IN THE HIGH COURT OF HIMACHAL PRADESH AT SHIMLA

ON THE 2nd DAY OF JUNE, 2022

BEFORE

HON'BLE MR. JUSTICE AJAY MOHAN GOEL

OMP No. 85 of 2022 IN COMS No. 07 of 2022
OMP No. 89 of 2022 IN COMS No. 08 of 2022
OMP No. 93 of 2022 IN COMS No. 09 of 2022
OMP No. 97 of 2022 IN COMS No. 10 of 2022

Between:-

OMP No. 85 of 2022 in COMS No. 07 of 2022

1) **BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG, D-55216, INGELHEIM AM RHEIN GERMANY THROUGH ITS POWER OF ATTORNEY HOLDER.**

2) **BOEHRINGER INGELHEIM (INDIA) PVT. LTD. UNIT NO. 202 AND PART OF UNIT NO. 201, 2ND FLOOR, GODREJ 2, PIROJSHA NAGAR, EASTERN EXPRESS HIGHWAY, VIKHROLI (E), MUMBAI-400079, THROUGH ITS POWER OF ATTORNEY HOLDER**

..PLAINTIFFS/APPLICANTS

(BY M/S ASHOK AGGARWAL AND VINAY KUTHIALA, SENIOR ADVOCATES WITH M/S ATUL JHINGAN, SHILPA SOOD, SANJAY KUMAR, ARPITA SAWHNEY, DHANANJAY SINGH, PRIYANK SHARMA, ABAY TANDON, AND PRIYANK SHARMA, ADVOCATES)

AND

1) **MSN LABORATORIES PRIVATE LIMITED 22-23, INDUSTRIAL AREA, MEHATPUR, UNA, HIMACHAL**

PRADESH, 174315 THROUGH ITS MANAGING DIRECTOR.

ALSO AT

MSN LABORATORIS PRIVATE LIMITED MSN HOUSE, PLOT NO. C-24, SANATH NAGAR INDUSTRIAL ESTATE SANATH NAGAR, TELANGANA 500018.

ALSO AT

MSN CORPORATE, H. NO. 2-91/10 & 11/MSN WHITEFIELDS, KONDAPUR, HYDERABAD 500084 TELANGANA.

2) ERIS LIFESCIENCES LIMITED AF-10 KANCHAN PHARMA HOUSE NATIONAL HIGHWAY NO. 8, ASLALI, AHMEDABAD-382 427, GUJARAT THROUGH ITS MANAGING DIRECTOR.

…….DEFENDANTS/NON-APPLICANTS

(BY MR. BIPIN CHANDER NEGI, SENIOR ADVOCATE WITH M/S GURU NATRAJ & SHRADHA KAROL, ADVOCATES FOR DEFENDANT/RESPONDENT NO.1.

M/S MIHIR THAKORE & NEERAJ GUPTA, SENIOR ADVOCATES, WITH M/S RAJESHWARI, SWAPNIL GAUR, ABHINEETA CHATURVEDI, ANUJ GUPTA, ZAINAB BHARMAL, SAINAB BHARMAL ADVOCATES, FOR DEFENDANT/RESPONDENT NO. 2).

<u>OMP No. 89 of 2022 in COMS No. 08 of 2022</u>

1) BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG, D-55216, INGELHEIM AM RHEIN GERMANY THROUGH ITS POWER OF ATTORNEY HOLDER.

2) BOEHRINGER INGELHEIM (INDIA) PVT. LTD. UNIT NO. 202 AND PART OF UNIT

NO. 201, 2ND FLOOR, GODREJ 2, PIROJSHA NAGAR, EASTERN EXPRESS HIGHWAY, VIKHROLI (E), MUMBAI-400079, THROUGH ITS POWER OF ATTORNEY HOLDER

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(BY M/S ASHOK AGGARWAL AND VINAY KUTHIALA, SENIOR ADVOCATES WITH M/S ATUL JHINGAN, SHILPA SOOD, SANJAY KUMAR, ARPITA SAWHNEY, DHANANJAY SINGH, PRIYANK SHARMA, ABAY TANDON, AND PRIYANK SHARMA, ADVOCATES)

AND

1) MSN LABORATORIES PRIVATE LIMITED 22-23, INDUSTRIAL AREA, MEHATPUR, UNA, HIMACHAL PRADESH, 174315 THROUGH ITS MANAGING DIRECTOR.

ALSO AT

MSN LABORATORIS PRIVATE LIMITED MSN HOUSE, PLOT NO. C-24, SANATH NAGAR INDUSTRIAL ESTATE SANATH NAGAR, TELANGANA 500018.

ALSO AT

MSN CORPORATE, H. NO. 2-91/10 & 11/MSN WHITEFIELDS, KONDAPUR, HYDERABAD 500084 TELANGANA.

…….DEFENDANT/NON-APPLICANT

(BY MR. BIPIN CHANDER NEGI, SENIOR ADVOCATE WITH M/S GURU NATRAJ & SHRADHA KAROL, ADVOCATES).

<u>OMP No. 93 of 2022 in COMS No. 09 of 2022</u>

1) BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG, D-55216, INGELHEIM

AM RHEIN GERMANY THROUGH ITS POWER OF ATTORNEY HOLDER.

2) BOEHRINGER INGELHEIM (INDIA) PVT. LTD. UNIT NO. 202 AND PART OF UNIT NO. 201, 2ND FLOOR, GODREJ 2, PIROJSHA NAGAR, EASTERN EXPRESS HIGHWAY, VIKHROLI (E), MUMBAI-400079, THROUGH ITS POWER OF ATTORNEY HOLDER

..PLAINTIFFS/APPLICANTS

(BY M/S ASHOK AGGARWAL AND VINAY KUTHIALA, SENIOR ADVOCATES WITH M/S ATUL JHINGAN, SHILPA SOOD, SANJAY KUMAR, ARPITA SAWHNEY, DHANANJAY SINGH, PRIYANK SHARMA, ABAY TANDON, AND PRIYANK SHARMA, ADVOCATES)

AND

1) MSN LABORATORIES PRIVATE LIMITED 22-23, INDUSTRIAL AREA, MEHATPUR, UNA, HIMACHAL PRADESH, 174315 THROUGH ITS MANAGING DIRECTOR.

ALSO AT

MSN LABORATORIS PRIVATE LIMITED MSN HOUSE, PLOT NO. C-24, SANATH NAGAR INDUSTRIAL ESTATE SANATH NAGAR, TELANGANA 500018.

ALSO AT

MSN CORPORATE, H. NO. 2-91/10 & 11/MSN WHITEFIELDS, KONDAPUR, HYDERABAD 500084 TELANGANA.

2) EMCURE PHARMACEUTICALS LIMITED SHOP NO. 15, 2ND FLOOR, CO. DUTTA MARKETINGS, SANJAULI, SHIMLA, THROUGH ITS MANAGING DIRECTOR.

ALSO AT:
PLOT NO. P2, IT-BT PARK, PHASE II,
MIDC HINJAWADI, PUNE 411057.

…….DEFENDANTS/NON-APPLICANTS

(BY MR. BIPIN CHANDER NEGI, SENIOR ADVOCATE WITH M/S GURU NATRAJ & SHRADHA KAROL, ADVOCATES).

OMP No. 97 of 2022 in COMS No. 10 of 2022

1) **BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG, D-55216, INGELHEIM AM RHEIN GERMANY THROUGH ITS POWER OF ATTORNEY HOLDER.**

2) **BOEHRINGER INGELHEIM (INDIA) PVT. LTD. UNIT NO. 202 AND PART OF UNIT NO. 201, 2ND FLOOR, GODREJ 2, PIROJSHA NAGAR, EASTERN EXPRESS HIGHWAY, VIKHROLI (E), MUMBAI-400079, THROUGH ITS POWER OF ATTORNEY HOLDER**

..PLAINTIFFS/APPLICANTS

(BY M/S ASHOK AGGARWAL AND VINAY KUTHIALA, SENIOR ADVOCATES WITH M/S ATUL JHINGAN, SHILPA SOOD, SANJAY KUMAR, ARPITA SAWHNEY, DHANANJAY SINGH, PRIYANK SHARMA, ABAY TANDON, AND PRIYANK SHARMA, ADVOCATES)

AND

1) **OPTIMUS PHARMA PRIVATE LIMITED C/O CURETECH SKINCARE, PLOT NO. 3-33/34, PHASE IV, HIMUDA, BHATOLIKALAN, SOLAN, HIMACHAL PRADESH-173205, THROUGH ITS MANAGING DIRECTOR.**

ALSO AT

SECOND FLOOR, SY. NO. 37/A & 37/P, PLOT NO. 6P, SIGNATURE TOWERS, KOTHAGUDA, KONDAPUR, HYDERABAD 500 084, TELENGANA.

…….DEFENDANT/NON-APPLICANT

(BY MR. BIPIN CHANDER NEGI, SENIOR ADVOCATE WITH M/S GURU NATRAJ & SHRADHA KAROL, ADVOCATES).

Pronounced on: 02.06.2022

Whether approved for reporting? Yes.

These applications coming on for pronouncement of order this day, Hon'ble Mr. Ajay Mohan Goel, passed the following:-

O R D E R

This order shall dispose of applications preferred under Order XXXIX, Rules 1 and 2 read with Section 151 of the Code of Civil Procedure, 1908 by the applicants/plaintiffs, praying for interim directions during the pendency of the suits, i.e., OMP No. 85 of 2022 in COMS No. 07 of 2022, OMP No. 89 of 2022 in COMS No. 08 of 2022, OMP No. 93 of 2022 in COMS No. 09 of 2022 & OMP No. 97 of 2022 in COMS No. 10 of 2022. The prayers made in the said applications in the respective suits are as under:-

OMP No. 85 of 2022 in COMS No. 07 of 2022

> *"a) Restrain the respondents, by themselves, their directors, partners, licensees, stockists and distributors, agents and/or anyone claiming through any of them, jointly and severally from infringing the patent rights of Applicant No. 1 under Indian Patent No. 243301 by advertising, launching, making, using,*

offering for sale, selling, importing and/or exporting the medicinal product, Linagliptin in any form whatsoever including Linagliptin API, Linagliptin formulation, "Linagliptin Tablet" and/or "Linagliptin + Metformin Hydrochloride Tablets" or any "generic version" thereof or any product sold under the trade marks/brand names "LINARES" and "LINARES M" or any other trade mark(s)/brand name(s), whatsoever, or any other product covered by the subject patent granted by the Controller of Patents on October 5, 2010 in favour of Applicant No. 1 subsists;"

OMP No. 89 of 2022 in COMS No. 08 of 2022

"a) Restrain the respondent, by itself, its directors, partners, licensees, stockists and distributors, agents and/or anyone claiming through any of them, jointly and severally from infringing the patent rights of Applicant No. 1 under Indian Patent No. 243301 by advertising, launching, making, using, offering for sale, selling, importing and/or exporting the medicinal product, Linagliptin in any form whatsoever including Linagliptin API, Linagliptin formulation, "Linagliptin Tablet" and/or "Linagliptin + Metformin Hydrochloride Tablets" or any "generic version" thereof or any product sold under the trade marks/brand names "LINANEXT" and "LINANEXT-M" or any other trade mark(s)/brand name(s), whatsoever, or any other product covered by the subject patent granted by the Controller of Patents on October 5, 2010 in favour of Applicant No. 1 subsists;"

OMP No. 93 of 2022 in COMS No. 09 of 2022

"a) Restrain the respondents, by themselves, their directors, partners, licensees, stockists and distributors, agents and/or anyone claiming through any of them, jointly and severally from infringing the patent rights of Applicant No. 1 under Indian Patent No. 243301 by advertising, launching, making, using, offering for sale, selling, importing and/or exporting the medicinal product, Linagliptin in any form whatsoever including Linagliptin API, Linagliptin formulation, "Linagliptin Tablet" and/or "Linagliptin + Metformin Hydrochloride Tablets" or any "generic version" thereof or any product sold under the trade marks/brand names "EMLINZ 5" and "EMLINZ M 500" or any other trade mark(s)/brand name(s), whatsoever, or any other product covered by the subject patent granted by the Controller of Patents on October 5, 2010 in favour of Applicant No. 1 subsists;"

