Delhi High Court

Astrazeneca Ab & Anr. vs Emcure Pharmaceuticals Limited on 15 January, 2020

* IN THE HIGH COURT OF DELHI AT NEW DELHI

% Reserved on: 24th October, 2019
Decided on: 15th January, 2020

\+ CS(COMM) 561/2019

ASTRAZENECA AB & ANR. ..... Plaintiff
Represented by: Mr. Pravin Anand, Ms. Vaishali Mittal, Mr. Siddhant Chamola, Ms. Ankita Sabharwal, Advs.

versus

EMCURE PHARMACEUTICALS LIMITED ..... Defendant
Represented by: Mr. J. Sai Deepak, Mr. G. Natraj, Mr. Abhishek Audhani, Advs.

\+ CS(COMM) 562/2019

ASTRAZENECA AB & ANR. ..... Plaintiff
Represented by: Mr. Pravin Anand, Ms. Vaishali Mittal, Mr. Siddhant Chamola, Ms. Ankita Sabharwal, Advs.

versus

MSN LABORATORIES LIMITED ..... Defendant
Represented by: Ms. Rajeshwari H., Ms. Nupur A. Goswami, Advs.

CORAM:
HON'BLE MS. JUSTICE MUKTA GUPTA

I.A. 13888/2019 (u/O 39 R 1&2 CPC) in CS(COMM) 561/2019
I.A. 13891/2019 (u/O 39 R 1&2 CPC) in CS(COMM) 562/2019

1. By these two applications the plaintiffs seek interim injunction restraining the defendants, its directors, agents, etc., from making, selling, distributing, exporting, offering for sale product comprising of the

compound TICAGRELOR under the brand TICAPLAT by the defendant Emcure Pharmaceuticals Limited in CS(COMM) 561/2019 and under the brandname TIARE by MSN Laboratories Pvt. Ltd., the defendant in CS(COMM) 562/2019 or any other product that infringes the subject matter of Indian Patents No. IN 209907, IN 247984 and IN 272674 as also directions to withdraw the stock and render accounts for the same, besides damages and costs.

2. Case of the plaintiffs is that they are owners of Indian Patent Nos. IN 209907, IN 247984 and IN 272674 which cover the pharmaceutical compound TICAGRELOR. The said patents being valid and subsisting, the defendants in breach of the plaintiffs valid and subsisting patents have launched their generic version of TICAGRELOR under the brand names as

aforesaid.

3. As per the plaintiffs, defendants claim that their products contain (1S, 2S, 3R, 5S)-3-[7-[(1R,2S)-2-(3,4-Difluorophenyl)cyclopropylamino]-5-(propylthio)-3H [1,2.3] triazolo [4,5-d]pyrimidin-3-yl]-5-(2-hydroxyethoxy)cyclopentane-1,2-diol which is the empirical formula of TICAGRELOR i.e. C23H28F2N604S and its molecular weight is 522.57 g/mol..."

4. Case of the plaintiffs is that it has successfully started manufacturing the product TICAGRELOR under the trade name BRILINTA which is an oral anti-platelet treatment for Acute Coronary Syndrome (ACS). According to the plaintiff BRILINTA is a direct-acting P2Y12 receptor antagonist in a chemical class called cyclopentyltriazolopyrimidines (CPTPs) and the first reversibly-binding oral ADP receptor antagonist. The drug of the plaintiff is priced at very reasonable and affordable price. The

drug BRILINTA was initially sold at 50 per tablet and to further increase the accessibility of the product to patients, in June 2015 plaintiffs entered into an agreement with Sun Pharmaceuticals Industries Limited, an Indian company to sell and market TICAGRELOR under a second brand name i.e. AXCER. The plaintiffs have further reduced the price of drug BRILINTA to 30 per tablet as its MRP to make it more accessible. It is the claim of the plaintiffs that in the year 2017 alone plaintiffs have generated revenue in excess of US$ 1 billion worldwide for BRILINTA and the sales figure of the Indian market for the year 2017 alone have been in excess of 29 crores for BRILINTA and 44 crores for AXCER.

5. According to the plaintiff its product TICAGRELOR under the name BRILINTA has since proven to be significantly more effective than the existing medications such as clopidogrel in preventing further cardiovascular events in ACS patients.

