IN THE HIGH COURT OF DELHI AT NEW DELHI

% Judgment delivered on: 24.04.2024

\+ **FAO(OS) (COMM) 178/2021 and CM Nos.46299/2021, 46300/2021, 46301/2021, 46302/2021, 19118/2022, 19119/2022 and 30850/2022**

NATCO PHARMA ..... Appellant

versus

NOVARTIS AG AND ANR. ..... Respondents

Advocates who appeared in this case:

For the Appellant : Mr J. Sai Deepak, Mr G. Nataraj, Mr Shashikant Yadav, and Mr Rahul Bhujbal, Advocates.

For the Respondents : Mr Hemant Singh, Ms Mamta Rani Jha, Mr Siddhant Sharma and Ms Garima Mehta, Advocates.

CORAM
HON'BLE MR JUSTICE VIBHU BAKHRU
HON'BLE MR JUSTICE AMIT MAHAJAN

JUDGMENT

VIBHU BAKHRU, J

INTRODUCTION

1. The appellant (hereafter referred to as *Natco*) has filed the present appeal impugning a judgment dated 13.12.2021 (hereafter *the impugned judgment*) delivered by the learned Single Judge in an application filed by the respondents (hereafter collectively referred to as *Novartis*) under

Order XXXIX Rules 1 and 2 of the Code of Civil Procedure, 1908 (hereafter *the CPC*) being IA No. 6980/2021 in CS(COMM) 256/2021, seeking an interim relief.

2. The respondents had filed the aforementioned suit, *inter alia*, seeking a decree of permanent injunction restraining Natco from using, manufacturing, importing, selling, offering for sale, exporting,–or dealing in Active Pharmaceutical Ingredient (hereafter *API*), or formulations containing Eltrombopag bis (monoethanolamine) as may amount to infringement of its suit patent IN 233161 (hereafter also referred to as *IN'161* or *the suit patent*). Novartis also seeks rendition of account of profits earned by manufacture and sale of infringing products; damages based on profits earned by Natco through its infringing activities; and a decree for delivery of stocks of products that infringe the suit patent.

3. The application for interim relief was allowed. In terms of the impugned judgment, the learned Single Judge has restrained Natco from manufacturing, using, selling, distributing, advertising, marketing, exporting, offering for sale, importing or dealing in any manner in API, pharmaceutical products, or formulation containing Eltrombopag bis (monoethanolamine) (hereafter *Eltrombopag Olamine* or *ELT-O*) either separately or in combination with any other compound, infringing the suit patent, of respondent no.1 (hereafter *Novartis AG*), either under the brand "Trombopag" or any other brand.

4. Novartis had filed the afore-mentioned suit alleging infringement of the suit patent, IN' 161, granted on 27.03.2009 (species patent) pursuant to the Patent Application No.3400/DELNP/2004, which was filed as a national phase entry of Patent Cooperation Treaty (PCT) International Application No.PCT/US2003/16255 dated 21.05.2003. The said application was filed by SmithKline Beecham Corporation (subsequently known as GlaxoSmithKline LLC). GlaxoSmithKline LLC had assigned the suit patent to Glaxo Group Limited on 05.10.2015. On the same date, Glaxo Group Limited had assigned the suit patent to Novartis Pharma AG, which in turn assigned the suit patent to Novartis AG (respondent no.1). Novartis claims that it was constrained to file the suit [CS(COMM) 256/2021] as it had become aware through the field force and medical practitioners that Natco had announced the launch of a pharmaceutical drug product containing ELT-O, which was covered by the suit patent.

5. It is Natco's defence that ELT-O was covered under an earlier Patent No. IN 213176 (hereafter *IN'176*), which expired on 24.05.2021. Thus, ELT-O was not entitled to any patent protection after 24.05.2021. Natco has filed its written statement contesting the suit principally on three fronts. First, that the suit is barred under Section 53(4) of the Patents Act, 1970 (hereafter *the Act*); Novartis has not, *prima facie*, satisfied the condition that the suit patent is valid and; the suit patent is invalid on several grounds as set out in Section 64(1) of the Act.

6. It is Natco's case that two separate patents were secured in respect of the same product being ELT-O by suppression and misrepresentation. Whilst, IN'176, which covered the API Eltrombopag (hereafter also referred to as *ELT*) as well pharmaceutically acceptable salts, expired on 24.05.2021, after expiry of the period of twenty years, the monopoly in respect of the same product is claimed on account of securing the suit patent. Natco claims that this is an attempt to evergreen the patent in respect of ELT.

7. There is no dispute that IN'176 covers the product ELT-O. However, Novartis claims that IN'176 is a Markush claim and discloses Eltrombopag free acid (ELT); it does not disclose ELT-O, which is the subject matter of rights under IN'161.

8. It is not seriously contested that ELT, which is covered under IN'176 is the API in the formulations marketed by Novartis under the brand names PROMACTA™ and REVOLADE™. REVOLADE™ received marketing approval in India on 05.01.2011. Admittedly, REVOLADE™ was covered in IN' 176.

9. ELT is also the API of Tromobopag (the formulation launched by Natco) and is the subject matter of the interim injunction issued in terms of the impugned judgement. The suit patent, IN' 161 covers the substance, ELT-O which is a salt form of ELT.

10. The principal controversy that falls for consideration is whether Natco has presented a credible challenge to the validity of IN'161.

Natco claims that there is no evidence or material on record to establish that ELT-O has a higher therapeutic efficacy than ELT, which is admittedly disclosed and covered by IN'176. It claims that ELT-O is a new (salt) of a known substance (ELT) and therefore, is not patentable on the anvil of Section 3(d) of the Act. It claims that ELT-O is not an invention and therefore its patent, IN'161 is invalid [Section 64(1)(d) of the Act].

11. Natco also assails the validity of the suit patent on the following grounds:

- Prior claiming [Section 64(1)(a) of the Act] as covered under the expired patent IN'176.
- The claim ELT-O is not an invention [Section 64(1)(d) of the Act] being a new form (Salt) of a known substance.
- Lack of novelty [Section 64(1)(e) of the Act]
- Lack of inventive step [Section 64(1)(f) of the Act]
- Obtained by misrepresentation [Section 64(1)(j) of the Act]
- Claim not patentable under the Act [Section 64(1)(k) of the Act]
- Failure to disclose information under Section 8 of the Act [Section 64(1)(m) of the Act]

12. In the present proceedings, Natco's principal challenge is founded on ELT-O not being an invention in terms of Section 3(d) of the Act which has been pressed in conjunction with the patent being invalid on account of prior claiming, prior publication, lack of inventive step amongst other grounds.

13. Novartis claims that although, ELT-O is a salt of ELT, it falls within the exception of Section 3(d) of the Act as its therapeutic efficacy is significantly higher than ELT on account of higher bioavailability.

FACTUAL BACKGROUND

14. As noticed above, the controversy in this appeal, essentially, involves the questions whether Natco has laid a credible challenge to the validity of the suit patent and whether Novartis was entitled to an interim injunction restraining Natco from dealing with ELT-O which was launched under the trade name TROMBOPAG™. The substratal dispute being, whether Novartis is entitled to patent rights in respect of ELT-O, notwithstanding that ELT-O was also covered under IN'176 which expired prior to Natco launching its product.

IN'176

15. Novartis AG is the patentee of the expired patent IN'176. SmithKline Beecham Corporation, a company organised under the laws of Pennsylvania, the United States of America had applied for the said

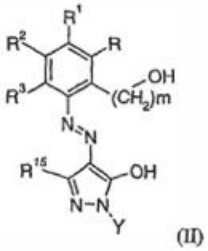
patent in continuation of the US Application No.10/296688 filed on 03.07.2000 claiming priority of International Application No.PCT/US01/16863 filed on 24.05.2001. The same was ultimately assigned to Novartis AG.

16. IN'176 expired on 24.05.2021.

17. The applicant had disclosed that invention related to Thrombopoietin (TPO) mimetics and their use as promoters of thrombopoiesis and megakaryocytopoiesis. The invention ELT, which is the subject matter of IN'176, was claimed to be effective as an agonists of TPO receptor and potent TPO mimetics. ELT is claimed to be useful in enhancing platelet production and is indicated for treatment of chronic idiopathic thrombocytopenia (that is, abnormally low platelet counts), which was noticed in patients suffering from immune system disorders, leukaemia as well as side effects due to certain drugs and surgical procedures.

18. The applicant had made, in all, nine claims. Claim Nos. 1 to 8 consist of substances and Claim no.9 relates to a process for preparing the compound. It is relevant to refer to Claim nos.1 to 8, which are set out below:

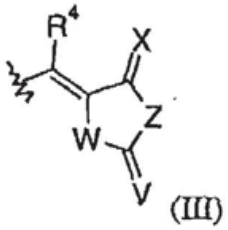
IN 213176
Claim 1: A compound represented by the following Formula (II):



(II)

wherein:

R, R^1, R^2 and R^3 are each independently selected from hydrogen, C_{1-6}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 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 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 **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**, 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 8: A pharmaceutical composition for use in enhancing platelet production which comprises a compound as claimed in claim 1 and a pharmaceutically acceptable carrier.

19. The background of the invention as set out in the patent application indicates that the invention Thrombopoietin (TPO) was found in several studies to increase platelet counts, platelet size, and isotope incorporation into platelets of recipient animals. Since, platelets (thrombocytes) are necessary for blood clotting, patients with low platelet count are at risk of death from haemorrhage. TPO has potentially useful application in both diagnosis and treatment of various haematological disorders. It was stated that ongoing clinical trials with TPO indicate that TPO can be administered safely to patients. Further, studies had provided the basis for projection of efficacy of TPO therapy in the treatment of thrombocytopenia, and particularly thrombocytopenia resulting from chemotherapy, radiation therapy, or bone marrow transplant as a treatment for cancer or a treatment of lymphoma. Thus, it would be desirable for the treatment of thrombocytopenia by acting as a TPO mimetic. The compounds as claimed were discovered as effective, agonists of TPO receptor and are potent TPO mimetics.

