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

Reserved on: 17th May, 2021
Decided on: 19th May, 2021

I.A. 5801/2021 in

\+ CS(COMM) 69/2021

FMC CORPORATION ..... Plaintiff

Through: Mr. Sandeep Sethi, Sr. Advocate with Mr. Sanjay Kumar, Ms.Arpita Sawhney, Mr. Arun Kumar Jana, Mr. Harshit Dixit and Ms. Priyansh Sharma, Advs.

versus

BEST CROP SCIENCE LLP & ANR. ..... Defendants

Through: Mr. Gopal Subramanium, Senior Advocate with Dr. Shilpa Arora, Mr.Sidharth Chopra, Ms. Sneha Jain, Dr.Amitavo Mitra, Dr. Victor Vaibhav Tadon, Ms. Shruti Jain, Ms. Hima Lawrence and Mr. Jayavardhan Singh, Advs.

I.A.5816/2021 in

\+ CS(COMM) 611/2019

FMC CORPORATION & ANR. ..... Plaintiffs

Through: Mr. Sandeep Sethi, Sr.Adv. with Mr. Sanjay Kumar, Ms. Arpita Sawhney, Mr. Arun Kumar Jana, Mr.Harshit Dixit and Mr. Priyansh Sharma, Advs.

versus

NATCO PHARMA LIMITED ..... Defendant

Through: Mr. J. Sai Deepak with Mr.G Nataraj, Mr.Avinash K Sharma and Mr.R. Abhishek, Advs.

CORAM:
HON'BLE MR. JUSTICE C. HARI SHANKAR

% JUDGMENT

1. This order disposes of IA 5801/2021 in CS (Comm) 69/2021 and IA 5816/2021 in CS (Comm) 611/2019.

2. Both these suits, instituted by M/s FMC Corporation, allege infringement, by the defendants, of Indian patents IN 201307 ("IN 307") and IN 213332 ("IN 332"), held by the plaintiff. Of these, IN 307 is a product patent and IN 332 is a process patent. The plaints allege that the defendants are intending to launch Chlorantraniliprole ("CTPR"), which is specifically covered and disclosed in IN 307 and IN 332, held by the plaintiff. The proposed action of commercially manufacturing and launching CTPR would, therefore, according to the plaint, infringe IN 307 and IN 332. The plaint, therefore, prays for a permanent injunction against the defendants from dealing in any product which could infringe IN 307 or using any of the processes claimed under IN 332.

3. The defendants' case, in opposition to the case set up by the plaintiff, is that CTPR stands covered by IN 204978 ("IN 978"), which is a genus/Markush patent held by the plaintiff. The plaintiff

has, in response, contended that, even if CTPR is covered by IN 978, it is not disclosed therein. As against this, the defendants contend, relying on the judgment of the Supreme Court in ***Novartis AG v. U.O.I.***[1], that coverage in the genus patent is sufficient and that the Supreme Court has specifically disapproved dichotomizing coverage and disclosure.

4. Detailed arguments have already been advanced before me over the course of several hearings, by both parties, on this nuanced issue, regarding the distinction between coverage and disclosure in the genus/Markush patent and whether coverage sans disclosure would be sufficient to invalidate the subsequent specie patent(s), i.e. in the present case, the suit patents IN 307 and IN 332. The defendants question the very validity of the suit patents, IN 307 and IN 332, contending that, once CTPR stood covered by IN 978, no separate patents could be issued specifically claiming CTPR. They contend that a person ordinarily skilled in the art could easily derive CTPR from the moeities disclosed in IN 978, without having to resort to any inventive step in that regard. In view thereof, the very validity of IN 307 and IN 332, according to the defendants, is highly questionable and, by seeking to base their claim on the said patents, the plaintiff is attempting to "evergreen" the Markush patent IN 978, even beyond its tenure.

5. IN 978 expired on 20th March, 2021, and the suit patents IN 307 and IN 332 are due to expire in August, 2022.

[1] **(2013) 6 SCC 1**

6. The basic premise, on which these applications are based, is that, as IN 307 and IN 332 are *ab initio* invalid patents and as IN 978 has expired, the defendants are now entitled to launch their CTPR product in the market.

