Astrazeneca Ab & Anr. vs Intas Pharmaceuticals Limited on 20 July, 2021

Author: Rajiv Sahai Endlaw

Bench: Rajiv Sahai Endlaw, Amit Bansal

* IN THE HIGH COURT OF DELHI AT NEW DELHI

% Date of decision: 20th July, 2021.

\+ FAO(OS) (COMM) 139/2020, CMs No. 28068/2020 (for placing on record additional documents), 28070/2020 (for stay) & 32664/2020 (of Natco Pharma Limited for intervention)

ASTRAZENECA AB & ANR. ..... Appellants
Through: Mr. Pravin Anand, Ms. Vaishali Mittal, Mr. Siddhant Chamola, Mr. Rohin Koolwal and Mr. Souradeep Mukhopadhyay, Advs.

Versus

INTAS PHARMACEUTICALS LTD. ..... Respondent
Through: Mr. C.S. Vaidyanathan, Sr. Adv. with Ms. Bitika Sharma, Mr. Adarsh Ramanujan, Ms. Nitya Sharma, Mr. Devanshu Khanna, Ms. Vrinda Pathak and Mr. Vikram Singh Dalal, Advs.

AND

\+ FAO(OS) (COMM) 140/2020 & CMs No. 28072/2020 (for placing on record additional documents) & 28074/2020 (for stay)

ASTRAZENECA AB & ANR. ..... Appellants
Through: Mr. Pravin Anand, Ms. Vaishali Mittal, Mr. Siddhant Chamola, Mr. Rohin Koolwal and Mr. Souradeep Mukhopadhyay, Advs.

Versus

FAO(OS)(COMM) 139/20, 140/20, 155/20, 156/20, 157/20, 158/20, 159/20, 160/20 & 161/20

ALKEM LABORATORIES LTD. ..... Respondent
Through: Mr. Adarsh Ramanujan, Ms. Bitika Sharma, Ms. Nitya Sharma, Mr. Devanshu Khanna, Ms. Vrinda Pathak and Mr. Vikram Singh Dalai,

Advs.

AND

\+ FAO(OS) (COMM) 155/2020 & CMs No.30695/2020 (for placing on record additional documents), 30696/2020 (for exemption) & 30697/2020 (for stay)

ASTRAZENECA AB & ANR. ..... Appellants
Through: Mr. Pravin Anand, Ms. Vaishali Mittal, Mr. Siddhant Chamola, Mr. Rohin Koolwal and Mr. Souradeep Mukhopadhyay, Advs.

Versus

ZYDUS HEALTHCARE LIMITED & ANR. ..... Respondents
Through: Mr. C.S. Vaidyanathan, Sr. Adv. with Ms. Bitika Sharma, Mr. Adarsh Ramanujan, Ms. Nitya Sharma, Mr. Devanshu Khanna, Ms. Vrinda Pathak and Mr. Vikram Singh Dalal, Advs.

AND

\+ FAO(OS) (COMM) 156/2020 & CMs No.30698/2020 (for placing on record additional documents), 30699/2020 (for exemption) & 30700/2020 (for stay)

ASTRAZENECA AB & ANR. ....

FAO(OS)(COMM) 139/20, 140/20, 155/20, 156/20, 157/20, 158/20, 159/20, 160/20 & 161/20
Through: Mr. Pravin Anand, Ms. Vaishali Mittal, Mr. Siddhant Chamola, Mr. Rohin Koolwal and Mr. Souradeep Mukhopadhyay, Advs.

Versus

ERIS LIFESCIENCES LIMITED ..... Respondent
Through: Ms. Rajeshwari H. and Mr. Tahir A.J., Advs.

AND

\+ FAO(OS) (COMM) 157/2020 & CMs No.30701/2020 (for placing on record additional documents), 30702/2020 (for exemption), 30703/2020 (for stay) & 1153/2021 (of Shiv Shivam Pharma & Ors. for intervention)

ASTRAZENECA AB & ANR. ..... Appellants
Through: Mr. Pravin Anand, Ms. Vaishali Mittal, Mr. Siddhant Chamola, Mr. Rohin Koolwal and Mr. Souradeep Mukhopadhyay, Advs.

Versus

USV PRIVATE LIMITED ..... Respondent
Through: Mr. J. Sai Deepak, Mr. Guru Natraj, Mr. Avinash K. Sharma and Mr. Ankur Vyas, Advs.

AND

\+ FAO(OS) (COMM) 158/2020 & CMs No.30704/2020 (for placing on record additional documents), 30705/2020 (for exemption) & 30706/2020 (for stay)

FAO(OS)(COMM) 139/20, 140/20, 155/20, 156/20, 157/20, 158/20, 159/20, 160/20 & 161/20
ASTRAZENECA AB & ANR. ..... Appellants
Through: Mr. Pravin Anand, Ms. Vaishali Mittal, Mr. Siddhant Chamola, Mr. Rohin Koolwal and Mr. Souradeep Mukhopadhyay, Advs.

Versus

TORRENT PHARMACEUTICALS LIMITED ..... Respondent
Through: Mr. C.S. Vaidyanathan, Sr. Adv. with Mr. S. Majumdar, Mr. Dominic Alvares, Mr. Afzal B. Khan and Mr.Samik Mukherjee, Advs.

AND

\+ FAO(OS) (COMM) 159/2020 & CMs No.30707/2020 (for placing on record additional documents), 30708/2020 (for exemption) & 30709/2020 (for stay)

ASTRAZENECA AB & ANR. ..... Appellants
Through: Mr. Pravin Anand, Ms. Vaishali Mittal, Mr. Siddhant Chamola, Mr. Rohin Koolwal and Mr. Souradeep Mukhopadhyay, Advs.

Versus

MSN LABORATORIES PRIVATE LIMITED ..... Respondent
Through: Mr. J. Sai Deepak, Mr. Guru Natraj, Mr. Avinash K. Sharma and Mr. Ankur Vyas, Advs.

AND

FAO(OS)(COMM) 139/20, 140/20, 155/20, 156/20, 157/20, 158/20, 159/20, 160/20 & 161/20

\+ FAO(OS) (COMM) 160/2020 & CMs No.30710/2020 (for placing on record additional documents), 30711/2020 (for exemption) & 30712/2020 (for stay)

ASTRAZENECA AB & ANR. ..... Appellants
Through: Mr. Pravin Anand, Ms. Vaishali Mittal, Mr. Siddhant Chamola, Mr. Rohin Koolwal and Mr. Souradeep Mukhopadhyay, Advs.

Versus

MICRO LABS LIMITED ..... Respondent
Through: Mr. J. Sai Deepak, Mr. Guru Natraj, Mr. Avinash K. Sharma and Mr. Ankur Vyas, Advs.

AND

\+ FAO(OS) (COMM) 161/2020 & CMs No.30713/2020 (for placing on record additional documents), 30714/2020 (for exemption) & 30715/2020 (for stay)

ASTRAZENECA AB & ANR. ..... Appellants
Through: Mr. Pravin Anand, Ms. Vaishali Mittal, Mr. Siddhant Chamola, Mr. Rohin Koolwal and Mr. Souradeep Mukhopadhyay, Advs.

Versus

AJANTA PHARMA LIMITED ..... Respondent
Through: Mr. S. Majumdar, Mr. Dominic Alvares, Mr. Afzal B. Khan and Mr. Samik Mukherjee, Advs.

FAO(OS)(COMM) 139/20, 140/20, 155/20, 156/20, 157/20, 158/20, 159/20, 160/20 & 161/20
CORAM:
HON'BLE MR. JUSTICE RAJIV SAHAI ENDLAW
HON'BLE MR. JUSTICE AMIT BANSAL

[VIA VIDEO CONFERENCING]

RAJIV SAHAI ENDLAW, J.

1. All these nine appeals, under Section 13(1A) of the Commercial Courts Act, 2015 read with Order XLIII Rule 1(r) of the Code of Civil Procedure, 1908 (CPC), impugn the orders/judgments of denial of interim relief, in suits instituted by the appellants/plaintiffs i.e. (i) AstraZeneca AB, Sweden and (ii) AstraZeneca Pharma India Ltd. against the respondent(s)/defendant(s) in each of the appeals, for permanent injunction restraining infringement of patent and for ancillary reliefs.

2. FAO(OS)(COMM) 139/2020 and FAO(OS)(COMM) 140/2020 impugn the common order/judgment dated 2nd November, 2020 in CS(COMM) No.410/2020 and in CS(COMM) No.411/2020 filed by the appellants/plaintiffs against Intas Pharmaceuticals Ltd. and Alkem

Laboratories Ltd. respectively.