IN'161

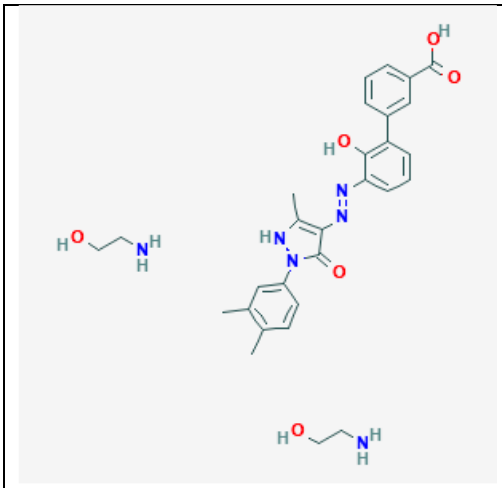
20. The suit patent is in respect of the following invention:

> "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)"

21. Novartis AG's predecessor claimed that the aforesaid invention relates to an improved thrombopoietin mimetic. The aforesaid invention is covered under Claim no.1. Claim no.2 is of the aforesaid compound as and when used as a pharmaceutical composition along with the pharmaceutically acceptable carrier or diluents of the kind as described. Claim no.3 related to the process of preparing the compound as claimed in Claim no.1.

22. Claim nos. 1, 2 and 3 in respect of the suit patent IN'161 are reproduced hereinbelow:

IN 233161
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). 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.

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

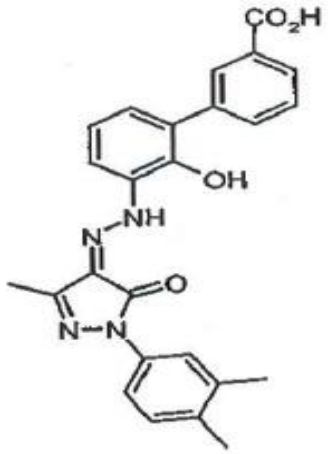
diluent/carrier etc are as "herein described". The preceding description stipulates that the diluents and carriers are conventional and exactly as those used in IN' 176.
Claim 3: A process for preparing the compound as claimed in claim 1, which process comprises: i) dissolving *3'-[(2Z)-[1 -(3,4-dimethyiphenyl)- 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 50ºC in a vacuum oven over night; and iii) isolating the prepared compound.

23. The detailed description of the invention, as set out, indicates that it expressly incorporates by reference, the entire disclosure made in IN'176 and further claims that Bis-(monoethanolamine), the salt of ELT (which is a free acid) had numerous advantages over the free acid. It is claimed that the free acid (ELT) was poorly soluble in water, which adversely affects its ability to be formulated into a pharmaceutical dosage form and reduce the bioavailability of the compound in vivo. It is claimed that the suit patent (IN'161) had advantages of enhanced

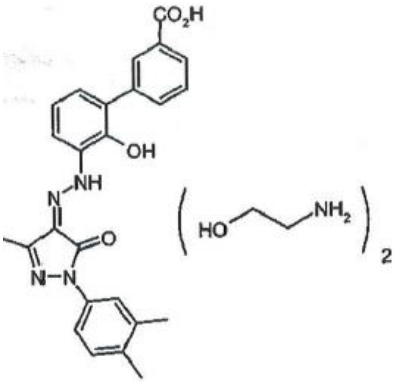
solubility and bioavailability. The relevant extract of the detailed description of invention is set out below:

> "3'-{N'-[1-(3,4-dimethylphenyl)-3-methyl-5-oxo-1,5-dihydropyrazol-4-ylidene]hydrazino)-2'-hydroxybiphenyl-3-carboxylic acid 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 receptor, particularly in enhancing platelet production and particularly in the treatment of thrombocytopenia, in International Application No. PCT/US01/16863, having an International filing date of May 24, 2001; International Publication Number WO 01/89457 and an International Publication date of November 29, 2001 (Indian Patent application no. IN/PCT/2002, 1666/MUM which is now Indian Patent No. 213176), the entire disclosure of which is hereby incorporated by reference. International Application No. PCT/US01/16863 does not specifically disclose a salt form for any of the compounds disclosed therein.
>
> It has now surprisingly been found that the bis-(monoethanolamine) salt of 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 has numerous advantages over the free acid. The free acid is poorly soluble in water (approximately 5 micrograms per milliliter). This poor solubility adversely affects the ability of the free acid to be formulated into pharmaceutical dosage forms and reduces the bioavailability of the compound in vivo."

24. The structure of ELT is as under:



25. The structure of ELT-O is set out below:



THE IMPUGNED JUDGMENT

26. The learned Single Judge examined the rival contentions in the light of the decisions rendered by the Supreme Court in ***Novartis AG v. Union of India & Ors.***[1]and the decision of this Court in ***Merck Sharpe***

[1] (2013) 6 SCC 1

& Dohme v. Glenmark Pharmaceuticals[2] and ***Astrazeneca AB and Anr. v. Intas Pharmaceuticals Ltd. & Ors.***[3] as well as various other decisions.

27. The learned Single Judge rejected the contention that enhanced bioavailability or solubility absent other factors enhancing the effectiveness of the invention as a drug cannot be used as the basis for claiming enhanced therapeutic efficacy. The learned Single Judge rejected the contention that the decision of the Supreme Court in ***Novartis v. UoI***[1] laid down any such proposition[4]. The learned Single Judge observed that the therapeutic efficacy of API would remain constant. However, if the therapeutic efficacy of API is enhanced by making the ingredient more available to the body, in the modified formulation, the same would be patentable under Section 3(d) of the Act[5].

28. After referring to various decisions, the learned Single Judge summarized the principles emanating from the various decisions in Paragraph no. 30 of the impugned judgement. The relevant extracts of the said paragraphs are set out below:

> "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

[2] 2015 SCC OnLine Del 8227
[3] (2021) SCC OnLine Del 1130
[4] Paragraph 14.2.11
[5] Paragraph 14.2.13

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.

(c) The triple test of patentability is, therefore, novelty, the existence of an inventive step and industrial applicability. In ***Merck v. Glenmark***, 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.

(e) "Patentability" requires that the product (a) must be an invention within the meaning of Section 2(j) and (b), must not fall within the exceptions in Section 3.

(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).

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

(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.

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

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

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

(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.

(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***, to be irrelevant. In a visible departure, however, where the claim of the plaintiff was rejected, ***Roche v. Cipla*** held this to be an indicator, *prima facie*, that the defendant's product infringed the suit patent.

(iv) Section 3(d)

(a) Once a patent was granted to an Active Pharmaceutical Ingredient (API), Section 3(d) protects all products of such API, in any form, from grant of a subsequent patent. The manufacture or marketing by any third party of any product-derivative of a patented API would amount to infringement. 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.

(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.

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

(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.

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

(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***, 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.

(v) Coverage, claim construction and disclosure

(a) The coverage of a claim, *for the purposes of determination the scope of protection under Section 48 of the Patents 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.

(b) The qualities of an enabling disclosure were well delineated in the ***Wands tests***. 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 the art and (viii) the breadth of the claims.

(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.

(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. the coverage which would be entitled to patent protection under Section 48. The following passage from ***Merck v. Glenmark*** 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. 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***, 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***. The claim in IN 816, as worded, encompassed "Sitagliptin with its pharmaceutically

acceptable salts". Sitagliptin Hydrochloride was specifically exemplified in the complete specifications in 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*** 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***, 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.

(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***. 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.

(h) Similarly, in ***Merck v. Glenmark***, 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 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.

(vi) Obviousness:

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

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

(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."

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

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

(b) imputing to a normally skilled but unimaginative addressee what was 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.

(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.

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

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

(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.

(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.

(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."

(vii) Industrial applicability and commercial utility:

(a) On the aspect of industrial applicability, in ***Merck v. Glenmark***, 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.

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

(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.

(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.

(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.

(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.

(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.

(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.

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

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

(e) At the interlocutory stage, it is normally not advisable to reject a request for injunction on the ground of violation, in obtaining the suit patent, of Section 8.

(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***, in the context of Erlotinib Hydrochloride *vis-à-vis* polymorph B thereof."

29. Insofar as Natco's challenge to the validity of IN'161 on the anvil of Section 3(d) of the Act is concerned, the learned Single Judge held that in the case of ***Novartis v. UoI***[1], the Supreme Court had accepted that bioavailability could be an indicator of increased therapeutic efficacy. The learned Single Judge further observed that the decision in the case of ***Novartis v. UoI***[1] was in the context of a challenge to the rejection of an application for registration of a patent and thus, the applicant was required to establish the increase in therapeutic efficacy of the invention. However, in the present case since, the patent in respect of ELT-O was granted, the onus would lie heavily on Natco to

establish the vulnerability of the suit patent on the ground of invalidity. The learned Single Judge held that the challenge to the validity of patent must be a credible challenge, which occupies a higher pedestal than a challenge, which is worthy of consideration.

30. The learned Single Judge referred to the data provided by Novartis and observed that ELT, when combined with Olamine increases the yield of Eltrombopag (the free acid). The learned Single Judge also, *prima facie*, accepted the contention that the maximum plasma concentration of ELT-O was thrice the plasma concentration of ELT. The learned Single Judge did not accept that Natco had laid a credible challenge to the validity of IN'161 on the ground that it did not enhance the therapeutic efficacy of ELT.

31. The learned Single Judge also rejected the contention that the suit patent was vulnerable under Section 64(1)(a) of the Act on the ground of anticipation by prior claim. The learned Single Judge held that the suit patent would be vulnerable only if ELT-O as claimed was contained in complete specifications of IN'176. The learned Single Judge held that to sustain the challenge under Section 64(1)(a) of the Act, the claim, the validity of which is challenged, must be identical to the claim in a prior art or of a co-equal extent and amplitude. Since, Claim no.1 in IN'161 specifically claimed ELT-O, it was necessary for Natco to establish that the prior art (IN'176) also specifically claimed ELT-O.

