**Astrazeneca Ab & Ors vs.p Kumar & Anr**

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**SooperKanoon Citation** : sooperkanoon.com/1224582

**Court** : Delhi

**Decided On :** Aug-08-2019

**Appellant** : Astrazeneca Ab & Ors

**Respondent** : P Kumar & Anr

**Judgement** :

$~J * % + + + IN THE HIGH COURT OF DELHI AT NEW DELHI Pronounced on:

08. 08.2019. IAs.3986/2018 & 5096/2018 in CS(COMM) 749/2018 ASTRAZENECA AB & ORS P KUMAR & ANR versus IA No.4771/2018 in CS(COMM) 792/2018 ASTRAZENECA AB & ANR T RAO & ANR versus ..... Plaintiffs ..... Defendants ..... Plaintiffs ..... Defendants IA No.9332/2018 in CS(COMM) 1023/2018 ASTRA ZENECA AB & ANR. ..... Plaintiffs versus ..... Defendant DR. REDDYS LABORATORIES LIMITED Present: Mr.Pravin Anand, Ms.Archana Shankar, Mr.Devinder Rawat, Mr.Nishchal Anand and Mr.Sanchith Shivakumar, Advs. for the plaintiffs. Mr.J.Sai Deepak and Mr.G.Nataraj, Advs. for the defendant in CS(COMM) 749/2018 Mr.C.M.Lall, Sr.Adv. with Ms.Rajeshwari, Adv. for the defendant in CS(COMM) 792/2018. Mr.Sai Krishan, Adv. and Ms.Gitanjali Mathew, Adv. for the defendant in CS(COMM) 1023/2018 CORAM: HON'BLE MR. JUSTICE JAYANT NATH JAYANT NATH, J.

IAs.3986/2018 & 5096/2018 in CS(COMM) 749/2018 IA No.4771/2018 in CS(COMM) 792/2018 CS(COMM.)749/2018 & etc. Page 1 of 57 IA No.9332/2018 in CS(COMM) 1023/2018 1. These are three suits filed by the plaintiffs seeking a

decree of permanent injunction to restrain the defendants from marketing, selling, distributing, etc. any product that infringes the subject matter of Indian Patent Nos. IN20990 (hereinafter referred to as IN907, i.e. the Species Patent), IN24798 (hereinafter referred to as IN984, i.e. the Polymorph Patent) and IN27267 (hereinafter referred to as IN674, i.e. the Formulation Patent).

2. By the present judgment, I will deal with the injunction applications filed by the plaintiffs being IA No.3986/2018 filed in CS(COMM) 749/2018, IA No.4771/2018 filed in CS(COMM) 792/2018, IA No.9332/2018 filed in CS(COMM) 1023/2018 and IA50962018 filed in CS(Comm.) 749/2018 by the defendants under Order 39 Rule 4 CPC seeking vacation of the interim orders.

3. The injunction applications are filed under Order 39 Rule 1 and 2 CPC seeking an injunction to restrain the defendants from selling, marketing or dealing with TICAGRELOR or any product which is in violation of the registered patent of the plaintiffs company IN907 IN984and IN674 4. CS(COMM) 749/2018 came up for hearing on 22.03.2018 when in IA No.3986/2018 this court passed an interim order in favour of the plaintiffs restraining the defendants from selling, marketing or dealing with TICAGRELOR tablet or any drug which is in violation of the registered patents of the plaintiffs being IN907 IN984 and IN674 On 23.04.2018 a similar interim order was passed in IA No.4771/2018 in CS(COMM) 792/2018. This court had then noted that when the written statement was filed a stand had been taken by the defendants that they had not launched the CS(COMM.)749/2018 & etc. Page 2 of 57 drug in question. However, this court on 23.04.2018 noted that while the matter was pending in court, the defendant had launched the drug. In CS(COMM) 1023/2008, a similar interim order was passed on 18.07.2018 in IA No.9332/2018.

5. The case of the plaintiff is that the drug TICAGRELOR falls within the scope of Indian Patent No.907 and 984. The finished formulation of TICAGRELOR is said to be covered within the scope of IN674 The said compound TICAGRELOR is said to have proved to be an effective platelet aggregation inhibitor. The said TICAGRELOR is the INN (international non- proprietary name) assigned to the molecule having the IUPAC name (1S,2S,3R,5S)-3-[7-[(1R,2S)-2-(3,4-

Difluorophenyl) cyclopropylamino]. 5- (propylthio)-3H-[l,2,3].triazolo[4,5-d].pyrimidin-3-yl].-5-(2-hydroxyethoxy) cyclopentane-l,2-diol. The empirical formula of TICAGRELOR is C23H28F2N6O4S and its molecular weight is 522.57. TICAGRELOR has the following structural formula:

7. Claim 1 of IN '907 discloses a class of compounds with the following Markush formula: CS(COMM.)749/2018 & etc. Page 3 of 57 6. TICAGRELOR is said to fall within the scope of claim 1 wherein R is OCH2CH2OH1, R' 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.

7. The Indian Patent No.907 is said to be a valid and subsisting patent which has remained unchallenged even though it was published way back in the year 2005. It was not subjected to any pre-grant or post-grant opposition under sections 25(1) and 25(2) of the Patents Act, 1970. However, in 2015 Micro Labs Limited i.e. defendant No.2 in CS(COMM) 749/2018 filed a petition for revocation of the said patent which is said to be pending before the Intellectual Property Appellate Board.

8. The plaintiff has also made reference to two other patents including Indian Patent No.984(polymorph patent) which is said to be a Crystalline form of A Triazolo (4.5-D) Pyrimidine Compound. It is stated that four Crystalline forms of TICAGRELOR are disclosed in patent No.IN984 The said patent is said to be a subsisting patent. CS(COMM.)749/2018 & etc. Page 4 of 57 Similarly, reference is made to Indian Patent No.674(formulation patent) which relates to a pharmaceutical composition of TICAGRELOR. It is said to be disclosed in claims 1-10 of IN674 It is pleaded that by virtue of section 48 of the Patents Act, the plaintiffs have exclusive rights to prevent others from making, using, selling, offering for sale or importing TICAGRELOR as well as its crystalline form (IN 984) and its finished formulation (as claimed in IN674) or any other product that falls within the scope of the claims of IN907 and the above two noted patents.

9. TICAGRELOR is said to be an antiplatelet drug prescribed to patients who have suffered a recent heart attack or unstable angina (chest pain) for reducing the chances of a thrombotic events such as a heart attack or a stroke. It is stated that before the introduction of TICAGRELOR, despite the widespread adoption of intensive monitoring and prompt treatment with existing medications, approximately 1 in 3 ACS patients died or had a repeat myocardial infraction, or required re-hospitalisation within six months. TICAGRELOR works by preventing the formation of new blood clots, thus maintaining blood flow in the body to help reduce the risk of another cardiovascular event.

10. It is stated that TICAGRELOR was first approved in the USA in 2011 and is marketed under the trademark BRILINTA. It has been approved in more than 100 countries. In India the plaintiff received drug regulatory approval in May 2012 and was commercially launched in India in October 2012 under the same trademark BRILINTA. The price of a tablet is said to be Rs.50/-. CS(COMM.)749/2018 & etc. Page 5 of 57 11. In CS(COMM) 749/2018 where defendant No.2 is Micro Labs Ltd, the plaintiff states that in the month of March 2018 plaintiff received business information through credible market sources that the defendants are planning to launch a generic version of TICAGRELOR under the probable name BIGRELOR in the first week of April 2018. It was also learnt that the defendants have printed their packaging for their generic product and their representatives are speaking with doctors about the same. It is stated that the defendants have filed revocation petition in respect of trademark IN984and IN907before the Intellectual Property Appellate Board (IPAB). It was pleaded that the acts of the defendant would cause immense damage to the plaintiffs business and public interest which cannot be accounted for in monetary terms. It would also be in blatant disregard of the plaintiffs intellectual property rights. Hence, the suit.

12. In CS(COMM) 792/2018, where defendant No.2 is Natco Pharma Ltd., the plaintiff has been pleaded that in the first week of April 2018, the plaintiffs received business information regarding the plan of the defendants to launch a generic version of TICAGRELOR in the third week of April 2018. It has also been stated that the defendants have uploaded their product list on the website where TICAGRELOR has been listed under the category of APIs-Under Development. It

has also been pleaded that to the plaintiffs best knowledge, the defendants have not yet commercially launched/marketed TICAGRELOR but based on the background facts and credible business intelligence, the defendants imminent launch of the product TICAGRELOR has been received by the plaintiffs. It has also been pleaded that the defendants are known habitual offenders. Hence, the present suit was filed against the said defendants. CS(COMM.)749/2018 & etc. Page 6 of 57 13. In CS(COMM) 1023/2018, where the defendant is Dr.Reddys Laboratories Ltd. the plaintiff has pleaded that in April 2018, plaintiff No.2 received certain caveats filed by the defendant which were vague and unambiguous. On 17.07.2018, it is stated that the plaintiffs received business information that the defendant is planning to launch a generic version of TICAGRELOR under the brand name TICAFLO. In fact, it is pleaded, the defendant has taken steps to introduce and offer the same for sale to its business partners and C&F Agents. The defendant has also obtained a manufacturing license for TICAGRELOR and is ready for a full commercial launch of the product. Hence, the present suit filed against the said defendant.