OMP No. 97 of 2022 in COMS No. 10 of 2022

"a) Restrain the respondent, by itself, its directors, partners, licensees, stockists and distributors, agents and/or anyone claiming through any of them, jointly and severally from infringing the patent rights of Applicant No. 1 under Indian Patent No. 243301 by advertising, launching, making, using, offering for sale, selling, importing and/or exporting the medicinal product, Linagliptin in any form whatsoever including Linagliptin API, Linagliptin formulation, "Linagliptin Tablet" and/or "Linagliptin + Metformin Hydrochloride Tablets" or any "generic version" thereof

or any trade mark(s)/brand name(s), whatsoever, or any other product covered by the subject patent granted by the Controller of Patents on October 5, 2010 in favour of Applicant No. 1 subsists;"

2. The suits of the plaintiffs are for passing of a decree of restraint and permanent injunction against the defendants/non-applicants by themselves or through their directors, partners licenses, stockiest and distributors, agents etc. from infringing the patent rights of plaintiff No.1 under Indian Patent No. 243301 by advertising, launching, making, using, offering for sale, selling, importing and/or exporting the medicinal product Linagliptin in any from whatsoever or any other product covered by the subject patent granted by the Controller of Patents on October 05, 2010, in favour of plaintiff No 1. In addition, the plaintiffs are also praying for a decree of damages. According to the plaintiffs/applicants, plaintiff No. 1 is a company incorporated under the laws of Germany and plaintiff No. 2 is a company registered under the Companies Act. Plaintiff No. 1 is the owner of plethora of patents worldwide, including Indian Patent No. 243301 (hereinafter to be referred as 'subject patent or IN' 301 for short). The subject patent was granted in favour of plaintiff No. 1 on 05.10.2010 as per Section 43 of the Indian Patents Act 1970, under IN' 301 for pharmaceuticals product titled "8 (3-AMINOPIPERDIN-1YL)-XANTHINE COMPOUNDS", for a term of 20 years from the date of filing.

3. The arguments on behalf of the plaintiffs/applicants were advanced by M/s Ashok Aggarwal and Vinay Kuthiala, learned Senior Counsel. Arguments on behalf of the defendant/non-applicant No. 1 in all the suits were advanced by Mr. Bipin Chander Negi, learned Senior Counsel and Mr. Guru Natarajan, learned counsel and in COMS No. 7 of 2022 arguments on behalf of defendant/non-applicant No. 2 were addressed by M/s Mihir Thakore & Neeraj Gupta, learned Senior Counsel.

4. Learned Senior Counsel appearing for the plaintiffs/applicants argued that for the purpose of grant of interim relief, three primary ingredients, i.e., *prima facie* case, balance of convenience and irreparable loss are all in favour of the plaintiffs/applicants. In addition, they argued that as the defendants/non-applicants have not been able to lay any credible challenge to the 'subject patent', therefore, this application be allowed by granting ad-interim injunction in favour of the plaintiffs/applicants.

5. On the other hand, learned counsel for the defendants/non-applicants have submitted that as the defendants/non-applicants have laid a credible challenge to the 'subject patent' therefore, the application filed under Order XXXIX, Rules 1 and 2 of the Code of Civil Procedure be dismissed.

6. To substantiate their contention that all ingredients exist in favour of the plaintiffs/applicants for grant of interim order, learned Senior Counsel argued that in the present case, the patent in issue, i.e. Indian

Patent No. 243301 (hereinafter to be referred as 'IN' 301') was granted to the applicants on 5th October, 2010 and as its international date of filing was 18th August, 2003, the term of the patent being 20 years, the patent is still alive and is to expire on 18th October, 2023. As per learned counsel, the patent was granted to the applicants after following the procedure prescribed in the Patents Act, 1970, as amended from time to time and the Rules framed thereunder. There was no opposition to the grant of patent at any stage after the application was filed for the grant of the patent and after the patent was granted on 5th October, 2010, by anyone, including the respondents in terms of statutory provisions of the Patent Act, 1970. The patent in issue is a commercially successful patent. The medicinal product "Linagliptin Tablet and Lenagliptin + Metformin Hydrochloride Tablets" covered by the said patent were introduced and launched in the Indian market under the brand name "Trajenta/Trajenta Duo" on 27.05.2012 and 21.06.2014, respectively. Learned Senior Counsel stressed that no party, including the respondents have filed any pre-grant opposition, post-grant opposition or a revocation petition against the subject patent especially against the quality and strength of the subject patent. They further submitted that the respondent-Company is an Indian Pharmaceutical Company and it had recently come within the knowledge of the applicants that the respondents-Companies have made preparation to launch and thereafter had launched infringing product Linagliptin 5mg tablets under the respective brand names.

As per learned Senior Counsel, the product Linagliptin tablets now being offered for sale by the respondents, are covered by the subject patent and manufacturing of the said product by the respondent-Company is an act of infringement of the exclusive rights of the subject patent of applicant No. 1. It was argued that as admittedly the respondent-Company neither has any patent nor it has got a licence to manufacture and sell the products covered by the subject patent from the applicants nor the respondents have applied for or have been granted compulsory licence to manufacture and sell the product, therefore, during the pendency of the suit, the respondents be restrained from manufacturing and selling the product in issue which are covered by the subject patent. According to the plaintiffs/applicants, the following points demonstrate that there exists a good case in their favour for grant interim order:-

> *"(a) 'subject patent' is old and well established;*
>
> *(b) 'subject patent' is commercially highly successful and extensively useful;*
>
> *(c) admittedly, no party, including the defendant, raised any pre-grant opposition, post-grant opposition, including against the quality and strength of the 'subject patent';*
>
> *(d) the patent was granted in favour of the plaintiffs after following the substantive provisions of the The Patents Act, 1970;*
>
> *(e) the patent has had a successful commercial run in India for more than eleven years,*

without any challenge, including that from the defendant;

(f) the Central Government has not filed any revocation for the 'subject patent' in terms of Section 64 of the Patents Act, 1970;

(g) the Central Government has not made any declaration for revocation of the 'subject patent' in public interest in terms of Section 67 of the Patents Act;

(h) none, including the defendant, applied under Section 84 of the Patents Act for grant of compulsory licence of the 'subject patent' on the grounds as mentioned therein;

(i) no challenge was ever put forth by the defendants to the 'subject patent' except immediately before the commercial launch of its infringing product in the month of February 2022, when a revocation petition was filed by the defendants under Section 64 of the Patents Act."

7. It was argued that above facts clearly and categorically demonstrate that there exists a *prima facie* case in favour of the plaintiffs/applicants and balance of convenience is also in their favour and in this backdrop, in case, ad-interim order is not granted and the defendants/non-applicants are permitted to infringe the 'subject patent' of the plaintiffs/applicants, then, the plaintiffs/applicants shall suffer irreparable loss, which cannot be compensated monetarily as all the hard work that has gone into the invention of the product in issue and getting it

patented would be washed away. Learned Senior Counsel further stressed that admittedly the defendants/non-applicants neither have any patent in their name nor did they lay any challenge at the time when the plaintiffs/applicants had applied for the 'subject patent' or even after the patent was granted in favour of the plaintiffs/applicants. They also submitted that the filing of a revocation petition by the defendants/non-applicants in COMS No. 7 of 2022, in close proximity with the launch of the infringing product was nothing but an afterthought to hold out that in lieu of their having filed a revocation petition, they have laid a credible challenge to the 'subject patent'.

8. Opposing the application, learned Counsel for the non-applicant/defendant No. 1 Sh. Bipin Chander Negi, Senior Advocate and Mr. Guru Natrajan, Advocate, argued that the applicants, in fact, have not approached the Court with clean hands as fact of the matter is that the applicants had obtained two patents, i.e. Patent No. 227719 (hereinafter to be referred as 'IN' 719') for the "Markush" formula being the 'genus' patent, which expired on 21st February, 2022 and subject patent IN' 301, which is a 'species' patent and both patents were granted for the same invention as it is nowhere disclosed either in the plaint or in the application as to what was the inventive step capable of industrial application, which distinguished patent IN301 from IN719. The Court was apprised by them that the non-applicants MSN Laboratories had filed a revocation petition against the patent in issue under Section 64 of the Patents Act, 1970 in

this High Court, in which, notices to the present applicants have been issued. It was argued that the non-applicants have rightly challenged the 'species' after the 'genius' has expired and as the plaint is conspicuously silent with regard to the difference between the 'genius' patent and the 'species' patent, therefore, the applicants are not entitled for any relief. It was argued that as a credible challenge stood made to the patent in issue by the respondent, therefore, no interim relief be granted. As per them, it is settled law that mere grant of patent does not lend a presumption of validity to the patent. The scheme of the Patents Act is to provide multi-layer challenges, which are available to a non-patentee to challenge and question the validity of a patent at any time and such validity has to be tested on the anvil of the provisions of the The Patents Act, 1970. It was argued that the provisions of Section 13(4) of the The Patents Act expressly set out the absence of any presumption of validity due to mere grant. It was also argued that in the case of pharmaceutical patents, which have been recognized as a specific species of patent infringement litigation, the overwhelming factor is that of public interest-namely the need to provide for affordable and accessible healthcare products. It was argued that in addition to the settled principles of *prima facie* case, balance of convenience and irreparable loss, the plaintiffs also have to satisfy that there is no **credible challenge** to the 'subject patent' which in the present case, the plaintiffs have not been able to demonstrate and in this view of the matter, prayer of the applicants/plaintiffs for interim

injunction is liable to be dismissed. Learned Counsel have submitted that the genus patent 'IN 719' has expired on 21st February, 2022, whereas the specie patent 'IN301'is to expire on 18th August, 2023. According to them, it is apparent and evident from the record that the plaintiffs/applicants themselves have held out on more than one occasions that the 'genus' patent and 'species' patent are the same. Learned Counsel drew the attention of the Court to the order passed by Hon'ble High Court of Delhi in Civil Suit (Comm.) No. 239 of 2019 with I.A. No. 6797 and I.A. No. 6798/2019, titled as *Boehringer Ingelheim Phara GMBH & Co. KG vs. Vee Excel Drugs and Pharmaceuticals Private Ltd. & Ors*., dated 10.05.2019 and by referring to para-10 thereof, they have argued that the plaintiffs/applicants cannot wriggle out from the admissions which have been made by them, as are borne out from the said order that the plaintiffs themselves have claimed to be owners of two patents, the first patent being IN719 and the second patent being IN301 and it stood submitted on behalf of the plaintiffs/applicants before the said Court that these two patents both cover Linagliptin and all its forms. It was argued that in the entire plaint, the plaintiffs/applicants have very conveniently concealed this fact that except a vague and short reference somewhere in between has been made that the plaintiffs were also holding patent ÍN719', which as per defendants in fact was for the same product for which subsequently the plaintiffs obtained patent ÍN'301. The difference between the same has not at all been explained by the

plaintiffs/applicants in the plaint. Learned Counsel for the defendant also submitted that the defendants are not infringing the suit patent as the product of the defendants is based on the teaching of IN' 719 after the expiry of the term of said patent and therefore, their act does not amount to an act of infringement. As per them, in terms of the provisions of Section 146(2) of the Patents Act, 1970, read with Rule 131 of the Patents Rules 2003, the plaintiffs/applicants have filled in Form-27, perusal whereof would demonstrate that the same product was being reflected in the said statutory Form under both genus patent and specie patent. Thus, they prayed that the interim order be not granted in favour of the plaintiffs/applicants. Learned Senior Counsel have further argued by referring to paras-30 & 33 to 41 of the reply filed to the application by non-applicant/defendant No. 1 that descriptions of IN' 719 and IN719 are identical in large portions and according to them, the averments so made in the reply were not controverted in the rejoinder. They have further submitted that the stand taken by the plaintiffs/applicants in the present suit was totally contrary to the stand which was taken by them in the suits filed in the High Court of Delhi. Learned Senior Counsel also relied upon the following judgments:-