7. At the time of issuance of notice in CS(Comm) 611/2019 on 14th November, 2019, the statement of Mr. Sai Deepak, learned counsel for the defendant, was thus recorded:

> "2. Mr. J. Sai. Deepak, learned counsel for the defendant states upon instructions that the defendant has applied for regulatory approval for manufacturing and marketing the product, which the plaintiff alleges infringes the suit patent, in September 2019. He states that approval usually takes 6 to 18 months to be processed. Consequently, it is further stated that there is no likelihood of commercial launch of the product prior to March, 2020. Recording the aforesaid statement, it is unnecessary to pass an *ad-interim* order at this stage. Mr. J. Sai Deepak also states for the record that the defendant has applied to the Intellectual Property Board for revocation of the suit patent IN 201307."

8. Effectively, therefore, the defendant seeks to resile from its statement as recorded on 14th November, 2019, citing changed circumstances as the justification thereof. Similar relief is sought in IA 5816/2021 in CS (Comm) 611/2019.

9. I have heard, at length, learned senior counsel, Mr. Gopal Subramanium, for the applicant in I.A. 5801/2021 and Mr. J. Sai Deepak, learned counsel for the applicant in I.A.5816/2021.

10. Mr. Subramanium initially invited my attention to paras 25 and 26 of CS (Comm) 69/2021, which read thus:

> "25. In fact during the prosecution of the application corresponding to the suit patent IN 201307 in the US, a Declaration was filed at the United States Patent and Trademarks Office (USPTO) comparing compounds disclosed in the suit patent with the closest, specifically disclosed compounds in IN'978. A copy of the said declaration is annexed with the list of documents filed with the present plaint.
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> 26. The said Declaration mentions tests conducted with the compounds of the selection invention (i.e. suit patent IN'307) and a comparison with the closest compounds disclosed in IN'978. In the tests, all the new compounds of the suit patent (IN'307) showed unexpected and unpredictable superior insecticidal activity compared with the closest compounds disclosed in IN'978. CTPR is not specifically disclosed in IN'978. A person skilled in the art would not arrive at CTPR from Formula 1 of IN'978 without human intervention and ingenuity on account of extensive, thorough and undue experimentation or hindsight knowledge. Nonetheless, CTPR is in the class of anthranilamides within the scope of the numerous compounds included in the Markush Formula disclosed and claimed in the IN'978 patent."

11. Mr. Subramanium, emphasises the concluding sentence in para 26 of the plaint in CS (COMM) 69/2021, which admits that CTPR "is in the class of anthranilamides within the scope of the numerous compounds included in the Markush formula disclosed and claimed in the IN'978 patent". Once this has been admitted by the plaintiff, and, IN 978 has expired, Mr. Subramanium would seek to contend that there can be no justification to further restrain his client from manufacturing and selling its CTPR product. Over the course of past year and a half, Mr. Subramanium submits that his client has acquired

all statutory clearances for the manufacture and launch of its CTPR product.

12. CTPR, points out Mr. Subramanium, is an agricultural insecticide, which is specifically used during the *kharif* season, which is due to come to an end in July, 2021. If, therefore, the defendant is not permitted to manufacture or sell its CTPR product, it would lose its entire business for this year and would be denied the right to exploit the IN 978 patent even after it has expired.

13. Mr. Subramanium also emphasises the aspect of public interest, by stating that the product of his client is priced 25% lower than the product of the plaintiff.

14. In these circumstances, submits Mr. Subramanium, the interests of justice would justify permitting the defendant to manufacture and sell its CTPR product, against which the defendant is prepared to maintain the accounts and is also willing to secure the damages of ₹ 2 crores, mentioned in the plaint, by way of an adequate security such as a bank guarantee. He, submits, that the principles of balance of convenience and irreparable loss, viewed in the backdrop of the fact that farmers would have access to the CTPR product at much lower rates, would, in Mr. Subramanium's submission additionally justify the prayers in this application.

