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

Judgement reserved on 22.10.2020
Judgement pronounced on 02.11.2020

I.A. No. 8826/2020
in
\+ **CS (COMM) No. 410/2020**

ASTRAZENECA AB & ANR .....Plaintiffs

Through : Mr. Kapil Sibal, Mr. Harish Salve and Mr. Sudhir Chandra, Senior Advocates with Mr. Pravin Anand, Ms. Vaishali Mittal, Mr. Rohin Koolwal, Mr. Siddhant Chamola, Ms. Devyani Nath and Mr. Souradeep Mukhopadhyay, Advocates.

versus

INTAS PHARMACEUTICALS LIMITED .....Defendant

Through : Mr. C.S. Vaidyanathan, Senior Advocate with Ms. Bitika Sharma, Ms. Namrita Kocchar, Ms. Nitya Sharma and Ms. Vrinda Pathak, Advocates.

I.A. No. 8859/2020
in
\+ **CS (COMM) No. 411/2020**

ASTRAZENECA AB & ANR .....Plaintiffs

Through : Mr. Kapil Sibal, Mr. Harish Salve and Mr. Sudhir Chandra, Senior Advocates with Mr. Pravin Anand, Ms. Vaishali Mittal, Mr. Rohin Koolwal, Mr. Siddhant Chamola, Ms. Devyani Nath and Mr. Souradeep Mukhopadhyay, Advocates.

versus

ALKEM LABORATORIES LIMITED .....Defendant

Through : Mr. Adarsh Ramanujam, Advocate with Ms. Bitika Sharma, Ms. Namrita Kocchar, Ms. Nitya Sharma and Ms. Vrinda Pathak, Advocates.

CORAM:
HON'BLE MR. JUSTICE RAJIV SHAKDHER

RAJIV SHAKDHER, J.:

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Preface: -

1. The captioned actions concern, principally, two patents. These being:

   a) Indian Patent No. 205147 [hereinafter referred to as: IN 147]

   b) Indian Patent No. 235625 [hereinafter referred to as: IN 625]

2. IN 147, as per the averments made in the plaint, is the genus patent while IN 625 is claimed to be the species patent. 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?

2.1 I must also state, at the very outset, that there are various shades and limbs to this broad frame which is the essence of the dispute obtaining between the parties.

2.2 Furthermore, for the sake of convenience, I would be referring to plaintiff no. 1 i.e. AstraZeneca AB as "Astra Sweden" and plaintiff no. 2 i.e. AstraZeneca Pharma India Limited as "Astra India". The defendant in CS (COMM) 410/2020 i.e. Intas Pharmaceuticals Limited will be referred to as "Intas"; while the defendant in CS (COMM) 411/2020 i.e. Alkem Laboratories Limited will be referred to as "Alkem".

2.3 Besides this, wherever the context requires, Astra Sweden and Astra India will collectively be referred to as the plaintiffs, and likewise, Intas and Alkem will be collectively referred to as the defendants.

Background: -

3. Before I proceed further, the following broad contours of the case are required to be noticed.

3.1 The first registered patent holder i.e. the grantee of these two patents is an entity going by the name Bristol Myers Squibb Company [in short "Bristol"]. Bristol, it appears, *via* an assignment deed dated 01.02.2014, assigned the rights in the aforementioned patents in favour of Astra Sweden. It is claimed that this

assignment deed was placed on record of the patent's office by Astra Sweden *via* its application dated 02.06.2014 and that as a result of this step having been taken, it was registered as the patent holder *qua* the aforementioned patents.

3.2 Insofar as Astra India is concerned, it is averred in the plaint that it is the only company in the country which has obtained the necessary statutory approvals for importing and marketing DAPA in India.

3.3 The plaintiffs claim that DAPA is used worldwide to treat people suffering from type-II diabetes mellitus. According to the plaintiffs, this is achieved by DAPA acting as an inhibitor of sodium-dependant glucose transporter i.e. SGLT2 in the kidneys.

3.4 It is, thus, claimed that DAPA aids in normalisation of plasma glucose levels, and perhaps, body weight by enhancing glucose excretion. It is averred, hyperglycaemia is a hallmark of type-II diabetes and the challenge, therefore, is to control plasma glucose levels so as to prevent complications which arise when the disease reaches an advance stage.

3.5 It is stated that plasma glucose is normally filtered in the kidneys in the glomerulus which is then actively reabsorbed in the proximal tubule. SGLT2, according to the plaintiffs, is a major transporter which is responsible for the reuptake of glucose in the glomerulus. The SGLT2 inhibitors such as phlorizin and other closely related analogues inhibit the re-uptake process. The selective inhibition of SGLT2 normalises plasma glucose by enhancing excretion of glucose in the urine, thereby, improving insulin sensitivity and, thus, delaying the development of diabetic complications such as neuropathy, nephropathy, and retinopathy, wound healing and other related diseases.

3.6 It is also averred by the plaintiffs that the main claim in IN 147 is a Markush structure, in other words, a patent covering a group of compounds which disclosed the possibility of individual permutations and combinations that can run into several million [if not more] structurally diverse compounds. In this context, it is also averred by the plaintiffs that, although, IN 147 [which is the

genus patent and bears a Markush structure] covered DAPA, it did not disclose the same. The case set up by the plaintiffs is that it was only when further research and development was carried out to discover the most suitable, stable and viable SGLT2 inhibitor, was DAPA invented.

4. Given this backdrop, it would be relevant, at this stage, to note the bibliography of IN 147 [the genus patent] and IN 625 [the species patent].

