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

% ***Judgment Reserved on : 27th January, 2023***
Judgment Delivered on : 29th March, 2023

\+ **CS(COMM) 239/2019 & CCP(O) 82/2019, I.A. 6797/2019 (O-XXXIX R-1 & 2 of CPC), I.A. 9272/2019 (O-VII R-11 of CPC), I.A. 2042/2020 (u/S 151 CPC), I.A. 2044/2020 (u/s 151 CPC)**

BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG ..... Plaintiff

Through: Dr. Sanjay Kumar, Ms. Arpita Sawhney, Mr. Arun Kumar Jana, Ms. Meenal Khurana, Mr. Harshit Dixit and Mr. Priyansh Sharma, Advocates.

versus

VEE EXCEL DRUGS AND PHARMACEUTICALS PRIVATE LTD. & ORS. ..... Defendants

Through: Mr. Mukesh Rana and Ms. Mamta, Advocates for defendants No.1 and 2

\+ **CS(COMM) 240/2019 & CCP(O) 81/2019, I.A. 6802/2019 (O-XXXIX R-1 & 2 of CPC), I.A. 9277/2019 (O-VII R-11 of CPC), I.A. 2036/2020 (u/S 151 CPC), I.A.2038/2020 (u/S 151 CPC)**

BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG & ANR. ..... Plaintiffs

Through: Dr. Sanjay Kumar, Ms. Arpita Sawhney, Mr. Arun Kumar Jana, Ms. Meenal Khurana, Mr. Harshit Dixit and Mr. Priyansh Sharma, Advocates.

versus

VEE EXCEL DRUGS AND PHARMACEUTICALS PRIVATE LTD. & ORS. ..... Defendants

Through: Mr. Mukesh Rana and Ms. Mamta, Advocates for defendant No. 1

\+ **CS(COMM) 236/2022, & I.A. 5801/2022 (O-XXXIX R-1 & 2 of CPC), I.A. 5802/2022(O-XXVI R-9 of CPC), I.A. 5803/2022(O-XI R-1 (6) as amended by the Commercial Court Act), I.A. 5804/2022 (for directions), I.A.22459/2022 (for condonation of delay of 88 days in WS to the CC)**

BOEHRINGER INGELHEIM PHARMA GMBH AND CO KG & ANR. ..... Plaintiffs

Through: Dr. Sanjay Kumar, Ms. Arpita Sawhney, Mr. Arun Kumar Jana, Ms. Meenal Khurana, Mr. Harshit Dixit and Mr. Priyansh Sharma, Advocates.

versus

ALKEM LABORATORIES LTD & ANR. ..... Defendants

Through: Mr. Adarsh Ramanujan, Ms. Bitika Sharma, Ms. Nitya Sharma, Ms. Vrinda Pathak, Mr. George Vithayathil and Mr. Skanda Shekhar, Advocates.

\+ **CS(COMM) 237/2022 & I.A. 5806/2022 (O-XXXIX R-1 & 2 of CPC), I.A. 5807/2022 (O-XXVI R-9 of CPC), I.A. 5808/2022 (O-XI R-1 (6) as amended by the Commercial Court Act), I.A. 5809/2022 (for directions)**

BOEHRINGER INGELHEIM PHARMA GMBH AND CO KG & ANR. ..... Plaintiffs

Through: Mr. Ashok Aggarwal, Sr. Advocate with Dr. Sanjay Kumar, Ms. Arpita Sawhney, Mr. Arun Kumar Jana, Ms. Meenal Khurana, Mr. Harshit Dixit and Mr. Priyansh Sharma, Advocates.

versus

MICRO LABS LIMITED ..... Defendant

Through: Mr. G. Nataraj, Mr. Ankur Vyas, Mr. Shashi Kant Yadav, Ms. Garima Joshi, Ms. Harshita Agarwal, Mr.Avinash K.Sharma, Mr.R.Abhishek and Mr. Rahul Bhujbal, Advocates.

\+ **CS(COMM) 238/2022 & I.A. 5811/2022 (O-XXXIX R-1 & 2 of CPC), I.A. 5812/2022 (O-XXVI R-9 of CPC), I.A. 5813/2022 (O-XI R-1 (6) as amended by the Commercial Court Act), I.A. 5814/2022 (for directions)**

BOEHRINGER INGELHEIM PHARMA GMBH AND CO KG & ANR. ..... Plaintiffs

Through: Mr. Ashok Aggarwal, Sr. Advocate with Dr. Sanjay Kumar, Ms. Arpita Sawhney, Mr. Arun Kumar Jana, Ms. Meenal Khurana, Mr. Harshit Dixit and Mr. Priyansh Sharma, Advocates.

versus

NATCO PHARMA LIMITED & ANR. ..... Defendants

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

\+ **CS(COMM) 296/2022 & I.A. 7109/2022 (O-XXXIX R-1 & 2 of CPC), I.A. 7110/2022 (O-XXVI R-9 of CPC), I.A. 7111/2022 (O-XI R-1 (6) as amended by the Commercial Court Act), 7112/2022 (for directions), I.A. 11729/2022 (u/S 151 CPC)**

BOEHRINGER INGELHEIM PHARMA GMBH AND CO. KG & ANR. ..... Plaintiffs

Through: Dr. Sanjay Kumar, Ms. Arpita Sawhney, Mr. Arun Kumar Jana, Ms. Meenal Khurana, Mr. Harshit Dixit and Mr. Priyansh Sharma, Advocates.

versus

MANKIND PHARMA LIMITED ..... Defendant

Through: Ms. Bitika Sharma, Ms. Nitya Sharma, Ms. Vrinda Pathak and Mr. George Vithayathil, Advocates.

CORAM:
HON'BLE MR. JUSTICE AMIT BANSAL

JUDGMENT

AMIT BANSAL, J.

I.A. 6797/2019 (O-XXXIX R-1 & 2 of CPC) in CS(COMM)239/2019
I.A. 6802/2019 (O-XXXIX R-1 & 2 of CPC) in CS(COMM) 240/2019
I.A. 5801/2022 (O-XXXIX R-1 & 2 of CPC) in CS(COMM) 236/2022
I.A. 5806/2022 (O-XXXIX R-1 & 2 of CPC) in CS(COMM) 237/2022
I.A. 5811/2022 (O-XXXIX R-1 & 2 of CPC) in CS(COMM) 238/2022
I.A. 7109/2022 (O-XXXIX R-1 & 2 of CPC) in CS(COMM) 296/2022

1. The present six suits have been filed on behalf of the plaintiff no.1, Boehringer Ingelheim Pharma Gmbh And Co. Kg and its group company, plaintiff no.2, Boehringer Ingelheim (India) Pvt. Ltd, against various defendants, who are Indian Pharmaceutical Companies, seeking permanent injunction restraining the defendants from infringing Indian Patent No. IN 243301 titled "8 - (3 AMINOPIPERIDIN–1–YL)-XANTHINE COMPOUNDS". All the aforesaid six suits were accompanied by

applications for grant of interim injunction under Order XXXIX Rules 1 and 2 of Code of Civil Procedure, 1908 (CPC).

Proceedings in the suits

2. Summons in CS(COMM) 239/2019 and CS(COMM) 240/2019 were issued on 10th May, 2019 and an ad interim injunction was granted in favour of the plaintiffs restraining the defendants from manufacturing LINAGLIPTIN tablets and the said interim order has continued till date.

3. Summons in CS(COMM) 236/2022, CS(COMM)237/2022 and CS(COMM) 238/2022 were issued on 19th April, 2022 and the following interim/*pro tem* arrangement was arrived at between the parties and the said arrangement has continued till date:

> *"15. After some hearing, learned Senior Counsel appearing on behalf of the Plaintiffs and learned counsels appearing on behalf of the Defendants, on instructions, agree that, as a pro-tem arrangement between the parties,* ***Defendants shall not manufacture, sell, offer for sale and/or use LINAGLIPTIN or LINAGLIPTIN tablets, or any other pharmaceutical preparations or formulations containing LINAGLIPTIN as the active pharmaceutical ingredient, till the next date of hearing.***
>
> *16. It is further agreed that Defendants shall be at liberty to sell the existing stock, already manufactured and the Defendants shall disclose the existing stocks and packaging, which they have already manufactured along with details of batch numbers, dates of manufacturing as well as the value of the stock, within a period of one week from today, on an affidavit.*
> *17. It is made clear that this is purely a pro-tem arrangement between the parties for expeditious*

disposal of the applications and will not be treated as a precedent in any other case."

4. Similar interim/*pro tem* arrangement was arrived at between the parties in CS(COMM) 296/2022.

5. Since the issues involved in all the aforesaid suits and applications for grant of interim injunction are broadly similar, they are being decided by way of this common judgment. As noted in the order dated 4th January, 2023, it was agreed between the parties that CS COMM (236/2022) shall be taken as the lead matter. Accordingly, for the sake of convenience, detailed facts of CS(COMM) 236/2022 have been recorded in the judgment. However, submissions on behalf of the counsels in all the aforesaid suits have been noted.

6. Submissions were heard on behalf of the counsels on 4th January, 2023, 5th January, 2023, 9th January, 2023, 11th January, 2023, 18th January, 2023 and 27th January, 2023 and the judgment was reserved on 27th January, 2023. Counsels for the parties have also placed on record various written submissions along with judgments relied by them.

Factual Background

7. Case set up by the plaintiffs in CS(COMM)236/2022 has been summarised below.

7.1 The plaintiff no.1 is engaged in the business of developing, manufacturing and marketing pharmaceuticals in India through the plaintiff no.2.

7.2 The plaintiff no. 1 was granted Patent IN 243301 (hereinafter also referred to as "suit patent" or "IN'301") on 5th October, 2010 under Section 43 of the Patents Act, 1970 (hereinafter "Patents Act") for the invention

titled "8- (3 AMINOPIPERIDIN–1–YL)-XANTHINE COMPOUNDS" for a term of 20 years with effect from 18th August, 2003. The bibliographic details of the suit patent are set out hereunder:

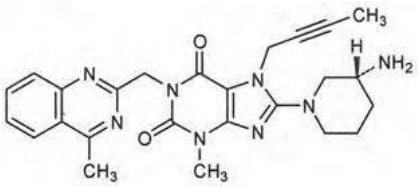
Sr. No.	**Particulars**	**Details**
1.	Indian Application Number	567/DELNP/2005
2.	International Application Number	PCT/EP2003/009127
3.	Priority date	21st August, 2002
4.	International filing date	18th August, 2003
	Indian filing date	14th February, 2005
5.	Date of publication under Section 11A	23rd January, 2009
6.	Date of grant	5th October, 2010
7.	Date of publication under Section 43(2)	8th October, 2010
8.	Term of Patent	20 Years
9.	Date of expiry of the patent	18th August, 2023

7.3 The medicinal products, "Linagliptin Tablets" and "Linagliptin + Metformin Hydrochloride Tablets", covered by the suit patent were

launched in the Indian market under the brand name “Trajenta/ Trajenta Duo” in the years 2012 and 2014 respectively.

7.4 The plaintiff no. 2 obtained the requisite permission of the Drugs Controller General of India (hereinafter referred to as “DCGI”) to import and market “Linagliptin Tablets” and “FDC of Linagliptin + Metformin Hydrochloride Tablets".

7.5 Linagliptin is an International Non-Proprietary Name (INN) of the product covered by the suit patent. WHO document “Recommended INN: List 61”, WHO Drug Information, Vol. 23 No. 1 (2009), 49-83 indicates the name Linagliptin, along with its chemical structure and chemical name, which is reproduced below:



7.6 No third party filed any pre-grant or post-grant opposition against the suit patent.

7.7 Earlier, an Indian Patent No. 227719 (hereinafter referred to as IN ‘719) titled “XANTHINE COMPOUNDS” was granted to the plaintiff no. 1 for the Markush formula being the “genus” patent and its term expired on 21st February, 2022. The bibliographic details of the genus patent are set out hereunder:

Sr. No.	Particulars	Details
1.	Indian Application Number	01092/DELNP/2003
2.	International Application Number	PCT/EP02/01820
3.	Priority date	24th February, 2001

4.	International filing date	21st February, 2002
5.	Indian filing date	14th July, 2003
6.	Date of publication under Section 11A	12th January, 2007
7.	Date of grant	19th January, 2009
8.	Date of publication under Section 43(2)	30th January, 2009
9.	Term of the patent	20 Years
10.	Date of expiry of the patent	21st February, 2022

7.8 The suit patent is the "species/selection patent" covering the specific commercial embodiments being marketed by the plaintiff no. 2 in India. The compound, Linagliptin, covered and claimed by the suit patent was invented upon further research, which was carried out subsequent to the filing date of IN '719 and before the earliest priority date of the suit patent.

7.9 The defendants are engaged in manufacturing and selling the product, Linagliptin 5mg tablets (hereinafter 'infringing product'), covered by the suit patent. Therefore, the infringing product contains "Linagliptin" and infringes the suit patent.

7.10 Accordingly, the present suit has been filed on behalf of the plaintiffs seeking relief of permanent injunction along with other ancillary reliefs.