15. Appearing on behalf of the applicant in I.A.5816/2021 in CS (Comm) 611/2019, Mr. J. Sai Deepak initially drew attention to para 6 of the plaint in CS (Comm) 611/2019, in which the plaintiff has

admitted that "the suit patents have been licensed and/or sub-licensed by the Plaintiffs to Syngenta Ltd., Syngenta Crop Protection AG; E.I. Du Pont de Nemours and Company, and the Scotts Company LLC". As such, submits Mr. Sai Deepak, the plaintiff has already licensed the suit patents, for exploitation by others. What, essentially, the plaintiff is interested in, therefore, according to Mr. Sai Deepak, is money in the form of the license fee, which the plaintiff would earn. In such circumstances, submits Mr. Sai Deepak, the considerations of public interest and balance of convenience would justify allowing the defendants to release their product in the market, for which purpose Mr. Sai Deepak places reliance on paras 35.5, 35.6, 36 and 36.2 of a recent judgment dated 2nd November, 2020, of this Court in ***Astra Zeneca AB v. Intas Pharmaceuticals Ltd.***[2] which are reproduced thus:

> "35.5 What persuades me to decline injunction, in addition to what I have stated above, is also the fact that in this case damages if proved at trial, appear to be compensable. The defendants have averred that the plaintiffs have, possibly, licensed their rights under the suit patents to two entities i.e. Sun and Abbott. The packaging of the products of the drug sold through these entities is indicative of this aspect. The plaintiffs, however, for reasons best known to them have not placed on record the agreements arrived at with these entities in support of their plea. Therefore, it has to be inferred that the said entities are licensees.
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> 35.6 Besides this, the plaintiffs also aver that they are importing their drug into the country. Therefore, the plaintiffs seek to monetize their invention. Thus, at the end of the trial, if they were to succeed, they could be granted damages, if proved, under the law. Thus, as long as a mechanism can be

[2] **2020 (84) PTC 326**

> put in place for securing the recovery of damages by the plaintiffs, it would, at this stage, balance the interest of the parties. [See: ***Dynamic Manufacturing, Inc. vs. David A. Craze, and Miller Industries, Inc.***, 1998 WL 241201].
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> 36. The parties have also advanced submissions on the aspect concerning public interest. The plaintiffs have submitted that the quality of the drug could be an issue. The plaintiffs have also contended that the drug sold by them is priced reasonably.
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> ****
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> 36.2 Clearly the difference in prices of drugs ranges between 250% to 350%. Therefore, as is apparent, if defendants were allowed to manufacture and market their drugs, it would be far cheaper. Concerns as to quality, at this juncture, appear to be a self-serving argument. The concerned statutory authority can, in my view, adequately deal with this issue if and when such a situation arises."

16. Mr. Sai Deepak has further adverted, at length, to the course of hearings in the present proceedings, in an effort in submitting that the plaintiffs have been guilty of unduly protracting the proceedings by filing misconceived applications. He submits that, even at the stage of rejoinder, the plaintiffs have delayed the matter, thereby subjecting the defendants to needless prejudice. Mr. Sai Deepak professes to exhibit greater generosity than Mr. Subramanium, by undertaking, on instructions, to furnish a bank guarantee for ₹ 5 crores, even though the damages computed in the plaint are only to the tune of ₹ 2 crores. Mr. Sai Deepak has also placed reliance on Section 144 of the CPC, whereunder the plaintiffs could always seek restitution at a later stage. He submits that no further justification exists, to restrain the defendants from exercising their legitimate rights by exploiting the

genus patent IN 978 and releasing their CTPR products in the market.

17. Arguing for the plaintiff/non-applicant, Mr. Sandeep Sethi, learned Senior Counsel submits that, were the present applications to be allowed, IA 2084/2021 in CS (Comm) 69/2021 and IA 15352/2019 in CS (Comm) 611/2019, preferred by the plaintiff under Order XXXIX Rules 1 and 2 of the CPC would be rendered infructuous. Apropos the equities of the case, Mr. Sethi submits that the defendants never filed any pre or post grant opposition to the suit patents or sought to challenge the suit patents by any other means known to law, except a belated revocation petition before the IPAB. He submits that damages can never constitute adequate recompense for infringement or violation of validly held patents, especially pharmaceutical patents and relies, for this purpose, on the following passages from ***Merck Sharp and Dohme Corpn. v. Glenmark Pharmaceuticals***[3]***:***

> "82. Addressing these principles in the circumstances of the present case, the Court notes six equitable principles that come into play in this case and must be considered. First, and this principle is now well established in Indian jurisprudence, the Court must look at the public interest in granting an injunction, as access to drugs, especially one for a condition as prevalent as diabetes, is an important facet of the patent regime. Here, the price difference between the commercial products sold by Glenmark and MSD is not so startling as to compel the court to infer that allowing Glenmark to sell the drug, at depressed prices would result in increased access. Permitting Glenmark to operate would not necessarily result in lowering of market prices. Importantly, whilst lower prices may result from competition amongst two competitors, no allegation has been made that MSD today sells its drugs at a relatively high price that hinders access to the drug. MSD has reduced its price by 1/5th from the United States, which shows

[3] **(2015) 63 PTC 257**

some receptivity to the Indian market; Glenmark has not disputed this submission.