3. FAO(OS)(COMM) 155/2020, FAO(OS)(COMM) 156/2020, FAO(OS)(COMM) 157/2020, FAO(OS)(COMM) 158/2020, FAO(OS)(COMM) 159/2020, FAO(OS)(COMM) 160/2020 and FAO(OS)(COMM) 161/2020 impugn the common order/judgment dated 18th November, 2020 in suits filed by the same appellants/plaintiffs, being

(i) CS(COMM) No.323/2020 against Torrent Pharmaceuticals Ltd.; (ii) CS(COMM) No.346/2020 against Micro Labs Limited; (iii) CS(COM) No.414/2020 against Zydus Healthcare Ltd. and Zydus Medica; (iv) CS(COMM) No.418/202 against Eris Lifesciences Ltd.; (v) CS(COMM) No.419/2020 against USV Pvt. Ltd.; (vi) CS(COMM) No.426/2020 against MSN Laboratories Pvt. Ltd.; and, (vii) CS(COMM) No.154/2020 against Ajanta Pharma Ltd.

4. It would thus be seen, that the challenge in these nine appeals is to two orders/judgments; both the orders/judgments were pronounced within a span of 16 days, with both, independently of each other, on the same facts, concluding that the appellants/plaintiffs, during the pendency of the suits for permanent injunction to restrain infringement of patent, are not entitled to any interim injunction restraining respondent(s)/defendant(s) from manufacturing and selling the pharmaceutical products which are alleged to be in breach of the patent of the appellants/plaintiffs.

5. From the proximity of the dates of the impugned orders/judgments, it appears that the hearing on the applications for interim injunction, before both the Hon'ble Judges, took place simultaneously. It is inexplicable, why the appellants/plaintiffs, who have argued all these nine appeals as one and not separately, did not have the two sets of suits clubbed before the same Commercial Division and which would have saved the judicial time spent in the adjudication undertaken by one of the Judges. It appears that the appellants/plaintiffs were taking a chance, of arguing on the same subject and controversy, before two Courts. However the appellants/plaintiffs failed before both.

6. The suits, from which FAO(OS)(COMM) 139/2020, FAO(OS)(COMM) 140/2020, FAO(OS)(COMM) 158/2020, FAO(OS)(COMM) 160/2020 and FAO(OS)(COMM) 161/2020 arise, were filed first, to restrain the respondent(s)/defendant(s) therein from manufacturing, selling or otherwise dealing in any manner whatsoever, the product comprising the compound 'Dapagliflozin' (hereinafter for convenience referred to as 'DAPA'), which was the subject matter of Indian Patent No.205147 (hereinafter for convenience referred to as 'IN 147') and Indian Patent No.235625 (hereinafter for convenience referred to as 'IN 625') and for other ancillary reliefs.

7. The suits, from which FAO(OS)(COMM) 155/2020, FAO(OS)(COMM) 156/2020, FAO(OS)(COMM) 157/2020 and FAO(OS)(COMM) 159/2020 arise, were filed subsequently, after lapsing of the validity of IN 147, to restrain the respondent(s)/defendant(s) therein from manufacturing, selling or otherwise dealing in any manner whatsoever, the product comprising the compound DAPA, amounting to infringement of IN 625.

8. The impugned order/judgment dated 2nd November, 2020 records the case/claim of the appellants/plaintiffs to be, (i) that both, IN 147 and IN 625 were granted to Bristol Myers Squibb

Company, which vide Assignment Deed dated 1st February, 2014, assigned the rights therein to the appellant/plaintiff AstraZeneca AB, Sweden, which stood registered as the patent holder qua the said patents; (ii) that DAPA, being the subject matter of the two patents, is used worldwide, to treat people suffering from type-II diabetes mellitus; (iii) that IN 147 is the genus patent and IN 625 is the species patent; (iv) that IN 147 is a Markush structure i.e. a patent covering a group of compounds, which disclosed the possibility of individual permutations and combinations running into several million structurally diverse compounds; (v) that IN 147, bearing a Markush structure, covered DAPA, though did not disclose the same; (vi) that on further research and development, DAPA was invented; (vii) that the dates of grant and expiry of IN 147 are 15th March, 2007 and 2nd October, 2020; (viii) that the dates of grant and expiry of IN 625 are 9th July, 2009 and 15th May, 2023; (ix) however the drug manufactured by the appellants/plaintiffs from the said new invention of DAPA got approval only in the year 2020; (x) that Sun Pharma Laboratories Limited and Abbott Healthcare Private Limited are the distributors of the appellants/plaintiffs and sell the said drug; (xi) that the appellants/plaintiffs have been granted patent for DAPA, in approximately 70 countries; (xii) that DAPA, in India, had neither been subjected to any pre-grant or post-grant opposition, nor any revocation proceedings with respect to DAPA filed prior to the year 2020; (xiii) that in the year 2020, the respondent(s)/defendant(s) started infringing IN 147 and IN 625 and some of the respondent(s)/defendant(s) also initiated post-grant opposition, revocation proceedings or counter-claims against IN 625; (xiv) that since DAPA was first synthesized in 2001 i.e. after 12 th August, 1999, being the priority date of IN 147, the question of DAPA being disclosed in IN 147 did not arise; (xv) that Markush formulae are well recognised under the Indian Patent Law; (xvi) that merely because a particular compound falls within the scope or periphery of a particular claim, does not amount to the said compound being disclosed with specificity; (xvii) that a single product may cover thousands of patents; example was given of a mobile phone, covered by multiple patents; (xviii) that the invention claimed in IN 147 is different from the invention claimed in IN 625; (xix) that IN 147 claims a class of compounds of the Markush structure; (xx) that IN 625 has only one specific molecule i.e. DAPA; (xxi) that it thus cannot be said that DAPA was claimed in IN 147; (xxii) that DAPA is not obvious from IN 147; (xxiii) moreover, IN 147 was published under Section 11A of the Patents Act, 1970, only on 18th March, 2005 i.e. after the priority date of IN 625 of 20 th May, 2002; there could thus be no question, of a person of ordinary skill in the art, from a reading of IN 147, being able to arrive at DAPA; (xxiv) that in the United States of America (USA/US) also, there was no publication of the patent corresponding to IN 147 prior to the filing of the patent corresponding to IN 625; (xxv) that DAPA is not obvious from IN 147 because IN 147 has a million possibilities; any attempt to reach DAPA from the Markush structure of IN 147 is nothing but an attempt to take recourse to hindsight, which is discouraged under Patent Law; (xxvi) that there is no indication in IN 147, as to which parameters are critical or even which direction if taken out of the many choices available, would lead to DAPA; (xxvii) that had DAPA been obvious from IN 147, it would have been developed by someone else, prior to IN 625 or prior to the appellants/plaintiffs obtaining approval of the drug in the year 2020; (xxviii) that DAPA is a man made drug, used not only for treating type-II diabetes but also approved in the year 2020 for treating hypertensive heart failure; (xxix) that IN 625 is in the 18th year of its life-cycle and is an old and established patent and thus carries with it presumption of its validity; (xxx) that IN 625 was subjected to examination in the Indian Patent Office, between the years 2002 and 2009; (xxxi) that the proceedings initiated for the first time in the year 2020, for revocation of IN 625, are mala fide and a counterblast to the

infringement actions undertaken by the appellants/plaintiffs; (xxxii) that neither of the respondent(s)/defendant(s) have carried out any research and development and are merely piggybacking on the inventions of the appellants/plaintiffs concerning DAPA; and, (xxxiii) that the appellants/plaintiffs have been selling their products based on the new invention, since the year 2015, including through their distributors Sun Pharma Laboratories Limited and Abbott Healthcare Private Limited.