Case set up in the written statement

8. The case set up by the defendants in their written statement filed in CS(COMM)236/2022 is summarised below.

8.1 The compound Linagliptin and its formulations were claimed in IN '719, the genus patent. The prior patent IN '719 expired on 21st February,

2022 and thus, the compound Linagliptin has fallen into public domain w.e.f. 22nd February, 2022.

8.2 Under the Patents Act, there can only be one patent for one invention. Therefore, the plaintiffs cannot have two patents for the same invention.

8.3 The plaintiffs are attempting to extend their monopoly over Linagliptin beyond original 20-years term, by a further period of 1.5 years (approximately) through a second subsequent patent, i.e., the suit patent/species patent, which is legally untenable and impermissible under Section 53(4) and Section 46(2) of the Patents Act, and amounts to double patenting and evergreening.

8.3 It has been admitted on behalf of the plaintiffs in various proceedings before Courts in India and abroad that the compound Linagliptin is protected and **covered** by IN '719. The plaintiffs now cannot reprobate on the said admission and assert that Linagliptin is 'specifically claimed' only in the suit patent.

8.5 The plaintiffs have falsely pleaded that Linagliptin was never claimed in IN '719 in paragraph 15 of the plaint in CS(COMM) 236/2022. The plaintiffs have admitted before the Indian Patent Office that Linagliptin is a part of the inventive step of earlier IN '719 patent and for the grant of the said patent, also included Linagliptin in the list of 371 examples filed as a part of the reply to the FER to show alleged enhancement in efficacy.

8.6 The plaintiffs have suppressed documents that are material to the present dispute, including complete specification along with claims granted in respect of earlier IN '719 patent; FER issued by the Indian Patent Office qua IN '719 patent; and reply to the said FER filed by the plaintiffs.

8.7 Linagliptin is the only commercial product for both IN' 719 patent and the subsequent IN '301 patent, which is evident from the identical Form 27s filed by the plaintiffs for both IN '719 patent and IN ‘301.

8.8 The suit patent, i.e., IN ‘301 is invalid and liable to be revoked under various provisions of Section 64 the Patents Act. The defendants have also filed a counter claim seeking revocation of the suit patent.

8.9 In terms of Section 13 (4) of the Patents Act, the grant of the subject patent by the Indian Patent Office does not warrant its validity or render presumption of validity of the same. Thus, the validity of the subject patent can be challenged at any stage including by way of counter claim in the instant infringement action.

8.10 The factum of plaintiffs instituting legal proceedings against various third parties, prior to the expiry of the genus patent IN '719 with respect to Linagliptin and asserting infringement of the genus patent IN '719 qua Linagliptin and its formulations, in itself amounts to an admission on part of the plaintiffs that the compound/ molecule Linagliptin and its formulations were “protected” by and “claimed” in IN '719.

8.11 The plaintiff no.1 filed a patent infringement complaint before the Canadian Federal Court asserting both the Canadian patents bearing no. CA 2435730 (equivalent to IN '719) and CA 2496249 (equivalent to IN '301), seeking to restrain a third party, Sandoz, from dealing directly or indirectly with Linagliptin.

8.12 The defendants have started commercializing Linagliptin from 22nd February, 2022, when the same has fallen into public domain. Thus, the defendants have not indulged in any infringing activity and have not violated rights of the plaintiffs envisaged under Section 48 of the Patents Act.

Submissions on behalf of the plaintiffs

9. Counsels appearing for the plaintiffs have made the following submissions:

I. The suit patent has been successfully enforced by the plaintiffs against various generic entities across the country. Reliance in this regard is placed on the judgment dated 2nd June, 2022 passed by the Himachal Pradesh High Court in OMP No. 85/2022 titled ***Boehringer Ingelheim Pharma GMBH & CO.*** **v.** ***MSN Laboratories Private Limited***.

II. The suit patent is an old patent, which is in its final year and has worked since 2012, without any successful challenge worldwide, including India. In fact, proceedings challenging the validity of the suit patent were instituted in China, which were dismissed and the suit patent was upheld. Reliance is placed on the judgment of this Court in ***National Research Development Corp of India*** **v.** ***Delhi Cloth & General Mills, (1979 SCC OnLine Del 206)*** to contend that if the patent is sufficiently old and has been worked, a mere challenge is not sufficient. The Court in such cases for the purpose of temporary injunction ought to presume the patent to be valid.

III. None of the defendants have either filed a pre-grant or a post-grant opposition in respect of the suit patent. Further, the revocation petitions have been filed by some of the defendants only at a belated stage.

IV. The defendants have admitted that they are manufacturing and selling the product, Linagliptin, and other formulations of the same. Admittedly, the defendants have not applied for a voluntary or a

compulsory licence from the plaintiffs. The aforesaid act of the defendants amounts to violation of the rights of the plaintiffs under Section 48 of the Act.

V. Once a patent is granted, the onus to make out a credible challenge to its validity would rest squarely on the party challenging it by placing on record cogent material. Reliance in this regard is placed on the judgment of this Court in ***FMC Corporation & Anr.* v. *Best Crop Science LLP & Anr. / NATCO Pharma Limited*, *(2021) 87 PTC 217***.

VI. The defendants have failed to raise a credible challenge to the suit patent. Only bald allegations have been made in the pleadings with regard to the validity of the suit patent.

VII. The defendants have relied upon various statements made by the plaintiffs that are subsequent to the priority date of suit patent, i.e, 21st August 2002. No reliance can be placed on the same as they fall into the category of hindsight analysis and ex-post facto cherry picking.

VIII. The genus patent IN '719 is not a prior art as the same was published on 6th September 2002 after the priority date of suit patent IN '301, i.e., 21st August 2002. Therefore, a person skilled in the art would not have access to IN '719 as on the priority date of IN '301.

IX. For the purpose of determining anticipation by prior claiming, the granted claims of the two patents have to be compared and not the descriptions of the inventions disclosed in the two patents. Only when the claim granted in the second patent is identical to the claim granted

in the first patent, the doctrine of prior claiming in terms of Section 13(1)(b) of the Act shall apply.

X. A comparison of claim 1 in IN '719 and claim 1 in IN '301 would show that Linagliptin *per se* is neither disclosed, nor claimed in the genus patent, IN '719. Therefore, no reliance can be placed on the Form 27s filed on behalf of the plaintiffs.

XI. The judgment in ***AstraZeneca AB & Anr.* v. *Intas Pharmaceuticals Ltd.*, *MANU/DE/1939/2020***, is not applicable to the facts of the present case as unlike the said case, in the present case, there are two independent inventions claimed under the two patents, IN '719 and IN '301.

XII. The Coordinate Bench of this Court in ***Novartis AG & Anr.* v. *Natco Pharma Limited*, *2021 SCC Online Del 5340***, has observed that the judgment of the Supreme Court in ***Novartis* v. *Union of India*, *(2013) 6 SCC 1***, was purely based on the facts of that particular case. The ***AstraZeneca*** (supra) has also been distinguished by the judgment of the Himachal Pradesh High Court in ***MSN Laboratories*** (supra).

XIII. Reliance placed by the defendants on the judgment of the Supreme Court in ***Novartis*** (supra) is misplaced as the said judgment deals with the issue of patentability of the invention claimed by Novartis in terms of Section 3(d) of the Act. Therefore, the scope of the proceedings before the Supreme Court was entirely different as compared to the present suit. The judgment in ***Novartis*** (supra) did not hold that there was no distinction between the "coverage" and "disclosure". It held

that a 'a wide gap' should not exist between the "coverage" and "disclosure" under the Indian Patent law.

XIV. Merely because one product encompasses working of both species and genus patent does not *ipso facto* disclose that the species patent is covered by the genus patent or that it is previously claimed in the genus patent. There is no legal basis for the defendants' submission that Form 27 disclosures are any admission of invalidity of species patent. Reliance in this regard is placed on the judgment of this Court in ***Novartis* v. *Natco*** (supra).

XV. The fact that 371 compounds were submitted by the plaintiffs before the Patent Office, does not advance the case of the defendants as the filing date of IN '301 was before the filing date of the said submission.

XVI. In the written statement filed on behalf of the defendants in CS(COMM) 239/2019 and CS(COMM) 240/2019, the defendants therein have specifically pleaded that Linagliptin is not covered by the genus patent, IN '719.

Submissions on behalf of the defendants

A. ***Submissions on behalf of defendants in CS(COMM) 236/2022***

I. Merely because the suit patent, IN '301 is an old patent does not mean that there cannot be any challenge to its validity. Section 13(4) of the Act does not make any such distinction between old or a new patent. The Patents Act, unlike the Trademark Act, 1999, does not have a

provision similar to Section 31 of the Trademarks Act, 1999, where registration is *prima facie* evidence of validity of a trademark.

II. Linagliptin is the only commercial product for both IN '719 and IN '301 patents as evidenced from the working statements under Form 27s filed on behalf of the plaintiffs.

III. The plaintiffs have taken benefits based on the assertions that Linagliptin is claimed and covered in IN '719 and therefore, now the plaintiffs cannot assert to the contrary that Linagliptin was not specifically claimed in IN '719. The plaintiffs cannot be permitted to approbate or reprobate at the same time.

IV. Annexure B to the affidavit filed on behalf of the co-inventor is dated 21st December, 2021, which is much after the priority date, 21st August, 2002, of the suit patent, IN '301. Therefore, no reliance can be placed on the said affidavit.

V. The defendants have also filed an affidavit of an expert in support of their submission that Linagliptin was covered and claimed in IN '719.

VI. Both IN '719 patent and IN '301 patent contain genus/Markush claims. Claim 1 of IN '301 is itself a genus of compounds covering 22 alternatives.

VII. All the members of a Markush patents are entitled to protection once the patent is granted. Therefore, the molecule Linagliptin was claimed and protected under IN '719 and which is sought to be claimed and

protected in IN '301, which amounts to re-monopolisation and is not permissible under the Patents Act.

VIII. Linagliptin is one of the 22 alternatives in claim 1 of IN '301 as also one of the 7 compounds listed in claims 5, 6 and 7 of IN '301. Linagliptin is also one of the alternatives in claim 1 as well as claim 3 of the earlier IN '719 patent.

IX. Reference to 'claims' in Section 64(1)(a) of the Patents Act has to be read with Section 10(4)(c) of the Patents Act, which refers to 'claims' as 'defining the scope of the invention for which the protection is claimed'. Therefore, what has to be examined is whether the later patent, IN '301, protects what is already protected in the earlier patent, IN '719.

X. The plaintiffs have already enjoyed a twenty-year monopoly on Linagliptin under IN '719 patent and the defendants have waited for the expiry of the aforesaid twenty-year monopoly before launching their product in the market.

XI. The plaintiffs can be compensated by way of monetary damages that are quantifiable in nature. In the present case, the plaintiffs have licensed the suit patent and therefore, monetary damages can be calculated in respect of the same.

XII. The plaintiffs import their products in India, while the defendants manufacture their products in India.

XIII. The product is a daily-use drug and there is a huge differential in the price of the drug of the plaintiffs and the one manufactured by the defendants. Therefore, public interest would be in favour of increased access to the more affordable version of Linagliptin, which is marketed by the defendants.

XIV. Reliance is placed on the Judgment passed by Rajiv Shakdher, J. in ***AstraZeneca*** (supra) and the judgment passed by the Division Bench of this Court in ***AstraZeneca AB & Anr.* v. *Intas Pharmaceuticals Ltd.*, *(2021) 87 PTC 374 (DB)***, upholding the aforesaid judgment. The dispute in the present suits is fully covered by the aforesaid judgments.

XV. The judgment in ***FMC*** (supra) was prior to the judgment of the Division Bench in ***AstraZeneca*** (supra) and was specifically cited before the Division Bench. Further, the judgment in ***FMC*** (supra) did not refer to the earlier judgment of Rajiv Shakdher, J. in ***AstraZeneca*** (supra)

XVI. Barring the judgment passed by the Himachal Pradesh High Court in ***MSN Laboratories*** (supra), all other orders concerning the suit patent do not address the issue of vulnerability of the suit patent. The Himachal Pradesh High Court in ***MSN Laboratories*** (supra) cites the judgment passed by the Division Bench in ***AstraZeneca*** (supra), but does not examine or apply the same to the facts of the said case.

B. ***Submissions on behalf of the defendants in CS(COMM) 237/2022 and CS(COMM) 238/2022***

I. Provisions of Section 64(1)(a) and Section 3(d) of the Patents Act are unique to the patent law in India. In fact, similar provisions existed in the UK Patent Act till 1977, when the UK Act was amended and the aforesaid provision was deleted. Therefore, even if patents are granted in favour of the plaintiffs worldwide, it would not alter the position in India.

II. Section 53(4) of the Patents Act only uses the word "covered". Therefore, the only determination that is required to be made is whether Linagliptin has been "covered" under the earlier patent. All other references in the Patents Act, i.e., Section 52(1) and Section 100(4) also use the term "covered". Therefore, even if the plaintiffs claim that Linagliptin has not been disclosed in the genus patent, the position would not change so long as it has been covered and claimed.