6. The plaintiff had an earlier patent being IN 241229 for the Markush formula being the genus patent and IN 209907 is the species patent thereof whereas IN 247984 is the crystalline form and IN 272674 the finished formulation. The plaintiffs genus patent IN 229 has since expired on 14th July, 2018 and the present suit patent i.e. IN 209907 would expire on 2nd December, 2019. While addressing arguments on the application learned counsel for the plaintiffs has confined his arguments qua the infringement of IN 907 and not IN 984 and IN 674.

7. The claim of the plaintiffs in IN 241229 was very broad being the genus patent, disclosing the possibility of individual permutations and combinations of making 1.5 X 1020 (quintillion) compounds. Learned counsel for the Plaintiffs states that a broad umbrella coverage is understood

as a genus patent in the format of Markush claim/ formula and is well-known under the patent law. A Markush claim refers to a chemical structure by means of symbol indicating substituent groups and in such a claim one or more parts of the claimed compound comprise multiple functionally equivalent entities. Markush type claims allow important innovations to be patented. They are very complex and can cover a wide range of chemical structures including valuable compounds that may be used in drugs. Claim

8 of IN 229 had specifically listed 144 compounds and specifically claimed 134 compounds which were also covered within the scope of Markush structure as claimed in claim 1 of IN 229. However the plaintiffs continued their research and development for a more stable, active and less toxic compound which would be most utilitarian as an effective platelet aggregation inhibitor resulting in developing the compound TICAGRELOR, which led to further inventions regarding different pharmaceutical compositions for TICAGRELOR which are stable and effective for the purpose of being administered medically to patients.

8. By the present suit the plaintiff does not seek to enforce its patent IN 229 but IN 907 which is directed to "A Triazolo [4,5-D] Pyriidine Compound of Formula (I)". Claim 1 of IN 907 discloses a class of compounds in the following formula:

9. According to the plaintiff TICAGRELOR falls within the scope of claim 1 of IN 907 wherein R is OCH2CH2OH, R1 is propyl, R2 is phenyl group substituted by two fluorine atoms, R3 and R4 are hydroxyl groups. Further, TICAGRELOR is specifically claimed as the third compound in claim 5 of the said patent. The process for making TICAGRELOR has also been specifically disclosed in example 3 of IN 907. The relevant extract of the said claim 5 (example 3) is as under:

> "S-[1,2,3(1S*,2R*),5]]-3-[7-[[2-(3,4-Difluorophenyl)cyclopropyl]amino]-5-(propylthio]-3H-1,2,3-triazolo[4,5-d]pyrimidin-3-yl] -5-(2-hydroxyethoxy)-cyclopentane-1,2-diol;"

10. Although under IN 229 TICAGRELOR was covered within its scope of umbrella structure which pertained to 1.5 x 1020 (quintillion) compounds, however TICAGRELOR has not been specifically disclosed anywhere in the patent IN 229. What are specifically disclosed are compounds in claim 8, which conform to the umbrella structure which has been disclosed in claim 1 of the said patent. However, TICAGRELOR is not among those compounds named in claim 8, or anywhere else in IN 229 and thus could not have been recognized as a compound by a person skilled in the art at the relevant time. Further though the priority date of IN 229 was 22nd July, 1997, the same was published only on 4th February, 1999 whereas the priority date of IN 907 is 4th December, 1998. Hence before the publication of IN 229, IN 907 had its priority date. Four crystalline forms of TICAGRELOR are disclosed by IN 984 and Form II of TICAGRELOR has specifically been claimed in IN 984. IN 674 relates to pharmaceutical composition of TICAGRELOR and the finished formulation of TICAGRELOR sold by the

plaintiffs commercially is covered within the scope of IN 674. Further pursuant to the plaintiffs patent IN 229 no commercially viable drug was manufactured or tested and the commercially viable manufactured drug was sold under patent IN 907.

11. The defendants claim that the plaintiffs patent IN 907 is hit by Section 3(1)(d) read with Section 64(1)(a) of the Patent Act is liable to be rejected for the reason the drug TICAGRELOR under IN 907 was neither a known substance nor had any efficacy because prior to IN 229 no drug was manufactured and tested. Claim of the defendant based on Form-27 wherein the plaintiffs have stated that the patent has worked even in respect of IN 229 deserves to be rejected for the reason the said Form did not at that time permit filling of more than one patents and the plaintiffs till IN 907 came into being disclosed that the patent under IN 229 had not worked upon. Sections 19, 91 and 141 of the Patents Act provide protection to multiple patents.