IN 147 – THE GENUS PATENT

Title	A C-ARYL GLUCOSIDE SGLT2 INHIBITORS AND METHOD
Application number	IN/PCT/2002/00433/MUM
Applicant name	BRISTOL-MYERS SQUIBB CO.
PCT International filing date	02.10.2000
International publication date	19.04.2001
Priority date	12.10.1999
Section 11A publication date	18.03.2005
Date of grant	15.03.2007
Date of expiry	02.02.2020

IN 625– THE SPECIES PATENT

Title	A COMPOUND (2S, 3R, 4R, 5S, 6R)-2(4-CHLOTO-3(4-ETHOXYBENZYL PHENYL)-6-(HYDROXYMETHLY) TETRAHYDRO-2H-PYRAN-3,4,5-TRIOL AND COMPOSITION COMPRISING
Application number	3573/DELNP/2004
Applicant name	BRISTOL-MYERS SQUIBB CO.
PCT International filing date	15.05.2003
International publication date	04.12.2003
Priority date	20.05.2002
Section 11A publication date	01.04.2005
Date of grant	09.07.2009
Date of expiry	15.05.2023

Submissions of the parties: -

5. It is in this background that the submissions were advanced on behalf of the plaintiffs by Mr. Kapil Sibal, Mr. Harish Salve and Mr. Sudhir Chandra, learned senior counsels and Mr. Pravin Anand instructed by Ms. Vaishali Mittal.

5.1 Likewise, submissions on behalf of Intas were advanced by Mr. C.S. Vaidyanathan, senior advocate instructed by Ms. Bitika Sharma while submissions on behalf of Alkem were advanced by Mr. Adarsh Ramanujam also instructed by Ms. Bitika Sharma. There was, in fact, another action listed before me i.e. CS (COMM) 407/2020 in which arguments were made by Mr. J Sai Deepak instructed by Mr. Guruswamy Nataraj. This action, at the interlocutory stage, was de-tagged from the captioned actions as Mr. Natraj, on instructions, made the following statement before me [which is recorded in the order dated 22.10.2020] *albeit* at the nth hour when the judgement in matter was about to be reserved:

> "***I.A. No. 8791/2020***
>
> *1. Mr. Guru Nataraj, who appears for the defendant, in the captioned matter, says that he has received fresh instructions [even while arguments were being heard in the captioned application] that the defendant will not be manufacturing and/or launching its product as it has lost commercial interest in Dapagliflozin. 1.1 The statement of Mr. Nataraj is taken on record. The defendant will be bound by the statement made before me.*
>
> *2. Mr. Pravin Anand, who appears on behalf of the plaintiffs, in the captioned matter, says that in view of the statement made by Mr. Nataraj today, he would have no objection if the captioned application is disposed of. 3. The captioned application is, accordingly, closed in terms of the statement made on behalf of the defendant.*"

6. The broad framework of the submissions made by each of the counsel are, set forth hereafter.

On behalf of the plaintiffs: -

i. DAPA is a new, novel and man-made molecule which was first synthesized in 2001. It is a SGLT2 inhibitor which is useful in treatment

of type-II diabetes. It normalizes plasma glucose by enhancing excretion of glucose in urine and, thus, improves insulin sensitivity.

ii. This drug, which is sold under the name Forxiga/Farxiga, has been approved in 2020 for treatment of hypertensive heart failure [HHF] as well. The plaintiffs' two distributors i.e. Sun Pharma Laboratories Limited and Abbott Healthcare Private Limited [hereafter referred to as "Sun" and "Abbott" respectively] market and sell the very same drug under various brand names such as OXRA, OXRAMET, OXRAMET IR, OXRAMET XR, GLEDEPA, GLEDEPA MET, GLEDEPA MET IR, AND GLEDEPA MET XR.

iii. IN 147, which is, the genus patent claims a Markush structure which has 22 variables and, hence, can lead to millions and perhaps billions of possible permutations and combinations. While the Markush structure claimed by the plaintiffs *qua* its genus patent i.e. IN 147 covers DAPA, it does not disclose the same.

iv. While the genus patent i.e. IN 147 discloses 80 exemplified compounds [as is evident from the complete specification of the said patent], DAPA is not one of the disclosed compounds.

v. DAPA has been specifically disclosed in the species patent i.e. IN 625. This patent has only two claims which specifically relate to DAPA. Claim 1 specifically lays the claim to compound DAPA as well as its pharmaceutical acceptable salts stereoisomers or prodrugesters. Claim 2 lays, likewise, specific claims to pharmaceutical compositions prepared using DAPA.

vi. IN 625 is a valid and a subsisting patent in India. It was granted on 07.07.2009, with 20.05.2002 as its priority date, and, accordingly, expires on 15.05.2023. It was published, in India, on 01.04.2005. The plaintiffs have been granted patents *qua* DAPA in approximately 70 countries. In

India, DAPA has not been subjected to any pre-grant or post-grant opposition or even revocation proceedings prior to 2020.

vii. It is only in 2020, some entities have embarked on infringing the aforementioned patents which led to institution of suits including the captioned suits for patent infringement. It is only in 2020 that some of these entities have initiated post-grant opposition, revocation proceedings or counter-claims against IN 625.

viii. Insofar as the genus patent i.e. IN 147 is concerned, in India, it was granted on 15.03.2007, with a priority date of 12.10.1999 and, thus, expired on 02.02.2020. The patent was first published, in India, on 18.03.2005.

ix. Since DAPA was first synthesized in 2001, that is, after the priority date of genus patent [IN 147] i.e. 12.10.1999, there can be no question of DAPA being disclosed in the genus patent.

x. The Patents Act, 1970 [in short "the Act] requires the patentee to disclose, with specificity, two aspects.

a) First, what is the invention?

b) Second, what is the best method of performing the invention as known to the inventor? Reliance, in this behalf, was placed on provisions of Section 10(4)(b), 11(3), 11(3)(a) and 11(4) of the Act.

xi. The defendants have placed considerable reliance on formula of Claim 1B within IN 147 i.e. the genus patent to emphasize their point that it discloses DAPA. This contention is flawed for the reason that formula 1B itself would have more than 1 billion permutations and combinations.

xii. The attempt of the defendants to reach DAPA, either through Claim 1 of IN 147 or from the genus formula 1B, is nothing but an application of hindsight wisdom which is a technique which Courts have not accepted under the patent law.

