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

Judgment Reserved on: 10/30.09.2021/
07.10.2021

% ***Judgment Pronounced on***: 28.10.2021

\+ **CS(COMM) 62/2019**

NOVARTIS AG & ORS. ..... Plaintiffs

Through Mr.Hemant Singh, Ms.Mamta Jha, Mr.Ankit Arvind and Ms.Mamta Bhadu, Advs.

Versus

NATCO PHARMA LIMITED. ..... Defendant

Through Mr.J.Sai Deepak, Ms.Rajeshwari H. and Mr.Saif Rahman Ansari, Advocates.

\+ **CS(COMM) 425/2020**

NOVARTIS AG & ANR. ..... Plaintiffs

Through Mr.Hemant Singh, Ms.Mamta Jha, Mr.Ankit Arvind and Ms.Mamta Bhadu, Advs.

versus

TORRENT PHARMACEUTICALS LIMITED ..... Defendant

Through Mr.C.S.Vaidyanathan, Sr.Adv. with Ms.Rajeshwari H. and Mr.Saif Rahman Ansari, Advs.

\+ **CS(COMM) 557/2020**

NOVARTIS AG & ANR. ..... Plaintiffs

Through Mr.Hemant Singh, Ms.Mamta Jha, Mr.Ankit Arvind and Ms.Mamta Bhadu, Advs.

Versus

ERIS LIFESCIENCES LIMITED ..... Defendant

Through Ms.Rajeshwari H. and Mr.Saif Rahman Ansari, Advs.

\+ **CS(COMM) 156/2021**

NOVARTIS AG & ANR. ..... Plaintiffs

Through Mr.Hemant Singh, Ms.Mamta Jha,

Mr.Ankit Arvind and Ms.Mamta Bhadu, Advs.

Versus

WINDLAS BIOTECH PVT LTD & ANR. ..... Defendants

Through Ms.Rajeshwari H. and Mr.Saif Rahman Ansari, Advs.

CORAM:
HON'BLE MR. JUSTICE JAYANT NATH

JAYANT NATH, J.

IA No.1803/2019 in CS(COMM) 62/2019
IA No.9072/2020 in CS(COMM) 425/2020
IA No.12284/2020 in CS(COMM) 557/2020 and
IA No.4728/2021 in CS(COMM) 156/2021

1. The issue in the aforenoted four suits are largely common and pertains to the plea of the plaintiffs' of alleged infringement of the Indian Patent IN 229051 of plaintiff No.1.

2. For the purpose of present judgment, I will deal with the facts of the first suit, namely, IA No. 1803/2019 in CS(COMM) 62/2019, titled '***Novartis AG & Ors. v. NATCO Pharma Limited***'.

3. This is an application filed on behalf of the plaintiffs under Order 39 Rules 1 and 2 CPC seeking an ex parte injunction to restrain the defendant, its agents, etc. from manufacturing, importing, selling, offering for sale, etc. any pharmaceutical composition comprising a combination of Valsartan or a pharmaceutically acceptable salt thereof and Sacubitril or a pharmaceutically acceptable salt and a pharmaceutically acceptable carrier or more specifically a pharmaceutical composition comprising combination of Sacubitril +Valsartan as a sodium salt complex or in any other form

which may amount to infringement of Indian Patent No.229051 of plaintiff No.1.

4. It is pleaded by the plaintiffs that plaintiff No.1 filed a patent application for the suit patent on 09.07.2004 as national phase entry of Patent Cooperation Treaty (PCT) International Application dated 16.01.2003 claiming priority from US Application dated 17.01.2002.

5. It is stated that the Indian Patent was examined for patentability and statutory compliances in accordance with the provisions of The Patents Act. The patent application was published in the official gazette on 10.02.2006. The suit patent was granted as Indian Patent No.229051 on 13.02.2009(*hereinafter referred to as 'IN 051'*).

6. The case of the plaintiffs is that plaintiff No.1 before filing of the patent application continued its research and development and used two compounds namely, Valsartan and Sacubitril in combination to treat cardiovascular diseases. It was found that the combination of Valsartan and Sacubitril achieves greater therapeutic effect than the administration of Valsartan, ACE inhibitors or NEP inhibitors alone. Hence, it is stated that the combination of Valsartan and Sacubitril for effective treatment of heart failure and hypertension involved great amount of research and experiments on the part of plaintiff No.1. It is stated that the suit patent has been granted in 50 countries and in India, there was no challenge to the grant of the suit patent IN 229051 either at the pre-grant stage or post-grant stage or by way of a revocation petition. It is urged that the suit patent is therefore a well established patent and is prima facie valid and subsisting and will expire on 16.03.2023.

7. Claim I of the suit patent is reproduced in the plaint as follows:-

"1. A pharmaceutical composition comprising

(i) the AT 1-antagonist valsartan or a pharmaceutically acceptable salt thereof and
(ii) N-(3-carboxy-l-oxopropyl)-(4S)-p-phenylphenylmethyl)-4-amino-2R-methylbutanoic acid ethyl ester or N-(3-carboxy-l-oxopropyl)-(4S)-p-phenylphenylmethyl)-4-amino-2R-methylbutanoic acid or a pharmaceutically acceptable salt thereof and a pharmaceutically acceptable carrier."

8. It is claimed that on a reading of Claim I, the invention comprises a pharmaceutical composition comprising combination of Valsartan and Sacubitril without any limitation in terms of salts, crystalline form, amorphous form, polymorphic forms, hydrates, supramolecular structure or mixture thereof. It is stated that the suit patent would be infringed by any unauthorised making, use, offering for sale any pharmaceutical composition comprising a combination of Valsartan and Sacubitril irrespective of a pharmaceutical formulation or arrangement thereof. It is stated that the plaintiff sells the drug formulation, marketed under the trade mark Vymada® in India and Entresto® internationally.