12. The decision in Novartis AG relied upon by learned counsels for the defendants has no application to the facts of the case. Learned counsel for the plaintiffs further states that though in principle it is settled that by little disclosure there would be low coverage, however vice-versa that with great disclosure there will be full coverage is not permissible and applicable.

13. Objection of the defendant Emcure to the present suit being barred under Section 10 of the CPC in view of the suit filed by the defendant Emcure Pharmaceuticals Limited at Pune deserves to be rejected, for the said suit at Pune relates to the suit patent of the plaintiff being IN 229 and not IN 907. Reliance is also placed on the judgment of this Court in EISAI CO. Ltd. & Anr. Vs. Satish Reddy & Anr. CS(COMM) 1169/2018 decided on

6th May, 2019. The defendants having never filed any pre-grant opposition nor any post-grant opposition nor having sought the license from the plaintiffs, have evidently "not cleared the way" as held by this Court.

14. Learned counsels for the defendants at the outset do not dispute that the active ingredient of their product being sold under the two brand names TICAPLAT and TIARE is TICAGRELOR. The objections of the defendants is that since the active ingredients resulting in the compound TICAGRELOR was claimed in IN 229 validity whereof has expired, the product IN 907 gives rise to anticipation under Section 13(1)(b) read with Section 64(1)(a) of the Patents Act by prior claiming. The suit patent IN 907 is also hit by Section 3(d) of the Patents Act as there is no enhanced efficacy or therapeutic value and the same was a known substance as earlier claimed in IN 229. Plaintiffs have not placed on record actual data to show enhancement of therapeutic efficacy to overcome the rigours of Section 3(d) of the Patents Act. The pharmaceutical data of IN 229 and IN 907 are identical and thus it does not amount to any new invention involving innovative steps. Learned counsels for the defendants claim that the date of publication has no relevance when revocation is sought in terms of Section 13(1)(b) read with Section 64 (1)(a) of the Patents Act as TICAGRELOR stands anticipated by prior claiming in IN 229. Defendants also claim that claims 1 & 7 of US 6251910 which is equivalent to claims 1 & 7 of IN 229 specifically claims TICAGRELOR.

15. Learned counsels for the defendants rely on the decision of the Supreme Court reported as (2013) 6 SCC 1 Novartis AG Vs. Union of India & Ors. It is contended that as in Novartis AG since the plaintiffs have claimed that the present drug emanates from the Markush formula of IN

229, the teaching of IN 907 being available in IN 229, the plaintiff cannot claim extension of term of the patent. Referring to Para 125 of the decision in Novartis, learned counsels for the defendants also refer to the dichotomy between disclosure and coverage and state that since the product under IN 907 as claimed is covered under IN 229 and disclosed therein, IN 907 is not a valid patent.

16. Learned counsels for the defendants have also taken this Court through the documents filed by the plaintiffs wherein statement of working of IN 229 was filled-in Form 27 and in the years 2011 to 2019 the plaintiffs mentioned the patent IN 229 and not IN 907 and though till the year 2012 it was claimed that the patent has not worked, however in the year 2013 to 2019 it has been mentioned has worked and the sales figures under the trade name BRILINTA have been mentioned. Thus, the plaintiffs have always claimed that their patented product TICAGRELOR sold under the brand name BRILINTA is a drug under IN 229 and not IN 907.

17. Learned counsels for the defendants also contend that the plaintiffs had earlier also filed suits against third parties wherein though initially an ex-parte ad-interim injunction was granted, however on hearing the parties, this Court vacated the injunction and in appeal a settlement was arrived at. The defendants not being party to the said settlement, the decision of the Division Bench in FAO (OS) Nos. 191/2019, 192/2019 and 194/2019 would not be binding on the defendants.