xiii. Disclosure is a question of fact which can be ascertained only by reading the patent document i.e. document pertaining to IN 147. Disclosure of information can only occur upon it being disclosed to the public at large. General or fleeting disclosure is not countenanced under patent law. Disclosure in the context of novelty can be established only if it is referred to in the earlier patent by way of chemical name; chemical formula; chemical structure etcetera. [See: ***Eli Lily, Apotex***, 2010 FCA 214]

xiv. Markush formulae are well recognised under the Indian patent law. Thus, while assessing novelty of the latter patent, which is, said to be covered with a Markush structure of an earlier patent, is determined by looking for clear, unambiguous and individual disclosures. In this behalf, reliance was placed on Patent Office Guidelines, 2013; Patents Office Manual, 2011; Patents Office Manual, 2008; Terrel on the law of patents, 18th edition, Sweet & Maxwell; and Modern law of patents, 2nd Edition, Consultant Editor – His Honor Judge Fysh, QC, SC.

xv. The crux of these references is briefly as follows. The mere possibility of an embodiment falling within the scope or periphery of a particular claim does not mean that the particular embodiment or compound has been disclosed with specificity. In other words, if prior art discloses a family of compounds with a general formula, which includes a particular compound which is not disclosed with specificity, then, that particular compound will still constitute an invention which is novel.

xvi. The contention of the defendants that reference to the aforementioned two patents in the working statements i.e. Form 27 filed with the Controller's office and submissions made in the United States of America [US] for patent term extension [PTE] as also to US Food and Drug Administration [FDA] Orange Book constitute admission is erroneous. In none of these documents, it is stated that DAPA was disclosed in IN 147 i.e. genus

patent. The PTE only states that Forxiga/Farxiga [which is the brand name for DAPA, as indicated above] is claimed by the aforementioned patents. There is no admission whatsoever that the genus patents i.e. IN 147 disclosed DAPA.

xvii. Assuming without admitting that these are admissions, admissions made after the priority date of the patent cannot alter the scope of the claims either by enlargement or reduction. [See: ***Glaverbel vs. British Coal***, 1995 RPC 255; and ***F. Hoffmann La Roche Ltd. and Anr. vs. Cipla Ltd.***, MIPR 2016 (1) 0001]

xviii. Likewise, the working statements i.e. Form 27 and US FDA orange book only advert to the fact that the drug Forxiga/Farxiga work with both genus and species patent. This is so as the genus patent, which covers DAPA, is necessarily worked through commercialisation of the drug which was disclosed in the species patent and, therefore, would not amount to an admission, as alleged or at all. [See: Judgement dated 15.01.2020, passed in CS (COMM) 561/2019, titled ***AstraZeneca AB & Anr. vs. Emcure Pharmaceuticals Limited***]

xix. A single product may cover thousands of patents. By way of illustration, reference was made to a mobile phone which is covered by multiple patents. In this behalf, reliance was placed on Section 141, Section 19 and Section 91(1) of the Act. If this rationale is followed through, the defendants are not free to make use of DAPA for manufacture and/or sale of their product(s) until all patents containing the said compound expire.

xx. The contention that because the plaintiffs filed a "terminal disclaimer" in the USA concerning the corresponding genus patent i.e. US 126 and species patent i.e. US 117, the instant case was of double-patenting and ever-greening and, therefore, the Indian species patent i.e. IN 625 stands invalidated, is flawed. The plaintiffs had filed the species patent in the US i.e. US 117, in 2002 as a continuation-in-part of the genus patent i.e. US

126 to overcome the non-final double patenting objection flagged by the US Patent Office [USPTO]. In the US, the mere filing of a terminal disclaimer is not construed as an admission of double patenting. It is an instance of expedient obviation rather than obviousness. It is an often use methodology to overcome such objections raised by USPTO. [See: ***Quad Environment vs. Union Sanitary***, 946 F2d 870]

xxi. The defendants' contention that because the plaintiffs filed the US species patent [US 117] as continuation-in-part of the corresponding genus patent [US 126] and, hence, should be construed as an admission of the fact that it disclosed no new subject matter is completely erroneous. Under the US law MPEP 201.08, a continuation-in-part application is an application filed during the lifetime of an earlier nonprovisional application, repeating some substantial portion or all of the earlier nonprovisional application and adding matter not disclosed in the said earlier nonprovisional application [See: ***In re Klein***, 1930 C.D 2., 393, O.G. 519 (Comm'r Pat., 1930)]. The continuation-in-part application may only be filed under 37 CFR 1.53 (b).

xxii. Furthermore, the attempt on the part of the defendants to draw a parallel between a continuation-in-part application and an application filed in India *qua* a patent for any improvement in or modification of an invention for grant of a patent of addition is flawed. The reason being that patents of addition as envisaged under Section 54 of the Act envisage minor improvements over an earlier patent. In India, patents of addition are never granted where the application claims new subject matter which was not disclosed in the prior application. It is this conceptual difference between the application for continuation-in-part filed in the USA and an application for grant of patents of addition which has been missed by the defendants. It is for this reason that the Controller of Patents in India does not scrutinize an application for grant of patents of addition from the

point of view of lack of inventive step or obviousness when compared with the main patent application. This aspect emerges upon a careful perusal of Section 56 of the Act.

xxiii. The reliance by the defendants on the judgement of the Supreme Court rendered in ***Novartis vs. Union of India***, (2013) 6 SCC 1 [hereafter referred to as ***Novartis*** case] is erroneous on account of the following distinguishing features.

a) ***Novartis*** was a case where the claimed invention i.e. imatinib mesylate had been disclosed in an earlier patent i.e. the Zimmerman patent and a finding to that effect had been recorded by the US board of appeals.

b) It was, thus, a case where the Supreme Court found that Novartis had not only claimed but also disclosed imatinib mesylate. The contention advanced by Novartis that the disclosure of imatinib in the Zimmerman patent did not involve disclosure of its invention i.e. beta crystalline form of imatinib mesylate was rejected by the Supreme Court as there was a clear disclosure of methane-sulphonic acid of imatinib in its patent application – a claim which included imatinib in its pharmaceutically acceptable salts.