9. It is further urged that after filing of the patent application, plaintiff No. 1 continued with additional experimentation. After much research, plaintiff No. 1 arrived at a supra molecular structure (or supra molecular complex) of Valsartan and Sacubitril. It is urged that the said supra molecular structure is a novel compound wherein two anionic components of Valsartan and Sacubitril together with sodium cations and water molecules are linked together non-covalently to form a single large and highly intricate supra molecular structure. It is stated that being a novel supra molecular structure, plaintiff No. 1 has filed an application for grant of

patent in respect thereof and the same is subject matter of Indian Patent application No. 4412/DELNP/2007 dated 08.11.2006. The said application was published on 24.08.2007. It is stated that the said application has been opposed by way of pre-grant oppositions by various parties including the defendant herein. The opposition by the defendant was filed on 06.09.2016 though the patent application was published in 2007 and is pending adjudication.

10. It is stated that the plaintiff through a press release dated 28.01.2019 issued by the defendant came to know about the act of the defendant in launching a pharmaceutical composition comprising of the patented combination of Sacubitril and Valsartan tablet under the brand VALSAC as a combination drug.

11. It is urged that the defendant's drug formulation cannot be made, used or offered for sale without infringing the suit patent IN 229051. Hence, it is urged that the plaintiff is entitled to prevent infringement of the suit patent. It is urged that all integers of Claim I of the suit patent are present in the infringing product of the defendant.

12. Hence, the accompanying suit for permanent injunction, damages and rendition of accounts, a decree of delivery, etc.

13. The defendant in the written statement states that the invention of the suit patent comprises a combination of Valsartan and Sacubitril which together inhibit AT-1 and NEP receptors respectively. The invention is hence nothing but a physical combination of the aforesaid Valsartan and Sacubitril. On the other hand, the defendant's product is a supra molecular complex comprising of Valsartan and Sacubitril anions with sodium cations and water molecules and does not fall within the scope of the suit patent.

The plaintiff, it is stated, has misleadingly and falsely stated that the said supra molecular complex is covered under the suit patent IN'051. It is urged that the above position has been reiterated several times by the plaintiff before several authorities.

14. Further, the plaintiff has deliberately suppressed the fact that the plaintiff has also a supra molecular complex which is covered by the pending patent application being application No.4412/DELNP/2007. In the said application, it is stated that the plaintiff has taken a stand that the supra molecular complex was invented much after the suit patent and was not known at the time of filing of the suit patent. It is urged that the claim of the plaintiff to all forms of combination of Valsartan and Sacubitril without limitation (including the defendant's product) is far-fetched and speculative. It is strongly urged that in the reply to the oppositions filed by various entities to the plaintiff's patent application being application No.4412/DELNP/2007, a categorical stand is taken by the plaintiff that IN'051 does not act as prior art or novelty for application No.4412. The product covered, namely, the supra molecular complex is not in any way concerned or related to the suit patent IN'051. It is stated that the plaintiff has also asserted that the product covered by the subsequent application No.4412 was never conceived or contemplated when the invention for the suit patent was made.

15. The defendant has also filed a counter-claim for revocation of the Indian Patent IN'051. The grounds for revocation are stated as follows:-

(a) Subject matter of the patent is obvious in nature and does not involve any inventive step having regard to what was publicly known or used or

published in India or elsewhere - Lack of inventive step under Section 64(1)(f).

It is submitted that the suit patent IN 229051 lacks inventive step in view of:-

i) US 5399578 (US'578');

ii) US 5217996 (US'996');

iii) EP 0498361 (EP'361');

iv) EP 0726072 (EP'072');

v) Nick et al; and J. Pharmacol. Experimental Therapeutics 272: 619-627(1195).

(b) Subject matter of the patent is not patentable under the Act – Claims are not patentable under Section 3(e) read with Section 64(1)(k);

It is urged that the said claims do not satisfy the definition of the term composition as the said claims merely relate to an admixture of an active and a pharmaceutically acceptable carrier.

(c) The subject matter of the Patent under No.229051 is not sufficiently or properly described - insufficient description - ground 64(l)(h).

It is urged that the suit patent does not describe how to manufacture a composition comprising AT-II and NEP inhibitors. Not a single example has been provided in the specification setting out a tablet comprising both Valsartan and Sacubitril.

(d) It is claimed that the subject matter of the patent is not patentable under the Act. Reliance is placed on Section 3(d) read with Section 64(1)(k) of the Act.

(e) It is claimed that the impugned suit patent does not possess any inventive steps and is obvious to a person skilled in the art. Reliance is placed on Section 64 (1) (d) of the Act.

16. The plaintiff has filed a replication to the written statement. It is submitted in the replication that the invention in the suit patent comprises a pharmaceutical composition comprising combination of Valsartan and Sacubitril or pharmaceutically acceptable salts thereof without any limitation in terms of salts, polymorphic forms, hydrates, supra molecular structure (or supra molecular complex), or mixture thereof, together with a pharmaceutically acceptable carrier. Therefore, the defendant's pharmaceutical composition which admittedly comprises of pharmaceutically acceptable salts of Valsartan and Sacubitril (as anions with sodium cations) and a pharmaceutically acceptable carrier, irrespective of how Valsartan and Sacubitril (or pharmaceutically acceptable salts thereof) are combined and/or in what form they are, would fall within the coverage for Claim I and would amount to infringement of the suit patent.

17. It is further urged that the defendant has now raised the issue of invalidity of the suit patent and has cited a handful of prior arts for the said purpose. It is urged that defendant was aware of the suit patent since, at least, September 2016 when it filed the pre-grant opposition to the plaintiff's patent application No. 4412. The ground taken in the said opposition is that the compound, subject matter of the said application, is a mere supra-molecular complex of combination of Valsartan and Sacubitril disclosed by the suit patent and the same is an immediate prior art to the application No.4412. It is urged that the defendant has in the opposition stated that the compound which is subject matter of the patent application No. 4412 of the

plaintiff is merely a new form of the substance already disclosed by the suit patent. However, at no stage has the defendant taken any steps to challenge the validity of the suit patent. It is only as a counter-blast, now when the present suit for injunction has been filed that the validity of the suit patent has been challenged. It is urged that none of the prior art citations relied upon by the defendant renders the suit patent obvious or lacking in novelty. It is reiterated that the suit patent was filed in July 2004 and there was no pre-grant opposition or post-grant opposition or challenge to its validity by way of revocation for the past 14 years. Thus, it is pleaded that a strong *prima facie* case is made out regarding the validity of the suit patent.