85. This leads us to the second principle, which is whether the Court can overlook the public interest in maintaining the integrity of the patent system itself, so that a legitimate monopoly is not distorted. As this Court noted in ***Bayer Corporation v. Cipla, Union of India (UOI), 162 (2009) DLT 371***

> *"[i]f, after a patentee, rewarded for his toil - in the form of protection against infringement - were to be informed that someone, not holding a patent, would be reaping the fruits of his efforts and investment, such a result would be destructive of the objectives underlying the Patents Act."*.

The Court must be mindful - especially in a case where a strong case of infringement is established, as here - there is an interest in enforcing the Act. It may be argued that despite this no injunction should be granted since all damages from loss of sales can be compensated monetarily ultimately if the patentee prevails. This argument though appealing, is to be rejected because a closer look at the market forces reveal that the damage can in some cases be irreparable. This in turn leads to the third principle, which is where an infringer is allowed to operate in the interim during the trial, it may result in a reduction in price by that infringer since it has no research and development expenses to recoup - most revenue becomes profit. The patentee however can only do so at its peril. Importantly, prices may not recover after the patentee ultimately prevails, even if it is able to survive the financial setback (or "hit") during the interim, which may take some time. The victory for the patentee therefore should not be pyrrhic but real. This irreparable market effect in cases of a sole supplier of a product has also triggered the decisions in ***Smith Kline Beecham v. Generics,*** **(2002) 25(1) IPD 25005** and ***Smithkline Beecham Plc (2) Glaxosmithkline UK Ltd. v. Apotex, [2003] EWCA Civ L37***, where in granting an interim injunction, it was held that damages would not be an adequate remedy for the plaintiff since it was the sole supplier of the product. New entrants to the market would be likely to cause its prices to go into a downward spiral, and Smith Kline's

> prices may not recover even if it wins eventually. Equally, granting the injunction would not prejudice Glenmark to an equal extent since - if the suit is dismissed - it may return to a market that is largely variable."

As such, submits Mr. Sethi, these applications merit outright dismissal.

18. In a short rejoinder, Mr. Sai Deepak points out that ***Merck Sharp & Dohme Corpn.***[3] was noticed by the Coordinate Bench of this Court in ***AstraZeneca***[2]. He further draws my attention to paras 35.1 and 35.3 of the decision in ***AstraZeneca***[2].

19. Having heard learned Senior Counsel Mr. Subramanium and learned Counsel Mr. Sai Deepak at length, I am unable to convince myself that any case, for grant of the prayers in these applications, exists.

20. To my mind, the entire issue is something of a no-brainer. The extensive reliance, by learned Counsel, on the fact that IN 978 has expired on 20th March, 2021 is neither here nor there. The plaintiff does not allege infringement, by the defendants, of IN 978. The plaintiff alleges infringement of IN 307 and IN 332. It is not in dispute that IN 307 and IN 332 are still alive, and would expire only in August, 2022.

21. Equally, the reliance, by Mr. Subramanium, on the acknowledgement, in para 26 of the plaint in CS(COMM) 69/2021, that CTPR is in the class of anthranilamides within the scope of the

numerous compounds included in the Markush Formula disclosed and claimed in IN 978 cannot advance the case of the defendants in these applications. This acknowledgement does not, in any manner, discountenance the case of the plaintiff. Even as per Mr. Sai Deepak, the plaintiff has specifically pleaded that CTPR is not disclosed in IN 978. According to the plaintiff, even if CTPR were to be regarded as covered by IN 978, in the absence of disclosure, mere coverage would not invalidate the specific suit patents issued for CTPR i.e. IN 307 and IN 332. Whether mere coverage of CTPR in IN 978 – assuming such coverage exists – would, in the absence of disclosure of CTPR in IN 978, be sufficient to invalidate the suit patents IN 307 and IN 332, is a matter for consideration and decision in the applications filed by the plaintiff under Order XXXIX of the CPC, which are presently at the stage of rejoinder. This Court cannot, obviously, in these applications, prejudge that issue and, indeed, Mr. Subramanium very fairly stated that the defendants were not requiring the Court to do so.