9. The case of the respondent(s)/defendant(s), as recorded in the impugned order/judgment dated 2nd November, 2020, is (a) that it is the case of the appellants/plaintiffs, that manufacture and sale of DAPA was in infringement of IN 147; the appellants/plaintiffs therefrom are deemed to have admitted that DAPA stood fully and particularly described in IN 147;

(b) that IN 147 expired on 2nd October, 2020 and there could thus be no interim injunction qua IN 147; (c) that the respondent(s)/defendant(s) have raised a credible challenge to the validity of IN 625 and once the Court finds that the respondent(s)/defendant(s) have a credible challenge to the validity of IN 625, no interim injunction can be granted; (d) that the appellants/plaintiffs have admitted that DAPA is claimed in IN 147; (e) that there was an objection by the US Patent and Trademark Office (USPTO) to the application of the appellants/plaintiffs equivalent to IN 625 in India, on the ground of prior claiming i.e. obviousness-type double patenting; the appellants/plaintiffs did not contest the said objection and on the contrary agreed to the term of patent thereunder to be coterminous with the term of the patent equivalent to IN 147; the same constitutes an admission by the appellants/plaintiffs of IN 625 having prior claim in IN 147; the appellants/plaintiffs having agreed to the term of US patent equivalent of IN 625 to be the same as that of US patent equivalent of IN 147, cannot make a case contrary thereto in India; (f) that the appellants/plaintiffs, in the working statement in Form 27 filed in relation to IN 147, also furnished the working of DAPA, again admitting DAPA to have been part of IN 147; (g) that all this shows that the appellants/plaintiffs did not consider IN 625 to be distinct from IN 147; (h) that IN 625 is also vulnerable to challenge on the ground that it was anticipated by what was published or publicly known from IN 147; while IN 147 was first published on 19th April, 2001, the priority date of IN 625 is 20th May, 2002; (i) that the appellants/plaintiffs, while filing their specification qua IN 147, claimed and particularly described DAPA; (j) that Supreme Court, in Novartis AG Vs. Union of India (2013) 6 SCC 1, rejected the argument that there was a dichotomy between coverage and disclosure and ruled that all molecules covered by the genus patent in that case were/are known therefrom; once the appellants/plaintiffs admitted that DAPA is covered by IN 147 and asserted that the respondent(s)/defendant(s) have infringed IN 147, it is evident that DAPA is also known from IN 147; (k) that IN 625 was also vulnerable to challenge, as it lacked inventive step, based on what was published or publically known from IN 147; (l) that IN 625 does not set out the economic significance of the product thereof, over that of the product of IN 147; consequently, IN 625 failed in the inventive step requirement, as there was failure to demonstrate technical advancement or economic significance, which was not previously known from IN 147; (m) that DAPA is obvious to a person skilled in the art, from IN 147; reliance was placed on F. Hoffman- La Roche Vs. Cipla Ltd. 2015 (225) DLT 391; (n) that merely because DAPA was one of the several compounds of IN 147 and the only compound of IN 625, would not qualify DAPA to protection under IN 625; even if prior art comprises of an infinite number of starting points, every such prior art is deemed to be suggestive to

the person skilled in the art and mere selection of one or more from several compounds does not constitute an inventive step; (o) that DAPA would be obvious to a person skilled in the art, on account of the manner in which he would appreciate the contents of IN 147; (p) that IN 625 is also vulnerable to challenge because the appellants/plaintiffs did not inform the Indian Patent Office about the status of all the corresponding foreign patent applications, which were filed in respect of the same or substantially same invention, as is the requirement of law; the appellants/plaintiffs concealed, that the USPTO, in its examination of the corresponding patent application found subject matter of the patent corresponding to IN 625 to have been disclosed in the US patent corresponding to IN 147 and that the appellants/plaintiffs in response thereto had voluntarily offered to limit the term of the patent corresponding to IN 625 to that of the patent corresponding to IN 147 and which patent has expired on 4th October, 2020; rather, the appellants/plaintiffs were able to prevent the rejection of the US application corresponding to IN 625, by making such concession; (q) that the appellants/plaintiffs, in the plaint in the subject suits also had admitted that DAPA is covered by both, IN 147 and IN 625 and claimed infringement by the respondent(s)/defendant(s) of both; the suits of the appellants/plaintiffs are liable to be dismissed on the basis of the said admission alone; (r) that the appellants/plaintiffs, in a suit filed in the District Court of Delaware, USA against Zydus Pharmaceuticals USA, also pleaded that Zydus Pharmaceuticals' application to market DAPA tablets infringed the US patent corresponding to IN 147; the appellants/plaintiffs therein admitted DAPA to have been disclosed in US application corresponding to IN 147; (s) that the appellants/plaintiffs were seeking to extend the term of statutory protection of DAPA; (t) that the balance of convenience was in favour of the respondent(s)/defendant(s) and against the appellants/plaintiffs; while the respondent(s)/defendant(s) were manufacturing their drug in India, the appellants/plaintiffs were importing their product for marketing in India; (u) that the appellants/plaintiffs, if denied interim protection, would not suffer any irreparable injury; they can always be compensated in monetary terms; (v) that Sun Pharma Laboratories Limited and Abbott Healthcare Private Limited had also obtained licenses qua IN 625, demonstrating that the appellants/plaintiffs are not exclusively marketing DAPA in India but are willing to monetise the patent via licensing; (w) that on the contrary, the respondent(s)/defendant(s), if injuncted, would suffer irreparable loss and injury; (x) that public interest also did not justify grant of interim injunction; while Sun Pharma Laboratories Limited and Abbott Healthcare Private Limited were marketing under various brand names and various disclosed combinations, at Rs.54.40 paise for a 5 mg. dose and at Rs.57.29 paise for a 10 mg. dose, the respondent(s)/defendant(s) were selling their drug for Rs.13.90 paise for 5 mg. dose and Rs.17.50 paise for a 10 mg/ dose; and, (y) that in the prevalent Corona Virus pandemic times, the probability of a diabetic person being afflicted with the virus is exponentially high.

10. Though the impugned order/judgment dated 2nd November, 2020 also records the arguments in rejoinder of the appellants/plaintiffs, but the need to encapsulate the same here is not felt since this Court is only exercising appellate powers within the domain of Wander Ltd. Vs. Antox India P. Ltd. 1990 Supp SCC 727, to see whether there is any perversity in the orders/judgments of the Commercial Divisions in denying interim injunction to the appellants/plaintiffs.

11. The Commercial Division, in the impugned order/judgment dated 2nd November, 2020, held that "the moot point, which arises for consideration in the instant actions, is: whether the compound-in-issue i.e. Dapagliflozin [in short "DAPA"] which, according to the plaintiffs, is covered

in IN 147 stands disclosed both, in law as well as on facts?" and proceeded to deny injunctions to the appellants/plaintiffs, finding/reasoning/holding (I) that the subject two suits were instituted on 30th September, 2020 i.e. two days before expiry of the validity period of IN 147, which ended on 2 nd October, 2020; (II) that under the scheme of the Patents Act, a challenge to a patent can be laid either at the stage when an application is moved for grant of a patent or even by seeking revocation, by moving the Intellectual Property Appellate Board or by way of a counter-claim in the infringement suit; (III) that Section 13(4) of the Patents Act makes it clear that the examination and investigations done by the Patent Office before grant of patent does not in any way warrant the validity of the patent; thus, even when the patent crosses the threshold of examination by the Patent Office, it does not, as per the Statute, warrant its validity; therefore, irrespective of when the challenge is laid, the challenger can put the patent in jeopardy; (IV) that the arguments of the appellants/plaintiffs, that since the patents were old, they should be presumed to be valid, could not be accepted because the scheme of the Act does not foreclose the right of the respondent(s)/defendant(s) to, in defence of an infringement action question the validity of the patent; (V) that the presumption of validity of the patent exists only till such time the patent is challenged; (VI) that for deciding an application for interim injunction, a mini-trial was not required to be conducted to ascertain the validity of IN 625; (VII) that validity of a patent is required to be looked at, at the stage of trial; (XVIII) that at the stage of adjudication of the application for interim injunction, the respondent(s)/defendant(s) were only required to demonstrate that they had a credible challenge or that the patent was vulnerable and that the challenge to the validity of the patent was not vexatious; (IX) that the appellants/plaintiffs, in the plaints in the subject two suits had themselves pleaded that IN 147 and IN 625 covered the appellants/plaintiffs drugs comprising inter alia the invention DAPA and that DAPA falls within the scope of both, IN 147 and IN 625; (X) that the documents on record also showed that IN 147 had been worked in India; (XI) that before the USPTO, the appellants/plaintiffs, to obviate the rejection of US application corresponding to IN 625 on the ground of obviousness/double patenting, agreed that the validity period of US patent corresponding to IN 625 would end on the same day on which the validity period of US patent corresponding to IN 147 would end; (XII) that similarly, in an action filed by the appellants/plaintiffs against Zydus Pharmaceuticals USA, in the Courts at USA, the appellants/plaintiffs had admitted that grant of approval to Zydus Pharmaceuticals USA to manufacture DAPA tablets would infringe the claims of the appellants/plaintiffs in the US patent corresponding to IN 147; (XIII) that there was thus a definite assertion by the appellants/plaintiffs before the USPTO as well as before the Courts in USA in the proceedings against Zydus Pharmaceuticals USA, that the DAPA was covered in US patents corresponding to both, IN 147 and IN 625; (XIV) that the contention of the appellants/plaintiffs however was, that DAPA, though covered in IN 147, was not "disclosed"" and the appellants/plaintiffs relied upon the Markush structure; (XV) that a Markush claim allows a patent drafter to condense a multitude of alternate dependent claims into one single claim; (XVI) however since the appellants/plaintiffs had taken out an infringement action, both for IN 147 and IN 625, it was sufficient at that stage to hold that DAPA was claimed in both the suit patents; (XVII) that it would be incongruous that a patent holder can take out an infringement action for a patent and yet aver that it was not disclosed; (XVIII) that under the scheme of Patents Act, an applicant who seeks grant of patent is required to fully and particularly describe the inventions and their operation or use and the method by which it is performed and the protection granted is with respect to all the said elements; (XIX) that on this