14. The defendants have filed their respective written statement to submit that the suit has no merit. Most of the submissions raised by the defendant are common. I may note some of salient submissions made which are relevant for disposal of these applications.

15. In CS (COMM) 749/2018 (defendant No.2 here is Micro Labs Ltd.) the defendant has broadly pleaded in the written statement as follows: (i) that the pharmaceutical formulation containing TICAGRELOR is purportedly sold in India by the plaintiffs under the name BRILINTA and AXCER. It is stated that it is the own admission of the plaintiff that the formulation is not manufactured in India but is apparently imported from Sweden and China. It is stated that the plaintiffs own affirmations before Regulatory Agencies, Courts and different patent offices would show that TICAGRELOR is covered by several patents with different dates of expiry including Indian Patent 241229 and its equivalents. CS(COMM.)749/2018 & etc. Page 7 of 57 (ii) It is further pleaded that the plaintiffs have deliberately suppressed material facts. The plaintiff has failed to mention that the patent No.241229 (the genus patent) expressly covers and discloses TICAGRELOR and

has expired on 14.7.2018. It is stated that the plaintiff has given a false impression that the TICAGRELOR cannot be recognized from the said patent No.241229. It is pleaded that there is sufficient material which also comprises admissions by the plaintiffs to show that TICAGRELOR is encompassed and claimed in IN241229 (hereinafter referred to as IN229 and its equivalent patents across the world. Reliance is placed on Form 27 filed in India for IN229which expressly refers to BRILINTA and AXCER products being covered by IN229 Reliance is also made on Patent Term Extension request filed before USPTO in respect of US910equivalent to IN229. Reference is also made to other such documents to plead that there are clear admissions of the plaintiff that TICAGRELOR is encompassed and claimed in IN229which patent expired on 14.07.2018. (iii) It is further pleaded that the plaintiffs have deliberately failed to state and mention that the foreign patent equivalents of the said patents have been held invalid in contested proceedings. Reference is made to the proceedings in China, Europe and South Korea. (iv) It is further pleaded that the present case is a textbook instance of patent Ever-greening by the plaintiffs perpetuated with the intent of illegally extending patent monopoly granted to them vide IN229 with respect to TICAGRELOR. It is pleaded that any party in India is free to manufacture or sell a generic version of TICAGRELOR after expiry of IN229 on 14.7.2018. It is further stated that the malafide of the plaintiff is also established by the fact that the plaintiffs sought illegal extension of this CS(COMM.)749/2018 & etc. Page 8 of 57 patent monopoly available under IN229 as is evident from the fact that the plaintiffs have filed/obtained patent protection with respect to the same Markush, namely, TICAGRELOR subsequently in IN907 and IN984 as well. (v) It is further pleaded that the plaintiffs are guilty of latches and delay. It is pleaded that the plaintiffs were aware about the factum of grant of approvals by the Indian Drug Regulator to defendant No.2 to manufacture TICAGRELOR in 2015. Hence, it is pleaded that the averments made in the plaint that the plaintiff had knowledge about the launch of the defendants product in only 2017 and thereafter is absolutely false. (vi) It is further stated that the defendants are neither manufacturing nor selling any products claimed by the suit patents. Therefore, there is no case for infringement of the suit patent. It is stated that defendant No.2 has not commercialized the pending TICAGRELOR in any form and does not intend to do so at least till

14.7.2018 when IN229 expires. (vii) It is further stated that no part of the cause of action has arisen in Delhi.

16. It is further stated in the written statement that the suit patents are invalid on the grounds stated in section 64 of the Indian Patent Act. It is pleaded that under section 107 of the Act, every ground under which a patent can be revoked based on Section 64 is available as a defence in a suit for infringement. Regarding the patent IN907the following broad submissions are raised: (i) Reliance is placed on Section 64(1)(a) of the Patents Act to state that IN907lacks novelty as the same is comprehensively covered in IN229CS(COMM.)749/2018 & etc. Page 9 of 57 which has an earlier priority date than IN907i.e. 22.07.1997. Compounds as disclosed and covered in IN907are known and anticipated through prior claiming based on IN229 Such compounds are easily developed by a person skilled in the art based on performing routine/regular experimentation including making substitution as disclosed in IN229 Hence, it is prayed that IN907is liable to be revoked being invalid based on anticipation by prior claiming through IN229 (ii) Reliance is also placed on Section 64(1) (f) of the Act to contend that the claims in IN907are obvious to a person skilled in the art and do not involve any inventive steps on the basis of prior art documents which provide sufficient teaching, suggestion and motivation to enable a person skilled in the art to prepare the compounds claimed in the impugned patents. There is sufficient teaching also in the common general knowledge that was prevalent in the field of drug designing/pharmaceuticals/chemistry before the priority date of the suit patent. (iii) Reliance is also placed on Section 64(1)(d) and 64(1)(k) of the Act to state that the subject matter of the claims IN907does not qualify as an invention within the meaning of the Patents Act and is invalid and liable to be revoked. It is reiterated that the compound TICAGRELOR lacks novelty being comprehensively anticipated by prior claiming through the claims in IN229 It is reiterated that this is admitted by the plaintiff by their affirmative acts when they filed Form 27 from 2012 to 2018 for IN229and IN907 (iv) Reliance is also placed on Section 64(1)(h) to submit that complete specifications to sufficiently and fairly describe the invention have not been CS(COMM.)749/2018 & etc. Page 10 of 57 given. Reliance is also placed on Section 64(1)(j) to plead that the patent was obtained by false suggestions and representations. (v) Reliance is also placed on Section 64(1)(m)

to claim that the applicant failed to disclose to the Controller information required under Section 8 of the Act.

17. Somewhat identical submissions are made to submit that the patent IN984and IN674are invalid.

18. In CS(COMM) 1023/2018, written statement has been filed after the arguments were concluded. However, a reply was filed to IA No.9332/2018. Defendant here is Dr.Reddys Laboratories Ltd. The following broad defences have been raised by the said defendant to plead that the suit is devoid of merits:-

"(i) It is pleaded that the plaintiffs own case is that the TICAGRELOR is covered within the generic scope of IN229genus patent which has expired on 14.07.2018. However, to overcome the effect of the expiry of the said patent, the plaintiffs are trying to create a false dichotomy between coverage and disclosure by asserting that IN229generically covers but does not specifically disclose TICAGRELOR. It is stated that this false dichotomy of coverage and disclosure is created to artificially extend its monopoly through subsequent patents on TICAGRELOR. (ii) It is further pleaded that the plaintiffs have attempted to Ever-Green its invention. It is stated that the present case is a classic case of Ever- greening of a life saving drug. It is further stated that primarily patent of IN229has expired on 14.07.2018 and that the plaintiffs are cleverly asserting three subsequent patents to overcome the limitation caused due to the said expiry. It is stated that that the present suit is merely a ploy to artificially CS(COMM.)749/2018 & etc. Page 11 of 57 extend the period of IN229 It is pleaded that the suit patents lack any inventive step. Further the suit patents do not exhibit any therapeutic efficacy over the known substances disclosed in IN229It is pleaded that there are no pleadings in the plaint regarding the enhancement of therapeutic efficacy of the subject matter of the suit patents. Hence, it is stated that the patent of the plaintiff is liable to be revoked under Section 64(1)(K), Section 2(1) (ja) and Section 3(d) of the Patent Act, 1970. (iii) Reliance is also placed on sections 64(1)(d) and 2(1) (ja) of the Patent Act to claim that a patent can be revoked if it is not an invention under the meaning of the Act. It is pleaded that the patent IN907does not involve any inventive step vis--vis the existing knowledge contained in IN229patent. It is stated that the plaintiffs are

trying to plead that a person skilled in the art could not have recognized TICAGRELOR from the generic disclosure of IN229. The plaintiffs also assert that TICAGRELOR is a genus patent over a Markush structure which covers 150 quintillion compounds (1.5 x 1020). It is pleaded that as per the plaintiffs own case, the US counterpart of IN229(US910 specifically indentifies and exemplifies 144 compounds, 134 out of which are specifically disclosed in claim 8 of IN229 Thus a person skilled in the art does not have to experiment with 150 quintillion compounds but only with 144 or 134 compounds which are readily available for him to further experiment and create/identify derivatives suitable as drug candidates. (iv) It is further stated that the defendant is selling TICAFLO i.e. TICAGRELOR and TICAGRELOR is generically disclosed in IN229which is admittedly sold in India under the name BRILINTA and AXCER. CS(COMM.)749/2018 & etc. Page 12 of 57 The defendant, it is pleaded, is practicing IN229which is now in the public domain by virtue of the expiry of IN229 (v) The pleas under Section 64(1) (a), (d), (e), (i), (j) and (k) are reiterated to plead that the suit patents are liable to be revoked. (vi) It is further pleaded that the plaintiff alleged loss and harm can be easily compensated as the loss of revenue and profits are clearly calculable and determinable. In case the plaintiff succeeds in the suit this loss can easily be compensated.

19. In CS(COMM) 792/2018, the main defendant here is Natco Pharma Ltd. Apart from repeating most of the above contentions, the defendants in the present suit reiterate that to the best knowledge of the defendant, the patent has been refused in several countries including China, Europe and South Korea. These details, it is pleaded, have been suppressed in the present suit.