III. There is no merit in the submission of the plaintiffs that the defendants have filed revocation petition belatedly. A person would file revocation petition only when there are commercial reasons to do so and in the present case, the defendants launched their product only in February, 2022. Immediately after receiving the cease and desist notice from the plaintiffs in December, 2021, the defendants filed the revocation petition.

IV. The judgment of Himachal Pradesh High Court in ***MSN Laboratories*** (supra) is erroneous both in facts and in law. The aforesaid judgment has placed reliance on the terms "covered" and "encompassed", when in fact the word used in Section 10(4) of the Patents Act is "claimed". In paragraph 28 of the said judgment, the finding is on the wrong facts as

the patent application referred therein refers to IN '719 and not the suit patent.

V. In terms of Section 64(1)(a) of the Patents Act, the only requirement that has to be seen is whether the suit patent has been claimed in the earlier patent. Admittedly, Linagliptin has been claimed in IN '719 as is evident from the admission made by the plaintiffs in various litigations in India and abroad and in terms of the regulatory filings made by the plaintiffs in India.

VI. The suit patent is liable to be revoked under Section 64(1)(f) of the Patents Act, as the invention under the suit patent is obvious and lacks inventive step in view of the genus patent, IN '719 having an earlier priority date.

VII. The suit patent is also liable to be revoked under Section 64(1)(m) of the Patents Act as the plaintiffs have failed to disclose to the Patent Office information required under Section 8 of the Patents Act.

VIII. The suit patent is not patentable in terms of Section 64(1)(d) and Section 64(1)(k) of the Patents Act. The absence of disclosure or any assertion in IN '301 that the compounds of claim 1 have any significant enhancement of therapeutic efficacy over IN '719 shows its invalidity due to Section 3(d) of the Patents Act.

C. ***Submissions on behalf of the defendants in CS(COMM) 239/2019 and CS(COMM) 240/2019***

I. The *ad interim* order dated 10th May, 2019 passed in the aforesaid suits was based on the submission of the plaintiffs that Linagliptin in all forms and combinations is "covered" by the two patents, IN '719 and IN '301.

II. The claims in IN '719 and IN '301 are identical claims and no claim for Linagliptin 5mg as a product was made in any of the claims under both the suit patents. What is claimed in the invention is not present in the final product, i.e., Linagliptin 5mg. The invention has not been properly described in either of the two suit patents and no skilled person can decipher the invention from the claims. Therefore, the suit patents have failed the test of patentability in terms of Section 2(1)(j), 2(1)(ja), Section 2(1)(ac) and Section 3(d) of the Patents Act.

III. The plaintiffs have failed to show the increase in potency, efficiency and viability in respect of the Claims in the suit patent, IN '301 in comparison to the Claims in genus patent, IN '719.

10. Counsel for the defendants in CS(COMM) 296/2022 adopts the submissions made on behalf of the defendants in the aforementioned suits and the same are not repeated for the sake of brevity.

Findings and Analysis

11. I have heard the counsels for the parties and perused the record of the suits.

12. Based on the submissions of the counsels, for the sake of clarity and ease of reading, I have formulated the following issues which require determination for the purposes of grant of interim injunction in favour of the plaintiffs:

I. Whether in cases of old patents, the validity of the same has to be presumed by the Court?

II. Whether the validity of the suit patent has to be presumed on account of defendants not having filed pre-grant or post-grant opposition to the suit patent or having filed revocation petition belatedly?

III. Whether the defendants have laid a credible challenge to the suit patent?

IV. Whether balance of convenience is in favour of the plaintiffs and against the defendants for the grant of interim injunction?

13. To begin with, I would address the first two issues formulated above.

I. Whether in cases of old patents, the validity of the same has to be presumed by the Court?

II. Whether the validity of the suit patent has to be presumed on account of defendants not having filed pre-grant or post-grant opposition to the suit patent or having filed revocation petition belatedly?

14. To decide these issues, a reference may be made to Section 13(4) of the Patents Act:

> *"**13. Search for anticipation by previous publication and by prior claim.—***
>
> *(4) **The examination and investigations required under section 12 and this section shall not be deemed in any way to warrant the validity of any patent**, and no liability shall be incurred by the Central Government or any officer thereof by reason of, or in connection with, any such examination or investigation or any report or other proceedings consequent thereon.*
>
> *xxx xxx xxx*

15. Section 13(4) of the Patents Act makes it abundantly clear that no distinction has been made between the old and the new patents. It specifically states that grant of patent would not, in any manner, warrant its validity. The Patents Act does not have any provision similar to Section 31(1)[1] of the Trademarks Act, 1999, wherein it is provided that the registration of a trademark would be a *prima facie* evidence of its validity. Therefore, under the scheme of the Patents Act, the grant of patent is not a *prima facie* evidence of its validity.

16. In ***Bishwanath Prasad Radhey Shyam* v. *Hindustan Metal Industries*, *AIR 1982 SC 1444***, the Supreme Court has observed that Section 13(4) of the Patents Act makes it clear that examination and investigations required under Section 12 and Section 13 of the Patents Act shall not be deemed to warrant the validity of the patent. Therefore, even when the patent crosses the threshold of examination by the patent office, the challenger can put the patent in jeopardy. The relevant portion of the judgment is set out below:

> "***32. It is noteworthy that the grant and sealing of the patent, or the decision rendered by the Controller in the case of opposition, does not guarantee the validity of the patent, which can be challenged before the High Court on various grounds in revocation or infringement proceedings. It is pertinent to note that this position viz. the validity of a patent is not guaranteed by the grant, is now expressly provided in Section 13(4) of the Patents Act. 1970. In the light of***

[1] **31. Registration to be *prima facie* evidence of validity.**—(*1*) In all legal proceedings relating to a trade mark registered under this Act (including applications under section 57), the original registration of the trade mark and of all subsequent assignments and transmissions of the trade mark shall be *prima facie* evidence of the validity thereof.

> ***this principle, Mr Mehta's argument that there is a presumption in favour of the validity of the patent, cannot be accepted***."

17. The aforesaid aspect was dealt with in the judgment of Rajiv Shakdher, J. in ***AstraZeneca*** (supra). In the said case also, an argument was raised on behalf of the plaintiffs therein that since the suit patents are old, their validity has to be presumed. Relying upon the judgment in ***Bishwanath Prasad*** (supra), Rajiv Shakdher, J. in ***AstraZeneca*** (supra) came to the conclusion that the challenge to the validity of the patent can be made at any stage and what is relevant is not the stage when the challenge is made, but the credibility of the challenge. Accordingly, the submission of the plaintiffs therein that older the patent, stronger the firewall was rejected by Rajiv Shakdher, J. by observing as under:

> *"18.3 Furthermore, the argument advanced on behalf of the plaintiffs that since the suit patents are old and thus, should be presumed to be valid cannot be accepted for two reasons.*
>
> *i. First,* ***there is a period of overlap between the genus patent i.e. IN 147 and the species patent i.e. IN 625. The defendants, in this case, chose to wait [in line with arguments advanced in their defence of the suit actions] till such time the validity period of the genus patent i.e. IN 147 expired.***
>
> *ii. Second, as indicated above, the scheme of the Act does not foreclose the right of the defendants in defence to an infringement action to question the validity of the patent.* ***Section 107 of the Act, expressly confers a right on the defendants to raise, in defence, in an infringement suit, all those grounds on which the patent can be revoked under Section 64 of the very same Act.*** *Therefore, the judgement in Bristol-Myers Squibb Company and Ors vs. J.D. Joshi and*

> *Ors., MANU/DE/1889/2015, if read in context, would demonstrate that it has not emasculated the right of the defendant, as conferred under the Act, to challenge the validity of the patent.* ***The presumption of validity exists only till such time the patent is challenged - a challenge which is credible and no further. In my opinion, if the plaintiffs' argument was to be accepted, then, it would have to be held that the older the patent, the stronger the firewall. Such an interpretation, in my view, would be contrary to the plain words of the Statute****."*

18. The aforesaid judgement of Rajiv Shakdher, J. was upheld by the Division Bench of this Court in the judgment in ***AstraZeneca*** (supra).

19. The plaintiffs have relied on the judgment of ***National Research*** (supra) to contend that for the purpose of deciding an application for temporary injunction, the patent ought to be presumed to be valid. The relevant extract of the said judgment is set out as under:

> *7. For the grant of temporary injunction, principles applicable to the infringement of Patent actions are that there is a prima facie case, that the patent is valid and infringed, that the balance of convenience is in favour of the injunction being granted and that the plaintiff will suffer an irreparable loss. It is also a rule of practice that if a patent is a new one, a mere challenge at the Bar would be quite sufficient for a refusal of a temporary injunction, but if the patent is sufficiently old and has been worked, the court would, for the purpose of temporary injunction, presume the patent to be valid one. If the patent is more than six years old and there has been actual user it would be safe for the court to proceed upon this presumption. Terrell on the Law of Patents Twelfth Edition in para 830 has observed as follows :*
>
> *"Prima facie evidence of validity :*

> *The plaintiff must first establish such facts as will satisfy the court that there are strong prima facie reasons for acting on the supposition that the patent is valid. The most cogent evidence for this purpose is either that there has been a previous trial in which the patent has been held to be valid, or that the patentee has worked and enjoyed the patent for many years without dispute, or it may be that as between the parties the plaintiff is relieved from the onus of establishing validity, as where the defendant has admitted it or is so placed in his relationship to the plaintiff as to be estopped from denying it".*

xxx *xxx* *xxx*

> *13. From the correspondence and other material on record it appears that the defendants wanted a licence and they admitted the validity of the process which has been patented. If the defendants were aware of know-how already, why they were negotiating with the plaintiff for a licence. The patent in question's more than six years old and under Section 48 of the Patent Act the patentee has the exclusive right by himself his agents or licensees to use the process. The patent relates to the process of manufacturing Anode, which is also used for the manufacture of Caustic Soda. Prima facie the patent in question is not invalid. If the defendants are not injuncted they would violate the patent and this would become a precedent for others to violate the patent. The balance of convenience would therefore be to injunct the defendants. The plaintiff has made inventions and therefore if the patent is allowed to be violated by defendants the plaintiff is likely to suffer injury."*

20. The aforesaid judgment attempted to borrow a rule of practice stemming from the English decision in ***Smith* v. *Grigg Ld., (1924) 41 RPC***

149, which is commonly referred to as the six-year rule. However, the application of this rule in the context of Indian Patent Law has been doubted in various decisions of this Court. In ***F. Hoffmann La Roch & Anr.*** **v.** ***Cipla Limited***¸ ***2008 SCC OnLine Del 382***, while commenting on the aforesaid six-year rule, a Single Judge of this Court specifically held that the same has to be a rule of caution and not a rule of practice.

21. In my considered view, the said six-year rule cannot be relied upon to presume the validity of a patent granted in India. The said rule can be explained as one cautioning the Courts that patent infringement actions stand on a slightly different footing from other cases, where the Courts should not automatically grant injunction on a *prima facie* satisfaction of infringement, since patents can be challenged even in defence.

22. The Division Bench of this Court in ***F. Hoffmann- LA Roche Limited v. Cipla Limited, ILR(2009)Supp.(2)Delhi 551,*** has considered this the specific submission that a plaintiff is entitled to the grant of an injunction, since the patent is granted after examination at several levels. Negating this submission, it was held that even if a patent survives the pre-grant and post-grant challenges, it can still be made vulnerable to revocation on grounds different from the ones raised at those stages.

23. This view is also fortified by Section 113 of the Patents Act, which is set out below:

> *"**113. Certificate of validity of specification and costs of subsequent suits for infringement thereof.**—(1) If in any proceedings before the Appellate Board or a High Court for the revocation of a patent under section 64 and section 104, as the case may be, the validity of any claim of a specification is contested and that claim is found by the Appellate Board or the High Court to*

> *be valid, the Appellate Board or the High Court may certify that the validity of that claim was contested in those proceedings and was upheld.*
>
> *(2) Where any such certificate has been granted, then, if in any subsequent suit before a court for infringement of that claim of the patent or in any subsequent proceeding for revocation of the patent in so far as it relates to that claim, the patentee or other person relying on the validity of the claim obtains a final order or judgment in his favour, he shall be entitled to an order for the payment of his full costs, charges and expenses of and incidental to any such suit or proceeding properly incurred so far as they concern the claim in respect of which the certificate was granted, unless the court trying the suit or proceeding otherwise directs: Provided that the costs as specific in this sub-section shall not be ordered when the party disputing the validity of the claim satisfies the court that he was not aware of the grant of* the certificate *when he raised the dispute and withdrew forthwith such defence when he became aware of such a certificate*."

24. A reading of Section 113 of the Patents Act demonstrates the intent of the legislature that it is only when the validity of the claim is upheld by the High Court in a revocation petition under Section 64 of the Patents Act, the High Court would issue a certificate to the said effect. Based on the aforesaid certificate, the patentee, in any subsequent suit for infringement shall be entitled to an order for payment of full costs, charges and other expenses. Therefore, under the scheme of the Act, no inference of validity arises at the stage of grant of patent.