18. I may note that when this matter came for hearing on the first date on 06.02.2019 along with the Caveat filed by the defendant, this court recorded that prima facie, there appears to be merit in the contentions of the learned senior counsel for the plaintiffs. The submission of the learned senior counsel for the defendant was noted, namely, that this court may in exercise of powers under Section 115 of the Patents Act appoint an independent Scientific Adviser to assist the court as to whether the product/drug of the defendant is made using the suit patent or arises from the suit patent. A submission was also made that till the next date of hearing, the defendant shall not release any further products of the impugned drug in the market. This court appointed a Scientific Adviser.

19. On 21.02.2019, this court changed the Scientific Adviser and appointed Mr. Rajendra Prasad from New Delhi as the Scientific Adviser. The following questions was referred for opinion of the Scientific Adviser:-

> "Q. Whether in the opinion of the learned Expert defendant's product described as a complex as given in para 10 of the patient

information leaflet is encompassed or subsumed by Claim I of suit patent:

> 1. A pharmaceutical composition comprising
> (i) the AT 1-antagonist valsartan or a pharmaceutically acceptable salt thereof and
> (ii)N-(3-carboxy-l-oxopropyl)-(4S)-p-phenylphenylmethyl)-4-amino-2R-, methylbutanoic acid ethyl ester or N-(3-carboxy-loxopropyl)-(4S)-p-phenylphenylmethyl)-4-amino-2 R-methylbutanoic acid or a pharmaceutically acceptable salt thereof and a pharmaceutically acceptable carrier.?

20. On 27.03.2019, the court recorded that the Scientific Adviser has filed his report. It also noted that the plaintiff has filed IA No. 5416/2019 being objections to the report of the Scientific Adviser. In view of the report of the Scientific Adviser, the defendant stated that they would not like to make any further undertaking as made on 06.02.2019. This court noting that the objections filed by the plaintiff would require a little more detailed considerations, directed that till further orders, the defendant is restrained from using the impugned product/pharmaceutical composition.

21. Against the said order, an appeal was filed being FAO(OS)(COMM) 81/2019. On 09.04.2019, the appeal was disposed of restoring the statement made on behalf of the defendant as recorded in the order dated 06.02.2019. The injunction as granted by the court was held to be no longer operative.

22. I have heard Mr.Hemant Singh, learned counsel for the plaintiffs, Mr.J.Sai Deepk, learned counsel for the defendant in CS(COMM) 62/2019, Mr.C.S.Vaidyanathan, learned senior counsel for the defendant in CS(COMM) 425/2020, and Ms.Rajeshwari H., learned counsel for the defendants in CS(COMM) 557/2020 and CS(COMM) 156/2021.

23. Learned counsel for the plaintiffs has made the following salient submissions:-

(i) It has been urged that in accordance with Section 10(4)(c) of the Patents Act 1970, the scope of an invention is defined and determined by the granted claims. Hence, it is urged that the scope of the invention for which protection has been granted in respect of the suit patent is as per Claim I, namely, a pharmaceutical composition comprising of Valsartan or a pharmaceutically acceptable salt thereof or Sacubitril or a pharmaceutically acceptable salt thereof and a pharmaceutically acceptable carrier. It is urged that there is no limitation in Claim I in respect of mode or manner of using or combining the use of Valsartan and Sacubitril and therefore, none can be read therein. It is urged that all pharmaceutical compositions comprising the three integers of Claim I, namely, Valsartan and Sacubitril and the pharmaceutically acceptable carrier would fall within the coverage of Claim I of the suit patent IN'051 and would constitute infringement under Section 48 of the Patents Act. It is urged that the defendant is proposing to manufacture/has been manufacturing, marketing Sacubitril and Valsartan tablets which contain all the integers of Claim I of the suit patent IN'051. Reliance is placed on the information literature of VALSAC of the defendant to reiterate the above contentions.

(ii) It is further urged that the reliance of the defendant on the subsequent patent application No.4412/DELNP/2007 of the plaintiff is misplaced and misconceived. It is stated that claims of two independent patents cannot be construed in reference to each other. The patent application of the plaintiff being application No.4412 pertains to mode and manner of combining of Valsartan and Sacubitril in form of a supra-molecular complex/compound.

The said application is based on the teaching of the earlier suit patent which is the basic patent. However, when the active ingredients of Valsartan and Sacubitril along with the pharmaceutically acceptable carrier are used as part of the pharmaceutical composition, the same would fall within the claim coverage of the suit patent and would tantamount to infringement of the suit patent.

(iii) It is urged that the defendant have also placed reliance on the judgment of the Supreme Court in the case of ***Novartis AG vs. Union of India & Ors., (2013) 6 SCC 1*** to contend that there cannot be a difference between coverage and disclosure and that since the complex is not disclosed in the suit patent, it cannot be covered. It is urged that there is no provision which mandates that the coverage is limited to disclosure. It is stated that this position has been clarified by this court in the case of ***FMC Corporation and Anr. vs. Best Crop. Science LLP & Anr., (2021) 87 PTC 217 DEL*** and in the case of ***AstraZeneca AB & Anr. Vs. Torrent Pharmaceuticals Ltd***. In any case, it is urged that in the present case, there is no gap between the coverage and the disclosure. The invention disclosed and claimed is "pharmaceutical combination comprising Valsartan or pharmaceutically acceptable salt thereof and Sacubitril or pharmaceutically acceptable salt thereof along with pharmaceutically acceptable carrier and a pharmaceutical composition comprising of the same". The impugned tablets fall within the coverage of the suit patent.

(iv) It is further urged that the reliance of the defendant on the report of the court appointed Scientific Adviser dated 07.03.2019 is misplaced as the same is not binding on the parties. It is stated that the Scientific Adviser in the present case was appointed under Section 115 of the Patents Act which

is limited to providing an opinion on technical matters and not on issue of infringement which involves question of law. Such an opinion, it is urged, is merely advisory. It is stated that objections have already been filed to the report of the Scientific Adviser. Reliance is also placed on the opinion of the experts filed by the plaintiffs.