1. *Dhanpat Seth & others Vs. Nil Kamal Plastic Crates Ltd., 2006 SCC OnLine HP 98*
2. *Dhanpat Seth & Ors. Vs. M/s. Nil Kamal Plastic Crates Ltd., AIR 2008 Himachal Pradesh 23.*

3. *AIIMS Vs. Sanjiv Chaturvedi and others (2020) 17 Supreme Court Cases 602*
4. *Mumbai International Airport Private Limited Vs. Golden Chariot Airport and another, (2010) 10 Supreme Court Cases 422.*

9. Shri Mihir Thakore, learned Senior Counsel appearing for non-applicant/defendant No. 2, in addition, while referring to the present plaint and the plaints filed by the plaintiffs/applicants before the Delhi High Court and the Gujarat High Court submitted that in other cases, plaintiffs/applicants never claimed IN' 301 as an improvement of IN'719. As per learned Senior Counsel, the subject patent was never claimed as an advancement of the genus patent and further the research was not pleaded in the earlier suits and this pleading was introduced in the present suit for the first time in para-15 thereof. By referring to the provisions of Section 10(4) of the Patents Act, 1970 learned Senior counsel argued that only part specifications were given in the application of subject patent by the plaintiffs/applicants, which violated Section Section 10(4) of the Patents Act, 1970. Linagliptin was squarely covered by IN' 719, but the genus patent was neither disclosed nor volunteered at the time of applying for the subject patent and this was also evident from the objections which were raised by the Examiner of the Patent Controller. Learned Senior Counsel also submitted that IN'719 was never claimed by the plaintiffs/applicants as a 'prior art' and product covered by the suit

patent IN' 301 was squarely covered/disclosed by a prior granted patent IN'719, which expired on 21.02.2022. He further submitted that suit patent IN' 301 was invalid due to anticipation by prior claiming in IN' 719. By referring to the averments made in para-9 of the preliminary submissions/objections to the reply filed to the application under Order XXXIX, Rules 1 & 2 of the Code of Civil Procedure, learned Senior Counsel argued that comparing the same with para-10 thereof clearly proved and demonstrated that the subject matter (Linagliptin), which was claimed by IN'719 was once again been claimed by IN'301. Learned Senior Counsel by referring to pages No. 918, 920 onwards, 962, 964 onwards, 998, 1013, 1062, 1064, 1065, 1066 onwards up to 1070 of the documents filed by defendant No. 2, which included copy of First Examination Reports of IN' 719 and IN' 301, argued that the same clearly demonstrated that Linagliptin was claimed under IN' 719 also by the plaintiffs/applicants, especially in Claim 3. In addition, Mr. Neeraj Gupta, learned Senior Counsel appearing for defendant No. 2 argued that taking into consideration the fact that there is public interest involved in the matter, as defendants are making available a drug to the public at large at a much lower price, on this count also, the plaintiffs are not entitled for any injunction. Learned Senior Counsel also relied upon the following judgments:-

1. *F. Hoffmann -LA Roche Ltd. & Anr. Vs. Cipla Ltd.* 2009 (110) DRJ 452 (DB).

2. Astrazeneca AB and another Vs. Intas Pharmaceuticals Ltd. 2021 SCC OnLine Del 3746.

10. In rejoinder, learned Senior Counsel appearing for the plaintiffs argued that there was no concealment of any fact either from the Patent Authorities or from the Courts. It was argued that in terms of Section 64(1)(a) of the Patents Act, a revocation petition was maintainable on the ground that 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. It was stressed that what was important was the 'priority date'. Learned Senior Counsel for the plaintiffs/applicants argued that if one day before the filing of the application for the grant of IN' 301, a person trained in the art without knowing the disclosures and teachings of IN' 301 could say on the basis of disclosures of IN' 719 that he can solve the problem solved by IN' 301, then evergreening could be claimed, but this, the defendants had failed to demonstrate. He submitted that the onus is to prove what was being alleged by the defendants/non-applicants by assessing the fact situation as it existed one day prior to the 'priority date' of IN' 301, which in this case was 21.02.2022. Learned Senior Counsel further argued that provisions of Section 64(1)(a) of the Patents Act were supreme and contents thereof were the touchstone for seeking revocation of a patent and not the contents of the pleadings of the parties or Form 27. As per him, the innovative steps which were taken and the scientific research

which was undertaken while claiming IN' 301 were placed on record and queries whatever raised by the Patent Authorities were duly answered to their satisfaction, resulting in the grant of IN' 301. He further submitted that here was a case where the genus patent had millions and trillions of compound, which was not in dispute and IN' 301 was a result of further inventive steps as well as scientific research. Learned Senior Counsel further argued that in the present suit, it was clearly mentioned in para-15 that Indian Patent No. 227719, i.e., IN' 719 granted to plaintiff No. 1, titled "XANTHINE COMPOUNDS" for the "Markush" formula being the 'genus' patent, the term thereof expired on February 21, 2022 and IN' 301 is the 'species' patent covering the specific commercial embodiments being marketed by plaintiff No. 1 through plaintiff No. 2 in India. In this para of the plaint, it stood specifically mentioned that the compound Linagliptin **"covered and claimed"** by the subject patent was invented upon further research carried out subsequent to the filing date of IN' 719 being the 'genus' patent and before the earliest priority date of the subject patent. Learned Senior Counsel has also placed reliance upon the affidavit deposed by Dr. Matthias Eckhardt, being the co-inventor of the inventions covered by IN' 719 and IN' 301, which is available on record with the documents of the plaintiffs/applicants, as Annexure-E. He submitted that whereas in the present case, the plaintiffs/applicants clearly stated that 'compound Linagliptin was covered and claimed' by the subject patent, whereas in the earlier suit, for example the suit filed by the plaintiffs in the

High Court of Delhi, i.e., CS(COMM) No. 240 of 2019, it was clearly mentioned that Linagliptin, as mentioned in the carton of the infringing product is a compound claimed and covered in Claim 1 of IN' 301, whereas, with regard to IN' 719, it was mentioned that Linagliptin, as mentioned in the carton of the infringing product was a compound **"claimed and encompassed"** in Claim 1 of IN' 719. Learned Senior Counsel by taking the Court through the plaint, which has been filed by defendant/non-applicant No. 2 stated that in more than 10 places, it was averred by the plaintiffs/applicants that whereas Linagliptin was a compound **"claimed and encompassed"** in Claim 1 of IN' 719, the same, i.e., Linagliptin was a compound claimed and covered in Claim No. 1 of IN' 301. On these bases, it was submitted that it was never held out at any stage by the plaintiffs that Linagliptin was a compound "covered in Claim of IN' 719" and plaintiffs/applicants have always claimed Linagliptin to be covered in Claim 1 of IN' 301. On these bases, he submitted that as there was no merit in the contentions of the defendants/non-applicants, the interim prayer being prayed for, be granted. Learned Senior Counsel has also relied upon the following judgments:-

1. *Novartis AG and another Vs. Natco Pharma Limited, 2021 SCC OnLine Del. 5340.*

2. *Merck Sharp and Dohme Corporation and another Vs. Glenmark Pharmaceuticals, 2015 SCC On Line Del. 8227.*

11. I have heard learned Counsel for the parties and I have also gone through the application filed under Order 39, Rules 1 and 2 of the Code of Civil Procedure as well as response(s) filed thereto.

12. Before proceeding further, I will refer to, two judgments of the Hon'ble Supreme Court and some of the case law that has been relied upon by learned Counsel for the parties.

13. In ***M/s Bishwanath Prasad Radhey Shyam*** Vs. ***Hindustan Metal Industries***, (1979) 2 Supreme Court Cases 511, Hon'ble Supreme Court has been pleased to hold that 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. Hon'ble Supreme Court further held that the 'validity of a patent is not guaranteed by the grant', was also expressly provided in Section 13(4) of the Patents Act, 1970.

14. Hon'ble Supreme Court of India in ***Dalpat Kumar and Another*** Vs. ***Prahlad Singh and Others***, (1992) 1 Supreme Court Cases 719 has held that it is settled law that the grant of injunction is a discretionary relief and exercise thereof is subject to the Court satisfying that (1) there is a serious disputed questions to be tried in the suit and that an act, on the facts before the Court, there is probability of his being entitled to the relief asked for by the plaintiff/defendant; (2) the Court's interference is necessary to protect the party from the species of injury. In

other words, irreparable injury or damage would ensue before the legal right would be established at trial' and (3) that the comparative hardship or mischief or inconvenience which is likely to occur from withholding the injunction will be greater than that would be likely to arise from granting it. In para-5 of the judgment, Hon'ble Apex Court has been further pleased to hold as under:-

> *"5. Therefore, the burden is on the plaintiff by evidence aliunde by affidavit or otherwise that there is "a prima facie case" in his favour which needs adjudication at the trial. The existence of the prima facie right and infraction of the enjoyment of his property or the right is a condition for the grant of temporary injunction. Prima facie case is not to be confused with prima facie title which has to be established, on evidence at the trial. Only prima facie case is a substantial question raised, bona fide, which needs investigation and a decision on merits. Satisfaction that there is a prima facie case by itself is not sufficient to grant injunction. The Court further has to satisfy that non-interference by the Court would result in "irreparable injury" to the party seeking relief and that there is no other remedy available to the party except one to grant injunction and he needs protection from the consequences of apprehended injury or dispossession. Irreparable injury, however, does not mean that there must be no physical possibility of repairing the injury, but means only that the injury must be a material one, namely one that cannot be adequately compensated by*

way of damages. The third condition also is that "the balance of convenience" must be in favour of granting injunction. The Court while granting or refusing to grant injunction should exercise sound judicial discretion to find the amount of substantial mischief or injury which is likely to be caused to the parties, if the injunction is refused and compare it with that it is likely to be caused to the other side if the injunction is granted. If on weighing competing possibilities or probabilities of likelihood of injury and if the Court considers that pending the suit, the subject-matter should be maintained in status quo, an injunction would be issued. Thus the Court has to exercise its sound judicial discretion in granting or refusing the relief of ad interim injunction pending the suit."

15. In ***F. Hoffmann-LA Roche Ltd. & Anr.*** Vs. ***Cipla Ltd.*** 2009 (110) DRJ 452 (DB), Hon'ble Division Bench of High Court of Delhi was dealing with an appeal filed by the plaintiffs against the judgment passed by learned Single Judge whereby the prayer for grant of interim injunction to restrain the defendant from manufacturing, offering for sale etc. the drug in issue was rejected. In the said judgment, Hon'ble Division Bench held 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 weigh-tage, 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. M/s Hindustan Metal Industries AIR 1982 SC 1444, Standipack Pvt. Ltd. v. Oswal Trading Co. Ltd. AIR 2000 Del 23, Bilcare Ltd. v. Amartara Pvt. Ltd. 2007 (34) PTC 419(Del), Surendra Lal Mahendra v. Jain Glazers (1979) 11 SCC 511. In BeechamGroup Ltd. v. Bristol Laboratories Pty Ltd. (1967-68) 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 22 nd 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." (emphasis supplied) 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."

16. It is pertinent to mention herein that in the above matter, the Court was dealing with a life saving drug relating to the treatment of Cancer. In this context, in para-84 of the judgment, Hon'ble Division Bench further held as under:-

"84. Even while considering this aspect, the Court is conscious that the defendant has been able to demonstrate prima facie that the plaintiffs do not hold a patent yet for the drug Tarceva, which is the Polymorph B form of the substance for which they hold a patent. Secondly, the defendant has raised a credible challenge to the validity of the patent held by the plaintiffs. In such circumstances, the public interest in greater public access to a life saving drug will have to outweigh the public interest in granting an injunction to the patent holder."