25. Axiomatically, it would not matter if the defendants had filed a pre-grant or a post-grant opposition to the suit patent. A challenge can be laid

either at the stage when an application is moved for grant of a patent, after its publication or after its grant, or even by seeking revocation or by way of a counterclaim in an infringement suit. It cannot be gainsaid that a person is expected to raise a challenge to the validity of the patent only when the need arises for the same. In case of commercial entities such as the defendant companies, the need to raise challenge would arise only on account of commercial realities and necessities.

26. Most of the defendant companies in the present suits did not launch their products till the expiry of the genus patent, IN '719, which expired on 21st February, 2022. When the defendants launched their products, the plaintiffs asserted their rights over the suit patent and claimed that the products of the defendants are covered by the suit patent. It was only at that stage that the cause of action arose in favour of the defendants to challenge the suit patent and soon thereafter, the revocation petitions have been filed on behalf of various defendants. Therefore, I do not find any merit in the submission of the plaintiffs that merely because the suit patents were old patents and no challenge was raised to their validity, the same have to be presumed as valid.

27. Now, I proceed to address the third issue flagged above.

III. Whether the defendants have laid a credible challenge to the suit patent?

28. In ***F. Hoffmann*** (supra), the Division Bench of this Court laid down the judicial standard, which ought to operate at the stage of granting interim injunction and observed that, at the preliminary injunction stage, the defendant is required to show that the patent is vulnerable and that the challenge to the validity of the patent raises a serious substantial question

and a triable issue. The relevant observations of the Court are set out as under:

> *"53. The plea of the plaintiff that since there is a multi-layered, multi-level examination of the opposition to the grant of patent it should accorded the highest weightage, is not entirely correct. The contention that there is a heavy burden on the defendant to discharge since it has to establish that it has a stronger prima facie case of the plaintiff is contra indicated of the decisions in the context of Section 13(4). Reference may be made to the decisions in Biswanath Prasad Radhey Shyam v. Hindustan Metal Industries [1979]2SCR757; Standipack Pvt. Ltd. v. Oswal Trading Co. Ltd. AIR2000Delhi23 ; Bilcare Ltd. v. Amartara Pvt. Ltd. 2007 (34) PTC 419(Del); Surendra Lal Mahendra v. Jain Glazers (1979) 11 SCC 511. In Beecham Group Ltd. v. Bristol Laboratories Pty Ltd. (1967) 118 CLR 618 and Australian Broadcasting Corporation v. O'Neill (2006) 229 ALR 457 it was held that the defendant alleging invalidity bears the onus of establishing that there is "a serious question" to be tried on that issue. In Hexal Australai Pty Ltd. v. Roche Therapeutics Inc. 66 IPR 325 it was held that where the validity of a patent is raised in interlocutory proceedings, "the onus lies on the party asserting invalidity to show that want of validity is a triable question." In Abbot Laboratories v. Andrx Pharmaceuticals Inc. decision dated 22nd June 2006 of the U.S.Court of Appeals for the Federal Circuit 05-1433 the Court of Appeals followed its earlier ruling in Helifix Ltd. v. Blok-Lok Ltd. 208 F.3d 1339 where it was held (at 1359):*
>
> > *In resisting a preliminary injunction, however, one need not make out a case of actual invalidity. Vulnerability is the issue at the preliminary injunction stage, while*

> *validity is the issue at trial. The showing of a substantial question as to invalidity thus requires less proof than the clear and convincing showing necessary to establish invalidity itself.*

In Erico Int'll Corprn v. Vutec Corprn U.S.Court of Appeals for the Federal Circuit 2007-1168 it was held that the "defendant must put forth a substantial question of invalidity to show that the claims at issue are vulnerable.

54. In the present case, the grant of a patent to the plaintiffs for Erlotinib Hydrochloride as a mixture of Polymorphs A and B will not ipso facto entitle them to an interim injunction if the defendant is able to satisfy the court that there is a serious question to be tried as to the validity of the patent. ***The use by the learned Single Judge of the expressions "strong credible challenge", "arguable case" or that the defendants claim being not unfounded, cannot be termed as vague and inconsistent since they convey the same meaning in the context of the strength of the defendant's challenge.***

55. The question before this Court is when can it be said that the defendant has raised a credible challenge to the validity of a patent held by the plaintiff in an infringement action? During the course of the argument it was suggested by counsel that the challenge had to be both strong and credible. Also, ***the defendant resisting the grant of injunction by challenging the validity of the patent is at this stage required to show that the patent is "vulnerable" and that the challenge raises a "serious substantial question" and a triable issue.*** *Without indulging in an exercise in semantics, the Court when faced with a prayer for grant of injunction and a corresponding plea of the defendant challenging the validity of the*

> *patent itself, must enquire whether the defendant has raised a credible challenge. In other words, that would in the context of pharmaceutical products, invite scrutiny of the order granting patent in the light of Section 3(d) and the grounds set out in Section 64 of the Patents Act 1970.* ***At this stage of course the Court is not expected to examine the challenge in any great detail and arrive at a definite finding on the question of validity. That will have to await the trial. At the present stage of considering the grant of an interim injunction, the defendant has to show that the patent that has been granted is vulnerable to challenge. Consequently, this Court rejects the contentions of the plaintiffs on this issue and affirms the impugned judgment of the learned Single Judge****."*

29. In light of the dicta of the aforesaid judgment, it has to be examined by the Court at the preliminary injunction stage, whether the defendants have raised a credible challenge to the validity of the suit patent. The challenger is required to establish that the patent is *prima facie* vulnerable to revocation. In the present batch of cases, the challenge to the validity of the suit patent is primarily based on the following grounds:

i. The suit patent has been prior claimed by the plaintiffs in the genus patent (IN '719)

ii. The plaintiffs are guilty of evergreening of the suit patent (IN '301).

30. At this stage, a reference may be made to the statutory provisions of the Patents Act relating to the above, which are set out below.

> ***"3. What are not inventions.****—The following are not inventions within the meaning of this Act —*
>
> *(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere*

discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

Explanation.—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy;

xxx xxx xxx

***7. Form of application**.—(1) **Every application for a patent shall be for one invention only** and shall be made in the prescribed form and filed in the patent office.*

xxx xxx xxx

10. Contents of specifications.—

(1)..
(2)..
(3)..
(4) Every complete specification shall—

(a) fully and particularly describe the invention and its operation or use and the method by which it is to be performed;

(b) disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection; and

(c) ***end with a claim or claims defining the scope of the invention for which protection is claimed****;*

(d) be accompanied by an abstract to provide technical information on the invention:

(5) ***The claim or claims of a complete specification shall relate to a single invention, or to a group of inventions linked so as to form a single inventive concept****, shall be clear and succinct and shall be fairly based on the matter disclosed in the specification.*

xxx xxx xxx

13. Search for anticipation by previous publication and by prior claim.—

1) The examiner to whom an application for a patent is referred under section 12 shall make investigation for the purpose of ascertaining whether the invention so far as claimed in any claim of the complete specification—

(a) has been anticipated by publication before the date of filing of the applicant's complete specification in any specification filed in pursuance of an application for a patent made in India and dated on or after the 1st day of January, 1912;

(b) ***is claimed in any claim of any other complete specification published on or after the date of filing of the applicant's complete specification, being a specification filed in pursuance of an application for a patent made in India and dated before or claiming the priority date earlier than that date.***

xxx xxx xxx

48. Rights of patentees. —

Subject to the other provisions contained in this Act and the conditions specified in section 47, a patent granted under this Act shall confer upon the patentee—

(a) where the subject matter of the patent is a product, the exclusive right to prevent third parties, who do not have his consent, from the act of making, using, offering for sale, selling or importing for those purposes that product in India;

xxx *xxx* *xxx*

53. Term of patent.—

(1) Subject to the provisions of this Act, the term of every patent granted, after the commencement of the Patents (Amendment) Act, 2002, and ***the term of every patent which has not expired*** *and has not ceased to have effect, on the date of such commencement, under this Act,* ***shall be twenty years from the date of filing of the application for the patent****.*
(2)...
(3) [Omitted by the Patents (Amendment) Act, 2005]
4) Notwithstanding anything contained in any other law for the time being in force, on cessation of the patent right due to non-payment of renewal fee or ***on expiry of the term of patent, the subject matter covered by the said patent shall not be entitled to any protection.***

xxx *xxx* *xxx*

64. Revocation of patents.—
1) ***Subject to the provisions contained in this Act, a patent, whether granted before or after the commencement of this Act, may, be revoked on a***

> ***petition of any person interested or of the Central Government by the Appellate Board or on a counter-claim in a suit for infringement of the patent by the High Court on any of the following grounds , that is to say***—
>
> *(a)* ***that the invention, so far as claimed in any claim of the complete specification, was claimed in a valid claim of earlier priority date contained in the complete specification of another patent granted in India****;*
> *(b) ..*
> *(c) ..*
> *(d) that the subject of any claim of the complete specification is not an invention within the meaning of this Act;*
> *(e)..*
> *(f)that the invention so far as claimed in any claim of the complete specification is obvious or does not involve any inventive step, having regard to what was publicly known or publicly used in India or what was published in India or elsewhere before the priority date of the claim:*
> *(k) that the subject of any claim of the complete specification is not patentable under this Act;*
> *(m) that the applicant for the patent has failed to disclose to the Controller the information required by section 8 or has furnished information which in any material particular was false to his knowledge;*

31. Section 7(1) of the Patents Act makes it abundantly clear that a patent application can be filed only in respect of one invention. This position is fortified by Section 10(5) of the Patents Act, which states that all the claims of a complete specification shall relate to one single invention or a group of inventions that are linked in a manner to form a single inventive concept. Sub-section (4) of Section 10 provides the ingredients of a complete

specification, which include complete description of the invention and the disclosure about the best method of performing the said invention, of which the claimant seeks protection, followed by the claims for which the protection is claimed, so that the protection is granted in terms of Section 48 of the Patents Act only in respect of what is sought for in the claims.

32. In order for a patent to be revoked under Section 64(1)(a)[2] of the Patents Act, the following factors have to be established:

i. The prior patent has to be the one granted in India.

ii. The said prior patent has to have an earlier priority date than the latter patent application.

iii. The invention claimed in the latter patent was also claimed in the earlier patent application.

iv. The date of publication of prior patent is irrelevant.

33. In the present case, it is undisputed that the genus patent, IN '719, is an Indian patent having an earlier priority date than the species patent, IN '301. Therefore, what has to be examined is whether what has been claimed in the species patent, has been claimed in the genus patent. The fact that in the present case, the publication date of the genus patent was after the priority date of the species patent, would not be relevant.

Comparison of suit patent and genus patent

34. A comparison of the similarities in Claims of both the genus patent as well as the suit patent is set out below:

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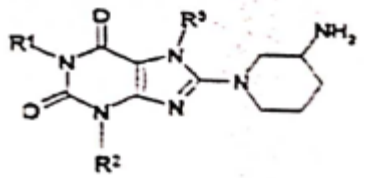
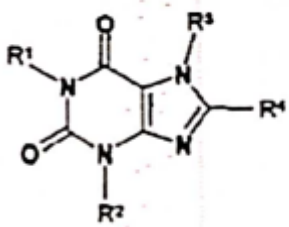
[2] Section 64(1)(a) of the Patents Act was taken from a similar provision that existed in the UK Patents Act, 1949. However, the said provision was repealed from the aforesaid U.K. Act in 1977. Section 64(1)(a) relating to prior claiming continues to exist in the Indian Patents Act. Therefore, as on date, Section 64(1)(a) is unique to the patent law in India.

IN '301 [Suit Patent]	**IN '719** [Genus Patent]
Claim 1 of the 301 patent is itself a genus/class of compounds approximately covering 22 alternatives (excluding isomers, tautomers etc.) of the following structure:  (I).	Claim 1 of the earlier 719 patent is also a genus/class of compounds but of a much larger size having the following structure:  (I).

35. The comparison above would show that substantial part of the chemical structure in the Claim 1 of the suit patent and the genus patent are structurally similar. Considering that the plaintiffs have themselves in the proceedings before the Controller admitted that Linagliptin is one of the possible substitutions of IN '719, it would leave no matter of doubt that both the patents are attempting to cover the same subject matter as well. Clearly, this would not be permissible under the Patents Act.

36. In addition to the proceedings before the Controller for the grant of patent in India, the International Search Report (ISR) issued with respect to the PCT publication of the suit patent by the International Search Authority, the European Patent Office in this case, is of significant relevance *(Page 618 of the documents filed on behalf of the plaintiffs along with their written statement to the counter claim filed on behalf of the defendants in CS(COMM) 236/2022).* The relevant snippets from the aforesaid ISR are extracted as under:

INTERNATIONAL SEARCH REPORT

International Application No
PC[redacted]EP 03/09127

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 C07D473/04 A61K31/522 A61P3/10

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 C07D A61K A61P

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, CHEM ABS Data, BEILSTEIN Data, BIOSIS, EMBASE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	WO 02/068420 A (BOEHRINGER INGELHEIM PHARMA ;ECKHARDT MATTHIAS (DE); HIMMELSBACH F) 6 September 2002 (2002-09-06) Ansprüche 1-18; Formel (I); Verbindungen (344),(471), (343), (439), (136), (528), (521), (520), (444), (524), (368), (525), (329)-(333), (361), (523), (482), (428), (138) und (469) -----	1-22

37. In the said ISR, the Examiner has highlighted the corresponding PCT publication of the genus patent IN'719, i.e., WO 02/068420 as a 'P, X' reference. 'P' references are not considered during the international phase. However, they can be used for determination of novelty and inventive step in regional/national procedures. Further, an 'X' reference indicates that the document is of particular relevance and the claimed invention cannot be considered to be novel or involve an inventive step when the document is taken alone.