(v) It is further urged that none of the defendants has advanced any submissions raising credible challenge to the validity of the suit patent IN'051. The pleas, it is urged, are misconceived.

24. Learned counsel for the defendant in CS(COMM) 62/2019 has urged the following salient submissions:-

(i) It is urged that the product of the defendant is a sodium salt supra molecular complex (also known as co-crystal) made with Valsartan, Sacubitril, solution ion and water molecules as a single molecule. On the other hand, the suit patent claims a composition where two separate molecules of Valsartan and Sacubitril that are held separately and are deliverable either as a unified tablet or in two different containers in a kit. It is urged that Valsartan and Sacubitril in a single molecule as a supra molecular complex is completely beyond the scope of the claims of the suit patent as well as its specifications. The plea of the plaintiff that all combinations comprising of Valsartan and Sacubitril are within the scope of the suit patent is misconceived and misplaced. The suit patent covers only physical/heterogeneous mixture of the two components and not a single molecule by way of a supra-molecular complex

(ii) Reliance is placed on the pending patent application of the plaintiff No. 4412. It is urged that the fact that the suit patent does not cover a supra-molecular complex containing Valsartan and Sacubitril was admitted by the

plaintiff in response to the objections raised before the concerned authorities in relation to the pending patent application of the plaintiff No. 4412. In response to the said objections, the plaintiff has urged that the cited prior art document (the suit patent) neither discloses a novel and unique compound having a dual mechanism of action of the present application nor a process for synthesis of such a compound. There is no teaching or enablement in any of the cited prior documents in respect of such a compound, much less a unique large compound having a supra-molecular structure as claimed in the present invention. It is urged that in view of the said admission of the plaintiff, it is incredible that the plaintiff seeks to resile from the said position and seeks injunction now against the defendant.

(iii) It is further urged that the judgment of the Division Bench of this court in the case of ***F.HOFFMANN-LA ROCHE LTD. & ANR. v. CIPLA LTD., (2016) 65 PTC 1*** has no application to the present case. The said judgment was delivered post trial whereas the present matter relates to an interim injunction. The conclusion in that suit was over an infringement of a combination of polymorphs A and B of Erlotinib Hydrochloride. The plaintiff therein had abandoned its patent application over polymorph B. In the present case the plaintiff has not abandoned the patent application No. 4412 over the supra-molecular complex.

(iv) It is further urged that the plaintiff's plea that the defendant has admitted in its pre-grant opposition to application No.4412 that the supra-molecular complex is covered by the suit patent is misconceived. The defendant have challenged the application No. 4412 on the ground that it lacks inventive steps i.e. a ground under Section 25(1)(e) of the Patents Act.

The ground of lack of novelty as provided under Section 25(1)(b) of the Patents Act has not been raised by the defendant in the pre-grant opposition

(v) Reliance is placed on the opinion of the Scientific Adviser appointed by this court to plead its case.

25. Learned senior counsel for the defendant, Mr.C.S.Vaidyanathan, has more or less reiterated the above contentions of learned counsel for the defendant in CS(COMM) 62/2019. He has reiterated that in view of Section 10(4)(c) and 10(5) of the Patents Act coverage cannot be beyond disclosure. It is further urged that judgment of the Division Bench of this court in ***F.HOFFMANN-LA ROCHE LTD. & ANR. v. CIPLA LTD.***(supra) pertains to the issue of section 3(d) of the Patent Act and no more.

26. Learned counsel appearing for the other defendants, Ms.Rajeshwari H, has urged that supra molecular complex in question is subsequent to the patent. Hence, it is urged that it cannot be covered under the suit patent. It is further strongly urged that the defendant does not cross the claim of the plaintiff. Admittedly, the supra molecular complex is not covered by the claim. The carrier is added only after supra molecular complex is made. The carrier is not used to make the supra molecule complex.

27. The main issue revolves around the interpretation of Claim I of the suit patent "IN 229051". Claim I of the suit patent IN 229051 reads as follows:-

> "1. ***A pharmaceutical composition comprising***
> (i) the AT 1-antagonist valsartan or a pharmaceutically acceptable salt thereof and
>
> (ii) N-(3-carhoxy-l-oxopropyl)-(4S)-p-phenylphenylmethyl)-4-amino-2R-methylbutanoic acid ethyl ester or N-(3-carboxy-loxopropyl)-(4S)-p-phenylphenylmethyl)-4-amino-2

> Rmethylbutanoic acid or a pharmaceutically acceptable salt thereof and a pharmaceutically acceptable carrier."

28. The plaint states that the coverage of Claim I of the suit patent is a pharmaceutical composition comprising of (a) Valsartan or a pharmaceutically acceptable salt thereof; and (b) Sacubitril or its active metabolite, Sacubitrilate or a pharmaceutically acceptable salt thereof. In essence, the inventive concept of the suit patent is claimed to be a pharmaceutical composition that comprises combination of Valsartan and Sacubitril. In the plaint, it is stressed that the invention comprises a combination of Valsartan and Sacubitril without any limitation in terms of salts, crystalline form, amorphous form, polymorphic forms, hydrates, supra molecular structure (supra-molecular complex), or mixture thereof. It is clarified that making, using, offering for sale, etc. any pharmaceutical composition comprising a combination of Valsartan or a pharmaceutically acceptable salt thereof and Sacubitril or its active metabolite, or a pharmaceutically acceptable salt thereof and a pharmaceutically acceptable carrier, without prior permission and license from plaintiff No.1 constitutes use/infringement of the patented composition which is covered within the scope of Claim I of the suit patent.

29. The defendant however stresses that the suit patent "IN 229051" covers only a physical/heterogeneous mixture of two components. It is admitted that the product of the defendant has a mixture of Valsartan and Sacubitril but it is urged that the same is a supra molecular complex made with Valsartan and Sacubitril anions with sodium ions and water molecules and does not fall within the scope of "IN 229051". Hence, as per the

defendant, the suit patent covers a physical and heterogeneous mixture of two components and not a single molecule by way of a supra molecular complex of the two components.