17. Learned Single Judge of Hon'ble High Court of Delhi in ***Glaverbel S.A.*** versus ***Dave Rose & Ors***. 2010 SCC Online Del 308,

while dealing with an application filed under Order 39, Rules 1 and 2 of the Code of Civil Procedure, held as under:-

> *"68. There is no res integra to the question that the grounds of challenge of the patent which are available to the defendant in revocation of the patent are also available to the defendant by way of challenging the validity of the same in an infringement suit. The same exposition of law has been discussed in Bishwanath Prasad Radhey Shyam"s case (supra) which has been the authority on the point and also discusses in detail the tests of patentability.*
>
> *69. There are other authorities which reiterate the said exposition of law from time to time and discuss the grant of injunction at the interlocutory stage, however, the recent one which encapsulates the law on the subject and lays down the parameters within which this court has to scrutinize the patents and the challenge thereto is decided by a Division Bench of this Court in F. Hoffmann- La Roche Ltd Vs. Cipla Ltd; 159(2009)DLT243 wherein the division bench while dealing with a similar issue of the grant of injunction laid down the extent of examination by the court for the grant of injunction which is stated as under :*
>
> *" Notwithstanding the above, assuming that the plaintiff held a valid patent for the product which has been subject matter of the suit for infringement, the grant of such patent to the plaintiffs will not ipso facto entitle them to an interim injunction if the defendant is able to satisfy the court that there is question to be tried as to the validity of the patent. In the present case, the defendant has raised a credible challenge to the validity of the patent by*

raising the serious triable and substantial question that renders it vulnerable to challenge."

70. Thus, this court has to examine the challenge made to the patent as to whether there is any serious, triable dispute which is made out and the same renders the patent vulnerable to challenge or not.

71. The another thing which requires discussion at this juncture is that novelty, inventive step and industrial application are the three trinity tests of patentability and the same are to be satisfied independently of each other although it is separate issue that they may be interdependent upon each other as novelty promotes invention which enhances its applicability in the industry. Thus, the challenge which in the present case is raised has to be looked into from the perspective of novelty or newness as well as inventive step or obviousness wherein the criterion is that the same invention cannot be known to the person skilled in the art. Discussion on submissions by the parties"

18. Hon'ble Division Bench of High Court of Delhi, in ***Astrazeneca AB and Another*** versus **Intas Pharmaceuticals Ltd.**, 2021 SCC Online Del 3746, held as under:-

"41. During the hearing, we also enquired from the counsel for the appellants/plaintiffs, that if DAPA was not disclosed in IN 147 and was in fact not known to the appellants/plaintiffs also, what would have been the situation if someone other than the appellants/plaintiffs had discov-

ered DAPA, even if from IN 147, before the appellants/plaintiffs.

46. In our opinion, a single formulation as DAPA, is incapable of protection under two separate patents having separate validity period. The appellants/plaintiffs, in their pleadings, are not found to have pleaded the difference, save for pleading that DAPA was discovered by further research. From the field of the invention subject matter of the two patents being verbatim same, at this stage, it also appears that there is no enhancement of the known efficacy, within the meaning of Section 3(d) of the Act, between the product subject matter of IN 147 and the product subject matter of IN625."

19. In ***Novartis AG*** Vs. ***Natco Pharma Ltd.***, 2021 SCC Online Del 5340, after taking into consideration the authorities referred to therein on the principles of grant of interim injunction in the patents matter, learned Single judge, *inter alia,* held as under:-

"173. Several stellar principles emanate from a reading of the afore- quoted judicial authorities. So pivotal are these principles to assessment of infringement, and the aspect of vulnerability of the "(5) The claim of 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." Patent alleged to be infringed, that, at the cost of repetition, I deem it appropriate to enumerate the principles, thus:

(i) On patentability
a) Inventions, alone, are entitled to patents.
b) An invention must (i) be new, i.e. not anticipated, (ii) involve an inventive step, (iii) be capable of industrial application, i.e. of being made or used in the industry and (iv) entail technical advance over existing knowledge, or have economic significance, rendering the invention not obvious to a person skilled in the Art.48

(c) The triple test of patentability is, therefore, novelty, the existence of an inventive step and industrial applicability. In Merck v. Glenmark16, it was held that these tests stood satisfied by the SFB disclosed in the Markush patent.

(d) The claim in a patent could conceivably encompass embodiments to be invented in future without particularly advantageous properties, provided such inventions employ the technical contribution made by the invention.49

(e) "Patentability" requires that the product (a) must be an invention within the meaning of Section 2(j) and

(b) must not fall within the exceptions in Section 3.50

(f) Section 3(d) is not an exception to Section 2(1)(j). While assessing patentability of a claim for grant of patent, it had to be examined, in the first instance, whether the product was disentitled to patent on any of the grounds envisaged by Section 3(d). The patentability of products would then have to be assessed, for determination of their patentability on the basis of Section 2(1)(j) read with Section 2(1)(j)(a).51

(g) A mere claim, without enabling disclosure, as would enable a person skilled in the art to work the invention, is not patentable.52

(h) The role of the complete specification accompanying a patent application is to teach what the invention was, how it was to be made, and how it was to be used.53

(i) One invention is entitled only to one patent. One patent may, however, cover more than one invention, provided all inventions involved the same inventive steps.

(j) Grant of repeated patents for the same invention results in the malaise of evergreening of a patent beyond its life, which is impermissible.55

(ii) Mere grant of a patent is not necessarily a prima facie indicator of its validity.56

(iii) Infringement:

(a) Examination of any claim of infringement requires (i) determination of the meaning and scope of the claims in the suit patent and (ii) comparison of the claim so interpreted with the allegedly infringing product of the defendants. The comparison has to be of the defendants' product vis-a-vis the plaintiffs' patent and not product-to-product.57
(b) This has to be determined on the basis of claim construction. The plea of a defendant that the plaintiff may have itself applied for grant of patent in respect of the allegedly infringing product, and abandoned the claim later, was held, in Merck v. Glenmark16, to be irrelevant. In a visible departure, however, where the claim of the plaintiff was rejected, Roche v. Cipla held this to be an indicator, prima facie, that the defendant's product infringed the suit patent.

(iv) Section 3(d)

(a) Once a patent was granted to an Active Pharmaceutical Ingredient (API), Section 3(d) protects all products of such API, in any form, from grant of a subsequent patent. The manufacture or marketing by any third party of any product-derivative of a patented API would amount to infringement.58 The API is the molecular entity which exerts the therapeutic effect of medicine and is biologically active. Patent protection is ordinarily granted to the API59.

(b) In the case of pharmaceutical products, the derivatives envisaged by Section 3(d) would include (a) prodrugs, which are not active, but are metabolized in the body so as to result in pharmaceutically active substances, (b) combinations of more than one APIs or the combination of an API with an inert carrier and (c) drug delivery systems, which are compositions enabling the constituents to be administered in a particular fashion.60

(c) In Novartis9, examining the vulnerability of Imatinib Mesylate to invalidity on the ground of Section 3(d), the Supreme Court held that (i) the obtaining of Refer Roche v. Cipla Ltd17 Refer Roche v. Cipla Ltd17 Refer Roche v. Cipla Ltd17 approval for Imatinib Mesylate on the basis of Zimmerman patent, (ii) the obtaining of patent term extension for the Zimmerman patent on the ground of pendency of regulatory approval for Imatinib Mesylate,

(iii) the obtaining, by Novartis, of injunction against marketing of Imatinib Mesylate by any third party on the basis of the Zimmerman patent and (iv) the view of the Board of Patent Appeals that the Zimmerman patent had the teaching to convert Imatinib to Imatinib Mesylate, in conjunction, indicated that Imatinib Mesylate was not a "new product", within the meaning of Section 3(d), vis-à- vis the Zimmerman patent, but merely a "known substance".

(d) "Efficacy" in Section 3(d) refers to the function, utility and purpose of the product under consideration. Hence, for pharmaceutical products, "efficacy" would mean "therapeutic efficacy". "Therapeutic efficacy" was required to be judged strictly and narrowly.61

(e) Enhanced properties, which were inherent to the forms of the known substance, visualized in the explanation to Section 3(d) would not imply enhanced efficacy. Enhanced therapeutic efficacy was a must.62

(f) "Enhanced solubility" is no indicator of enhanced efficacy in pharmaceutical products.63

(g) Applying this principle, the admission, by Novartis, that "all indicated inhibitory and pharmacological effects of the β-crystalline form of Imatinib Mesylate are present in the free base", was held by the Supreme Court in Novartis9, to indicate that the β- crystalline form of Imatinib Mesylate did not possess enhanced efficacy vis-à-vis the Imatinib free base.

(h) As no research data had been placed by Novartis on record to indicate enhanced therapeutic efficacy of the β-crystalline form over the Zimmerman patent, except in respect of properties already possessed by the Zimmerman patent, the Supreme Court, in Novartis, that the β-crystalline form of Imatinib Mesylate did not possess en-

hanced therapeutic efficacy vis-à-vis the free base or the non crystalline form of Imatinib Mesylate.

(i) Whether increased bioavailability would or would not, result in enhanced therapeutic efficacy had to be decided on the basis of research data, and had to be specifically claimed.64

(v) Coverage, claim construction and disclosure

(a) The coverage of a claim, for the purposes of determination the scope of protection under Section 48 of the Patents Act65 had to be determined by claim construction. Claim construction involved reading of the wording of the claim with its enabling disclosures as contained in the complete specifications, as understood by a person skilled in the art, acquainted with the technology in question. A product could be treated as covered by the claim, for the purposes of patent protection if, on the basis of the wording of the claim read with the enabling disclosures in the complete specifications, the person skilled in the art would be in a position to work the invention so as to make it available to the public by the expiry of the patent term.66

(b) The qualities of an enabling disclosure were well delineated in the Wands tests33. They involved (i) the quantity of experimentation necessary, (ii) the amount of guidance available in the patent, (iii) the presence/absence of working examples, (iv) the nature of invention, (v) the state of prior art, (vi) the related skill of those in the art, (vii) the predictability/unpredictability of

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

for those purposes the product obtained directly by that process in India."

ReferMerck v. Glenmark16 the art and (viii) the breadth of the claims.67

(c) Some of the principles of claim construction are that (I) the claim defines the scope and territory of the patent, (ii) claims in a patent may be dependent or independent, (iii) different claims in one patent define different embodiments of the same inventive concept, (iv) invalidation must be of each claim separately and independently, (v) where the claim was worded using the expression "comprising of" various elements, the addition of another element would infringe the patent, (f) where, however, the claim was "consisting of" various elements, infringement would require the subsequent patent to have all the elements in the claim and non other, with the addition of any other element defeating infringement and (g) claims were not to be construed on the basis of prior material or subsequent conduct68.

(d) In this context, in my opinion, demystification of the concept of "coverage", when used in the concept of claim construction and claim protection in patent law, is essential, as there is considerable debate on this issue in nearly every case, with Counsel, relying on the same decisions, adopting near irreconciliable stances. There is, in my view, a distinction between the "broad coverage"of a claim in a patent, and the "protected coverage", i.e. Refer Merck v. Glenmark16 Refer Roche v. Cipla Ltd17 the coverage which would be entitled to patent protection under Section 48. The following passage from Merck v. Glenmark16 is important in this regard:

"Construction of the patent by this court, to verify its coverage is fundamental. This coverage depends on the nature of the claims made (and enabling disclosures specified) by MSD in its 'Complete Specification' under Form 2 of the Act. The words used to describe the claims - as read by a person of ordinary skill in the art - determine the breadth of the monopoly granted by the patent, for which the substantive (and indeed, substantial) rights under Section 48 of the Act are triggered."