38. In India, considering that prior claiming is a ground for revocation under Section 64(1)(a) of the Patents Act, 1970, the 'P, X' reference

document highlighted by the ISA is striking at the novelty and inventive step of the suit patent. Therefore, there are indications of prior claiming not just in the suit patent, but there were such indications even during the International Phase of the prosecution of the suit patent.

39. In ***AstraZeneca*** (supra), the plaintiff, AstraZeneca, had a genus patent (IN '147) in its favour, which had priority dates of 12th October, 1999 and 5th April, 2000. Subsequently, AstraZeneca also filed a species patent (IN '625) bearing 20th May, 2002 as its priority date. AstraZeneca asserted infringement of their genus and species patents in various law suits in India as well as abroad in respect of the compound, DAPA GLIFLOZIN (hereinafter 'DAPA'). The Court was seized of the issue whether the DAPA was covered and disclosed in both the aforesaid patents.

40. Two Coordinate Benches of this Court, Rajiv Shakdher, J. and Mukta Gupta, J., delivered separate judgments refusing grant of interim injunction, though on separate grounds. Relying upon the aforesaid provisions of the Patents Act and the pleadings filed by AstraZeneca in the suits before this Court and before the US District Court, Rajiv Shakdher, J., in his judgment, observed that there was a definitive assertion that DAPA was covered in both the genus and the species patents. Further, the fact that the plaintiffs have filed an infringement suit for both the genus patent as well as the species patent, leads to a *prima facie* view that DAPA has been claimed in both the aforesaid patents. The relevant findings of Rajiv Shakdher, J are set out below:

> *"22.* ***In my view, the fact that the plaintiffs have taken out an infringement action both for IN 147 and IN 625 is a sufficient clue, at least at this juncture, that DAPA is claimed in both suit patents. It seems***

incongruous to me that a patent holder can take out an infringement action for a patent and yet aver it is not disclosed.

22.1 This is especially so as under our Act the "complete specification" provision encapsulated in various subclauses of subsection (4) of Section 10 require setting out by an applicant who seeks grant of patent to fully and particularly describe the invention and its operation or use and the method by which it is performed, disclose the method of performing the invention which is known to her/him and for which she/he is entitled to claim protection and end with a claim or claims defining the scope of the invention. [See: Section 10(4)(a) to (c)] The applicant is also required to provide an abstract of technical information qua the subject invention. ***The claim or claims forming part of complete specification inter alia are required to be "fairly based on the matter disclosed in the specification****" [See: Section 10(5) of the Act].*

22.2 Therefore, in my view, ***the defendants' submission that IN 625 should be revoked on account of prior claiming under the provisions of Section 64(1)(a) of the Act has substance, at least at this stage****.*

22.3 What lends credence to this plea are the provisions of Section 13 (1) (b) of the Act which require the examiner to ascertain as to whether the application referred to him for investigation under Section 12 adverts to an invention which is anticipated by a prior claim. Section 13 (1) (b), simply put, allows an examiner to make use of an Indian patent application or an Indian patent which, though published, after the impugned patent bears a priority date which is earlier than the impugned patent. The fact that the said patent was published after the

> *impugned patent does not come in the way of the investigation carried out by the examiner.*
>
> *22.4* ***In the present case, the Indian genus patent i.e. IN 147 bears the priority dates 12.10.1999 and 05.04.2000 whereas the Indian species patent i.e. IN 625 bears 20.05.2002 as its priority date. For the purposes of Section 64(1)(a) this ingredient is sufficient. Therefore, as long as the defendant can establish that the inventions so far claimed in any claim of the complete specification [in this case IN 625] was claimed in a valid claim of an earlier priority date contained in the complete specification of another patent [i.e. IN 147] – a ground for revocation is made out.****"*

41. Mukta Gupta, J., in her judgment in ***AstraZeneca AB* v. *Emcure Pharmaceuticals Ltd.*, *2020 SCC Online Del 101***, also did not grant interim injunction in favour of AstraZeneca, though the grounds for not granting injunction differed with the grounds taken by Rajiv Shakdher, J. Mukta Gupta, J. in the aforesaid judgment observed that the defendants have laid a credible challenge to the validity of the suit patent on the ground of obviousness under Section 64(1)(f) of the Patents Act and on account of non-compliance of Section 8(2) of the Patents Act.

42. Both the judgments of Rajiv Shakdher, J. as well as Mukta Gupta, J. were taken in appeal by AstraZeneca. The Division Bench, of which I was a part, dismissed the said appeals with costs of Rs. 5,00,000/- in favour of each of the defendants. The Division Bench held that infringement of genus patent, as claimed in the plaint, could arise only if DAPA was disclosed in the genus patent. The relevant observations of the Division Bench are set out below:

"18. ***Our doubts stemmed from, the appellants/plaintiffs averring and pleading manufacture and sale by the respondent(s)/defendant(s) of DAPA to be in infringement of two patents i.e. IN 147 and IN 625. It was felt, that if DAPA was not disclosed and/or known at the time of seeking patent IN 147 or US equivalent thereof and was invented only subsequently and patent thereof obtained in IN 625 or US equivalent thereof, there could be no infringement by respondent(s)/defendant(s) of IN 147 by manufacturing and/or selling DAPA. Conversely, once the appellants / plaintiffs claimed infringement of IN 147 also, it necessarily followed that DAPA was subject matter thereof and once it was the subject matter thereof, how it could be the subject matter of subsequent patent IN 625.***

19. It was thus enquired from the counsel for the appellants/plaintiffs, that if the patent IN 147 was/is not of DAPA, how could the appellants/plaintiffs in the suits from which these appeals arise, claim infringement by the respondent(s)/defendant(s) of IN 147 also, by manufacturing DAPA. It was further enquired, whether not from the factum of the appellants/plaintiffs, in the suits from which these appeals arise, having claimed infringement by the respondent(s)/defendant(s) of both, IN 147 as well as IN 625, the appellants/plaintiffs are deemed to have admitted DAPA as the subject matter of both, IN 147 and IN 625.

20. We, at this stage, spell out the thought process behind the aforesaid query.

21. ***In our opinion, with respect to one invention, there can be only one patent. The appellants/plaintiffs herein however, while claiming one invention only i.e. DAPA, are claiming two patents with respect***

> ***thereto, with infringement of both, by the respondent(s)/defendant(s). The same alone, in our view, strikes at the very root of the claim of the appellants/plaintiffs and disentitles the appellants/plaintiffs from any interim relief.****"*

43. With regard to the submission made on behalf of AstraZeneca that DAPA is only covered and not disclosed in the genus patent and being disclosed for the first time in the species patent, the Division Bench rejected the aforesaid submission by observing as under:

> *"32. As far as the arguments of the counsel for the appellants/plaintiffs, of DAPA being only covered and not disclosed in IN 147 and being disclosed for the first time in IN 625, and of DAPA being not obvious from and capable of being anticipated from IN 147 are concerned, we are also of the opinion that* ***once the appellants/plaintiffs, in the plaints in their suits claimed the action of the respondent(s)/defendant(s) of manufacturing medicines having DAPA as their ingredient to be an infringement of both IN 147 and IN 625, the appellants/plaintiffs are deemed to have admitted DAPA to be the invention subject matter of both, IN 147 and IN 625. Without DAPA being disclosed in IN 147, there could be no patent with respect to DAPA in IN 147 and which was being infringed by the respondent(s)/defendant(s) by manufacturing drugs/medicines with DAPA as ingredient****.*
>
> *36. From the aforesaid provisions it follows, that from IN 147 and/or US equivalent thereof, the invention as described therein could be worked by anyone, save for the exclusivity for the term thereof in favour of the appellants/plaintiffs. However* ***the claim of the appellants/plaintiffs is, that DAPA was not disclosed in the specifications of IN 147 but 80 other compounds were disclosed. However if that were to be***

> ***the case, it being not the case of the appellants/plaintiffs that the respondent(s)/ defendant(s) were manufacturing any of the said 80 compounds, the appellants/plaintiffs, for manufacture by respondent(s)/defendant(s) of DAPA, cannot claim infringement of IN 147 and could have claimed infringement only of IN 625 in which DAPA was disclosed.***
>
> *37.* ***The appellants/plaintiffs have also not pleaded industrial application or sale of any product subject matter of IN 147, other than DAPA….****"*

44. The principles of law that emerge from the judgment of the Division Bench are as follows:

i. Once a patentee claims infringement of an earlier genus patent in respect of a product, it necessarily follows that the said product was the subject matter of the earlier genus patent.

ii. Only one patent can be granted in respect of one inventive concept. Therefore, a patentee cannot claim infringement of the two patents in respect of the same inventive concept.

iii. The term of a patent is twenty years in terms of the Patents Act and it cannot be granted successive protection by means of separate patents.

iv. The Indian law permits grant of a Markush patent. However, if one of the combinations in the Markush patent includes the product in question, it would form part of the inventive concept of the earlier patent and cannot again be claimed as an inventive concept of a subsequent patent.

v. The pleadings made on behalf of the plaintiff in the suit can be considered by the Court to determine the stand of the plaintiff vis-à-vis the genus patent and the species patent.

45. The special leave petition filed by AstraZeneca against the aforesaid judgment of the Division Bench, was dismissed vide order dated 19th July, 2022.

46. Now, I proceed to examine the facts in the present batch of cases in light of legal principles laid down in the aforesaid judgments to see if a credible challenge has been laid by the defendants to the suit patent.

47. At first, it may be relevant to refer to the pleadings of the plaintiffs in CS(COMM) 239/2019 and CS(COMM) 240/2019. In both the aforesaid suits, which were filed before the expiry of the genus patent, the plaintiffs claimed infringement of both the genus (IN '719) and species patents (IN '301), by the defendants seeking to sell Linagliptin tablets or generic version thereof. The relevant pleadings in the plaints filed on behalf of plaintiffs in CS(COMM) 239/2019 and CS(COMM) 240/2019, which are identical, are set out below:

> *"7.* ***It is submitted that Plaintiff No. 1 was granted subject patents on January 19, 2009 and October 5, 2010 under Section 43 of the Patents Act, 1970 (hereinafter referred to as "the Patents Act") under IN '719 and IN '301 for pharmaceutical products entitled "XANTHINE COMPOUNDS" and "8-(3-AMINOPIPERIDIN-1-YL) - XANTHINE COMPOUNDS" respectively as disclosed in its applications for a term of 20 years.*** *Copy of the Letters Patents Documents (patent certificates) has been filed as documents along with the patent specifications of the subject patents as granted by the Patent Office- which also has been filed as documents.*
>
> *xxx* *xxx* *xxx*
>
> *9.* ***It is submitted that the medicinal product "Linagliptin Tablet" and "Linagliptin + Metformin Hydrochloride Tablets" covered by the subject patents***

was introduced and launched in the Indian market under the brand name "Trajenta/ Trajenta Duo" in the year May 27, 2012 and January 21, 2014 respectively. The Plaintiffs have an active presence in India since then.

*10. Through the accompanying suit, the Plaintiffs seek to enforce its subject patents and restrain the Defendants from making, using, offering for sale, selling, importing and/ or exporting the medicinal product "**Linagliptin Tablet" and/ or "Linagliptin + Metformin Hydrochloride Tablets" covered by the subject patents.***

xxx xxx xxx

*19. **It is submitted that the aforesaid acts of the Defendants, being inter alia, making, using, offering for sale and selling, the product, including Linagliptin/ Linagliptin Tablets covered by the subject patents and manufacturing the said product, are acts of infringement of Plaintiff No. l's exclusive rights in the subject patents.***

xxx xxx xxx

INFRINGEMENT ANALYSIS OF CLAIMS OF THE PATENT IN IN '301

*Therefore, **Linagliptin as mentioned in the carton of the infringing product is a compound claimed and covered in Claim 1 of IN' 301.***

The Tablets as mentioned therein contain "Linagliptin".

Therefore, Defendants' product, generic version of Linagliptin Tablets, being manufactured by Defendant No. 1, marketed by Defendant No. 2 and sold by Defendant No. 3 fall Within the scope of Claim 1 of IN' 301 and accordingly, infringes it.