Further as per the defendant, the plaintiffs have themselves applied for a patent to cover a supra molecular complex containing Valsartan and Sacubitril by application No.4412. In response to the objections filed to the said application by the defendant, the plaintiffs have claimed that the suit patent does not disclose any process for synthesis of the supra molecular complex as described in the patent application No.4412.

30. Learned counsel for the plaintiffs has however clarified that on a plain reading of Claim I what is protected is a combination of Valsartan or a pharmaceutically acceptable salt and Sacubitril or a pharmaceutically acceptable salt and a pharmaceutically acceptable carrier. If the defendant were to only sell a combination of Valsartan and Sacubitril as a supra molecular complex without adding pharmaceutically acceptable carrier, it would not be covered by Claim I of the suit patent.

31. Essentially, the dispute is as to whether the combination of Valsartan and Sacubitril, which is a supra molecular complex comprising of a single molecule with a pharmaceutically acceptable carrier is covered by Claim I of the said patent "IN 051".

32. I may see as to how Claims are to be interpreted.

33. Section 10(1) & (4) of the Patents Act reads as follows:-

> "10 Contents of specifications: -
>
> (1) Every specification, whether provisional of complete, shall describe the invention and shall begin with a title sufficiently indicating the subject-matter to which the invention relates.

******

(4) Every complete specification shall-

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

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

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

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

34. Hence, as per section 10(4)(c) each complete specification shall end with a claim or claims defining the scope of the invention for which protection is claimed.

35. The Division Bench of this court in ***F.HOFFMANN-LA ROCHE LTD. & ANR. v. CIPLA LTD.***(supra) was dealing with a patent relating to the product Erlotinib Hydrochloride. The plaintiff therein applied for and was granted patent for the said product Erlotinib Hydrochloride. The plaintiff also applied for patent of polymorph B of Erlotinib Hydrochloride in India which was rejected. The main issue was as to whether in view of the rejection of the application of the plaintiff for the patent of polymorph B, the defendant was entitled to deal with the same product i.e. polymorph B without violating the patent of the plaintiff. The Division Bench on the issue of interpretation of Claims held as follows:-

"66. Before we apply the aforenoted legal position to the facts of the instant case we need to discuss the legal position concerning

construction of claims. In the decision reported as AIR 1969 BOMBAY 255 FH & B v. Unichem Laboratories it was held that specifications end with claims, delimiting the monopoly granted by the patent and that the main function of a Court is to construe the claims without reference to the specification; a reference to the specification being as an exception if there was an ambiguity in the claim. Claims must be read as ordinary English sentences without incorporating into them extracts from body of specification or changing their meaning by reference to the language used in the body of the specification. In a recent decision in FAO (OS) No. 190/2013 Merck v. Glenmark the Division Bench held that claim construction to determine the coverage in the suit patent has to be determined objectively on its own terms with regard to the words used by the inventor and the context of the invention in terms of the knowledge existing in the industry. Abandonment of an application cannot remove what is patented earlier nor can it include something that was excluded earlier and that a patent is construed by the terms used by the inventor and not the inventors subjective intent as to what was meant to be covered. Merely because an inventor applies for a latter patent that is already objectively included in a prior patent, but which inventor subjectively feels needs a separate patent application, doesn't mean it is to be taken at face value and therefore neither Section 3(d) or abandonment of subsequent patent application can be used to read into terms of prior application, which has to be construed on its own terms. In the decision reported as 415 F. 3d 1303 Edward H. Phillips v. AWH Corporation it was held that claims have to be given their ordinary and general meaning and it would be unjust to the public, as well as would be an evasion of the law, to construe a claim in a manner different from plain import of the terms and thus ordinary and customary meaning of the claim term is the meaning of the term to a Person of Ordinary Skill in the Art as of effective date of filing of the patent application. In case of any doubt as to what a claim means, resort can be had to the specification which will aid in solving or ascertaining the true intent and meaning of the language employed in the claims and for which the court can consider patent prosecution history in

order to understand as to how the inventor or the patent examiner understood the invention. The Court recognized that since prosecution is an ongoing process, it often lacks clarity of the specification and thus is less useful for claim construction. The Court also recognizes that having regard to extrinsic evidence such as inventor testimony, dictionaries and treaties would be permissible but has to be resorted to with caution because essentially extrinsic evidence is always treated as of lesser significance in comparison with intrinsic evidence. In the decision reported as 457 F.3. 1284 (United States) Pfizer v. Ranbaxy the Court held that the statements made during prosecution of foreign applications are irrelevant as they are in response to unique patentability requirements overseas. The Court also held that the statement made in later unrelated applications cannot be used to interpret claims of prior patent. In the decision reported as 1995 RPC 255 (UK) Glaverbel SA v. British Coal Corp the Court held that a patent is construed objectively, through the eyes of a skilled addressee. The Court also held that the whole document must be read together, the body of specification with the claims. But if claim is clear then monopoly sought by patentee cannot be extended or cut down by reference to the rest of the specification and the subsequent conduct is not available to aid the interpretation of a written document.

67. For the above conspectus, pithily put, principles of claim construction could be summarized as under: -

(i) Claims define the territory or scope of protection (Section 10(4) (c) of the Patents Act, 1970.

(ii) There is no limit to the number of claims except that after ten claims there is an additional fee per claim (1st Schedule of the Act).

(iii) Claims can be independent or dependent.

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

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

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

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

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

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

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

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

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

claim which is dependent upon it'. (Landis on Mechanics of Patent Claim Drafting)

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

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

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112. If Roche's patent was for a polymorphic form of Erlotinib Hydrochloride and not the molecule itself and Cipla had argued that theirs was a 'new substance', then alone the Court could have relied on evidence of use of the X-Ray diffraction technique and a consequential analysis of the peaks of both to ascertain whether they are identical or dissimilar compounds. However in that situation too, the comparison would have to be between a product made on the basis of Roche's patent claim and Cipla's product and not between Roche's product as sold in the market and Cipla's product. This subtle distinction is important to be kept in mind because the holder of a patent is by no means limited to only manufacture and sell only those products that are disclosed in the claims of the patent and hence a different polymorph manufactured by the patent holder which is not the subject of the registered patent cannot be used for the purpose of comparison with the infringer product; the very product disclosed in the patent claims must be used.

