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

Reserved on: 4th June, 2021
Pronounced on: 13th December, 2021

\+ CS(COMM) 256/2021 & I.A. 6980/2021

NOVARTIS AG & ANR. ..... Plaintiffs
Through: Mr. Hemant Singh, Adv. with Ms. Mamta Jha, Mr. Ankit Arvind and Ms. Mamta Bhadu, Advs.

versus

NATCO PHARMA LIMITED ..... Defendant
Through: Mr. J Sai Deepak, Mr. Guruswamy Nataraj, Mr. Avinash K. Sharma, Mr. R. Abhishek and Mr. Ankur Vyas, Advs.

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

J U D G M E N T

% 13.12.2021

I.A.6980/2021 (under Order XXXIX Rules 1 & 2 of CPC)

1. This order decides IA 6980/2021, whereby the plaintiffs have sought an interlocutory injunction against the perceived infringement, by the defendant, Natco Pharma Ltd, of the plaintiffs' suit patent IN 233161 (in short, 'IN 161').

2. Arguments were advanced on behalf of the plaintiffs by Mr. Hemant Singh, and on behalf of the defendant by Mr. J. Sai Deepak. Copious written submissions have also been filed by both sides.

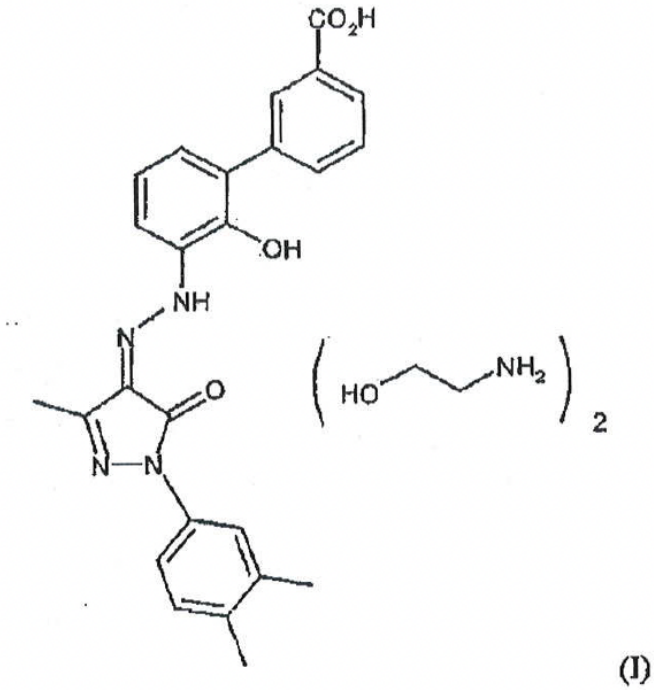
3. The plaintiffs would collectively be referred to, hereinafter, for ease of reference, as "Novartis".

Facts

4. The suit patent was originally granted to M/s SmithKline Beecham Corporation (later renamed "GlaxoSmithKline LLC") on 27th March, 2009. Novartis claims that the suit patent was first assigned by GlaxoSmithKline LLC to the Glaxo Group Ltd on 5th October, 2015, on which date, by a back-to-back assignment deed, the suit patent was assigned by the Glaxo Group Ltd to Novartis Pharma AG, who, by another assignment deed of the same date, i.e. 5th October, 2015, assigned the suit patent to Plaintiff 1. Plaintiff 2 is the Indian subsidiary of Plaintiff 1, which imports and markets the patented product in India. The defendant does not dispute these assertions, at least at this stage.

5. The invention patented by the suit patent was titled "3-[(2Z)-[1-(3,4-Dimethylphenyl)-1,5-Dihydro-3-Methyl-5-Oxo-4H-Pyrazol-4-Ylidene] Hydrazino]-2'-Hydroxy-[1,1'-Biphenyl]-3-Carboxylic Acid Bis-(Monoethanolamine)". Reckoned from 21st May, 2003, being the International Filing Date of the suit patent, the patent would remain alive till 21st May, 2023, by virtue of Section 53(1) of the Patents Act,

1970 ("the Patents Act"), read with the Explanation thereto[1]. The invention was granted the non-proprietary United States Adopted Name (USAN) name "Eltrombopag Olamine" (abbreviated, for the sake of convenience, as "EO"), and has the following chemical structure:



(I)

The Complete Specifications of the suit patent, as filed with the Indian Patent Office (IPO) for grant of the patent declares that Eltrombopag "is a compound which is disclosed and claimed, along with pharmaceutically acceptable salts, hydrates, solvates and esters thereof, as being useful as an agonist of the TPO[2] receptor,

[1] **"53. Term of patent. –**

(1) Subject to the provisions of this Act, the term of every patent granted, after the commencement of the Patents (Amendment) Act, 2002, and the term of every patent which has not expired and has not ceased to have effect, on the date of such commencement, under this Act, shall be twenty years from the date of filing of the application for the patent.

Explanation. – For the purposes of this sub-section, the term of patent in case of International applications filed under the Patent Cooperation Treaty designating India, shall be twenty years from the International filing date accorded under the Patent Cooperation Treaty."

[2] Thrombopoietin

particularly in enhancing platelet production and particularly in the treatment of thrombocytopenia". Further, in respect of EO, the complete specifications declare that "while the free acid is highly useful as an agonist of TPO receptor particularly in enhancing platelet production and particularly in the treatment of thrombocytopenia, the bis-(monoethanolamine) salt of [Eltrombopag] has the added advantages of enhanced solubility and bioavailability." We need not, for the purposes of the present dispute, concern ourselves with the intricacies of EO as a chemical formulation; suffice it to state that EO is used for the treatment of thrombocytopenia, denoting insufficiency of platelets in the body. EO is marketed, by the plaintiffs, under the tradename "REVOLADE". IN 161 claimed the following:

> "1. The compound 3'[(2Z)[1-(3,4-dimethylphenyl)-1,5-dihydro-3-methyl-5-oxo-4H-pyrazol-4-ylidene]hydrazino]-2'-hydroxy-[1,1'-Biphenyl]-3-Carboxylic Acid bis-(monoethanolamine).
>
> 2. A compound as claimed in claim 1 as and when used as a pharmaceutical composition along with the pharmaceutically acceptable carrier or diluents of the kind such as herein described.
>
> 3. A process for preparing the compound as claimed in claim 1, which process comprises:
>
> i) dissolving 3'-[(2Z)[1-(3,4-dimethylphenyl)-1,5-dihydro-3-methyl-5-oxo-4H-pyrazol-4-ylidene]hydrazino]-2'-hydroxy-[1,1'-biphenyl]-3-carboxylic acid in an appropriate organic solvent, preferably Tetrahydrofuran (THF) and ethanol to form a solution;
>
> ii) adding two or more equivalents of ethanolamine to the solution; and resulting dark red suspension was stirred and dried at 50°C in a vacuum oven over night; and

iii) isolating the prepared compound."

6. The defendants, admittedly, are launching their branded EO in the market. This, alleges the plaintiff, infringes Claim 1 of the suit patent (which is still alive) as the defendants have obtained no license from the plaintiffs. Ergo, the plaintiff seeks an injunction against the defendants from infringing the suit patent, and the present application seeks interlocutory injunctive orders.

7. The defendant contests the suit by questioning the validity of the suit patent IN 161, invoking, for the purpose, Section 107(1)[3], read with clauses (a), (d), (e), (f), (j), (k) and (m)[4] of Section 64 of the

[3] **107. Defences, etc., in suit for infringement.** –
(1) 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.

[4] **64. Revocation of patents.** –
(1) Subject to the provisions contained in this Act, a patent, whether granted before or after the commencement of this Act, may, be revoked on the petition of any person interested or of the Central Government or on a counter-claim in a suit for infringement of the patent by the High Court on any of the following grounds that is to say –

(a) that the invention, so far as claimed in any claim of the complete specification, was claimed in a valid claim of the earlier priority date contained in the complete specification of another patent granted in India;

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(d) that the subject of any claim of the complete specification is not an invention within the meaning of this Act;

(e) that the invention so far as claimed in any claim of the complete specification is not new, having regard to what was publicly known or publicly used in India before the priority date of the claim or to what was published in India or elsewhere in any of the documents referred to in section 13;

(f) that the invention so far as claimed in any claim of the complete specification is obvious or does not involve any inventive step, having regard to what was publicly known or publicly used in India or what was published in India or elsewhere before the priority date of the claim;

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(j) that the patent was obtained on a false suggestion or representation;

(k) that the subject of any claim of the complete specification is not patentable under this Act;

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(m) that the applicant for the patent has failed to disclose to the Controller the information required by section 8 or has furnished information which in any material particular was false to his knowledge;

Patents Act. The challenge is predicated on treating IN 213176 (in short, 'IN 176'), also held by the plaintiffs, as prior art.

8. The title of IN 176 was "A compound and a pharmaceutical composition for use in enhancing platelet production". The International Filing Date of IN 176 was 24th May, 2001; ergo, the patent expired on 24th May, 2021. EO was, according to the defendant, the "subject matter covered by" IN 176; hence, it was not entitled to any protection after 24th May, 2021, by virtue of Section 53(4)[5] of the Patents Act. According to the defendant, Claim 1 of IN 161 was covered by Claims 1 to 4 and 6 of IN 176, Claim 2 of IN 161 was covered by Claim 8 of IN 176 and Claim 3 of IN 161 was covered by Claim 9 of IN 176.

Rival Submissions

9. Submissions of defendant: The submissions of Mr. Sai Deepak, on the basis of which he questions the entitlement of the plaintiff to an injunction, may be enumerated as under.

9.1 The Active Pharmaceutical Ingredient (API), which provided therapeutic activity against thrombocytopenia, is Eltrombopag, and not EO. EO functioned only as a pro-drug, which enabled delivery of Eltrombopag to the target site. EO does not have any inherent therapeutic activity. Reliance was placed, in this regard, on the leaflet and prescribing information for REVOLADE, which indicated that

[5] "(4) Notwithstanding anything contained in any other law for the time being in force, on cessation of the patent right due to non-payment of renewal fee or on expiry of the term of patent, the subject matter covered by the said patent shall not be entitled to any protection."

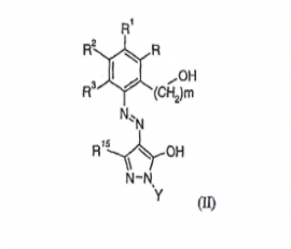
EO was present, in the tablets, in a quantity which was sufficient to enable providing of equivalent specified amounts/dosages of Eltrombopag to the patient.

9.2 Anticipation by prior claiming – Section 64(1)(a)

9.2.1 The suit patent was invalid on the ground of anticipation by prior claiming, under Section 64(1)(a) of the Patents Act. Mr. Sai Deepak has, in this context, exhorted the Court to read Section 64(1)(a) in conjunction with Section 13(1)(b)[6]. IN 176 being a patent granted in India, with priority dates (25th February, 2000 and 30th August, 2000) earlier than the priority date of the suit patent IN 161 (22nd May, 2002), the coverage of the subject matter of the claims in the suit patent by the claims in IN 176, submits Mr. Sai Deepak, disentitles the claims in IN 176 – which cover EO – to any protection after 24th May, 2021. Mr. Sai Deepak has sought to demonstrate, in a tabular fashion, the coverage of the various Claims in the suit patent IN 161, by the Claims in IN 176, thus:

IN 213176	IN 233161
Claim 1: A compound represented by the following Formula (II):	The compound 3'[(2Z)[1-(3,4-dimethylphenyl)-1,5-dihydro-3-methyl-5-oxo-4H-pyrazol-4-ylidene]hydrazino]-2'-hydroxy-[1,1'-Biphenyl]-3-

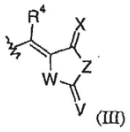
[6] "**13. Search for anticipation by previous publication and by prior claim. –**
(1) The examiner to whom an application for a patent is referred under section 12 shall make investigation for the purpose of ascertaining whether the invention so far as claimed in any claim of the complete specification –
(a) has been anticipated by publication before the date of filing of the applicant's complete specification in any specification filed in pursuance of an application for a patent made in India and dated on or after the 1st day of January, 1912;
(b) is claimed in any claim of any other complete specification published on or after the date of filing of the applicant's complete specification, being a specification filed in pursuance of an application for a patent made in India and dated before or claiming the priority date earlier than that date."



(II)

wherein:

R, R^1, R^2 and R^3 are each independently selected from hydrogen, $C_{1\text{-}6}$alkyl, $-(CH_2)_pOR^4$, $-C(O)OR^4$, formyl, nitro, cyano, halogen, aryl, **substituted aryl**, substituted alkyl, $-S(O)_nR^4$, cycloalkyl, $-NR^5R^6$, protected -OH, $-CONR^5R^6$, phosphonic acid, sulfonic acid, phosphinic acid, $-SO_2NR^5R^6$, and a heterocyclic methylene substituent as represented by Formula (III),



(III)

where

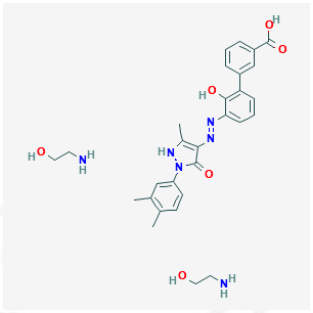
p is 0-6,

n is 0-2,

V, W, X and Z are each independently selected from 0, S, and NR^{16}, where R^{16} is selected from: hydrogen, alkyl, cycloalkyl; C_1-C_{12}aryl, substituted alkyl, substituted cycloalkyl and substituted C_1-C_{12}aryl,
R^4 is hydrogen, alkyl, cycloalkyl, C_1-C_{12}aryl, substituted alkyl, substituted cycloalkyl, and substituted C_1-C_{12}aryl, and
R^5 and R^6 are each independently

Carboxylic Acid bis-(monoethanolamine).

ELT Olamine is represented by the following chemical structure:



A transposition of the substituents from IN'176 is as follows:
R is substituted aryl where the substitution is -COOH:;
R^1, R^2 and R^3 are each -H;
M=0 which leads to only -OH being present at position 5 on the phenyl
R^{15} is alkyl i.e. methyl ;
Y is phenyl substituted with two alkyl i.e. two methyl moieties
and the sale is a monoethanolamine salt.

selected from hydrogen, alkyl, substituted alkyl, C_{3-6}cycloalkyl, and aryl, or R^5 and R^6 taken together with the nitrogen to which they are (attached represent a 5 to 6 member saturated ring containing up to one other heteroatom selected from oxygen and nitrogen; **R^{15} is** selected from the group consisting of **alkyl**, C_1-C_{12}aryl, hydroxy, alkoxy, substituted alkyl, substituted C_1-C_{12}aryl and halogen; **m is 0-**6; and **Y is** selected from alkyl, substituted alkyl and a cyclic or polycyclic **aromatic ring containing from 3 to 14 carbon atoms** and optionally containing from one to three heteroatoms, provided that when the number of carbon atoms is 3 the aromatic ring contains at least two heteroatoms and when the number of carbon atoms is 4 the aromatic ring contains at least one heteroatom, and **optionally substituted with one or more substituents selected from the group consisting of: alkyl**, substituted alkyl, C_1-C_{12} aryl, substituted cycloalkyl, substituted C_1-C_{12}aryl, hydroxy, aryloxy, alkoxy, cycloalkyl, nitro, cyano, halogen and protected -OH; **and pharmaceutically acceptable salts**, hydrates, solvates and esters **thereof**; **provided that at least** one of **R**, R^1, R^2 and R^3 **is a substituted aryl group** or a heterocyclic methylene substituent as represented in Formula (III).	

Claim 2: A compound represented by Formula (II), as claimed in claim 1, wherein: either: **R is a substituted aryl and R1 is hydrogen**; or: R is hydrogen; and R1 is a substituted aryl; and in either case: **R2 and R3 are each independently** selected from **hydrogen**, C1-6 alkyl, C1-6alkoxy, nitro, cyano, halogen, aryl, substituted aryl, substituted alkyl, cycloalkyl, phosphonic acid, phosphinic acid and sulfonic acid; **R^{15} is** selected from the group consisting of **alkyl**, substituted alkyl, C1- C12 aryl, alkoxy and halogen; **m is 0**-4; and **Y is** selected from **phenyl**, pyridinyl and pyrimidinyl, where the phenyl, pyridinyl and pyrimidinyl are optionally **substituted with from one to three substituents selected from the group consisting of: alkyl**, substituted alkyl, C1-12aryl, substituted C1-12aryl, alkoxy and halogen; and **pharmaceutically acceptable salts**, hydrates, solvates and esters **thereof**.	Claim 1 : same explanation as above
Claim 3: A compound represented by Formula (II), as claimed in claim 1 or 2, wherein: **R is a substituted C1-C12aryl; and** **R1 is hydrogen;** **R2 and R3 are each independently** selected from	Claim 1 : same explanation as above

hydrogen; C1-6alkyl, C1-6alkoxy, nitro, cyano, halogen, substituted alkyl and cycloalkyl; **R15 is** selected from the group consisting of **alkyl**, substituted alkyl, C1-C12 aryl, alkoxy and halogen; **m is 0-2**; and **Y is** selected from **phenyl**, pyridinyl and pyrimidinyl, where the phenyl, pyridinyl and pyrimidinyl are optionally **substituted with from one to three substituents selected from the group consisting of: alkyl**, substituted alkyl, C1-C12 aryl, substituted C1-C12 aryl, alkoxy and halogen; and **pharmaceutically acceptable salts**, hydrates, solvates and esters **thereof**.	
Claim 4: A compound represented by Formula {II), as claimed in any one of claims 1 to 3, wherein: **R is a substituted phenyl or pyridinyl ring; and** **R1 is hydrogen;** **R2 and R3 are each independently** selected from **hydrogen**, C1-6alkyl, C1-6 alkoxy, nitro, cyano, halogen, substituted alkyl and cycloalkyl; **R15 is** selected from the group consisting of **alkyl**, substituted alkyl, C1-C12aryl and halogen; **m is O**; and **Y is** selected from, **phenyl**, pyridinyl and pyrimidinyl, where the phenyl, pyridinyl and pyrimidinyl is optionally **substituted with from one to three substituents selected from the group consisting of: alkyl**,	Claim 1 : same explanation as above

substituted alkyl, C1-Cl2 aryl, substituted C1-C12 aryl, alkoxy and halogen; and **pharmaceutically acceptable salts**, hydrates, solvates and esters **thereof**.	
Claim 6: A compound as claimed in claim 1, which is 3'[(2Z)[1-(3,4-dimethylphenyl)-1,5-dihydro-3-methyl-5-oxo-4H-pyrazol-4-ylidene]hydrazino]-2'-hydroxy-[1,1'-Biphenyl]-3-Carboxylic Acid **and pharmaceutically acceptable salts**, hydrates, solvates and esters thereof.	Claim 1 : same explanation as above
Claim 8: A pharmaceutical composition for use in enhancing platelet production which comprises a compound as claimed in claim 1 and a pharmaceutically acceptable carrier.	Claim 2: A compound as claimed in claim 1 as and when used as a pharmaceutical composition along with the pharmaceutically acceptable carrier or diluents of the kind such as herein described. Note: Claim 2 of IN'161 specifically stipulates that the diluent/carrier etc are as "herein described". The preceding description stipulates that the diluents and carriers are conventional and exactly as those used in IN' 176.

9.2.2 EO, points out Mr. Sai Deepak, is a pharmaceutically acceptable salt of Eltrombopag. Claim 6 in IN 176 clearly claims Eltrombopag with its pharmaceutically acceptable salts. Even on a plain reading, therefore, according to him, Claim 6 of IN 176 claimed EO.

9.2.3 Mr. Sai Deepak submits that the plaintiffs cannot, by asserting IN 161, seek to "evergreen" IN 176 beyond the life of the latter patent. As, according to him, IN 161 is invalid on the various grounds urged by him, manufacture and marketing of EO, by his client, cannot be alleged to amount to infringement. I may observe, here, that the plaintiffs do not dispute the priority dates of IN 176 or IN 161, as asserted by the defendant.

9.2.4 SmithKline Beecham Corporation had, while applying for grant of patent CA 2486697 ('CA 697' in short) in respect of the compound claimed in the suit patent IN 161, 3-[(2Z)-[1-(3,4-Dimethylphenyl)-1,5-Dihydro-3-Methyl-5-Oxo-4H-Pyrazol-4-Ylidene] Hydrazino-2'-Hydroxy-[1,1'-Biphenyl]-3-Carboxylic Acid Bis-(Monoethanolamine), before the Canadian Intellectual Property Office (IPO), admitted, in its response to objections raised by the Examiner in the Canadian IPO, that a salt form of some of the final compounds was inevitably formed during the reaction towards the final step in arriving at Examples 64 and 85 in that patent. The following recital, as contained in the said response of SmithKline Beecham, to the objections of the Examiner in the Canadian IPO, have specifically been emphasised by Mr. Sai Deepak:

> "The reference to the PCT/US01/16863 document on page 1, lines 21-22 and page 2, lines 2 and 25 has been deleted. While the cancelled sentence is a true statement, however, it is noted that the reaction conditions for the final step in certain Examples (e.g. 64 and 85) involve a solution that contains a strong acid, such as trifluoroaceticacid. *Even though none of the final compounds in International Application No. PCT/US01/16863 specifically disclose a salt form, a salt form of some of the final compounds appears to have inevitably formed.*"

(Emphasis supplied)

9.2.5 The assertions with respect to identification of the patented invention, the quantum of the product covered by the patented invention imported into India, and its values in Form 27 – filed by the plaintiff in accordance with Rule 131 (1)[7] of the Patents Rules, 2003 read with Section 146(2)[8] of the Patents Act – in respect of IN 176 and IN 161, for each calendar year, were identical. The product was also identified, in the Form 27s, filed in respect of both the patents, as REVOLADE which was, therefore, identified as a commercial product representing the invention covered by both the patents.