18. Before further proceeding with the matter it would be appropriate to note with regard to the interim injunction granted and subsequently vacated by a Coordinate Bench of this Court in CS(COMM) Nos. 749/2018, 792/2018 and 1023/2018 between the plaintiffs and third parties in respect

of its patent IN 907, IN 984 and IN 674. In the said suits, the Coordinate Bench of this Court had granted ex-parte ad-interim injunctions in favour of the plaintiffs restraining the defendants from marketing, selling, distributing, etc., any product that infringes the subject matter of Indian Patents No. IN 299907, IN 247984 and IN 272674, however on the defendants entering appearance and filing their replies, the learned Single Judge vide the decision dated 8th August, 2019 vacated the interim injunction. One of the grounds for vacation of interim injunction was the plaintiffs statement of working in Form 27 before the Controller of Patents and noted that the plaintiffs have claimed their drug BRILINTA under the patent IN 229 in Form 27. The Coordinate Bench of this Court also relied upon the documents filed by the defendants in respect of litigations by the plaintiffs in US against Mylan.Inc and Mylan Pharmaceuticals Inc. and held that the plaintiffs have acknowledged and stated that dealing in TICAGRELOR is in breach of US 910 equivalent to IN 229. The Coordinate Bench of this Court while dealing with the issue of coverage and disclosure of a genus patent as raised in the decision in Novartis AG (supra) rejected the plaintiffs argument that coverage in a patent might go much beyond disclosure. In view of the admissions of the plaintiffs that IN 229 had worked through TICAGRELOR, the Coordinate Bench also noted that the plaint was silent about any theraupatic use of the suit patent viz-a-viz IN 229. It was thus noted that as the defendants had raised a strong credible challenge to the validity of suit patent under Section 64(1)(f) read with

Section 3(d) and Section 64(1)(a), 64(1)(d), 64(1)(f) and 64(1)(k) of the Patents Act, the suit patents are vulnerable to challenge and hence the injunction applications were dismissed. In the appeals filed by the plaintiffs

a settlement was arrived at between the parties that respondents therein i.e. defendants in the said suits will not sell their product TICAGRELOR till 2nd November, 2019.

19. Learned counsels for the defendants at the outset state that the findings of the Division Bench are not binding as the same are based on a settlement arrived at between the parties therein, however in view of the decision of the learned Single Judge this Court would dismiss the injunction applications and grant no injunction to the plaintiffs.

20. Before proceeding further it would be appropriate to note the principles for construction of claim as laid down by this Court in the decision reported as 2015 SCC Online Del 13619 F. Hoffmann-La Roche Ltd. & Anr. Vs. Cipla Ltd. 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 (1 st 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.

In the case of (52 F.3d 967 also 517 US 370) Herbert Markman Vs. Westview the Courts held that an infringement analysis entails two steps:-

(a) First step is to determine the meaning and scope of the patent claims asserted to be infringed.

(b) Second step is to compare the properly construed claim with the device accused of infringing.

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

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

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

Further some terms are close ended such as consisting of, i.e. in a claim of three elements, A,

B and C a defendant would infringe if he has all three elements. In case the defendant adds a fourth element D he would escape infringement.

(xvi) Each claim has a priority date so that in a group of claims in a specification you could have multiple priority dates. This only means that if a patent application with certain priority date and claims was followed by another application with different claims

and different priority dates, then if they were consolidated or cognate with another application, each claim would retain the original priority date [Section 11(1)]."

21. Contention of the defendants during the course of arguments in the two applications is that the claim of the plaintiffs under IN 907 is covered under the claim IN 229; specifically under claim 1 and claim 4 of the claims in IN 229, which read as under:

"WE CLAIM:

1. A triazolo [4,5-d]primidine compound of formula (I)

Wherein

R1 is a C1-6 alkyl, C2-6 alkenyl, C2-6 alkynyl, C3-8-cycloalkyl or a phenyl group, each group being optionally substituted by one or more substituents selected from halogen, OR8, NR9R10, SR11 or C1-6 alkyl (itself optionally substituted by one or more halogen atoms0;

R2 is C1-8 alkyl optionally substituted by one or more substituents selected from halogen, OR8, NR9R10, SR11, C3-8-cycloalkyl, aryl (optionally substituted by one or more alkyl groups and/or halogen atoms), or C1-6-alkyl; or R2 is a C3-8-cycloalkyl group optionally substituted by one or more substituents selected from halogen, OR8, NR9R10, SR11, C1-6-alkyl or phenyl (which may be fused to a 5- or 6-membered saturated ring containing one or two oxygen atoms, the said 5- or 6-membered saturated ring carrying no further substituents, the latter two groups being optionally substituted by one or more substituents selected from halogen, NO2, C(O)R8, OR8, SR11, NR12R13, phenyl or C1-6-alkyl the latter two groups being optionally substituted by OR8, NR9R10 or one or more halogen atoms;