c) In the ***Novartis*** case, the inventor himself had written articles wherein a reference had been made to the fact that imatinib mesylate had been disclosed in the Zimmerman patent.

d) On the other hand, there is no disclosure of DAPA in IN 147. Unlike the ***Novartis*** case, there is no finding of any Court or tribunal to this effect.

e) The contention of Novartis that beta crystalline form of imatinib mesylate was a two-step invention i.e. from imatinib to imatinib mesylate and from imatinib mesylate to its beta crystalline form was rejected as it was hit was Section 3 (d) of the Act. The beta

crystalline form was considered only as a polymorph which did not reveal any enhanced therapeutic efficacy. DAPA, on the other hand, is a new compound. It is not a salt, ester, ether, polymorph, metabolite etcetera of a known substance and, hence, does not fall within the purview of Section 3 (d) of the Act. Importantly, in the instant case, Dr. William N. Washburn's affidavit [who led the group which invented the compound-in-issue] has demonstrated DAPA's enhanced efficacy over example 12 of IN 147. In this behalf, the following assertions have been made by Dr. Washburn.

A. Enhanced ability: for blood sugar 25%; for plasma sugar 58% and 1.7 times selective for SGLT2 over SGLT1.

B. Example 12 never morphed into a drug and had no known efficacy as it was never tested on human beings.

C. DAPA was synthesized only in 2001.

f) The aspect concerning whether a compound is covered or disclosed should be construed as an obiter as it came up because of arguments advanced on behalf of Novartis that there was no disclosure of imatinib mesylate in the Zimmerman patent, although, it was covered by its broad claims.

g) The reliance placed by the defendants on paragraph 134 of the ***Novartis*** case needs to be examined in the background of the following factors.

A. It displays a desire for the law to develop in a certain way in future.

B. There is no finding in the judgement that Markush claims are bad in law. The Supreme Court was not concerned with this issue. There is, in fact, a recognition by the Supreme Court in the very same paragraph that there could be some gap between what is covered as against that which is disclosed.

Therefore, what the defendants submit requires not a judicial decision but a legislative interdiction. In this behalf, it requires to be borne in mind that the Court did not rule one way or the other on the issue: if the gap between what was disclosed and covered was too wide, would that invalidate the patent? In other words, would the patent become unenforceable *qua* compounds which are not disclosed? In any event, in the instant case there is no gap between the genus patent and species patent i.e. IN 147 and IN 625. In the ***Novartis*** case, public interest was an issue as the drug manufactured by Novartis cost INR 1, 20,000 whereas that manufactured by the defendant in that case cost INR 8, 000. The price difference was vast. In the present case, the price difference is only INR 37 per capsule. In this context, one cannot lose sight of the fact that DAPA, which is, used to treat diabetes is not a life-threatening disease. [See: ***Merck Sharp and Dohme Corporation and Ors. vs. Glenmark Pharmaceuticals***, MANU/DE/0852/2015]

xxiv. Section 13 (1) (b) of the Act, which concerns the defence of anticipation by prior claiming has no application in the instant case as the earlier claim i.e. IN 147 and the patent claim i.e. IN 625 are not identical. [See: ***Daikin Kogyo Co. Ltd. (Shingu and Another's) Application***, (1974) R.P.C. 18; and Manual of Patent Office Practice and Procedure Version 01.11 as modified on March 22, 2011]

xxv. The invention of IN 147, as claimed, is different from the invention claimed in IN 625. IN 147 claims a class of compounds of the Markush structure.

xxvi. IN 147 teaches a pharmacophore comprising elements:

A. A sugar that is a glucoside;

B. A C-aryl link;

C. A phenyl proximal moiety attached to a linker and a distal phenyl moiety;

D. There could be many substitutions on the 9 carbon atoms on the 2 phenyl moieties;

E. The substitutions can be in hundreds or thousands - H, Halogen (Cl, Br, F), OCF3, OCH3, OC2H5, OBe, SCH3, CH3, C2H5, C3H7, OH, COCH3 etc. [spread over 22 variables].

xxvii. Extensive research is required to understand which linker required research. Extensive research was also required to understand which substitutions are required, as indicated above. Furthermore, which of the 9 carbon positions had to be substituted, also requires extensive research.

xxviii. On the other hand, IN 625 has only one specific molecule, i.e., Dapagliflozin. Therefore, it is clear that prior claiming has no application to the present case.

xxix. The defence of anticipation by prior publication does not apply in this case for the following reasons.

a) IN 147 is not prior art as it was published only on 18.03.2005, that is, after the priority date of IN 625 which is 20.05.2002.

b) There can be no disclosure in law if a forest or a library of compounds is encompassed by a Markush structure wherein few species are disclosed only by way of examples. [See: ***Dr Reddy's Laboratories (UK) Ltd vs. Eli Lilly and Co Ltd.*** (2009) EWCA 1362; ***In re: Petering***, 301 F.2d 676; and ***Apotex Pty Ltd (formerly GenRx Pty Ltd) vs Sanofi-Aventis*** [2008] FCA 1194]

xxx. The defendants are wrong in contending that where a genus patent is granted, subsequent species patent cannot be granted. Unique features of breakthrough inventions are critical and, hence, need to be protected by a

grant of patents. [See: ***F. Hoffmann La Roche Ltd. and Anr. vs. Cipla Ltd.***, MIPR 2016 (1) 0001; and ***Eisai Co. Ltd. and Ors. vs. Satish Reddy and Ors.,*** MANU/DE/1621/2019]

xxxi. For the defence of obviousness to apply, it must be demonstrated that a person with average skill and average knowledge, who has no creative or inventive faculties, can reach claimed inventions on reading the prior art. Thus, simply put, obviousness is something which is claimed and easily understood by persons skilled in art. To reach a conclusion of obviousness, the teaching contained in the document must be read as a whole. The document must not teach away from a certain concept. Pertinently, hindsight reconstruction is not permissible. [See: Judgement dated 30.01.2020, passed in CS (COMM) 27/2020, titled ***Bristol-Myers Squibb Holdings Ireland Unlimited Company & Ors. vs. BDR Pharmaceuticals International Pvt. Ltd. & Anr.***; and ***The General Tire & Rubber Company vs. The Firestone Tyre and Rubber Company Limited and Others***, (1972) RPC 17]

xxxii. DAPA, on the other hand, is not obvious contrary to what is contended by the defendants. The reliance of the defendants, in this behalf, on example 12 of IN 147 is flawed. The reasons for the same are as follows:

A. First, why should one look at example 12 when genus formula 1B has large number of compounds?

B. Second, why should one look at example 12 when 80 examples are given of which examples 1 and 2 are synthesised on a large scale?