(Emphasis supplied) Judgements are not to be read like statutes.69 While referring to a precedent, it is necessary to discern, with care, what exactly the court seeks to convey. The reference to "coverage", in the afore-

extracted passage from Merck v. Glenmark16, is, in my view, to be understood as referring not to the "broad coverage" of the claim, but to that coverage which would be entitled to patent protection under Section 48. The Division Bench holds that the coverage encompassed by the claim, as worded, read with the enabling disclosure, would be entitled to protection under Section 48. A case in point is SPM, which was subject matter of consideration in Merck v. Glenmark16. The claim in IN 816, as worded, encompassed "Sitagliptin with its pharmaceutically acceptable salts". Sitagliptin Hydrochloride was specifically exemplified in the complete specifications in Bharat Petroleum Corporation Ltd v. N.R. Vairamani, (2004) 8 SCC 579. The SFB, and Sitagliptin Hydrochloride, therefore were, on a plain reading, entitled to patent protection. Paras 38 and 39 of the report in Merck v. Glenmark16 goes on to suggest that, possibly, enabling disclosure, in respect of SPM, was also to be found in IN 816 (though, later, the judgement leaves this issue open for more detailed analysis). The paragraphs (to the extent relevant) read thus:

"38. ... The section 'Detailed Description of the Invention', which discloses Formula 1 (reproduced below), corresponds to claim 1 of the patent specification, discloses the following compound structure:

39. This is the Sitagliptin free base. Each element of this structure, and selection of particular elements to reach this structure, is further detailed at pages 5 and 6 of the specification. Page 10 further details the separation of racemix mixtures of the compound to isolate individual enantiomers, including the R form of the compound that is ultimately used in Januvia and Janumet. The term "pharmaceutically acceptable salts"

- it is stated - "refers to salts prepared from pharmaceutically acceptable non-toxic bases or acids including" inter alia phosphoric acid, which is the second element in SPM (i.e. the P in SPM). The M - or monohydrate - is indicated by stating that "salts... may also be in the form of hydrates" (page 10 of the Form 2 filing)."

If, thus, the disclosure contained in IN 816 enabled the person skilled in the cart to arrive at SPM, SPM would also be covered by IN 816 so as to be entitled to patent protection under Section 48." This, then, would, as held in para

38 of Merck v. Glenmark16, be the "coverage" which would trigger the protection provided by Section

(e) As against this, the "broad coverage" of the claim in the patent, as worded, may include products for which there is no enabling disclosure. For example, in IN 816, all pharmaceutically acceptable salts of Sitagliptin are within the "broad coverage" of the claim as worded. Assuming, however, that there is, in the complete specifications in IN 816, no enabling disclosure (arguendo) except in respect of SPM - excepting Sitagliptin Hydrochloride, which is claimed by exemplification, such pharmaceutically acceptable salts, which are not disclosed in IN 816, but are, nonetheless, within the coverage of the claim as worded, would not be entitled to patent protection under Section 48. "Coverage", in this sense, is, therefore, wider than "disclosure".

(f) While this distinction between "coverage" of a claim, as understood in absolute terms, and the "disclosures" in the complete specifications relating thereto does exist, the gap between coverage and disclosure could not be so wide as to enable an artful draftsman to so draft a claim as to escape coverage by the prior art70.

(g) Applying this principle, the contention of Novartis that the Zimmerman patent covered, but did not disclose Imatinib Mesylate, was rejected by the Supreme Court in Novartis9. The Supreme Court held that (a) as the Imatinib free base was covered and disclosed in the Zimmerman patent, (b) the Zimmerman patent also claimed pharmaceutically acceptable salts of the Zimmerman free base, (c) Imatinib Mesylate was a "known substance" from the Zimmerman patent and (d) Imatinib Mesylate was a pharmaceutically acceptable salt of the Imatinib free base, Imatinib Mesylate was claimed and disclosed in the Zimmerman patent.71

(h) Similarly, in Merck v. Glenmark16, even while expressing no final opinion in that regard, it was observed that (a) the disclosure, in the prior art, of the method of isolation of the Sitagliptin free base, (b) the identification of pharmaceutically acceptable salt of Sitagliptin, in the prior art, as including salts made from phosphoric acid and (c) the suggestion, in the prior art, that pharmaceutically acceptable salts of the Sitagliptin free base may also be in

the form of hydrates, indicated that SPM was disclosed in the prior art.

(i) Where the attached salt radical was a mere inert Refer Novartis9 career, and pharmaceutical activity was attributable to the free base, the disclosure of the free base in prior art would imply disclosure of the salt, as novelty existed in the free base, even if the combination with the inert salt radical was useful for effective administration of the drug72.

(vi) Obviousness:
(a) "Prior disclosure", for the purposes of obviousness,

meant disclosure which, if performed, would infringe the patent73.

(b) Prior art, for the purposes of obviousness, was required to have been published before the priority date of the suit patent74.

(c) The test of obviousness was whether, if the prior art document was placed in the hands of a competent draftsman endowed with common general knowledge at the priority date, faced with the problem which the patentee solved in the suit patent, but not endowed with the knowledge of the patented invention, the draftsman would have said "this gives me what I want."75

(d) In Roche v. Cipla-I17, various combination tests have been approved by the Division Bench, to assess "obviousness". These are the following:

(i) The first is the triple test of obviousness, involving determination of the scope and content of the prior art, difference between the prior art and the claims and issue and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or non-obviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.
(ii) The second test involves the following four steps:
(a) identifying the inventive concept embodied in the patent;

(b) imputing to a normally skilled but unimaginative addressee what was commongeneral knowledge in the art at the priority date;
(c) identifying the differences if any between the matter cited and the alleged invention; and
(d) deciding whether those differences, viewed without any knowledge of the alleged invention, constituted steps which would have been obvious to the skilled man or whether they required any degree of invention.
(iii) The third test involves the following five steps:
"Step No. 1 - To identify an ordinary person skilled in the art, Step No. 2 - To identify the inventive concept embodied in the patent, Step No. 3 - To impute to a normal skilled but unimaginative ordinary person skilled in the art what was common general knowledge in the art at the priority date.
Step No. 4 - To identify the differences, if any, between the matter cited and the alleged invention and ascertain whether the differences are ordinary application of law or involve various different steps requiring multiple, theoretical and practical applications, Step No. 5 - To decide whether those differences, viewed in the knowledge of alleged invention, constituted steps which would have been obvious to the ordinary person skilled in the art and rule out a hideside (sic hindsight) approach."
(e) The reason or motivation for making the choices which would lead the persons skilled in the art to arrive at the suit patent from the prior art, must be apparent in the prior art, i.e. in the claim in the prior art read with its enabling disclosure, for "obviousness" to exist. The "motivation" must include the motivation to select and the motivation to combine.76
(f) The suit patent is obvious from the prior art if the invention claimed in the suit patent, as a whole, would have been obvious, prior to the priority date of the suit patent, to a person skilled in the art, from the claim in the prior art read with its enabling disclosures. In this, the first step is the selection of the prior art as the lead compound.
(g) Clear differences in molecular structure would militate against any inference of obviousness77.

(h) In assessing obviousness, hindsight analysis is im-permissible. In other words, while assessing whether the

suit patent is vulnerable to invalidity on the ground of obviousness, the teachings in the suit patent cannot be used as a guide. If the teachings in the suit patent are required to be referred, it would imply that the exercise is one of hindsight analysis.78

(i) The simple test to ascertain whether the suit patent is obvious from the prior art, is, therefore, to arm the mythical person skilled in the art with the complete specifications of the prior art, and the objective which the suit patent ultimately achieved. If the person is able to use the teaching in the prior art to arrive at the suit patent, the suit patent is obvious. If he is not able to do so, it is not.

(j) The "person skilled in the art" is "a person who practices in the field of endeavor, belongs to the same industry as the invention, possesses average knowledge and ability and is aware of what was common general knowledge at the relevant date".79

(k) A claim of infringement, by the product of the defendant, of the suit patent as well as the prior art, would itself defeat, prima facie, the allegation of infringement, as it would imply that the suit patent is obvious from the prior art80.

(l) In the case of a Markush patent, and a subsequent patent for a specific entity, where the Markush does not contain any precise enabling disclosure teaching the way to the subsequent patent, the question to be addressed while examining the vulnerability of the subsequent patent as obvious from the Markush, would be as to how far the subsequent patent is subsumed in the earlier Markush patent81.

(m) Where the inventor of the prior art and the suit patent is the same, the appropriate test to be applied would be that of "a person in know, rather than a person skilled in the art.82"

(vii) Industrial applicability and commercial utility:

(a) On the aspect of industrial applicability, in Merck v. Glenmark16, it was held that, once the SFB had been disclosed, alongwith disclosure of its usefulness in treating diseases and the mode of administration of the drug

resulting from the free base, the SFB was capable of industrial application.
(b) Capability of industrial application has to be decided on the basis of the API, not on the basis of the particular salt. The requirement of combination of the API with an inert career, for its administration, was irrelevant to the issue of industrial application83.
(c) The inert career is not the crux of the invention, as the therapeutic efficacy is attributable to the API alone84.

Refer Astrazeneca v. Intas20 Refer Merck v. Glenmark16 Refer Merck v. Glenmark16

(d) The criteria to assess industrial application are (i) that the patent must disclose its practical application and be of profitable use, (ii) the use of the patent in industrial practice must be derivable directly from the description in the complete specifications read with common general knowledge, (iii) speculative use is insufficient in this regard and (iv) the complete specification, read with common general knowledge, was required to be sufficient to enable a person skilled in the art to exploit the invention without undue burden and without having to carry out a research programme85.

(e) In pharmaceutical compounds, generally, a patent is capable of industrial application if (i) the function of the entity is disclosed in the patent and (ii) the function disclosed relates to usefulness of the entity in the medical industry86.

(f) Breakthrough inventions, even if not commercially viable at the time of their conceptualization, or invention, are nonetheless useful and industrially applicable. In this context, "commercial utility" must be distinguished from "patentable utility". "Commercial utility" is not a sine qua non for patentability.87 Refer Merck v. Glenmark16 Refer Merck v. Glenmark16 Refer Roche v. Cipla Ltd17

(g) Any challenge to the validity of a patent on the ground of want of commercial utility, in order to succeed, would require the challenger to show that the later commercially successful patent owed nothing to the original patent88.

(h) A patent could be treated as lacking commercial utility only if, even if worked as suggested by the complete specifications, it would not yield the promised result. If it does, commercial utility is established.89

(viii) Section 8:

(a) The requirement of compliance with Section 8 of the Patents Act is mandatory.

(b) As violation of Section 8 renders the patent vulnerable to revocation, the provision is required to be strictly construed.90

(c) Section 8 is applicable only to foreign patents.91

(d) The use of the word "may" in Section 8 indicates that, breach does not automatically result in revocation of the patent and that revocation is discretionary.

(e) At the interlocutory stage, it is normally not advisable to reject a request for injunction on the ground of violation, in obtaining the suit patent, of Section 8.93

(f) The failure, by the plaintiff, to disclose the earlier application filed by the plaintiff for the patent in respect of the allegedly infringing product later released by the defendant, would not be fatal where, at the time of applying for the suit patent, the plaintiff was of the opinion that the allegedly infringing product was a separate invention. This principle was applied in Roche17, in the context of Erlotinib Hydrochloride vis-à-vis polymorph B thereof.

174. Infringement admitted: The defendant acknowledges the fact that it is manufacturing and dealing in Eltrombopag Olamine. If the suit patent is valid, therefore, infringement is admitted. What is required, therefore, to be seen, is whether the defendant has set up a credible challenge of vulnerability of the suit patent to invalidity. The grounds urged by Mr. Sai Deepak in this regard would have to be examined in the light of the principles delineated hereinabove.

175. It is made clear that the observations/findings that follow are prima facie, and intended only for deciding the application for interlocutory injunction under Order XXXIX

Rules 1 and 2 of the CPC. The Supreme Court has, time and again, cautioned Courts, especially in intellectual property matters, not to give detailed findings on merits, as would exhibit a final opinion regarding the rival contention of the parties."