32. It was contended on behalf of Natco that selecting the appropriate compounds as mentioned in the specification in IN'176 would yield ELT-O solubility. However, the said contention was rejected as the learned Single Judge was of the view that the selection of various compounds was by resorting to hindsight deduction. The learned Single Judge was of the view that it was not permissible for Natco to make out a case of vulnerability of IN'161 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 site in the Markush moiety as to arrive at the suit patent.*" The learned Single Judge held that for claiming anticipation by prior claiming, the claim in the suit patent must be shown to have been claimed in the prior art.

33. The learned Single Judge sought to draw a distinction between a broad coverage of a claim based on its wording and the coverage of a claim as would entitle patent protection under Section 48 of the Act. The learned Single Judge held that protection under Section 48 of the Act is 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. Thus, although Claim no.6 in IN'176 would broadly cover ELT-O as a pharmaceutically acceptable salt of ELT, but it could not be accepted that ELT-O was claimed under Claim no.6 in IN'176 read with the enabling disclosure.

34. The learned Single Judge also rejected the contention that the PTE (Patent Term Extension) and SPC (Supplementary Protection Certificate) applications filed by Novartis for its predecessor in respect of US'870 and EP'378 or the entry in the orange book could constitute the basis for a credible challenge to the suit patent- IN'161.

35. The learned Single Judge did not *prima facie* accept the contention that ELT-O was claimed and disclosed either in US'870 or in EP'378 merely, because it was stated that the said patents "read on" to the approved drug product (that is, Eltrombopag Olamine). The learned Single Judge held that these are matters, which would require the detailed examination during trial.

36. The learned Single Judge did not accept that Form No.27 filed by Novartis in respect of IN'176 and IN'161 were relevant in determining whether ELT-O was claimed in IN'176.

37. The learned Single Judge did not accept that Natco's challenge to IN'161 on the ground of obviousness under Section 64(1)(d) of the Act *prima facie* presented a credible challenge to IN'176. The learned Single Judge held that on a plain comparison of Claim nos.1 to 4 in IN'176 and Claim no. 1 in Suit Patent, IN'161, it is clear that the exercise to show that ELT-O was obvious from the teachings of IN'176 was an exercise of hindsight, which was not permissible. The learned Single Judge held that motivation to select certain compounds out of several compounds provided in the prior art (IN'176) and the

motivation to substitute them at the appropriate site so as to achieve the desired purpose, are both required to be shown to exist in the prior art itself. The learned Single Judge held that the exercise undertaken to arrive at Claim no.1 of IN'176 from Claim no.1 to 5 of IN'161 was clearly one of hindsight analysis.

38. The learned Single Judge *prima facie* accepted the contention that ELT-O was unknown as a pharmaceutically acceptable salt of ELT prior to the priority date of IN'161. Therefore, it was a novel invention. The learned Single Judge, therefore, rejected the contention that Claim no.6 of IN'176 enabled a person skilled in the art to arrive at ELT-O. Natco had cited certain prior arts, which reflected the use of Olamine. Natco had claimed that a person skilled in art could, thus, arrive at a suit patent by using Olamine to form a pharmaceutically acceptable salt of ELT. In view of the above, the learned Single Judge restrained Natco from manufacturing or distributing ELT-O.

REASONS AND CONCLUSION

Standard of Challenge to validity at Interim stage

39. At the outset, it is relevant to note that there is no presumption of validity of a patent by virtue of the same being granted by the Patent Office. Thus, the fact that the examiners have conducted necessary investigations prior to the grant of patent does not render a patent immune from challenge to its validity. The contention that there was no

pre-grant or post-grant opposition to IN'161 and therefore, Natco has to cross a very high threshold to assail the validity of the patent, is unmerited. The Act expressly enables a challenge to the validity of a patent at various stages. Section 25(1) of the Act enables any person to challenge the grant of a patent after the application for the patent has been published. This is, essentially, in aid of the examination process[6]. In terms of Section 25(2) of the Act, an interested person can challenge the grant of a patent on the grounds as set out in the said sub-section, subject to the said challenge being raised within a period of one year from the date of publication of the patent. Section 64(1) of the Act also enables a person to file a petition for revocation of a patent on the grounds as set out in Section 64(1) of the Act. In terms of Section 64(1) of the Act, any person interested, or the Central Government is entitled to apply for revocation of the patent, either, by way of a petition or by way of a counter-claim in a suit for infringement on the grounds as set out in Section 64(1) of the Act. Additionally, in terms of Section 105 of the Act, any person is entitled to institute a suit for declaration, that the use by him of any process, or the making, use or sale of any article by him does not, or would not constitute infringement of a claim of a patent.

40. It is also material to note that there is no statutory provision similar to Section 31 of the Trade Marks Act, 1999, which posits a statutory presumption of validity on grant of a patent. It is also relevant

[6] UCB Farchim Sa v. Cipla Ltd. & Ors.: 2010 SCC OnLine Del 523

to refer to Section 13(4) of the Act, which expressly provides that the investigation required under Section 12 of the Act – the pre-grant investigations and inquiries leading to the grant of patent – does in any way warrant the validity of any patent.

41. Absent any statutory presumption and given the scheme of the Act, which enables challenge to the validity of a patent at several stages, there is neither any presumption as to the validity of a patent nor renders the patent immune for challenge to its validity.

42. Thus, in an action for infringement of a patent, defence as to the invalidity of the patent on the grounds as provided in Section 64(1) of the Act, is available to the defendant. The court is required to examine the challenge with an open mindset and not from the standpoint of an assumption that the patent is validly granted.

43. Unless there is no real prospect of the defendant to succeed in its challenge and an appropriate application to allow the action is made prior to framing of issues, the questions as to the validity of the patent asserted, are required to be determined at the trial. However, at the stage of interim relief, the defendant has to establish its assertion that its defence is not insubstantial and sets out a credible challenge to the validity of the patent. The defendant is not required to establish that the patent is invalid, it has to merely show that the patent is vulnerable. If the challenge raised to the validity is substantial, the threshold standard for resisting an interim injunction in this regard – subject to other

relevant considerations –would be met. In this context, it is relevant to refer to the decision of the Division Bench of this Court in ***F. Hoffmann-LA Roche Ltd. & Anr. v. Cipla Ltd.***[7]. In the said case, the Division Bench had rejected the contention that the defendant had a heavy burden to discharge and would have to establish a stronger *prima facie* case than the plaintiff. The Division Bench had also not accepted the contention that since there is a multi-level examination of opposition to the grant of patent, it ought to be accorded the highest weightage. The relevant extract of the said decision is set out below:

> "53. The plea of the plaintiff that since there is a multi-layered, multi-level examination of the opposition to the grant of patent it should accorded the highest weightage, is not entirely correct. The contention that there is a heavy burden on the defendant to discharge since it has to establish that it has a stronger *prima facie* case of the plaintiff is contra indicated of the decisions in the context of Section 13(4). Reference may be made to the decisions in *Biswanath Prasad Radhey Shyam v. Hindustan Metal Industries*, (1979) 2 SCC 511 : AIR 1982 SC 1444 : Supp (1) PTC 731 (SC), *Standipack Pvt. Ltd. v. Oswal Trading Co. Ltd.,* AIR 2000 Del 23 : (1999) 19 PTC 479 (Del), *Bilcare Ltd. v. Amartara Pvt. Ltd.,* (2007) 34 PTC 419 (Del), *Surendra Lal Mahendra v. Jain Glazers*, 1980 SCC OnLine Del 219. In *Beecham Group Ltd. v. Bristol Laboratories Pty Ltd.,* (1967-1968) 118 CLR 618 and *Australian Broadcasting Corporation v. O'Neill*, (2006) 229 ALR 457 it was held that the defendant alleging invalidity bears the onus of establishing that there is "a serious question" to be tried on that issue. In *Hexal Australai Pty Ltd. v. Roche Therapeutics Inc*., 66 IPR 325 it was held that where the validity of a patent is raised in interlocutory

[7] 2009 SCC OnLine Del 1074

proceedings, "the onus lies on the party asserting invalidity to show that want of validity is a triable question." In *Abbot Laboratories v. Andrx Pharmaceuticals Inc*. (decision dated 22nd June 2006 of the U.S. Court of Appeals for the Federal Circuit 05-1433) the Court of Appeals followed its earlier ruling in *Helifix Ltd. v. Blok-Lok Ltd*. 208 F.3d 1339 where it was held (at 1359): "In resisting a preliminary injunction, however, one need not make out a case of actual invalidity. Vulnerability is the issue at the preliminary injunction stage, while validity is the issue at trial. The showing of a substantial question as to invalidity thus requires less proof than the clear and convincing showing necessary to establish invalidity itself." (emphasis supplied) In *Erico Int'll Corprn v. Vutec Corprn* (U.S. Court of Appeals for the Federal Circuit, 2007-1168) it was held that the "defendant must put forth a substantial question of invalidity to show that the claims at issue are vulnerable."

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

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

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

44. It is also relevant to refer to the decision of the learned Single Judge of this Court in ***Astrazeneca AB & Anr. v. Intas Pharmaceuticals Ltd.***[8]. In the said case, the learned Single Judge rejected the contention that since the suit patents were old, they should be presumed to be valid. The learned Single Judge did so for two reasons. First, the learned Single Judge found – much like in the present appeal where it is the stated case that ELT-O is covered under both IN' 176 and the suit patent IN' 161 – that there was an overlap in the genus patent and the species patent. And second, that the presumption of validity exists only till such time the patent is challenged and the challenge is credible. The relevant extract of the said decision is set out below:

[8] 2020 SCC OnLine Del 2765

"**51**. Furthermore, the argument advanced on behalf of the plaintiffs that since the suit patents are old and thus, should be presumed to be valid cannot be accepted for two reasons.

i. First, there is a period of overlap between the genus patent i.e. IN 147 and the species patent i.e. IN 625. The defendants, in this case, chose to wait [in line with arguments advanced in their defence of the suit actions] till such time the validity period of the genus patent i.e. IN 147 expired.

ii. Second, as indicated above, the scheme of the Act does not foreclose the right of the defendants in defence to an infringement action to question the validity of the patent. Section 107 of the Act, expressly confers a right on the defendants to raise, in defence, in an infringement suit, all those grounds on which the patent can be revoked under Section 64 of the very same Act. Therefore, the judgment in Bristol-Myers Squibb Company v. J.D. Joshi, 2015 SCC OnLine Del 10109, if read in context, would demonstrate that it has not emasculated the right of the defendant, as conferred under the Act, to challenge the validity of the patent. The presumption of validity exists only till such time the patent is challenged - a challenge which is credible and no further. In my opinion, if the plaintiffs' argument was to be accepted, then, it would have to be held that the older the patent, the stronger the firewall. Such an interpretation, in my view, would be contrary to the plain words of the Statute.