9.2.6 In applications filed by the plaintiffs or their predecessors in interest, for extension of the term of US Patent 7160870 (in short, 'US 870') – corresponding to IN 176, as admitted *ad idem* – before the US Patent Office, it had been averred that US 870 "reads on the approved product, Promacta tablets", because the approved product, EO, was a compound encompassed by Claim 1 of US 870. Having thus admitted, for obtaining the Patent Term extension from the USPTO, that EO was encompassed by Claim 1 in US 870, the plaintiff could not seek to contend that IN 176 did not claim EO. In this regard, reliance has also been placed, by the defendant, on a communication dated 23rd February, 2011 from the US Food and Drugs Administration (US

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[7] **"131. Form and manner in which statements required under section 146(2) to be furnished. –**
(1) The statements which shall be furnished by every patentee and every licencee under sub-section (2) of section 146 in Form 27 which shall be duly verified by the patentee or the licencee or his authorised agent."

[8] **"146. Power of Controller to call for information from patentees. –**
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(2) Without prejudice to the provisions of sub- section (1), every patentee and every licensee (whether exclusive or otherwise) shall furnish in such manner and form and such intervals (not being less than 6 months) as may be prescribed statements as to the extent to which the patented invention has been worked on a commercial scale in India."

FDA) to the USPTO, in which it is stated that US 870 "claims Promacta (eltrombopag olamine)".

9.2.7 The US Orange Book, a register maintained by the US FDA, expressly included US 870 as one of the patents claiming EO.

9.2.8 Plaintiff 1 had voluntarily included CA 2411468 ('CA 468', in short), the Canadian equivalent of IN 176, as well as CA 2486697 ('CA 697', in short), the Canadian equivalent of IN 161, in its declaration filed before the Canadian Patent Office, as patents which covered EO, commercially sold as REVOLADE.

9.2.9 Analogous to the provision of Patent Term Extension in the US, Supplementary Protection Certificates (SPCs) could be obtained in respect of European patents under the European Patent Convention, for extension of the term of a patent. IN 176 corresponded to European Patent EP 1294378 ('EP 378', in short). Plaintiff 1 had secured 12 separate SPCs, in different European jurisdictions, on the basis of the regulatory approval granted to REVOLADE, expressly stating that the SPCs covered Eltrombopag, optionally in the form of a pharmaceutically acceptable salt, specifically EO.

9.2.10 Having thus made the aforesaid admissions, before various foreign jurisdictions, in respect of patents corresponding to IN 176, the plaintiffs could not seek to contend that IN 176 did not claim EO.

9.3 Anticipation by prior publication – Section 64(1)(e) – Mr. Sai Deepak submits that the documents, already cited hereinabove in the context of the defence of anticipation by prior claiming, along with

the entire disclosure in WO 2001/089457 ('WO 457', in short) indicated that the suit patent IN 161 was also invalid on the ground of anticipation by prior publication. Though para 61 of the written submissions filed by the defendant places reliance on "the entire disclosure of WO 457", this disclosure is not forthcoming on record.

9.4 "Coverage" *vis-à-vis* "disclosure":

9.4.1 Mr. Sai Deepak has also sought to contend, relying on the judgement of the Supreme Court in ***Novartis AG v. U.O.I.***[9], that coverage, *ipso facto*, implies disclosure and there is no distinction between the two. Once, therefore, in published documents relating to equivalent patents granted in other jurisdictions, the plaintiff, or its predecessor in interest, had admitted coverage of EO by patents corresponding to IN 176, Mr. Sai Deepak submits that the plaintiff could not contend, here, that IN 176 did not disclose EO.

9.4.2 The contention, of the plaintiffs, that EO was not disclosed in IN 176, has also sought to be rebutted by relying on Section 11(2)[10] of the Patents Act.

9.4.3 Additionally, the defendant has sought to contend that, "after having enjoyed the genus patent IN 176 for the entire duration, the

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[9] **(2013) 6 SCC 1**

[10] "**11. Priority date of claims of the complete specification. –**
(2) Where a complete specification is filed in pursuance of a single application accompanied by –
(a) a provisional specification; or
(b) a specification which is treated by virtue of a direction under sub- section (3) of section 9 as a provisional specification,
and the claim is fairly based on the matter disclosed in the specification referred to in clause (a) or clause (b), the priority date of that claim shall be the date of the filing of the relevant specification."

(plaintiffs could not now contend) that IN 176 lacked the disclosure to support its claims"[11] .

9.5 Section 3(d)

9.5.1 The subject matter of IN 161 was not patentable, submits Mr Sai Deepak, in view of Section 3(d)[12] of the Patents Act. Eltrombopag being a "known substance" by virtue of IN 176, Mr. Sai Deepak contends that, in order for any new form of Eltrombopag to be eligible for a patent, the complete specifications had to disclose the existence of additional efficacy. The only assertions of the plaintiff, regarding the advantages of EO over Eltrombopag *per se*, were that EO had better solubility and bioavailability and, therefore, better pharmacodynamic factors. Therapeutic effect, even to EO, was owing to Eltrombopag. ***Novartis***[9], he submits, had clearly held that enhanced bioavailability was insufficient to indicate enhanced therapeutic efficacy, for the purposes of the Explanation to Section 3(d). IN 161 was, therefore, invalid on this ground as well.

9.5.2 In this context, the defendant also points out that, in its response to the objections raised by the IPO against the application for grant of patent in respect of IN 161, the affidavit of Mr. Stephen Moore , the

[11] Quoted, verbatim, from the written submissions of the defendant

[12] "**3. What are not inventions. –** The following are not inventions within the meaning of this Act, –

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(d) the mere discovery of a new form of known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or a new use for known substance or of the mere use of known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

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

inventor of the suit patent stated that EO showed "superior solubility which was expected to lead to superior pharmacodynamics of the compound". As such, the claim of enhanced efficacy was, at best, speculative even at that stage. Further, points out the defendant, there was no assertion of enhanced therapeutic efficacy, as a result of the speculative enhanced bioavailability of EO. Precisely this contention, it is submitted by the defendant, was raised by Novartis before the Supreme Court in respect of the β-crystalline form of Imatinib Mesylate, and was rejected.

9.6 Obviousness/lack of inventiveness step – Section 64(1)(f) – The defendant has sought to contend that the documents filed with the written submissions clearly taught the formation of ethanolamine and monoethanolamine as salts of pharmaceutical substances. Specific reliance has been placed, in this context, on US Patents US 4898976 ('US 976'), US 6211185 ('US 185'), US 4582831 ('US 831') and US 4678666 ('US 666') as teaching the possibility of ethanolamine/monoethanolamine salts, albeit with other free acid radicals. IN 161 did not disclose how, in the circumstances, the creation of the "bismonoethanolamine" salt of eltrombopag involve any inventive step, or why it was not obvious from Eltrombopag *per se*. Nor did it indicate any technical challenges in the use of eltrombopag, or how they were overcome.

9.7 Failure to disclose details to the PO – Section 64(1)(m) read with Section 8(2)[13] of the Patents Act and Rule 12(3)[14] of the Patents

[13] "**8. Information an undertaking regarding foreign applications. –**

Rules – Relying on the judgement of a Division Bench of this Court in ***Chemtura Corpn v. U.O.I.***[15], the defendant seeks to contend that IN 161 is rendered vulnerable to revocation. The defendant refers, in this context, to the First Examination Report dated 24th September, 2007, in response to the application for registration of the suit patent. The IPO required the plaintiff to submit copies of such examination reports in at least the USA, EP and Japan. The defendant takes exception to the plaintiff, in its response filed on 28th July, 2008, filing the Examination Reports from USA, Europe, China and Columbia and suppressing, in the process, the office action issued in respect of the Canadian patent CA 697, and the response of Novartis to the Canadian IPO in which the formation of some salts during the reaction process was admitted. The same infirmity, the defendant contends, attaches to the response of the plaintiff to the Second Examination Report dated 1st September, 2008 and the Third Examination Report dated 22 September 2008. As a result, contends the defendant, the Controller of Patents in the IPO was denied awareness of the response of Novartis in the patent proceedings in Canada.

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(2) At any time after an application for patent is filed in India and till the grant of a patent or refusal to grant of a patent made thereon, the Controller may also require the applicant to furnish details, as may be prescribed, relating to the processing of the application in a country outside India, and in that event the applicant shall furnish to the Controller information available to him within such period as may be prescribed."

[14] "**12. Statement and undertaking regarding foreign applications. –**

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(3) When so required by the Controller under sub- section (2) of section 8, the applicant shall furnish information relating to objections, if any, in respect of novelty and patentability of the invention and any other particulars as the Controller may require which may include claims of application allowed within six months from the date of such communications by the Controller."

[15] **(2009) 41 PTC 260 (Del)**

9.8 Clearing the way – A contention, advanced by the plaintiffs, that the defendant had not "cleared the way", before proceeding to illegally exploit the suit patent IN 161, was sought to be met by submitting that, having waited for the expiry of IN 176 before launching its EO product, no further clearing of the way was required on the part of the defendant. This, the written submission asserts, was "sufficient clearing of the way". In this context, the defendant has also sought to distinguish the judgement of the Division Bench of this Court in ***Merck Sharp & Dohme Corpn v. Glenmark Pharmaceuticals***[16] (***"Merck v. Glenmark"***, hereinafter). Among other things, the fact that, in ***Merck v. Glenmark***[16], the specie patent was not asserted, and the assertions were restricted to the genus patent, has been emphasised as a point of distinction. If the genus and the specie patent were to be simultaneously asserted, contends the defendant, the specie patent would become vulnerable to revocation under Section 13(1)(b) read with Section 64 of the Patents Act. That apart, it is also contended that ***Merck v. Glenmark***[16] is *per incuriam*, as it is contrary to the earlier decision of the Division Bench of this Court in ***F. Hoffman la Roche v. Cipla Ltd***[17] ("***Roche v. Cipla-I***", hereinafter).

9.9 It has also been sought to be contended that, as the price of the plaintiff's product was much higher than that of the defendant, public interest also justifies the refusal of the plaintiff's prayer for interlocutory injunction.

[16] **2015 (63) PTC 257 (Del-DB)**
[17] **(2009) 40 PTC 125 (Del-DB)**

9.10 Reliance was also placed on the judgement of a Division Bench of this Court in ***Natco Pharma v. Bristol Myers Squibb Holding***[18], which cautions against grant of *ad interim* injunctions in cases of alleged infringement of pharmaceutical patents. This principle especially applies, contends the defendant, in the case of life-saving drugs, as held by the Division Bench of this Court in ***Roche v. Cipla-I***[17].

9.11 Reliance has also been placed on the judgement of the Supreme Court in ***Bishawanath Prasad Radhey Shyam v. Hindustan Metal Industries***[19], to contend that grant of patent was no indicator of his *prima facie* validity, and that, even at the interlocutory stage, the validity was open to test.

9.12 The simultaneous assertion, by the plaintiffs, of the genus patent IN 176 and the specie patent IN 161, submits Mr. Sai Deepak, relying on ***AstraZeneca AB v. Intas Pharmaceuticals***[20] ("***Astrazeneca v Intas***", hereinafter), itself rendered the specie patent IN 161 vulnerable to invalidity.

9.13 Mr. Sai Deepak repeatedly emphasised the fact that, at the interlocutory stage, the defendant was only required to make out a case of a credible challenge regarding the vulnerability of the suit patent to revocation. This standard, he submits, has amply been met by the grounds raised by him.

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[18] **(2020) 266 DLT 724**
[19] **(1979) 2 SCC 511**
[20] **(2021) SCC OnLine Del 1130**

9.14 It has also been sought to be contended that, in ***AstraZeneca AB v. P. Kumar***[21], ***AstraZeneca v. Intas***[20] and ***AstraZeneca AB v. Zydus Cadila***[22], in identical fact circumstances, interlocutory injunction was refused. Mr Sai Deepak, however, questions the correctness of the view expressed in ***AstraZeneca v Zydus***[22] in respect of Section 13(1)(b) and 53(4) of the Patents Act, on the ground that it was contrary to the view expressed in the earlier decision in ***AstraZeneca v. Intas***[20], which was not noticed. Nonetheless, he submits that, on the aspect of invalidity on the ground of obviousness, and consequent vulnerability to revocation, the decisions were *ad idem*.

10. Submissions of plaintiff:

10.1 Responding to the submissions of Mr. Sai Deepak, Mr. Hemant Singh, learned Counsel for the plaintiffs submits that EO was a novel and inventive compound. EO, he submits, was a salt which did not form part of any approved drug prior to the suit patent IN 161. It was a technical advancement over Eltrombopag *per* se, which was claimed and disclosed in prior art. EO, was, therefore, a new and inventive product.

10.2 Comparing IN 176 with the suit patent IN 161, Mr. Hemant Singh submits that the subject matter of IN 176 was Eltrombopag *per se*. Claim 1 in IN 176, he submits, was a Markush claim and Claim 6

[21] **(2019) 262 DLT 118**
[22] **(2020) 275 DLT 361**

claimed Eltrombopag and its pharmaceutically acceptable salts thereof. No particular salt was, however, disclosed in IN 176, and no drug, including Eltrombopag, was taught by IN 176. EO, the subject matter of Claim 1 of the suit patent IN 161, was the outcome of protracted research and development undertaken on Eltrombopag. EO was a breakthrough drug used for treatment of chronic idiopathic thrombocytopenia, and had been marketed, in India, since 2011 under the brand name "REVOLADE". EO itself had been granted patent protection in over 60 jurisdictions. The therapeutic efficacy of EO stood recognised in over 90 countries, in which patent protection had been granted to it. EO was, therefore, a novel, inventive and technical advancement over IN 176. The subject matter of the invention claimed in Claim 1 of the suit patent IN 161 was, therefore, distinct and different from the entity claimed in Claim 6 of IN 176. Mr. Hemant Singh submits that there could be no question of any claim, or disclosure, of EO in IN 176, as EO was not known a pharmaceutically acceptable salt of Eltrombopag prior to the priority date of IN 161.

10.3 Apropos the challenge to the validity of the suit patent IN 161 on the anvil of Section 13(1)(b) read with Section 64(1)(a) of the Patents Act, Mr. Hemant Singh submits that the scope of any claim had to be seen in the light of the description of the claim and the disclosure in the complete specifications relating to the claim. Coverage of a subsequent invention in the scope of an earlier invention, he submits, does not amount to anticipation by prior claiming. In this context, Mr. Hemant Singh seeks to draw a distinction between claim and coverage. Specifically with respect to

EO, Mr. Hemant Singh submits that, as EO is a pharmaceutically acceptable salt of Eltrombopag, it would fall, generally speaking, within the coverage of claim 6 of IN 176. Illustrating this position with respect to EO, Mr. Hemant Singh submits that EO is only one of several pharmaceutically acceptable salts of Eltrombopag, which was unknown at the time of grant of IN 176. As all pharmaceutically acceptable salts of Eltrombopag are covered by Claim 6 of IN 176, EO was also covered by the said description. The coverage of a subsequent novel and inventive product in the broad description of an earlier patent would not, according to Mr. Hemant Singh, result in anticipation by prior claiming, so as to invalidate the latter patent. He points out that EO was never claimed in IN 176.

10.4 This position, asserts Mr. Hemant Singh, also flows from a juxtaposed reading of Section 3(d) and 19 of the Patents Act. He submits that if these two sections are read in conjunction, a subsequent patent, for a new form of the known substance covered by an earlier patent is nonetheless eligible, provided it has added efficacy. Potentially infringing patents can also, therefore, according to Mr. Hemant Singh be granted, as infringement would depend on coverage whereas the entitlement to a patent would depend on prior claiming or prior publication. An application for patent in respect of an entity which has not been earlier claimed is eligible, even if it falls within the coverage of a patent which has earlier been claimed and granted. For this reason, though EO falls within the coverage of IN 176, being a pharmaceutically acceptable salt of Eltrombopag, which has been specifically patented in the said patent, the application for

patent filed in respect of EO was, nonetheless maintainable. Coverage, he submits, is based on claim construction on the basis of disclosure in the complete specifications. Coverage, *per se,* does not amount either to prior claiming or prior disclosure. The claim is required to be construed on the basis of the wording of the claim seen in the light of the enabling disclosure provided in the complete specifications.

10.5 Mr Hemant Singh relied, for these submissions, on the judgements of Division Benches of this Court in ***F. Hoffmann-La Roche Ltd. v. Cipla Ltd.***[23] (***Roche v. Cipla-II***, hereinafter) and ***Merck v. Glenmark***[16]. He points out that, in ***Merck v. Glenmark***[16], though the suit patent IN 816 claimed Sitagliptin and its pharmaceutically acceptable salts, Sitagliptin phosphate monohydrate, though a salt of Sitagliptin, was not claimed in IN 816, as it was not disclosed in the said patent. What is claimed, therefore, he submits depends on what is disclosed. Resultantly, the complete specifications, read with the enabling disclosure and claim construction, in totality, made up the claim.

10.6 Apropos Section 13(1)(b) of the Patents Act, and the submission of Mr Sai Deepak that the suit patent was vulnerable to invalidity on the ground of prior claiming, Mr Hemant Singh submits that there has, in fact, been *no prior claiming* of EO, prior to IN 161. He emphasises, in this context, the words "prior claiming", as contained in Section 13(1)(b). What is required for Section 13(1)(b) to apply, submits Mr. Hemant Singh, is that the suit patent is claimed in

[23] **225 (2015) DLT 391: (2016) 65 PTC 1**

prior art . The invention as claimed in the suit patent must, therefore, be identical to the invention claimed in prior art. Only then, he submits, can it be said that the invention claimed in the suit patent was claimed and anticipated in the genus patent/prior art. The onus, to establish such prior claiming, is on the defendant. The defendant is required to show, positively, that the invention claimed in the suit patent was earlier claimed in its entirety by individualised description, exemplification or illustration, in prior art. Tested on this high touchstone, Mr. Hemant Singh submits that it could not be said that EO was claimed or disclosed in IN 176. He cites, in this context, ***Fabewerke Hoechst Aktiengtesellscaft Vormals Meister Lucius Bruning a Corporation v. Unichem Laboratories***[24].

10.7 Relying, for the purpose, on ***Dr Reddy's Laboratories v. Eli Lilly & Co.***[25], Mr. Hemant Singh submits that an earlier generic disclosure would not invalidate a later specific patent or detract from the novelty of the latter, unless the subject matter of the latter patent was individually disclosed in the former patent. The prior art, he submits, must contain clear and unmistakable directions to do what the plaintiff claims to have invented, for which proposition he relies on ***The General Tire & Rubber Co v. Firestone Tire & Rubber Co.***[26]

10.8 Acceptance of the submissions canvassed by Mr. Sai Deepak, he submits, would render incremental inventions, resulting in technical advancements over the known prior art, non-patentable, as all derivatives would be covered by the prior art. Section 3(d) would,

[24] **AIR 1969 Bom 255**
[25] **(2019) 262 DLT 118**
[26] **(1972) RPC 457**

thereby, be rendered otiose. For this, Mr. Hemant Singh cites ***Eisai Co. Ltd v. Satish Reddy***[27]**.** The reliance, of Mr. Sai Deepak, on Section 54 is also, therefore, according to him, misplaced, as Section 54 deals with existing inventions/modifications and is not applicable to new inventions.

10.9 Mr. Hemant Singh, thereafter, addressed the issue of obviousness, *vis-à-vis* US 976. He submits that US 976 did not even pertain to pharmaceutical products, but related to an ethanolamine salt of N-nitrosophenylhydroxylamine (NPHA), which was used in the acrylic industry to provide a solution to prevent polymerisation over the ammonium salt of NPHA. As such, he submits, US 976 is not even relevant prior art, for the purpose of obviousness. The chemical structure of NPHA, too, he submits, is not compatible with EO. Further, the stoichiometric ratio of the 2 entities are different, with US 976 having a stoichiometric ratio of 1:1, whereas the suit patent has a stoichiometric ratio of 1:2. For the same reason, none of the other US patents, on the basis of which Mr. Sai Deepak based his challenge to the suit patent as obvious, he submits, can be regarded as relevant. US 185 dealt with concentrates for veterinary use, and could never, therefore, be obvious to a person skilled in the art as a source from which to derive EO. US 831 advised against the use of olamine salts. US 666 referred to monoethanolamine as an excipient in its laundry list. It did not teach any method for increasing bioavailability of the compounds such as Eltrombopag. It dealt with the olamine salt of piroxicam. Relying on the judgement of the Division Bench of this Court in ***Roche v. Cipla-II***[23], Mr. Hemant Singh submits that the

[27] **2019 (79) PTC 568 (Del)**

defendant had not discharged the burden, on it, to establish vulnerability of the suit patent IN 161 to invalidity on the ground of obviousness. All these patents, he submits, were invoked only on hindsight analysis. He reiterates that, prior to IN 161, there was no pharmaceutically acceptable salt of Eltrombopag, with the olamine radical, known to the industry.

10.10 Mr. Hemant Singh next addressed Section 3(d) of the Patents Act. This provision, he submits, was *ex facie* inapplicable, as no drug came out of IN 176 and no drug, containing Eltrombopag, was ever approved prior to IN 161. The subject matter of IN 161, i.e. Eltrombopag Olamine, he submits, was not a "known substance" within the meaning of Section 3(d), but was a "new compound" altogether.