INFRINGEMENT ANALYSIS OF CLAIMS OF THE PATENT IN IN '719

*..... Therefore, **Linagliptin as mentioned in the said letter of the Office of the Joint Commissioner (Drugs),***

> ***carton of the infringing product is a compound <u>claimed and encompassed in Claim 1 of IN '719.</u>***
>
> *The Tablets as mentioned therein contain "Linagliptin".*
>
> *Therefore, Defendants' product, generic version of Linagliptin Tablets, being manufactured by Defendant No. 1, marketed by Defendant No. 2 and sold by defendant No. 3 fall within the scope of Claim 1 of IN '719 and accordingly, infringes it."*

48. Similar assertions as set out above in respect of Claim 1, have been made with regard to Linagliptin falling within the scope of Claims 2, 3, 5, 6 and 7 of the genus patent. The same are not reproduced for the sake of brevity.

49. Similar pleadings were also made by the plaintiffs in the suit filed before Commercial Court, Ahmedabad, against Cadila Healthcare Limited, and the same are not reproduced for the sake of brevity.

50. A perusal of the aforesaid extracts from the plaints would show that repeated assertions have been made on behalf of the plaintiffs that Linagliptin was "**<u>covered</u>**" by the subject patents. Admittedly, the subject patents of CS(COMM)239/2019 and CS(COMM)240/2019 were both genus and species patents. In fact, in paragraph 7 extracted above, it has been averred that pharmaceutical products titled 'XANTHINE COMPOUNDS' and "8-(3-AMINOPIPERIDIN-1-YL)-XANTHINE COMPOUNDS" have been "**<u>disclosed</u>**" in the patent applications in respect of both the suit patents. Further, it has been specifically averred in the aforesaid suits that Linagliptin is a compound "claimed" and "encompassed" in the genus patent, IN '719 and therefore, the plaintiffs claim infringement of both genus and species patents. Hence, the submission made on behalf of the plaintiffs

that Linagliptin is not "covered" or "disclosed" in the genus patent is erroneous on the face of it.

51. Based on the aforesaid averments in the plaints and the submission of the plaintiffs that Linagliptin is "**covered**" both in genus and the species patents, this Court passed an ad interim order dated 10th May, 2019 in CS(COMM) 239/2019 and CS(COMM)240/2019. The relevant extracts of the said order are set out below:

> *"11. The case of the Plaintiffs is that the Plaintiff No. 1 is the owner of the two granted patents. The first patent IN 227719 is in respect of a large class of XANTHINE COMPOUNDS. The said patent dates back to July, 2003. The second patent being IN 243301 dated February 2005, is in respect of specific compounds. The case of the Plaintiffs is that one of the compounds which is covered by the said two patents is l-[(4-methylquinazolin-2-yl]-3-methyl-7-(2-butyn-J-yl)-8-(3-(S)-amino-piperidin-l-yl)-xanthine' as well as all its derivatives including enantiomers, isomers and pharmaceutically acceptable salts thereof The said chemical compound was allotted the International Non-proprietary Name (INN) - 'LINAGLIPTIN' by the WHO.* ***The Plaintiffs, thus, submit that the said two granted patents cover LINAGLIPTIN in all forms, including combinations thereof.***
>
> *12. The Plaintiffs submit that recently* ***they came across the Defendants manufacturing LINAGLIPTIN 5 mg tablets under the names 'UNIGLIP' and LINAMOND. These two products are, in fact, completely covered by the patents which are granted in favour of the Plaintiff and accordingly, the Plaintiffs seek an injunction against manufacture and sale of these products.***
>
> *xxx* *xxx* *xxx*

> *19. LINAGLIPTIN, has the chemical formula l-[(4-methyl-quinazolin-2-yl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(S)-amino-piperidin-1 -yl)-xanthine. The INN name of this chemical compound is LINAGLIPTIN. The said compound is clearly covered by patent nos. IN 243301. IN 227719 relates to a Markush formula. While this court refrains from giving any opinion as to the validity of either of the Patents, the fact that they are old patents and there has been no challenge to the same since 2003 and 2005, does tilt the balance in favour of the Plaintiff...*
>
> *21. Under these circumstances, the Defendants are restrained from manufacturing LINAGLIPTIN or LINAGLIPTIN tablets, or any other pharmaceutical preparations or formulations containing LINAGLIPTIN as the active pharmaceutical ingredient till the next date. The Defendants shall, however, disclose the existing stocks and packaging which it had already manufactured. There shall, however, be no restraint against the already manufactured stock provided an affidavit is filed disclosing the stock and value thereof to the Court within a period of one week."*

52. A perusal of the aforesaid order shows that the same was passed on the basis of the submissions of the plaintiffs that Linagliptin is "**covered**" under both the patents.

53. Now, a reference may be made to the statement of claims filed by the plaintiffs in the Federal Court in Canada in the proceedings against another drug manufacturing company, Sandoz.

> *"**A declaration pursuant to a 6(1) of the Parented Medicines (Notice of Compliance) Regulations, SOR/93-133 as amended ("NOC Regulations") that the making, constructing, using and/or selling of linagliptin tablets at a strength of 5 mg for oral administration (the "Sandoz Product)** in accordance*

> *with abbreviated new drug submission no 241601 ("ANDS") filed with the Minister of Health by Sandoz Canada Inc. Sandoz) for a Notice of Compliance ("NOC") for this drug, as referenced in Sandoz's letter dated November 23, 2020,* ***would infringe or induce infringement of Canadian Patent Nos. 2,435,730 ("730 patent"), 2,496,249 ("249 patent),…, more particularly:***
>
> - ***Claims 1-14, 16, 17, 19, 20, 22-26 of the 730 patent ("730 Asserted Claims");***
> - ***Claims 1-17, 19-24, 26-29, 31-42 of the 249 patent ("249 Asserted Claims");"***

54. Once again, a clear assertion has been made on behalf of the plaintiffs that the selling of Linagliptin tablets by Sandoz would amount to infringement of Canadian patent no. 730, which is equivalent to IN '719 and the Canadian patent no. 249, which is equivalent to IN '301.

55. At this stage, a reference may be made to the Examination Report of the Patent Office in respect of the genus patent application and the reply to the said report. In the Examination Report of the Patent Office dated 6th September, 2007 in respect of IN '719, an objection was raised on behalf of the Patent Office under Section 3(d) of the Act. In order to overcome the aforesaid objection, a reply was filed on behalf of the plaintiffs on 6th September, 2008, wherein, to substantiate that the claimed compounds were novel, the plaintiffs submitted a list of 371 compounds, one of which was Linagliptin. Therefore, Linagliptin was specifically claimed by the plaintiffs to obtain the grant of the genus patent. However, in the rejoinder filed on behalf of the plaintiffs to I.A. 5806/2022, the plaintiffs make a complete U-turn and state that Linagliptin has not been claimed in IN '719.

56. Now, a reference may also be made to the Form 27s filed by the plaintiffs before the Indian Patent Office. Form 27 is a statutory form required to be filed by a patentee in terms of Section 146[3] of the Patents Act read with Rule 131[4] of the Patent Rules, 2003. By way of the aforesaid Form, a patentee has to provide periodical statements demonstrating that the patented invention has commercially worked in India.

57. To illustrate, Form 27s filed in respect of the suit patent and the genus patent for the year 2019 are set out below:

> *"**In the matter of Patent No. 243301 of 2003***
>
> *The patentee(s) under Patent No. **243301** hereby furnish the following statement regarding the working of the patented invention referred to above on a commercial scale in India for the year 2019:*
>
> *(i)The patented invention:*
>
> *(✓) Worked ( ) Not worked [Tick (✓) mark the relevant box]*
>
> *a) If not worked: reasons for not working and steps being taken for working of the invention: NOT APPLICABLE*

---

[3] **146. Power of Controller to call for information from patentees.**—(1) *The Controller may, at any time during the continuance of the patent, by notice in writing, require a patentee or a licensee, exclusive or otherwise, to furnish to him within two months from the date of such notice or within such further time as the Controller may allow, such information or such periodical statements as to the extent to which the patented invention has been commercially worked in India as may be specified in the notice.*

(2) Without prejudice to the provisions of sub-section (1), every patentee and every licensee (whether exclusive or otherwise) shall furnish in such manner and form and at such intervals (not being less than six months) as may be prescribed statements as to the extent to which the patented invention has been worked on a commercial scale in India.

[4] **131. Form and manner in which statements required under section 146(2) to be furnished.—**
Form and manner in which statements required under section 146(2) to be furnished
(1) The statements shall be furnished by every patentee and every licensee under subsection (2) of section 146 in Form 27 which shall be duly verified by the patentee or the licensee or his authorised agent.
(2) The statements referred to in sub-rule (1) shall be furnished once in respect of every financial year, starting from the financial year commencing immediately after the financial year in which the patent was granted, and shall be furnished within six months from the expiry of each such financial year.
(3) The Controller may publish the information received by him under subsection (1) or subsection (2) of section 146.

b) If worked: quantum and value (in Rupees), of the patented drug

(i) manufactured in India: NIL

(ii)imported from other countries. (give country wise details): Details given as under:

Details given as under:

- *Trajenta and Ondero - Imported from USA*
- *Trajenta Duo, Ondero Met, Glyxambi. Ajaduo - Imported from Germany*
- *Trajenta Duo, Ondero Met - Imported from Greece*

Product	Imported		Sales	
	Volume in number of strips**	Value in Indian Rupees	Volume in number of strips*	Value in lndian Rupees
TRAJENTA 5 MG	75,95,541.00	1,02,03,14,350	64,83,139.00	4,73,37,77,480.00
ONDERO 5 MG	30,49,767.00	40,97,18,119.5	26,19,855	61,10,54,980.2
TRAJENTA DUO 850MG	3,27,726.00	3,12,65,137.09	2,11,809	3,80,25,174.45
TRAIENTA DUO 500MG	31,18,380.00	29,75,64,088.4	23,10,350.00	41,27,84,125.00
TRAJENTA DUO 1000MG	12,36,948.00	10,01,35,051.3	9,23,284.00	17,13,90,094.00
ONDERO MET 850MG	3,12,792	2,98,43,301.85	2,68,236	3,40,01,595.36
ONDERO MET 500MG	35,01,906	33,40,82,652	32,08,890	39,91,72,558.5
ONDERO MET 1000MG	10,74,432	9,18,26,944.95	9,46,314	12,24,53,031.6
GLYXAMBI 25+5 mg	9,79,677.00	30,66,39,067.4	7,29,898.00	39,28,89,821.03
GLYXAMBI 10+5 mg	7,17,273.00	20,43,14,922.8	4,34,691.00	21,29,46,302
AJADUO 25+5 mg	9,42,939	29,51,40,320.1	8,70,543	33,61,16,652.3
AJADUO 10+5 mg	4,40,541	12,54,87,521	3,02,103	10,61,74,099.4

** *Volume is given in terms of strip of 10 tablets*

xxx *xxx* *xxx*

In the matter of Patent No. 227719 of 2002

*The patentee(s) under Patent No.**227719** hereby furnish the following statement regarding the working of the patented invention referred to above on a commercial scale in India for the year 2019:*

(i) The patented invention:

(✔) Worked ( ) Not worked [Tick (✔) mark the relevant box]

c) If not worked: reasons for not working and steps being taken for working of the invention: NOT APPLICABLE

d) If worked: quantum and value (in Rupees), of the patented drug

(iii) manufactured in India: NIL

(iv) imported from other countries. (give country wise details): Details given as under:

- *Trajenta and Ondero - Imported from USA*
- *Trajenta Duo, Ondero Met, Glyxambi. Ajaduo - Imported from Germany*
- *Trajenta Duo, Ondero Met - Imported from Greece*

Product	Imported		Sales	
	Volume in number of strips**	Value in Indian Rupees	Volume in number of strips**	Value in Indian Rupees
TRAJENTA 5 MG	75,95,541.00	1,02,03,14,350	64,83,139.00	4,73,37,77,480.00
ONDERO 5 MG	30,49,767.00	40,97,18,119.5	26,19,855	61,10,54,980.2
TRAJENTA DUO 850MG	3,27,726.00	3,12,65,137.09	2,11,809	3,80,25,174.45
TRAJENTA DUO 500MG	31,18,380.00	29,75,64,088.4	23,10,350.00	41,27,84,125.00
TRAJENTA DUO 1000MG	12,36,948.00	10,01,35,051.3	9,23,284.00	17,13,90,094.00
ONDERO MET 850MG	3,12,792	2,98,43,301.85	2,68,236	3,40,01,595.36
ONDERO MET 5OOMG	35,01,906	33,40,82.652	32,08,890	39,91,72,558.5
ONDERO MET 1OOOMG	10,74,432	9,18,26,944.95	9,46,314	12,24,53,031.6
GLYXAMBI 25+5 mg	9,79,677.00	30,66,39,067.4	7,29,898.00	39,28,89,821.03
GLYXAMBI 10+5 mg	7,17,273.00	20,43,14,922.8	4,34,691.00	21,29,46,302

AJADUO 25+g mg	9,42,939	29,51,40,320.1	8,70,543	33,61,16,652.3
AJADUO 10+5 mg	4,40,541	12,54,87,521	3,02,103	10,61,74,099.4

** *Volume is given in terms of strip of 10 tablets.*

(ii) the licences and sub-licences granted during the year: Trajenta, Trajenta Duo and Glyxambi are marketed by Boehringer Ingelheim India Private Limited and Ondero, Ondero Met and Ajaduo are marketed by Lupin Limited.