C. Third, if example 12 is relevant, why is the need to change methoxy?

D. Fourth, in any case, properties of example 12 i.e. efficacy or other data or SAR are not known.

E. Fifth, the teaching of IN 147 is to add hydrogen on central phenyl ring [in 60 % of examples].

F. Sixth, there is no ethoxy on the distal phenyl in any of the 80 examples.

G. Lastly, DAPA is far more effective than example 12.

xxxiii. For defence of obviousness to be sustained, it would have to be established that the earlier patent was published as on the date when the latter patent was granted. In the instant case, the admitted facts reveal that the species patent i.e. IN 625 has a priority date of 20.05.2002 whereas the genus patent was published under Section 11A of the Act only on 18.03.2005. This being the position, there can be no question of a person of ordinary skill in the art, having read example 12 or any other teaching in the genus patent i.e. IN 147, to arrive at DAPA. This submission is further strengthened by the fact that the corresponding species patent US 117 bears a priority date of 20.05.2002 while the corresponding genus patent i.e. US 126 was published in the US only in September 2002.

xxxiv. Since there was no publication of the genus patent in USA prior to the filing of the species patent there is no question of the person of ordinary skill in the art of reaching DAPA by absorbing the teaching given in example 12 or any other teaching given in the genus patent i.e. IN 147.

xxxv. DAPA is not obvious because formula 1B of IN 147 has a million possibilities. Any attempt to reach DAPA from the Markush structure of Claim 1 of IN 147 or genus formula 1B is nothing but an attempt to take recourse to hindsight which is discouraged under patent law.

xxxvi. Of the 25 examples in IN 147 that fall within the genus of compounds of Structure IB, 13 (over 50%) have hydrogen as R1. Of the remaining 12 examples that have non-hydrogen R1 groups, over 65% (8/12) have lower alkyls – not a chloro group as in dapagliflozin.

xxxvii. Similarly, over 50% (13/25) of the examples in IN 147 that fall within the genus of compounds of Structure IB have alkyl or thioalkyl at R4 and of the remaining Examples that fall within the genus of compounds of

Structure 1B that have an alkoxy at R4, none is ethoxy as in dapagliflozin.

xxxviii. Thus, given the complete absence of structure-activity data in IN 147, the large number of potential modifications of any exemplified compound therein, the clear preference demonstrated for compounds having hydrogens on the central phenyl ring, and the absence of any examples with an ethoxy substituent on the distal ring, one of ordinary skill in the art would not have had a reason or motivation to make dapagliflozin with a reasonable expectation of success.

xxxix. It is, thus, the case of the plaintiffs that a person of ordinary skill in the art would have to take recourse to various permutations and combinations before it could reach DAPA. This is so as the prior art i.e. IN 147 gives no indication as to which parameters are critical or even which direction if taken out of the many choices available would lead to success.

xl. The Court is required to take secondary factors also in account while appreciating the defence of obviousness. In DAPA's case, the following secondary factors need to be noticed.

A. DAPA is a drug which has attained great commercial success.

B. It is the first SGLT2 inhibitor.

C. It has been approved for treatment of hypertensive heart failure.

D. Various entities are attempting to copy the drug either by infringing or attempting to infringe the species patent

E. Had DAPA been so obvious then why is it that no other entity has been able to develop the same. [See: ***Graham vs. John Deere Co.***, 383 U.S. 1 (1966)]

xli. There is a presumption that the patent is valid having regard to its age. [See: ***Bristol-Myers Squibb Company and Ors. vs. J.D. Joshi and Ors.***, MANU/DE/1889/2015] Likewise, it is also settled law that if there is no presumption of validity, there is also no presumption of invalidity of

patent. [See: Order dated 15.03.2018, passed in CS (COMM) 737/2018, titled ***Pfizer Inc. and Ors. vs. Nagesh Palepu and Ors.***; and Judgement dated 09.07.2015, passed in CS(OS) 442/2013, titled ***Telefonaktiebolaget LM Ericsson (PUBL) vs. Mercury Electronics & Anr.***]

xlii. The assertion of the defendants that the plaintiffs have kept back information from the Controller of Patents in India concerning corresponding foreign applications filed with USPTO is incorrect. The plaintiffs have disclosed all material information with the Indian Patent Office. There has been substantial compliance with the provisions of Section 8 of the Act. This is demonstrated by having regard to the following.

A. Form 3 was filed by Bristol i.e. the erstwhile owner of the patent which was assigned to the plaintiffs only in 2014. Since then Astra Sweden has made filings under Form 3 as required under Section 8(1) of the Act on 16.11.2004, 10.01.2005, 01.09.2009 and 17.12.2009. In these forms there is a specific reference to the corresponding species patent granted in USA i.e. US 117. Insofar as the Indian Patent Office was concerned an objection under Section 8(2) of the Act was raised *via* the first examination report dated 12.10.2007. The patent office, thus, required the plaintiffs to provide details regarding corresponding patents in major patent offices. Resultantly, the plaintiffs provided documents pertaining to European Patent [EP] and the consequent grant of patent. Furthermore, the plaintiffs on their own *vide* letter dated 10.01.2005 and Form 3 filings furnished documents concerning the corresponding US patent as well. In particular, with the letter of 10.01.2005, the plaintiffs enclosed the application for US species patent i.e. US 117 along with its granted claims. This application revealed that it is a continuation-in-part of the genus patent i.e. US

126. As would be evident, all relevant information and material particulars concerning the corresponding US species patent i.e. US 117 were provided to the Indian Patent Office nearly two years before objection was raised on 12.10.2007. Thus, the assertion of the defendants that there was a concealment is not borne out from the facts on record.