[Emphasis added]

45. The appeal against the said decision was dismissed by the Division Bench of this Court as being without any merit.

46. In the present case, the learned Single Judge held that even if a *prima facie* ground for revocation is made out, revocation is not automatic as the patent authority retains discretion not to revoke the

patent if not absolutely necessary. And, the vulnerability to revocation must also be adjudged on the same standard. The learned Single Judge also concluded that this standard is therefore, high rather than low. It was further observed that the credible challenge occupies a higher pedestal than challenge, which is merely worthy of consideration. The learned Single Judge held that "*When an infringer seeks to defend infringement on the ground that the patent 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"*". The standard as articulated in the impugned judgement is in clear variance with the decision of the Division Bench of this court in ***F. Hoffmann-LA Roche Ltd. & Anr. v. Cipla Ltd.***[7]. In the said case, the Division Bench had expressly rejected the contention that the defendant has a heavy burden to discharge as it has to establish a stronger *prima facie* case. It is apparent that in the present case, the learned Single Judge has applied a higher standard for examining whether a credible challenge to the validity of a patent is made out, than as explained by the Division Bench. In effect, the learned Single Judge has read in a presumption as to the validity of the patent, where none exists. Obviously, a challenge to a patent, that is insubstantial, would be wholly insufficient to resist an order of interdiction. However, if a *prima facie* ground of revocation is made out, the threshold standard of credible challenge is met notwithstanding the discretion vested with the patent authority in regard to revocation of the patent. The fact that the patent authority may have the discretion not to revoke the patent despite a ground for the same

being established, is not a relevant consideration for granting an interim injunction restraining the infringement of a patent on the ground that the defendant has not met the threshold standard of a credible challenge to the validity of the patent, if a *prima facie* ground for revoking the patent is made out.

47. If the defendant raises a substantial challenge, which merits a trial, the question whether an injunction ought to be granted would necessarily have to be determined on other considerations for grant of such injunctions including balance of convenience and irreparable harm.

Natco's principal challenge

48. Natco's principal challenge to the validity of IN'161 is premised on basis that the same substance was claimed and covered in IN'176. As noted at the outset, there is no dispute that ELT-O was covered in IN'176. Novartis also claims that Natco's product TROMBOPAG™ would also infringe IN'176 during its term. It is Novartis' contention that although, ELT-O was covered under IN' 176, it was not disclosed and therefore, Natco's challenge to IN'161 on the ground of prior claiming and prior publication fails. Additionally, the challenge on the ground of lack of inventive step and obviousness, which is also to some extent premised on the grant of IN'176, is also liable to be rejected. Novartis claims that ELT-O is an incremental invention with added advantages and it satisfies the requirements of patentability, novelty and inventive step.

49. The tension between a 'genus patent' and a 'species patent', which often finds its way in Courts in different forms, is central to the present dispute. The term 'genus patent' and the term 'species patent' are not statutorily defined. However, the expression 'genus patent' is often used for patents in respect of claims that are broad and cover several compounds with a common core and inventive concept. In pharmaceutical substances, it usually discloses molecules with therapeutic value, which are used in formulations. The term 'species patent' is used to describe one or more specific compounds falling within the broad claims covered under the term 'genus patent'. In ***Novartis v. UoI***[1] the appellant claimed patent in respect of β-crystaline-Imatinib Mesylate (hereafter *β-IM*). According to the appellant, β-IM (species patent) was developed from the invention Imatinib free base – a derivative of a chemical compound called 'N-phenyl-2-pyrimidine-amine', – US Zimmermann Patent No.5,521,184 (genus patent). In ***Merck vs Glenmark***[2], the appellant/plaintiff (hereafter *Merck*) claimed that the respondent/defendant's product Sitagliptin Phosphate Monohydrate (species patent) infringed Sitagliptin Molecule, covered by IN'209816 (genus patent). Similarly, in ***Astrazeneca AB & Anr. v. Intas Pharmaceuticals Ltd.***[9] the appellants/plaintiffs filed nine appeals restraining the respondents/defendants from infringing the product comprising of the compound Dapaglifrozin (hereafter *DAPA*). DAPA

[9] 2021 SCC OnLine Del 3746

was said to be the subject matter of two pre-existing Indian patents, IN'147 (genus patent) and IN'625 (species patent).

50. In cases where a genus patent and species patent are asserted by the patentee, the issue that arises is whether monopoly granted in respect of the substance can be extended on account of it being covered under a patent that expires later.

51. It is common ground that ELT-O was covered under the broad Markush claim 'IN' 176'. Thus, the patent holder of IN' 176 (Novartis AG as the assignee) was during the term of the patent entitled to prevent any person from manufacturing, using or selling any products that included the API ELT (Eltrombopag), which was admittedly disclosed in the complete specifications of IN'176. It now seeks an extension of the said rights by virtue of a species patent (IN'161) granted in respect of ELT-O, which is a salt of ELT.

52. Natco's main challenge to the validity of IN' 161 is premised on the basis that it is a new form of a known substance covered in IN' 176. Whilst, there is no serious dispute that ELT-O is a salt of ELT, Novartis claims that ELT-O is a novel substance and qualifies all tests of patentability (novelty, utility and non-obviousness). It claims that IN'161 is an incremental invention and has added advantages of enhanced *solubility* and *bioavailability* over Eltrombopag (ELT). Natco disputes that ELT-O is an invention as the claimed added advantages

do not include increased therapeutic efficacy. Section 3(d) of the Act is at the core of this dispute.

Section 3(d) of the Act

53. The Act was amended by the Patents (Amendment) Ordinance, 2004 (Ordinance No. 7 of 2004) which came into effect from 01.01.2005. The said amendments were made to broadly make the patent law compliant with the mandate of the TRIPS (Trade-Related Aspects of Intellectual Property Rights Agreement) for granting product patent for pharmaceutical and agricultural chemical substances. The said ordinance was replaced by the Patents (Amendment) Act, 2005 (hereafter *the 2005 amendment*). Clause (d) of Section 3 of the Act was amended. The language of the clause was changed and an Explanation was added. The Pre-Amendment clause and the Amended clause, read as under:

The Pre-Amendment Clause

> "3(d) the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant;"

The Amended Clause

> "3(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless

> such known process results in a new product or employs at least one new reactant.
>
> Explanation.—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy;"

54. In ***Novartis v. UoI***[1]**,** the Supreme Court has noted the legislative history and the reasons why Clause (d) of Section 3 of the Act was amended in the manner that it was. It was contended on behalf of Novartis in that case that the amendment to clause (d), particularly the introduction of the Explanation, was *ex majore cautela* (out of abundant caution) and even prior to the 2005 amendment, forms of known substances were not inventions. The Supreme Court rejected the said contention and held that Section 3(d) of the Act as amended, sets a higher invention threshold for medicines, drugs and other chemical substances. The relevant observations of the Supreme Court are set out below:

> "87**.** We are clearly of the view that the importance of the amendment made in Section 3(*d*), that is, the addition of the opening words in the substantive provision and the insertion of the Explanation to the substantive provision, cannot be underestimated. It is seen above that, in course of the Parliamentary debates, the amendment in Section 3(*d*) was the only provision cited by the Government to allay the fears of the Opposition members concerning the abuses to which a product patent in medicines may be vulnerable. We have, therefore, no doubt that the amendment/addition made in Section 3(*d*) is meant

> especially to deal with chemical substances, and more particularly pharmaceutical products. The amended portion of Section 3(*d*) clearly sets up a second tier of qualifying standards for chemical substances/ pharmaceutical products in order to leave the door open for true and genuine inventions but, at the same time, to check any attempt at repetitive patenting or extension of the patent term on spurious grounds."

55. There is no cavil that Section 3(d) of the Act sets a higher invention threshold in respect of medicines, drugs and other chemical substances. The *second tier of the qualifying standards* for chemical substances/pharmaceutical products is that its properties must *differ significantly with regard of efficacy*. Thus, the challenge to the validity of IN'161 is required to be examined on the anvil whether it qualifies the higher standard as indicated in Section 3(d) of the Act.

56. The Explanation to Section 3(d) of the Act amply sets out what are not be considered as inventions. The statute expressly provides that salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance would be considered as the same substance. However, the legislature also left room for incremental inventions and has excluded from the Explanation substances, which differ significantly in their properties with regard to efficacy (therapeutic efficacy in pharmaceutical/chemical products)

57. The learned Single Judge held that as the first step, it is to be examined whether the claim qualifies as an invention under Section 3(d) of the Act and then to determine whether it is patentable.

58. The term "invention" is defined in clause (j) of Section 2(1) of the Act, which reads as under:

> "Section 2. Definitions and interpretation.—(1) In this Act, unless the context otherwise requires,—
>
> (j) "invention" means a new product or process involving an inventive step and capable of industrial application."

59. The expression "inventive step" is defined as under:

> "(ja) "inventive step" means 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;"

60. As is apparent from the above, there are two features of an inventive step. First, that it involves a technical advancement as compared to existing knowledge or economic significance or both. And second, that the invention is not obvious to a person skilled in the art.