One of R3 and R4 is hydroxyl and the other is hydrogen, hydroxyl or NR9R10; R is a group (CR5R6)mOR7 where m is 0 or 1, R5 and R6 are independently hydrogen, C1-6 alkyl or phenyl the latter two groups being

optionally substituted by halogen, and R7 is hydrogen, C1-6 alkyl or (CR5R6)nR14 where R5 and R6 are as defined above, n is 1 to 3 and R14 is

OR15, NR16R17 or CONR16R17;
Or R is a C1-4 alkyl or C2-4 alkenyl group, each of which is substituted by one or more groups selected from =S, =NR20 or OR20 and optionally substituted by one or more groups selected from halogen, C1-4 alkyl, phenyl, SR21, NO2 or NR22R23 (where R21, R22 and R23 are independently hydrogen, C1-4 alkyl or phenyl; R20 is OR24 or NR25R26, where R24 is hydrogen, C1-4 alkyl or phenyl, and R25 and R26 are independently hydrogen, C1-4 alkyl, aryl, C1-6 acyl, arylsulphonyl or arylcarbonyl);
R8 is hydrogen, C1-6 alkyl optionally substituted by halogen or R8 is phenyl optionally substituted by one or more substituents selected from halogen, NO2, C(O)R6, OR6, SR9, NR10R11;
R9, R10 and R11 are independently hydrogen or C1-6 alkyl; R12 and R13 are independently hydrogen, C1-6 alkyl, acyl, alkyl sulfonyl optionally substituted by halogen, or phenyl sulfonyl optionally substituted by C1-C4 alkyl; and
R15, R16 and R17 are independently hydrogen or C1-6 alkyl; or a pharmaceutically acceptable salt or solvate thereof.
2. A compound of formula (I) having the following stereochemistry:

3. A compound as claimed in claim 1 or 2 wherein R1 is C1-4 alkyl or phenyl substituted by trifluoromethyl.
4. A compound as claimed in any one of claims 1 to 3 wherein R2 is butyl or cyclopropyl optionally substituted by phenyl, the phenyl group itself being optionally substituted by one or more halogen, C3-8 alkyl, phenoxy or phenyl groups.
5. A compound as claimed in any of claims 1 to 4 wherein R3 and R4 are both hydroxy.
6. A compound as claimed in any one of claims 1 to 5 in which R5 and 6
R are both hydrogen.
7. A compound as claimed in any one of claims 1 to 6 in which R is OH, CH2OH, CH2CH2OH, OCH2CH2OH, CH2OCH2C(CH3)2OH and OCH2C(CH3)2OH."

22. Claims 1 and 5 of the plaintiffs in IN 907 are as under:
"WE CLAIM:
1. A triazolo [4,5-d]pyrimidine compound of formula [I]

Wherein:
R1 is C3-5 alkyl optionally substituted by one or more halogen atoms;
R2 is a phenyl group, optionally substituted by one or more fluorine atoms;
R3 and R4 are both hydroxyl;
R is XOH, where X is CH2, OCH2CH2 or a bond;
or a pharmaceutically acceptable salt or solvate thereof, or a solvate of

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such a salt
provided that:
when X is CH2 or a bond, R1 is not propyl.
When X is CH2 and R1 is CH2CH2CF3, butyl or pentyl, the phenyl group at
R2 must be substituted by fluorine.
When X is OCH2CH2 and R1 is propyl, the phenyl group at R2 must be
substituted by fluorine.
...
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5. A compound according to claim I which is:

[1R-[1,2,3(1R*,2S*),5]]-3-[7-[[2-(4-

Fluorophenyl)cyclopropyl]amino]-5-

[(3,3,3-trifluoropropyl)thio]-3H-1,2,3-triazolo[4,5-d]pyrimidin-3-yl] -5-(hydroxymethyl)-5-(hydroxymrthyl)-cyclopentane-1,2-diol; [1R-[1,2,3 (1R*, 2S*), 5]]-3-[7-[[2-(3,4-