22. It is not – and, indeed, it cannot be – disputed that, were these applications to be allowed, nothing substantial would survive for consideration in IA 2084/2021 and IA 15352/2019, filed in these suits under Order XXXIX of the CPC. Once allegedly infringing products are in the market, there can obviously be no stay against the infringement and even if any stay were to be granted, the exercise would be fundamentally chimerical in nature. It is also a well settled position in law that damages are entirely insufficient as panacea for the holder of a valid patent, which is infringed by another. Intellectual property has its own sanctity. The prejudice caused even by a single

day's infringement of intellectual property is, in principle, incalculable. It is fundamentally incongruous, therefore, to suggest that, even while the applications for injunction, preferred by the plaintiff in the suits under Order XXXIX of the CPC, are being heard by this Court and are, in fact, at the stage of rejoinder, the defendants should be allowed to launch the allegedly infringing CTPR products.

23. The decision in ***AstraZeneca***[2] can hardly help the defendants. Paras 35.5, 35.6, 36 and 36.2 of the said decision are only in the nature of residual findings, after a detailed examination of the merits of the case, in the preceding paragraphs. This Court has not, in the said decision, permitted release of allegedly infringing pharmaceutical products in the market even while the *prima facie* merits of the application under Order XXXIX of the CPC was under consideration before it, as is the prayer in the present case. I also find substance in the reliance, by Mr. Sethi, on paras 82 and 85 of the judgment of the Division Bench of this Court in ***Merck Sharp & Dohme Corporation***[3]**,** which emphasized the fact that in cases of alleged infringement of pharmaceutical patents, damages are poor solace.

24. I posed a specific query to Mr. Sai Deepak as to how, if this Court were to find that there was, *prima facie*, infringement of the plaintiff's suit patent by the defendants and that, therefore, a *prima facie* case for grant of the relief in IA 2084/2021 and IA 15352/2019, filed by the plaintiff under Order XXXIX of the CPC existed, any meaningful order could be passed, if the defendants were to be allowed to release the allegedly infringing CTPR products in the

market in the interregnum. Despite attempting to answer the query with the considerable legal acumen at his command, I am constrained to observe that no satisfactory response was forthcoming. Rather, Mr. Sai Deepak, with characteristic candour, acknowledged that it was not his case that damages were adequate recompense for a plaintiff who had suffered infringement of its intellectual property. Once this position is admitted, there can be no reasonable justification for permitting the defendants, even while the arguments in the plaintiff's applications under Order XXXIX of the CPC are at the stage of rejoinder, to allow the defendants to release the allegedly infringing CTPR products in the market, thereby effectively rendering the applications under Order XXXIX of the CPC infructuous.

25. In view thereof, I am of the opinion that no case for grant of the prayer for permitting the defendants to release their allegedly infringing CTPR products in the market, can be said to exist at this stage.

26. Learned Senior Counsel Mr. Subramanium and learned counsel Mr. Sai Deepak, pray towards the conclusion of the proceedings that, even if this Court were not inclined to allow the prayers in these applications, the IA 2084/2021 and IA 15352/2019 be set down for conclusion of arguments in rejoinder on a date convenient to the Court and as expeditiously as possible. The record reveals that arguments in rejoinder have been advanced by the plaintiff in these applications, on 21st January, 2021, 3rd February, 2021, 15th February, 2021 and 22nd February, 2021. The issue involved in the case is serious, far-reaching

and justifies an expeditious disposal, especially as it involves pharmaceutical patents. Accordingly, list on 25th May, 2021 from 2:15 to 4:30 pm and on 28th May, 2021 from 2:15 to 3:15 pm, for conclusion of the rejoinder submissions of the plaintiff. Submissions in surrejoinder, if any and subject to the discretion of the Court, would be entertained from 3:15 pm to 4:30 pm on 28th May, 2021. *It is made clear that these times would be adhered to, by the clock, with no further time to either side whatsoever.* Once submissions are concluded, both parties would be at liberty to file their respective written submissions after exchanging copies with each other, within the time that would, at that stage, be stipulated in that regard.

27. With the aforesaid observations, these applications stand disposed of.

C. HARI SHANKAR, J

MAY 19, 2021
ss/r.bararia/kr