61. Section 3(d) of the Act, in effect, sets a supra standard to qualify as an invention. This is in addition to being a new product and involving an inventive step. As held in ***Novartis v. UOI*** [1], Section 3(d) of the Act sets a higher threshold to qualify as an invention in respect of medicinal products and chemical substances. In view of Section 3(d) of the Act as

amended, the inventive step as defined is, in effect, further narrowed in respect of pharmaceutical products and chemicals. Thus, a pharmaceutical product/chemical may satisfy the criteria involving technical advancement over existing knowledge and not being obvious to a person skilled in the art, and yet be excluded from being considered as an invention if it is a new form (as specified in the Explanation to Section 3(d) of the Act) of a known substance. The said Explanation excludes certain forms of known substance (salts, esters, ethers, polymorphs, metabolites, pure form, particle size, other forms etc.) as expressly set out. The clear objective of specifically excluding such forms of pharmaceutical substances/chemicals is to posit a higher threshold for a claim to be eligible for grant of patent by excluding claims on the basis of known and usual qualities attributed to the specified forms. However, to retain room for incremental inventions, the Explanation admits exceptions to the given forms if their properties in respect efficacy (therapeutic efficacy in pharmaceutical/chemical products) differ significantly from those of the known substance.

62. In the context of the present case, ELT-O being a pharmaceutical salt of the known substance (ELT) would not qualify as an invention notwithstanding that (i) it may involve technical advancement (as compared to the existing knowledge); (ii) it has economic significance; and (iii) it is not obvious to a person skilled in the art, if its properties are not significantly different in regard to the therapeutic efficacy of the known substance (ELT).

63. Thus, unless the person claiming a patent in respect of one of the forms of pharmaceutical substances/ chemicals establishes that the medicine, drug or chemical substance differs significantly in properties with regard to efficacy from known-substance, the new chemical / medicine would not be patentable. In the context of a medicine, the Supreme Court had clarified that the test of efficacy can only be on '*therapeutic efficacy*'[10].

64. Undisputedly, ELT-O would not qualify the higher standard for being considered as an invention if its properties did not differ significantly in respect of therapeutic efficacy from those of ELT.

65. It is relevant to note that the only added advantage that was claimed in respect of ELT-O over 'IN 176' was that of enhanced *solubility* and *bioavailability*. The specifications of 'IN 176' incorporated the entire disclosure in 'IN 176' as a part of its disclosure. It is claimed that ELT, which was admittedly disclosed in 'IN 176", is poorly soluble in water and this affects its ability to be formulated into pharmaceutical dosage forms. However, ELT-O had added advantage of enhanced solubility and bioavailability over the free acid (ELT). The relevant extract of the said application is set out below:

> "It has now surprisingly been found that the bis-(monoethanolamine) salt of 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 has numerous advantages over

[10] Paragraph 157 of *Novartis AG v. Union of India & Ors.: (2013) 6 SCC1*

> the free acid. The free acid is poorly soluble in water (approximately 5 micrograms per milliliter). This poor solubility adversely affects the ability of the free acid to be formulated into pharmaceutical dosage forms and reduces the bioavailability of the compound in vivo.
>
> While the free acid is highly useful as an agonist of the TPO receptor, particularly in enhancing platelet production and particularly in the treatment of thrombocytopenia, the bis-(monoethanolamine) salt of 3'-[(2Z)-[l-(3,4-dimethylphenyl)-1,5-dihydro-3-methyll-5- -4H-pyrazol-4-ylidene] hydrazino}-2'-hydroxy-[1,1'-biphenyl-3-carboxylic acid *has the added advantages of enhanced solubility and bioavailability*."
>
> [emphasis added]

66. In the aforesaid context one of the principal questions to be addressed was whether the properties of enhanced solubility and bioavailability can be construed as higher *therapeutic efficacy* or merely overcome the disadvantage of ELT's poor solubility which *adversely affects its ability to be formulated into pharmaceutical dosage forms*

67. As noted above, in ***Novartis v. UoI***[1], the Supreme Court had considered the interpretation of the Explanation to Section 3(d) of the Act and the significance of excluding salts, esters, ethers etc. of known substance as inventions. The Supreme Court accepted the contention that inherent properties of the forms mentioned in the Explanation of Section 3(d) of the Act would not be considered as enhancing therapeutic efficacy. Paragraphs 158 and 159 of the said decision are relevant and are set out below:

> "**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.
>
> **159.** We have just noted that the test of enhanced therapeutic efficacy must be applied strictly, but the question needs to be considered with greater precision. In this connection, we take note of two slightly diverging points of view urged before this Court."
>
> [emphasis added]

68. It is well accepted that properties such as greater bioavailability, solubility, stability, and hygroscopicity are usual properties of the given forms. A well-known text[11] mentions the salt form as one of the factors affecting absorption and bioavailability as under:

> "ii) Salt Form
>
> The dissolution rate of a particular salt is usually different from that of the parent compound. Salts of weakly acidic drugs as a rule, are highly water soluble. Free acidic drug is precipitated from these salts in a microcrystalline form which has faster dissolution rate and hence enhanced bioavailability, e.g., tolbutamide sodium and phenytoin sodium have better bioavailability than tolbutamide and phenytoin (as free drugs)."

[11] H.L. SHARMA & K.K. SHARMA, PRINCIPLES OF PHARMACOLOGY 32-32 (Paras Medical Publisher 3d ed. 2018)

69. Undisputedly, properties of higher solubility and bioavailability are common properties associated with the salt form.

70. As noted above, the rationale of excluding the specified forms of known substances was to exclude the evergreening of the patents in respect of pharmaceutical/chemical substances. The transition was from a position when product patents in respect of pharmaceutical and agricultural chemicals were not granted to a position where monopoly was granted for a period of twenty years but no more. Thus, Section 5 of the Act was deleted and Section 3(d) was amended. The objective of the 2005 amendment to Section 3(d) of the Act is to ensure that the monopoly in respect of a pharmaceutical or a chemical substance ends with the expiry of the patent term and it is not rejuvenated by introduction of another form. Therefore, notwithstanding that the given new forms of the pharmaceutical products may be novel or include inventive steps, the same were not eligible for being monopolised. However, this did not exclude incremental inventions provided, the same resulted in added therapeutic efficacy.

71. The question whether greater bioavailability could be considered as enhanced therapeutic efficacy was also raised before the Supreme Court in ***Novartis v. UoI***[1]. It was contended on behalf of certain objectors that a demonstration of increase in bioavailability is not a demonstration of enhanced efficacy. The said submissions are recorded in the aforesaid judgment and are reproduced below:

"**160**. Mr. Anand Grover, learned counsel appearing for one of the objectors, Cancer Patients Aid Association, took a somewhat rigid position. The learned counsel submitted that in the pharmaceutical field, drug action is explained by "pharmacokinetics" (effect of the body on the drug) and "pharmacodynamics" (effect of the drug on the body). He further submitted that efficacy is a pharmacodynamic property, and contended that, in the field of pharmaceuticals, efficacy has a well-known meaning. Efficacy is the capacity of a drug to produce an effect. The IUPAC describes efficacy as "the property that enables drugs to produce responses". It is that property of a drug which produces stimulus. When comparing the efficacy of two substances, efficacy describes "the relative intensity with which agonists vary in the response they produce even when they occupy the same number of receptors". [*IUPAC Glossary of Terms Used in Medicinal Chemistry,* 1998 in CPAA Compilation Vol. 9, at p. 7.]. In the words of Goodman and Gilman, "the generation of response from the drug receptor complex is governed by a property described as efficacy". They further clarify that "efficacy is that property intrinsic to a particular drug that determines how good an agonist the drug is" [Goodman and Gilman in CPAA Compilation, Vol. 9, at p. 22, LHC]. Another source describes efficacy as "the ability of the drug to produce the desired therapeutic effect" [*Dorland's Medical Dictionary* in Novartis' Vol. P, at p. 19].

161. Mr. Grover further submitted that in pharmacology, efficacy is distinct from affinity, potency and bioavailability. Affinity, a pharmacodynamics property, "is the tendency of a molecule to associate with another". The affinity of a drug is its ability to bind to its biological target (receptor, enzyme, transport system, etc.). Potency is "the dose of drug required to produce a specific effect of given intensity as compared to a standard reference". Bioavailability, on the other hand, is a pharmacokinetic property. It "is the term used to indicate the fraction extent to which a dose of drug reaches its site of action or a

biological fluid from which the drug has access to its site of action" [Goodman and Gilman in CPAA Compilation, Vol. …, internal p. 4]; or "the degree to which a drug or other substance becomes available to the target tissue after administration" [*Dorland's Medical Dictionary* in Novartis' Vol. B, at p. 65]. A demonstration of increase in bioavailability is not a demonstration of enhanced efficacy.

162 Prof. Basheer, who appeared before this Court purely in academic interest as an intervenor-cum-amicus, agreed that not all advantageous properties of a new form (such as improved processability or flow characteristics, storage potential, etc.) ought to qualify under Section 3(*d*), but only those properties that have some bearing on efficacy. However, taking a less rigid position than Mr Grover, Prof. Basheer argued that safety or significantly reduced toxicity should also be taken into consideration to judge enhanced therapeutic efficacy of a pharmaceutical product in terms of Section 3(*d*). [Prof. Basheer traced the origins of the amended part of Section 3(*d*) in Article 10(2)(*b*) of the European Drug Regulatory Directive, 2004 which defines a "generic medicinal product" as:"… a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. In such cases, additional information providing proof of the safety and/or efficacy of the various salts, esters or derivatives of a authorised active substance must be supplied by the applicant." He pointed out that the expressions used in a different context in the European Drug Regulatory Directive were incorporated in the Patents Act for an

> altogether different purpose and raised some important and interesting points for interpretation of Section 3(*d*) but in this case we see no reason to go into those aspects of the matter.]"