20. In ***Merck Sharp and Dohme Corporation and Anr.*** vs. ***Glenmark Pharmaceuticals***, 2015 SCC Online Del 8227, Hon'ble Division Bench of Delhi High Court in paras 84 to 89 held as under:-

"84. At this stage, the Court must address the issue of public interest in respect of access to drugs. In the Hoffman La Roche case (supra) at the interlocutory stage, both at the stage of the Single Judge and the Division Bench, considerable attention was given to the nature of the drug and the price differential. The Court also concluded prima facie that the defendant, a generic manufacturer, had made out a credible defence and a credible challenge to the validity of the patent. The Court located the public interest concern in the debate on balance of convenience and noting that the price differential was about 300% in relation to a life-saving drug (one which treated lung cancer), held that balance of convenience did not lie in favour of grant of injunction as the possibility of several thousands using the generic product being denied access, and consequently their lives, was real. Such consequence was an in-compensable eventuality. Here, no such startling consequences are discernible. Diabetes is more of a lifestyle disorder, which requires management and treatment. The new line of treatment offered by MSD improves efficient management of the condition FAO (OS)

190/2013 Page 74 which cannot be termed as life threatening, so as to characterize the patented product as a life-saving drug (without going into what are life-saving drugs, because of an element of subjectivity and fact dependence, but recognizing a broad distinction which is sufficient for the purposes of this case). In this context, it would be useful to notice that in the World Health Organization's (WHO's) Model list of Essential medicines, besides three forms of insulin, "Glibenclamide Tablet: 2.5 mg; 5 mg" and "Metformin Tablet: 500 mg (hydrochloride)" no other drug-including none with any Sitagliptin combination has been shown.15

85. This leads us to the second principle, which is whether the Court can overlook the public interest in maintaining the integrity of the patent system itself, so that a legitimate monopoly is not distorted. As this Court noted in Bayer Corporation and Ors. v. Cipla, Union of India (UOI) and Ors., 162 (2009) DLT 371 "[i]f, after a patentee, rewarded for his toil - in the form of protection against infringement - were to be informed that someone, not holding a patent, would be reaping the fruits of his efforts and investment, such a result would be destructive of the objectives underlying the Patents Act.".

The Court must be mindful - especially in a case where a strong case of infringement is established, as here - there is an interest in enforcing the Act. It may be argued that despite this no injunction should be granted since all damages from loss of sales can be compensated monetarily ultimately if the patentee prevails. This argument though

appealing, is to be rejected because a closer look at the market forces reveal that the damage can in some cases be irreparable. This in turn leads to the third principle, which is where an infringer is allowed to operate in the interim during the trial, it may result in a reduction in price by that infringer since it has no research and development expenses to recoup - most revenue becomes profit. The patentee however can only do so at its peril. Importantly, prices may not recover after the patentee ultimately prevails, even if it is able to survive the financial setback (or "hit") during the interim, which may take some time. The victory for the patentee therefore should not be pyrrhic but real. This irreparable market effect in cases of a sole supplier of a product has also triggered the decisions in SmithKline Beecham v. Generics, (2002) 25(1) IPD 25005 and Smithkline Beecham Plc (2) Glaxosmithkline UK Ltd v. Apotex, [2003] EWCA Civ L37, where in granting an interim injunction, it was held that damages would not be an adequate remedy for the plaintiff since it was the sole supplier of the product. New entrants to the market would be likely to cause its prices to go into a downward spiral, and Smith Kline‟s prices may not recover even if it wins eventually. Equally, granting the injunction would not prejudice Glenmark to an equal extent since - if the suit is dismissed - it may return to a market that is largely variable.

86. In the present case, given the size of the diabetes drug market in India, and the sheer number of patients, from all economic strata of society, the demand for low-priced medicines will remain, rather than any distortion of demand due to brand loyalty or a first mover‟s advan-

tage to MSD. As noticed earlier, the price differential between MSD"s drug and the infringing products is 30%, a significant portion of which is due to the customs duty paid by MSD. Learned senior counsels appearing for MSD had stated that it FAO (OS) 190/2013 Page 76 would compensate Glenmark for loss of earnings if the suit were to be dismissed. Thus this arrangement not only ensures that Glenmark will - if successful - be able to return to the market without any handicap, but moreover, it will be compensated at market value for the period for which it was excluded. The balance of convenience thus clearly lies in favour of MSD.

87. A related concern that this Court heeds - the fourth principle operative in this case - is that of the chronology of events and Glenmark"s decision to release Zita without first challenging Januvia or Janumet. Undoubtedly, the Act creates a right to oppose patents even after grant. There is no obligation to only utilize the pre or post grant opposition mechanisms. Neither does a patent benefit from a presumption of validity if it is challenged in the course of an infringement suit. However, if a defendant is aware that there may be a possible challenge to its product, but still chooses to release the drug without first invoking revocation proceedings or attempting to negotiate, that is surely a relevant factor. The defendant"s legal right to challenge the patent at any point in time is intact, but that does not mean that this factor cannot determine the interim arrangement. This is more so where Glenmark today argues that MSD ought to have disclosed international patent applications for SPM and Sitagliptin plus Metformin

since they were the "same or substantially the same" as the suit patent under Section 8. That is Glenmark‟s stated position. Such being the state of things, it is surely reasonable for Glenmark to detect the possibility to challenge, when a US patent application for SPM filed by it was opposed by MSD. Despite this, Glenmark released the drug without initiating revocation proceedings under the Act, which is also a right vested FAO (OS) 190/2013 Page 77 in Glenmark that would have obviated the need for the interim arrangement we are today considering. This does not mean that Glenmark‟s right to question the validity of the patent in an infringement is affected, but the manner of challenge is a relevant factor against it at the interim stage. As Justice Jacob noted in both Smithkline Beecham cases (supra):

"I remain of the same opinion that I was in the Generics case. Where litigation is bound to ensue if the defendant introduces his product he can avoid all the problems of an interlocutory injunction if he clears the way first. That is what the procedures for revocation and declaration of non-infringement are for."

Similarly, in the Australian decision of Pharmacia Italia S.p.A v. Interpharma Pty Ltd, [2005] FCA 1675, the Court noted the fact that Inter- pharma had acted in full knowledge of Pharmacia‟s patent and the possible consequences flowing from that. This consideration that the patentee is already in the market and has been operating the patent has found favour in Indian Courts as well. In K. Ramu v. Adayar Ananda Bhavan and Muthulakshmi Bhavan, 2007 (34) PTC 689 (Mad), Bajaj

Auto Ltd. v. TVS Motor Company Ltd., 2008 (36) PTC417 (Mad) and National Research Development Corporation of India v. The Delhi Cloth and General Mills Co. Ltd. and Others, AIR 1980 Del 132, the fact that the patentee was already dealing in the market on the basis of the patent weighed in as a factor in granting the interim injunction.

88. Ultimately, the Court must look to the combination of the three primary factors. A strong case can in some instances offset an equal balance of conveniences between parties. In this case, MSD has established a prima facie case of infringement, an interim arrangement that secures the interests of both parties and which maintains the public interest involved is available, FAO (OS) 190/2013 Page 78 which also ensures that the possibility of irreparable harm to the patentee is removed.

89. Accordingly, for the above reasons, this Court holds that the order of the learned Single Judge dismissing the application for grant of an interim injunction is liable to be and is set aside. The interim injunction claimed for by the plaintiff MSD in IA 5167/2013 is granted. Additionally, the following directions are issued:

i) MSD shall furnish an affidavit undertaking (to be filed by its director duly authorised by its Board of Directors) in the pending suit, that in the event the suit is dismissed, it would compensate Glenmark for the damage or loss caused, including but not limited to loss of earnings. The affidavit shall be filed in two weeks.

ii) Glenmark shall furnish an undertaking to comply with the injunction within two weeks from today in the suit.

iii) Glenmark shall file a detailed account of its earnings (including gross turnover figures) from the products, from the date of the filing of the present suit; the account shall be accompanied by an affidavit of one of its Board of Directors authorized directors, which shall also undertake to pay such damages, if any- which may be decided by the court if the ultimate result of the suit is a decree in favour of the plaintiff MSD. The statement shall be filed with a supporting affidavit of its duly authorized director, within four weeks. The statement of account shall be accompanied by the certificate of a chartered accountant verifying its genuineness.

iv) It is clarified that the defendant Glenmark is permitted to sell the products in question which are already in the market (i.e. with its FAO (OS) 190/2013 Page 79 distributors, retailers etc.). However, in compliance with the injunction granted in favour of the plaintiff/MSD - it shall not henceforth further sell, distribute or in any manner take any steps towards placing in the market the drug in question, Zita and Zitamet and such of the pharmaceutical products which are covered by the claim for interim injunction in the suit. If any stocks of such goods are in its factory premises or awaiting the distribution channel, a true and correct account thereof shall be given to the Court along with the affidavit to be filed in compliance with directions (iii) above. Likewise, Glenmark shall also indicate in the said affidavit details of the drug Zita and Zitamet (and such of the pharmaceutical products which are covered by the claim for interim injunction in the suit) which are in the market and have been permitted to be sold.

v) The parties are directed to appear before the Single Judge in the suit on 10th April, 2015.

This Court was informed during the hearing that the suit is at the stage of trial. The learned Single Judge shall endeavour to ensure that parties agree to limited oral evidence of experts and shall also endeavour to appoint a technical expert in consultation with parties under Section 115 of the Patents Act for better appreciation of the technical nature of the evidence. All these are aimed at expediting the final hearing of the trial."

21. In ***AIIMS*** Versus ***Sanjiv Chaturvedi and others***, ***(2020) 17 Supreme Court Cases 602***, Hon'ble Supreme Court held as under:-

"65. It is true that the interim order passed by a Court does not operate as a precedent and the law declared by the Supreme Court with regard to the precedential value of judgments of Benches of larger strength may not operate as a binding precedent in the facts and circumstances of this case. The judgments referred to in the preceding paragraphs lay down the norms of judicial decorum and propriety which give 11 (1976) 3 SCC 677 12 (2001) 4 SCC 448 precedence to Benches of higher strength. There is no reason at all why the same principles should not apply even to interim orders in pending proceeding."

22. In ***Mumbai International Airport Private Limited*** Vs. ***Golder Chariot Airport and another***, ***(2010) 10 Supreme Court 422,*** Hon'ble Supreme Court has held that a contesting party cannot be

permitted to take a complete volte-face of its previous stand taken before the Court of law. A litigant cannot be permitted to change and choose its stand to suit its convenience.

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."*

24. Let's apply these decisions vis-a-vis the respective contentions of the parties to decipher as to whether the defendants have laid a credible challenge which has rendered the patent of the plaintiffs to be vulnerable at this stage to refuse the grant of interim relief or not.

25. This Court is not oblivious to the fact that vulnerability is the issue at the primary injunction stage while validity is the issue at the stage of trial and all that this Court has to see at this stage is as to whether the defendants have raised a credible challenge to the validity of the patent held by the plaintiffs and whether the patent is vulnerable. The principal ground which has been urged by the defendants is that subject patent is evergreening of IN719, and in this view of the matter, there is indeed a credible challenge to the subject patent which renders the same vulnerable. All other contentions raised hover around this principal contention of the defendants. To substantiate their contention, much stress was laid upon the pleadings of the plaintiffs in the civil suit, which stands filed by them in the High Court of Delhi, reference of which has already been made hereinabove, in which suit, as per defendants, the plaintiffs were claiming the infringement of IN719 and IN301 qua Linagliptin, and which as per the defendants, makes it amply evident that IN301 was nothing but evergreening of IN719. Learned Senior Counsel at length took the Court through the documents filed by the respective parties to substantiate their contentions. It was also urged that the factum

of IN301 to be evergreening of IN719 was also evident from the queries which were raised by the Patents Office at the time of the consideration of the application of the plaintiff qua the subject patent.