20. The said defendant has also filed counter claims for revocation of Indian Patent IN907 IN984and IN674 21. In the counter-claim filed to seek revocation of IN984some of the salient contents raised are as follows:-

"(i) It is pleaded that the suit patent is not novel having regard to what was publicly known or published in India or elsewhere. Reliance is placed on Section 64(1)(e) to contend that it lacks novelty. It is claimed that the impugned claim is not novel in view of WO00034283 (WO283). Reliance is placed on an experiment conducted

by Dr.Fritz B. Blatter on 27.8.2012 where it was demonstrated that the final product of example 3 of WO283is nothing but a crystal compound claimed in the impugned patent. It is stated CS(COMM.)749/2018 & etc. Page 13 of 57 that as a result of the above disclosure the European Patent Office revoked the patent. (ii) It is further stated that the subject matter patent is obvious in nature and does not involve any inventive step having regard to what was publicly known or published in India or anywhere else. Reliance is placed on Section 64(1)(f) of the Act. It is pleaded that the aforesaid claims are obvious in view of the prior art WO283 It is stated that WO283 taken together with other prior art documents as well as available common general knowledge would enable a person skilled in the art to identify the polymorph claimed in the impugned patent. (iii) It is further stated that impugned patent is not sufficiently or properly described. Reliance is placed on section 64(1) (h). (iv) It is also pleaded that the patent is not patentable under the Act. Reliance is placed on section 3(d) read with section 64(1) (k) of the Act. It is stated that there is no data to demonstrate therapeutic efficacy of the compound over known compounds specially TICAGRELOR which is disclosed by WO283 Hence, the claim is invalid in view of section 3(d) of the Patent Act. (v) Reliance is also placed on section 64(1)(d) to contend that the said claim is not an invention within the meaning of the Act. The impugned suit patent does not possess an inventive step and is obvious to a person skilled in the art. (vi) It is also pleaded that the plaintiff has failed to comply with section 8 of the Act. It is stated that the plaintiff has failed to intimate the Indian Patent Office of the status of all corresponding foreign applications including details regarding grant, refusal, abandonment etc. Reliance is also placed on CS(COMM.)749/2018 & etc. Page 14 of 57 section 64 (1)(m) of the Act to state that the impugned patent is liable to be revoked.

22. Counter-claim is also filed for revocation of Indian Patent 209907. It has been claimed in the counter-claim that the invention as claimed was claimed in a valid claim of earlier priority date i.e. IN229 It is stated that the compound already claimed and granted in IN229has once again been claimed and granted in IN907 It is pleaded that the plaintiff has played a fraud on the Indian Patent Office and before this court as the correct picture has not been placed before the court. It is pleaded that based on prior claim the claims of the impugned patent are liable to

be rejected. Reliance is also placed on section 64(1)(f) of the Act. It is reiterated that the impugned patent does not involve any inventive step having regard to what was publicly known and used in India. A person skilled in the art armed with the prior art and with common general knowledge would be in a position to arrive at TICAGRELOR. Reliance is also placed on section 64(1)(h) of the Act. It is stated that the impugned patent is not properly described. Reliance is also placed on section 64(1)(k) read with section 3(d) of the Act. It is stated that the specification of the plaintiff does not provide any data to demonstrate therapeutic efficacy of the compound or know compounds especially TICAGRELOR which is disclosed by IN229 Reliance is also placed on section 64(1)(d) and section 2(1)(j) of the Act to claim that the patent is liable to be revoked. Reliance is also placed on section 8 read with section 64 (1)(m) of the Act. CS(COMM.)749/2018 & etc. Page 15 of 57 23. Another counter-claim is also filed seeking revocation of Indian Patent No.272 674 substantially on the same aforenoted grounds.

24. The plaintiff has filed its replication/written statement to the counter- claim.

25. I have heard the learned counsel for the plaintiffs and the learned senior counsel/counsel for the defendants. Learned senior counsel/counsel for the defendants have raised somewhat common contentions. I may note some of the salient contentions.

26. Learned senior counsel for the defendants i.e. Micro Labs Ltd. in CS(COMM7492018 has broadly raised the following contentions to plead that this court may vacate the interim orders passed by this court: (i) It has been pleaded that IN229discloses TICAGRELOR which patent has expired on 14.07.2018. It is stated that this is evident from the fact that in the US equivalent of IN229 i.e. US910, the plaintiffs have expressly made an admission that US910discloses and claims TICAGRELOR. Reliance is also placed on Section 13(1)(b) of the Act. (ii) It has further been pleaded that the suit patents are a classic instance of Ever-Greening. IN229expressly discloses and covers through its claims 1 and 7 TICAGRELOR. The product TICAGRELOR, it is reiterated, has been admitted by the plaintiffs in US litigations for infringement of US910to be revealed in IN229 It is further stated that even before the Indian Patent Office while filing forms 27, the

plaintiffs expressly admit that IN229covers and claims TICAGRELOR. It is pleaded that Form 27 filed by the plaintiff for IN229is identical to Form 27 filed in respect of IN907 IN984and IN674 Hence, it is stated that at this stage, in view of the stated CS(COMM.)749/2018 & etc. Page 16 of 57 admissions made by the plaintiff, this court may not grant interim injunction to protect the plaintiffs. (iii) It has been further pleaded that the patents which correspond to IN907and IN984have been refused in various countries. It is stated that the European Patent corresponding to IN984has been revoked by the European Patent Office Opposition Board, Chinese Patent corresponding to IN907was invalidated in October 2017. It is pleaded that these material facts have been suppressed by the plaintiffs. It is further pleaded that there is non- compliance of Section 8(1) & Section 8(2) of the Act since details of this revocation and such proceedings were concealed from the Indian Patent Office. (iv) It has further been pleaded that defendant No.2 filed two separate revocation petitions before IPAB in respect of IN907and IN984in October 2015 much prior to filing of the present suit. The revocation petitions, it is urged, are bona fide and not a counter blast to the suit. It has been pleaded that a credible challenge to the two patents is pending prior to filing of the present suit and that itself would be a ground for this court to vacate the present interim orders passed. Reliance is placed on the judgment of a Division Bench of this court in F.Hoffman LA Roche Ltd. vs. Cipla Ltd., 2009 (40) PTL125(Del) to argue that where there is a credible challenge to the validity of the patent it is sufficient to deny interim relief to the plaintiff. (v) It is further submitted that the plaintiff has not come to court with clean hands. The plaintiff has impleaded defendant No.1 as one Mr.P.Kumar whereas the main defendant is Micro Labs Ltd. Hence, Mr.P.Kumar was added only to mask the target Micro Labs Ltd. CS(COMM.)749/2018 & etc. Page 17 of 57 27. Learned senior counsel for the defendants Natco Pharma Ltd. in CS(COMM) 792/2018 has broadly urged as follows to plead that this court may vacate the interim orders passed:-

"(i) It has been strongly pleaded that the plaintiffs have deliberately and mischievously impleaded Mr. T. Rao as defendant No.1. The suit and the cause of action is actually against defendant No.2 which is Natco Pharma Ltd. The plaintiffs have deliberately and mischievously filed the memo of parties in this manner impleading defendant No.1 who has no role to play in the present litigation to

mislead the defendant and the court. (ii) He submits that IN229discloses TICAGRELOR which is prior claimed. TICAGRELOR was already claimed in claim 2-7 of IN229 Reliance is also placed on admissions made by the plaintiff while filing Form 27 which as filed for IN907are the same as the Form 27 filed for IN229 Reliance is also placed on similar admissions made by the plaintiff in USA for patent term extension. It is further pleaded that this is a case of re- patenting or re-claiming. Hence, it is pleaded that the said patent is liable to be revoked under Section 13(1)(b) read with Section 64(1)(a) of the Act. (iii) It has been strongly reiterated that TICAGRELOR is very much disclosed in IN229 Working statements of the two patents, namely, IN229and IN907are identical. The drug which has been marketed by the plaintiffs BRILINTA and AXCER is TICAGRELOR only. TICAGRELOR forms an integral part of IN229which patent has expired. (iv) It has been further stressed that other countries have revoked the patents of the plaintiffs which is equivalent to IN907 Chinese patent equivalent to IN907was invalidated in China. European patent equivalent to IN984was revoked, the Korean patent was also revoked. Chinese patent CS(COMM.)749/2018 & etc. Page 18 of 57 equivalent to IN674was refused. It is stated that all these facts have been suppressed by the plaintiff before the India Patent Office and before this court. Hence, it is pleaded that the patents of the plaintiffs are liable to be revoked on account of suppression of facts and this court should on this ground alone vacate the interim orders. (v) It has also been strongly urged that the drug in question is being sold by the plaintiffs at Rs.50 per tablet whereas the defendants propose to sell the same at Rs.20 each. It is stated that in view of this fact the interim order passed will cause grave and irreparable loss and injury and hence the interim order be vacated by this court.