113. Thus the question at hand is really whether Cipla's Polymorph B (Erlocip) was subsumed in the claims of IN '774.

We find the answer in the decision reported as [2008] EWHC Civ 445 Servier v. Apotex. Servier's attempt to secure a patent for the α-form of the t-butylamine salt of perindopril failed both before the Patents Court and the Court of Appeals which observed that the crystal form could easily be obtained by carrying out the process disclosed in the basic patent. In refusing to 'evergreen' the basic patent it was clear that the Court of Appeals was not denying Servier the right to enforce the basic patent against a third party attempting to manufacture the α-form crystals. In the present case too, the correct analysis that the Learned Single Judge ought to have employed was a construction of the IN '774 claim to understand whether it encompassed the manufacture of Polymorph B of Erlotinib Hydrochloride. By focusing on evidence involving the analysis of X-Ray diffraction data, the Learned Single Judge has erroneously compared the products of Roche and Cipla when he ought to have mapped the claims of the suit patent against Cipla's product. Counsels for both the Appellant and the Respondent have not been able to assist the court with authorities to support their stand on the test of infringement required to be employed and much of the arguments have been on first principles.

114. It is therefore left to the Court to study the specification and claims of the suit patent and note that as they are in relation to Erlotinib Hydrochloride and are not restricted to any specific Polymorph, they would be infringed by any manufacture of Polymorph B by a third party as the same would use the subject matter of IN '774 as its basic starting point. The Learned Single Judge has correctly applied the principle in the decision reported as AIR 1969 Bom 255 F.H & B v. Unichem, in stating that in case of any ambiguity of the Claim of the suit patent then resort can be taken to the specification of the said suit patent and nothing else. He correctly recognized that a Purposive Construction of the claims is necessary in order to not construe claims too narrowly. Yet we find that neither of these tests have been applied in the present case to construct the claims themselves and hence a conclusion that the IN '774 patent covers Polymorphs A+B itself is erroneous."

36. Similarly, another Division Bench of this court in the case of ***Merck Sharp and Dohme Corporation and Anr v. Glenmark Pharmaceuticals, (2015) 63 PTC 257*** held as follows:-

> "55. Accordingly, questions of whether the abandonment of SPM in the subsequent patent application (5948/DELNP/2005) affects the claim of SPM in the suit patent assumes lesser importance. The Court at the same time, notes that the claim construction to determine the coverage in the suit patent is to be determined objectively on its own terms with regard to the words used by the inventor and the context of the invention in terms of knowledge existing in the industry. The subsequent abandonment of a patent for SPM cannot remove what is patented earlier (if an objective reading, as indicated above, considers it to be included); nor can it include something that was excluded earlier. The motives for abandonment - since MSD claims that it abandoned the claim due to Section 3(d) of the Act - play no part in the claim construction. Considerable argument was addressed to the Court on this aspect; learned Senior Counsel for MSD argued that the subsequent patent was abandoned because of Section 3(d), as SPM had not enhanced therapeutic value and would not be granted an independent patent but be included in the original patent as well (thus arguing the concept of 'basic' and 'improvement' patent); Glenmark urged that this would be contrary to the purpose of Section 3(d) - whilst improvements in patents not disclosed in the patent application are hit by that section, this does not mean that they are included in the original patent. These arguments make the construction of the claim dependant on the scope of Section 3(d) vis-à-vis improvements to basic patents.
>
> 56. Section 3(d) does not work backwards, such that two independent patent claims are to be construed in reference to each other. Each claim is regulated by its own terms, subject to the statutory prescriptions of inventive step and industrial applicability. Moreover, such an argument also introduces an undeserved subjectivity in the patent construction process. A patent is construed by reference to the words used by the

inventor, and not her subjective intent as to what was meant to be covered (as was noted in Kirin-Amgen Inc v. Hoechst Marion Roussel Limited, [2004] UKHL 46, "[there is no window into the mind of the patentee or the author of any other document. Construction is objective in the sense that it is concerned with what a reasonable person to whom the utterance was addressed would have understood the author to be using the words to mean."]. Merely because an inventor applies for a later patent - that is already objectively included in a prior patent, but which the inventor subjectively feels needs a separate patent application - does not mean that it is taken to be at face value. The intent of the inventor, through the use of the words that have been employed, must be judged, but the subjective intent cannot replace a detailed analysis of the text of the patent. This Court has already noted - on a different basis - that the coverage of SPM in the suit patent is questionable on account of Section 10(4)(b), although the issue is ultimately tied to important factual disputes. The same decision significantly provided the following rationale for patent construction in terms of the words and expressions used:

> "The courts of the United Kingdom, the Netherlands and Germany certainly discourage, if they do not actually prohibit, use of the patent office file in aid of construction. There are good reasons: the meaning of the patent should not change according to whether or not the person skilled in the art has access to the file and in any case life is too short for the limited assistance which it can provide. It is however frequently impossible to know without access, not merely to the file but to the private thoughts of the patentee and his advisors as well, what the reason was for some apparently inexplicable limitation in the extent of the monopoly claimed. One possible explanation is that it does not represent what the patentee really meant to say. But another is that he did mean it, for reasons of his own; such as wanting to avoid arguments with the examiners over enablement or prior art and have his patent granted as soon as possible. This feature of the practical life of a patent

> agent reduces the scope for a conclusion that the patentee could not have meant what the words appear to be saying."
>
> This Court is furthermore also cautious of using either Section 3(d) or the abandonment of a subsequent patent application to read into the terms of a prior application which has to be construed on its own terms. Accordingly, while the coverage of SPM is shrouded in some uncertainty that requires detailed examination of facts and evidence, the Court notes that the Sitagliptin free base is prima facie disclosed, claimed and thus covered by the suit patent."

37. Clearly, the claims have to be read as ordinary English sentences without incorporating or changing their meaning by reference to the language used in the body of the specification. The coverage in the suit patent is to be determined objectively on its own term. The subsequent steps taken by the plaintiff cannot remove what is patented earlier nor can it include something that was excluded earlier.