26. Now, when one peruses the plaint which has been filed by the plaintiffs in the High Court of Delhi, one finds that what has been pleaded by the plaintiffs in the said suit, is that whereas Linagliptin is a compound "**claimed and covered**" in Claim No. 1 of IN301, Linagliptin was a compound "**claimed and encompassed**" in Claim No. 2 of IN719. Thus, whereas on one hand the plaintiffs claimed Linagliptin as a compound to have been claimed and encompassed in Claim No. 2 of IN719, the said compound was stated to be claimed and covered in Claim No. 1 of IN301. This demonstrates that Linaglipin compound was not claimed to be covered in patent IN719, as has been urged by the defendants. In this background, when one peruses the averments, which have been made in the present plaints, one finds that in these cases the stand of the plaintiffs is that Linagliptin is a compound covered by the subject patent IN301. In this backdrop, now the Court would like to refer to the queries which were raised by the Patent's Office while processing the application of the plaintiffs for the grant of subject patent. These documents have been placed on record by defendant No. 2 in COMS No. 7 of 2022. There is on record a communication dated 06.09.2007 issued by the Patents Office to the plaintiffs on the subject "Examination Report"

of the application of the plaintiffs qua IN301, relevant portion whereof is quoted herein below:-

> *"To,*
> *REMFRY & SAGARREMFRY HOUSE, MILLENNIUM PLAZASECTOR 27, GURGAON 122 002, INDIA*
> *SUB: **Examination Report***
> *APPLICATION NUMBER: 01092/DELNP/2003*
> *DATE OF FILING 14/07/2003*
> *DATE OF REQUEST FOR EXAMINATION: 16/12/2005*
> *DATE OF PUBLICATION: 12/01/2007*
> *a. With reference to request no.5624/RQ-DEL/2005 dt.16/12/2005 by you for examination, the above quoted application has been examined under section 12 of the Patent Act, 1970 as amended and the First Examination Report containing a statement of objection is forwarded herewith for compliance thereof.*
>
> *The documents enclosed shall be resubmitted within 12(Twelve) months from the date of issue of the said report together with your observation if any, in connection with the compliance of the requirements of this First Examination Report.*
>
> *The application referred to will be deemed to have been abandoned under section 21(1) unless all the requirements imposed by the said Act and the rules there under are complied with within the above said prescribed period.*
>
> *The pages of the complete specification should be freshly typed wherever corrections of interpolation are made. The typed pages in duplicate should be on white pages in order that clear photocopies of the specification can be prepared. The original pages in that case should be returned to this office duly cancelled.*
>
> *It is in the interest of the applicant to comply with the requirements at the earliest.*
> *a. Encl:*
> *1. Form-1-Application for Grant of Patent*
> *2 Form-2-Provisional/Complete Specification*
> *3. Form-3-Statement & Undertaking*
> *4. Form-5-Declaration as to Inventorship*
> *NOTE: All Communications to be sent to the Controller of Patents at the above address.*
> *a Observations:*

1. Claims I and 18 define a plurality of Distinct inventions.
2 Claim 16 neither process nor product hence does not constitute an invention u/s 2(1) of Indian Patents Act 3. Claims not clear in respect of the expression as indicated therein.
4. Claims are not clearly worded as indicated therein. 5. Claims do not sufficiently define the invention as indicated therein.
Form 5 should be corrected as indicated therein 7. Abstract should be prepared in accordance with the instructions contained in the Rule 13(7) of the Patent Rules, 2003(as amended in 2006).

8 International application number given on form-1 incorrect. 9. Extraneous matter should be deleted from complete specification and fresh retyped pages should be filed.
10. Pages of complete specification should be renumbered. 11. Form 3 should be corrected as indicated therein."

27. Response thereto dated 13.06.2008 is also on record filed by defendant No. 2 in COMS No.7 of 2022 and relevant portion thereof is reproduced as under:-

"DDB/lvs/IP: 1092/DELNP/2003
June 13, 2008
THE CONTROLLER OF PATENTS
THE PATENT OFFICE
DELHI
Examiner: Sh. Rohit Rathore Final date: September 06, 2008
Dear Sirs,
Re:BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG., Indian Patent Application No. 1092/DELNP/2003 Filing date: July 14, 2003
Reference is made to the official letter dated September 06, 2007. Documents received with the official letter are returned duly amended to meet the objections raised.
Regarding paragraphs 1 to 5, the claims have been thoroughly revised in light of the objection of the learned Examiner and in accordance with the claims as allowed in the corresponding application in EP Le. EP 1368349. It is

submitted that the revised claims are all directed to the compound of claim 1 and do not relate to distinct inventions. It is respectfully submitted that the original PCT claim set has been restricted by deleting original claims 1 to 6. Present revised claim 1 results from original claim 7, in which the definition of heteroaryl in RI is replaced by the respective definition from original claim 1. Present claim 2 results from original claim 7. Present claims 3 to 9 result from original claims 8 to 14, in which the back references have been adapted accordingly. Original composition claim 15, use claim 16 and process claims 17 and 18 have been removed form the present claim set.

In light of the submission provided and the revisions carried out in the claims, the learned Examiner is requested to reconsider and withdraw the respective objections.

As regards the objection of the learned Examiner on the compound claims under Section 3(d), it is respectfully resisted and submitted that the claimed compounds are novel and may accordingly not be rejected as mere derivatives of known substances, In this regard, the kind attention of the learned Examiner is respectfully invited to the positive opinion of the International Searching Authority. Further, we have the honour to enclose a list of 371 additional compounds supporting the scope of the present claims. All of these 371 compounds show an IC50 value even below 100nM measured on the assay originally described in the present application: The learned Examiner is accordingly requested to waive the objection under Section 3(d).

The amendments carried out to the specification have necessitated retyping of pages 289 to 362 as fresh pages 290 and 327 respectively. The retyped pages are submitted herewith in duplicate along with the former pages duly cancelled. The pages of the specification have been correspondingly numbered.

Regarding paragraph 7, we have the honour to submit an abstract of the invention fin duplicate) in accordance with Rule 13(7) Patent Rules, 2006, Regarding paragraph 8, we have corrected the International application no. in Form 1.

Regarding paragraph 12, we have already submitted the details of corresponding foreign applications vide our letter dated December 27, 2007. Further, we have the honour to submit the petitions under Rules 137 and 138 for obviating

irregularity and condoning delay in submitting the details of corresponding foreign applications.
Regarding paragraph 13, we have already submitted the prosecution details of corresponding applications vide our letter dated February 28, 2008. As and when we received any further details, we shall submit the same.
We have the honour to submit a substitute power of authority in favour of our attorneys.
All the remaining requirements have been complied with.
Grant of a patent on this application within the final and in-extendible period expiring an September 06, 2008, is respectfully requested.
Before taking any adverse decision on this case, the Controller is respectfully requested to give an opportunity to the applicants to be officially heard in this matter.
Yours faithfully,".

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.

29. This Court hastens to add that the contention of the defendants that the subject patent is bad cannot be construed so as to render the subject patent vulnerable at the threshold stage. In other words, vulnerability of a patent cannot be concluded simply on the assertions/defence of the defendants which is yet to be proved as per law. To elaborate it, grant of patent in favour of the plaintiffs is a matter of record. Though, mere grant of the patent does not means that challenge

cannot be laid to it as per the provisions of the Patents Act, yet, fact of the matter is that a challenge, which is yet to be proved, cannot be placed at a higher pedestal than the statutorily granted patent until and unless the challenging party can demonstrate in terms of the provisions of the Patents Act that the patent is vulnerable so as to refuse grant of interim relief. This test obviously has to be in terms of grounds of challenge. Coming back to the facts of these cases, the ground of challenge of the defendants to the subject patent is in terms of the provisions of Section 64(1)(a) of the Patents Act, 1970. As of now, nothing has been placed on record from which it can be inferred that the invention claimed in IN301 of the complete specifications was also claimed in the complete specifications of IN719 and this was evident a day before the priority date of IN301, the subject patent to a person skilled in the art.

30. In the case in hand, the patent in issue, i.e. 'IN301' was granted in favour of the plaintiffs in India on 5th October, 2010 and the terms of the patent is 20 years, which is to expire on 5th October, 2023 as the international filing date of the patent application in the present case is August 18, 2003.

31. On the other hand, admittedly, the defendants do not have any patent qua the infringing product and no challenge, either to the application filed by the plaintiffs for grant of patent was laid by the defendant nor any post patent challenge was laid by it. Of course, in light of law laid down by Hon'ble Supreme Court in M/s Bishwanath Prasad

Radhey Shyam (supra), grant of patent does not guarantee the validity of a patent, which can be challenged before the High Court on various grounds in revocation or infringement proceedings, but the factum of a patent being there in favour of the plaintiffs and the factum of no pre or post grant challenge to the same by anyone, including the defendant, except recently by way of a revocation petition which was filed in close proximity to the launch of the infringing product, does creates a *prima facie* case and balance of convenience in favour of the plaintiffs. The Court is observing so for the reason that as per the plaintiffs, since the patent was granted on 5th October, 2010, the same has had a successful commercial run till date which continues and there is no serious dispute qua the same. The patent is an old patent and it has not been granted recently to the plaintiffs. Therefore, these facts do create *prima facie* case and balance of convenience in favour of the plaintiffs vis-a-vis the defendant, who admittedly does not has any patent qua the infringing product.

32. In the light of what has been discussed hereinabove, if an infringer is not restrained from infringing the patent of patent holder, then, but of course, the patent holder will suffer from irreparable loss and it cannot be said that the infringer stands on the same pedestal on which the patent holder is. Of course, the patent of the plaintiffs is vulnerable. It is open to challenge and now it has also been challenged by the defendant by way of a revocation petition. But mere filing of revocation

proceedings cannot be treated to be a “credible challenge” to the old and successful patent of the plaintiffs. As far as the element of public interest is concerned, it may be observed that in the present case, the Central Government has not invoked the provisions of Section 66 of the Patents Act and after following the procedure referred to therein, made a declaration in the Official Gazette to the effect that the patent of the plaintiffs stand revoked in public interest. Not only this, the defendant has not approached the competent authority under Section 84 of the Patents Act after the expiry of three years from the grant of the patent for grant of compulsory licence of patent on the conditions enumerated therein.

33. At this stage, it is relevant to refer to Section 48 of the Patents Act as it stood prior to the amendment and also post amendment, which amendment was carried out in the said section w.e.f. 20.05.2003.

34. Section 48 of the Patents Act, which deals with rights of the patentees, before amendment provided as under:-

> “**Section 48. Rights of patentees**
>
> *(1) Subject to the other provisions contained in this Act, a patent granted before the commencement of this Act, shall confer on the patentee the exclusive right by himself, his agents or licensees to make, use, exercise, sell or distribute the invention in India.*
>
> *2) Subject to the other provisions contained in this Act and the conditions specified in Section 47, a patent granted after the commencement this Act shall confer upon the patentee--*

(a) where the patent is for an article or substance, the exclusive right by himself, his agents or licensees to make, use, exercise, sell or distribute such article or substance in India;

(b) where a patent is for a method or process of manufacturing an article or substance, the exclusive right by himself, his agents or licensees to use or exercise the method or process in India."

After amendment, said Section now reads as under:-

"***Section 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;

(b) where the subject-matter of the patent is a process, the exclusive right to prevent third parties, who do not have his consent, from the act of using that process, and from the act of using, offering for sale, selling or importing for those purposes the product obtained directly by that process in India:"

35. It is evident that though subject to other provisions contained in the Patents Act, including Section 47 thereof, a patent granted under the Patents Act does confers upon the patentee, where the subject matter

of the patent is a product, the exclusive right to prevent a third party, who do not have his consent, from the act of making, using, offering for sale etc. of that product in India. Thus, a statutory right, which has been conferred upon the patentee, clothes the patentee with an umbrella of safety qua the infringement of its patent by a third party.

36. Now this Court will refer to the two judgments of this Court which have been relied upon by the plaintiffs as well as defendants.

37. In ***Dhanpat Seth & others*** Vs. ***Nil Kamal Plastic Crates Ltd.***, 2006 SCC OnLine HP 98, learned Single Judge of this Court while dealing with an application filed under Order XXXIX, Rules 1 and 2 of the Code of Civil procedure for grant of temporary injunction with regard to the infringement of the Patent granted to the plaintiffs therein in respect of a device of manual hauling of an agricultural produce, after perusing the Patent device in the Court, observed that the the basket got patented by the plaintiffs was not a hauling device and the device was made of synthetic polymeric material, which had been invented long back and that the process by which the substance was moulded into various articles like baskets, buckets, mugs, jugs, furniture and so many other articles was also well known and there was nothing new about the so called device. On these findings, leaned Single Judge rejected the prayer for grant of interim relief.