Difluorophenyl)cyclopropyl]amino]-5-

[3,3,3-trifluoropropyl)thio]-3H-1,2,3-triazolo[4,5-d]pyrimidin-3-yl]-5-(hydroxyrnethyl)-cycoperntane-1,2-diol;

[1 S-(1,2,3 (1S*, 2R*), 5]]-3-[7-[[2-(3,4-

Difluorophenyl)cyclopropyl]amino]-5-

(propylthio)-3H-1,2,3-triazolo[4,5-d]pyrimidin-3-yl]-5-(2-hydroxyethoxy)- cyclopentane-1,2-diol;

[1 R-(1,2,3 (1R*, 2S*), 5]]-3-[5-(Butylthio)-7-(2-(3,4-difluorophenyl)cyclopropyl]amino]-3H-1,2,3-triazolo[4,5-d]pyrimidin-3-yl]-5-(hydroxyethoxy)-cyclopentane-1,2-diol;"

23. A perusal of the claim 1 in the two claim prima facie reveals that in IN 907 R2 is a phenyl group, optionally substituted by one or more fluorine atoms whereas in IN 229 R2 is C1-8 alkyl optionally substituted by one or more substituents selected from halogen, OR8, NR9R10, SR11, C3-8-cycloalkyl, aryl (optionally substituted by one or more alkyl groups and/or halogen atoms), or C1-6-alkyl; or R2 is a C3-8-cycloalkyl group optionally substituted by one or more substituents selected from halogen, OR 8, NR9R10, SR11, C1-6-alkyl or phenyl (which may be fused to a 5- or 6-membered saturated ring containing one or two oxygen atoms, the said 5- or 6- membered saturated ring carrying no further substituents, the latter two groups being optionally substituted by one or more substituents selected from halogen, NO2, C(O)R8, OR8, SR11, NR12R13, phenyl or C1-6-alkyl the latter two groups being optionally substituted by OR8, NR9R10 or one or more halogen atoms. Further in IN 907 R is specified as XOH, where X is CH2, OCH2CH2 or a bond; or a pharmaceutically acceptable salt or solvate thereof, or a solvate of such a salt provided that: when X is CH2 or a bond, R1 is not propyl. When X is CH2 and R1 is CH2CH2CF3, butyl or pentyl, the

phenyl group at R2 must be substituted by fluorine. When X is OCH2CH2 and R1 is propyl, the phenyl group at R2 must be substituted by fluorine.

24. Section 3(d) of the Patents Act provides as under:

> "[3. What are not inventions - The following are not inventions within the meaning of this Act:-
>
> (d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.
>
> Explanation. -For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy;]"

25. Section 3(d) provides about the enhanced efficacy of the product invented. In the present two suits there are specific pleadings by the plaintiff stating that the product TICAGRELOR which was of high potency, high metabolic stability and demonstrated bio availability was produced under IN 907. Thus the claim of the plaintiffs is that IN 229 did not result in a product medicine and BRILINTA its medicine is specifically attributable to IN 907 thus passing the test of enhanced efficacy. In view of the pleadings in the two suits it cannot be said that IN 907 did not result in any invention with enhanced efficacy.

26. Plaintiffs have stated that their product was initially being sold at 50 per tablet which was reduced to 30 per tablet and the difference in price was only 5 per tablet and hence it is not a case where the product of the plaintiff is contrary to the public interest. To meet the requirements of the public, plaintiffs have already granted a license to an Indian company Sun Pharmaceuticals Limited which is distributing and selling the products TICAGRELOR under the brand name AXCER.

27. Learned counsels for the defendants have also vehemently contended that the claim in IN 907 is anticipated in IN 229 and hence not a new innovative/ inventive step. Section 13(1)(2) of the Patents Act reads as under:

> "13. Search for anticipation by previous publication and by prior claim.-
>
> (1) The examiner to whom an application for a patent is referred under section 12 shall make investigation for the purpose of ascertaining whether the invention so far as claimed in any claim of the complete specification-

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

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

(2) The examiner shall, in addition, make such investigation 3 [***] for the purpose of ascertaining whether the invention, so far as claimed in any claim of the complete specification, has been anticipated by publication in India or elsewhere in any document other than those mentioned in sub- section (1) before the date of filing of the applicant's complete specification."