28. Learned counsel appearing in CS(COMM) 1023/2018 has reiterated the above contentions to plead that this court may vacate the interim orders passed. He broadly pleads as follows: (i) He submits that the defendant is using IN229which is an expired patent. It is pleaded that the plaintiffs admit that TICAGRELOR is covered by IN229 It is further stated that the plaintiff claims that TICAGRELOR is covered but not disclosed by IN229 It is pleaded that such a contention was completely rejected by the Supreme Court in its judgment in the case of Novartis AG. v. UOI, 2013 (6) SCC1 It is hence pleaded that the contentions of the plaintiff

cannot be accepted. (ii) It is reiterated that IN229is admittedly a valid prior art for IN984and IN674 To support this contention, it is stated that IN229was published on 04.02.1999 prior to the priority date of IN984(02.02.2000) and IN674(21.08.2006). Clearly, it is pleaded that these two patents are in any case invalid. CS(COMM.)749/2018 & etc. Page 19 of 57 (iii) It is further stated that the suit patent IN907has been revoked in China. IN984has been revoked in China, Europe and South Korea. It has been refused in Brazil and Argentina. Hence, it is pleaded that the suit patent is clearly vulnerable to challenge in these proceedings. (iv) It is further stated that it is the admission of the plaintiffs that TICAGRELOR is structurally closest to the compound of example 68 of IN229 It is hence stated that being a derivative of a known substance, TICAGRELOR is squarely hit by Section 3(d) of the Indian Patents Act. It is pleaded that there is not a whisper in the plaint claiming enhanced therapeutic efficacy for IN907i.e. the suit patent. Reliance is again placed on the judgment of the Supreme Court in Novartis AG. v. UOI (supra) to contend that in the absence of enhanced efficacy, the said product would not be patentable.

29. Learned counsel for the plaintiffs has however rebutted the aforesaid contentions of the defendants and pleaded that the interim orders passed be confirmed by this court. He has pleaded as follows:-

"(i) On the plea of the defendants on anticipation i.e. section 13(1)(a) of the Act it is stated that the genus patent (IN229 was published on 2nd February 1999 i.e. after the priority date of the species patent (IN907 (4.12.1998). Therefore, it is stated that the genus patent cannot constitute a prior art document for evaluating the novelty of the species patent. Hence, it is stated that the plea of anticipation raised by the defendant is not applicable to the present case. It is further stated that there is no specific or enabling disclosure of TICAGRELOR in the genus patent. Genus patent only discloses (1.5 x 1020) compounds one of which was later discovered to be TICAGRELOR. A person of ordinary skill in the art would not have been CS(COMM.)749/2018 & etc. Page 20 of 57 able to identify or isolate TICAGRELOR based on the teaching of the genus patent. It is further pleaded that that the analysis undertaken by the defendant to show that TICAGRELOR can be derived from general Markush formula in the genus patent is untenable and is a

case of hind sight bias i.e. cherry picking of substituents based on ex post facto knowledge of the final molecule to be obtained. (ii) On the contention of the defendants of prior claiming i.e. section 13(1)(b) of the Act, it is stated that the same requires a specific individualized claim. A broad claim which may cover TICAGRELOR among millions of other compounds is insufficient for the purpose of prior claiming. It is reiterated that there is no claim in the genus patent which specifically claims TICAGRELOR. Hence, it is stated that the plea of Prior Claiming of the defendant is not applicable. (iii) On the applicability of section 3(d) of the Patent Act i.e. Ever- greening it is pleaded that the defendants have not been able to point out any known substance from the genus patent of which TICAGRELOR could be considered a new form/derivative. Merely because examples 32 and 68 are structurally close to TICAGRELOR does not mean that TICAGRELOR is a new form or derivative of the former. Mere structural similarity is not sufficient to trigger section 3(d) of the Act. It is further stated that even otherwise TICAGRELOR has demonstrably greater therapeutic efficacy as can be seen from the affidavit of Dr.Robert Riley which is relied upon by the defendants Dr.Reddys Laboratory. It is stated that this affidavit shows that TICAGRELOR has a CS(COMM.)749/2018 & etc. Page 21 of 57 vastly superior metabolic stability and its availability in the body would be far greater. (iv) On the argument about non disclosure of various revocation proceedings outside India i.e. alleged non-compliance of Section 8 of the Act it is stated that equivalent of IN907was revoked in China but an appeal has been filed which implies an automatic stay of the operation of the revocation order. It is further stated that 57 countries have granted patent for the same. Regarding IN984it is accepted that in Europe and China the patent was revoked. However, as an appeal has been filed and there is an automatic stay in operation. It is reiterated that the patent has been granted in 55 countries. Regarding the patent IN674it is stated that there is no revocation order passed and the patent is subsisting in 60 countries, It is stated that there is substantial compliance by the plaintiff of the statutory provisions and there is no mala fide suppression and hence section 8 of the Patent Act would have no application. (v) Regarding the reliance of the defendants on the alleged admissions made by the plaintiff in the US Patent Term extension applications and in form 27 filed by the plaintiff in India, it is stated that form 27 only states that the

genus patent has worked through TICAGRELOR. This does not mean that TICAGRELOR has been disclosed therein. It is stated that multiple patents can cover a single product. It is further stated that the genus patent discloses an entire class of compounds and thus does not pertain to a commercialized substance. It is the only after the act of isolation of TICAGRELOR through species patent that the plaintiff has been able to state that the genus patent is being worked or commercialized through Brilinta. CS(COMM.)749/2018 & etc. Page 22 of 57 Regarding the litigation filed in USA and the alleged admission in the proceedings, it is stated that the plaintiffs action is consistent with the US Laws in the said proceedings. (vi) It has been reiterated that the plaintiffs are servicing around 6 lac patients a year and not 72,000/- as claimed by the defendants. Hence, it is prayed that the interim order passed by this court may continue as plaintiff has a strong prima facie case. (vii) Learned counsel has also vehemently argued that the judgment of the Supreme Court in the case of Novartis v. UOI, (supra) has no application to the facts of this case. It is stated that the Supreme Court in the said case has stated that coverage (for the purpose of infringement) will not be granted by the court unless a specific disclosure has been made in the patent. This does not mean that disclosure can be deemed to the extent of coverage asserted. It is stated that in the said case there had been an actual disclosure of Imatinib Mesylate in the Zimmermann patent.

30. I may now deal with the submissions of the parties. [I]. Is TICAGRELOR disclosed and covered in the now expired patent IN229 31. One of the main disputes relates to the contention of the defendants that IN229covers/discloses TICAGRELOR and that the suit patents cannot be said to be an invention. It is stated that compounds as claimed in the suit patents are known and anticipated in the light of IN229 The plaintiff claims that TICAGRELOR is not disclosed in IN229and that TICAGRELOR is an invention and is patentable. CS(COMM.)749/2018 & etc. Page 23 of 57 32. To determine the dispute, I may look at some of the relevant statutory provisions. Reference may be had to Section 2(j), 2(ja), 2(m) and Section 3(a), (c) and (d) of the Patent Act. The said sections read as follows:-

"2. Definitions and interpretation.-. (1) xxx to technical advance as compared [(j) "invention" means a new product or process involving an inventive step and capable of industrial application;]. [[(ja) "inventive step" means a feature of an invention that involves the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art;].]. xxx (m) "patent" means a patent for any invention granted under this Act;]. xxx 3. What are not inventions.-.The following are not inventions within the meaning of this Act,- (a) an invention which is frivolous or which claims anything obviously contrary to well established natural laws; (b) xxx (c) the mere discovery of a scientific principle or the formulation of an abstract theory 20 [or discovery of any living thing or non- living substances occurring in nature].; [(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, CS(COMM.)749/2018 & etc. Page 24 of 57 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;]. 33. Reference may be had in this context to the judgment of the Supreme Court in the case of Novartis AG vs. Union of India, 2013 (6) SCC1where the Supreme Court held as follows:-

"74. Section 2(1)(j) requires a product to satisfy three conditions to qualify as an invention: (i) It must be new, that is to say it must not have been anticipated; (ii) Its coming into being must involve an inventive step; and 34. It must be capable of industrial application, that is to say it must be capable of being made or used in an industry [Section 2(1)(ac)]..

75. Inventive step is separately defined in Section 2(ja) to mean a feature of an invention that involves technical advance as compared to the existing knowledge, or having economic significance or both and that makes the invention not obvious to a person skilled in the art. To paraphrase, the invention that creates the product

must have a feature that involves technical advance as compared to the existing knowledge or having economic significance or both and this feature should be such as to make the invention not obvious to a person skilled in the art.

76. On a combined reading of clauses (j), (ac) and (ja) of Section 2(1), in order to qualify as invention, a product must, therefore, satisfy the following tests: (i) It must be new; (ii) It must be capable of being made or used in an industry; CS(COMM.)749/2018 & etc. Page 25 of 57 (iii) It must come into being as a result of an invention which has a feature that: (a) entails technical advance over existing knowledge; or (b) has an economic significance; and (c) makes the invention not obvious to a person skilled in the art.