38. In appeal, Hon'ble Division Bench of this Court while upholding the order passed by the learned Single Judge in ***Dhanpat Seth &***

Ors. Vs. ***M/s. Nil Kamal Plastic Crates Ltd.***, AIR 2008 HP 23 has held as under:-

> *"11. A bare perusal of the definition of invention clearly shows that even a process involving an inventive step is an invention within the meaning of the Act. It is, therefore, not necessary that the product developed should be a totally new product. Even if a product is substantially improved by an inventive step, it would be termed to be an invention. The definition of 'inventive step' provides that when technical advances as compared to existing knowledge take place in an existing product or there is improved economic significance in the development of the already existing device and the invention is not obvious to people skilled in the art, it would amount to an inventive step.*
>
> *12. The learned single Judge had seen the products of the plaintiffs, the defendant and the traditional Kilta. We also called upon the parties to produce their respective devices as well as the traditional Kiltas.*
>
> *13. A Kilta is a traditional product which has been used since time immemorial for carrying produce including agricultural produce in hill areas especially in the State of Himachal Pradesh. The traditional Kilta is made of bamboo. The shape of a kilta is conical having a wider circular opening on the top and it tapers*

and narrows down at the bottom. There is virtually no difference in the overall design of the tradition Kilta or the 'devices' developed by the plaintiffs and: the defendant. A visual comparison of the' three items prima facie establishes that the articles manufactured by the plaintiffs and the defendant are virtual copies of the traditional Kilta. The only difference is that the Kilta is made of bamboo and the Kilta made by the plaintiffs is made of polypropylene copolymer (PP). The Kilta made by the defendant is also made of polymeric material. The Kilta manufactured by the defendant is made of high density polyethylene (HDP). In actual fact, both the materials are polymers in common parlance known as plastic. The only visible difference is that device now being manufactured is having detachable nylon straps with buckles. The question which arises for consideration is whether this change of material from bamboo to plastic and the development of adjustable nylon straps with buckles is an inventive step falling within the meaning of Section 2(ja).

14. Shri Vinay Kuthiala, contended that by changing the material from bamboo to plastic there is a great economic gain and there is technical advance of economic significance. Though the cost of Kilta made of plastic may be higher than that of Kilta made of bamboo, its life is much longer making it more economic. He

further submits that the Kilta is designed in such a manner as to make it easy to carry heavy load and, therefore, this is an inventive step.

15. After having seen the traditional Kijta and the devices of the parties and having examined the same, we are prima facie of the view that the devices being manufactured by the parties are only imitations of the traditional Kilta. Shri Vinay Kuthiala has contended that the traditional Kilta was only supported by rope on the forehead. This assertion is in fact incorrect. The traditional Kilta used in Himachal Pradesh is by and large supported by adjustable ropes going over the shoulders. In some cases, the supporting strap goes over the forehead. Both types have been in existence for times immemorial.

16. The Apex Court in M/s. Bishwanath Prasad Radhey Shyam v. Hindustan Metal Industries, while dealing with the meaning of the words 'inventive step' held as follows:

21. It is important to bear in mind that in order to be patentable an improvement on something known before or a combination of different matters already known, should be something more than a mere workshop improvement; and must independently satisfy the test of invention or an "inventive step". To be patentable the improvement or the combination

must produce a new result or a new article or a better or cheaper article than before. The combination of old known integers may be so combined that by their working inter-relation21.

It is important to bear in mind that in order to be patentable an improvement on something known before or a combination of different matters already known, they produce a new process or improved result. Mere collection of more than one integers or things, not involving the exercise of any inventive faculty, does not qualify for the grant of a patent.

17. The device being manufactured by the plaintiffs is basically a Kilta but made out of synthetic polymeric material which is commonly known as plastic. The process of making traditional items out of such polymers is a well known and well established process. This Court can take judicial notice of the fact that much prior to the device being manufactured by the plaintiffs, traditional items made out of woods, steel, brass, leather and other natural materials have been replaced by plastic. In this regard reference may be made to chairs, tables, Jugs, baskets, shoes and numerous other items which were traditionally made of natural material but are now made of plastic. Therefore, in our opinion, the mere fact that the device is made of polymeric material instead of bamboo is not an inventive step involving any novelty. There is

nothing new about the process of manufacturing the traditional Kilta made of natural material from synthetic material. Even nylon straps now added are virtually copies of the ropes used in the traditional Kilta. The ropes in the Kilta can also be adjusted by the user keeping in view the height of the person using the Kilta and the weight being carried by him. The mere introduction of buckles would not amount to a new device being called an invention or an inventive step.

18. Shri Vinay Kuthiala has laid great emphasis on the order dated 2-7-2007 passed by the Assistant Controller, Patents and Designs, whereby he has rejected the application for revocation filed by the defendant.

19. At the outset, it would be pertinent to mention that the Controller before dealing with the matter did not even take the traditionally built Kilta into consideration as a citation. His reasoning in this regard is as follows:

"Exhibit A is a Bamboo made Kilta with a strap but there is no proof of date of its publication. Hence the said document cannot be taken into consideration as a citation."

20. We fail to understand the reasoning given by the Assistant Controller, Patents and

Designs in not taking into traditionally built Kilta into consideration. Even the case set up by the plaintiffs was not that he had invented an entirely new product but his case was that he had developed a traditional Kilta by means of inventive steps in such a fashion that it amounts to a new invention. The contentions of both the parties could not have been appreciated without first taking into consideration the traditional Kilta. On this short ground alone we feel that much reliance can be placed on the aforesaid order.

21. Mere grant of patent in favour of the plaintiffs by itself does not mean that the plaintiffs are entitled to any injunction. This is a factor which may be taken into consideration and would be a relevant factor but the grant of patent would not ipso facto entitle the plaintiffs to grant of an injunction without taking into consideration other relevant factors. In fact Section 107 of the Patents Act clearly provides that in any suit for infringement of a patent every ground on which it may be revoked under Section 64 shall be available as a ground for defence. Therefore, the defendant is entitled to argue before this Court that the patent granted is not valid. Reliance placed upon by the plaintiffs on the judgment of the Apex Court in Midas Hygiene Industries (P) Ltd. and Anr. v. Sudhir Bhatia and Ors. is

totally misconceived. The action in the case was under the Trade Marks Act where the provisions are different. It may be true that Section 28 of the Trade Marks Act is similar to Section 28 of the Patents Act but under the various provisions of the Patents Act, such as Sections 64 and 107(2) even after the patent is granted, the same can be challenged in appropriate proceedings.

22. We also find that the device manufactured by the plaintiffs has been termed as hauling device. The learned single Judge is absolutely right in holding that the so-called-device is not a device of hauling but basically a device for carrying the produce.

23. The House of Lords, in (1975) All England Law Reports 504, American Cyanamid Co. v. Ethicon Ltd., clearly laid down that the governing principle with regard to grant of injunction is that the court should first consider whether if the plaintiff were to succeed at the trial in establishing his right to a permanent injunction he could be adequately compensated by an award of damages for the loss he would have sustained as a result of the defendant's continuing to do what was sought to be enjoined between the time of the application and the time of the trial. If damages in the measure recoverable at common law would be adequate remedy and

the defendant would be in a financial position to pay them, no interlocutory injunction should normally be granted, however, strong the plaintiffs claim appeared to be at that stage. If, on the other hand, damages would not be an adequate remedy to the plaintiff in the event of the success in the trial, the Court can grant injunction in favour of the plaintiff by ensuring that the defendant is adequately compensated in case the trial culminates in his favour. If damages in the measure recoverable under such an undertaking would be an adequate remedy and the plaintiff would be in a financial position to pay them, there would be no reason on this ground to refuse an interlocutory injunction.

24. It also held that where other factors appear to be evenly balanced the rule of prudence would be to preserve the status quo. In the case before the House of Lords, the defendant had not started manufacturing of absorbable surgical sutures and it is in these facts that relief of temporary injunction was granted. In the present case, the defendant has already started manufacturing and selling the Kiltas and has been doing so for a number of years. In our opinion, at this stage it would not be appropriate to put the clock back.

25. In respect of the arguments addressed on the doctrine of anticipation,

even if we discount the production of the device by the plaintiffs prior to 24-5-2002, it is clear that prior to this date, the defendant had sent the drawing for production of the Kilta to Taiwan. At this stage of the suit when evidence is still to be recorded, the said material cannot be discarded.

26. Keeping in view the aforesaid discussion, we are clearly of the view that the device developed by the plaintiffs is in fact the result of traditional knowledge and aggregation /duplication of known products such as polymers and, therefore, cannot be said to be an invention. The plaintiffs are, therefore, not entitled to any injunction."

39. A perusal of the above mentioned judgments of this Court as well as the judgment of the Hon'ble Supreme Court in *Bishwanath Prasad Radhey Shyam* Vs. Hindustan Metal Industries, AIR 1982 SC 1444, which stands taken note by the Hon'ble Division Bench of this Court demonstrates that in the said two cases, the Patent article was physically seen by the Court and the same was of such nature that the Hon'ble Judges were in a position to *prima facie* conclude as to whether there was any inventive step involved in the Patent product, as defined in the Patents Act or not. However, in my considered view, the above mentioned judgments are of no assistance in the present case, for the reason that here the Patent is of a drug and infringement is also alleged

by way of a drug being marketed and sold by the defendants based on the Patent of the plaintiffs. Unlike in the cases referred to above, by no stretch of imagination this Court by comparing the tablet of the plaintiffs/applicants with the tablet of the defendants/non-applicants with a naked eye can conclude as to whether any inventive step was involved in the Patent of the plaintiff or not.

40. Similarly, by referring to the applications and documents appended therewith, which were submitted by the plaintiffs/applicants for grant of IN' 719 and IN' 301, this Court cannot conclude even prima facie that IN' 301 is evergreening of IN'719. Therefore, this Court has no hesitation in holding at this stage that it cannot be said that the defendants/non-applicants have been able to lay any credible challenge to the Patent of the plaintiffs or that they have been able to convince the Court that the said Patent is vulnerable so as to refuse the grant of interim protection.

41. There is one more aspect of the matter. Wheras on the one hand, the plaintiffs/applicants do have a Patent in their favour with regard to the compound Linagliptin, the defendants/non-applicants do not have one. Yet knowing fully well that the drug they intended to introduce in the market was duly covered by the subject Patent, they took a calculated risk to do so. It is not in dispute that the defendants/non-applicants do admit that the drug in issue, which is being manufactured by them is covered by the subject Patent, because if that was not the case, then there was no

occasion for them to have had taken the plea of plaintiffs' evergreening Patent IN' 719. Now, Patent IN' 719, which has recently expired, was in public domain, yet before manucaturing their respective products and before marketing the same, the defendants/non-applicants did not seek revocation of the Subject Patent well in time during the validity of Patent IN' 719. This also in the considered view of the Court, tilts the balance of convenience in favour of the plaintiffs.

42. Accordingly, the applications filed by the plaintiffs/applicants under Order XXXIX, Rules 1 and 2 of the Code of Civil Procedure are allowed and the defendants/non-applicants in the respective Civil Suits are restrained either themselves or through their directors, partners licenses, stockiest and distributors, agents etc., jointly and severally from infringing the subject Patent, i.e., IN'301 by advertising, launching, making, using, offering for sale, selling, importing and/or exporting the medicinal product, Linagliptin in any form whatsoever including Linagliptin API, Linagliptin formulation, "Linagliptin Tablet" and/or "Linagliptin + Metformin Hydrochloride Tablets" or any "generic version" thereof or any other product sold under the trade marks/brand names "LINARES" and "LINARES M" in COMS No. 07 of 2022, "LINANEXT" , "LINANEXT-M" in COMS No. 08 of 2022, "EMLINZ 5" and "EMLINZ M 500" in COMS No. 09 of 2022 and generic version of subject patent in COMS No. 10 of 2022 or any other trade mark(s)/brand name(s), whatsoever, or any other product covered by the subject patent granted by the Controller of Patents

on October 5, 2010 in favour of applicant/plaintiff No. 1 in all the suits. The applications stand disposed of.

A copy of this order be placed in each of the Files.

(Ajay Mohan Goel)
Judge

June 02, 2022
(bhupender/narender)