10.11 Even if, *arguendo*, it were to be assumed that EO was a new form of a known substance, within the meaning of Section 3(d), Mr. Hemant Singh submits that it would, nonetheless, be patentable, as it had enhanced therapeutic efficacy over the claims in IN 176. IN 176, he submits, claimed the free acid Eltrombopag, which had no known efficacy. He relies on the decision of a coordinate bench of this Court in ***Bristol-Myers Squibb Holding Ireland Unlimited Co. v. B.D.R. Pharmaceuticals International Pvt Ltd***[28] to contend that the very fact that the marketable drug had first emerged from the suit patent IN 161 was itself an indicator of its enhanced efficacy over the claims in IN 176. Without prejudice to this submission, Mr. Hemant Singh further refers to the responses dated 29th July, 2008 and 22nd September 2008,

[28] **2020 (81) PTC 551 (Del)**

as well as the written submissions dated 1st October, 2008, filed by Novartis before the Controller of Patents, which were accompanied by the affidavit of the inventor Stephen Moore. The enhanced efficacy of EO, *vis-à-vis* the Eltrombopag free acid, he points out, was identified in the following tabular statement, provided in the said responses:

Table-1

Salts with organic Bases of the compound of claim 1

Base	Yield (1%)	Solubility in water (mg/ml)	Acid: Base ratio (by ^{1}H nmr)
bis-monoEthanolamine	90	19	1:2
N-Methyl glucamine	93	4.2	1:2
Ethanolamine	99	4.1	1:1
N- Methyl glucamine	83	3.7	1:1
t-Butylamine	89	2.9	1:1
Ethylenediamine	35	0.7	1:1
bis-Ethylenediamine	76	0.66	1:2
Tris-(hydroxymethyl)-aminomethane	84	0.7	1:1
Choline	44	0.3	1:1
Morpholine	86	0.3	1:1
Piperazine	87	0.2	1:1
Dibenzylethylene diamine	79	0.03	2:1
Diethylamine	78	0.01	1:1

Mr. Hemant Singh further emphasises the increased bioavailability of Eltrombopag, when ingested as EO, *vis-à-vis* the bioavailability in the free acid form, in respect of which the following statement was made by Novartis in its responses before the Controller of Patents:

> "Data: The bioavailability comparison of eltrombopag free acid and eltrombopag bio-monoethanolamine was conducted

in dogs-dosed as granules in capsules C_{max} and AUC were approximately 3 fold higher for GR salt compared to fee acid. The mean (±SD) pharmacokinetic parameter estimates for SB-497115 in male Beagle dogs following oral administration (5 mg/kg) are summarised in the following table:

Formulation	**C_{max} (µg/mL)**	**T_{max} (h)**	**AUC(0.inf) (µg.h/mL)**
Milled Free Acid (Wet granulation as capsule)	2.98±0.42	2.38±1.38	45.3±29.3
Milled Ethanolamine Salt (Wet Granulation) as capsule	8.19±2.61	1.38±0.26	102.7±28.0

Based on the said data, it is submitted that the bioavailability of free acid was about 21% and for GR salt about 48%."

As EO had higher yield of Eltrombopag, as well as enhanced solubility and bioavailability as compared to the free acid form, Mr. Hemant Singh submits that the therapeutic efficacy of EO was greater than Eltrombopag in the free acid form. He also submits that the maximum plasma concentration of EO was thrice the plasma concentration of Eltrombopag in free acid form, in half the time, resulting in higher AUC ("Area Under the Curve", on the basis of which bioavailability was assessed). This indicated that the bioavailability of EO was thrice the bioavailability of Eltrombopag in free acid form. This enhanced solubility and bioavailability, he submits, had led to drug development and, consequently, enhanced therapeutic efficacy of the compound claimed in the suit patent IN 161. That enhanced bioavailability could be an indicator of enhanced therapeutic efficacy, he submits, is also recognised by the Supreme Court in para 189 of the report in ***Novartis***[9]. Despite recognising this

fact, the reluctance of the Supreme Court to hold, in ***Novartis***[9], that the subject matter of the patent in controversy before it (i.e. the β-crystalline form of Imatinib Mesylate) had increased therapeutic efficacy was because no material, in that regard, had been produced before the Supreme Court. Besides, he submits, the Supreme Court was examining a situation in which Imatinib Mesylate, in salt form, was already known and marketed, and increased therapeutic efficacy was being claimed in respect of the β-crystalline form thereof. Unlike the situation that obtained there, Mr. Hemant Singh submits that, in the present case, EO was an unknown substance prior to IN 161. He also relies on the observation, in paras 191 and 192 of the report in ***Novartis***[9], that Section 3(d) did not bar "incremental inventions of chemical and pharmaceutical substances" and that a new product was not necessarily required to be non-existent, before the suit patent. The Supreme Court, he submits, had observed that the new product could "mean something different or better than the recent previous or same kind subject to test of enhanced efficacy."

10.12 As such, submits Mr. Hemant Singh, the suit patent IN 161 could not be regarded as vulnerable to invalidity on the ground of Section 3(d) of the Patents Act.

10.13 Addressing the submission of Mr. Sai Deepak that the suit patent IN 161 was vulnerable to invalidity as Novartis had infracted Section 8 of the Patents Act by suppressing, from the Patent Office, the details regarding the prosecution proceedings in respect of CA 2486697 ("CA 697", in short), Mr. Hemant Singh submits that the

Canadian proceedings did not relate to the Eltrombopag free acid or to any pharmaceutically acceptable salts of the Eltrombopag free acid, or to EO. Examples 64 and 85 of the Canadian patent, he submits, claimed basic compounds and not the free acid which forms subject matter of the claim in IN 176. To support the submission that there was no violation of Section 8 by his client, Mr. Hemant Singh relies on ***Roche v. Cipla-II***[23] and ***Merck v. Glenmark***[16].

10.14 Apropos the grant of Patent Term Extension ('PTE', hereinafter) and Supplementary Protection Certificate ('SPC', hereinafter) to the US and European equivalents of IN 176, Mr. Hemant Singh submits that the criterion for eligibility for grant of PTE or SPC was coverage, not claiming. Under US law, Mr. Hemant Singh submits that the patentee was entitled to file more than one application for grant of PTE, for more than one patent, but that, ultimately, PTE would be granted only to one patent. EO, he asserts, was claimed and disclosed for the first time in US 719, which was equivalent to IN 161, though it was covered under both US 870 and US 719. For the same reason, Mr. Hemant Singh submits that the Orange Book included patents which covered and encompassed the invention, as well as those patents which claimed the invention. The reliance, placed by Mr. Sai Deepak on the entries in the Orange Book is also, therefore, according to him, misplaced.

10.15 The grounds of challenge, raised by Mr. Sai Deepak to the validity of the suit patent IN 161 are, thus, without substance, submits Mr Hemant Singh. Infringement of the suit patent having been admitted by the defendant, Novartis is entitled to injunction. The

defendant cannot be entitled to manufacture and market EO, during the subsistence of the suit patent IN 161.

10.16 No steps have been taken by the defendant, points out Mr. Hemant Singh, to clear the way before proceeding to infringe the suit patent IN 161 of Novartis. The submission of Mr. Sai Deepak, in this regard, that the defendant had cleared the way by waiting for the expiry of the patent term of IN 176 before taking steps towards the manufacture and marketing of EO, he submits, is completely misconceived, as the suit asserts IN 161, and not IN 176.

Analysis

11. Some prefatory observations:

11.1 Deconstruction, perceptive comprehension, and arriving at a *prima facie* view in the matter has, in view of the incisive and undoubtedly learned submissions of Counsel, been a fascinating exercise. My impression that, with my earlier decision in ***FMC Corporation v. Best Crop Science***[29], I had demystified, to some extent, the principles relating to pharmaceutical patents, stands, in the process, completely debunked. It was as though I was treading, once again, fertile, unploughed, ground, though the fields stand harvested, thoroughly, by my elders and superiors. That, however, I suppose, is what lends law its magic.

[29] **2021 (87) PTC 217 (Del)**

11.2 Apart from the judgement of the Supreme Court in ***Novartis***[9], there are authoritative pronouncements, by Division Benches of this Court, which set, at rest, many of the issues in controversy in the present case. These are, chronologically, ***Merck v. Glenmark***[16], ***Roche v. Cipla-II***[23] and ***Astrazaneneca v Intas***[20]. I may note, here, that there are also interlocutory orders, passed by various single benches of this Court, in similar fact circumstances, and learned Counsel for both sides have placed reliance on these decisions. To my mind, where the law stands enunciated by the Division Benches, no occasion arises for the Court to refer to any interlocutory order by a Single Bench. It is trite that interlocutory orders, which are merely *prima facie* opinions, and are always subject to revision at any later stage of the proceedings, have no precedential value whatsoever.[30] They do, however, have a limited role to play, as harbingers of consistency, as Courts are expected to maintain consistency in interim orders, where the facts are similar, and warrant a similar approach.[31] Beyond this, however, interlocutory orders cannot aspire.

11.3 Interestingly, in ***Merck v. Glenmark***[16], the Division Bench of this Court clearly deferred from the view expressed by an earlier Division Bench in ***Roche v. Cipla-I***[17], observing that the latter decision was merely a judgement rendered on an appeal against an interim order of a Single Judge. If a final judgement on an appeal preferred against an interim order of a Single Judge is not binding, and another Division Bench can differ from the said decision without

[30] Refer **State of Assam v Barak Upatyaka D.U. Karamchari Sanstha, (2009) 5 SCC 694**
[31] Refer **Vishnu Traders v. State of Haryana, 1995 Supp (1) SCC 461**

referring it to a Larger Bench, still less would be the precedential value of an interlocutory order of a learned Single Judge.

11.4 Another aspect, that I deem it appropriate to address, here, is the tendency to rely on judgements of foreign courts, in intellectual property and, especially, in patent matters. Patent law is, unquestionably, still in an adolescent, even if not infantile, stage, and much of the territory remains, even as on date, unexplored. It remains, nonetheless, an area of law governed by statute, and, therefore, in my view, one has, in the first instance, to be guided by decisions of Indian courts, rendered in the light of the Patents Act applicable to this country, before seeking sustenance from decisions rendered abroad. Of course, this would apply only where the field is occupied by decisions of Indian courts, and not where the court finds itself in virgin territory. Where there are binding precedents of Indian courts, therefore, I confess my reluctance to resort, extensively, to foreign decisions, especially when they are cited with no attempt at comparing and contrasting the statutory interdicts, applicable in the country to which the decision pertains, with those that apply here. A Constitution Bench of the Supreme Court cautioned, over half a century ago in ***State of West Bengal v. B.K. Mondal***[32], thus, albeit in the context of Section 70 of the Indian Contract Act, 1872:

> "The question which the appellant has raised for our decision falls to be considered in the light of the provisions of Section 70 and has to be answered on a fair and reasonable construction of the relevant terms of the said section. *In such a case, where we are dealing with the problem of construing a specific statutory provision it would be unreasonable to invoke the assistance of English decisions dealing with the*

[32] **AIR 1962 SC 779**

> *statutory provisions contained in English law.* As Lord Sinha has observed in delivering the judgment of the Privy Council in ***Ramanandi Kuer v. Kalawati Kuer [55 IA 118 : (1928) ILR 7 Pat 221]*** "it has often been pointed out by this Board that where there is a positive enactment of the Indian Legislature the proper course is to examine the language of that statute and to ascertain its proper meaning uninfluenced by any consideration derived from the previous state of the law or of the English law upon which it may be founded". *If the words used in the Indian statute are obscure or ambiguous perhaps it may be permissible in interpreting them to examine the background of the law or to derive assistance from English decisions bearing on the point; but where the words are clear and unambiguous it would be unreasonable to interpret them in the light of the alleged background of the statute and to attempt to see that their interpretation conforms to the said background. That is why, in dealing with the point raised before us we must primarily look to the law as embodied in Section 70 and see to put upon if a fair and reasonable construction.*"
>
> (Emphasis supplied)

Unfortunately, when citing authorities, rendered abroad in intellectual property matters, no attempt is made to compare, far less parallelize, the statutory provisions applicable in India with those applying in the jurisdiction where the decision has been rendered. Observations in foreign decisions are cited as authoritative propositions, without drawing the attention of the Court to the applicable statutory position in that jurisdiction. This, in my view, should be avoided. At least at the *prima facie* stage, the Court, if it is to rely on a decision rendered abroad, has to be satisfied that, even in the arena of the Patents Act in India, the decision would apply, and has also to assess the extent of such applicability. This is an involved exercise and, therefore, at the stage of interlocutory injunction, the extent to which the Court can rely on foreign authorities has, in my view, necessarily to be limited.

11.5 Having said that, it is always a healthy practice to support the view taken on the basis of the Indian Patents Act, and the law as it has developed in this country, from decisions rendered in foreign climes, where the decisions provide such support. To that extent, the international and trans-border ramifications of patents, and of patent law, have, undoubtedly, to be borne in mind, but no more.

11.6 For analogous reasons, I find it a trifle unjustified for the Court, at a *prima facie* Order XXXIX stage, to rely on declarations provided to patent authorities in foreign jurisdictions. Reliance on such declarations, or responses provided in reply to queries by patent offices located abroad, would require the Court to be sensitized as to the procedural laws that apply in the concerned jurisdiction, the requirements as to declaration and disclosure that apply there (which vary, often, from jurisdiction to jurisdiction) and the circumstances in which the declaration, or response, was tendered. Arriving, even at a *prima facie* view, on these issues would, in my opinion, be hazardous. They involve detailed examination, which ought, appropriately, to be consigned to the stage of trial. The Court should, therefore, in my considered opinion, be circumspect in basing its decision to grant, or refuse, interlocutory relief, in patent matters, on such representations made before foreign patent authorities.

11.7 The understanding of the law has, therefore, to be guided by the judgement of the Supreme Court as well as authoritative pronouncements of Division Benches of this Court.

12. With these prefatory observations, I proceed to a *prima facie* analysis of the issues in controversy.

Novartis

13. Facts:

13.1 ***Novartis***[9] did not deal with infringement. Imatinib was one of the derivatives of N-phenyl-2-pyrimidine-amine, which was invented by Jürg Zimmermann, and which could inhibit certain protein kinases, for treatment of tumours. US patent 5521184 (US 184) was granted to Zimmerman, by the US Patent Office, for these derivatives. ***Novartis***[9] refers to this patent as the "Zimmerman patent". Novartis applied to the Chennai Patent Office for grant of patent for the β-crystalline form of Imatinib Mesylate, which was a salt of Imatinib. Novartis claimed to have invented Imatinib Mesylate from the free base Imatinib and to have synthesised the β-crystalline form therefrom. Novartis claimed 18th July, 1997 as the priority date of its patent, being the date on which it had applied for grant of patent for the β-crystalline form of Imatinib Mesylate in Switzerland.

13.2 It is important to note that the patent application of Novartis did not claim any pharmacological superiority of the β-crystalline form of Imatinib Mesylate, over the Imatinib free base. Rather, it was admitted, in the patent application, that "all the indicated inhibitory and pharmacological effects" of the β-crystalline form of Imatinib Mesylate were "also found with the free base". Thereafter, Novartis filed, before the Patent Office, affidavits of experts in which it was

claimed that the β-crystalline form of Imatinib Mesylate had "much higher bioavailability", as compared to the free base Imatinib. This, in my view, is a very important factor, for reasons which will become apparent presently.

13.3 The application of Novartis, for grant of patent for the β-crystalline form of Imatinib Mesylate, was rejected by the Patent Office *vide* order dated 25th January, 2006, on four grounds. These were that (i) the β-crystalline form of Imatinib Mesylate was anticipated by prior publication by the Zimmerman Patent, (ii) the β-crystalline form of Imatinib Mesylate was obvious to a person skilled in the art, in view of the disclosure contained in the complete specifications in the Zimmerman Patent, (iii) Section 3(d) of the Patents Act rendered the β-crystalline form of Imatinib Mesylate non-patentable and (iv) Novartis had wrongly claimed the priority date of filing of the patent application in Switzerland as the priority date for the β-crystalline form of Imatinib Mesylate. The appeals, preferred by Novartis against the decision of the Patent Office were dismissed by the Intellectual Property Appellate Board (IPAB) by judgement dated 26th June, 2009, solely invoking, for the purpose, Section 3 (d). It was held, in Novartis' favour, by the IPAB, that Novartis was entitled to claim 18th July, 1997 as the priority date for its application and that the β-crystalline form of Imatinib Mesylate satisfied the test of novelty and non-obviousness; however, falling foul of Section 3(b) and Section 3(d) of the Act, no product patent of β-crystalline form of Imatinib Mesylate could be allowed. This order of the IPAB was assailed, by Novartis, directly before the Supreme Court.

14. The judgement:

14.1 Patentability:

14.1.1 Para 74 and 75 of the report in ***Novartis***[9] delineated the criteria required to be satisfied for a product to qualify as an "invention", and the result of an "inventive step", within the meaning of clauses (j) and (ja) of Section 2(1) of the Patents Act, thus:

> "Section 2(1)(j) requires a product to satisfy three conditions to qualify as an invention:
>
> (i) It must be "new", that is to say it must not have been anticipated;
>
> (ii) Its coming into being must involve an "inventive step"; and
>
> (iii) It must be "capable of industrial application", that is to say it must be capable of being made or used in an industry [Section 2(1)(ac)]."
>
> 75. "Inventive step" is separately defined in Section 2(ja) to mean a feature of an invention that involves technical advance as compared to the existing knowledge, or having economic significance or both and that makes the invention not obvious to a person skilled in the art. To paraphrase, the invention that creates the product must have a feature that involves technical ["Adjective: 1. of or relating to a particular subject, art, or craft or its techniques. 2. of, involving, or concerned with applied or industrial sciences", The New Oxford Dictionary of English, Edn. 1998.] advance as compared to the existing knowledge or having economic significance or both and this feature should be such as to make the invention not obvious to a person skilled in the art.

Para 76 of the report went on to further observe as under:

"On a combined reading of clauses (j), (ac) and (ja) of Section 2(1), in order to qualify as "invention", a product must, therefore, satisfy the following tests:

(i) It must be "new";

(ii) It must be "capable of being made or used in an industry";

(iii) It must come into being as a result of an invention which has a feature that:

(a) entails technical advance over existing knowledge;

or

(b) has an economic significance;

and

(c) makes the invention not obvious to a person skilled in the art."

The Supreme Court held that a product, in order to be entitled to grant of a patent, was required, in addition to being an "invention" within the meaning of Section 2(1)(j), not to fall foul of the exceptions from patentability engrafted in Section 3. Sub-section (d) of Section 3, it was observed, delineated the circumstances in which, despite being an "invention", the product was not entitled to a patent. The 2005 amendment of Section 3(d), it was held, was aimed at dealing with pharmaceutical products.

14.1.2 On the aspect of patentability of the β-crystalline form of Imatinib Mesylate, the submissions of Novartis, before the Supreme Court, stand identified, in the judgement, thus:

(i) Example 21 of the Zimmerman Patent specifically claimed Imatinib.

(ii) The formulation of the following two inventions were involved in the production of the β-crystalline form of Imatinib Mesylate, from the free base Imatinib:

(a) The first invention, in the process of conversion of Imatinib to the β-crystalline form of Imatinib Mesylate, was Imatinib Mesylate itself. For this, Example 21 had to be selected out of the 37 examples specified in the Zimmerman Patent and methanesulphonic acid had to be chosen, to produce Imatinib Mesylate. These steps were neither "taught" nor suggested, by Example 21 of the Zimmerman Patent, to a person skilled in the art. In producing Imatinib Mesylate from Imatinib, therefore, technical advance was involved, as compared to the existing knowledge, and a new substance had come into being.

(b) The second invention was the invention which Novartis desired to patent, namely the β-crystalline form of Imatinib Mesylate. The necessity of this invention, contended Novartis, was to ensure that Imatinib Mesylate was suitable for administration in solid oral dosage form. The processual parameters, resulting in the creation of

the β-crystalline form of Imatinib Mesylate, were also required to be defined. Novartis pointed out that the Zimmerman Patent made no reference to polymorphism or to any crystalline structure. The crystalline form of Imatinib Mesylate was, therefore, it was contended, a distinct, and further, invention, beyond Imatinib Mesylate itself. While thus synthesising the β-crystalline form of Imatinib Mesylate, suitability of administration to human beings was also required to be ensured. Comparing the characteristics of the β-crystalline form of Imatinib Mesylate with the free base Imatinib, Novartis submitted that the Zimmerman Patent described (i) how to prepare the free base Imatinib and (ii) the anti-tumour properties of the free base Imatinib. Both the steps involved in proceeding from the free base Imatinib to the β-crystalline form of Imatinib Mesylate, therefore, it was submitted, resulted in distinct inventions.

14.1.3 Dealing with these submissions, the Supreme Court noted that the complete specifications in the Zimmerman Patent, which was granted on 28th May, 1996, included the respective salts of the derivatives of N-phenyl-2-pyrimidine-amine, with the specific recital that "any reference to the free compounds should be understood as including the corresponding salts, where appropriate and expedient". The compounds of Formula I in the Zimmerman Patent (which was the general description ascribed to the derivatives claimed in the patent), it was claimed, exhibited anti-tumour activity

by "(inhibiting) the tyrosine kinase activity of the receptor for the epidermal growth factor", thereby preventing metastasising of tumours and promoting regression thereof. Example 21 specifically claimed Imatinib. Towards the end of the application, Claim 1 of Formula I was identified as "N-{5-[4-[(4-methyl-piperazino-methyl)-benzoylamido] 2-methyl-phenyl}-4 (3-pyridyl)-2-pyrmimdine-amine or a pharmaceutically acceptable salt thereof". The Supreme Court went on to note that the application, of Novartis, for a patent extension for the Zimmerman Patent, "*leaves no room for doubt that Imatinib Mesylate, marketed under the name Gleevec, was submitted for grant approval as covered by the Zimmerman Patent*". Application for a Patent Term Extension, therefore, according to the Supreme Court, implied coverage.

14.1.4 The Board of Patent Appeals had, in ***Novartis***[9], reversed the decision of the patent examiner, rejecting Novartis' application for grant of patent for the β-crystalline form of Imatinib Mesylate. The Board of Patent Appeals, while affirming that the Zimmerman Patent did teach a person skilled in the art how to use Imatinib, or its pharmaceutically acceptable salts thereof, in a pharmacological composition for treating tumours, it did not go further to the β-crystalline form of Imatinib Mesylate. The Board of Patent Appeals held that the conversion of Imatinib Mesylate to its β-crystalline form represented a "manipulative step" in treating of tumours.

14.1.5 In appeal, the Supreme Court rejected the contention of Novartis that Imatinib Mesylate was a new invention *vis-à-vis* Imatinib, involving technical advance over existing knowledge. It was

noted, by the Supreme Court, that, since the grant of the Zimmerman Patent, Novartis had always been maintaining that Gleevec (the brand name under which Imatinib Mesylate was marketed) was part of the Zimmerman Patent. Grant of approval had been obtained for Gleevec on that basis. Extension of the term of the Zimmerman Patent was also sought, by Novartis, on the ground that the regulatory review for Gleevec was pending. Novartis had, moreover, stopped NATCO Pharma from marketing its drug in the UK on the basis of the Zimmerman Patent. The Board of Patent Appeals, too, had held that the Zimmerman Patent contained the requisite teaching for conversion of Imatinib to Imatinib Mesylate, and also taught the use of Imatinib in a pharmacological composition for treating tumours. These findings were binding on Novartis. In view thereof, the Supreme Court held that it was inconceivable as to how Imatinib Mesylate could be regarded as a "new product", *vis-à-vis* the Imatinib free base. As held by the Supreme Court:

> "Imatinib Mesylate is all there in the Zimmerman Patent. It is a known substance from the Zimmerman Patent."