ground alone, there was a credible challenge by the respondent(s)/defendant(s) to the validity of IN 625; (XX) that if the respondent(s)/defendant(s) established that the invention claimed in IN 625 was claimed in IN 147, IN 625 would be revoked; (XXI) that the argument of the appellants/plaintiffs, that DAPA was not claimed in IN 147, in view of the above, at the stage of interim injunction, was untenable; (XXII) that the respondent(s)/defendant(s) had also contended that there was a credible case of DAPA being known and anticipated by what was published or publically known from IN 147; (XXIII) that on the basis of material on record, at that stage, it could not even be said that the respondent(s)/defendant(s) had no credible challenge to validity of IN 625; (XXIV) that the appellants/plaintiffs, at least at that stage had been unable to demonstrate that there was any technical advancement in IN 625 for the existence of any inventive step over that in IN 147; the respondent(s)/defendant(s) thus had a credible challenge to the validity of IN 625 on the ground of the same lacking in inventive step; (XXV) that the respondent(s)/defendant(s) at that stage had made out a credible case of violation by the appellants/plaintiffs of the requirements of disclosure in terms of Section 8 of the Patents Act; the appellants/plaintiffs did not provide to the Indian Patent Office the examination report issued by the USPTO with respect to US patent application corresponding to IN 625 and also did not disclose that the appellants/plaintiffs before the USPTO had agreed to the term of US patent corresponding to IN 625 ending on the same day as that of US patent corresponding to IN 147; (XXVI) that the balance of convenience was also in favour of the respondent(s)/defendant(s) and not in favour of the appellants/plaintiffs; (XXVII) that the respondent(s)/defendant(s), during the validity period of IN 147 had held themselves in check and it would not be appropriate to injunct them when they had made a credible challenge to IN 625; (XXVIII) moreover, if the appellants/plaintiffs ultimately succeeded, they could always be compensated by damages; (XXIX) that it was the case of the respondent(s)/defendant(s) that the damages could be determined from the licences granted by the appellants/plaintiffs in favour of Sun Pharma Laboratories Limited and Abbott Healthcare Private Limited; though the appellants/plaintiffs had claimed that Sun Pharma Laboratories Limited and Abbott Healthcare Private Limited were distributors and not licensees, but had failed to place the documents in this regard on record; and, (XXX) that the difference in the prices of drugs of the appellants/plaintiffs and the respondent(s)/defendant(s) ranged between 250% to 350%; thus if the respondent(s)/defendant(s) continued to manufacture and market the impugned drugs, the same would be available to the public at large at a much cheaper rate than those being marketed by the appellants/plaintiffs or their licensees; thus public interest was also in favour of non-grant of injunction.

12. Accordingly, vide the impugned order/judgment dated 2nd November, 2020, though the interim injunction claimed by the appellants/plaintiffs was declined but the respondent(s)/defendant(s) were directed to place on record the details, quantum and value of the drug manufactured and sold as also indirect and direct taxes paid in that behalf as well as their assets, from which the damages, if any awarded against them, could be recovered.

13. On the same facts and pleas of the appellants/plaintiffs, vide the impugned order/judgment dated 18th November, 2020 in the aforesaid seven suits also, interim injunction was denied, finding/observing/reasoning (A) that the main challenge to the validity of IN 625 by the respondent(s)/defendant(s) in each of the suits was on the ground of prior disclosure and

anticipation by prior claiming in IN 147--these grounds would normally arise in most of the cases of grant of genus patent and the species patent, as substantial portion of the claim/claims in a species patent are bound to be imbibed in the claims of the genus patent; (B) that in India and abroad, grant of patents for Markush claim and the selection claim i.e. the genus and species patents, is legally permissible; (C) that to ascertain, whether IN 625 is disclosed or claimed in IN 147, claims in the two patents were required to be compared; (D) that construction of the claim, to verify its coverage, even at the stage of interim injunction, is fundamental; (E) that coverage depends on the nature of the claims made and enabling disclosures specified in the complete specification; (F) that the words used to describe the claims, as understood by a person of ordinary skill in the art, determine the breadth of the monopoly granted by the patent; (G) that in determining whether a prima facie case exists, a mini trial is not required to be resorted to; (H) that to constitute prior disclosure of an invention, the matter relied upon as prior art must disclose subject matter which, if performed, would necessarily result in infringement of the patent; (I) that Markush formula with number of variables can be granted a valid patent; (J) that a selection patent, which though covered under the Markush formula, is not disclosed clearly and unambiguously in the Markush formula, can also be granted a valid patent; (K) that a selection patent must show substantial advantage or avoidance of disadvantage, by use of the selected members of the species patent, as compared to the non-selected members of the genus patent; (L) that it is the case of the appellants/plaintiffs, that the pharmaceutical composition of DAPA was not arrived at, much less manufactured or marketed pursuant to IN 147 and the pharmaceutical composition of DAPA specifically disclosed in IN 625 clearly showed a substantial advantage and hence it could not be held that DAPA was disclosed in IN 147; (M) that it was the case of the appellants/plaintiffs, that though IN 147 covered DAPA, however it nowhere disclosed DAPA and the same was specifically disclosed in IN 625 and that IN 147 disclosed only 80 exemplified compounds and DAPA was not one amongst these 80 compounds; (N) however according to the respondent(s)/defendant(s), example 12 of IN 147 disclosed the compound claimed in IN 625; it was further the case of the respondent(s)/defendant(s), that example 12 of IN 147 gave five methods of preparation--the appellants/plaintiffs rebutted the said arguments by contending that in example 12 of IN 147, all the procedures relate to methoxy substitution and not to ethoxy and that in the entire example 12 of IN 147, there was no teaching in favour of ethoxy--from a reading of claims in IN 147 and in IN 625, it was clear that IN 147 comprised of a group of claims belonging to a family and even the closest example in IN 147 disclosed methoxy benzophenone as the ingredient of the compound and there was no disclosure of a compound with ethoxy group, as in DAPA; (O) however the respondent(s)/defendant(s) further contended that since the appellants/plaintiffs, in their pleadings had admitted that DAPA was covered in IN 147 and that there was no distinction between coverage and disclosure, as held in Novartis supra, IN 625 was invalid, having been disclosed in IN 147; (P) however a reading of Novartis supra showed that the Supreme Court clearly noted the distinction between coverage and disclosure; thus it would have to be determined on the facts of each case, whether the species patent was merely covered by the Markush claim or was disclosed in the same; (Q) that applying the test laid down in Novartis supra to the facts of the present suits, it was evident that in the claims specifications of IN 147, the composition of DAPA was not mentioned and only the general properties of Markush claim with various permutations and combinations were mentioned; (R) that the appellants/plaintiffs also did not apply for drug approval based on IN 147 and applied for drug approval based on IN 625; (S) that on a prima facie view of the matter, it could not be said that