38. A reading of Claim I shows that it comprises of composition of (i)Valsartan or a pharmaceutically acceptable salt; (ii) Sacubitril or a pharmaceutically acceptable salt; and a composition of pharmaceutically acceptable carrier.

39. As noted above in the judgment of ***F.HOFFMANN-LA ROCHE LTD. & ANR. V. CIPLA LTD.***(supra), the term "comprising" is open ended, which means that if the claim contains three elements 'A', 'B' and 'C', it would still be an infringement if someone adds a fourth element 'D'. Hence, in view of the language used in Claim I, a composition comprising of Valsartan or a pharmaceutically acceptable salt and Sacubitril or a

pharmaceutically acceptable salt and a pharmaceutically acceptable carrier would fall within Claim I of the suit patent.

40. Admittedly, it has not been denied by the learned counsel for the defendant that the impugned product of the defendant comprises of Valsartan, Sacubitril and a pharmaceutically acceptable carrier.

The argument of the defendant that Claim I of the plaintiff does not cover the product of the defendant which is a supra molecular complex made with Valsartan and Sacubitril, solution ion and water molecules as a single molecule is a plea wholly contrary to a plain reading of Claim I of the impugned patent. A bare reading of Claim I shows that it includes a composition of Valsartan, Sacubitril and the carrier. The defendant's product falls within such a composition. The claim does not prima facie deal with all compositions of Valsartan, Sacubitril and the stated carrier.

41. The defendant has also strongly urged relying upon the patent application No.4412 of the plaintiffs to plead that it is the own case of the plaintiffs that the suit patent does not cover a supra molecule containing Valsartan and Sacubitril. It is urged that such a plea has been raised by the plaintiffs in response to the objections raised to the patent application No.4412 by the defendant and others.

42. I may note that the Division Bench in ***F.HOFFMANN-LA ROCHE LTD. & ANR. V. CIPLA LTD.***(supra) has noted as follows:-

> "66. ..... Merely because an inventor applies for a latter patent that is already objectively included in a prior patent, but which inventor subjectively feels needs a separate patent application, doesn't mean it is to be taken at face value and therefore neither Section 3(d) or abandonment of subsequent patent application

> can be used to read into terms of prior application, which has to be construed on its own terms."

43. Similarly, the Division Bench in ***Merck Sharp and Dohme Corporation and Anr v. Glenmark Pharmaceuticals***(supra) has noted that the subsequent abandonment of an application cannot remove what is patented earlier nor can it include something that was excluded earlier, abandonment of a claim plays no part in the claim construction.

44. Hence, merely because the plaintiffs have filed an application for registration of a supra molecular complex of the two components of Valsartan and Sacubitril being application No.4412 does not modify or change the position *vis-a-vis* interpretation of Claim I of the suit patent. *Prima facie,* there is no merit in the said plea of the defendant.

45. Another plea strongly raised by the learned counsel for the defendant is that the judgment of the Division Bench in ***F.HOFFMANN-LA ROCHE LTD. & ANR. V. CIPLA LTD***(supra) does not apply to the facts of this case. The said plea is without any merit. Merely because the said judgment of the Division Bench was delivered post-trial or related to polymorph B of the product Erlotinib Hydrochloride or dealt with an abandoned application of polymorph B would make no difference to the ratio of the said judgment.

46. I also cannot help noticing few facts. The suit patent application was filed in 2004. The patent "IN 229051" was granted on 13.02.2009. Similarly, the plaintiffs filed an application bearing No.4412 for the supra molecular structure comprising of Valsartan and Sacubitril on 08.11.2006. It was published on 24.08.2007. The defendant filed its opposition to the same on 06.09.2016. Now in January, 2019, the defendant has chosen to start

manufacturing the impugned product. After the present suit was filed, they filed a counter-claim to challenge the suit patent "IN 229051". *Prima facie,* the defendant has clearly acted belatedly.

47. I may note that the defendant has also filed a counter-claim in CS(COMM) 62/2019 and CS(COMM) 425/2020 seeking to challenge the suit patent.

48. This court in ***Astrazeneca AB & Ors v. P Kumar & Anr.***, CS(COMM) 749/2018, decided on 08.08.2019 held as follows:-

> "39. It is manifest from the above submission that there are two rival stands available on record. The stand of the defendants is that there is similarity of structure that exists between the prior patent IN 229 and the subsequent patents. They plead that IN 229 discloses TICAGRELOR. The plaintiff denies this. The Supreme Court in ***Biswnath Prasad Radhey Shyam v. Hindustan Metal Industries Ltd.***(supra) held that as to whether an alleged invention involves novelty or is an inventive step is a mixed question of law and facts. A Co-ordinate Bench of this court in ***Bristol-Myers Squibb Company & Ors. v. Mr.J.D.Joshi & Anr., 2015 (64) PTC 135 (Del)*** has noted that the challenges which can be raised under the provisions of the section 64 of the Patents Act, 1970 are in the nature of questions dependent on facts or the mixed question of facts and laws. The claim of the defendant stated above i.e. that IN 229 discloses TICAGRELOR would be a mixed question of law and fact.
>
> 40. A Co-ordinate Bench of this court in the case of ***Merck Sharp & Dohme Corporation & Anr. v. Glenmark Pharmaceuticals Ltd., 223 (2015) DLT 454,*** on this context noted as follows:
>
> > "57. From the facts narrated hereinabove it is clear that matter involves invention of a chemical molecule/compound in the medicinal field and is of highly technical nature. In such like matter Court has to go by the opinion of the experts in the field, whose testimony is found trustworthy

and reliable, inasmuch as, is supported by the documents. The Court has not to super impose its view over and above the technical experts, more so when judges are not experts in chemical and medicinal filed. In ***Martin F.D'Souza v. Mohd. Ishfaq,*** 157(2009) DLT 391 (SC) = 12(2009) CPJ 32 (SC) = II(2009) SLT 20 = (2009) 3 SCC 1, Supreme Court held thus: "the Courts and Consumer Fora are not experts in medical science, and must not substitute their own views over that of specialists".

41. I may only note that at this stage the parties have yet to lead their evidence. It is only once the evidence of the experts is recorded and subjected to appropriate cross-examination, a conclusion can be reached as to whether the submissions as stated above would show as to whether the claims of the genus patent IN 229 discloses TICAGRELOR."