The contention of Novartis that Imatinib Mesylate was an "invention", *vis-à-vis* the Imatinib free base was, therefore, rejected by the Supreme Court.

14.2 Section 3(d) and "enhanced efficacy":

14.2.1 Having, thus, held that Imatinib Mesylate was a "known substance", *vis-à-vis* Imatinib, the Supreme Court went on to examine whether, in the light of Section 3(d), the β-crystalline form of Imatinib Mesylate was patentable. Once Imatinib Mesylate was a "known

substance", the Supreme Court held that, in order for the β-crystalline form to escape the rigour of Section 3(d), it would have to be established that it possessed enhanced efficacy, *vis-à-vis* Imatinib Mesylate. This, held the Supreme Court, it did not do. The Supreme Court placed reliance on the express admission, in the patent application filed by Novartis, that "all the indicated inhibitory and pharmacological effects of the β-crystalline form of Imatinib Mesylate are also found with the free base…" In this context, the Supreme Court noted two affidavits of experts, which had been filed by Novartis. These affidavits, held the Supreme Court, were of no use to Novartis, as they attested to enhanced efficacy of the β-crystalline form of Imatinib Mesylate, *vis-à-vis* the Imatinib free base. The Supreme Court observed that the immediately preceding known substance being the non-crystalline form of Imatinib Mesylate, Novartis, in order to escape Section 3(d), would have to produce evidence to establish that the β-crystalline form of Imatinib Mesylate had enhanced efficacy over the non-crystalline form of Imatinib Mesylate. No material, in this regard, it was noted, was produced by Novartis.

14.2.2 The claim of "enhanced solubility", in the affidavits filed by Novartis, it was observed, might well have been the property of Imatinib Mesylate itself, as salts were known to be more soluble than compounds in the free base form. Once enhanced solubility was ignored, the Supreme Court noted that the additional properties possessed by the β-crystalline form of Imatinib Mesylate, as per Novartis, were more beneficial flow properties, better thermodynamic

stability and lower hygroscopicity. The Supreme Court also revisited the contention of Novartis that the enhanced solubility of Imatinib Mesylate added to its therapeutic efficacy, as the free base Imatinib was incapable of administration to a human being owing to its non-soluble nature, which would result in the substance, if administered, passing out of the body with no therapeutic action whatsoever. The submissions prompted the Supreme Court to deal, in some detail, with the concept of "efficacy", in the context of Section 3(d), thus (in paras 157 and 158 of the report):

> "157. What is "efficacy"? "Efficacy" means "the ability to produce a desired or intended result" [The New Oxford Dictionary of English, Edn. 1998.]. Hence, the test of efficacy in the context of Section 3(d) would be different, depending upon the result the product under consideration is desired or intended to produce. In other words, the test of efficacy would depend upon the function, utility or the purpose of the product under consideration. Therefore, in the case of a medicine that claims to cure a disease, the test of efficacy can only be "therapeutic efficacy". The question then arises, what would be the parameter of therapeutic efficacy and what are the advantages and benefits that may be taken into account for determining the enhancement of therapeutic efficacy? With regard to the genesis of Section 3(d), and more particularly the circumstances in which Section 3(d) was amended to make it even more constrictive than before, we have no doubt that the "therapeutic efficacy" of a medicine must be judged strictly and narrowly. Our inference that the test of enhanced efficacy in case of chemical substances, especially medicine, should receive a narrow and strict interpretation is based not only on external factors but there is sufficient internal evidence that leads to the same view. It may be noted that the text added to Section 3(d) by the 2005 Amendment lays down the condition of "enhancement of the known efficacy". Further, the Explanation requires the derivative to "differ significantly in properties with regard to efficacy". What is evident, therefore, is that *not all advantageous or beneficial properties are relevant, but only*

such properties that directly relate to efficacy, which in case of medicine, as seen above, is its therapeutic efficacy.

158. While dealing with the Explanation it must also be kept in mind that each of the different forms mentioned in the Explanation have some properties inherent to that form e.g. solubility to a salt and hygroscopicity to a polymorph. These forms, *unless they differ significantly in property with regard to efficacy*, are expressly excluded from the definition of "invention". Hence, *the mere change of form with properties inherent to that form would not qualify as "enhancement of efficacy" of a known substance*. In other words, the Explanation is meant to indicate what is not to be considered as therapeutic efficacy."

(Italics in original; underscoring supplied)

14.2.3 Clearly, therefore, enhanced efficacy, within the meaning of Section 3 (d), is required to be enhanced therapeutic efficacy. The Supreme Court clearly held that Novartis, in order to succeed in its contention that the β-crystalline form of Imatinib Mesylate possessed enhanced therapeutic efficacy, was required to establish, definitively, that the therapeutic properties of the β-crystalline form were superior to those of the free base Imatinib Mesylate or its non-crystalline form.

14.2.4 Once Novartis had itself admitted, in its application for grant of patent in respect of the β-crystalline form of Imatinib Mesylate, that "all indicated inhibitory and pharmacological effects" of the β-crystalline form of Imatinib Mesylate were "also found with the free base", the onus was on Novartis to establish that, despite the inhibitory and pharmacological effects of the β-crystalline form of Imatinib Mesylate being already found in the free base, the β-crystalline form had, nonetheless, enhanced therapeutic efficacy.

14.2.5 *Though I would again be adverting to this issue, I deem it appropriate to venture, even at this stage, my opinion that, in understanding the observations of the Supreme Court regarding enhanced bioavailability as a basis to claim enhanced therapeutic efficacy, the fact that the Imatinib free base, as well as Imatinib Mesylate, whether in its non-crystalline or β-crystalline form, acted by inhibiting certain protein kinases, and the admissions by Novartis in that regard, cannot be overlooked or ignored. The therapeutic activity of Imatinib Mesylate, or of the Imatinib free base was, avowedly, by inhibiting protein kinases. Once Novartis had, in its application for grant of patent for the β-crystalline form of Imatinib Mesylate, acknowledged, in so many words, that the inhibitory effect of the β-crystalline form of Imatinib Mesylate also existed in the free base, the submission, of Novartis, that the β-crystalline form possessed enhanced therapeutic efficacy had already lost much of its steam.*

14.2.6 *Even so, the Supreme Court went on to examine the contention, advanced by Novartis before it, that the enhanced bioavailability and solubility of the β-crystalline form of Imatinib Mesylate, enhanced its suitability to act as a drug. No research data, to this effect, having been placed on record by Novartis, the Supreme Court rejected the contention that the β-crystalline form of Imatinib Mesylate had enhanced therapeutic efficacy over either the free base Imatinib Mesylate or its non-crystalline form.*

14.2.7 ***Novartis***[9] is often cited as an authority for the proposition that enhanced bioavailability or solubility, absent other factors

enhancing the effectiveness of the invention is a drug, cannot be used as a basis for claiming enhanced therapeutic efficacy over the known prior art. As an absolute proposition, I am unable to agree with this contention. To my mind, ***Novartis***[9] does not lay down any such absolute proposition of law. At the cost of reiteration, there are two important factors, which are required to be borne in mind while examining the principle laid down in ***Novartis***[9] on this point, specifically in the context of Section 3(d) of the Patents Act. The first is that the Supreme Court itself noted that enhanced therapeutic efficacy was required to be established, by Novartis, before it, of the β-crystalline form of Imatinib Mesylate, not *vis-à-vis* the Imatinib Mesylate free base, but *vis-à-vis* the non-crystalline form of Imatinib Mesylate, as that was the known immediate prior art. The second is that *there was an admission, in the application filed by Novartis for grant of patent in respect of the β-crystalline form of Imatinib Mesylate, that all pharmacological and inhibitory properties of the β-crystalline form were present in the Imatinib free base. Once all inhibitory properties of the β-crystalline form of Imatinib Mesylate were admitted, in the application for the patent, as being present in the Imatinib free base, the onus was heavily on Novartis to establish, with positive data, that the enhanced bioavailability or solubility, possessed by the β-crystalline form of Imatinib Mesylate added to its therapeutic efficacy, as an inhibitor of protein kinases. Absent sufficient research data in this regard,* the Supreme Court refused to accept Novartis' contention that the therapeutic efficacy of Imatinib Mesylate, *vis-à-vis* Imatinib free base, was enhanced by its additional solubility or bioavailability. *It would be folly, in my view, to*

extrapolate this conclusion, in ***Novartis***[9]*, to a case in which there is no admission, by the seeker of the subsequent patent, of the therapeutic properties of the subsequent patent being already present in the prior art.*

14.2.8 What is "bioavailability"?

14.2.9 "Bioavailability" is, etymologically, a portmanteau of the words "biological" and "availability". "Bioavailability", therefore, refers to the "biological availability" of the drug; meaning, thereby, the availability of the drug to the body, when administered.

14.2.10 Specifically on bioavailability, paras 165 to 167 of the report in ***Novartis***[9] observe thus:

> "**165.** This leaves us to consider the issue of increased bioavailability. It is the case of the appellant that the β-crystalline form of Imatinib Mesylate has 30% increased bioavailability as compared to Imatinib in free base form. **If the submission of Mr Grover is to be accepted, then bioavailability also falls outside the area of efficacy in case of a medicine. Leaving aside the submission of Mr Grover on the issue, however, the question is, can a bald assertion in regard to increased bioavailability lead to an inference of enhanced therapeutic efficacy?** Prof. Basheer quoted from a commentator [42 FR 1640 (1977). Cf. Moffitt, Jane, "Appropriateness of Bioavailability and Bioequivalency as Pre-Market Clearance Considerations", 34 Food Drug Cosm LJ 640 (1979)] on the issue of bioavailability as under:
>
> > "It is not the intent of a bioavailability study to demonstrate effectiveness, but to determine the rate and extent of absorption. If a drug product is not bioavailable, it cannot be regarded as effective. *However a determination that a drug product is bioavailable is not in itself a determination of effectiveness*."

(emphasis supplied)

> **166.** Thus, even if Mr Grover's submission is not taken into consideration on the question of bioavailability, **the position that emerges is that just increased bioavailability alone may not necessarily lead to an enhancement of therapeutic efficacy. Whether or not an increase in bioavailability leads to an enhancement of therapeutic efficacy in any given case must be specifically claimed and established by research data. In this case, there is absolutely nothing on this score apart from the adroit submissions of the counsel.** No material has been offered to indicate that the β-crystalline form of Imatinib Mesylate will produce an enhanced or superior efficacy (therapeutic) on molecular basis than what could be achieved with Imatinib free base in vivo animal model.
>
> **167.** Thus, in whichever way Section 3(*d*) may be viewed, whether as setting up the standards of "patentability" or as an extension of the definition of "invention", it must be held that on the basis of the materials brought before this Court, the subject product, that is, the β-crystalline form of Imatinib Mesylate, fails the test of Section 3(*d*), too, of the Act."
>
> (Italics in original; emphasis otherwise supplied)

14.2.11 "Therapeutic efficacy" refers to efficacy as therapy, i.e. efficacy as a mode of treatment of the malaise sought to be remedied. Seen thus, bioavailability cannot be said to be altogether irrelevant, while assessing therapeutic efficacy. The underscored words in the passage from ***Novartis***[9], extracted hereinabove, also observe as much. If, when administered in a particular modified form, or formulation, hitherto unknown, the availability of the active pharmaceutical ingredient, for treatment of the disease, is increased, the modified form, or formulation, would certainly have greater therapeutic efficacy than the active pharmaceutical ingredient when administered in free base or free acid form. Of course, it would be for the seeker of

the patent for such modified form or formulation to provide material, with its application, vouchsafing such enhanced efficacy. Once material in that regard is produced, and patent granted, it would be for the person challenging the validity of the patent to demonstrate, with positive evidence, that the patented form, or formulation, does not possess additional efficacy. It is such a form, or formulation, which is referred to, often, as an "incremental innovation".

14.2.12 Interestingly, in para 25.5.7 of the written submissions tendered by Mr Harish Salve, appearing for Cipla, before the Supreme Court in ***Novartis***[9], it was contended, with italicised emphasis, that *"greater bioavailability, solubility, hygroscopicity therefore, are not part of efficacy"*. The Supreme Court did not, however, accept this submission, as propounded before it. Rather, the decision in ***Novartis***[9] clarifies that the onus would be on the patent applicant/holder, who asserts increased bioavailability of his invention to be enhancing its therapeutic efficacy, to so establish. I find it strange that the absolute proposition that bioavailability could never be part of therapeutic efficacy, advanced before the Supreme Court and *not accepted*, is again being advanced before this Court, exhorting its acceptance.

14.2.13 This position, in my view, is additionally apparent even from a bare reading of Section 3(d), which makes new forms of known substances patentable. The only requirement is that the new form must possess enhanced efficacy, *vis-à-vis* the existing form, known in the prior art. The therapeutic efficacy of the active pharmaceutical ingredient would, in any event, normally remain

constant, as the ingredient itself does not change. Therapeutic efficacy of the ingredient, as a remedy for the illness being sought to be addressed may, however, be enhanced by making the ingredient more available to the body, in a modified formulation. If this happens, the modified formulation becomes patentable under Section 3(d). In ***Novartis***[9], it was admitted, even in the application for patent for the β-crystalline form of Imatinib Mesylate, that the inhibitory properties contained in the β-crystalline form were also present in the free base Imatinib Mesylate. It was in this background that the Supreme Court held that, once such an admission existed on record, it was for Novartis to produce research data to substantiate its contention regarding enhanced therapeutic efficacy of the β-crystalline form of Imatinib Mesylate, over the free base or the non-crystalline form of Imatinib Mesylate. Whether such research data was, or was not, produced, is always a question of fact. There can be no precedent on the point, which could bind under Article 141 of the Constitution of India. On facts, the Supreme Court found, in ***Novartis***[9], that no such additional research data, which could indicate enhanced therapeutic efficacy of the β-crystalline form of Imatinib Mesylate, over and above the therapeutic efficacy possessed by the free base Imatinib Mesylate, as an inhibitor of protein kinases, was produced. Ergo, held the Supreme Court, the β-crystalline form of Imatinib Mesylate had failed the Section 3(d) test.

14.2.14 That ***Novartis***[9] is required to be so understood is apparent even from the following passages from the decision, with which the

Supreme Court commences its analysis of the applicability of Section 3(d):

> "**141.** It is noted in the earlier part of the judgment that the patent application submitted by the appellant contains a clear and unambiguous averment that all the therapeutic qualities of the β-crystalline form of Imatinib Mesylate are also possessed by Imatinib in free base. The relevant extract from the patent application is once again reproduced here:
>
> > "It goes without saying that *all the indicated inhibitory and pharmacological effects are also found with the free base*, 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-(4-pyridin-3-yl) pyrimidin-2-ylamino)phenyl] benzamide, *or other cells thereof*. The present invention relates especially to the ß crystal form of the methanesulfonic acid addition salt of a compound of Formula I in the treatment of one of the said diseases or in the preparation of a pharmacological agent for the treatment thereto."
> >
> > (emphasis supplied)
>
> **142.** Now, when all the pharmacological properties of the β-crystalline form of Imatinib Mesylate are equally possessed by Imatinib in free base form or its salt, where is the question of the subject product having any enhanced efficacy over the known substance of which it is a new form?"
>
> (Underscoring supplied)

14.2.15 I deemed it appropriate to deal with this aspect, on first principles, at this stage itself. The applicability thereof, to the facts of the present case, would be examined in greater detail later in this judgement.

14.3 "Coverage v. disclosure":

14.3.1 Novartis then sought to contend that, even if Imatinib Mesylate was covered by the Zimmerman Patent, it was not disclosed

by the Zimmerman Patent. Disclosure, it was sought to be contended, had to be "enabling" in character, as would enable a person skilled in the art to synthesise Imatinib Mesylate from Imatinib. The Zimmerman Patent, while covering and claiming the Imatinib free base, it was contended, did not refer to any salt of a compound, much less Imatinib Mesylate. Nor did it disclose the manner in which Imatinib Mesylate could be synthesised from the Imatinib free base. The conversion of the Imatinib free base to Imatinib Mesylate was, therefore, inventive in nature. The Supreme Court rejected this contention, observing that it did not approve of a wide gap between coverage and disclosure, using which an artful draftsman could so draft the claim as to escape the coverage of the original patent. In sum, it held that Imatinib Mesylate did not qualify the test of "invention" as defined in Section 2(1)(j), read with Section 2(1) (ja).

14.3.2 The Supreme Court, in the circumstances, examined, in ***Novartis***[9], the distinction between "coverage" and "disclosure" of a patent. Mr. Sai Deepak sought to contend that ***Novartis***[9] held, in authoritative terms, that there could be no distinction between "coverage" and "disclosure". I have had an occasion to examine this aspect, in some detail, in my earlier decision in ***FMC Corporation***[29]. As was noted in the said decision, the contention of Novartis, before the Supreme Court, was that, though Imatinib Mesylate, as a pharmaceutically acceptable salt of Imatinib, was "covered" by the Zimmerman patent, it was not disclosed in it. Novartis contended that "coverage that is granted in respect of patent is not always co-extensive with what is disclosed in the patent", and that "the patent

may be entitled to larger coverage than what was specifically disclosed in it". The teaching in the patent, contended Novartis, lay "in the disclosure/specification that supports the claim", which "describe the invention".

14.3.3 Disapproving of this line of reasoning, the Supreme Court (in para 119 of the report) held that "the dichotomy… sought to be drawn between coverage of claim on the one hand and disclosure or enablement of teaching in a patent on the other hand, (seemed) to strike at the very root of the rationale of the law of patents". I have observed, in ***F.M.C. Corporation***[29], that this proposition, as expounded by the Supreme Court in ***Novartis***[9], laid down the law in absolute terms, and could not be restricted to the patents forming subject matter of consideration in that case.

14.3.4 Even so, the Supreme Court did not equate "coverage" with "disclosure". It held that there was no "*dichotomy*" between "coverage" and "disclosure", but did not hold that there was no *distinction* between these two expressions. What was impermissible, according to the Supreme Court, *was a wide gap* between "coverage" and "disclosure". The observation that a gap should not be wide, plainly, presumes the possibility of existence of a gap. If coverage and disclosure were to be treated as synonymous, there *would be no gap*, which would render this finding of the Supreme Court meaningless and superfluous. It is axiomatic that words used by the Supreme Court are, especially in view of their constitutionally binding nature under Article 141 on all authorities in the country, to be regarded as having been carefully chosen.

14.3.5 Apropos the facts before it, the Supreme Court held thus, in para 135 of the report:

> "In light of the discussions made above, we firmly reject the appellant's case that Imatinib Mesylate is a new product and the outcome of an invention beyond the Zimmermann Patent. We hold and find that *Imatinib Mesylate is a known substance from the Zimmermann Patent itself. Not only is Imatinib Mesylate known as a substance in the Zimmermann Patent, but its pharmacological properties are also known in the Zimmermann Patent and in the article published in the Cancer Research journal referred to above.* The consequential finding, therefore, is that Imatinib Mesylate does not qualify the test of "invention" as laid down in Section 2(1)(*j*) and Section 2(1)(*ja*) of the Patents Act, 1970."

Once, therefore, Imatinib, in free base form was disclosed by the Zimmerman Patent, which also claimed the pharmaceutically acceptable salts thereof, the Supreme Court held that it was impermissible for Novartis to contend that Imatinib Mesylate was not disclosed in the Zimmerman Patent, merely because there was no specific reference by way of exemplification, or otherwise, of Imatinib Mesylate therein. Stock was taken, by the Supreme Court, while holding thus, of the fact that the Mesylate salt was one of the pharmaceutically acceptable salts of Imatinib.

14.4 Based on the above premise, the Supreme Court rejected Novartis' appeal.

Merck v. Glenmark[16]

15. The Issue: Merck Sharp and Dohme Corporation (Merck) alleged infringement, by Glenmark Pharmaceuticals (Glenmark), of

its patent IN 209816 (IN 816), which claimed Sitagliptin. Glenmark was importing and selling, after local packaging, Sitagliptin Phosphate Monohydrate (SPM) under its brand name "Zita" in India. Merck alleged that this activity infringed IN 816. Accordingly, an injunction was sought against Glenmark.

16. Rival Contentions:

16.1 Merck submitted that (i) Sitagliptin was covered in 13 claims of IN 816, (ii) Sitagliptin and its pharmaceutically acceptable salts were specifically claimed in Claim 19 of IN 816, (iii) Claim 1 of IN 816 claimed the Sitagliptin molecule with all its salts, (iv) SPM, the product of Glenmark, was, therefore, covered in Claim 19 and in 13 claims of IN 816, (v) SPM could not be prepared without manufacturing the active ingredient, which was the Sitagliptin molecule/Sitagliptin free base (SFB) and (vi) use of Sitagliptin by Glenmark to prepare SPM, therefore, infringed IN 816.

16.2 Glenmark contended, *per contra,* that Merck had suppressed the fact that it had itself applied for a separate patent for Sitagliptin Phosphate, which was, thereafter abandoned. The fact that Merck had applied for a separate patent for Sitagliptin Phosphate, contended Glenmark, itself indicated that Sitagliptin Phosphate was not claimed in the suit patent IN 816, as in its application for a separate patent for Sitagliptin Phosphate, Merck claimed Sitagliptin Phosphate to be a novel compound and a new discovery. The title of the application filed by Merck, pointed Glenmark, was "Phosphoric Acid Salt of DPP-IV Inhibitor", whereas Sitagliptin, *per se*, was merely a DPP-IV

Inhibitor. In view of a separate application filed by it in respect of Sitagliptin Phosphate, it was contended that Merck could not assert that SPM infringed the suit patent IN 816.

17. Judgement of the learned Single Judge: The learned Single Judge held, against Merck, that Merck had not pleaded that the addition of phosphate to Sitagliptin did not embody any inventive advancement. Additionally, observed the learned Single Judge, Merck had not shown that Sitagliptin Phosphate was merely a new form of Sitagliptin, medically equivalent to Sitagliptin.