B. In any case, at the highest, errors, if any, in filing can only be considered as inadvertent which perhaps occurred as an oversight. These errors cannot be construed as material suppression given the conduct of the plaintiffs. There has been no failure on part of the plaintiffs to comply with the mandatory requirement. The allegation of the defendants that there has been a failure to comply with the provisions of Section 8 of the Act is ultimately a matter of trial. [See: Judgement dated 07.11.2014, passed in FAO (OS) No. 16/2014, titled ***Maj. (Retd.) Sukesh Behl & Anr. vs. Koninklijke Phillips Electronics***; and ***F. Hoffmann La Roche Ltd. and Anr. vs. Cipla Ltd.***, MIPR 2016 (1) 0001]

xliii. According to the plaintiffs, the defendants should be denied the relief of injunction for the following reasons.

A. The defendants are either manufacturing or intending to manufacture DAPA and, therefore, infringement is admitted.

B. DAPA is a man-made drug which is used for treating not only type-2 diabetes but is also approved for treating hypertensive heart failure in 2020.

C. The species patent is an old and established patent and, therefore, carried with it the presumption of validity. This patent is in its 18th year of life cycle.

D. The species patent was subjected to examination by the Indian Patent Office for seven years i.e. between 2002 [the year of priority] and 2009 [the year of grant].

E. Both genus and species patent have not been subjected to any pre-grant or post grant opposition or even subjected to revocation proceedings up until 2020. Proceedings filed in 2020 are *mala fide*, counter-blast or peremptory strikes against patent infringement suit actions filed by the plaintiffs.

F. The defendants have not conducted any research and development and, therefore, want to piggyback the inventions of the plaintiffs concerning DAPA.

G. The plaintiffs have been selling the products under various brand names since 2015, both, directly and/or through their distributors i.e. Sun and Abbott at reasonable prices.

H. Insofar as the defendant in CS (COMM) 410/2020 is concerned, the plaintiffs have acquired knowledge from their investigator that it was planning to launch its product using the DAPA compound. Although, the defendants before this Court, on 01.10.2020, stated that they have not commenced manufacture of their drug, that may not be quite correct. The defendants being aware of the fact that the plaintiffs have been granted a patent for DAPA should have the way cleared for proceeding further with their manufacturing and/or selling activities by adopting any one of the following routes.

- Seek a voluntary license.
- Seek a compulsory license.
- Filing revocations.
- Filing a pre-grant or a post-grant opposition.
- File a declaratory action for non-infringement.

I. Likewise, the defendants at the appropriate stage could have also filed pre or post-grant opposition; a step that they did not take. [See: ***Eisai Co. Ltd. and Ors. vs. Satish Reddy and Ors.***, MANU/DE/1621/2019; and ***Merck Sharp and Dohme Corporation and Ors. vs. Glenmark Pharmaceuticals***, MANU/DE/0852/2015.]

J. For the aforesaid routes to be taken, the defendants had 15 years at their disposal since both patents were published under Section 11A of the Act in 2005. Likewise, if the date of grant is taken the defendants had available to them 13 and 11 years since the registration of the genus patent i.e. IN 147 and the species patent i.e. IN 625 respectively.

K. The plaintiffs have filed several suit actions in which interim injunctions have been granted by this court.

L. Thus, according to the plaintiffs, given what is stated above, the defendants have failed to make out a prima facie case and the balance of convenience is also titled against them.

M. Plaintiffs will suffer an irreparable loss if injunction, as prayed, is not granted as it will destroy the market for them whereas, insofar as the defendants are concerned, the launch of their product will only be postponed. Furthermore, since 3 companies i.e. Eris Life Sciences, USV and Zydus have already launched their infringing products, despite suits filed against them, which are pending adjudication, the market has already been flooded with the infringing products.

N. Besides this, medical practitioners have expressed concerns as to what would be the ultimate quality of the drug if the defendants are permitted to launch their products. Damages caused by the

infringing activity are difficult to compute in monetary terms and that in any event they are not adequate.

O. The plaintiffs have an interest in enforcing the provisions of the Act. Their victory has to be real and not pyrrhic. [See: ***Merck Sharp and Dohme Corporation and Ors. vs. Glenmark Pharmaceuticals***, MANU/DE/0852/2015]

xliv. In a nutshell, the defendants should be restrained from infringing plaintiffs' species patent i.e. IN 625 during the pendency of the suit action.

On behalf of the defendants: -

7. There were joint-arguments addressed on behalf of the defendants [to avoid overlap] not only *qua* the captioned applications, filed in the two suits referred to hereinabove, but also in I.A. No. 8791/2020, filed in CS (COMM) 407/2020, as indicated right at the outset.

7.1 The burden of the arguments, though, for the sake of convenience, on behalf of the defendants, was shared up until then by the following three counsels who appeared on behalf of the defendants i.e. Mr. C.S. Vaidyanathan, Senior Advocate, Mr. Adarsh Ramanujam and Mr. J Sai Deepak. The written submissions were also circulated by these counsels having regard to the same. Pertinently, Mr. J Sai Deepak had advanced arguments on behalf of Emcure Pharmaceuticals Limited [in short "Emcure"] in CS (COMM) No. 407/2020. Given the development, concerning CS (COMM) No. 407/2020, Mr. Vaidyanathan and Mr. Ramanujam stated that they would adopt the legal submissions made by Mr. Sai Deepak apart from what had been argued by them to avoid repetition.