77. We have seen the meaning of invention; we have also seen earlier that the Patents Act, 1970, dealt with invention and patentability as two distinctly separate concepts. The duality of the two concepts is best illustrated by Section 4 of the Act, which prohibits the grant of patent (either process or product) in respect of inventions relating to atomic energy falling within sub- section (1) of Section 20 of the Atomic Energy Act, 1962, and which has not undergone any change since inception. It is, therefore, fundamental that for grant of patent the subject must satisfy tests of invention and patentability. Something may be an invention as the term is generally understood and yet it may not qualify as an invention for the purposes of the Act. Further, something may even qualify as an invention as defined under the Act and yet may be denied patent for other larger considerations as may be stipulated in the Act. Having, therefore, seen the meaning of invention, we may now advert to Section 3 as it stands after the amendment of the Act in 2005. twin the 34. For the purpose of deciding the aforesaid dispute, reference may also be had to the judgment of the Supreme court in the case of Bishwanath Prasad Radhey Shyam vs. Hindustan Metal Industries, AIR 1982 SC1444 The Supreme Court held as follows:-

"25 Whether an alleged invention involves novelty and an 'inventive step', is a mixed question of law and fact, depending largely on the circumstances of the case. Although no absolute test uniformly applicable in all circumstances can be devised, certain CS(COMM.)749/2018 & etc. Page 26 of 57 indicated. Whether

broad criteria can be the "manner of manufacture" patented, was publicly known, used and practised in the country before or at the date of the patent ?. If the answer to this question is 'yes', it will negative novelty or 'subject matter'. Prior public knowledge of the alleged invention which would disqualify the grant of a patent can be by word of mouth or by publication through books or other media. "If the public once becomes possessed of an invention", says Hindmarch on Patents (quoted with approval by Fry L. J.

in Humpherson v. Syer, "by any means whatsoever, no subsequent patent for it can be granted either to the true or first inventor himself or any other person; for the public cannot be deprived of the right to use the invention..... the public already possessing everything that he could give."

26. The expression "does not involve any inventive step" used in Section 26(1) (a) of the Act and its equivalent word "obvious", have acquired special significance in the terminology of Patent Law. The 'obviousness' has to be strictly and objectively judged. For this determination several forms of the question have been suggested. The one suggested by Salmond L. J.

in Rado v. John Tye & Son Ltd. is apposite. It is:

"Whether the alleged discovery lies so much out of the Track of what was known before as not naturally to suggest itself to a person thinking on the subject, it must not be the obvious or natural suggestion of what was previously known."

27. Another test of whether a document is a publication which would negative existence of novelty or an "inventive step" is suggested, as under:

"Had the document been placed in the hands of a competent craftsman (or engineer as distinguished from a mere artisan), endowed with the common general knowledge at the 'priority date', who was faced with the problem solved by the patentee but without knowledge of the patented invention, would he have said, "this gives me what I want?." (Encyclopedia Britannica; ibid). To put it in another form:

"Was it for practical purposes obvious to a skilled worker, in the field concerned, in the state of knowledge existing at the date of the patent to be found in the literature then CS(COMM.)749/2018 & etc. Page 27 of 57 available to him, that hewould or should make the invention the subject of the claim concerned ?." Halsbury, 3rd Edn, Vol. 29, p. 42 referred to by Vimadalal J.

of Bombay High Court in Farbwrke Hoechst & B. Corporation v. Untchan Laboratories, MNU/MH/0064/19

AIR1969 Bom 255. 35. It is the case of the plaintiffs that the genus patent being IN229discloses a huge class of 1.5 x 1020 compounds one of which was later discovered to be TICAGRELOR. It further stated that claim 5 of the species patent i.e. IN907covers the molecule TICAGRELOR selected out of 150 quintillion compounds covered by IN229 It is further the case of the plaintiffs that a person ordinarily skilled in the art would not have been able to identify or isolate TICAGRELOR based on the teachings of the genus patent.

36. The defendants have denied the said contention of the plaintiffs. The defendants submit that TICAGRELOR can be achieved from substitution and preferences listed in IN229 They also rely upon various admissions to this effect allegedly made by the plaintiffs while filing statutory details in India and abroad and also while pursuing litigation abroad to support their case.

37. Dr. Reddys Laboratories Ltd. raises a plea that TICAGRELOR is covered and disclosed in the claims of IN229which are elaborated as follows:-

"that Ticagrelor Furthermore, is explicitly covered and disclosed in the claims of IN229 can been demonstrated from the below table, which shows how Ticagrelor can be achieved from the limitations of claims of IN229:-

"CS(COMM.)749/2018 & etc. Page 28 of 57 229 compound of Formula (la) patents claims Substituting hydroxy, i.e. OH group at R3 and R4 Substituting Hydroxyethoxy, i.e. OCH2CH2OH group at R Substituting propyl at R1 229 patent claims compound of Formula (la) Page 5 - Suitably one of R3 and R4 is hydroxy and the other is hydrogen, hydroxy or NR9 R10. Preferably R3 and R4 are both

hydroxy. Claim 5 - R3and R4 are both Hydroxyl Page 5 : Preferred R groups include OH, CH2OH, CH2CH2OH and OCH2CH2OH. Claim 7 - R is OH, CH2OH, CH2CH2OH, OCH2CH2OH, CH20CH2C(CH3)20H and 0CH2C(CH3)20H2 Page 4 - "Suitably R1 is a C1-6 alkyl, C2-6 alkenyl, 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 atoms). Preferably R1 is C1-3 alkyl or phenyl substituted by trifluoromethyl. More preferably R1 or trifluoromethylphenyl."

Claim 3 - C1-4 alkyl or phenyl propyl is CS(COMM.)749/2018 & etc. Page 29 of 57 substituted by trifluoromethyl. Page 5 - "Suitably R2 is C1-8 alkyl optionally substituted by one or more substituents selected from halogen, , SR11 or C1-6 - OR8, NR9R10 cycloalkyl, aiyl (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 or C1-6 - alkyl or phenyl, the latter two groups being optionally substituted by one or more substituents selected from halogen, NO2, C(0)R8 OR8 , SR1, NR12R13 fused 5-or 6-membered saturated ring containing one or two oxygen atoms, phenyl or Cl-6-alkyl the latter two groups being optionally substituted by OR8, NR9 R10 or one or more halogen atoms. Aryl groups include phenyl and naphthyl groups. Acyl groups include C(0)C1-6 alkyl such as acetyl and 1-oxopropyl. Preferably R2 is C1-6 alkyl or a C3. 8- cycloalkyl group optionally substituted by phenyl. More cvclopropvl optionally substituted by phenvL the phenvl group itself beiiiff optionally substituted by one or more halogen, C3-8 alkyl, alkoxy, phenoxy or phenyl groups. Claim 4 - R2 is a butyl or cyclopropyl optionally substituted by preferably or is butyl CS(COMM.)749/2018 & etc. Page 30 of 57 a phenyl, the phenyl group itself being substituted by one or more halogen, C3-8-alkyl, phenoxy or phenyl groups 38. The defendant Micro Labs Ltd. states that IN229specifically discloses and covers through claim 1 and claim 7 the product TICAGRELOR. The defendant NATCO Ltd. states that claims 2-7 of IN229leads to TICAGRELOR. It is stated that claims 2 to 7 specifically claim certain compounds and TICAGRELOR can be derived from the substitution as suggested in the claim. IN229claims A Triazolo (4, 5-0) Pyrimidine compound of formula (I) IN907it is stated claims the same product.

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 IN229and the subsequent patents. They plead that IN229discloses 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) PTC135(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 IN229discloses TICAGRELOR would be a mixed question of law and fact. CS(COMM.)749/2018 & etc. Page 31 of 57 40. A Co-ordinate Bench of this court in the case of Merck Sharp & Dohme Corporation & Anr. v. Glenmark Pharmaceuticals Ltd., 223 (2015) DLT454 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.DSouza v. Mohd. Ishfaq, 157(2009) DLT391(SC) = 12(2009) CPJ32(SC) = II(2009) SLT20= (2009) 3 SCC1 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 IN229discloses TICAGRELOR.

42. However, for the purpose of this application there are other facts i.e. alleged admissions said to have been made by the plaintiffs which have been heavily

relied upon by the defendants to argue and submit that the plaintiffs have themselves admitted that TICAGRELOR is disclosed in IN229 I may look at some of these alleged admissions.

43. A reference has been made by the defendants to the Statement of Working stated in Form 27 filed by the plaintiffs before the Controller of CS(COMM.)749/2018 & etc. Page 32 of 57 Patents. It is stated that the plaintiffs have declared TICAGRELOR as patented invention of IN229 For IN229 on 21.03.2018, the plaintiffs filed the following Form 27 which reads as follows- CS(COMM.)749/2018 & etc. Page 33 of 57 44. Similarly, for IN907the following Form 27 was filed on the same date i.e. 21.03.2018 for the same period i.e. 2017:-

"CS(COMM.)749/2018 & etc. Page 34 of 57 45. Similar information has been filed for IN984and IN674for the same period i.e. 2017 which read as follows:-

"CS(COMM.)749/2018 & etc. Page 35 of 57 CS(COMM.)749/2018 & etc. Page 36 of 57 46. A perusal of the above forms would show that the same and identical returns are being filed for different patents by the plaintiff i.e. for IN229 IN907 IN984and IN674 The above returns show that for the year 2017, a sale of BRILIANTA of 1,884,470 PACKS has been shown in the returns for each of the four noted patents. Similarly, for drug AXCER, the same quantum, namely 1,797,194 PACKS sale have been stated under the four patents. Some of the defendants have also filed the said Form 27 filed by the plaintiff for the previous years starting from 2014. In each of the returns the same situation exists. It is clear from a reading of the said forms that the plaintiffs are not in any manner showing separate figures for the working of the said four patents or the quantum and value of the patented products that was sold. The same product and quantity is stated to show the working of the three suit patents and the expired patent IN229 47. Reference may also be had to another document/ alleged admissions relied upon by the defendants which relates to a litigation in US against Mylan INC to enforce US Patent 6251910 (equivalent to IN229. In the said proceedings filed before the United States District Court for the District of Delaware, the plaintiffs stated as follows:-

"1. 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 CS(COMM.)749/2018 & etc. Page 37 of 57 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"). 5. Plaintiff AstraZeneca UK Limited is a company operating and existing under the laws of United Kingdom, with its principal place of business at 15 Stanhope Gate, London, United Kingdom WIY6N. AstraZeneca UK Limited is the owner of the '910, '060, and '419 patents, and Defendant specifically directed its Notice Letters to AstraZeneca UK Limited. Hence, in the above noted proceedings the plaintiffs have acknowledged and stated that dealing in TICAGRELOR is in breach of US patent 910 (equivalent of IN229 also.