18. Further contentions of Glenmark:

18.1 Glenmark further contended that IN 816 was vulnerable to invalidity as Merck had not supplied details of foreign patent applications in respect of the same or similar products, as was required by Section 8 of the Patents Act. It was further contended, by Glenmark, that IN 816 did not disclose the process by which the SFB could be isolated from Sitagliptin. The only salt claimed with an enabling disclosure in IN 816, it was contended, was Sitagliptin Hydrochloride. No other salt was exemplified in the suit patent. As such, Glenmark contended that no salt other than Sitagliptin Hydrochloride was claimed or covered by the suit patent IN 816. The suit patent IN 816, contended Glenmark, did not disclose the SFB.

18.2 By resorting to broad claiming, contended Glenmark, Merck was seeking to enlarge its patent protection to a large number of

compounds including SPM, though the details of SPM were not forthcoming from the suit patent IN 816.

18.3 Glenmark further contended that the SFB was not disclosed in the application for suit patent either as raw material or as an intermediate product. This, contended, Glenmark was because Merck was well aware that the SFB, being unstable and lacking industrial application, was non-patentable.

19. The judgement:

19.1 The Division Bench, having thus noted the submissions made by both sides, observed, in para 29 of the report, that *ex parte*/*in limine* injunctions in patent disputes are ordinarily to be avoided.

19.2 Having sounded this note of caution, the Division Bench observed that, principally, five pleas had been advanced by Glenmark, to oppose the plaint viz., that

(i) IN 816 was too broad to be workable, as it was stated to cover approximately 4.9 billion compounds,

(ii) IN 816 only disclosed Sitagliptin Hydrochloride and did not disclose either the SFB or SPM,

(iii) the SFB, even if disclosed in IN 816, was unstable and incapable of industrial application,

(iv) IN 816 was invalid on the ground of anticipation by prior art, in the form of European Patent (EP) 1406622 and WO/01/34594, and

(v) several crucial facts were suppressed by Merck, while

applying for the suit patent, IN 816.

If, on the other hand, the suit patents were valid, and covered SPM, the Division Bench noted that the matter would end there.

19.3 In this context, the Division Bench noted the contention of Glenmark that, even if IN 816 were to be treated as valid but only disclosing the SFB rather than SPM, no case of infringement of IN 816 could be said to exist, as Glenmark neither used the SFB nor the lone salt disclosed in the suit patent, namely, Sitagliptin hydrochloride as its raw material and neither the SFB nor Sitagliptin hydrochloride was generated as an intermediate in the manufacturing process. Additionally, Glenmark contended that SPM had enhanced pharmaceutical properties, over those possessed by the SFB. As such, Glenmark contended that the manufacture of SPM, by it, did not infringe the patent, even if it were to be assumed to cover the SFB.

19.4 At the outset of its analysis and findings, the Division Bench noted that the mere grant of a patent was not a presumption of its validity as held by the Supreme Court in ***Bishwanath Prasad Radheyshyam***[19]. This principle, it was held, applied equally at the interlocutory stage.

19.5 Coverage and disclosure:

19.5.1 Coverage of a patent, it was held, was required to be discerned by construction of the patent, which would involve a reading of the claims with their enabling disclosures, as understood by a person ordinarily skilled in the art. Thus read, the claims in the suit

patent would cover all rights exercised thereunder, available under Section 48 of the Act. The question before it was, therefore, as to how far SPM was subsumed within the core of the suit patent IN 816, without any precise enabling disclosure leading one to SPM. In other words, the court was required to consider how elastic the claims in the suit patent could be.

19.5.2 The SFB, it was found, was disclosed in Formula-1 in the "Detailed Description of the Invention" in IN 816 and was also claimed in Claim 1 of its complete specifications. The complete specifications further described the method of isolation of the R-enantiomer of the SFB, which was the enantiomer ultimately used by Glenmark in 'Zita'. Thus, the method of isolation of the SFB was clearly set out in IN 816.

19.5.3 Further, IN 816 identified the "pharmaceutically acceptable salts" of the SFB as including salts prepared from, *inter alia*, phosphoric acid. Phosphates of Sitagliptin stood, thereby, claimed in IN 816. Further, the complete specifications went on to explain that the salts "may also be in form of hydrates". Thus, the monohydrate form of salts of Sitagliptin also stood claimed. Thus, this Court found, in para 39 of its report, that, while the SFB was clearly disclosed in IN 816, there was a possible disclosure of SPM as well.

19.5.4 On the aspect of disclosure of the SFB, it was further noted that the methods for preparing compounds of Sitagliptin were illustrated in the schemes set out in the complete specifications. Of these, Scheme 6, it was noted, explained how to prepare the SFB. The

SFB, therefore, was clearly claimed and disclosed in IN 816.

19.5.5 The court went on to clarify, at this point, that a mere claim, without an enabling disclosure, meaning a disclosure as would enable a person ordinarily skilled in the art to work the invention, could not be sustained under the Patents Act.

19.5.6 This, therefore, gave rise to the question of whether the SFB and SPM were sufficiently disclosed in the suit patent IN 816. The first question, noted the Division Bench, had already been answered by it in the affirmative.

19.5.7 Claim construction: The Division Bench thereafter went on to examine and explain how claims in patents were to be construed. It was explained, in this context, that a claim in a patent was required to be construed in the light of the accompanying complete specifications. The complete specifications were, therefore, to be read as a whole, in the light of the state of knowledge of a person ordinarily skilled in the art; not R.K. Laxman's immortal "Common Man", but one who was acquainted with the technology in question. Explained otherwise, the disclosure had to be such as would enable the person ordinarily skilled in the art to make the claimed invention, so as to make it available to the public by the expiry of the patent term. The court also went on to endorse criteria determinative of the sufficiency of the disclosure/disablement, termed the ***Wands test***[33]. These criteria were (i) the quantity of experimentation necessary, (ii) the amount of directions/guidance contained in the patent, (iii) the presence/absence

[33] Proposed in **In re Wands**, **858 F. 2d 731, 737, 8 USPQ 2d 1400 (Fed. Cir. 1988)**

of working examples, (iv) the nature of the invention, (v) the state of the prior art, (vi) the relative skill of those in the art, (vii) the predictability/unpredictability of the art and (viii) the breadth of the claims.

19.5.8 In the case of SPM, or for that matter any other pharmaceutically acceptable salt of Sitagliptin, it was observed that the active pharmaceutical ingredient (API) was the SFB. The attached salt was only an inert carrier, which wore away once the drug was in the system. The activity of the SFB was not affected by the attached carrier radical, even if the efficacy of the administration of the Sitagliptin free base was influenced thereby. The SFB, previously unknown as a compound which could affect the DPP enzyme was a new and, arguably, a novel invention.

19.5.9 The Division Bench went on to hold that, to constitute "prior disclosure", the prior art was required to disclose the subject matter which, if performed, would infringe the suit patent. This may be taken as a definitive test of "disclosure in prior art" which, if established, would lead to a case of anticipation by prior claiming.

19.5.10 The question of whether SPM was disclosed in the suit patent, noted the Division Bench, was a vexed question. SPM was neither claimed nor disclosed in any of the examples or schemes contained in the complete specifications of IN 816. The only reference to SPM, in IN 816, was to be found in the mention of a phosphate salt as a possible pharmaceutically acceptable salt of Sitagliptin. The parties before it, noted the Court, were strongly divided on key

aspects. Glenmark contended that generic reference to phosphate salts did not amount to a disclosure of SPM; Merck contended, *per contra*, that such a generic reference was also sufficient disclosure for the carrier salts. Glenmark contended that SPM was physically and chemically different from the SFB, whereas Merck denied this contention. Glenmark contended that the conversion of the SFB to SPM was not obvious to a person ordinarily skilled in the art from IN 816, as there were several phosphate salts derivable from the SFB. As against this, Merck contended that SPM was known in the industry. These disputes, observed the Division Bench, were technical in nature and could not be decided at the Order XXXIX stage. In order to determine these disputes, a detailed examination of the issue by an expert would be required.

19.5.11 Section 3(d): The applicability of Section 3(d), i.e. whether Sitagliptin Phosphate was a known product and, if so, whether it possessed any therapeutic advantages over the SFB too, noted the Division Bench, could not be decided at the interlocutory stage.

19.5.12 The coverage of the claim in the suit patent IN 816, it was observed, was required to be determined on the terms of the suit patent, with reference to the words used by the inventor and in the context of the invention in terms of the existing knowledge in the industry. The applicability of Section 3(d), or the abandonment of the subsequent application for Sitagliptin Phosphate, could not affect the issue of coverage of the claim in the suit patent IN 816, which was required to be determined on its own terms. As the SFB was, *prima*

facie, disclosed in IN 816, the Division Bench held that it was claimed and thus, covered by the suit patent.

19.5.13 Glenmark contended that the suit patent IN 816 was bad as it was overbroad and created a false monopoly for undisclosed compounds. It was, therefore, alleged to be invalid on the ground of insufficiency of disclosure. On this aspect, the Division Bench observed that a claim in a patent, conceivably, could encompass embodiments which would be provided/invented in future and had no particularly advantageous properties, provided they employed in a technical contribution made by the invention.

19.5.14 Having said this, the Division Bench left open the question of whether IN 816 disclosed SPM for detailed examination during and after trial. Nonetheless, it held that IN 816 did sufficiently disclose the SFB, which was the active ingredient in SPM. The SFB, observed the Division Bench, passed the triple test of patentability, i.e. novelty, inventive step and industrial application. As such, IN 816 was held to be a valid Markush patent.

19.6 Industrial application – Section 64(1)(g):

19.6.1 Glenmark further contended that the SFB had no industrial application and was, therefore, vulnerable to invalidity under Section 64(1)(g). This contention, too, was rejected by the Division Bench. The complete specifications of IN 816, it was observed, clearly noted that it was useful for treating various diseases, on account of the presence of the DPP-IV enzyme. It also detailed the

modes of administration of the drug covered by the suit patent. It also recognized the fact that the SFB may have required combination with other compounds for effective delivery. Industrial applicability, noted the Division Bench, was to be decided on the active ingredient, i.e. the SFB instead of any particular salt. The suit patent contemplated that the active ingredient, i.e. the SFB, which imparted therapeutic effect, would be combined with a carrier in some form. The essential focus of IN 816 was, therefore, industrial application of the main therapeutic ingredient, namely, the SFB. It was admitted, in the complete specifications of IN 816, that the SFB would be combined with some carrier, which had no therapeutic value.

19.6.2 Section 2(1)(ac), it was observed defined "capable of industrial application" as capable of being made/used in the industry. Sitagliptin undoubtedly had therapeutic effect. Even so, Glenmark contended that Sitagliptin simplicitor could not be administered and did not, therefore, have any industrial application on its own.

19.6.3 The Division Bench observed that the complete specifications had to be read as a whole. The role of the complete specifications, it was noted, was to "teach" (i) what the invention was, (ii) how the invention was to be made and (iii) how the invention was to be used. The complete specifications of IN 816 recognized that the SFB, though claimed and disclosed in the patent, would be attached to some industrial carrier for administration. This carrier, however, was not the crux of the invention, but was only an inert component, which did not add to the therapeutic value of the invention. As the SFB was the active ingredient of the claim of the entity claimed in IN 816, and

the SFB possessed clear therapeutic properties, it was held that Sitagliptin could not be regarded as useless for any known purpose. Additionally, it was also noted that the SFB was unknown earlier, and provided for inhibition of the DPP-IV enzyme by a method previously unknown.

19.6.4 The criteria to be fulfilled for industrial applicability of a claim in a patent to be set to exist were, it was held, (i) that the patent was required to disclose practical application and had to be of some profitable use, (ii) the use of the patent in industrial practice, had to be derivable directly from the description coupled with common general knowledge, (iii) speculative use was insufficient and (iv) the complete specifications of the patent, coupled with common general knowledge, were required to be sufficient to enable a person skilled in art to reproduce/exploit the invention without undue burden and without having to carry out a research program.

19.6.5 In as much as Sitagliptin had definite therapeutic effect on humans, the Division Bench held that it had practical industrial application. However, to administer Sitagliptin, a carrier was necessary. The carrier was, therefore, only required for commercial exploitation of Sitagliptin, and was, otherwise, an inert entity, with no separate therapeutic value or effect. The necessity of coupling with the carrier, in order to commercially exploit the SFB (which was the entity having therapeutic value) was, therefore, irrelevant to the patentability of the SFB, unless it was sought to be contended that the SFB was incapable of being coupled with any carrier. That, however, was not Glenmark's contention.

19.6.6 Generally, in pharmaceutical compounds, held the Division Bench, industrial applicability would exist if (i) the function of the entity was disclosed and (ii) the function disclosed that the entity was useful in the medical industry.

19.6.7 Viewed thus, the Court held that the claim in IN 816 was not in the mere nature of a pre-emptive claim but that it had definite therapeutic value and was a novel invention unknown prior thereto as a mode for inhibiting the DPP-IV enzyme. The contention of Glenmark that Sitagliptin/the SFB did not possess industrial application was, therefore, rejected.

19.7 Prior disclosure: The Court thereafter proceeded to the aspect of whether Sitagliptin was disclosed in the prior art EP 622. This aspect, however, it was found, did not arise for consideration as EP 622 was not a prior art for the suit patent IN 816, as it was published after the priority date of IN 816, even though the priority date of EP 622 was prior to the priority date of IN 816.

19.8 Section 8:

19.8.1 Lastly, the Division Bench examined the challenge led by Glenmark on the ground of Section 8. Glenmark argued that, as Merck had failed to disclose information regarding other patents, for the same entity, it had violated Section 8 and that, therefore, IN 816 was vulnerable to invalidity under Section 64(1)(m).

19.8.2 Section 8, it was noted by the Division Bench, was a mandatory dispensation and violation of Section 8 rendered a patent liable to revocation under Section 64(1)(m) of the Patents Act. As the consequence of its violation was drastic, Section 8 was required to be literally construed.

19.8.3 Section 8, observed the Court, applied only in respect of foreign patents. Noting the fact that this was contrary to the view expressed by an earlier Division Bench in ***Roche v. Cipla-I***[17], the Division Bench in ***Merck v. Glenmark***[16] differed with the view expressed in ***Roche v. Cipla-I***[17]. However, it observed, the order in ***Roche v. Cipla-I***[17] was merely on an appeal against an interlocutory order refusing injunction. The matter had been remanded to the learned Single Judge, who thereafter passed a final order in which Section 8 was correctly interpreted by him as applying only to foreign patents.

19.8.4 It was further observed that the use of the word "may" in Section 64 indicated that violation of Section 64(1)(m) did not automatically result in revocation of the patent, but that the power to revoke the patent, conferred by Section 64(1)(m), was discretionary in nature.

19.8.5 In view of this position, the Division Bench opined that, at the interlocutory stage, it was normally not advisable to reject a prayer for injunction on the ground of vulnerability to revocation of the suit patent under Section 64(1)(m), unless the breach was patent and manifest. In the case of the suit patent before it, the Division

Bench held that no case for sustaining, at the interlocutory stage, the objection of Glenmark, predicated on Section 8 read with Section 64(1)(m), was made out.

19.9 Glenmark further sought to contend that its process of manufacture was different. This argument was held by the Court to be unconvincing. The Court observed that production of Sitagliptin Phosphate would necessarily precede production of SPM and that, therefore, production of SPM would itself amount to infringement of the suit patent.

19.10 The Court also held that the denial to Merck of its patent application for Sitagliptin Phosphate by the Indian Patent Office was irrelevant and that this fact could not be a basis for denying the inventive steps inherent in the SFB, on the basis of which the suit patent had been granted to Sitagliptin.

19.11 Following these findings, the Court observed that as Glenmark was using the SFB as the active component in its chemical formulation SPM, *prima facie*, a case of infringement was made out.

Roche v. Cipla-II[23]

20. F. Hoffmann-La Roche Ltd ("Roche") sued Cipla for infringement of its suit patent IN 774, which was granted on 23rd February, 2007 in India. IN 774 claimed Erlotinib Hydrochloride. Erlotinib Hyrochloride was marketed, by Roche, as a combination of two polymorphs A and B.

21. Subsequent to grant of the suit patent IN 774, Roche applied for grant of patent in respect of polymorph B of Erlotinib Hydrochloride, *vide* Application No. DEL 507 on the ground that subsequent research had revealed that polymorph B was more thermodynamic and, consequently, had enhanced efficacy over Erlotinib Hydrochloride *per se*. Though polymorph B of Erlotinib Hydrochloride had been granted patent in 40 other jurisdictions, including US 221, the Indian Patent Office rejected the application of Roche for grant of patent for polymorph B of Erlotinib Hydrochloride (DEL 507).

22. Roche alleged, in its suit against Cipla, that Cipla had infringed IN 774, which claimed the Erlotinib Hydrochloride molecule. It was asserted that Erlotinib Hydrochloride had demonstrated breakthrough capabilities as an Epidermal Growth Factor Receptor inhibitor, which enhanced survival benefits in cancer, especially patients with non-small cell lung cancer.

23. <u>The judgement</u>:

23.1 The Division Bench of this Court, in the appeal against the judgement of the learned Single Judge addressed, first, the aspect of infringement and, thereafter, the grounds on which Cipla sought to assail the validity of the suit patent IN 774.

23.2 At the outset, the Division Bench analysed Section 3 of the Patents Act *vis-à-vis* Section 2(1)(j). Cipla had sought to contend that Section 3 was an exception to Section 2(1)(j). The Division Bench

rejected this contention. In fact, held the Division Bench, Section 3(d) laid down the threshold test for patent eligibility. It postulated that, ordinarily, new forms of known substances would not be entitled to grant of patent, unless they differed significantly in properties with regard to efficacy. The Explanation to Section 3(d) clarified that the derivatives referred to therein, i.e. salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance would be treated to be the same substance. The protection from re-patentability, granted by Section 3(d) to "known substances" also, thereby, extended, by operation of the Explanation, to the various kinds of derivatives envisaged therein. Section 3(d), however, engrafted an exception to its rigour where the new form had enhanced efficacy over the known substance.

23.3 The Division Bench in ***Roche v. Cipla-II***[23] held that, when examining patentability of a product, the authority was first required to apply Section 3(d) to ascertain whether the product was prohibited from patentability under the said provision. If Section 3(d) did not apply, the product became entitled to be considered for patentability by applying Section 2(1)(j) and (ja). It was not as though, therefore, by escaping Section 3(d), the product became, *ipso facto*, entitled to a patent. It had, thereafter, to be tested on the anvil of Section 2(1)(j) and (ja). Thus, held the Division Bench, Section 3(d) could not be regarded as an exception to Section 2(1)(j) or (ja).

23.4 The Division Bench thereafter went on to explain the concept of an "active pharmaceutical ingredient" (API). It was held that APIs

were the molecular entities that exerted the therapeutic effects of medicines and were biologically active. Patent protection was, ordinarily, granted to the API. Where the API was patented, any product of the API, in any form, stood protected. Any manufacture or marketing, by a third party, of such a product/derivative of the API would, therefore, infringe the patent granted to the API. Section 3(d), it was held, envisaged a variety of derivatives of known substances. Among these were (i) prodrugs, which were not active in themselves, but were metabolised in the body to form active drugs, (ii) compositions consisting of combinations of two or more APIs or a combination of a pharmaceutical carrier with a compound not used as a drug prior thereto and (iii) a drug delivery system, which was a composition which enabled its constituents to be administered in a particular way.

23.5 Claim construction, it was held, was pivotal to the examination of any infringement action. Having referred to various authorities, including ***Novartis***[9], ***Merck v. Glenmark***[16], ***Edward H. Phillips v. AWH Corporation***[34], ***Pfizer v. Ranbaxy***[35] ("***Pfizer-I***", hereinafter) and ***Glaverbel SA v. British Coal Corpn***[36], the Division Bench enumerated the following principles of claim construction:

> "(i) Claims define the territory or scope of protection (Section 10(4) (c) of the Patents Act, 1970.
>
> (ii) There is no limit to the number of claims except that after ten claims there is an additional fee per claim (1st Schedule of the Act).

[34] 415 F. 3d. 1303
[35] 457 F. 3. 1284 (US)
[36] 1995 RPC 255 (UK)

(iii) Claims can be independent or dependent.

(iv) The broad structure of set of claims is an inverted pyramid with the broadest at the top and the narrowest at the bottom (Manual of Patents Office - Practice and procedure).

(v) Patent laws of various countries lay down rules for drafting of claims and these rules are used by Courts while interpreting claims.

(vi) One rule is that claims are a single sentence defining an invention or an inventive concept.

(vii) Different claims define different embodiments of same inventive concept.

(viii) The first claim is a parent or mother claim while remaining claims are referred to as subsidiary claims.

(ix) If subsidiary claims contain an independent inventive concept different from the main claim then the Patent office will insist on the filing of a divisional application.

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

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

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

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

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

(xv) The parts of the claim include its preamble, transition phrase and the body. The 'transition phrase' includes terms like:

(a) Comprising;
(b) Consisting;
(c) Consisting essentially of;
(d) Having;
(e) Wherein;
(f) Characterised by;

Of these terms some are open ended, such as 'comprising' which means that if the claim contains three elements 'A', 'B' and 'C' it would still be an infringement for someone to add a fourth element 'D'.

Further some terms are close ended such as 'consisting of', i.e. in a claim of three elements, 'A', 'B' and 'C' a defendant would infringe if he has all three elements. In case the defendant adds a fourth element 'D' he would escape infringement.

(xvi) Each claim has a priority date so that in a group of claims in a specification you could have multiple priority dates. This only means that if a patent application with certain priority date and claims was followed by another application with different claims and different priority dates, then if they were consolidated or cognate with another application, each claim would retain the original priority date [Section 11(1)]."

23.6 Additionally, the Division Bench held, relying on ***Merck v. Glenmark***[16] and ***Glaverbel***[36], that the claim was required to be interpreted on its own language, and not by reference to subsequent conduct or prior material.