8. With this preface, let me indicate the broad contours of the submissions advanced on behalf of the defendants.

i. The plaintiffs cannot be permitted to take mutually destructive pleas. The plaintiffs, having alleged that manufacture and/or sale etcetera of DAPA infringes IN 147 i.e. the genus patent, it stands to reason that the said compound stands fully and particularly described in IN 147 i.e. the genus patent; this being a mandatory requirement of Section 10(4)(a) read with Section 10(4)(c) of the Act.

ii. Strangely, when defendants cite IN 147 [i.e. the genus patent] as prior art or prior published document to invalidate the species patent [i.e. IN 625], the plaintiffs aver that DAPA, though covered/claimed, is not disclosed in IN 147 i.e. the genus patent. If this assertion of the plaintiffs is accepted, then, it is quite clear that they would fall foul of the provisions of Section 10(5) of the Act.

iii. Insofar as the defendants are concerned, since they have not manufactured DAPA [a statement which was made on the first date of hearing i.e. 01.10.2020]; there cannot be any infringement by them of IN 147 i.e. the genus patent.

iv. The plaintiffs have averred that there is a reasonable apprehension of the defendants manufacturing DAPA without producing any tenable material on record. What is, however, admitted by the plaintiffs is that the defendants have not launched their product containing DAPA. Since IN 147 i.e. the genus patent, admittedly, expired on 02.10.2020, there is no case of grant of injunction *qua* IN 147 i.e. the genus patent in the future.

v. There is no case for grant of injunction *qua* IN 625 as the defendants have raised a credible challenge as to its validity. The Statute i.e. Section 13(4) of the Act makes that amply clear. [See: ***Bishwanath Prasad Radhey Shyam vs. Hindustan Metal Industries***, (1979) 2 SCC 511]

vi. This Court should, therefore, evaluate as to whether or not defendants have established a credible challenge to the validity of IN 625. In this behalf, the defendants are only required to demonstrate that IN 625 is vulnerable to challenge and/or there is an issue which requires trial. [See: ***Hoffman La Roche vs. Cipla***, 2009 (110) DRJ 452 (DB)]

vii. IN 625 i.e. the species patent is vulnerable to challenge under the provisions of Section 64(1)(a), (e) and (f) of the Act. The test, however, to be applied *vis-à-vis* the provisions of Section 64(1)(a) and the other two sections i.e. 64(1)(e) and (f) are different. While the provisions of Section 64(1)(a) requires comparison of claims, insofar as Section 64(1)(e) and (f) are concerned, a broader assessment is to be made as to what is "publicly known or used in India" and/or what was "published in India or elsewhere".

viii. Clause (a) of subsection (1) of Section 64 of the Act was adopted from a *pari materia* provision contained in Section 32 (1) (a) of the UK Patents Act, 1949 which reads thus:

"***32. Revocation of patent by court***

(1) Subject to the provisions of this Act, a patent may, on the petition of any person interested, be revoked by the court on any of the following grounds, that is to say, —

(a)that the invention, so far as claimed in any claim of the complete specification, was claimed in a valid claim of earlier priority date contained in the complete specification of another patent granted in the United Kingdom; ...."

ix. Interestingly, while India has retained subclause (a) of subsection (1) of Section 64, in UK, in the 1977 enactment, Section 32(1) has not been retained. However, interpretation accorded by the English courts to Section 32(1)(a) is that the Court is required to assess whether the subsequent patent seeks to re-monopolise something which already stands protected. [See: ***Merck & Co (Macek's) Patent***, [1966] F.S.R. 381].

x. In this context, it is necessary to bear in mind the admissions made by the plaintiffs that DAPA is already claimed in IN 147 [See: plaint paragraphs 36 and 86 of the plaint in CS (COMM) No. 410/2020]; and statements made in the US litigation and the contents of Form 27 filed in IN 147]. Form 27 constitutes working statement which has to be read in the context of Section 146 (2) and Section 10(4)(c) of the Act.

xi. The fact that DAPA is prior claimed in IN 147 is apparent by the conduct of the plaintiffs while pursuing their patent applications before USPTO. The record would show that the plaintiffs' US patent application i.e. US 117 which is equivalent to IN 625, when objected to on the ground of prior claiming i.e. "obviousness-type double patenting", it was resolved by the plaintiffs filing a terminal disclaimer. Such a step taken by the plaintiffs would be a clue that the patentee did not consider IN 625 to be distinct from IN 147. In any case, it raises a credible challenge to the validity of IN 625 under Section 64(1)(a) of the Act.

xii. IN 625 is vulnerable to challenge also because it is anticipated by what is published or publicly known from IN 147. In this behalf, the following dates and events need to be borne in mind.

A. IN 147 was first published on 19.04.2001, whereas, the priority date of IN 625 is 20.05.2002.

B. Since the plaintiffs, while filing their specification *qua* IN 147, have claimed as also fully and particularly described the same in IN 147, DAPA would be publicly known in India. The expression "publicly known" will necessary mean that patented invention is known to persons who are engaged in the pursuit of knowledge concerning the patented product. Such persons would *inter alia* be men of science. [See:

Monsanto Company v. Coromandel Indag Products, (1986) 1 SCC 642]

xiii. The Supreme Court in ***Novartis*** case dealt with the expression "known" in the context of Section 3(d) of the Act. In that case, the Supreme Court rejected the argument that there was a dichotomy between coverage and disclosure. In that case, the Supreme Court was called upon to rule whether the salt imatinib mesylate was known in the earlier Zimmerman patent which concerned free base (Imatinib). The Supreme Court concluded that both, the free base and the salt were known from the Zimmerman patent which was a genus patent much like IN 147. The Supreme Court, therefore, upon reading the Zimmerman patent which was prior published came to determine as to what was known. The Court ruled that all molecules covered by the genus patent i.e. Zimmerman patent are or were known. Therefore, since the plaintiffs have admitted that DAPA is covered by prior patent i.e. IN 147 and assert that defendants infringe this prior patent, it undoubtedly presents a circumstance that DAPA is also known from IN 147.

xiv. Without prejudice to the contentions made hereinabove, IN 625 is also vulnerable to challenge as it lacks inventive step based on what was published or publicly known from IN 147. [In this behalf, See: Section 64(1)(f) and Section 2 (1) (ja) of the Act].

