the specified statutes are provided the safe harbor under Sub-section (5) of Section 3 of the Competition Act and only to such extent. This also entails right to impose reasonable conditions. The words "or to impose reasonable conditions" are placed between two commas and thus must be interpreted as being placed in*

parenthesis that explains and qualifies the safe harbor of Sub-section (5) of Section 3 of the Competition Act. Plainly, the exclusionary provision to restrain infringement cannot be read to mean a right to include unreasonable conditions that far exceed those that are necessary, for the aforesaid purpose. The question whether an agreement is limited to restraining infringement of patents and includes reasonable conditions that may be necessary to protect such rights granted to a patentee, is required to be determined by the CCI. Subsection (5) of section 3 of the Competition Act does not mean that a patentee would be free to include onerous conditions under the guise of protecting its rights."

67. In view of the above, the objections taken by Vifor with regard to jurisdiction are found to be without merit and the same are thus, rejected.

68. Before delving into the merits of the matter, the Commission notes that Vifor has filed a letter dated 10.10.2022, seeking to bring on record some facts and instances of alleged suppression and misrepresentation by the Informant. The Commission observes that according to it there is no necessity to go into the subsequent facts brought on record, as the analysis and *prima facie* findings as contained herein, have been undertaken from a competition perspective. Further, the Commission notes that some of these facts emanate out of proceedings which are *sub-judice* before the Hon'ble Delhi High Court.

69. As far as the facts that lie before this Commission, the issue that is most germane and that arises for consideration based on the allegations raised in the Information is the Informant's requirement of access to the patent(s) in '*Soluble FCM Iron Injectables*' owned and patented by Vifor.

70. The Informant has pitched its claim for licencing of the patent belonging to Vifor primarily on the ground that these Iron Injectables are available in India in the form of few brands, sold by Lupin and Emcure, who are the only two companies authorised by Vifor to import/manufacture and sell to patients in India its soluble FCM iron injectables. These

injectables are stated by the Informant to be highly priced as there is no effective price competition between the brands which are sold by the said licensee companies *i.e.*, Lupin and Emcure. There are neither other soluble iron injectables which are effective alternatives to the injectables patented by Vifor, nor can the oral Iron medicines be used as effective substitutes by the patients for soluble iron injectables, which based on the characteristics of the product belong to a different relevant market. Vifor is thus, stated to be abusing its dominant position by not granting more licenses to other interested manufacturers in India who if granted right to manufacture and sell injectables can market them at lower and affordable prices for large number of patients in India.

71. The Informant has also assailed the differential pricing in place for soluble Iron Injectables which is offered at a lower price by the aforementioned licensees while supplying under public procurement initiative of the government, as opposed to high priced retail sale. The differences in prices at which these soluble Iron Injectables are offered in other countries has also been highlighted by the Informant.

72. Based *inter alia* on the above submissions, the Informant has implored the Commission to allow licensing of the patented product of Vifor to correct the distortion created in the market.

73. Vifor on the other hand has stated that both soluble injectables iron and oral iron medicines belong to the same relevant market, having same therapeutic use and when considered so, the market share of soluble iron injectables of Vifor is abysmally low and it wields no dominant power. On the aspect of pricing of soluble iron injectables, Vifor has made categorical assertion that it has no control over the pricing of its patented product of which the license has been granted to Lupin and Emcure. Further, it has suggested that prices charged to end consumers are not determined just by manufacturer but involves considerable distributors and retail margin as well. It has also stated that prices of oral iron medicines, though portrayed by the Informant to be on the lower side, is not the case as when such oral medicines are required to be taken in sufficient dosage, the prices tend to be higher than soluble injectables iron medicines.

74. The Commission has examined the license agreement submitted by Vifor along with its reply, that it has entered into with the aforesaid Indian Companies which appear to have, in their own independent standing, good presence in the Indian market, in respect of the pharma products dealt with by them, which is independent of Vifor. The Commission having given due consideration to the facts and issues involved and the respective assertion of the parties is of the *prima facie* view that there arises no requirement of defining a precise relevant market and accessing the dominance of Vifor, for the reasons adumbrated hereinunder.