23.7 Examination of any infringement action would, it was held relying on ***Herbert Markman v. Westview***[37], require the Court, in the first instance, to determine the meaning and scope of the claims in the suit patent, applying the above principles of claim construction and, in the second, to compare the claim, thus deconstructed, with the allegedly infringing product or device. The Division Bench was at pains to observe that examination of an infringement claim involved a comparison of the product of the defendant with the claim of the plaintiff. What was required, therefore, was a product-to-patent comparison, and not a product-to-product comparison. In fact, the Division Bench held that one of the errors in the judgement of the learned Single Judge was that it proceeded on a product-to-product comparison, instead of a product-to-patent comparison.

23.8 Cipla sought to contend, before the Division Bench, that the very filing, by Roche, of a separate application (DEL 507) for polymorph B of Erlotinib Hydrochloride itself indicated that polymorph B was a separate invention, not disclosed, enabled or claimed in IN 774. Roche was not, therefore, it was urged, entitled to contend that the manufacture and marketing, by Cipla, of polymorph B of Erlotinib Hydrochloride infringed the suit patent IN 774.

[37] **517 U.S. 370 (1996)**

23.9 The Division Bench rejected this contention. Rather, it was held that the rejection, by the Patent Office, of the application, of Roche, for grant of patent in respect of polymorph B of Erlotinib Hydrochloride was based on Section 3(d), which itself indicated that polymorph B was merely a new form of Erlotinib Hydrochloride, without sufficient matter to identify it as a "new product", i.e. without any substantial added efficacy. Any manufacture, by a third party, of polymorph B of Erlotinib Hydrochloride would, therefore, it was held, infringe IN 774.

23.10 Cipla further sought to contest the validity of the suit patent IN 774 as being bereft of commercial utility. Cipla contended that it was the polymorph B of the entity patented by IN 774 (which Cipla was marketing) which, alone, was capable of commercial exploitation and, consequently, deserving of a patent. This argument was found, by the Division Bench, to essentially ignore the concept of breakthrough inventions. The Division Bench held that breakthrough inventions, though not commercially viable at the time of their conceptualisation or invention, were nonetheless useful and industrially applicable. Such breakthrough inventions, it was observed, provided the stepping stone for further improvement. The Division Bench emphasised the distinction between commercial utility and patentable utility. Commercial utility, it was held, relying on ***American Cynamid Co. v. Ethicon Ltd***[38], ***Edison & Swan Light Co. v. Holland***[39] and ***E. H. & B. v. Unichem Laboratories***[24], was not a *sine qua non* for patentability. Breakthrough inventions, for example, though not immediately

[38] **(1975) 2 WLR 316**
[39] **(1887) 34 Ch. D., 261**

capable of commercial exploitation were, nevertheless, patentable. In order for the defendant to succeed in its challenge to the patentability of the suit patent on the ground of absence of usefulness, as Cipla sought to do in respect of IN 774, the defendant would have to establish that the later commercially successful invention owed nothing to the original patent. The mere fact that the original patented invention had to be subjected to subsequent improvements, which might have even rendered obsolete, did not, in any manner, detract from the patentability of the original invention. "Non-utility", it was held, implied that, even if the original invention was worked as suggested by its specifications, it would not yield the result that it promised. If it did, its utility was established. Even misstatements as to the purposes for which the results obtained by working the patent could be employed, it was held, would not invalidate the original patent.

23.11 Cipla also disputed the allegation of infringement by contending that the product relatable to IN 774 was marketed as a combination of polymorphs A and B of Erlotinib Hydrochloride, whereas Cipla's product was polymorph B of Erlotinib Hydrochloride. Rejecting this contention, the Division Bench agreed with the submission, of learned Counsel for Roche, that infringement was being claimed of Erlotinib Hydrochloride *per se*, which was patented in IN 774, and not of any polymorph of Erlotinib Hydrochloride. The Division Bench observed that polymorph B of Erlotinib Hydrochloride could not be made without, in the first instance, synthesising Erlotinib Hydrochloride. The fact that the

defendant was marketing polymorph B of Erlotinib Hydrochloride, therefore, it was held, indicated that the defendant was manufacturing Erlotinib Hydrochloride in the first instance. This clearly infringed the suit patent IN 774.

23.12 That apart, as Roche was asserting IN 774, which claimed Erlotinib Hydrochloride, and Cipla's product was the polymorphic form of Erlotinib Hydrochloride which, even as per the Explanation to Section 3(d), was to be treated as the same substance, the Division Bench found Cipla to have infringed the suit patent IN 774.

23.13 The Division Bench, thereafter, went on to comment on the usefulness of X-ray diffraction in examining patent infringement claims. In product patent infringement cases, it was held that X-ray diffraction was of little utility, as what was required was to compare the defendant's product with the plaintiff's patent, and the coverage of the latter. Had the suit patent claimed the polymorphic form of Erlotinib Hydrochloride, X-ray diffraction, it was observed, might have been of some use in estimating whether the polymorphic form which was marketed by Cipla was infringing the polymorphic form of Erlotinib Hydrochloride, in respect of which Roche held the patent, by comparing the defendant's product which the product disclosed in the suit patent. Where, however, the suit patent disclosed and claimed Erlotinib Hydrochloride *per se*, and infringement was alleged thereof, X-ray-diffraction, it was found, was of little utility. By concentrating on X-ray diffraction results, the Division Bench found that the learned Single Judge had erred in failing to apply the correct test, which was

an examination of the scope of the suit patent IN 774, to ascertain whether it would encompass the product of the defendant.

23.14 As Cipla's product was a polymorphic form of Erlotinib Hydrochloride, which was claimed in the suit patent IN 774, the Division Bench held that Cipla had infringed the suit patent.

23.15 Thereafter, as already noted, the Division Bench went on to examine the vulnerability of the suit patent IN 774 to revocation, on the grounds urged by Cipla.

23.16 Cipla urged that the suit patent was invalid, as Roche had violated Section 8 of the Patents Act, by failing to disclose, in its application (which resulted in the grant of IN 774) the fact that it had applied for grant of patent in respect of polymorph B of Erlotinib Hydrochloride, resulting in the grant of US 221.

23.17 Observing, in the first instance, that there was no specific allegation, in this regard, in the pleadings of Cipla, the Division Bench went on, nonetheless, to examine the challenge on merits. It was held that the failure, of Roche, to disclose, in its application for grant of patent for Erlotinib Hydrochloride, the fact that it had earlier applied and been granted patent for polymorph B of Erlotinib Hydrochloride, was not fatal, as, on that day, both Roche and Cipla were of the opinion that polymorph B of Erlotinib Hydrochloride was a separate invention, distinct from Erlotinib Hydrochloride *per se*. Being based on this *bona fide* impression, it was held that the failure, of Roche, to

disclose the grant of US 221 in respect of polymorph B of Erlotinib Hydrochloride, was not fatal to the suit patent.

23.18 Cipla also pleaded that the suit patent IN 774 was invalid on the ground of obviousness, under Section 64(1)(f) of the Patents Act, for which purpose it relied on European Patent (EP) 226. Cipla contended that Example 51 of EP 226 was the closest prior art cited in the suit patent IN 774, and that any person skilled in the art would be motivated to use the said example as a starting point. The Division Bench found that there were differences in the molecular chemical structure of Example 51 of EP 226 which, seen in the light of the evidence that emerged during trial, defeated Cipla's claim of invalidity on the ground of obviousness. While the conclusion of the Division Bench, on this point, is not of particular significance, as it is specific to the facts of that case, certain observations of the Division Bench, in arriving at that conclusion, are relevant. The Division Bench held that "obviousness" and the "lack of inventiveness", as a ground to plead invalidity under Section 64(1)(f), had to be seen vis-à-vis the facts which were publicly known or publicly used in India, or published in India or elsewhere before the priority date of the suit patent. The following passage, from the well-known decision of the Supreme Court in ***Bishwanath Prasad v. Hindustan Metal Industries***[19] was relied upon, as a definitive authority on the test to be applied, while examining obviousness for want of inventive step:

> "**25.** Another test of whether a document is a publication which would negative existence of novelty or an "inventive step" is suggested, as under:
>
> Had the document been placed in the hands of a competent draftsman (or engineer as distinguished from a mere artisan),

> endowed with the common general knowledge at the 'priority date', who was faced with the problem solved by the patentee but without knowledge of the patented invention, would he have said, 'this gives me what I want?' (Encyclopaedia Britannica; ibid). To put it in another form:'Was it for practical purposes obvious to a skilled worker, in the field concerned, in the state of knowledge existing at the date of the patent to be found in the literature then available to him, that he would or should make the invention the subject of the claim concerned?' "

The Division Bench also endorsed the following "triple test of obviousness", as postulated by the US Supreme Court in ***KSR International Co. v. Teleflex Inc.***[40]:

> "Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; 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."

Additionally, in paras 150 and 151 of the report, the Division Bench relied on ***Windsurfing International Inc. v. Tabur Marine (Great Britain) Ltd.***[41] and ***Eisai Co. Ltd***[42], thus:

> **150.** In ***Windsurfing International Inc***[33] the Court of Appeals noted the four steps to answer the question of obviousness which were followed in ***Pozzoli SPA v. BDMO SA***[43] as under : -
>
> > "(i) identifying the inventive concept embodied in the patent;

[40] 550 US 398 (2007)
[41] 1972 RPC 457
[42] 16 USPQ.2d 1897
[43] (2007) F.S.R. 37

(ii) imputing to a normally skilled but unimaginative addressee what was common general knowledge in the art at the priority date;
(iii) identifying the differences if any between the matter cited and the alleged invention; and
(iv) 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."

151. In ***Eisai Co. Ltd.***[42] the Board of Appeals of European Patent Office applying the problem solution approach which consists essentially in (a) identifying the closest prior art, (b) assessing the technical results (or effects) achieved by the claimed invention when compared with the closest state of the art established, (c) defining the technical problem to be solved as the object of the invention to achieve these results, and (d) examining whether or not a skilled person starting from the closest prior art "would" arrive at something falling within claim by following the suggestion made in the prior art held that when deciding upon inventive step in relation to pharmacologically active compounds it is not essential whether a particular substructure of a compound could be replaced by another known isosteric one, but whether information was available on the impact of such a replacement on the pharmacological activity of the specific group of compounds concerned."

23.19 Even so, the Division Bench echoed the note of caution, sounded by the High Court of Bombay in ***F.H & B v. Unichem***[24], against regarding a patent as invalid on the ground of obviousness by resorting to hindsight analysis or reconstruction, using the teaching in the suit patent itself as a guide to reach the suit patent. The Division Bench also endorsed the observation in ***Pfizer Inc. v. Teva Pharmaceuticals***[44] ("***Pfizer-II***", hereinafter) that "a patent challenger however must demonstrate the selection of a lead compound based on

[44] **520 F.3d. 1358**

its promising and useful properties, not a hindsight driven search for structurally similar compounds". These authorities, it was held, identified the following inquiries, which were required to be conducted while examining the claim of obviousness/lack of inventive 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."

23.20 Thus, it was held, "to show obviousness besides structural similarity there should be a reason or motivation shown in the prior art to make the particular structural change in order to achieve the properties that the applicant was seeking". The following passages from the judgment of the Court of Appeals in ***Pfizer-II***[44] were cited, with emphasis:

> "The determination of obviousness is a legal conclusion based on underlying facts. ***Allergan, Inc. v. Sandoz Inc., 726 F.3d 1286, 1290-91 (Fed. Cir. 2013).*** After a bench trial, we review the district court's factual findings for clear error and

its conclusions of law de novo. ***Honeywell Int'l, Inc. v. United States, 609 F.3d 1292, 1297 (Fed. Cir. 2010)***. A patent claim is invalid for obviousness if "the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains." ***35 U.S.C. § 103***. The "underlying factual considerations in an obviousness analysis include the scope and content of the prior art, the differences between the prior art and the claimed invention, the level of ordinary skill in the art, and any relevant secondary considerations[,]" which include "commercial success, long-felt but unsolved needs, failure of others, and unexpected results." Allergan, 726 F.3d at 1290-91 (citations omitted). Patent invalidity must be established by clear and convincing evidence. ***Microsoft Corp. v. i4i Ltd. P'ship, 131 S.Ct. 2238, 2242 (2011).***

Whether a new chemical compound would have been prima facie obvious over particular prior art compounds follows a two-part inquiry under our precedent. First, the court determines whether a chemist of ordinary skill in the art would have selected the asserted prior art compound as a lead compound, or starting point, for further development. ***Eisai Co. v. Dr. Reddy's Labs., Ltd., 533 F.3d 1353, 1359 (Fed. Cir. 2008).*** A lead compound is a compound in the prior art that would be "most promising to modify in order to improve upon its activity and obtain a compound with better activity." ***Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd., 492 F.3d 1350, 1357 (Fed. Cir. 2007).*** The selection analysis may be guided by evidence of the compound's pertinent properties, such as chemical activity or potency. See ***Eli Lilly & Co. v. Zenith Goldline Pharm., Inc., 471 F.3d 1369, 1378 (Fed. Cir. 2006).*** Mere structural similarity between a prior art compound and the claimed compound does not inform the lead compound selection. ***Otsuka Pharm. Co. v. Sandoz Inc., 678 F.3d 1280, 1292 (Fed. Cir. 2012)***; *see* ***Daichii Sankyo Co. v. Matrix Labs., Ltd., 619 F.3d 1346, 1354 (Fed. Cir. 2010).***

Proof of obviousness of a chemical compound "clearly depends on a preliminary finding that one of ordinary skill in

> the art would have selected [a particular prior art compound] as a lead compound." ***Takeda, 492 F.3d at 1357***. The second step of the obviousness analysis requires a showing that the prior art would have taught a skilled artisan to make "specific molecular modifications" to a lead compound so that the claimed compound may be made with a reasonable expectation of success. ***Id. at 1356-57.***"

23.21 ***Eli Lilly & Co. and Lilly Industries Ltd. v. Zenith Goldline Pharmaceuticals***[45] was cited, to reiterate the position that "to establish a *prima facie* case of obviousness based on a combination of elements in the prior art, the law requires a motivation to select the references and to combine them in the particular claimed manner to reach the claimed invention".

23.22 Having, thus, referred to earlier authorities on the point, the Division Bench concluded, on the aspect of obviousness, thus:

> "**159.** Thus though initially '*structural obviousness*' alone was deemed to create a presumption of unpatentability however the Courts expressing dissatisfaction with the Rule opined that the properties were also material to show unpatentability of new chemical and must be considered. Thus prior art disclosure should not merely be structurally similar compound but also at least to some degree demonstrate the same desired property which is relied on for the patentability of the new compound. In other words '*idea of new compounds is not separable from the properties that were sought by the inventor when making the compounds and structure and properties are essential compounds of the invention as a whole*'. (See ***In re. Dillon***[46]).
>
> **160.** Thus obviousness is a question of law based on facts and the burden to prove is on the party which alleges however after the party which alleges makes out a prima facie case of

[45] **471 F.3d 1369 (Fed. Cir. 2006)**
[46] **800 F.2d 1091**

> invalidity on the ground of obviousness, the burden shifts on the inventor to disprove obviousness."

23.23 In this context, the Division Bench also explained "the features of a person skilled in the art (as being) that of a person who practices in the field of endeavour, 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".

23.24 Applying these principles, it was held that Cipla had failed to establish that IN 774 was invalid on the ground of obviousness.

Astrazeneca v. Intas[20]

24. These were appeals against orders, by learned Single Judges, rejecting the prayer of the appellant Astrazeneca for injunction against infringement, by the various defendants in the appeals, of IN 205147 ('IN 147', in short) and IA 235625 ('IN 625', in short), by manufacturing and selling Dapagliflozin ('DAPA', hereafter). Astrazeneca asserted that DAPA was subject matter of both IN 147 and IN 625. It was pleaded that IN 147 was a Markush structure, covering a group of compounds, including DAPA, though it did not disclose DAPA. DAPA, it was submitted by Astrazeneca, was invented consequent on further research and development using the Markush structure of IN 147 as the starting point. It was pointed out that DAPA was first synthesised in 2001, after 12th August, 1999, which was the priority date of IN 147. As such, there could be no question of DAPA been disclosed in IN 147. Astrazeneca pleaded that

"merely because a particular compound falls within the scope or territory of a particular claim, does not amount to the said compound been disclosed with specificity". The inventions claimed in IN 147 and IN 625 were different, according to Astrazeneca, with IN 147 claiming a class of compounds of the Markush structure, whereas IN 625 had only one specific claim for the DAPA molecule. DAPA was, therefore, pleaded Astrazeneca, neither claimed nor disclosed in IN 147. As IN 147 was published, under Section 11A of the Patents Act only on 18th March, 2005, after the priority date of IN 625, it was pleaded that there was no question of a person ordinarily skilled in the art arriving at DAPA from a reading of IN 147. DAPA, it was submitted, was not obvious from IN 147, as IN 147 was a Markush structure covering a million possibilities. Any successful attempt at reaching DAPA from IN 147, submitted Astrazeneca, could only be by recourse to hindsight. There was no indicator or teaching in IN 147, which could enable a person skilled in the art to arrive at DAPA. It was also pleaded that IN 625 was an old and established patent, in the 18th year of its life and, therefore, was presumed to be valid.

25. As against this, the respondents relied on the pleading, by Astrazeneca, that DAPA infringed IN 147 as well as IN 625, to contend that Astrazeneca had, thereby, admitted complete coverage of DAPA by IN 147. IN 147 having expired on 2nd October, 2020, it was submitted that there could be no interlocutory injunction against exploitation of DAPA. This, even by itself, it was submitted, constituted a credible challenge to the validity of IN 625. Reliance was also placed on the working statement filed by Astrazeneca in

Form 27 in relation to IN 147, which furnished the working of DAPA; this, too, it was submitted by the respondents, amounted to an acknowledgement, by Astrazeneca, that DAPA was part of IN 147. The respondents further submitted that IN 625 was vulnerable to challenge on the ground of anticipation by prior publication, as IN 147 was published on 19th April, 2001, prior to the priority date of IN 625, which was 20th May, 2002. The complete specifications filed by Astrazeneca, before IN 147 was obtained, it was submitted, claimed and particularly described DAPA. Reliance was placed on the decision in ***Novartis***[9] to contend that there was no distinction between coverage or disclosure; ergo, once Astrazeneca had admitted coverage of DAPA by IN 147, and also alleged infringement, by the defendants, of IN 147, DAPA was obviously known from IN 147, which rendered IN 625 vulnerable to challenge. Further, it was submitted, the subject matter of IN 625 did not contain any inventive step, *vis-à-vis* what was published and publicly known from IN 147. No technical advancement or economic significance of IN 625, over IN 147, was demonstrated. DAPA, therefore, it was submitted, was obvious to a person skilled in the art from the disclosure in IN 147. Once it was accepted that DAPA was one of the compounds covered by the Markush claim in IN 147, it was submitted that Astrazeneca could not plead protection of DAPA on the ground that it was particularly or specifically claimed in IN 625. A selection of one or more, from several compounds in a Markush structure, it was submitted, did not constitute any inventive step. The susceptibility of IN 625 to invalidation was also pleaded on the ground that Astrazeneca had not informed the Indian Patent Office about the status of all its

corresponding foreign patent applications, in respect of the same or substantially the same invention.

26. The Division Bench held that Astrazeneca had, by contending that the defendants' patents infringed both IN 147 and IN 625, *ipso facto* rendered itself ineligible for any interim injunction. It was opined, by the Division Bench, that, by alleging the impugned patents infringed IN 147, Astrazeneca impliedly acknowledged that DAPA was subject matter of IN 147. This, even by itself, rendered IN 625 invalid, *prima facie*. Observing that one invention could be covered by only one patent, the Division Bench held that the very allegation, by Astrazeneca, that the defendants' patents infringed both IN 147 and IN 625, struck at the very root of its plea for interim relief. Allowing repeated inventions for the same patent, observed the Division Bench, would lead to evergreening of the prior art beyond its expiry, rendering it inaccessible to the public; a consequence to be sedulously avoided.

27. Having so observed, the Division Bench went on, nonetheless, to compare the fields of invention as claimed in IN 147 and IN 625, and noted that they were identical, word for word. IN 625, therefore, did not claim to have any technical advancement, or economic significance, over that possessed by IN 147. Noting the fact that the inventor of IN 147 and IN 625 was the same, the Division Bench held that, by failing to cite any technological advancement or economic significance of IN 625 over IN 147 in the plaint specification, the inventor had himself rendered the validity of IN 625 open to trial. On this aspect, the Division Bench forged new jurisprudence, by holding

that the test of obviousness of the infringed patent from the suit patent, where the inventor was the same, would have to be on the basis of the "person in the know", rather than the "person ordinarily skilled in the art". This aspect of the decision, however, is not particularly relevant to the case at hand, as the inventors of IN 176 and IN 161 are different.

28. Even while holding that one invention was entitled only to one patent, the Division Bench relied on Section 10(5) of the Patents Act[47] to observe that one patent could cover many inventions, provided they involved a single inventive step. In such a case, the holder of the patent could sue anyone for infringement, who, by making a slight change in the inventive step, claimed his product to be different. It was clarified, however, that a patent could not be granted for a stage in the inventive process which did not result in a product capable of industrial application.

29. Having claimed infringement of both IN 147 and IN 625, the Division Bench held that Astrazeneca could not, at least at the *prima* facie stage, be granted interlocutory injunction.

The upshot

30. 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

[47] "(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) <u>On patentability</u>

(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. Glenmark***[16], 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

[48] Refer **Novartis**[9]
[49] Refer **Merck v. Glenmark**[16]

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.[54]

[50] Refer **Novartis**[9]
[51] Refer **Roche v. Cipla Ltd**[17]
[52] Refer **Merck v. Glenmark**[16]
[53] Refer **Merck v. Glenmark**[16]
[54] Refer **Astrazeneca v. Intas**[20]

(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. Glenmark***[16], 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.

[55] Refer **Astrazeneca**[20]
[56] Refer **Merck v. Glenmark**[16]
[57] Refer **Roche v. Cipla Ltd**[17]

(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 API[59].