72. However, the Supreme Court did not address the issue whether bioavailability was a pharmacokinetic property and thus, not a demonstration of enhanced efficacy because the decision on the question involved in that case – whether Novartis was entitled to patent in respect of β-crystaline-Imatinib Mesylate was rightly rejected by the Patent Office – could be rendered without considering the said issue. This is apparent from the following passages that were penned down by the Supreme Court after noting the aforesaid submissions:

> "163. We have taken note of the submissions made by Mr Grover and Prof. Basheer in deference to the importance of the issue and the commitment of the counsel to the cause. However, we do not propose to make any pronouncement on the issues raised by them, as this case can be finally and effectively decided without adverting to the different points of view noted above.
>
> 164. In whatever way therapeutic efficacy may be interpreted, this much is absolutely clear: that the physico-chemical properties of the beta crystalline form of Imatinib Mesylate, namely, (*i*) more beneficial flow properties, (*ii*) better thermodynamic stability, and (*iii*) lower hygroscopicity, may be otherwise beneficial but these properties cannot even be taken into account for the purpose of the test of Section 3(*d*) of the Act, since these properties have nothing to do with therapeutic efficacy.
>
> 165. This leaves us to consider the issue of increased bioavailability. It is the case of the appellant that the beta crystalline form of Imatinib Mesylate has 30 per cent

> 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 on the issue of bioavailability as under:
>
> > "It is not the intent of a bio-availability study to demonstrate effectiveness, but to determine the rate and extent of absorption. If a drug product is not bio-available, it cannot be regarded as effective. *However a determination that a drug product is bio-available is not in itself a determination of effectiveness*." (emphasis added)
> >
> > 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 beta 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."

73. The learned Single Judge has construed the above observations to hold that enhanced bioavailability is relevant while assessing enhanced therapeutic efficacy. We find ourselves unable to concur with the said view. The Court did not conclude that the property of enhanced

bioavailability was a relevant factor in determining whether the invention had a higher therapeutic efficacy. On the contrary, the Court had emphasized the quote from a text – "*However a determination that a drug product is bio-available is not in itself a determination of effectiveness*".

74. After noting the submissions on behalf of the Objectors [as recorded in Paragraphs 161 to 163 in ***Novartis v. UoI***[1]], the Supreme Court clarified that it did not propose to make pronouncement on the issues raised as the matter could be decided without adverting to those contentions. It is also apparent that the Supreme Court did not accept that a demonstration of increase in bioavailability was a demonstration of increase in enhanced efficacy. This is evident from the observations made by the Supreme Court that "*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*".

75. At this stage it is relevant to recall that the only added advantages claimed by the patentee in respect of ELT-O over ELT acid free base, are enhanced solubility and bioavailability. In so far as *solubility* is concerned, the same is a Physico-chemical property and not a property of therapeutic efficacy. Mr Hemant Singh fairly did not press that the said claimed advantage in regard to this property falls within the exception of the Explanation to Section 3(d) of the Act.

76. In the aforesaid view, it would be necessary to consider whether enhanced bioavailability is *per se* indicative of higher therapeutic efficacy and whether ELT-O has significant advantage of a higher therapeutic efficacy.

77. Mr. Hemant Singh had contended, we may add quite forcefully, that there would be no question of enhanced therapeutic efficacy as ELT-O was not a drug and therefore, there was no question of ELT having any therapeutic efficacy. He contended that the data provided in IN'176 is only in vitro data and therefore, there was no question of ELT having any therapeutic efficacy. We are unable to accept this contention.

78. A plain reading of the field of invention and background of invention as set up in the application for the grant of IN'176 clearly indicates that the substance claimed has a useful application in treatment of platelet disorders. The summary of invention as set out in the application for IN'176 clearly states that:

> "present invention also relates to the discovery that the compounds of Formula (I) are active as agonists of the TPO receptor. In a further aspect of the invention there is provided novel processes and novel intermediates useful in preparing the presently invented TPO mimetic compounds"

79. It is also noted that the

> "pharmaceutically active compounds within the scope of invention are useful as TPO mimetic in mammals particularly humans, in need thereof. Some of the preferred

compounds within the scope of the invention showed activation from about 4% to 100% control at a concentration of 0.001-10 uM in the luciferase assay. The preferred compounds of the invention also promoted the proliferation of UT7TPO and 32D-mpl cells at a concentration of 0.003 uM. The preferred compounds of the invention also showed activity in the CD41 megakaryocytic assay at a concentration of 0.003 to 30uM. The present invention therefore provides a method of treating thrombocytopenia and other conditions with depressed platelet production, which comprises administering a compound of Formula (I) or a pharmaceutically acceptable sale, hydrate, solvate or ester thereof in a quantity effective to enhance platelet production. The compounds of Formula (I) also provide for a method for treating the above indicated disease states because of their demonstrated ability to act as TPO mimetic. The drug may be administered to a patient in need thereof by any conventional route of administration, including, but not limited to intravenous, intramuscular, oral, subcutaneous, intradermal, and parenteral"

80. The application also describes the dosage units which would be efficacious and nontoxic. The relevant extract of the said application is set out below:

"Doses of the presently invented pharmaceutically active compounds in a pharmaceutical dosage unit as described above will be an efficacious, nontoxic quantity preferably selected from the range of 0.001 – 100 mg/kg of active compound, preferably 0.001-50 mg/kg. When treating a human patient in need of a TPO mimetic, the selected 5 dose is administered preferably from 1-6 times daily, orally or parenterally. Preferred forms of parenteral administration include topically, rectally, transdermally, by injection and continuously by infusion. Oral dosage units for human administration preferably contain from 0.05 to 3500 mg of active compound. Oral administration, which uses lower dosages is preferred. Parenteral administration, at high

dosages, however, also can be used when safe and convenient for the patient".

81. It is also relevant to refer to Examples 114, 115 and 116 set out in the application, which were in respect of the Capsule Composition, Injectable Parenteral Composition and Tablet Composition, respectively. It is also relevant to refer to the following extract of the last example as provided by the patentee:

> "The most preferred among the compounds of the invention is,
>
> 3'-{N-[1-(3,4-Dimethylphenyl)-3-methyl-5-oxo-1,5-dihydro-pyrazol-4-ylidene] hydrazino}-2'-hydroxybiphenyl-3-carboxcylic acid.
>
> The compound 3'{N'-[1-(3,4-Dimethylphenyl)-3-methyl-5-oxo-1,5-dihydropyrazol-4ylidene] hydrazino} – 2'-hydroxybiphenyl -3-carboxylic acid demonstrated an activity of EC50=0.03 uM, 100% TPO in the above proliferation assay."
>
> [emphasis added]

82. Mr. Hemant Singh referred to the response submitted to the Patent Office to contend that Novartis had provided data to establish that ELT-O had a higher therapeutic efficacy than ELT free acid. The said response is also set out in the impugned judgment and is reproduced below:

> "Data: The bioavailability comparison of eltrombopag free acid and eltrombopag bio-monoethanolamine was conductedin dogs-dosed as granules in capsules Cmax 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	Cmax (pg/ml)	Tmax (h)	AUC(0.inf) (ug.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"

83. The learned Single Judge had *prima facie* accepted the aforesaid data as that establishing enhanced therapeutic efficacy.

84. We are unable to concur with the said view as the data clearly discloses that it sets out the comparison between the bioavailability data of milled ELT free acid and milled Ethanolamine Salt. Bioavailability is one of the pharmacokinetic parameters and not a direct measure of therapeutic efficacy.

85. The text in Essentials of Medical Pharmacology[12] explains the expression "Bio Availability" as under:

> "BIOAVAILABILITY
>
> Bioavailability refers to the rate and extent of absorption of a drug from a dosage form as determined by its concentration-time curve in blood or by its excretion in

[12] K.D. TRIPATHI, ESSENTIALS OF MEDICAL PHARMACOLOGY 16-16 (Jaypee Brothers Medical Publishers (P) Ltd. 7th ed. 2013)

> urine (Fig.206). It is a measure of the fraction (f) of administered dose of a drug that reaches the systemic circulation in the unchanged form. Bioavailability of drug injected i.v. is 100%, but is frequently lower after oral ingestion because–
>
> (a) the drug may be incompletely absorbed.
>
> (b) the absorbed drug may undergo first pass metabolism in the intestinal wall/liver or be excreted in bile.
>
> Incomplete bioavailability after s.c. or i.m. injection is less common, but may occur due to local binding of the drug."

86. Enhanced bioavailability is not synonymous with higher therapeutic efficacy. As noted above, in ***Novartis v. UoI*** [1], the Supreme Court had – without going into the question whether increased bioavailability by itself would lead to an enhancement of therapeutic efficacy, expressly held that, if such a claim is made, the same would require to be established by research and data.

87. The assumption that enhanced bioavailability necessarily leads to higher therapeutic efficacy is too broad an assumption. It is desirable to have optimal pharmacokinetic parameters. In cases where a formulation has side effects, a lower bioavailability may be more beneficial.

88. In the present case, the applicant (the predecessor in interest of Novartis AG) had made no claim for enhanced therapeutic efficacy in its patent application; the only added advantage claimed in respect of ELT-O was "enhanced solubility and bioavailability".

89. Essentials of Medical Pharmacology[13] explains 'therapeutic efficacy' in the following terms:

> "Therapeutic efficacy
>
> The 'therapeutic efficacy' or 'clinical effectiveness' is a composite attribute of a drug different from the foregoing pharmacological description of 'potency' and 'efficacy'. It depends not only on the relative potency and efficacy of the drug, but on many pharmacokinetic and pathophysiological variables as well. It is often expressed in terms of (a) degree of benefit/relief afforded by the drug (in the recommended dose range) or (b) the success rate in achieving a defined therapeutic end point. For example, the degree of relief in parkinsonian symptoms afforded by levodopa-carbidopa is much greater than that possible with trihexyphenidyl: the former has higher therapeutic efficacy than the latter. A drug which makes a higher percentage of epileptic patients totally seizure free than another drug, is the more therapeutically effective antiepileptic."

90. We may at this stage also refer to observations made by the Division Bench of this Court in ***Merck v. Glenmark***[2] in respect of the defence raised on account of the challenge raised by Merck Sharp and Dohme in respect of its patented product "Sitagliptin" (genus patent) having Indian Patent No. 209816 on account of utility and lack of industrial applicability. The Court rejected the contention that the suit patent, Sitagliptin (the genus patent) did not disclose utility. The Court noted that the claim referred to an active ingredient, which results in

[13] K.D. TRIPATHI, ESSENTIALS OF MEDICAL PHARMACOLOGY 55-55 (Jaypee Brothers Medical Publishers (P) Ltd. 7th ed. 2013)

therapeutic effect. It was contemplated that the said active ingredient (Sitagliptin molecule) would be combined with a carrier of some form. However, the said carrier would be inert and of no therapeutic value. It is also relevant to note that in that case, the respondent had also contended that since, Sitagliptin simpliciter cannot be administered, it had no real application. This is the mirror image of the contentions advanced on behalf of Novartis in this case. The same being that since, ELT (free acid) cannot be administered, as it is not soluble, ELT-O must necessarily be considered as one enhancing therapeutic efficacy, as without the pharmaceutical salt (Olamine), ELT would not be available to the body for any therapeutic effect.