48. Similarly, the defendant-Micro Labs Ltd. also relies upon the stated admissions of the plaintiffs in the Orange Book of US FDA, Estonian Supplementary Protection Certificate and Canadian Patent Office Health Register where it is stated that the plaintiffs have voluntarily listed US910as TICAGRELOR.

49. Regarding Form 27 the plaintiffs deny the above submissions of the defendant being any admission that TICAGRELOR is disclosed in IN229 The plaintiffs state that Form 27 only states that the genus patent (IN229 has worked through TICAGRELOR and that this does not mean that the TICAGRELOR has been disclosed therein. It is pleaded that multiple patents can cover a single product. It is further pleaded in the written submissions filed that the genus patent IN229 discloses an entire class of compound. Thus, it does not pertain to commercialized substances. It is only after isolation of TICAGRELOR through species patent IN907 the plaintiffs CS(COMM.)749/2018 & etc. Page 38 of 57 have been able to

state that the genus patent is being worked or commercialized through BRILINTA.

50. Regarding the proceeding in Delaware the plaintiff has taken the stand that the assertion that genus patent is also infringed in the litigation above in the US is as it is permissible in USA. Coverage is sufficient to institute an infringement action in the US. It has been stated that the plaintiffs action in the US are consistent with US laws.

51. Learned counsel for the plaintiff has also relied upon the judgments in the case of Dr.Reddys Laboratories (UK) Ltd. v. Eli Lilly & Co.Ltd., (2008) EWHC2345(Pat) of the Royal Courts of Justice, London; Eli Lilly & Company Ltd. v. Apotex Pty Ltd., (2013) FCA214of Federal Court of Australia; and a judgment of the Supreme Court of Canada in Apotex Inc. v. Sanofi-Synthelabo Canada Inc., Sanofi-Synthelabo & Minister of Health, (2008) 3 S.C.R. 265 to stress his submission about difference between coverage of a genus patent and disclosure.

52. I may look at the aforenoted judgments relied upon by learned counsel for the plaintiff. In Dr.Reddys Laboratories (UK) Ltd. v. Eli Lilly & Co.Ltd.(supra), the court held as follows: 91. The notion that a prior disclosure does not take away the novelty of a claim to a specific compound unless the compound is disclosed in individualised form is, I believe, a sound one. I will endeavour to explain why.

92. Firstly, a general formula is an extremely powerful way of covering large number of chemical compounds: hence their frequent use in patent disclosure. It is, of course possible that someone could write down in succession all the compounds covered by all possible permutations of the variable substituents of the formula: but it is wholly artificial to suppose that anyone would. Attention would focus on CS(COMM.)749/2018 & etc. Page 39 of 57 compounds actually described, the remainder of the class being no more those compounds. theoretical penumbra around than a 53. In Eli Lilly & Company Ltd. v. Apotex Pty Ltd.(supra), the court held as follows: 326. I do not consider that it is as simple as he suggests, namely, that the skilled addressee would begin with the thienobenzodiazepine of the core and build appropriate analogies by the use of the variable substituents that need to be added to the core to arrive at olanzapine. No other witness accepted that this was the position. I accept the submission of Eli Lilly that it is not

only the ex post facto cherry-picking of specific substituents that one is liable to reach olanzapine from the compounds disclosed in the 235 Patent. The large number of compounds disclosed in the 235 Patent reflects the breadth of the teaching of that patent, and underscores the magnitude of the difficulty in selecting a single compound from the extensive class identified. Even if the skilled addressee limited attention to the most preferred class, there is no real guidance as to why it is preferred. 54. In Apotex Inc. v. Sanofi-Synthelabo Canada Inc., Sanofi- Synthelabo & Minister of Health(supra), the court held as follows: 96. The concern expressed by Apotex is that the doctrine of selection patents allows a patent holder to evergreen an invention. The original genus patent is granted for a finite period of years. If a selection patent is later obtained by the owner of the genus patent covering the same invention as the genus patent, the number of years the owner is entitled to exclude other from making or using the invention is extended, contrary to the limited period of exclusivity provided by the original patent. CS(COMM.)749/2018 & etc. Page 40 of 57 97. Evergreening is a legitimate concern and, depending on the circumstances, strategies that attempt to extend the time limit of exclusivity of a patent may be contrary to the objectives of the Patent Act. The Act aims to promote inventiveness by conferring exclusivity for a limited period of time while providing for public disclosure of the invention to enable others to make or use it after expiry of the period of exclusivity.

98. However, a generalized concern about evergreening is not a justification for an attack on the doctrine of selection patents for two reasons. First, a selection patent may be sought by a party other than the inventor or owner of the original genus patent. In such a case, anticipation or obviousness may be an issue, but evergreening does not arise.

99. At the hearing, counsel for Apotex submitted that, in the pharmaceutical industry, the only party that would ever attempt to obtain a selection patent would be the genus patent holder. This is a highly competitive industry and a market participant who is able to develop a more effective product might be expected to be anxious to do so and seek patent protection through a selection patent even if it requires the making of an agreement with the holder of the genus patent to allow for the marketing of the selected product. However, even if counsel is correct, the

doctrine of genus and selection patents is not restricted to the pharmaceutical industry. It is of general applicability. importantly, selection patents 100. Second and more encourage improvements by selection. The inventor selects only a bit of the subject matter of the original genus patent because that bit does something better than and different from what was claimed in the genus patent. CS(COMM.)749/2018 & etc. Page 41 of 57 55. The said issue relating to coverage and disclosure of a genus patent was raised by the appellant before the Supreme Court in Novartis AGs v. Union of India & Ors.(supra). In the said judgment the Supreme Court noted the submission of the learned senior counsel for the appellant, namely, that the scope of coverage is distinct from the scope of disclosure in a patent. It was further contended that coverage under a patent of the Markush kind cannot lead to any presumption of disclosure, much less any enabling disclosure of all the compounds. The plea was rejected by the Supreme Court stating as follows: 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 CS(COMM.)749/2018 & etc. Page 42 of 57 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. Hence, the Supreme Court negated the argument that is sought to be made by learned counsel for the plaintiff that coverage in a patent might go much beyond disclosure. The plea of the plaintiff that genus patent has worked through TICAGRELOR though TICAGRELOR is not disclosed in IN229cannot prima facie, at this stage, be accepted. For the purpose of the present injunction application, it can be said that the plaintiff have prima facie failed to explain the admissions/conduct as contained in Form 27 filed as noted above and the litigation commenced in USA against Mylan INC.

56. What is further surprising is that the plaint is strikingly silent about the said aspect of the patent IN229especially keeping in view the own admissions of the plaintiff whereby they have claimed that IN229is worked through TICAGRELOR.

57. The date of grant of IN229is 24.06.2010. The date of grant of IN907is 11.09.2007. The plaintiff states in the plaint that the drug regulatory approval for the drug TICAGRELOR came in May 2011 and the same was commercially launched in India in October, 2012 under the trademark BRILINTA. It is the case of the plaintiffs in their submissions that it is only the act of isolation of TICAGRELOR through the species patent i.e. IN907that the plaintiffs have CS(COMM.)749/2018 & etc. Page 43 of 57 been able to state that the genus patent is being worked or commercialized through Brilinta. Hence, the stand is that prior to isolation of TICAGRELOR through species patent, there was no commercial working of IN229 Surprisingly, no such averment has been made in the plaint by the plaintiffs. The only averment in the plaint about the patent IN229is that the same is a genus patent covering vast number of compounds and TICAGRELOR is not specifically disclosed in the genus patent though it is technically within the generic scope of numerous compounds including in Formula-I of the said application. It is further stated that a person skilled in the art could not have recognized TICAGRELOR from the genus patent. That is the sum and substance of the averment made by the plaintiffs in the plaint regarding the patent IN229and its connect with TICAGRELOR. None of the above facts/explanations were pleaded or stated in

the plaint. There is no averment in the plaint to claim that IN229(genus patent) was worked through TICAGRELOR though not disclosed in the said patent as is now sought to be pleaded in course of arguments. There is no averment in the plaint that IN229does not pertain to a commercialized patent.