(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 ***Novartis***[9], examining the vulnerability of Imatinib Mesylate to invalidity on the ground of Section 3(d), the Supreme Court held that (i) the obtaining of

[58] Refer **Roche v. Cipla Ltd**[17]
[59] Refer **Roche v. Cipla Ltd**[17]
[60] Refer **Roche v. Cipla Ltd**[17]

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

[61] Refer **Novartis[9]**
[62] Refer **Novartis[9]**

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 ***Novartis***[9], 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 enhanced 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) <u>Coverage, claim construction and disclosure</u>

[63] Refer **Novartis**[9]
[64] Refer **Novartis**[9]

(a) The coverage of a claim, *for the purposes of determination the scope of protection under Section 48 of the Patents Act*[65] 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 tests***[33]. 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

[65] **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."

[66] Refer **Merck v. Glenmark**[16]

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 conduct[68].

(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.

[67] Refer **Merck v. Glenmark**[16]
[68] Refer **Roche v. Cipla Ltd**[17]

the coverage which would be entitled to patent protection under Section 48. The following passage from ***Merck v. Glenmark***[16] 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. Glenmark***[16], 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. Glenmark***[16]. The claim in IN 816, as worded, encompassed "Sitagliptin with its pharmaceutically acceptable salts". Sitagliptin Hydrochloride was specifically exemplified in the complete specifications in

[69] **Bharat Petroleum Corporation Ltd v. N.R. Vairamani, (2004) 8 SCC 579**

IN 816. 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. Glenmark***[16] 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. Glenmark***[16], be the "coverage"

which would trigger the protection provided by Section 48.

(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 art[70].

[70] Refer **Novartis[9]**

(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 ***Novartis***[9]. 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. Glenmark***[16], 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

[71] Refer **Novartis**[9]

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 drug[72].

(vi) Obviousness:

(a) "Prior disclosure", for the purposes of obviousness, meant disclosure which, if performed, would infringe the patent[73].

(b) Prior art, for the purposes of obviousness, was required to have been published before the priority date of the suit patent[74].

(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-I***[17], various combination tests

[72] Refer **Merck v. Glenmark**[16]
[73] Refer **Merck v. Glenmark**[16]
[74] Refer **Merck v. Glenmark**[16] and **Roche v. Cipla Ltd**[17]
[75] Refer **Roche v. Cipla Ltd**[17]

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 common general 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 obviousness[77].

(h) In assessing obviousness, hindsight analysis is impermissible. 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

[76] Refer **Roche v. Cipla Ltd**[17]
[77] Refer **Roche v. Cipla Ltd**[17]
[78] Refer **Roche v. Cipla Ltd**[17]

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 art[80].

(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 patent[81].

[79] Refer **Roche v. Cipla Ltd**[17]
[80] Refer **Astrazeneca v. Intas**[20]
[81] Refer **Merck v. Glenmark**[16]

(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. Glenmark***[16], 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 application[83].

(c) The inert career is not the crux of the invention, as the therapeutic efficacy is attributable to the API alone[84].

[82] Refer **Astrazeneca v. Intas**[20]
[83] Refer **Merck v. Glenmark**[16]
[84] Refer **Merck v. Glenmark**[16]

(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 programme[85].

(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 industry[86].

(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]

[85] Refer **Merck v. Glenmark**[16]
[86] Refer **Merck v. Glenmark**[16]
[87] Refer **Roche v. Cipla Ltd**[17]

(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 patent[88].

(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.[92]

[88] Refer **Roche v. Cipla Ltd**[17]
[89] Refer **Roche v. Cipla Ltd**[17]
[90] Refer **Merck v. Glenmark**[16]
[91] Refer **Merck v. Glenmark**[16] which, on this aspect disagrees with **Roche v. Cipla-I**[17]
[92] Refer **Merck v. Glenmark**[16]

(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 ***Roche***[17], in the context of Erlotinib Hydrochloride *vis-à-vis* polymorph B thereof.

31. 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.

32. 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,

[93] Refer **Merck v. Glenmark**[16]

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.

33. Re. Section 3(d) and enhanced efficacy

33.1 Mr. Sai Deepak has questioned the patentability of EO on the ground that the entire therapeutic efficacy of EO is contained in the Eltrombopag free acid, in respect of which IN 176 already stands granted. EO is, according to Mr. Sai Deepak, merely a "new form of a known substance" and is not patentable, by virtue of Section 3(d), for want of any enhanced therapeutic efficacy of EO over the Eltrombopag free acid. Mr. Hemant Singh has, on the other hand, contended that, by conjunction with the olamine radical, the bioavailability of Eltrombopag to the body is increased manifold. In this context, Mr. Hemant Singh has relied on the tabular statements already extracted in para 9.11 (*supra*).

33.2 That increased bioavailability can be an indicator of increased therapeutic efficacy stands acknowledged even in ***Novartis***[9], the only requirement being that it would be for the holder of the patent, seeking to assert its validity, to establish that the increased bioavailability results in increased therapeutic efficacy. In ***Novartis***[9], the Supreme Court held that no research data in that regard was forthcoming. It cannot be forgotten that these observations in ***Novartis***[9] were in the context of a challenge to the rejection, by the patent office, by ***Novartis***[9] for registration of the patent for its product. In the present case, EO stands already patented *vide* IN 161. ***Merck v. Glenmark***[16]

recognizes that a patent is granted only after a thorough study of the patentability of the product concerned and that, therefore, the Courts must be slow, at the interim stage, in holding patents to be invalid. The onus would be heavily on the defendant to, therefore, establish vulnerability of the suit patent to revocation on the ground of invalidity.

33.3 The challenge in this regard must be credible. Credibility indicates that, on the face of the challenge, it must merit favourable consideration. A credible challenge occupies a higher pedestal than a challenge, which is merely worthy of consideration.

33.4 The tabular and other data provided by Mr. Hemant Singh, extracted in para 10.11 *supra* and which forms part of the record, indicates that, when combined with olamine, there is a much higher yield of Eltrombopag, insofar as bioavailability is concerned. In support of the plea of enhanced therapeutic efficacy, Mr Hemant Singh has, further, pointed out that the maximum plasma concentration of EO was thrice the plasma concentration of the Eltrombopag free acid, which, too, enhanced the therapeutic efficacy of EO vis-a-vis the Eltrombopag free acid. These facts are not denied by the defendant. *This, therefore, is not a case, like* ***Novartis***[9]*, in which the plaintiff has not provided any research data in support of its case. Besides, the Supreme Court, in* ***Novartis***[9]*, was examining the applicability of Section 3(d) from the standpoint of a challenge to rejection of an application for grant of a patent, whereas, here, the issue is one of vulnerability of a granted patent to revocation, and the merits of the claim of the plaintiff to interlocutory injunction in the*

face of admitted infringement by the defendant.

33.5 In the present case, there is no admission, by Novartis, of the therapeutic inhibitory properties of EO being present in the Eltrombopag free base. In view thereof, the contention, of Novartis, that the product patented in IN 161, by reason of its enhanced solubility and bioavailability, possessed enhanced therapeutic efficacy over the product already patented in IN 176 cannot, in my view, be rejected based on ***Novartis***[9], on the premise that, in that decision, the Supreme Court has held, in so many words, that enhanced solubility and bioavailability can never be, by themselves, evidence of enhanced therapeutic efficacy. In my view, they can, but the onus to so establish would be on the person who so asserts.

33.6 I am not, therefore, inclined to hold, at a *prima facie* stage, that a credible challenge to the validity of a suit patent IN 161 has been made out on the ground of want of therapeutic efficacy, either by itself or *vis-a-vis* the Eltrombopag free acid, so as to disentitle the plaintiff to interim injunction.

33.7 As such, no credible challenge to the validity of the suit patent IN 161, on the anvil of Section 3(d) of the Patents Act can, in my view, be said to have been made out by the defendant.

34. <u>Section 64(1)(a) – anticipation by prior claiming</u>

34.1 Mr. Sai Deepak has next contended that the suit patent IN 161 is liable to be invalidated under Section 64(1)(a) of the Patents Act.

Section 64(1)(a) renders patents liable to revocation, where the invention, so far as claimed in any claim of complete specification was claimed in a valid claim of earlier priority date contained in the complete specification of another patent granted in India. The "other patent granted in India" on which Mr. Sai Deepak pegs his challenge under Section 64(1)(a) is IN 176.

34.2 Claim 1 of IN 161 specifically claims EO. The "invention" claimed in the claim in the complete specification of the suit patent is, therefore, EO. The suit patent can be rendered vulnerable to revocation under Section 64(1)(a), because of IN 161, only, therefore, if EO is claimed in a valid claim contained in the complete specification of IN 176. Mr. Sai Deepak has himself provided a tabular comparison of the claims IN 161 and IN 176 and the manner in which according to him, the claims in IN 176 covered the claim in IN 161, which stands reproduced in para 9.2.1 *supra.*

34.3 Mr. Sai Deepak has sought to plead vulnerability to revocation, of the suit patent, IN 161**,** on the ground of anticipation by prior claiming, by dovetailing Section 64(1)(a) and Section 13(1)(b) of the Patents Act. When one examines these provisions, it is immediately apparent that the grounds for revocation of patents are exhaustively contained in Section 64, which constitutes a self-contained code in that regard. Section 64 is not dependent on any other provision of the Patents Act, including Section 13. Section 13, in fact, has nothing whatsoever to do with revocation of patents. Section 13 merely sets out the considerations which are to be borne in mind by the examiner,

to whom an application for grant of patent is marked. How this provision can ever be of relevance while examining the vulnerability of a patent to revocation, frankly, completely escapes me. Section 13, on its face, neither deals with the requirements of a valid patents, grounds for its invalidity or circumstances in which it could be revoked. Where the considerations in Section 13 are relevant for the purpose of Section 64, the statute specifically so states, as in the case of Section 64(1)(e).

34.4 I do not propose, therefore, to advert to Section 13 at all, as, in my view, it is irrelevant when examining the merits of a challenge to validity of a granted patent under Section 64(1)(a).

34.5 Section 64(1)(a) envisages, as a ground for revocation of a patent, the circumstance that "*the invention, so far as claimed in any claim of the complete specification*, was claimed in a valid claim of earlier priority date contained in the complete specification of another patent granted in India".

34.6 The words "so far as claimed", in interpreting Section 64(1)(a), are, in my view, of paramount significance. By using the expression "so far as", the Legislature has made it clear that Section 64(1)(a) would apply only *where the extent to which an innovation is claimed in the complete specification of the patent under challenge is the same as the extent to which it is claimed in the prior art*, on which the challenger places reliance. The claim, whose validity is being challenged, as it appears in the patent, must be identical to the claim in the prior art, or of co-equal extent and amplitude.

34.7 Claim 1 in IN 161 specifically claims EO. If, therefore, Section 64(1)(a) is to be cited as a ground to question the validity of the claim, it would have to be established by the person who is so asserting that the prior art also specifically claims EO, as only then it could be said that EO, *so far as claimed in IN 161*, *stands claimed in the prior art.*

34.8 When one examines the manner in which Mr. Sai Deepak has, in the table extracted at para 9.2.1 *supra*, arrived from the claims in IN 176, to the allegedly corresponding claims in IN 161, one notices the following:

(i) Mr. Sai Deepak has sought to juxtapose Claim 1 in the suit patent IN 161 with Claims 1,4 and 6 of the prior art IN 176 and Claim 2 of the suit patent IN 161 with Claim 8 in the prior art IN 176. He has also sought to juxtapose Claim 3 in the suit patent with claim 9 in the prior art. However, as the plaint does not assert the process patent in Claim 3, it is not necessary to comment on the manner in which Mr. Sai Deepak seeks to contend that Claim 3 in IN 161 was anticipated by prior claiming in Claim 9 of IN 176.

(ii) The manner in which Claim 2 in the suit patent IN 161 is alleged to be anticipated by prior claiming in Claims 1 to 4 in the prior art IN 176 is similar, whereas the manner in which Mr. Sai Deepak links Claim 6 in IN 176 with Claim 1 in IN 161 is somewhat different.

(iii) Claims 1 to 4 in IN 176 are Markush moieties, with suggested substitutions. According to Mr. Sai Deepak, by choosing select substituents from the radicals suggested for substitution in the disclosures accompanying these claims, one can arrive at EO. The manner in which Mr. Sai Deepak conducts this exercise is identical, in so far as Claims 1 to 4 of IN 176 are concerned, and may be explained thus:

(a) In the Markush moiety in IN 176, there are six suggested substitutions, denoted as "R", "R^1", "R^2", "R^3", "R^{15}" and "Y", "R" further contains, for some of the suggested radicals, further substitutions "R^4", "R^5" and "R^6", for each of which there are a number of choices.

(b) The choices suggested for substitution, "R", "R^1", "R^2" and "R^3" are $C_{1\text{-}6}$alkyl, $-(CH_2)_pOR^4$, $-C(O)OR^4$, formyl, nitro, cyano, halogen, aryl, substituted aryl, substituted alkyl, $-S(O)_nR^4$, cycloalkyl, $-NR^5R^6$, protected -OH, $-CONR^5R^6$, phosphonic acid, sulfonic acid, phosphinic acid, $-SO_2NR^5R^6$, and a heterocyclic methylene substituent as represented by Formula (III).

(b) From the suggested substitutions Mr. Sai Deepak selects as under:

(i) For "R", Mr Sai Deepak selects the substituted aryl radical, with a -COOH substitution. The -COOH substituent is not,

however, one of the substituents indicated or "taught" in Claim 1 of IN 176.

(ii) For "R^1", "R^2" and "R^3", Mr. Sai Deepak selects, in each case, hydrogen, from the several substitutions suggested in the said radicals.

(iii) For the figure "M", Mr. Sai Deepak selects "0" from the suggested choices 0 to 6, thereby doing away with the $–CH_2$ radical altogether and retaining only the –OH radical at the fifth position on the phenyl ring.

(iv) For R^{15}, Mr. Sai Deepak selects "alkyl" from the suggested choices which include, apart from "alkyl" C_1-C_{12}aryl, hydroxy, alkoxy, substituted alkyl, substituted C_1-C_{12}aryl and halogen and chooses methyl as the alkyl of choice.

(v) For "Y", Mr. Sai Deepak chooses a six member phenyl aromatic ring, with two methyl substitutions, out of the optional substitutions provided in the complete specifications of Claim 1 of IN 176, which include, apart from alkyl (methyl being an alkyl), substituted alkyl, C_1-C_{12} aryl, substituted cycloalkyl, substituted C_1-C_{12}aryl,

hydroxy, aryloxy, alkoxy, cycloalkyl, nitro, cyano, halogen and protected –OH.

(vi) Finally, Mr Sai Deepak chooses the monoethanolamine salt of the moiety in Claim 1, as the pharmaceutically acceptable salt of the said moiety.

(iv) Insofar as arriving at Claim 1 in IN 161 from Claim 6 in IN 176 is concerned, Mr. Sai Deepak's simple submission is that Claim 6 in IN 176 specifically claims Eltrombopag and its pharmaceutically acceptable salts and that, as EO is a pharmaceutically acceptable salt of Eltrombopag, it stands claimed in Claim 6 of IN 176.

(v) The linkage of Claim 8 in IN 176 with Claim 2 in IN 161 is essentially a fallout of the manner in which Mr. Sai Deepak links Claim 1 in IN 161 with Claims 1 to 6 in IN 176. Claim 2 in IN 161 covers a compound as claimed in Claim 1 of IN 161, as and when used as a pharmaceutical composition along with pharmaceutically acceptable carrier described in the said claim. These carriers being "conventional", Mr. Sai Deepak submits that, as Claim 1 in IN 161 stands claimed in Claims 1 to 6 of IN 176, *per sequitur* Claim 2 in IN 161 would stand claimed in Claim 8 of IN 176.

34.9 Anticipation by prior claiming, it is trite, cannot be asserted by resort to hindsight deduction. It is not permissible for the defendant to

make out the case of vulnerability of the suit patent IN 161 to revocation on the ground of anticipation by prior claiming by cherry picking substituents from those suggested in the complete specifications in the prior art, and substituting them at the appropriate sites in the Markush moiety as to arrive at the suit patent. For anticipation by prior claiming, the claim in the suit patent must be shown to have been claimed as such in prior art.

34.10 EO has not, as such, been claimed in any of the claims in IN 176, which is the prior art. As such, no case of anticipation by prior claiming, *prima facie*, exists, based on the manner in which Mr Sai Deepak has substituted radicals, on the Markush moieties claimed in IN 161, from the substitutions suggested in the accompanying disclosures.

34.11 Mr. Sai Deepak also relied on the Canadian Patent CA 697, PTE applications of the plaintiff (or its predecessor) in respect of the US patent US 870 as well as the application for SPCs, in respect of EP 378, a communication dated 23rd February, 2011 from the USFDA to the USPTO, the entries in the US Orange Book and the declaration filed by the plaintiff before the Canadian Patent Office. The submissions in this regard already stand noted in paras 9.2.4 to 9.2.9 (*supra*).

34.12 Mr. Hemant Singh submits, on the other hand, that the applications for PTE or grant of SPC, per procedure, required disclosure of all patents related to the invention for which extension or

certificate was sought. He submits that the law in the US and in the European Union allows filing of parallel applications for genus and specie patents and that, ultimately, the PTE/ SPC would be granted only for one patent. Similarly, he submits that the US Orange Book includes patents which cover as well as claim an invention in question.

34.13 This throws up the issue of "coverage versus disclosure", on which I have already expressed my opinion, in detail, in the foregoing paragraphs of this judgment. As I have observed, there is a difference between the broad coverage of a claim, based on its wording, and the coverage of the claim as would entitle it to patent protection under Section 48. Patent protection under Section 48 would be available only to the coverage of the claim, as it emerges from the claim construction read with the enabling disclosure accompanying the claim in the complete specifications. Viewed thus, though the broad coverage of Claim 6 in IN 176 would also embrace EO, as a pharmaceutically acceptable salt of Eltrombopag, it cannot be said that EO is claimed in Claim 6 of IN 176, as the wording of the claim read with the enabling disclosure contained in the complete specifications, does not lead one to EO.

34.14 Unlike the situation which obtained in the case of SPM in ***Merck v. Glenmark***[16], as noted by the Division Bench in paras 38 and 39 of the report in that case, there is no enabling teaching, in the complete specifications of IN 176, as would point towards EO, the subject matter of Claim 1 in the suit patent IN 161.

34.15 The reliance by Mr. Sai Deepak on CA 697, the PTE and SPC

applications filed by the plaintiff or its predecessor, in respect of US 870 and EP 378, as well as the entry in the Orange Book, cannot, in my view, constitute the basis for a credible challenge, as would render the suit patent IN 161 vulnerable to revocation under Section 64 of the Patents Act. CA 697 merely states that, in the reaction which proceeds towards the final step to reach Examples 64 and 65 in that patent, "a salt of some form" is inevitably formed. This is a completely vague statement. In fact, the very same specification goes on to state, clearly, that none of the final compounds in the PTE application corresponding to US 870 specifically discloses a salt form. In so far as the applications of Novartis, or its predecessor, for grant of PTE or SPC, are concerned, Mr. Hemant Singh has pointed that the reference, in the applications, to US 870 as "reading on" the approved drug product would, at best, indicate that it *covered* the drug product, and not that it *disclosed* or *claimed* it. In this context, he has also pointed out that, in the US, a patentee could file PTE applications for more than one patent covering the same drug product.

34.16 Given the difference between "coverage" and "disclosure", and the claim being dependent on enabling disclosure rather than coverage, I am, *prima facie*, unable to hold that, merely because Novartis, or its predecessor, while applying for PTE for US 870 or SPC for EP 378, may have stated that the said patents "read on" to the approved drug product, EO stood claimed or disclosed either in US 870 or in EP 378. At best, these are matters which would require detailed examination during trial. They cannot be treated as evincing a credible challenge regarding vulnerability of the suit patent IN 161.

This conclusion would also apply, with equal force, to the entries in the US Orange Book as well as the communication from the USFDA to the USPTO.

34.17 That apart, I am of the considered opinion that, absent other circumstances, such applications and communications, relating to patents for the drug in question, applied for or granted in foreign jurisdictions, can be relevant for assessing the vulnerability of a patent granted in India only to a limited extent, and no more. Else, the challenger relying on such material would have to make a *prima facie* case of synonymity, or at least considerable similarity, between patent law as it obtains in this country and patent law as it obtains in the concerned foreign jurisdictions. Absent such analogy, following the principles enunciated in ***Merck v. Glenmark***[16], it would be hazardous for the court to refuse a prayer for interim injunction, even where infringement is otherwise established, by relying on such material, pertaining to applications for grant of PTE or SPC made in foreign jurisdictions, or on communications between entities located in such jurisdictions.

34.18 These facts, too, do not, therefore, in my view, make out a case of vulnerability of the suit patent IN 161 to revocation on the ground of anticipation by prior claiming.

34.19 Mr. Sai Deepak has also relied on the Form 27s, filed by Novartis in respect of IN 176 and IN 161, before IN 161 was patented and thereafter. He has invited my notice to the fact that, prior to IN 161 bein patented, the Form 27s filed by Novartis in respect of IN 176

reflected the patent as "not worked" and did not quite obviously contain details of any product. As against this, the Form 27s filed even in respect of IN 176 after IN 161 had been patented, reflected IN 176 as "worked" and contain the details of EO, which were identical to the details provided in the corresponding yearly Form 27s filed in respect of IN 161. Mr. Sai Deepak's attempt is to convince the Court that the identity of the declarations in the Form 27s filed by Novartis after IN 161 had been patented indicates that EO was the patented invention both for IN 176 and IN 161. This, according to him, indicates that EO was claimed in IN 176 and that, therefore, IN 161 is liable to revocation on the ground of anticipation by prior claiming.

34.20 On first principles, and applying the law laid down by the Division Bench of this Court in ***Merck v. Glenmark***[16] read with the discussion hereinabove, this argument, *prima facie,* does not commend acceptance. ***Merck v. Glenmark***[16] has made it absolutely clear that claim construction is to be based on the wording of the claim read with its enabling disclosures as contained in the complete specifications. Whether or not, a subsequent patent is vulnerable to revocation on the ground of anticipation by prior claiming would, therefore, have to be examined by comparing the claims, construing them by applying these principles. In ***Merck v. Glenmark***[16]**,** however, it is clarified that, in construing the claim in a patent, *one is not to refer to any declaration or representation made prior to the grant of the patent or subsequent thereto*. The representations made in the yearly Form 27s, filed after the patent was granted, cannot, therefore, be of significant value in construing the claim or examining the issues of vulnerability of the patent or of infringement.