28. For qualifying as an anticipation by previous publication and by a prior claim under Clause (a) and (b) of sub-section 1 of Section 13 the anticipation is if on the date of filing of the applicants complete specification there is a prior art which has been published in India. Even under sub-section (2) the examiner for the purpose of ascertaining whether the claim is anticipated by publications in India or elsewhere is required to investigate any document published prior to the date of filing of the complaint. The date of publishing of IN 229 is 4th February, 1999 whereas the priority date of IN 907 is 4th December, 1998. Hence the claim with its complete specification in IN 907 was submitted prior to the publishing date of IN 229 and cannot be held to be anticipated in terms of Section 13 of the Patents Act.

29. Further claim 8 of IN 229 specifically listed 144 compounds and specifically claimed 134 compounds whereas TICAGRELOR though covered under the Markush structure of IN 229 is neither one of the 134 compounds nor 144 compounds nor disclosed in any of the claims of IN 229.

30. As regards the admissions of the plaintiff in Form-27 is concerned, wherein in IN 229 it has been claimed that it has worked through the drug BRILINTA; a perusal of the Form 27 as filed by the plaintiffs before the Patents Authorities reveals that till IN 907 came into being, the claim of the plaintiff even under IN 229 in Form 27 was that the patent has not worked. It is only after BRILINTA was manufactured and tested under IN 907 the plaintiff claimed that it has worked even under IN 229 for the reason IN 907 is a species of the genus/markush formula IN 229.

31. Leaned counsels for the defendants also rely upon the various admissions of the plaintiffs in their earlier litigations in U.S. wherein the claim of the plaintiffs is that their drug BRILINTA i.e. (TICAGRELOR) in the tablet form in 60 mg or 90 mg dosage strengths is covered by U.S. Patents No. 6251910, 6525060, 7250419, 7265124 and 8425934 out of which except 7250419 the corresponding Indian Patents are IN 229, IN 907, IN 984 and IN 674 respectively. The admission of the plaintiff in a proceedings filed by the plaintiff before the United States District Court for the District of Delaware in proceedings against Mylan.Inc. are as under:

> "This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, against defendants Mylan Inc. and Mylan Pharmaceuticals Inc. (collectively "Mylan" or "Defendant"). This action relates to Abbreviated New Drug Application ("ANDA") No. 208597 ("ticagrelor ANDA") filed by Defendant with the U.S. Food and Drug Administration ("FDA") for approval to market generic versions of AstraZeneca's BRILINTA® (ticagrelor) drug product in tablet forms and in 60 mg and 90 mg dosage strengths, prior to expiration of AstraZeneca's U.S. Patent Nos. 6,251,910 ("the '910 patent"); 6,525,060 ("the '060 patent"); 7,250,419 ("the '419 patent); 7,265,124 ("the '124 patent"); and 8,425,934 ("the '934 patent") that are listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") for BRILINTA® (collectively "the Orange Book Patents")."

32. It may be noted that the plaintiffs U.S. Patents No. 6251910, 6525060, 7265124 and 8425934 correspond to Indian Patent IN 241229, 209907, 247984, 272674. It is never the case of the plaintiffs that its product TICAGRELOR is not covered under US 910 or IN 229, however it states that the TICAGRELOR has been specifically disclosed in IN 907. Further the teachings do not suggest that a more stable, active and less-toxic compounds would be formulated by using the fluoride formulation out of the individual permutation and combinations of making 1.5 X 1020 (quintillion) compounds.

33. The Supreme Court of India in Novartis AG (supra) held:

> "118. The submissions of Mr. Andhyarujina and Mr. Subramanium are based on making a distinction between the coverage or claim in a patent and the disclosure made therein. The submissions on behalf of the Appellant can be summed up by saying that the boundary laid out by the claim for coverage is permissible to be much wider than the disclosure/ enablement/ teaching in a patent.
>
> 119. The dichotomy that is sought to be drawn between coverage or claim on the one hand and disclosure or enablement or teaching in a patent on the other hand, seems to strike at the very root of the rationale of the law of patent. Under the scheme of patent, a monopoly is granted to a private individual in exchange of the invention being made public so that, at the end of the patent term, the invention may belong to the people at large who may be benefited by it. To say that the coverage in a patent might go much beyond the disclosure thus seem to negate the fundamental rule underlying the grant of patents.
>
> xxxxx
>
> 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 skillful lawyers, and where patents are traded as a commodity not for production and marketing of the patented products but to search for someone who may be sued for infringement of the patent."