(iii) state whether public requirement has been met partly/adequately/to the fullest extent at reasonable price: YES, public requirement has been met adequately at reasonable price."

58. A perusal of the two Form 27s of the same period as extracted above, would show that all the pharmaceutical products which the two patents claim to be working in India, are exactly the same. In addition, the quantum and value of import and sales of the said is also the same. Therefore, it is evident that both IN '301 and IN '719 are directed towards the same invention, which is not permissible as per Section 10 of the Act.

59. Senior counsel appearing on behalf of the plaintiffs submits that even if there are "mistakes" in the Form 27s filed on behalf of the plaintiffs, the same cannot be a relevant factor for deciding the grant of interim injunction.

60. Frankly, I was quite amazed to note the aforesaid submission and I am not sure if the aforesaid submission was made on instructions from the plaintiffs. Such a statement, on the face of it, would amount to making a submission that incorrect details have been provided by the plaintiffs in their Form 27. Section 122[5] of the Patents Act provides for stiff consequences

[5] **122. Refusal or failure to supply information.**—(*1) If any person refuses or fails to furnish— (a) to the Central Government any information which he is required to furnish under sub-section (5) of section 100; (b) to the Controller any information or statement which he is required to furnish by or under section 146, he shall be punishable with fine which may extend to ten lakh rupees.*

including fine and/or imprisonment for providing false information in Form 27 under Section 146 of the Patents Act. Therefore, the aforesaid submission is noted only to be rejected at the very outset.

61. In my considered view, the present batch of cases are squarely covered by the judgment of Rajiv Shakdher, J. in ***AstraZeneca*** (supra) and the judgment of the Division Bench in ***AstraZeneca*** (supra). The facts in the present batch of cases are very similar to the facts in ***AstraZeneca*** (supra) and the similarities can be summarized below:

i. Like in the case of ***AstraZeneca*** (supra), in the present matters also, there is a batch of 9 suits. In some of the suits, genus and species patents were asserted, while in the other suits only the species patent was asserted as the genus patent had expired.

ii. Like in the case of ***AstraZeneca*** (supra), in the present case also, the plaintiffs have asserted that Linagliptin was 'claimed' in genus patent in the infringement suits filed in India as well as abroad.

iii. In ***AstraZeneca*** (supra), an argument was taken that genus patent covered DAPA but does not disclose the same. The same argument was also taken in the present matters that the genus patent covers Linagliptin, but does not disclose the same.

iv. Like in the case of ***AstraZeneca*** (supra), the genus patent in the present matters also have Markush claims.

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(2) If any person, being required to furnish any such information as is referred to in subsection (1), furnishes information or statement which is false, and which he either knows or has reason to believe to be false or does not believe to be true, he shall be punishable with imprisonment which may extend to six months, or with fine, or with both.

v. Like in the case of ***AstraZeneca*** (supra), the action for infringement of the genus patent, has also been made in the foreign jurisdictions.

vi. Like in the case of ***AstraZeneca*** (supra), in the present matters also, the drug in question are daily-use drugs used for treatment of Diabetes.

62. The plaintiffs have placed strong reliance on the judgement of C. Hari Shankar, J. in ***Novartis* v. *Natco*** (supra). C. Hari Shankar, J. had distinguished the judgment of the Division Bench in ***AstraZeneca*** (supra) on the ground that the Division Bench judgment was confined to the facts of that particular case. In view of the discussion above, I have come to the conclusion that the facts of the present case are very similar to the facts in ***AstraZeneca*** (supra). Therefore, the present batch of cases are squarely covered by the judgment of the Division Bench in ***AstraZeneca*** (supra), which is binding on me. Hence, the need is not felt to delve into the judgment in ***Novartis* v. *Natco*** (supra). The judgment in ***Novartis AG* v. *Natco Pharma Limited***¸ 2023 SCC Online Del 106, does not make any reference to the judgment of the Division Bench in ***Astrazeneca*** (supra) and the judgment in ***FMC*** (supra) was delivered prior to the judgment of the Division Bench in ***AstraZeneca*** (supra).

Judgement of the Supreme Court in Novartis

63. In ***Novartis*** (supra), the Supreme Court was dealing with the issue whether the therapeutic drug, beta crystalline form of Imatinib Mesylate, qualifies as an invention under Section 2(1)(j) and Section 2(1)(ja) of the Patents Act and whether the patent can be refused under Section 3(d) of the Patents Act. Rejecting the submission of Novartis seeking to make a

distinction between coverage or claim in a patent and disclosure made thereunder, the Supreme Court held as under:

> *"118. The submissions of Mr. Andhyarujina and Mr. Subramanium are based on making a distinction between the coverage or claim in a patent and the disclosure made therein. The submissions on behalf of the Appellant can be summed up by saying that the boundary laid out by the claim for coverage is permissible to be much wider than the disclosure/enablement/teaching in a patent.*
>
> *119. The dichotomy that is sought to be drawn between coverage or claim on the one hand and disclosure or enablement or teaching in a patent on the other hand, seems to strike at the very root of the rationale of the law of patent. Under the scheme of patent, a monopoly is granted to a private individual in exchange of the invention being made public so that, at the end of the patent term, the invention may belong to the people at large who may be benefited by it.* ***To say that the coverage in a patent might go much beyond the disclosure thus seem to negate the fundamental rule underlying the grant of patents.***
>
> *xxx xxx xxx*
>
> *156. However, before leaving Hogan and proceeding further, we would like to say that in this country the law of patent, after the introduction of product patent for all kinds of substances in the patent regime, is in its infancy.* ***We certainly do not wish the law of patent in this country to develop on lines where there may be a vast gap between the coverage and the disclosure under the patent; where the scope of the patent is determined not on the intrinsic worth of the invention but by the artful drafting of its claims by skillful lawyers, and where patents are traded as a commodity not for production and marketing of the patented products but to search for someone who may be sued***

for infringement of the patent."

Judgment of Himachal Pradesh High Court dated … in Boehringer* v. *MSN Laboratories in OMP No. 85/2022

64. The plaintiffs have placed strong reliance on the abovementioned judgement of a Single Judge of the Himachal Pradesh High Court, filed by the plaintiffs against other defendants raising identical grounds as raised in the present batch of cases. The principles laid down in the aforesaid judgment with regard to the grant of injunction in a patent case as mentioned in paragraph 23 of the said judgment are set out below:

> *"23. The principles which could be culled out on the basis of various pronouncements which have been made by the Courts while dealing with applications filed under Order 39, Rules 1 and 2 of the Civil Procedure Code in patents cases are as under-*
>
> > *"(i) The registration of a patent per se does not entitle the plaintiffs to an injunction. The certificate does not establish a conclusive right.*
> >
> > *(ii) There is no presumption of validity of a patent, which is evident from the reading of Section 13(4) as well as Sections 64 and 107 of the Patents Act.*
> >
> > *(iii) The claimed invention has to be tested and tried in the laboratory of Courts.*
> >
> > *(iv) The Courts lean against monopolies. The purpose of the legal regime in the area is to ensure that the inventions should benefit the public at large.*
> >
> > *(v) The plaintiff is not entitled to an injunction if the defendant raises a credible challenge to the patent. Credible challenge means a serious question to be tried. The defendant need not make out a case of actual invalidity.*

> *Vulnerability is the issue at the preliminary injunction stage whereas the validity is the issue at trial. The showing of a substantial question as to invalidity thus requires less proof than the clear and convincing showing necessary to establish invalidity itself.*
>
> *(vi) At this stage, the Court is not expected to examine the challenge in detail and arrive at a definite finding on the question of validity of the patent. That will have to await at the time of trial. However, the Court has to be satisfied that a substantial, tenable and credible challenge has been made.*
>
> *(vii) The plaintiff is not entitled to an injunction, if the patent is recent, its validity has not been established and there is a serious controversy about the validity of the patent."*

65. Applying the aforesaid principles, the Single Judge of the Himachal Pradesh High Court accepted the submission of the plaintiffs that Linagliptin was "*claimed and covered*" only in IN '301, but was not "*claimed to be covered*" in patent IN '719. Linagliptin was only "*claimed and encompassed*" in IN '719.

66. Relying on the aforesaid observations, the plaintiffs submit that what has been asserted in the pleadings is that Linagliptin was "claimed" and "encompassed" in the genus patent, IN '719. However, it has not been averred that Linagliptin is "covered" or "disclosed" in the genus patent. There is a difference between the word "covered" and "encompassed". The word "encompassed" cannot be taken to be equivalent of "covered".

67. I do not find any merit in the aforesaid submission. As can be seen from the paragraphs extracted from the plaints in CS(COMM)239/2019 and

CS(COMM)240/2019, repeated assertions have been made on behalf of the plaintiffs that Linagliptin is "covered" by both genus and species patent and is also disclosed in both. In any case, the aforesaid submission is in the teeth of the judgment of the Supreme Court in ***Novartis*** (supra), more particularly, the paragraphs extracted above.

68. In the present case also, the plaintiffs are trying to make a distinction between the words, "claimed", "covered", "encompassed" and "disclosed". The words, "covered" and "encompassed" essentially mean the same thing and the plaintiffs are only relying on semantics to make an artificial distinction, which does not exist. When the product is specifically "covered" in the claims of a patent, whether specific disclosure with regard to the same has been made or not is immaterial. In fact, if the submissions of the plaintiffs that Linagliptin has not been disclosed in the suit patent is to be accepted, it would result in violation of the requirement of Section 10(4) of the Patents Act that every complete specification of a patent must satisfy.

69. With the greatest respect, the aforesaid observations of Himachal Pradesh High Court are at variance with the findings of the Supreme Court in ***Novartis*** (supra) and the judgment of the Division Bench in ***AstraZeneca*** (supra)**.** With due respect, I am not in agreement with the aforesaid view taken by the Himachal Pradesh High Court.

70. The Himachal Pradesh High Court judgment extracts the Examination Report dated 6th September, 2007 issued by the Patent Office to the plaintiffs. Though, the judgement notes that the said Examination Report pertains to IN '301, the counsels for both the sides are in agreement that the Examination Report reproduced in the judgment pertains to IN '719. Similarly, the judgment also reproduces the reply of the plaintiffs dated 13th

June, 2008 to the aforesaid Examination Report. Once again, the counsels for both sides agree that the response set out is also in relation to IN '719 and not IN '301.

71. Senior counsel appearing on behalf of the plaintiffs submits that this is only a typographical error in the judgment and hence, the same may be disregarded by this Court. On the other hand, the counsels for the defendants submit that this is not a typographical error and had an important bearing on the final outcome of the judgment.

72. The aforesaid Examination Report and the response by the plaintiffs to the said Examination Report were relied by the Court to come to the following conclusion:

> *"28. The fact that subsequently subject patent was granted to the plaintiffs demonstrates that the Patents Office was satisfied with the response so submitted to its queries by the plaintiffs. That being the case, it cannot be said that by highlighting these very facts or the pleadings of plaint filed before the Delhi High Court, the defendants could be said to have had laid credible challenge to the subject patent so as to make it vulnerable to deny interim relief to the plaintiffs at this stage."*

73. The Single Judge has relied on the aforesaid Examination Report and the response thereto by the plaintiffs to come to the conclusion that the Patent Office was satisfied with the response, so as to grant the suit patent in favour of the plaintiffs and also concluded that it cannot be said that the defendants have laid a credible challenge to the subject patent.

74. With due respect, this was not a typographical error but a factual error, leading to a definite conclusion with regard to the validity of the suit patent. If it was only a typographical error, the plaintiffs would have filed an

appropriate application for rectification of the said error. No such submission has been made on behalf of the plaintiffs of having filed such an application.

Approbate and Reprobate

75. In ***Novartis*** (supra), Novartis had made admissions that its drug was a part of a Zimmerman patent (genus patent) and had obtained drug approvals on the basis of the aforesaid patent. Novartis also successfully stopped Natco from marketing its drug in UK on the basis of the said Zimmerman patent. Taking note of the aforesaid, the Supreme Court held that Novartis cannot take a contrary plea later to the effect that its drug was covered in the said patent, but not disclosed therein. The relevant observations of the Supreme Court are set out below:

> *"126. From the above discussion it would be clear that the drug Gleevec directly emanates from the Zimmermann Patent and comes to the market for commercial sale. Since the grant of the Zimmermann Patent, the appellant has maintained that Gleevec (that is, Imatinib Mesylate) is part of the Zimmermann Patent. It obtained drug approval for Gleevec on that basis. It claimed extension of the term of the Zimmermann Patent for the period of regulatory review for Gleevec, and it successfully stopped NATCO Pharma Ltd. from marketing its drug in UK on the basis of the Zimmermann Patent. Not only the appellant but the US Board of Patent Appeals, in its judgment granting patent for beta crystalline form of Imatinib Mesylate, proceeded on the basis that though the beta crystalline form might not have been covered by the Zimmermann Patent, the Zimmermann Patent had the teaching for the making of Imatinib Mesylate from Imatinib, and for its use in a pharmacological compositions for treating tumours or*

> *in a method of treating warm-blooded animals suffering from a tumoral disease. This finding was recorded by the US Board of Patent Appeals, in the case of the appellant itself, on the very same issue that is now under consideration. The appellant is, therefore, fully bound by the finding and cannot be heard to take any contrary plea."*

76. The aforesaid findings in ***Novartis*** (supra) are squarely applicable in the present case. In the present case also, the plaintiffs obtained interim orders against the defendants in CS(COMM)239/2019 and CS(COMM)240/2019 on the specific assertion that Linagliptin is "covered" under IN '719 and therefore, infringed both genus and species patents. Till the time the genus patent expired, the plaintiffs sought injunctive reliefs claiming that Linagliptin is covered in both in IN '719 and IN '301. It is only after the expiry of the term of IN '719, the plaintiffs made the assertion in the subsequent suits that Linagliptin is covered only in IN '301.