DAPA was disclosed in IN 147; (T) that IN 625 was also prima facie not liable to be revoked on the ground of prior claiming; (U) that the statement of the appellants/plaintiffs, that IN 147 had been worked through the drug "FORXIGA", could not be read as admission or disclosure of DAPA in IN 147, in view of admission of the respondent(s)/defendant(s) that DAPA was first disclosed in US patent equivalent of IN 625; (V) that there was a difference between "subsequent claim being disclosed in the prior art" and "subsequent claim being obvious"; for a claim to be obvious, the person skilled in the art has to move forward from the teachings of the prior art to arrive at the subsequent claim; on the contrary for disclosure of the subsequent claim in the prior art, the subsequent claim should be so embedded in the prior art that it is evident to even a layman; (W) that the only difference in example 12 of IN 147 and IN 625 was, use in example 12 of methoxy and in IN 625 of ethoxy; however both ethoxy and methoxy were lower alkyls; a person with ordinary skill in the art would have been motivated to bring this single change, of substitution of methoxy with ethoxy, to find out if predictable results ensued; (X) that thus, prima facie IN 625 was vulnerable on the grounds of obviousness, in view of example 12 of IN 147; (Y) that no presumption of lack of patentability of IN 625 could be drawn from the appellants/plaintiffs, before the USPTO having agreed to the period of validity of US patent equivalent to IN 625 to be the same as that of US patent equivalent to IN 147; (Z) that non-furnishing by the appellants/plaintiffs of the objections raised by USPTO with respect to US patent equivalent of IN 625 could not, at the interim stage, be held to be deliberate concealment and suppression, within the meaning of Section 8(1) of the Patents Act; (AA) that the appellants/plaintiffs had however failed to comply with Section 8(2) of the Patents Act; the Indian Patent Office had inter alia required the appellants/plaintiffs to furnish details of applications for patents filed outside India and of search and/or examination reports in respect of the same; in reply thereto, the appellants/plaintiffs furnished copies of the European Patent Office's (EPO) decision of grant and the EPO granted patent only, and not the documents qua USPTO where on an objection being raised, the appellants/plaintiffs sought a terminal disclosure; the appellants/plaintiffs having not complied with Section 8(2), the validity of IN 625 was vulnerable for non-compliance of Section 8(2); (BB) that the respondent(s)/defendant(s), except Torrent Pharmaceuticals Ltd., in none of the suits, had challenged the patent in favour of the appellants/plaintiffs and had thus not "cleared the way" before launching their drug; (CC) that the respondent(s)/defendant(s) had thus prima facie made a credible challenge to the validity of IN 625 on the ground of obviousness and for non- compliance of Section 8(2) of the Patents Act; (DD) that the appellants/plaintiffs had not made out a prima facie case for grant of interim injunction; and, (EE) that the ingredients of balance of convenience and irreparable loss, though were in favour of the appellants/plaintiffs, in the absence of a prima facie case in favour of appellants/plaintiffs and in the face of vulnerability of the validity of IN 625, could not entitle the appellants/plaintiffs to interim injunction. Accordingly, though interim injunction was denied but the respondent(s)/defendant(s) were directed to maintain accounts of manufacture, sale and supply of the impugned drugs and to furnish the same to the Court.

14. We heard Mr. Pravin Anand, counsel for the appellants/plaintiffs and Mr. C.S. Vaidyanathan, Senior Advocate and Mr. S. Majumdar, Mr. Adarsh Ramanujan, Ms. Rajeshwari H., Mr. J. Sai Deepak, Advocates for the respondent(s)/defendant(s).

15. Supreme Court, in order dated 16th August, 2017 in Civil Appeal No.18892/2017 titled AZ Tech (India) Vs. Intex Technologies (India) Limited, commented on the disturbing trend, of the orders of disposal of applications for interim relief in Intellectual Property Rights matters governing parties for a long time, with exhaustive judgments, virtually on merits of the suit, being written and expressed the need for addressing the said malady. In fact, suo moto Writ Petition (Civil) No.8/2017 titled Re:

> Case Management of Original Suits, was initiated in pursuance to the said order and in which proceedings this Court informed the Supreme Court of the remedial measures being taken. It was thus felt that the hearing of arguments in these appeals should not go on endlessly and the order/judgment disposing of these appeals, should not be exhaustive. Thus, while commencing hearing on 25th February, 2021, we requested for the virtual arguments to be confined to two hours for the appellants/plaintiffs and two hours for all the respondent(s)/defendant(s). However, notwithstanding the same, the time limits were not abided by and the counsel for the appellants/plaintiffs addressed arguments in opening, on 25th February, 2021 and 16th March, 2021; the counsels for the respondent(s)/defendant(s) addressed their arguments on 23rd March, 2021, 5th April, 2021, 7th April, 2021 and 12th April, 2021; the counsel for the appellants/plaintiffs addressed arguments in rejoinder on 18th May, 2021, 25th May, 2021 and 28th May, 2021, when orders were reserved.

16. It is the contention of the counsel for the appellants/plaintiffs, (i) that the inventor does not keep the invention a secret, but discloses the invention in a document known as the complete specification; the description of the invention has to be complete, for a person of ordinary skill in the art to be able to practice the invention, once the patent term expires--in return, the inventor gets a monopoly of 20 years to commercialize the invention; (ii) that thus, disclosure of the invention is the key to the patent system; (iii) that disclosure of a chemical compound is done by identifying the same through its chemical formula, name, structure etc.; (iii) that genus is the discovery of a core structure which is a man made molecule, not found in nature--it is referred to as and is known as a "breakthrough invention"; breakthrough inventions, in pharmaceutical research are well-known, as forming the basis of a genus patent represented through a core or a Markush formula; (iv) that in the present case, a Markush formula was invented in the year 1999; however it is a structure which represents a group of related chemical compounds commonly used in patent claims; a Markush formula is a general description of the molecules, rather than detailing each and every molecule covered by the said Markush formula; a Markush formula is the inventive concept referred to in Section 10(5) of the Patents Act; (v) that as distinct from the genus patent IN 147, the species patent IN 625 concerns DAPA, which was invented in the year 2001 only and is separately protected as an invention, distinct from the genus invention; (vi) that after the genus was invented, further research was necessary to discover the best candidate amongst the millions and this research lead to the invention of the species patent, namely DAPA; (vii) therefore, to constitute a disclosure within the meaning of Patent Laws, it must be clear, real and factual, as distinct from implied, deemed or inferred; (viii) that when DAPA is not even identified in IN 147, it could not be said to be disclosed therein; (ix) that the invention in IN 147 comprised of a basic core structure, permutations wherein could run into millions of compounds; however of these millions, only 80 compounds were

synthesized and identified in the patent specifications of IN 147 and of these 80 compounds, the method of manufacture was also disclosed; however each of the said 80 compounds had the common property of inhibiting re-absorption of sugar in the kidneys, resulting in excess sugar being thrown out of the body through urine; (x) however the efficacy, potency, toxicity, solubility, thermodynamic stability and other drug like properties of each of the said 80 compounds varied considerably and the right molecule, which would have the best combination of these properties, had not been identified in IN 147; (xi) that in the year 2001, the appellants/plaintiffs invented the right candidate, namely DAPA and applied for its patent; (xii) that DAPA became a very successful drug and solved the problem of re-absorption of sugar in the kidneys; (xiii) that IN 147 is analogous to the forest found in a particular geographical location, whose longitude and latitude, rain conditions etc. were defined; (xiv) that IN 625 is analogous to the leaf on a specific tree in the said forest, having magical properties; (xv) that a person of ordinary skill in the art would have no teaching or guidance, on which example in IN 147 to look at so as to improve upon the patent and come out with an inhibitory compound; the respondent(s)/defendant(s) have not disclosed why such a person would look at example 12 of IN 147 only; the respondent(s)/defendant(s) are referring to example 12 of IN 147 in hindsight of IN 625; (xvi) moreover, even in example 12, thousands of substitutions are possible; hence, what location to substitute by what variable, is an endless enquiry which could take a long time of experimentation; (xvii) thus, DAPA cannot be said to be obvious from IN 147; (xviii) that both the impugned judgments err in holding the appellants/plaintiffs to have violated Section 8 of the Patents Act; (xix) that the appellants/plaintiffs had disclosed, that IN 625 was based on a US patent corresponding to IN 625 and which was a continuation-in-

part of the US patent corresponding to IN 147; (xx) that the appellants/plaintiffs, after the first examination report, also brought the patent granted in Europe to the attention of the Indian Patent Office; (xxi) that the appellants/plaintiffs were not required to bring to the notice of Indian Patent Office, the objection raised by the USPTO; (xxii) that since the patent corresponding to IN 625 was filed before the USPTO as a continuation-in-part of the US patent corresponding to IN 147 and which fact was disclosed to the Indian Patent Office, the Indian Patent Office was aware that the US patent corresponding to IN 625 has the same priority and expiry date as the US patent corresponding to IN 147 and in the light thereof, the objection of the USPTO and in response to which the appellants/plaintiffs expressly agreed to the period of validity of the US patent corresponding to IN 625 ending on the same day as of the US patent corresponding to IN 147, was not disclosing anything further; (xxiii) that the appellants/plaintiffs had thus not indulged in any concealment; (xxiv) that rather, the appellants/plaintiffs responded to the objection of the USPTO as aforesaid because it was not making any difference; (xxv) that the Indian Patent Office, even otherwise was conscious about obviousness objection and raised an objection with respect thereto and was satisfied with the response of the appellants/plaintiffs thereto; (xxvi) that unintentional non- disclosure of irrelevant material is not a violation of Section 8; (xxvii) that owing to the long time entailed in prosecuting a patent application and the extensive searching that is done by highly qualified examiners, the patent, once granted, ought to be treated as prima facie valid; (xxviii) that IN 625 is 18 years old, and for over 15 years from publication in the year 2005 under Section 11A, has not been challenged in a pre-grant or post-grant or revocation proceedings; (xxix) that IN 625 has been granted in over 70 countries of the world and at this interim stage, weightage has to be given to the said fact; (xxx) that the respondent(s)/defendant(s), before launching their products,