91. The Division Bench rejected the aforesaid contention and observed that "*carrier, however, is not the crux of the invention, but only an inert component that does not add value to the therapeutic or medical value, which is the true core of the invention*". The learned Division Bench further observed that "*Whilst manufacturers may determine which salt carriers the active component the best – those carriers do not in any manner affect the therapeutic working of the active component itself*." The said observations suggest that efficiency of administration of an API by choice of an appropriate carrier, would not affect the API's therapeutic value.

92. It is also material to note that the data relied upon by Novartis, is the comparison between milled Ethanolamine Salt and milled Free Acid. IN'176 is not in respect of free acid alone. The examples and

claims also include salts. This is apart from the fact that IN' 176 expressly claims the formula in Claim No.1 of IN'176 and pharmaceutically acceptable salts. The said claim reads as under:

> "6. A compound as claimed in claim 1, which is
>
> 3'-{N'-(1-(3,4-Dimethylphenyl)-3-methyl-5-oxo-1,5-dihydropyrazol-4-ylidene] hydrazino}-2'-hydroxybiphenyl-3-carboxylic acid, and a pharmaceutically acceptable salts, hydrates, solvates, and esters, thereof"

93. In the given facts, the conclusion that Natco has not raised a credible challenge to the validity of IN'176 is erroneous.

94. The question whether ELT-O was disclosed in IN' 176 is a contentious issue. However, assuming that ELT-O was not disclosed in 'IN 176' it would be necessary to examine the enhanced efficacy of ELT-O in comparison with compounds that were disclosed in 'IN 176'.

Coverage vs Disclosure

95. In addition to challenging the validity of IN'161 on the ground that it was not in respect of invention in view of Section 3(d) of the Act [Section 64(1)(d) of the Act]. Natco had also laid challenge to the validity of the suit patent on other grounds including that it was claimed in a valid claim of earlier priority date contained in the complete specifications of another patent granted in India [Section 64(1)(d) of the Act] and lack of novelty as disclosed in a prior publication [Section 64(1)(e) of the Act].

96. The aforesaid challenges were founded on the basis that Eltrombopag free acid along with pharmaceutically acceptable salts, was expressly claimed in IN'176. Since, ELT-O is a pharmaceutically acceptable salt of ELT, the same was covered in the claims under IN'176 – a patent in respect of which the patentee had enjoyed a monopoly for the full term of twenty years. Novartis does not dispute that ELT-O is covered under IN'176; it claims that it is covered, but not disclosed. The learned Single Judge to some extent accepted the contention that a patent may cover a substance and yet not disclose the same and held that there may be a gap between the coverage of a patent and its disclosure. Natco's challenge to the validity of IN'161 on the ground of prior claiming [Section 64(1)(a) of the Act] and lack of novelty [Section 64(1)(e) of the Act] was rejected on the ground that ELT-O was not specifically disclosed in the complete specifications of IN'176.

97. We are unable to concur with the reasoning of the learned Single Judge to the extent that it accepts that there is a gap between coverage and disclosure. The learned Single Judge also referred to ***Novartis v. UoI***[1], supporting the said view. However, a plain reading of the said judgment indicates to the contrary. The relevant extract of the said decision is set out below:

> "119. The dichotomy that is sought to be drawn between coverage or claim on the one hand and disclosure or enablement or teaching in a patent on the other hand, seems to strike at the very root of the rationale of the law

> of patent. Under the scheme of patent, a monopoly is granted to a private individual in exchange of the invention being made public so that, at the end of the patent term, the invention may belong to the people at large who may be benefited by it. To say that the coverage in a patent might go much beyond the disclosure thus seem to negate the fundamental rule underlying the grant of patents."

98. There is no ambiguity in the aforesaid decision that there cannot be dichotomy between coverage or claim on one hand and the disclosure on the other. However, the learned Single Judge had referred to Paragraph no. 134 of the said decision and concluded that the Supreme Court had accepted that there could be some gap between coverage and disclosure. Paragraph 134 of the decision of the Supreme Court is set out below:

> "134. However, before leaving Hogan and proceeding further, we would like to say that in this country the law of patent, after the introduction of product patent for all kinds of substances in the patent regime, is in its infancy. We certainly do not wish the law of patent in this country to develop on lines where there may be a vast gap between the coverage and the disclosure under the patent; where the scope of the patent is determined not on the intrinsic worth of the invention but by the artful drafting of its claims by skilful lawyers, and where patents are traded as a commodity not for production and marketing of the patented products but to search for someofne who may be sued for infringement of the patent."

99. We are unable to accept, on a plain reading of the aforesaid observation of the Supreme Court, that the same in any manner, contradicts or militates against the Supreme Court's decision to reject

the contention that there is any dichotomy between the coverage or claim on one hand and disclosure on the other. The Supreme Court has in an unequivocal language held that such a dichotomy seems "*to negate the fundamental rule underlying the grant of patents*".

100. A Division Bench of this Court had considered the similar contention in ***Merck v. Glenmark***[2]. The Division Bench referred to the decision of the Supreme Court in ***Novartis v. UoI***[1] and concluded that *"mere claims, without an enabling disclosure, cannot be sustained. The patent must – as a quid pro quo for the grant of monopoly – enable a person of ordinary skill in the art to work the invention as claimed*."

101. A similar contention was also rejected by the Division Bench of this Court in ***Astrazeneca AB & Anr. v. Intas Pharmaceuticals Ltd. & Ors.***[9] in the following words:

> "32. As far as the arguments of the counsel for the appellants/plaintiffs, of DAPA being only covered and not disclosed in IN 147 and being disclosed for the first time in IN 625, and of DAPA being not obvious from and capable of being anticipated from IN 147 are concerned, we are also of the opinion that once the appellants/plaintiffs, in the plaints in their suits claimed the action of the respondent(s)/defendant(s) of manufacturing medicines having DAPA as their ingredient to be an infringement of both IN 147 and IN 625, the appellants/plaintiffs are deemed to have admitted DAPA to be the invention subject matter of both, IN 147 and IN 625. Without DAPA being disclosed in IN 147, there could be no patent with respect to DAPA in IN 147 and which was being infringed by the

respondent(s)/defendant(s) by manufacturing drugs/ medicines with DAPA as ingredient."

102. Having stated the above, it is also necessary to clarify that a broad claim, which covers a large number of compounds with a common inventive concept at its core, also referred to as a Markush claim, is permissible, provided that the same is not overbroad or vague. The disclosure made would require to be seen in the light of the invention sought to be patented and disclosed. Thus, in cases where an active therapeutic ingredient, having therapeutic value is claimed and disclosed, the same may be patentable. The protection in respect of the said claim would extend to substances disclosed as well as to those that are not specifically disclosed but are obvious to a person skilled in art and/or can be anticipated. The gap between coverage and disclosure would thus, necessarily have to be confined to only those substances which are otherwise anticipated or obvious to a person skilled in the art. It cannot extend to other substances or products that are neither disclosed nor are obvious to or anticipated by a person skilled in the art.

103. Mr Hemant Singh had relied on the decision in ***Merck v. Glenmark***[2], and had suggested that the later decision in ***Astrazeneca AB and Anr. v. Intas Pharmaceuticals Limited***[9] conflicted with the said decision. In ***Merck v. Glenmark***[2], Merck had instituted an action for restraining Glenmark from using its patented product Sitagliptin covered by IN'209816. The said patent concerned a medicinal compound for lowering blood sugar levels in Type II Diabetes Mellitus

patients. Glenmark had launched its products (Zita and Zitamet) containing Sitagliptin Phosphate Monohydrate (*SPM* in short) salt. Merck sought an injunction restraining Glenmark from manufacturing, selling or dealing with the said products. Glenmark resisted the said action *inter alia* on the plea that SPM had different physical and chemical properties than Sitagliptin. It relied on the fact that the patentee had filed a separate application (Application No. 5948) in respect of "Phosphoric Acid Salt of DPP-IV Inhibitor", which claimed Dihydrogenphosphate salt of Sitagliptin, and had subsequently abandoned the application. In the said application, Merck had made assertions to the effect that Dihydrogenphosphate salt of Sitagliptin was novel.

104. In addition, Glenmark claimed that the suit patent did not disclose SPM but Sitagliptin free base and SPM did not use Sitagliptin free base or Sitagliptin Hydrochloride salt, as raw material. Further, the same was also not generated or formed as an intermediate in the manufacturing process. Additionally, Glenmark claimed that SPM was qualitatively different from Sitagliptin free base and enhanced its pharmaceutical qualities. The first claim of the suit patent was in respect of Sitagliptin free base. Claim No. 1 represented a general formula of complex chemical structure. Under Claim No. 19, the patentee claimed Sitagliptin free base "*or a pharmaceutical acceptable salt thereof*". However, the claim did not specifically disclose SPM. The only salt specifically disclosed was Sitagliptin Hydrochloride salt. The Trial

Court declined the interim injunction sought by Merck and it appealed the said decision before the Division Bench. The Division Bench noted that the active therapeutic component of the invention is Sitagliptin free base and not the attaching Phosphate, Hydrochloride salt or other carriers. It was acknowledged that such carrier salts are needed to deliver the drug into the body and the salt must contain certain crucial properties that allow the drug to be administered properly. However, the Division Bench noted that the Sitagliptin free base activity on the DPP-IV enzyme was not affected by the attached salts, although the efficacy of administration of the drug was dependent on the carrier.

105. It is also material to note that it was conceded by Merck that Sitagliptin Hydrochloride salt, specifically disclosed as example no. 7, is not desirable for solid dosage formulations due to flow issues. The Division Bench observed that Sitagliptin Hydrochloride salt could not be used as a commercial drug, but SPM had no such issues and was used by both the parties as a commercial drug. Notwithstanding, that SPM was not specifically disclosed in the specifications. The Division Bench allowed the appeal and granted the interim injunction as claimed by Merck, *albeit* subject to certain conditions. The Division Bench also permitted Glenmark to sell the stocks that were already manufactured.