34. In Novartis AG (supra) the Supreme Court was dealing with the grant of patent for the beta crystalline form of Imatinib Mesylate and held that the Zimmermann Patent had the teaching for the making of Imatinib Mesylate from Imatinib, and for its use in a pharmacological compositions for treating tumours or in method of treating warm-blooded animals suffering from tumoral disease, which finding was also recorded by the US Board of Patent Appeals. The Supreme Court also considered the contemporaneous articles on the issue authored by several people including Jurk Zimmermann. The articled had a detailed discussion about the anti-tumoral property of Imatinib and its methane sulfonate salt i.e. Imatinib Mesylate.

35. In the light of these materials which had been duly published, the Supreme Court held that the Imatinib Mesylate could not be said to be a new product having come into being through an "invention" that had a feature that involves technical advance over the existing knowledge and that would make the invention not obvious to a person skilled in the art. It was held that Imatinib Mesylate is a known substance from Zimmermann Patent. Further it was noted that the appellant therein had never sought for patent for Imatinib Mesylate in its non-crystaline form and thus rejected the contention that development of Imatinib Mesylate from Imatinib was outside the Zimmermann Patent and constitutes an infringement.

36. On the issue of dichotomy between coverage of the claim, and disclosure or the teachings in the claim, Supreme Court distinguished the decision of the United States Court of Customs and Patents Appeal in Hogan, in re 559 F 2d 595. Supreme Court held that the Court in Hogan seems to have taken the view that the amorphous form did not exist at the time of patent application and therefore the patentee could not have expected to claim the amorphous form at that time, and that the decision in Hogan was in the context of special set of facts and circumstances of the litigation over polypropylene and that in subsequent decisions the Federal Circuit Court appears to have drastically narrowed down the scope of the precedent laid down in Hogan.

37. Supreme Court though noted that the law in the country should not be developed on the lines where there is a vast gap between the coverage and disclosure however acknowledges the fact that the scope of the patent should be determined from the intrinsic worth of invention and not by the artful drafting of the claim. Further, the Supreme Court in Novartis (supra) also did hold that in no case a species patent be granted once a genus patent had been granted no patent be granted.

38. Learned counsel for the defendant/ Emcure Pharmaceuticals Ltd. in CS(COMM) 561/2019 had also taken the plea that the present suit was barred under Section 10 of the CPC in view of the fact that the defendant had already filed a suit before the City Civil Court Pune against the plaintiffs to which learned counsel for the plaintiffs state that the said suit of the defendant was based on the right to sell its product TICAPLAT in view of the expiry of IN 229, however in the present suit the

plaintiffs herein have claimed infringement of its patent IN 207, IN 984, IN 674 and not IN 229. In the absence of pleadings in the suit filed by the defendant before the City Civil Court Pune clarifying the prayers therein and whether the cause of action in the two suits is the same, the plea of the defendant at this stage stating that the present suit was not maintainable by virtue of Section 10 CPC cannot be entertained.

39. From the facts noted hereinabove this Court finds that the claim of the plaintiffs that the compound TICAGRELOR was produced and marketed under IN 907 even though its formula is covered under the Markush formula i.e. IN 229 is based on the material on record. Thus the plaintiffs have made out a prima facie case in their favour. However, in respect of the grant of interim injunction in favour of the plaintiffs and against the defendants, it may be noted that the date of expiry of the plaintiffs patent IN 907 was 2nd December, 2019. The defendants have already launched their product and in view thereof this Court does not find any ground to grant an ad-interim injunction pending hearing of the suit in favour of the plaintiffs and against the defendants. However, the defendants are directed to maintain their accounts of sale from the date of launch of their impugned products till 2nd December, 2019. Defendants will file their statements of accounts supported by affidavit of one of its director and duly authenticated by the chartered accountant on the basis of records including the tax records. Though the claim of the plaintiffs is that its compound TICAGRELOR is also covered under the suit patent IN 984 and IN 674, however no arguments have been addressed on these two patents and hence no decision is being rendered on the said count at this stage.

40. Applications are disposed of.

(MUKTA GUPTA) JUDGE JANUARY 15, 2020 'ga'