58. The Division Bench of this court in F. Hoffmann-LA Roche Ltd. & Ors. vs. Cipla Ltd. (supra) had on the question of disclosure as in the facts of that case noted as follows:-

"40. This Court holds that in an application seeking ad interim injunction in a suit for infringement of patent, it would be incumbent on the plaintiffs to make a full disclosure of the complete specification of the product whose patent is claimed to have been infringed. The plaintiffs will also have to disclose to Court the x-ray diffraction data of the product, particularly if it is a pharmaceutical drug. The plaintiffs have to make an unequivocal disclosure that the patent they hold covers the drug in question; CS(COMM.)749/2018 & etc. Page 44 of 57 whether there are any other pending applications seeking the grant of patent in respect of any derivatives or forms of the product for which they already hold a patent and the effect of such applications on the suit patent. Short of the above details, the Court being approached for the grant of an ad interim relief will be unable to form a view on whether the plaintiff has made out a prima facie case. Otherwise it would be a case of suppression of material facts that would have a bearing on the question. 59. As noted above, the facts here show that the plaintiffs have been showing working of IN229through TICAGRELOR to the Controller of Patents while filing Form 27. The plaintiffs have filed proceedings for breach of IN229when the drug in question was TICAGRELOR in USA. These are important facts which have a material bearing on the issue as to whether TICAGRELOR is disclosed in IN229and is known and anticipated. The plaintiffs were obliged to have revealed the full facts in the plaint. This is especially so, keeping in view the fact that Micro Labs Ltd. had already filed an application for revocation of the suit patents before IPAB in 2015 where various grounds were urged including the fact that the suit patents are disclosed and covered in IN229 The said petition clearly states that the compounds as disclosed in IN907and IN984are known and anticipated in light of IN229and could have been developed by a person skilled in the art. There is clear

omission of the plaintiff to mention these materials and important facts in the plaint.

60. The above facts, in my opinion, show that the claim of the plaintiff that TICAGRELOR is not disclosed in IN229and is not anticipated is subject to a strong challenge by the defendant. This is so on account of the admissions which prima facie the plaintiff have not been able to explain CS(COMM.)749/2018 & etc. Page 45 of 57 properly. This is also shown on account of the conduct of the plaintiff as noted above. (II) Objections under section 3(d) of Patents Act 61. Another plea strongly raised by the defendant including Dr.Reddys Laboratories Ltd. is that TICAGRELOR is derived from a known substance/element disclosed in IN229 Being a derivative of a known substance, it is pleaded that the suit patents are squarely hit by 3(d) of the Patent Act inasmuch as there is no statement claiming enhanced therapeutic efficacy over IN229 In fact it is stated that there is no whisper in the plaint claiming that the suit patents have enhanced therapeutic efficacy vis--vis IN229 Hence, it is pleaded that the patent is even otherwise liable to be revoked.

62. The plaintiffs have denied the aforesaid submissions. It is stated that mere structural similarity is not sufficient to trigger Section 3 (d) of the Act. TICAGRELOR is not a new form or derivative of a known substance. Hence, it is pleaded that section 3(d) of the Act has no application. It is further stated that even if for some reason it is held that section 3(d) of the act is applicable to the present case, it has been pleaded that, TICAGRELOR has a greater therapeutic efficacy. Reliance is placed on the affidavit of Mr.Robert Riley which has been filed by the defendant Dr. Reddys Laboratories Ltd. It is stated that as per the said affidavit, TICAGRELOR has a vastly superior metabolic establishment which has a direct bearing on the curative effect of the substance. Hence, it is stated that TICAGRELOR falls outside the scope of Section 3(d) of the Act.

63. It is a matter of fact that the plaint is completely silent about any therapeutic efficacy of the suit patents vis--vis IN229 CS(COMM.)749/2018 & etc. Page 46 of 57 64. For the sake of completeness, reference may again be had to section 3(d) of the Patent Act, which reads as follows:

3. What are not inventions.-.The following are not inventions within the meaning of this Act:-

"xxxxxx [(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;]. 65. The CIPIH (Commission on Intellectual Property Rights Innovation and Public Health) describes evergreening as occurring when, in the absence of any apparent additional therapeutic benefits, patent-holders use various strategies to extend the length of their exclusivity beyond the 20-year patent term. 66. Reference in this context may again be had to the judgment of the Supreme Court in Novartis AGs v. Union of India & Ors.(supra). While interpreting section 3(d) of the Patent Act, the Supreme Court held as follows: 88. We have so far seen Section 3(d) as representing "patentability", a concept distinct and from "invention". But if Clause (d) is isolated from the rest of Section separate CS(COMM.)749/2018 & etc. Page 47 of 57 3, and the legislative history behind the incorporation of Chapter II in the Patents act, 1970, is disregarded, then it is possible to see Section 3(d) as an extension of the definition of "invention" and to link Section 3(d) with Clauses (j) and (ja) of Section 2(1). In that case, on reading Clauses (j) and (ja) of Section 2(1) with Section 3(d) it would appear that the Act sets different standards for qualifying as "inventions" things belonging to different classes, and for medicines and drugs and other chemical substances, the Act sets the invention threshold further higher, by virtue of the amendments made in Section 3(d) in the year 2005. xxxx 157. What is "efficacy"?. Efficacy means "the ability to produce a desired or intended result". Hence, the test of efficacy in the context of Section 3(d) would be different, depending upon the result the product under consideration is desired or intended to produce. In other words, the test of efficacy would depend upon the function, utility or the purpose of the product under consideration. Therefore, in the

case of a medicine that claims to cure a disease, the test of efficacy can only be "therapeutic efficacy". The question then arises, what would be the parameter of therapeutic efficacy and what are the advantages and benefits that may be taken into account for determining the enhancement of therapeutic efficacy?. With regard to the genesis of Section 3(d), and more particularly the circumstances in which Section 3(d) was amended to make it even more constrictive than before, we have no doubt that the "therapeutic efficacy" of a medicine must be judged strictly and narrowly. Our inference that the test of enhanced efficacy in case of chemical substances, especially medicine, should receive a narrow and strict interpretation is based not only on external factors but there are sufficient internal evidence that leads to the same view. It may be noted that the text added to Section 3(d) by the condition of "enhancement of the known efficacy". Further, the explanation requires the derivative to "differ significantly in properties with regard to efficacy". What is evident, therefore, is that not all the 2005 amendment lays down CS(COMM.)749/2018 & etc. Page 48 of 57 advantageous or beneficial properties are relevant, but only such properties that directly relate to efficacy, which in case of medicine, as seen above, is its therapeutic efficacy. xxxxx 169. Section 2(1)(j) defines invention to mean, a new product or , but the new product in chemicals and especially pharmaceuticals may not necessarily mean something altogether new or completely unfamiliar or strange or not existing before. It may mean something different from a recent previous or one regarded as better than what went before or in addition to another or others of the same kind [The New Oxford Dictionary of English, Edn. 1998.]. . However, in case of chemicals and especially pharmaceuticals if the product for which patent protection is claimed is a new form of a known substance with known efficacy, then the subject product must pass, in addition to clauses (j) and (ja) of Section 2(1), the test of enhanced efficacy as provided in Section 3(d) read with its Explanation.

67. In this context reference may also be had to the judgment of the Division Bench of this court in F.Hoffman LA Roche Ltd. vs. Cipla Ltd.(supra), where the court held as follows: to particularly 60. The above submissions have been considered. It is not possible to accept the contention of the plaintiffs that the Section 3(d) does not bring any significant change to the Patents Act. Not only has the substantive portion of Section 3(d) indicated a change in 2005 but the

Explanation which has been added appears target pharmaceutical products. It discourages evergreening and prevents such derivative or other forms of the already patented product being granted patent unless the derivatives or other forms "differ significantly in properties in regard to efficacy."

The plaintiffs contest the argument that Erlotinib Hydrochloride is a derivative of a known substance EP'226. However, it appears that the closest prior art does teach the compound for which patent has been granted to the plaintiffs. CS(COMM.)749/2018 & etc. Page 49 of 57 Therefore, unless the enhanced efficacy as mandated by Section 3(d) was demonstrated, patent could not have been granted. The defendant has been able to show that order of the Controller of Patents was arguably deficient on this aspect. The defendant therefore must be taken to have raised a credible challenge to the validity of the patent. I have already noted in the above paras the admissions of the plaintiffs 68. as contained in the Form 27 filed before the concerned authority in India where the patent IN229is shown to be working through TICAGELOR and the admissions made in the proceedings in the American Court filed against Mylan INC. Prima facie, I have held that the plaintiffs have not been able to explain these admissions. It appears that prima facie in the light of the above facts, the suit patents cannot said to be something altogether new or completely unfamiliar. The said suit patents would have to pass the test of enhanced efficacy as provided under section 3(d) read with its explanation.

69. The plaintiffs had to show compliance of section 3(d) of the Patent Act. As noted above, the plaint is completely silent about any enhancement of known therupatic efficacy for the suit patents. However, plaintiff states that even if for some reason it is held that the said Section applies, reliance is placed on an affidavit of Dr.Robert J.

Riley which has been filed by the defendant-Dr. Reddy Laboratories Ltd. to state that IN907has better therapeutic efficacy.