49. The above observations are clearly also applicable to the facts of this case.

50. Another plea that was raised by the defendant is the reliance on the opinion of the Expert Scientific Adviser dated 07.03.2019. This court framed the following question to the Scientific Adviser:-

"Q. Whether in the opinion of the learned Expert defendant's product described as a complex as given in para 10 of the patient information leaflet is encompassed or subsumed by claim 1 of suit patent:

"1. A pharmaceutical composition comprising

(i) the AT-l-antagonist valsartan or a pharmaceutically acceptable salt thereof and

(ii) N-(3-carhoxy-l-oxopropyl)-(4S)-p-phenylphenyl methyl) 4-amino-2R-methyibutanoic acid ethyl ester or N-(3-carDoxy-l-oxopropyl)-(4S)-p-phenylphenylmethyl)- 4-

amino2R methylbutanoic acid or a pharmaceutically acceptable salt thereof

and a pharmaceutically acceptable carrier.?""

51. The opinion of the Scientific Adviser is as follows:-

"No, the Defendant's product described as a complex as given in para 10 of the Patient information Leaflet is NOT encompassed or subsumed by Claim 1 of the suit patent IN 299051

Because

whereas the Defendant's product is claimed to be a sodium salt supramolecular complex (also known as cocrystal) made with Valsartan, Sacubitril, solution ion and water molecules as a single molecule, the Claim 1 of suit patent iN299051 protects a combination of two separate moieties of Valsartan and Sacubitrii held separately which may be delivered either as a unified tablet or in two different containers in a kit.

The complex of Defendant is a supramolecular complex which is scientifically a different entity in chemistry and would have different physical properties from either of Vaisartan and Sacubitril or both together even though their medicinal effects may be similar. Thus, it would not be encompassed or subsumed by Claim 1 of iN299051."

52. Hence, the Scientific Adviser concluded that the product of the defendant is a supra-molecule complex made with Valsartan and Sacubitril, solution ion and water molecules as a single molecule whereas Claim I of the suit patent IN 229051protects a combination of two separate moieties of Valsartan and Sacubitril held separately.

53. Section 115 of the Patent Act reads as follows:-

"Scientific advisers

(1) In any suit for infringement or in any proceeding before a court under this Act, the court may at any time, and whether or not an application has been made by any party for that purpose, appoint an independent scientific adviser to assist the court or to inquire and report upon any such question of fact or of opinion (not involving a question of interpretation of law) as it may formulate for the purpose.

(2) The remuneration of the scientific adviser shall be fixed by the court and shall include the costs of making a report and a proper daily fee for any day on which the scientific adviser may be required to attend before the court, and such remuneration shall be defrayed out of moneys provided by Parliament by law for the purpose."

54. Hence, a scientific adviser is to be appointed by the court to assist the court or to inquire and report upon any question of facts or provide scientific opinion (not involving a question of interpretation of law) as the court may formulate. The view of the Scientific Adviser is not binding on the court.

55. Reference may be had to the judgment of the Supreme Court in the case of ***State of H.P. v. Jai Lal & Ors., (1999) 7 SCC 280***. The court held as follows:

> "18. An expert is not a witness of fact. His evidence is really of an advisory character. The duty of an expert witness is to furnish the Judge with the necessary scientific criteria for testing the accuracy of the conclusions so as to the enable the Judge to form his independent judgment by the application of this criteria to the facts proved by the evidence of the case. The scientific opinion evidence, if intelligible, convincing and tested becomes a factor and often an important factor for consideration alongwith the other evidence of the case. The credibility of such a witness depends on the reasons stated in support of his

> conclusions and the data and material furnished which form the basis of his conclusions.
>
> 19. The report submitted by an expert does not go in evidence automatically. He is to be examined as a witness in court and has to face cross-examination. This court in the case of *Hazi Mohammad Ekramul Haq v. State of W.B.* concurred with the finding of the High Court in not placing any reliance upon the evidence of an expert witness on the ground that his evidence was merely an opinion unsupported by any reasons."

56. Similarly, a Division Bench of the Madras High Court in the case of ***La Renon Health Care Pvt. Ltd. v. Union of India, Ministry of Commerce & Industry and Ors., 2019 SCC OnLine Mad 4441*** held as follows:

> "123. In *Madan Gopal Kakkad v. Naval Dubey*, (1992) 3 SCC 204, it was held that "A medical witness called in as an expert to assist the court is not a witness of fact and the evidence given by the medical officer is really of an advisory character given on the basis of the symptoms found on examination. The expert witness is expected to put before the court all materials inclusive of the data which induced him to come to the conclusion and enlighten the court on the technical aspect of the case by explaining the terms of science so that the court although, not an expert may form its own judgment on those materials after giving due regard to the expert's opinion because once the expert's opinion is accepted, it is not the **opinion of the medical officer but of the court**". Though the above view was rendered in the context of tape, the reasoning is relevant in the present as well"

57. In view of the above judgments, it is clear that the report of the expert does not go in evidence automatically. He is to be examined as a witness in court and has to face cross-examination. The scientific opinion, if

convincing, becomes an important factor for consideration alongwith other evidence of the case.

58. *Prima facie,* for the reasons spelt out above, the Scientific Adviser has wrongly interpreted Claim I of the suit patent IN 229051.

59. Accordingly, an injunction is passed in favour of the plaintiffs and against all the defendants restraining the defendants, their agents etc. from manufacturing, importing, selling, offering for sale, etc. any pharmaceutical composition comprising a combination of Valsartan or a pharmaceutically acceptable salt, and Sacubitril or a pharmaceutically acceptable salt and a pharmaceutically acceptable carrier or more specifically a pharmaceutical composition comprising combination of Sacubitril +Valsartan as a sodium salt complex or in any other form which may amount to infringement of Indian Patent IN 229051 of plaintiff No.1. All applications i.e. IA No.1803/2019, IA No.9072/2020, IA No.12284/2020 and IA No. 4728/2021 stand disposed of accordingly.

JAYANT NATH, J.

OCTOBER 28, 2021
rb/v