did not challenge IN 625; (xxxi) that the appellants/plaintiffs are not indulging in ever-greening; of the two patents, only one commercial product i.e. DAPA has come out; (xxxii) that DAPA, even otherwise, instead of 20 years, would enjoy the benefits of commercialisation for a period of only 11 years globally, and for a period of only 8 years in India, as the marketing approval in India could be secured only in the year 2015; (xxxiii) that the price difference for an entire month, between the drug of the appellants/plaintiffs and of the respondent(s)/defendant(s), is of about Rs.1,100/- only; given the huge time, effort and monies spent in research and development, the said price difference is negligible and completely justified; (xxxiv) that denial of interim injunction to the appellants/plaintiffs wipes out the share of the appellants/plaintiffs in the market and/or would force the appellants/plaintiffs to reduce prices; all this would result in the appellants/plaintiffs being unable to recoup a portion even of the research and development expenses incurred in the development of DAPA; (xxxv) that on the contrary, grant of injunction would restrain the respondent(s)/defendant(s) from manufacturing and selling the drugs with DAPA as a component, for a period of two years only and which is a miniscule harm in comparison to the loss which will be suffered by the appellants/plaintiffs from denial of interim injunction; (xxxvi) that though both the impugned orders/judgments deny interim injunction to the appellants/plaintiffs, but on entirely different grounds; (xxxvii) that while the impugned order/judgment dated 2nd November, 2020 declines interim injunction to the appellants/plaintiffs on the grounds of, (a) IN 147 having disclosed DAPA, (b) IN 625 having no technical advancement from IN 147; and, (c) for the reason of the appellants/plaintiffs failure to furnish information under Section 8 of the Patents Act being an important factor to be taken into account at a preliminary injunction stage, the impugned order/judgment dated 18th November, 2020 holds, (a) DAPA to be not disclosed in or anticipated by prior claiming from IN 147, (b) the appellants/plaintiffs to be not in breach of Section 8(1) of the Patents Act, and declines interim injunction, only on the grounds of obviousness and non-compliance of Section 8(2) of the Patents Act; and, (xxxviii) that such vital differences between the two impugned orders/judgments alone are enough for this Court to, in appeal hold the appellants/plaintiffs to be entitled to interim injunction.

17. Though ordinarily we would have recorded the arguments of the counsels for the respondent(s)/defendant(s) also but need therefor is not felt in the facts of the present case since during the hearing itself, we entertained doubts/reservations as spelled out herein below, and which doubts inter alia also form the defence of the respondent(s)/defendant(s).

18. Our doubts stemmed from, the appellants/plaintiffs averring and pleading manufacture and sale by the respondent(s)/defendant(s) of DAPA to be in infringement of two patents i.e. IN 147 and IN 625. It was felt, that if DAPA was not disclosed and/or known at the time of seeking patent IN 147 or US equivalent thereof and was invented only subsequently and patent thereof obtained in IN 625 or US equivalent thereof, there could be no infringement by respondent(s)/defendant(s) of IN 147 by manufacturing and/or selling DAPA. Conversely, once the appellants / plaintiffs claimed infringement of IN 147 also, it necessarily followed that DAPA was subject matter thereof and once it was the subject matter thereof, how it could be the subject matter of subsequent patent IN 625.

19. It was thus enquired from the counsel for the appellants/plaintiffs, that if the patent IN 147 was/is not of DAPA, how could the appellants/plaintiffs in the suits from which these appeals arise,

claim infringement by the respondent(s)/defendant(s) of IN 147 also, by manufacturing DAPA. It was further enquired, whether not from the factum of the appellants/plaintiffs, in the suits from which these appeals arise, having claimed infringement by the respondent(s)/defendant(s) of both, IN 147 as well as IN 625, the appellants/plaintiffs are deemed to have admitted DAPA as the subject matter of both, IN 147 and IN 625.

20. We, at this stage, spell out the thought process behind the aforesaid query.

21. In our opinion, with respect to one invention, there can be only one patent. The appellants/plaintiffs herein however, while claiming one invention only i.e. DAPA, are claiming two patents with respect thereto, with infringement of both, by the respondent(s)/defendant(s). The same alone, in our view, strikes at the very root of the claim of the appellants/plaintiffs and disentitles the appellants/plaintiffs from any interim relief.

22. Rights of a patentee, unlike that of the proprietor of a trade mark, are not natural or common law rights, but are a creation of law i.e. are statutory rights. Thus, for a patentee to enjoy protection, the rights have to be within the four corners of the statute i.e. the Patents Act and there are no rights independently thereof or inherent or common law rights of an inventor or patentee. We thus proceeded to examine the relevant statutory provisions.

23. A "patent", per Section 2(m) of the Patents Act, means a patent for any invention granted under the Act. A "patented article" and a "patented process", per Section 2(o) mean respectively, an article or process, in respect of which a patent is in force. "Invention", per Section 2(j) means a new product or a process involving an inventive step and capable of industrial application. "Inventive Step", per Section 2(ja) means a feature of an invention that involves a 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. "New Invention", per Section 2(l) means any invention or technology which was not anticipated by publication or used before the date of filing of patent application with complete specification. However, Section 3 of the Act declares certain acts to be not invention within the meaning of the Act; per Clause (c) thereof, the mere discovery of a scientific principle or formulation of an abstract theory, is not an invention; per Clause (d) thereof, 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, is not an invention; per Clause (n) thereof, a presentation of information is not an invention.

24. Thus, for the grant of a patent with respect to an article, as DAPA is, it was essential that, (a) it was a new product; (b) it was technically advanced as compared to the existing knowledge or having economic significance, or both; (c) it was capable of industrial application; (d) it was not obvious to a person skilled in the art; (e) it had not been anticipated by any publication in any document; (f) it had not been used at any time before the date of filing of patent application with complete specification; (g) it was not a mere discovery of a scientific principle or formulation of an abstract theory; (h) it was not a mere discovery of a new form of a known substance which did not result in enhancement of known efficacy of that substance; and, (i) it was not a presentation of information.

25. With "invention", as defined in the statute, forming the core of a patent and the appellants/plaintiffs in their suits having claimed only one invention i.e. DAPA, as subject matter of both the patents, we wondered whether there could be two patents with respect to the same invention and proceeded to examine the two patents, to decipher the invention claimed in each.

26. IN 147 sets out the field of invention as under:

> "The present invention relates to C-aryl glucosides which are inhibitors of sodium dependent glucose transporters found in the intestine and kidney (SGLT2) and to a method for treating diabetes, especially type II diabetes, as well as hyperglycemia, hyperinsulinemia, obesity, hypertriglyceridemia, Syndrome X, diabetic complications, atherosclerosis and related diseases, employing such C-aryl glucosides alone or in combination with one, two or more other type antidiabetic agent and/or one, two or more other type therapeutic agents such as hypolipidemic agents".

27. IN 625 sets out the field of invention as under:

> "The present invention relates to C-aryl glucosides which are inhibitors of sodium dependent glucose transporters found in the intestine and kidney (SGLT2) and to a method for treating diabetes, especially type II diabetes, as well as hyperglycemia, hyperinsulinemia, obesity, hypertriglyceridemia, Syndrome X, diabetic complications, atherosclerosis and related diseases, employing such C-aryl glucosides alone or in combination with one, two or more other type antidiabetic agent and/or one, two or more other type therapeutic agents such as hypolipidemic agents".

28. As would immediately be obvious from above, there is complete identity, without any difference whatsoever, between the field of invention as set out in the two patents i.e. IN 147 and IN 625. For IN 625 to be with respect to a 'new product' involving an inventive step i.e. a feature involving a technical advance as compared to existing knowledge including of IN 147 or having economic significance and which was not anticipated by earlier publication or use including of IN 147, to say the least, we expected the description of the field of invention in IN 625 to describe the technical advancement and / or the difference in efficacy, from that in IN 147.

29. It cannot be lost sight of, that the inventor of both, IN 147 and IN 625 and/or of US equivalents thereof was/is the same. The said inventor, as compared to a third person, was best placed to know the inventive step i.e. technical advancement in the invention subject matter of IN 625, over that of the earlier invention subject matter of IN 147. However, in the description of field of invention of IN 625, neither any technical advancement or difference in efficacy of the new products subject matter thereof over the product subject matter of IN 147 is mentioned nor any economic significance of the new invention claimed. Once the inventor himself, while writing and seeking the patent, has not mentioned so, the subsequent claims of the assignee of the patent, in this regard, at least at the stage of judging prima facie case, cannot be accepted and have to be necessarily put to trial.