70. This belated reliance of the plaintiffs on the affidavit filed by Dr.Rober J.

Riley does not help the case of the plaintiff. Relevant part of the affidavit dated 8.3.2000 reads as follows: CS(COMM.)749/2018 & etc. Page 50 of 57 2. I am aware of both US patent number 6,251,910 (Guile et al) and US patent application number 09/508,195 (Hardern etal) that each disclose compounds which act as P2T-receptor antagonists. These compounds may be used as pharmaceutical agents for Inhibition of platelet aggregation. Both the patent (Guile et at) and the patent application (Hardern et at) have been assigned to AstraZeneca UK Limited. I am familiar with the compounds disclosed and I have been involved in testing and analyzing their biological activity. xxx that these compounds demonstrate 10. For the compounds exemplified in Hardern et al it can be shown the unexpected advantage of being active at a lower predicted dose in man as a result of a combination of increased metabolic stability together with high affinity for the P2T-receptor. 71. No doubt, the affidavit does state that equivalent of IN907(Hardern) has some advantages over equivalent of IN229(Guile). However, it categorically states that both the compounds, namely, equivalent of IN229and IN907can be used as pharmaceutical agents for inhibition of platelet aggregation. This view re-inforces my prima facie finding above that the suit patents are not something altogether new or completely unfamiliar or unconnected to IN229 72. Coming to the enhancement of therapeutic efficacy, the affidavit of Dr.Riley states that equivalent of IN907shows advantage of a lower predicated dose and increased metabolic stability. There is no explanation from the plaintiff as to how the stated advantage, namely, lower dose and increased metabolic stability would tantamount to enhancement of therapeutic efficacy over IN229 As noted by the Supreme Court in the case of Novartis v. UOI (supra) not all advantageous or beneficial properties are CS(COMM.)749/2018 & etc. Page 51 of 57 relevant but only such properties that directly relate to therapeutic efficacy. The belated reliance on the affidavit of Dr.Riley does not help the case of the plaintiff. Clearly, the plaintiff have prima facie failed to show enhancement of known efficacy of the suit patents over the products and fail the test of section 3(d) of the Act. [III]. Non-compliance of Section 8 read with section 64(1)(m) of the Act 73. Another contention of the defendants is that the plaintiffs have suppressed the pendency of the litigations in USA, South Korea and China and that plaintiffs have also suppressed that China Patent application which corresponds to IN907was

invalidated on 17.10.2017, European Patent which corresponds to IN984was revoked by EPO on 24.06.2014. Hence, it is pleaded that the patent is liable to be invalidated under Section 8 and Section 64(1)(m) of the Patent Act.

74. A Co-Ordinate Bench of this court in Chemtura Corporation v. Union of India & Ors., 2009 (41) PTC260(Del) noted the requirements of section 8 of the Act stating that section 8 (1) (a) requires an applicant for a patent to file along with his application a statement setting out the detailed particulars of the application filed by such applicant in any country outside India in respect of the same or substantially the same invention. Section 8 (1) (b) requires such applicant to also furnish an undertaking that up to the date of the grant of patent in India he will keep the Controller of Patents informed in writing from time to time of detailed particulars as required under clause (a) in respect of such application made in a country outside India. The corresponding rule is Rule 12 (1) of the Rules which states that CS(COMM.)749/2018 & etc. Page 52 of 57 the statement and undertaking to be filed in terms of Section 8 (1) of the Act will be in Form 3.

75. In the present case as noted above, the plaintiffs have given reasonable explanation about the proceedings abroad. It is explained that IN907was revoked in China. However, an appeal was filed and there is an automatic stay of the operation of the impugned order. Similarly IN984was revoked by EPO and China and an appeal was filed and here there is an automatic stay of the operations. Equivalent of IN907has been granted by 57 countries. Equivalent to IN984has been granted by 55 counties and equivalent to IN674have been granted by 60 countries.

76. In my opinion, in the given facts there is reasonable disclosure of the relevant facts in the case. It cannot be said that there has been suppression of any material facts on this account which have a material bearing on grant of the injunction application by the plaintiffs to warrant vacation of the stay order.

77. The Co-Ordinate Bench of this court in Bristol-Myers Squibb Company & Ors. v. Mr.J.D.Joshi & Anr.(supra) regarding non-compliance of provisions of section 8 of the Act, noted as follows: Non Compliance of Section 8 58. I have gone through the objection taken by the defendants as to non compliance of the provisions of

Section 8 of the Act. Although, the said plea raised by the defendants is not argued at the time of hearing. Still, I am inclined to deal with it. The provisions of Section 8 are already discussed at great length by the courts as such wherein the Court may or may not revoke the patent depending upon the nature of the information not supplied to the controller, relevance of the information and the conduct of the patentee etc CS(COMM.)749/2018 & etc. Page 53 of 57 78. Reference may also be had to the judgment of this court in the case of F.HOFFMANN-LA ROCHE LTD & ANR vs. CIPLA LTD., 2015 (225) DLT391 The Division Bench of this court noted as follows:-

"this Court 90. Thus though as a general rule if a consequence is provided then the rule has to be interpreted as mandatory however in the present case the consequence itself is not mandatory because of use of the word may in Section 64(1). This issue came up for consideration before Division Bench of in Maj.(Retd.) Sukesh Behl (supra) wherein this Court held that though it is mandatory to comply with the requirement under Section 8(1) of the Patents Act and non-compliance of the same is one of the grounds for revocation of the patent under Section 64(1)(m), however the use of the word may in Section 64(1) itself indicates the intention of the legislature that the power conferred thereunder is discretionary and consequently it is necessary for the Court to consider the question as to whether omission on the part of the applicant was intentional or whether it was a mere clerical and bona-fide error. 79. In my opinion, there is prima facie substantial compliance of the statutory requirements of Section 8 of the Act by the plaintiffs. The failure of the plaintiffs to mention about the proceedings in China, proceedings regarding the European Patent are not material enough to warrant vacation of the interim orders passed by this court. [IV]. Conclusion 80. Should the court continue the interim injunction granted earlier?.

81. The Division Bench in F. Hoffmann-LA Roche Ltd. & Ors. vs. Cipla Ltd. (supra) on this aspect had noted as follows:-

"55. The question before this Court is when can it be said that the defendant has raised a credible challenge to the validity of a patent held by the plaintiff in an infringement action?. During the course of the argument it was suggested by

counsel that the CS(COMM.)749/2018 & etc. Page 54 of 57 challenge had to be both strong and credible. Also, the defendant resisting the grant of injunction by challenging the validity of the patent is at this stage required to show that the patent is vulnerable and that the challenge raises a serious substantial question and a triable issue. Without indulging in an exercise in semantics, the Court when faced with a prayer for grant of injunction and a corresponding plea of the defendant challenging the validity of the patent itself, must enquire whether the defendant has raised a credible challenge. In other words, that would in the context of pharmaceutical products, invite scrutiny of the order granting patent in the light of Section 3(d) and the grounds set out in Section 64 of the Patents Act 1970. At this stage of course the Court is not expected to examine the challenge in any great detail and arrive at a definite finding on the question of validity. That will have to await the trial. At the present stage of considering the grant of an interim injunction, the defendant has to show that the patent that has been granted is vulnerable to challenge. Consequently, this Court rejects the contentions of the plaintiffs on this issue and affirms the impugned judgment of the learned Single Judge.

85. To summarise our conclusions: xxxxxx xxx (vi) Notwithstanding the above, assuming that the plaintiffs held a patent for the product which was the subject matter of the suit for infringement, the grant of such patent to the plaintiffs will not ipso facto entitle them to an interim injunction if the defendant is able to satisfy the court that there is a serious question to be tried as to the validity of the patent. In the present case, the defendant has raised a credible challenge to the validity of the patent by raising a serious triable and substantial question that renders it vulnerable to challenge. xxx 82. A Co-Ordinate Bench of this court in Bristol-Myers Squibb Company & Ors. v. Mr.J.D.Joshi & Anr.(supra) stated as follows: CS(COMM.)749/2018 & etc. Page 55 of 57 54. It is noteworthy to mention here that the challenges which can be raised under the provisions of the Section 64 of the Patents Act 1970 (as amended in the year 2005) are in the nature of the questions dependent on facts or the mixed question of facts and laws. Where in the case after applying the facts in the form of challenge and legal position, it can be prima facie readily inferred that the good ground for the challenge is made out which raises a credible challenge to the validity of the patent, then such inference

can be drawn prima facie to state that the credible challenge to the validity is raised. As against the same, there are certain questions within the challenges which requires the enquiry into more facts or complicated questions on which no opinion by the preference one set of facts over the other can be formed at the prima facie stage till the time those facts are ascertained in the trial as they are disputed question of the facts. . 83. Hence, the legal position as follows is that the grant of patent does not ipso facto entitle the plaintiff to an interim injunction. If the defendant is able to show that there exist serious and substantial questions which render the patent vulnerable to its validity, an injunction may not be granted. In view of the prima facie finding recorded by me above in Paras I and II, it is clear that the defendants have raised a strong credible challenge to the validity of the 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 Patent Act. The issues raised render the suit patents vulnerable to challenge.

84. In view of the aforementioned reasons, I am of the view that the plaintiffs have failed to make out a prima facie case. The balance of convenience is also in favour of the defendant. This is especially so as the original patent in question IN229has already expired on 14.07.2018. CS(COMM.)749/2018 & etc. Page 56 of 57 Further, the drugs being sold by the defendants are substantially at a lower price.

85. Hence, I vacate the interim order passed by this court on different dates. The defendants will however continue to maintain correct and true accounts regarding the sale of the impugned drugs which are sold or dealt by them in any manner. They will also file quarterly accounts in this court supported by the affidavit of one of its directors affirming the veracity of the account. The defendant will also file account statements of sale figures of the said drug duly authenticated by the chartered accountant of the defendant on the basis of the records including tax returns.

86. The applications stand disposed of as above. (JAYANT NATH) JUDGE AUGUST08 2019/n/rb/v CS(COMM.)749/2018 & etc. Page 57 of 57