75. In the view of the Commission, *prima facie* the clauses of the agreement do not appear to be one sided or to be couched in such terms which can be said to be not reasonable in relation to protection of right of a patent holder *qua* its licensees, when seen from the perspective of Section 3(4) of the Act. There is nothing on record to *prima facie* indicate that Lupin and Emcure are said to be distribution channel partners with such pervasive presence in the market that allows them to exclude competition from other pharma companies operating in the Indian market dealing with diverse product, both generic and non-generic. Further, *prima facie* there is nothing to suggest that construct of the market is such that impedes the free entry of other manufacturer of soluble iron injectables, should they like to operate in the market either independently or through Indian pharma companies, save the *interse* restrictions between Vifor and its two licensees as discussed above.

76. Further, Vifor has submitted that it has no control over prices of soluble FCM Iron injectables sold in the market through these companies and has not restricted its licensees to *inter se* compete through any unilateral anti-competitive policies. According to the Commission what is also noteworthy is that, these license agreements entered into by Vifor are not of a long-term nature but entered into for a limited period of three years with provision for extension upon expiry. There is also no restriction that Vifor cannot enter into more licensing arrangements should it want. Also, the termination clause contained in such agreements do not appear to be *prima facie* erroneous on the two licensees so as to place them at any disadvantageous position in the bargain. Another significant aspect that has weighed with the Commission is that the patent granted to Vifor in respect of its soluble FCM iron

injectables is said to expire in the year 2023 and it is expected that the patented FCM should then be available for free exploitation by interested parties.

77. As regards the price discrimination alleged by the Informant, the Commission observes that all price differentiations may not be discriminatory, more so when the same is based on reasonable classification of consumers to which they are offered. Prices offered in government procurement may not be comparable with the products being sold in open market on quantity criteria (bulk vs. individual buying) as well as purpose (public purpose or distribution free of cost vs private consumption). As regards pricing of FCM injectable in another country *i.e.* Bangladesh, the Commission does not find this to be a correct parameter to adjudge the reasonability of pricing in India. Different countries may have different tax and import duty regimes besides other conditions not being homogenous.

78. Another aspect that has been highlighted is the freedom available to Vifor to choose its trading partner, as has been recognised by the Commission in Case No. 18 of 2021 (*In re: Hiveloop and Britannia*). The Commission in this regard would like to reiterate that this legal position as has been claimed by Vifor is not absolute in nature, but within the confines of the legal principle as has been enunciated in the decision of the Commission in such case. However, the Commission is mindful of the fact that not every company has a right to seek access to the patent of Vifor, unless it demonstrates that there is indeed a need for such access, basing on the existing supply conditions of an essential product/facility as against its demand by the consumers, so as to affect the market adversely by non-dealing on the part of the entity with significant market power. Vifor has submitted that it did not receive any satisfactory request for grant of license of its patent from any entity and that it has responded to two requests it has received recently. Any company requesting for grant of access should also demonstrate its ability to the patent holder, to satisfy the requirements specified for receipt of the grant of license.

79. In the backdrop of the discussion as above, the Commission does not *prima facie* find any contravention on the part of Vifor either under Section 4 or Section 3(4) of the Act and the Information merits to be closed under Section 26(2) of the Act.

80. Notwithstanding the order passed above, the Commission emphasises that the findings reflect the views of the Commission purely from the standpoint of the provisions of the Competition Act, 2002 and may not be construed as expressing any opinion on merits, in any manner, in respect of other ongoing proceedings inter-se the parties in any other forum/tribunal/court.

81. Before concluding this order, the Commission observes that Vifor had filed its submissions in confidential as well as non-confidential versions. Accordingly, confidentiality, as claimed, is granted for a period of 3 years from the passing of this order, subject to the provisions of Section 57 of the Act. It is, however, made clear that no such confidentiality claim shall be available in respect of the information that might have been referred to in this order.

82. The Secretary is directed to communicate to the parties, accordingly

Sd/-
(Ashok Kumar Gupta)
Chairperson

Sd/-
(Sangeeta Verma)
Member

Sd/-
(Bhagwant Singh Bishnoi)
Member

Date: 25/10/2022
New Delhi