30. The tests of "obvious to a person skilled in the art" and "anticipation by publication" and "use before the date of filing of patent application with complete specification", in the context of an earlier patent and its specifications, in our view, have to be different, when the inventor of both is the same. The counsel for the appellants/plaintiffs has argued, that owing to delays in obtaining approvals of Drug Regulators in different jurisdictions, for marketing of a new drug/medicine, after obtaining patent with respect thereto, results in the inventor/patentee being not able to enjoy the exclusivity granted under the Patent Laws to the inventor/patentee, for the full term of the patent. However merely because there are such delays, would not be a reason for the Court to give to the patent a longer life than provided in the statute. The cure therefor is with the Legislature and not with the Courts, by allowing more than one patent with respect to the same invention. The said argument of the counsel for the appellants/plaintiffs has however made us suspicious, that the appellants/plaintiffs, though invented DAPA at the time of seeking IN 147 and/or US equivalent thereof, though „covered it therein (to prevent others from inventing it) but intentionally did not disclose it, to subsequently claim patent with respect thereto, and in the interregnum obtain approvals of the Drug Regulators. When the inventor is the same, the tests aforesaid, in our opinion, cannot be in the context of "person ordinarily skilled in the art" but have to be of the "person in the know". The enquiry, in such a situation, has to be guided by, whether the inventor, while writing first patent, knew of the invention claimed in the subsequent patent.

31. The Patents Act, though protects the rights and interests of inventors, but for a limited period, whereafter the monopoly of the patentee ceases and comes to an end and the invention with respect to which patent was granted, falls in public domain i.e. open for all to practice and reap benefit of. A patent, vide Section 48 of the Act, confers a right on the patentee of a product patent, as DAPA is, to, during the life of the patent, prevent others from making, using, offering for sale, selling or importing, the new product with respect whereto patent is granted. The life of a patent is limited, whereafter, notwithstanding the new product having been invented by the patentee, patentee no longer has exclusive right to make, use or offer for sale the same and anyone else interested can also make, use or offer for sale the said new product invented by the patentee, without any interference from the patentee. If patents with respect to the same invention can be granted more than once, successively in time, the same will negate the legislative intent of limiting the life of the patent and enable the patentee to prevent others from making, using or offering for sale, the new product invented by the patentee, till the time patentee successively keeps on obtaining patent therefor.

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

33. "Markush", in In Re: Harnisch 631 F. 2d 716 (of the United States Court of Customs and Patent Appeals) has been explained as under:

> ""Markush" was the name of an applicant for patent (Eugene A. Markush) who happened to use in a claim a type of definition *720 of a genus or subgenus by enumeration of species, which he did not devise and which had been used before in patent claims. The examiner considered the claim to be "alternative"

in form, objected to it, and Markush petitioned the Commissioner. Assistant Commissioner Kinnan, in Ex parte Markush, 1925 CD 126 (Com.Pat. 1924), approved the form of claim and granted the petition, thus requiring the examiner to examine it for patentability. Thus the name "Markush" became attached to a type of claim expression, and that is all it connotes."

34. The words 'Markush', 'Genus', 'Species', do not find mention in the Patents Act. We thus proceeded to examine, whether in the Indian statutory regime, what the counsel for the appellants/plaintiffs has argued, is permissible i.e. of a patent being first granted of "a core structure" and/or of a formula, only "generally describing the molecules, rather than detailing each and every molecule covered by the formula" and thereafter a second patent being granted detailing each and every molecule. The counsel for the appellants/plaintiffs referred to Section 10(5) in this regard.

35. Section 7 of the Act prescribes the form in which application for patent is to be filed and inter alia provides, (i) that the application shall be for one invention only; and, (ii) that the application shall be accompanied by a provisional or a complete specification. Section 9 requires a complete specification to be filed within 12 months, if the application for patent is accompanied by a provisional specification. Section 10 is titled "Contents of Specification" and requires the provisional or complete specification to,

(a) describe the invention, indicating the subject matter to which the invention relates; (b) fully and particularly describe the invention and its operation or use and the method by which it is to be performed; (c) disclose the best method of performing the invention and for which protection is claimed; (d) end with a claim or claims defining the scope of invention for which protection is claimed; and, (e) be accompanied by an abstract to provide technical information on the invention. Section 10(5) provides that "The claim or claims of a complete specification shall relate to a single invention, or to a group of inventions linked so as to form a single inventive concept, shall be clear and succinct and shall be fairly based on the matter disclosed in the specification". Section 25 permits grant of patent to be opposed on the ground of the complete specification furnished, not sufficiently and clearly describing the invention or the method by which it is to be performed. All these provisions show that the patent once granted, is complete, disclosing to the world at large the product with respect whereto patent is granted and from a mere reading whereof, anyone else, but for the exclusivity granted to the patentee, can manufacture the product for which the patent is granted. Section 84 titled "Compulsory Licences", empowers the Controller of Patents to grant compulsory licence of patent, enabling the person other than the patentee or whom the patentee has permitted to work the patent, to also work the patent. The said section is indicative of, patent,

particularly the specifications therein, being self-sufficient to enable working thereof by others, even without the assistance of the patentee.

36. From the aforesaid provisions it follows, that from IN 147 and/or US equivalent thereof, the invention as described therein could be worked by anyone, save for the exclusivity for the term thereof in favour of the appellants/plaintiffs. However the claim of the appellants/plaintiffs is, that DAPA was not disclosed in the specifications of IN 147 but 80 other compounds were disclosed. However if that were to be the case, it being not the case of the appellants/plaintiffs that the respondent(s)/defendant(s) were manufacturing any of the said 80 compounds, the appellants/plaintiffs, for manufacture by respondent(s)/defendant(s) of DAPA, cannot claim infringement of IN 147 and could have claimed infringement only of IN 625 in which DAPA was disclosed.

37. The appellants/plaintiffs have also not pleaded industrial application or sale of any product subject matter of IN 147, other than DAPA. The response of the counsel for the appellants/plaintiffs to our said observation was, that patent is not a right to work a patent but a right to exclude others from working the patent. Though we entertain doubts as to the same, the Patents Act having provided consequences of not working the patent, but the need to delve into the said aspect is not felt. It is the contention of the counsels for the respondent(s) / defendant(s) that the appellants / plaintiffs, while reporting working of IN 147, reported manufacture and sale of DAPA only.

38. Section 10(5) of the Patents Act, in our view, permitted the appellants/plaintiffs to obtain IN 147 with respect to a group of inventions, as many as 80 according to the appellants/plaintiffs clearly and succinctly disclosed in the specifications thereof, forming a single inventive step, with the new product of each of the 80 compounds subject matter thereof having the effect as claimed in the description of the field of invention therein. Section 10(5) obviated the need for the appellants/plaintiffs to apply for and obtain separate patents with respect to each of the said 80 compounds specifically disclosed. Section 10(5), in our view also empowers and enables an inventor/patentee to sue for infringement, a person, who merely by making a slight change in the group of inventions relating to a single inventive step subject matter of such a patent, claims his product to be different. Thus, in the facts of the present case, even though none of the 80 compounds disclosed in the specifications of IN 147 have 'ethoxy', but Section 10(5) would have enabled the appellants/plaintiffs to claim that merely from substitution of 'ethoxy' for 'methoxy' disclosed in one of the 80 compounds, it could not be contended that there was no infringement, inasmuch as it was a part of the single inventive step, subject matter of IN 147 and both 'ethoxy' and 'methoxy' being 'lower alkyls'. That, in our view, is the reason for the appellants/plaintiffs, in the suits from which these appeals arise, claiming infringement not only of IN 625 but also of IN 147--

the inventive step being subject matter of IN 147 only and which could not in law again be the inventive step of subsequent patent IN 625.

39. Rather, according to the arguments of the counsel for the appellants/plaintiffs, IN 147 was with respect to mere discovery of a scientific principle or formulation of an abstract theory or was a mere presentation of information and qua which under Sections 3(c) and 3(n) respectively, no patent

could be granted. However, not only was the patent obtained but also infringement thereof claimed in the suits from which these appeals arise, admitting DAPA to be the new product subject matter of IN

147. If IN 147 did not disclose DAPA and specifications thereof did not describe DAPA or the best method of industrially manufacturing DAPA, there could be no infringement of IN 147 from the action of the respondent(s)/defendant(s) making and selling medicines/drugs with DAPA as ingredient thereof. The provisions afore noticed of the Patents Act, in our view, do not permit a patent to be granted with respect to the important stage in the inventive process and at which stage there is no product capable of industrial application, even if having technical advancement as compared to the existing knowledge. The appellants/plaintiffs on the other hand, as aforesaid, not only claimed patent IN 147 at the "breakthrough" stage, when according to them DAPA was not even known but even after obtaining patent IN 625 with respect to DAPA, by suing the respondent(s)/defendant(s) have pleaded infringement of IN 147 also. At least at this stage the same has to be treated as an admission of DAPA being known while obtaining IN 147.