77. Further, to meet the objection raised in the examination report under Section 3(d) of the Patents Act, the plaintiffs relied upon Linagliptin as one of the products to show enhancement in efficacy. Not only that, in order to show the working of IN '719, the plaintiffs relied upon the manufacture and sale of Linagliptin as is evidenced in Form 27 filed on behalf of the plaintiffs. Having obtained all these benefits based on the assertion that Linagliptin is claimed and covered in genus patent, now it does not lie in the mouth of the plaintiffs to take a stand to the contrary. The plaintiffs cannot be allowed to approbate and reprobate.

78. It has been vehemently contended on behalf of the plaintiffs that no reliance can be placed on any post grant admissions made by the plaintiffs after the priority date of the suit patent. However, in the judgments of the

Supreme Court in ***Novartis*** (supra) as well as the judgment of the Division Bench in ***AstraZeneca*** (supra), the Court has placed reliance on admissions made by the plaintiffs in the pleadings that were filed much after the grant of the suit patent. Therefore, there is no merit in the submission of the plaintiffs that reliance cannot be placed on any admissions made by the plaintiffs after the priority date or after the grant of the suit patent.

79. As regards the reliance placed on behalf of the plaintiffs on the affidavit of the expert, in my considered view, the effect of the same can be considered at the stage of trial and not at this interlocutory stage, when the Court is only taking the *prima facie* view with regard to the credibility of the challenge raised by the defendants on the validity of the suit patent. The defendants have also filed affidavit of the experts in support of their contention that Linagliptin is covered under the genus patent and these aspects can only be considered at the stage of trial.

80. The pleadings/admissions made by the plaintiffs in the present case, when examined in light of the scheme of the Patents Act and the principles of law laid down by the judgments above, leads me to a *prima facie* view that Linagliptin was "disclosed", "claimed" and "covered" under the genus patent, IN '719 as well as the suit patent, IN '301. Had Linagliptin not been disclosed or claimed in the genus patent, the plaintiffs could not have made a claim for infringement of the genus patent in CS(COMM) 239/2019 and CS(COMM) 240/2019. Therefore, at an interlocutory stage at least, the requirements with regard to prior claiming under Section 64(1)(a) of the Patents Act are satisfied in the present case.

Evergreening

81. Mr. Sandeep Sethi, senior counsel appearing for the plaintiffs, had used the analogy of patenting parts of a forest with the approach of patenting adopted by the plaintiffs. He submitted that a patentee first files patents for the tree and subsequently for specific leaf of that tree. This strategy where the patentee first patents a large set of alternatives for the solution of a particular problem and thereafter, a specific or more specific sets of solutions of a problem is referred to as Selection Patents.

82. In the context of Indian Patent Law, the selection of optional substitutions or selection of specific substances or compounds after coverage in a prior patent is prohibited in terms of the decision of the Supreme Court in ***Novartis*** (supra). Further, as per Section 10(4)(b) of the Patents Act, a patentee has to disclose the best method of performing the invention, which is known to the applicant. In the present case, if Linagliptin, which appears to be the best method of performance of the genus patent was not disclosed, then even the genus patent did not satisfy all the requirements that a complete specification of a patent document needs to satisfy.

83. If the submission of the plaintiffs that Linagliptin was the product of further research and development after filing of the genus patent is considered, the species patent can at best be a patent of addition under Section 54 of the Patents Act. The term of the patent of addition is also only limited to the term of the original patent, which would be the genus patent in this case.

84. On the issue of evergreening of the patent, the Division Bench in ***AstraZeneca*** (supra) held that if the patent with respect to the same invention is granted more than once, then it will be against the legislative

intent of limiting the life of the patent. Therefore, a patentee cannot restrain a third party from dealing with the new product invented by the patentee pursuant to further research, after the expiry of 20 years-term of the patent. The observations made by the Division Bench in this regard are set out as under:

> *"31. The Patents Act, though protects the rights and interests of inventors, but for a limited period, whereafter the monopoly of the patentee ceases and comes to an end and the invention with respect to which patent was granted, falls in public domain i.e. open for all to practice and reap benefit of. A patent, vide Section 48 of the Act, confers a right on the patentee of a product patent, as DAPA is, to, during the life of the patent, prevent others from making, using, offering for sale, selling or importing, the new product with respect whereto patent is granted.* ***The life of a patent is limited, whereafter, notwithstanding the new product having been invented by the patentee, patentee no longer has exclusive right to make, use or offer for sale the same and anyone else interested can also make, use or offer for sale the said new product invented by the patentee, without any interference from the patentee. If patents with respect to the same invention can be granted more than once, successively in time, the same will negate the legislative intent of limiting the life of the patent and enable the patentee to prevent others from making, using or offering for sale, the new product invented by the patentee, till the time patentee successively keeps on obtaining patent therefor****."*

85. A Coordinate Bench of this Court in ***FMC Corporation And Ors* v. *GSP Crop Science Private Limited***, ***2022 SCC OnLine Del 3784***, held that

filing of multiple patents for different aspects of the same product with an intention to extend the initial monopoly is not permissible under the Patents Act. The relevant observations of the Court in ***GSP Crop Science*** (supra) are set out below:

> *"31. Admittedly, the Markush patent and both the product and process patents relating to CTPR have expired in August 2022 and there can be no exclusivity in the same. However, if one goes by the list of granted and pending patents applications, the various components, intermediates and manufacturing processes of CTPR, if granted/validated, would result in the Plaintiffs monopoly and exclusive rights till 2041 i.e., a further period of 19 years.*
>
> *32. Thus,* ***in the opinion of this Court, filing of such multiple patents for different aspects of the same product with an intention to extend the initial monopoly in some form or the other, would not be permissible. It is this very abuse that Section 3(d), mandatorily required disclosures under S.10 and other provisions of the Act, intend to curb.***
>
> *33.* ***Undoubtedly, multiple patents can be filed for different aspects of a particular product, if the tests for novelty, inventive steps and industrial applicability are satisfied and the inventions are patentable. However, serial patenting in order to 'Evergreen' a particular monopoly, is not permissible.****"*

86. The aforesaid observations are also applicable in the present case. In the present case also, the plaintiffs by filing multiple patents for different aspects of the same product are seeking to extend the term of the patent beyond twenty years, granted in respect of the genus patent, which expired on 21st February 2022. In my considered view, the action of attempting to patent both the genus and species patent would amount to evergreening or

layering of patent protection, which is impermissible under the Indian Patent Law. Section 3(d) of the Patents Act has been incorporated in the statute to ensure that such action of evergreening and layering is prevented.

87. In view of my findings above, it would not be necessary to consider other grounds of revocation raised in the suits, which shall be considered at the stage of the trial.

Balance of convenience

88. Finally, I would address the issue with regard to balance of convenience and irreparable injury, the fundamental principles which govern the grant of interim injunction.

i. *Whether balance of convenience is in favour of the plaintiffs and against the defendants for the grant of interim injunction?*
ii. *Whether the plaintiffs would suffer irreparable injury on account of non-grant of interim injunction?*

89. Rajiv Shakdher, J. in ***AstraZeneca*** (supra) also deliberated on the issue of balance of convenience and irreparable harm while considering grant of interim injunction. The relevant observations in this regard are set out below:

> *"35.4 This is acutely true when seen in the context of enforcement of patents concerning drugs.* ***The Court has to be vigilant towards attempts of the patentee that aims at evergreening an invention which does not inter alia involve an inventive step i.e. technical advance or economic significance. Therefore, depriving the defendants, at this stage, from manufacturing and selling their drugs, when, during the validity period of the genus patent i.e. IN 147 they largely held themselves in check would, in my***

> ***opinion, not be appropriate, especially, when they have set up a credible challenge to the suit patents.***
>
> *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.*
>
> *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 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]"*

90. The aforesaid findings in respect of balance of convenience are also squarely applicable in the facts and circumstances of the present case. In the present case, the plaintiffs have enjoyed a twenty-year monopoly of Linagliptin under the genus patent. Except the defendants in CS (COMM) 239/2019 and CS(COMM)240/2019, the defendants waited for the twenty-years term of the genus patent to expire on 21st February, 2022, before launching their drugs in the market.

91. In the present batch of cases also, the plaintiffs do not manufacture

their drugs in India, but import their drugs into India. The plaintiffs have licensed the suit patent to Lupin and Eli Lily**,** for which royalties are payable by the said entities to the plaintiffs. Clearly, the intention of the plaintiffs is to monetise the said invention. Therefore, the present case is one where monetary damages can be calculated and awarded to the plaintiffs, in the event, the plaintiffs succeed in the present suits. It is a settled position of law that where monetary damages are the adequate compensation for the plaintiffs, an interim injunction should not be granted.

92. Rajiv Shakdher, J in his judgment in ***AstraZeneca*** (supra), also delved into the aspect of public interest and noted that a big gap existed between the price of the drug offered by the plaintiffs, as against the price of the defendants' drugs. Taking note of the fact that the drug is used in the treatment of diabetes, which has wide prevalence in India, it was held that balance of convenience would be in favour of the defendants.

93. Considering the elements of public interest, in the present case also, the drug Linagliptin is used for treatment of diabetes, which is a widely prevalent disease in India. In fact, diabetes is also considered as a co-morbidity factor in the cases of Corona Virus infection, which resulted in a global pandemic and large number of fatalities in India. Therefore, the public interest also demands that large segments of population should have easy and affordable access to an anti-diabetes drug. Undeniably, the products of the defendants are significantly cheaper than that of the plaintiffs and taking into account that Linagliptin is a daily-use drug, affordability plays a major role in its access to wide sections of the public.

94. Therefore, in my considered view, balance of convenience would tilt in favour of the defendants and against the plaintiffs. Irreparable injury

would be caused not only to the defendants but also to the public, if the interim injunction is granted in favour of the plaintiffs.

Conclusion

95. Based on the discussion above, I am of the *prima facie* view that the suit patent of the plaintiffs, i.e., IN'301 is vulnerable to revocation on the ground of prior claiming in terms of Section 64(1)(a) of the Patents Act. I am also of the *prima facie* view that by filing multiple patent claims in respect of the same invention, the plaintiffs have made an attempt towards evergreening the invention and re-monopolizing the same. These attempts on behalf of the patentees strike at the root of patent law in India. The aforesaid conduct of the plaintiffs defeats the rights of the manufacturers of generic drugs such as the defendant companies and is also detrimental towards the public interest.

96. In view of the discussion above, the plaintiffs have failed to make out a *prima facie* case for grant of interim injunction. Balance of convenience is in favour of the defendants and against the plaintiffs. Irreparable injury would be caused not only to the defendants but also to the public, if the interim injunction is granted in favour of the plaintiffs.

97. Accordingly, all the applications in the aforesaid suits for grant of interim injunction are dismissed with costs of Rs 2,00,000/- to each of the defendants. In addition, costs of Rs. 2,00,000/- are also awarded in favour of Delhi High Court Legal Services Committee on account of detriment caused to the public interest.

98. The costs shall be paid to the defendants and Delhi High Court Legal Services Committee within four weeks of the passing of this order.

99. The defendants shall maintain complete accounts of manufacture and

sale of the impugned products and file statement of accounts on half yearly basis.

100. In view of the above, the interim order dated 10th May, 2019 passed in CS(COMM) 239/2019 and CS(COMM) 240/2019 stands vacated. The *pro-tem* arrangements arrived at between the parties in CS(COMM) 236/2022, CS(COMM) 237/2022 and CS(COMM) 238/2022 vide order dated 19th April, 2022 and in CS(COMM) 296/2022 vide order dated 9th May, 2022, also stand vacated.

101. There shall be no impediment on the manufacture and sale of products with Linagliptin as the API on account of the suit patent i.e., IN'301. The defendants are permitted to manufacture and sell the aforesaid products, if so advised, subject to necessary approvals.

102. Needless to state that the observations made herein are only for the purpose of deciding the present applications and shall have no bearing on the final outcome of the suits and the counter claim.

CS(COMM) 239/2019, CS(COMM) 240/2019, CS(COMM) 236/2022, CS(COMM) 237/2022, CS(COMM) 238/2022 & CS(COMM) 296/2022

103. List before Joint Registrar on 23rd May, 2023 for further proceedings.

AMIT BANSAL, J.

MARCH 29, 2023
sr