34.21 Declarations in Form 27s cannot, *prima facie*, constitute a basis for asserting anticipation by prior claiming where, on its plain reading, the claim of the invention, *so far as claimed* in the suit patent, is not claimed in the prior art. The fact that, in the Form 27s which may have been filed in respect of the prior art, after the suit patent was granted, the product emerging from the suit patent was cited, cannot lead to a conclusion of anticipation by prior claiming.

34.22 On the binding effect of declarations made in Form 27s, in respect of a claim of vulnerability to revocation on the ground of anticipation by prior claiming, there is no direct authority of either of the Supreme Court or of any Division Bench of this Court. Learned Single Judges of this Court have differed on the point, with one view[94] being that the declarations in the Form 27s would not make a difference, where the identity in the Form 27s for the prior art and the suit patent was only after the suit patent had been granted, and another[95] being that the identity in the Form 27s indicated, *prima facie*, that the product claimed in the prior art and in the suit patent were the same. Both are *prima facie* opinions and are not, therefore, binding. For myself, I am inclined to the former view.

34.23 In this context, it is also relevant to note that Section 146(2) of the Patents Act requires the patentee to furnish statements "as to the extent to which the patented invention has been worked on a commercial scale in India". Prior to IN 161 being granted, IN 176

[94] **Astrazeneca AB v Torrent Pharmaceuticals Ltd. (2020) 275 DLT 361**
[95] **Astrazeneca AB v P. Kumar. 2019 SCC OnLine Del 9555 ,** supra note 19

was not being worked on a commercial scale in India. There is no dispute about the fact that EO is a pharmaceutically acceptable salt of Eltrombopag and is, to that extent, covered by Claim 6 of IN 176. If, therefore, after IN 161 had been granted, and EO, which was covered (though not disclosed) in Claim 6 in IN 176 was specifically patented, Novartis reflected this position in the Form 27s filed by it in respect of IN 176, that, in my view, cannot *prima facie* lead to a conclusion that EO stood *claimed* in Claim 6 of IN 176. The declarations in Form 27 filed by Novartis in respect of IN 176, cannot, therefore, substantiate the claim of anticipation by prior claiming, as raised by Mr. Hemant Singh.

34.24 In ***Astrazeneca v. Intas***[20], there is a finding, by the Division Bench, that the assertion, of Astrazeneca, that the product of the respondents in the appeals infringed both the genus (IN 147) as well as the specie (IN 625) patents itself disentitled Astrazeneca to interim injunction. Mr. Sai Deepak has sought to contend that, in the present case, too, Novartis had alleged, in the plaint, that the defendants' product had infringed both IN 176 as well as IN 161 and was, therefore, *ipso facto* disentitled to interlocutory relief. I am not inclined to agree. While it is true that this observation does find place in ***Astrazeneca v. Intas***[20], the Division Bench did not dismiss Astrazeneca's appeal on that sole ground. Rather, it queried, of Astrazeneca, as to whether it was continuing to assert both IN 147 and IN 165. Para 43 of the report, in fact, expresses surprise at Astrazeneca, despite this query, continuing to assert both the patents, and goes to the extent of opining that the Bench expected Astrazeneca to have given up the plea of infringement of the genus patent IN 147.

Astrazeneca having, however, not chosen to do so, the Division Bench held that it had disentitled itself from any right to interlocutory relief. The corollary, obviously, is that, had Astrazeneca agreed not to press the genus patent, the Bench would have viewed the issue otherwise. In the present case, though there is an averment, in para 11 of the plaint, that the defendant had infringed both IN 176 as well as IN 161, Mr. Hemant Singh has, during arguments, confined himself to asserting IN 161. The written submissions filed by Mr. Hemant Singh are also to the same effect. The lone reference in para 11 of the plaint cannot, therefore, in my view, be treated as a basis for refusing interim injunction to the plaintiff. Significantly, the Division Bench in ***Astrazeneca v. Intas***[20], too, did not content itself with proceeding on the basis of the "dual assertion" by Astrazeneca, but went on to examine, on merits, the aspect of infringement, as well as the plea of vulnerability of IN 625 to invalidity.

35. Section 64(1)(d) and obviousness:

35.1 The arguments of Mr. Sai Deepak, predicated on the table from his written submission, extracted in para 9.2.1 *supra*, may, at best, be urged as a ground to plead vulnerability of the suit patent IN 161, to revocation on the ground of obviousness from the prior art IN 176. For obviousness to be established, however, it has to be shown that a person skilled in the art, in possession of the complete specifications of the prior art, and intending to arrive at a formulation which fulfils the purpose achieved by the suit patent would, on the basis of the teaching in the prior art, be able to arrive at the suit patent without

having to undergo any detailed exercise or research. When one compares Claims 1 to 4 in the prior art IN 176 with Claim 1 in the suit patent IN 161, it is clear that the exercise undertaken by Mr. Sai Deepak is one of hindsight analysis. The submission of Mr. Sai Deepak does not indicate why, out of the several substitutions suggested for each of the radicals in Claims 1 to 4 in IN 176, he picks and chooses the substitutions which would lead him to Claim 1 in IN 161. Nor does Mr. Sai Deepak make out a case that the requisite teaching, to select the said substitutions, is to be found in the prior art IN 176.

35.2 Motivation to select the particular substitution out of the several substitutions provided in the prior art, and motivation to substitute at the appropriate site, so as to achieve the purpose that the suit patent achieves, are both required to be shown to exist in the prior art itself, in order for a *prima facie* case of obviousness to be made out. The submissions of Mr. Sai Deepak stop short of showing that any such motivation exists. Nor, on a reading of the complete specifications of the prior art, IN 176, is the court able to discern any such teaching as would render it obvious, to a person skilled in the art and in possession of the complete specifications of IN 176, that he is required to effect the substitutions that Mr. Sai Deepak has sought to effect. The exercise undertaken by Mr. Sai Deepak, in arriving at Claim 1 of IN 176, from Claims 1 to 5 of IN 161, is, therefore, clearly one of hindsight analysis which, as per ***Roche v. Cipla***[17], is not permissible.

35.3 Claim 6 in IN 176, on the other hand, does actually claim Eltrombopag and pharmaceutically acceptable salts thereof. Mr. Sai Deepak's pointed submission was that, as EO, is a pharmaceutically acceptable salt of Eltrombopag, Claim 6 in IN 176 claims and discloses EO. Mr. Hemant Singh contends, *per contra,* that there are several pharmaceutically acceptable salts of Eltrombopag, and that every pharmaceutically acceptable salt of Eltrombopag cannot be treated as having been disclosed in Claim 6 in IN 176. He contends that, in fact, EO as a pharmaceutically acceptable salt of Eltrombopag, was unknown prior to the priority date of IN 161, and that, therefore, it was a novel invention, at which the plaintiff arrived after undertaking considerable research.

35.4 The inventors of IN 176 and IN 161 are different. The Court does not, therefore, have the benefit of the view of the inventor as was available to the Division Bench in ***Merck v. Glenmark***[16].

35.5 In view of the principles enunciated hereinabove, it cannot be said that Claim 6 contains an enabling disclosure, as would enable a person skilled in the art to arrive at EO from the said claim in IN 176.

35.6 Nor do the complete specifications in IN 176 contain any such teaching, guideline or indicator, on the basis of which, applying any of the various tests suggested in ***Roche v. Cipla***[17] to assess obviousness, it can be said that the selection of olamine as the pharmaceutically acceptable salt of Eltrombopag, in order to arrive at the purpose satisfied by EO, was obvious. The onus to prove obviousness is on the

party asserting obviousness. It would be, therefore, for the defendant, who seeks to allege that EO was obvious from Claim 6 in IN 176, to establish that the complete specifications in IN 176 contained the requisite teaching as would enable a person skilled in the art to select the olamine radical as the pharmaceutically acceptable radical to be combined with Eltrombopag, to enable him to arrive at an effective treatment for chronic idiopathic thrombocytopenia, having the advantages possessed by EO.

35.7 At a *prima facie* stage, I am hesitant to hold that such a case is made out. Simply put, it does not appear to me, *prima facie,* that every pharmaceutically acceptable salt of Eltrombopag, even if known prior to the priority date of the suit patent, IN 161, is obvious from the teachings in IN 176. This, in my view, would amount to stretching the principle of obviousness beyond all known acceptable limits.

35.8 I am unable, therefore, to hold, *prima facie,* that the claim in the suit patent, IN 161 is vulnerable to revocation on the ground of obviousness, *vis-à-vis* Claim 6 in IN 176. In this context, the decision in ***Merck v. Glenmark***[16], provides guidance, as, in that case, too, though, SPM was, admittedly, a pharmaceutically acceptable salt of the SFB, the Division Bench was hesitant to hold, at the *prima facie* stage, that SPM was obvious from the teachings in the prior art. This, even after having, in paras 38 to 39 of the report, held that, *prima facie,* the requisite teaching on the basis of which one could proceed from the SFB to SPM was *actually contained* in the prior art (IN 816). The Division Bench noted the fact that, in IN 816, the SFB was expressly claimed, and, further, the teachings forward included

reference to the racemix enantiomer of the free base, its phosphate salt and hydrates thereof. Despite such detailed teaching contained in the prior art in IN 816, the Division Bench in ***Merck v. Glenmark***[16], did not choose to return a *prima facie* finding that the route, to arrive at SPM, was actually charted out in IN 816, stating that this was appropriately a matter to be decided in trial.

35.9 The same principle, in my view, would have to apply in the present case, when examining the contention of Mr. Sai Deepak that Claim 1 in the suit patent, IN 161 was obvious from the teachings in Claim 6 of IN 176. Unlike the position which obtained in ***Merck v. Glenmark***[16], there is no teaching in Claim 6 of IN 176, except a reference to "pharmaceutically acceptable salts", as would indicate, to a person skilled in the art, that he would have to choose the olamine salt.

35.10 In this regard, the submission of Mr. Hemant Singh that, prior to the priority date of the suit patent IN 161, EO as a pharmaceutically acceptable salt of Eltrombopag was altogether unknown, also merits consideration. Though Mr. Sai Deepak has referred to certain prior arts which refer to olamine salts, Mr. Hemant Singh has pointed out that none of those prior arts deal with any product which is even akin to the claim in the suit patent. He has pointed out that US 976 relates to the Ethanolamine salt of NPHA used in acrylic industry in paints, fibers, building and construction and automobiles, as an advantage to prevent polymerisation over the ammonium salt of NPHA. It does not, therefore, belong to a pharmaceutical salt or relate to the

pharmaceutical industry. The person skilled in the art, for the purpose of obviousness, cannot be treated as so skilled that he would look towards prior art which has nothing to do with pharmaceuticals, to arrive at a compound which could treat chronic idiopathic thrombocytopenia. The "art", in which the person is required to be skilled, is, obviously, the art to which the patent, the validity of which is being sought to be called into question on the ground of obviousness, relates. The "person skilled in the art" has, therefore, in the present case, to be a person skilled in the "pharmaceutical art", aware of Eltrombopag and its angularities.

35.11 US 976 is not, therefore, relevant prior art for IN 161.

35.12 Though Mr. Sai Deepak did not advance oral arguments on any of the other foreign patents on the basis of which obviousness was pleaded by the defendant in its written statement, he has, in his written submissions, adverted to US 185, US 831 and US 666, in support of the plea of obviousness. The corresponding written submissions of Mr. Hemant Singh have dealt with these patents as well.

35.13 US 185, it is pointed out, is a formulation for use of sulphonamides, to be added to drinkable water for consumption by animals. The product covered by the patent is, therefore, essentially veterinary in nature. US 831, it is pointed out, advices against use of the olamine salts in conjunction with the piroxicam radical, which was subject matter of that patent, as piroxicam ethanolamine

destabilises at 30^0 C. US 666, too, does not advocate the use of the methanolamine radical, again in the context of piroxicam.

35.14 The reliance by Mr. Sai Deepak, on these patents is, in my view, fundamentally misplaced, as they do not deal with the olamine radical in conjunction with Eltrombopag. Mr. Hemant Singh has categorically asserted that EO, as a salt, was unknown prior to the priority date of the suit patent IN 161. This assertion cannot be sought to be traversed by merely pointing out that Olamine, as a base radical, in conjunction with other free acid radicals was known to the industry, especially where the salts do not even deal with pharmaceuticals, let alone with treatment of chronic idiopathic thrombocytopenia. No case of vulnerability of the suit patent IN 161 to revocation on the ground of obviousness, by reference to these patents can, therefore, be said, *prima facie*, to have been made out.

36. Section 64(1)(e) and anticipation by prior publication:

36.1 Mr. Sai Deepak also questions the validity of the suit patent IN 161 on the ground of anticipation by prior publication, invoking for the purpose, Section 64(1)(e) of the Patents Act. He relies for this purpose, on the publications contained in WO 457.

36.2 Section 64(1)(e) envisages, as a ground for revocation of a patent, "that the invention so far as claimed in any claim of the complete specification is not new, having regard to what was publicly known or publicly used in India before the priority date of the claim or

to what was published in India or elsewhere in any of the documents referred to in Section 13". The plea of vulnerability of the suit patent IN 161 on the ground of anticipation by prior publication, as advanced by Mr. Sai Deepak, is predicated on the latter half of this Clause. Section 64(1)(e) refers back to Section 13. Anticipation by publication finds reference in Clauses (1)(a) and (2) of Section 13. Section 13(1)(a) refers to anticipation by publication of the applicant's complete specifications in any specification filed in pursuance of an application for a patent made in India and does not, therefore, apply to the ground taken by Mr. Sai Deepak. Section 13(2) refers to anticipation by publication of the invention, so far as claimed in any claim of the complete specification, by publication in India or elsewhere in any document before the date of filing of the complete specification of the suit patent. The use of the expression "so far as claimed", in Section 13(2) would, therefore, require identity in the extent of claim contained in the specification in the suit patent and in the specification of the prior art which is cited for the purpose of alleging anticipation by prior publication.

36.3 Mr. Sai Deepak has alleged anticipation by prior publication of the suit patent IN 161 on the basis of the WIPO patent WO457 – which is the basis of all the suit patents granted in respect of Eltrombopag, including IN 176, the SPC and PTE requests filed in respect of EP 378 and US 870, the letter from the US FDA to the US PTO relating to US 870 and the details in the Canadian Health Register. Though the disclosure in WO 457 is relied upon, the defendant has not placed it on record. WO 457 was, however, none

other than the International Publication corresponding to IN 176. It is but natural, therefore, that the disclosures in WO 457 and IN 176 would be identical. The reference to WO 457, therefore, is, clearly, merely an attempt to make it appear that EO was published in yet another document and, in my view, does not make out an additional ground in favour of the defendant.

36.4 The applications filed for PTE in respect of US 870, SPC in respect of EP 378, the communication from the US FDA to the US PTO and the details relating to the Canadian patent have already been dealt with hereinbefore.

37. Section 8 – alleged suppression of details relating to proceedings in respect of Canadian patent

37.1 Mr. Sai Deepak contends that, while applying for grant of IN 161, Novartis suppressed the details relating to CA 2486697 ("CA 697") as was required by Section 8 and that, therefore, IN 161 is vulnerable to revocation under Section 64(1)(m) of the Patents Act.

37.2 ***Merck v. Glenmark***[16] clearly holds that, ordinarily, unless the breach is clear and indisputable, a prayer for injunction ought not to be refused on the ground of vulnerability to revocation for violation of Section 8, at the interim stage.

37.3 That apart, CA 697 which forms the fulcrum of the allegation of Mr. Sai Deepak regarding infraction, by Novartis, of Section 8, is not forthcoming from the record. Specific reliance has been placed by Mr. Sai Deepak on examples 64 and 85 in the said patent. What these

examples refer to, is anybody's guess. Mr. Sai Deepak has extracted certain passages from the response dated 6th July, 2007 filed by the plaintiff to the inquiry of the examiner, in respect of the patent application filed by the plaintiff. The response notes that the reaction conditions for the final step in arriving at the claims in examples 64 and 85 of CA 697 involved reaction with trifluoroacetic acid. Mr. Sai Deepak has not placed anything on record to indicate that in any reaction relating to IN 176, trifluoroacetic acid is used.

37.4 At the very least, it is apparent that the details placed on record by Mr. Sai Deepak are woefully insufficient for this Court to hold that IN 161 is vulnerable to revocation under Section 64(1)(m) of the Patents Act, especially in view of the note of caution sounded in this regard by the Division Bench in ***Merck v. Glenmark***[16].

37.5 Mr. Sai Deepak has also placed reliance on the alleged inclusion, by Novartis, in the Canadian Health Register, of the 25 mg and 50 mg doses of Revolade, in connection with both CA 2411468 (hereinafter 'CA 468', which corresponds to IN 176) and CA 697. This, according to Mr. Sai Deepak indicates that CA 468 claimed EO.

37.6 There is nothing to indicate that, while making an entry in the Canadian Health Register, the compounds cited are necessarily those which are claimed in the patents to which reference is made. Even otherwise, it is obvious, to me, that entries made in the Canadian Health Register can hardly serve as a basis to question the validity of IN 161, on the anvil of Section 64 of the Patents Act.

38. A concluding observation

38.1 Before closing the discussion, I wish to enter a final observation. There appears, *prima facie*, to me, to be a fundamental misconception relating the concepts of a "credible challenge" and of "vulnerability". The submissions advanced by the defendant seem to have been predicated on the premise that the slightest shadow of doubt, which could be cast on the suit patent, was sufficient to constitute a credible challenge, exposing its vulnerability to revocation. This proposition, according to me, is completely misconceived. Para 28 of the report in ***Bishwanath Prasad Radheyshyam***[19] recognises the fact that, prior to grant of a patent, especially for a pharmaceutical product, a thorough study is normally undertaken by the Patent Office, regarding the validity of the patent as sought. When an infringer seeks to defend infringement on the ground that the patent that he infringes is invalid, the onus, to prove such invalidity heavily lies on him. This standard has to be met, when applying the principle of "credibility". Repeated attempts were made to convince me that any and every ground that the defendant sought to raise, and for which a cast iron response from the plaintiff was not immediately forthcoming, was sufficient to establish vulnerability of the suit patent to revocation. Revocation is a drastic act, and a patent, once granted, cannot be treated as easily vulnerable to revocation. Even if, *prima facie*, a ground for revocation is made out, as is noted in ***Merck v. Glenmark***[16], revocation is not automatic, but remains a matter of discretion, for the patent authority. The grant of such discretion is itself a pointer to the legislative intent that, before

revoking a patent, the authority is required to satisfy itself, that, all considerations having been mould in mind, revocation is absolutely necessary. Vulnerability to revocation has also to be judged on the same standard. It is only when, judged on that standard, a credible challenge to the validity of the patent as vulnerable to revocation is made out, that an infringer can escape the consequences of infringement. The standard is, therefore, high, rather than low.

38.2 This would especially be so in a situation, as in the present case, the infringer never choose to challenge the suit patent either at pre-grant or at post-grant stage, by filing oppositions. The defendants have not, therefore, "cleared the way", before exploiting the suit patent. Mr. Sai Deepak sought to contend that, by deferring the release of their Eltrombopag Olamine, till the expiry of the term of IN 176, the defendants had sufficiently cleared the way. Mr. Hemant Singh has disputed this contention, and I confess that I agree with him. IN 161 was granted as far back as on 27th March, 2009. It has remained in force for 12 years. The defendants have neither chosen to launch any pre-grant or post-grant, opposition to IN 161. Nor have they filed any proceedings before the patent office or the IPAB, to cancel or suspend the registration granted to IN 161. Rather, even while IN 161 continues to remain valid, the defendants have, without blinking an eyelid, sought to exploit the subject matter of the said patent, i.e. EO. That they have done so with the full awareness that EO is specifically claimed in IN 161, is not disputed. Clearly, therefore, the defendants have, by their attitude, as well as by failing to clear the way before

exploiting the suit patent, IN 161, exposed themselves to an interlocutory injunction.

38.3 It is only when they have been "caught in the act", as it were, that the infringer defendants, unable to dispute the charge of infringement on facts, seek to question the validity of the suit patent. While Section 64, undoubtedly, allow them to do so, the challenge has to be credible, not incredible. The defendants, in the present case, neither launched any pre-grant nor any post-grant, opposition to IN 161. They have not initiated any proceeding before IPAB or any other authority, for revocation, cancellation or removal of the suit patent from the register of patents. In such circumstances, the holder of the suit patent would ordinarily be entitled to an injunction against continued infringement. Absent any *prima facie* case of vulnerability of the suit patent to revocation on the ground of invalidity, therefore, injunction cannot be refused, once infringement is established.

39. Arguments before me, by both sides, were protracted and amounted almost to an argument of the entire suit. At a *prima facie* stage, I do not propose to deal with these submissions in any further detail than I have chosen to do hereinabove. Suffice it to state that, on the submissions of Mr. Sai Deepak, despite his eloquence do not convince me that a *prima facie* case of vulnerability of the suit patent IN 161 to revocation exists, on any of the grounds envisaged by Section 64 of the Patents Act and on which Mr. Sai Deepak has placed reliance.

40. Infringement being established, the plaintiff is entitled to an order of injunction.

41. Conclusion

41.1 Accordingly, pending further orders, the defendant is restrained by itself or through its directors, group companies or sister concerns, associates, divisions, assigns in business, licensees, franchisees, agents, stockist, distributors and dealers from using, manufacturing (either through itself or through third parties), importing, selling, offering for sale either by way of promotion or tender or any other means, exporting, directly or indirectly dealing in Active Pharmaceutical Ingredient (API), pharmaceutical products, or formulation containing Eltrombopag Olamine (Eltrombopag bis(monoethanolamine)) either alone or in combination with any other compound or API or in any other form as may amount to infringement of suit patent IN 233161 of the Plaintiff 1 either under the brand Trombopag or any other brand;

41.2 The application stands allowed accordingly.

C. HARI SHANKAR, J.

DECEMBER 13, 2021
kr/r.bararia/dsn/ss