40. The example given by the counsel for the appellants/plaintiffs, of a telephone instrument comprising of several patents, is not apposite. A telephone instrument, though perceived by the consumer thereof as one product, comprises of several components, each of which is also a product in itself and capable of independent patent. However, DAPA is disclosed to be a single compound and cannot have more than one patent.

41. During the hearing, we also enquired from the counsel for the appellants/plaintiffs, that if DAPA was not disclosed in IN 147 and was in fact not known to the appellants/plaintiffs also, what would have been the situation if someone other than the appellants/plaintiffs had discovered DAPA, even if from IN 147, before the appellants/plaintiffs.

42. The counsel for the appellants/plaintiffs, on the next date of hearing, in response to our aforesaid query, contended that the appellants/plaintiffs as holders of IN 147, being a genus patent, even prior to the discovery of DAPA, could sue another who discovered DAPA before the appellants/plaintiffs; however such other could also sue anyone including appellants/plaintiffs on the basis of its DAPA patent and the appellants/plaintiffs also could not manufacture DAPA without such others' permission. It was further explained that if 'A' has a patent for a basic invention and 'B' later obtains a patent for an improvement to this invention, then 'B' is not free to use his invention without permission of 'A' and 'A' cannot use the improved version without permission of 'B'.

43. However, under the Indian regime, patent is to be sought and granted with respect to a new product or process. "Product" is not defined in the Act. The said word is thus deemed to have been used in the Act, as commonly understood. "Product" is understood as something that is made to be sold, usually something that is produced by an industrial process or, less commonly, something that is grown or obtained through farming. However, the arguments of the appellants/plaintiffs before us make out IN 147 to be a discovery/invention of a group of formulations, which was capable, with further research, of acting as a drug/medicine for inhibiting re- absorption of sugar in kidneys. The appellants/plaintiffs, on the basis thereof could not have manufactured any drug/medicine and have

not pleaded any drug/medicine manufactured post IN 147 and thus it prima facie appears, could not have restrained any other person who discovered DAPA, even if from IN 147. In fact we wondered, why the appellants/plaintiffs have pleaded and claimed infringement by the respondent(s)/defendant(s) of both, IN 147 and IN 625. Though in response to our query aforesaid, we expected the appellants/plaintiffs to confine their claim for infringement to IN 625 only but the appellants/plaintiffs stuck to their stand of the respondent(s)/defendant(s) being also in infringement of IN 147. It is obvious therefrom that the appellants/plaintiffs have no legs to stand on, by claiming infringement of IN 625 only, without also claiming infringement of IN 147. However, as held in the impugned judgment/order dated 2nd November, 2020, the question of the respondent(s)/defendant(s), by working DAPA, infringing IN 147 could arise only if DAPA was disclosed in IN 147. If DAPA was disclosed in IN 147, even if better disclosed in IN 625, cannot enjoy two rounds of 20 years of protection, when the legislative policy is to grant protection for a period of one term of 20 years only.

44. We have perused the plaint in the suit from which FAO(OS)(COMM) 139/2020 arises and therein also do not find the appellants/plaintiffs to have disclosed any difference in IN 147 and IN 625; rather the appellants/plaintiffs, in paragraph 3 of the plaint have pleaded, "....the Plaintiffs are asserting exclusive rights in IN '147 and in IN '625 since they vest exclusive rights to manufacture, use, sell, export, import etc. Dapagliflozin". The appellants/plaintiffs, in paragraph 16 of the plaint have further pleaded, "The Plaintiffs suit patents IN 205147 [genus patent] and IN 235625 [species patent] cover the Plaintiffs' drugs comprising inter alia its invention DAPAGLIFLOZIN". The appellants/plaintiffs, in paragraph 22 of the plaint have pleaded, "DAPAGLIFLOZIN falls within the scope of the Plaintiff s Indian Patent Numbers IN 205147; IN 235625". The appellants/plaintiffs, in paragraph 28 of the plaint have pleaded, "Although the genus patent covered a Markush structure, it did not disclose DAPAGLIFLOZIN. Further research and development by the Plaintiffs to find the most suitable, stable and viable SGLT2 inhibitor led to the invention of DAPAGLIFLOZIN". The appellants/plaintiffs, in paragraph 36 of the plaint have pleaded, "DAPAGLIFLOZIN is covered by the Markush claim in patent IN '147. However, it is specifically disclosed only in patent IN 235625 (IN '625) and falls within the scope of claim 1 thereof".

45. We, at least at this stage are unable to, in the face of the aforesaid pleadings of the appellants/plaintiffs themselves, find any difference between IN 147 and IN 625. The appellants/plaintiffs themselves are found to be pleading DAPA to have been disclosed generally in IN 147 and specifically in IN 625. In the face of the said pleading, no case for injuncting the respondent(s)/defendant(s) during the pendency of the suits is made out. As aforesaid, we entertain doubt as to the very basis of the claim of the appellants/plaintiffs, as noted in the judgment/order dated 2nd November, 2020 identifying the key question in the dispute to be "whether the compound-in-issue i.e. Dapagliflozin [in short "DAPA"] which, according to the plaintiffs, is covered in IN 147 stands disclosed both, in law as well as on facts".

46. In our opinion, a single formulation as DAPA, is incapable of protection under two separate patents having separate validity period. The appellants/plaintiffs, in their pleadings, are not found to have pleaded the difference, save for pleading that DAPA was discovered by further research. From the field of the invention subject matter of the two patents being verbatim same, at this stage,

it also appears that there is no enhancement of the known efficacy, within the meaning of Section 3(d) of the Act, between the product subject matter of IN 147 and the product subject matter of IN

625.

47. To hold, that an inventor, merely on the basis of his work, research, discovery and prior art, but which has not yielded any product capable of commercial exploitation, is entitled, by obtaining patent thereof, to restrain others from researching in the same field, would in our view, not be conducive to research and development and would also be violative of the fundamental duties of the citizens of this country, enshrined in Article 51A of the Constitution of India, to develop the scientific temper and a spirit of inquiry. The same will enable busy bodies to, by walking only part of the mile, prevent others also from completing the mile.

48. The counsels, during the hearing have referred to a plethora of judgments. However if we, in this judgment deal with each of the said judgments, this judgment will fall foul of what has been held in AZ Tech (India) supra and In Re: Case Management of Original Suits supra. Suffice it is to state that we have perused the judgments, not only during the hearing but thereafter and have thereafter reasoned as aforesaid.

49. We are also of the opinion, that the mere fact that there is a difference in the reasoning in the two impugned orders/judgments, would not entitle the appellants/plaintiffs to interim injunction. We have already hereinabove commented on the appellants/plaintiffs having wasted the time of two Hon'ble Judges of this Court by pursuing the same subject matter separately, and the appellants/plaintiffs, in appeal, cannot be permitted to reap any benefit thereof. It is not as if, one impugned order/judgment grants interim relief to the appellants/plaintiffs and the other denies. Though for different reasons, both the impugned orders/judgments find the appellants/plaintiffs to be not entitled to interim relief. Suffice it is to state, that no perversity requiring interference in appellate jurisdiction, within the meaning of Wander Ltd. supra is found in the two orders/judgments.

50. We are also of the prima facie view, that once the appellants/plaintiffs, before the USPTO applied for and agreed to the validity period of US patent equivalent of IN 625 ending on the same day as the validity period of the US patent equivalent to IN 147, the appellants/plaintiffs, in this country are not entitled to claim different periods of validity of the two patents.

51. The counsel for the appellants / plaintiffs, on 12th July, 2021 mentioned the matter, to draw attention to judgment dated 7 th July, 2021 in applications for interim relief in CS(COMM) No.69/2021 and CS(COMM) No.661/2019 titled FMC Corporation Vs. Best Crop Science LLP. In taking the view aforesaid, we have considered the said judgment also, in which infringement of one patent only was claimed.

52. There is thus no merit in the appeals, which are dismissed, with costs assessed at Rs.5,00,000/- to the respondent(s)/defendant(s) in each of the suits.

RAJIV SAHAI ENDLAW, J.

AMIT BANSAL, J.

JULY 20, 2021 „bs ..