106. It is material to note that the Division Bench had also briefly considered (on a *prima facie* basis) the applicability of Section 3(d) of the Act in the context of the application for Dihydrogenphosphate salt of Sitagliptin being abandoned. The Court held that Section 3(d) of the

Act would not be applicable backwards. Each claim was regulated by its own terms. Insofar as the objection regarding industrial application is concerned, the court accepted the contention that Sitagliptin free base was capable of industrial application and for use in the medical industry. It specifically noted that for the purposes of industrial applicability, it was recognised that the Sitagliptin free base would be attached to some carrier. However, the carrier was not the invention but only an inert component that did not add to the therapeutic or the medicinal value, which was the true core of the invention. The relevant extract of the said decision is set out below:

> "67. This Court notes that a "*specification must be read as a whole, just as any document is*" (*Cornish* at 183). The role of the specification is to teach (i.e written description) what the invention is and the method of making and using it (i.e enablement). While the claim (claims 1 and 19) disclose the Sitagliptin free base, the description relating to the issue of industrial applicability recognizes that the Sitagliptin free base will be attached to some carrier. That carrier, however, *is not the crux of the invention*, but only an inert component that does not add value to the therapeutic or medical value, which is the true core of the invention. It would be a far cry to hold that Sitagiptin "*is useless for any known purpose*" (*Chiron Corp v. Murex Diagnostics Ltd. and Other, [1996] RPC 535*). Sitagliptin was not known before, and its introduction allows for the inhibition of the DPP-IV enzyme in such a manner as previously unknown. It can - in that sense - be used, whether through one inert carrier or another."
>
> [emphasis original]

107. We are inclined to agree with the contentions advanced by Shri. Sai Deepak on behalf of Natco that the decision in the case of ***Merck v.***

Glenmark[2] and the decision of the Division Bench in ***Astrazeneca AB and Anr. v. Intas Pharmaceuticals Limited***[9] are two sides of the same coin.

108. In ***Merck v. Glenmark***[2], the suit patent was in the nature of a Markush claim, which sought to cover Sitagliptin and all pharmaceutical acceptable salts thereof. One of the challenges raised by Glenmark was that it was too broad and included possibly 4.9 billion compounds. It claimed that such elastic claims could not be sustained. The court interdicted the use of the salt form (SPM), which Glenmark claimed had different physical and chemical properties. At the interim stage, the court did not go into the question whether the suit patent disclosed SPM and left the question open. The court proceeded on the basis that since the suit patent sufficiently discloses Sitagliptin free base, which was the active ingredient and to that extent, the suit patent was *prima facie* valid. In ***Astrazeneca AB and Anr. v. Intas Pharmaceuticals Limited***[9], the appellants/plaintiffs had claimed that the product in question, DAPA was covered under IN'147 (which was the genus patent) as well as IN'625 (which was the species patent) and the manufacturer of DAPA infringed both the patents. In the aforesaid context, the Division Bench denied the interim relief on the *prima facie* view that one product could not be covered by two patents. The court also noted that the appellants/plaintiffs had not pleaded industrial application of any product other than DAPA in respect of IN'147. In the

present case as well, Novartis claimed that IN'176 has been worked on account of manufacture and sale of the drug ELT-O.

109. Thus, in both cases, ***Merck v. Glenmark***[2] and the decision of the Division Bench in ***Astrazeneca AB and Anr. v. Intas Pharmaceuticals Limited***[9], the interim orders were passed on the basis that the genus patent covered the product in question. In the former case, the interim injunction was granted, and in the latter, it was denied. We do not find the said decisions to be conflicting, as contended by Mr Hemant Singh.

110. The learned Single Judge has sought to distinguish the decision in the case of ***Astrazeneca AB and Anr. v. Intas Pharmaceuticals Limited***[9], *inter alia,* on the basis that in the said decision, the appellants/plaintiffs had claimed that the product DAPA infringed both the suit patents, IN'147 and IN'625. The court reasoned that if the appellants/plaintiffs had elected to pursue the claim of infringement in respect of only one patent, the decision would have been different. We are unable to accept that the decision in ***Astrazeneca AB and Anr. v. Intas Pharmaceuticals Limited***[9] could be distinguished on the aforesaid basis, from the facts as obtaining in the present case. In the present case too, Novartis is claiming that the product in question (ELT-O) infringes both IN'176 and IN'161. The fundamental question involved in both cases is whether a patentee can claim protective rights in respect of the same compound as covered under two product patents: one, a broad claim covering several compounds with an essential core,

claiming to possess therapeutic value, and the second a specific claim, in respect of the compound in question.

111. The decision in ***Astrazeneca AB and Anr. v. Intas Pharmaceuticals Limited***[9] is, at the interim stage, squarely applicable to the facts in this case as well.

112. Natco had also asserted that the predecessor-in-interest of Novartis had specifically claimed that ELT-O, which was being sold under the brand name PROMACTA™ was covered under Claim 1 of US Patent 7160870 (US'870). Undisputedly, Claim No.1 of US'870 is Claim No.6 of IN'176. It was contended on behalf of Natco – and not controverted by Novartis – that the predecessor-in-interest of Novartis had applied for a Patent Term Extension (PTE) for US'870 to compensate for the time spent in obtaining regulatory approvals. And, had, *inter alia*, averred as under:

> "Patent Claims to the Approved Product:
>
> As indicated above, the following claims of U.S. Patent No. 7,160,870 read on the approved product.
>
> 1. A compound selected from the group consisting essentially of: 3'-{N'-(1-(3,4-Dimethylphenyl)-3-methyl-5-oxo-1,5-dihydropyrazol-4-ylidene] hydrazino}-2'-hydroxybiphenyl-3-carboxylic acid, and a pharmaceutically acceptable salt, a hydrate, a solvate, and an ester, thereof.
>
> **Claim 1 of U.S. Patent No. 7,160,870 reads on the approved product, Promacta® tablets, because the active ingredient of the approved product, eltrombopag olamine, is encompassed**

by claim 1. Eltrombopag is present in the approved product as a 2-aminoethanol (1:2) salt.

2. The compound of claim 1, wherein the compound is the pharmaceutically acceptable salt.

Claim 2 of U.S. Patent No. 7,160,870 reads on the approved product, Promacta® tablets, because the active ingredient of the approved product, eltrombopag olamine, is a compound encompassed by claim 1. Eltrombopag is present in the approved product as a pharmaceutically active salt.

3. The pharmaceutical composition which comprises the compound of claim 1 and a pharmaceutically acceptable carrier.

Claim 3 of U.S. Patent No. 7,160,870 reads on the approved product, because the approved product is a pharmaceutical composition that contains eltrombopag olamine, which is a compound encompassed by claim 1, and several inactive ingredients, which are pharmaceutically acceptable carriers.

[emphasis added]"

113. The US Food and Drug Administration (USFDA) had also sent a communication dated 22.02.2011 to the US Patent Office confirming that US'870 (which is the counterpart of IN'176) claims PROMACTA™ (Eltromopobag Olamine).

114. As noticed earlier, Novartis has also furnished "*statement regarding the working of patented invention on commercial scale in India*" in Form 27 regarding IN'176 and IN'161. The said statement

indicated that Novartis had worked the patent inventions on a commercial scale in India on the basis of ELT-O.

115. Mr Hemant Singh contended on behalf of Novartis that the application for PTE for US'870 could not be construed to mean ELT-O was disclosed in US'870. He also stated that the patent regulations in the United States of America were different. Although there is some variance in the patent laws as applicable in the United States of America and India. However, the statement of fact made by the predecessor-in-interest of Novartis to the effect that Claim 1 of US'870 "*reads on the approved product, PROMACTA™ tablets*" must be construed as it reads at least at the interim stage. As noticed hereinabove, it was not seriously disputed that ELT is the API and ELT-O being a salt form aids in its administration on account of its properties. The insert in the packaging of the drug REVOLADE™ also indicates that ELT is the API of the formulation.

116. It is relevant to refer to Section 10 of the Act. Section 10(1) of the Act requires that every specification shall describe the invention and shall begin with the title indicating the subject matter to which the invention relates. Section 10(4) of the Act requires every complete specifications to (a) fully and particularly describe the invention and its operation or use and the method by which it is to be performed; (b) disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection; (c) end

with a claim or claims defining the scope of the invention for which protection is claimed; and (d) be accompanied by an abstract to provide technical information on the invention.

117. In terms of Section 10(5) of the Act, the claim or claims of a complete specification shall relate to a single invention, or to a group of inventions linked so as to form a single inventive concept. Thus, a claim can be made in respect of a group of inventions linked to form a single inventive concept. However, the same must be fully and particularly described. It would also be necessary to describe the best method of performing the invention.

118. If the complete specifications furnished are compliant with Section 10 of the Act and the claim is valid, then it would follow that a compound, which is covered within the said claim is also included in the complete specifications. Thus, the second patent for such a compound that was fully covered would be vulnerable to challenge on the ground of prior claiming [under Section 64(1)(a) of the Act] and lack of novelty [Section 64(1)(e) of the Act] and lack of inventive steps [Section 64(1)(f) of the Act].

119. In view of the above, Natco did satisfy the standard of raising a credible challenge to the validity of IN'161. The impugned judgement to the extent it holds otherwise is set aside. It is not necessary for the Court to dilate in other issues as the term of IN'161 has expired and it is not necessary for this Court to pass any further orders.

120. It is clarified that the observations made in the present order are *prima facie* views, and are for the limited purpose of considering the challenge to impugned judgement denying interim relief. The same would not preclude the parties from raising such contentions as advised in the pending suit. All rights and contentions of the parties are reserved.

121. The appeal is disposed of in the aforesaid terms. All pending applications are also disposed of.

VIBHU BAKHRU, J

AMIT MAHAJAN, J

APRIL 24, 2024
RK/GSR