xv. Inventive step requires an assessment of two aspects as per the provisions of Section 2(1)(ja) and both aspects/conditions are conjunctive in nature. First, the invention should involve "technical advance" as compared to existing knowledge or have economic significance. Second, the invention should not be obvious to the person skilled in art. A new product, which does not involve inventive step as per the condition stipulated in Section 2 (1) (ja) and is not capable of industrial application, falls foul of Section 64 (1) (f).

xvi. The term technical advance was borrowed from German law which requires IN 625 to demonstrate technical superiority over IN 147. IN 625 does not state that DAPA is superior to the compound adverted to in IN 147 with reference to any property. [See: Toshiko Takenaka (ed.), Patent Law and Theory: A Handbook of Contemporary Research (Edward Elgar, 2008)] Importantly, for the person skilled in the art, IN 625 simply denotes that DAPA will have the same function as compounds of IN 147 i.e. SGLT2 inhibition activity.

xvii. Furthermore, IN 625 does not set out the economic significance over compounds of IN 147. Consequently, IN 625 fails the inventive step requirement as there is failure to demonstrate technical advance or economic significance which was not previously known from IN 147.

xviii. Besides this [and without prejudice to what is stated hereinabove, that is, IN 625 fails the test of inventive step], DAPA is obvious to a person skilled in art from IN 147 if the five-step analysis as laid down in ***F. Hoffman-La Roche vs. Cipla Ltd.***, 2015 (225) DLT 391 is followed.

A. Step 1 requires the identification of the person skilled in the art. Such a person would be [in the context of the present case] a person who is a PhD in medical or organic chemistry with a few years' experience in drug development. He would also be a person of ordinary creativity, although, not an automaton but at the same time would not be inventive. He would have the ability to make workshop improvement modification furthering the stage of knowledge. He will also be someone who would read all relevant literature carefully and with sufficient interest to be in a position to apply his mind to practical application. Plaintiffs have failed to identify such a person.

B. Step 2, in this case, doesn't require further enquiry as the only inventive concept is the compound DAPA.

C. Step 3 requires an input of a person skilled in the art having common general knowledge. The independent expert, in this case, Dr. Stephen F. Martin has stated that methyl and ethyl being homologues possessing similar properties can routinely involve substitution of methyl group with ethyl group in organic chemistry; being common general knowledge.

D. Step 4 involves identification of differences between inventive concepts and prior knowledge. The defendants contend that there is no difference between the two in the instant case as DAPA has been disclosed as one of the most preferred structure in IN 147 patent. This is so, in view of structure I (B) and preferred definitions of alkyl and halogen in IN 147. Alternatively, according to the defendants, the best scenario for the plaintiffs is that IN 625 differs from IN 147 on account of methyl vs. ethyl substitution or methoxy vs. ethoxy substitution when example 12 of IN 147 is compared with DAPA. However, as per the expert i.e. Dr. Martin; this is a matter of common general knowledge for the person skilled in the art and, therefore, this distinction cannot be used to justify that IN 625 involves an inventive step.

E. Step 5: To decide whether those differences viewed in the knowledge of the alleged invention constituted steps which would have been obvious to the person skilled in the art without taking recourse to hindsight wisdom.

xix. Without prejudice to the aforesaid, the plaintiffs' contention that the defendants must demonstrate as to why one must select DAPA from

infinite compounds of IN 147 or isolate example 12 as the starting point or what would motivate substitution of methyl group with ethyl group especially when there are unexpected benefits as suggested by the affidavit of Dr. Washburn, is flawed, due to the following reasons.

A. Such an argument that an inventive step arises due to a selection from purported infinite compound was rejected both in the European Union (EU) and the United Kingdom (UK) [See: ***AgrEvo UK Limited***, Case Number T 0938/92 -3.3.1 which was approved by The United Kingdom Supreme Court in ***Actavis Group PTC EHF and others vs. ICOS Corporation and another***, [2019] UKSC 15] The observation therein was that even if prior art comprises of an infinite number of starting point every such prior art is deemed to be suggestive to the person skilled in the art. It went on to state that a mere arbitrary selection of one or more compounds from a laundry list in the prior art cannot itself confer inventive step. The only exception to this is where the patentee is able to fulfil two conditions.

   - The identification/selection is based on an "unknown technical effect".

   - This unknown technical effect must be justified by difference in structure between the identified/selected compound and the rest of the molecules from the prior art.

B. IN 625 fails on both counts. It neither discloses unknown technical effect not does it justify such unknown technical effect by reference to substitution with methyl group at one location. It simply states that DAPA has the same activity/utility as the compounds of IN 147 which is a known technical effect. The

attempt of the plaintiffs to overcome this fatal error by relying on Dr. Washburn's affidavit will not shore up their case for the following reasons.

a) This affidavit was sworn in April 2020 and was placed before the Court for the first time on 12.10.2020. Dr. Washburn's affidavit did not form part of IN 625 from its inception and most certainly did not exist on its priority date i.e. 20.05.2002. This submission, though, is made dehors the stand of the defendants concerning credibility and the veracity of the data relied upon in Dr. Washburn's affidavit.

b) The plaintiffs could have relied upon such data post the priority date only if the specification itself "plausibly demonstrated" such unknown technical effect. This is so because the validity of the patent is to be assessed on its priority date. IN 625 does not state, let alone plausibly demonstrate, such unknown technical effect, on its priority date. [See: ***Generics (UK) Limited vs. Yeda Research and Development Co. Limited***, (2014) R.P.C. 4]

xx. Without prejudice to the above, it requires to be noticed that DAPA would be obvious to the person skilled in the art on account of the manner in which he would appreciate the contents of IN 147. Reliance by the plaintiffs on the judgement rendered in ***In re Petering***, 301 F.2d 676, in fact, supports the submissions of the defendants. This judgement holds that even a prior art disclosure of an infinite number of molecules would be construed by a person skilled in the art in a logical manner to filter down to a smaller class of compound if the document itself lays out series of specific preferences which allows him to envisage a smaller class of

compounds. The submissions advanced by the plaintiffs seem to suggest that a person skilled in the art does not have ordinary intelligence but is a dullard. The instant case presents, precisely, this situation which is captured in ***In re Petering***.

xxi. Without prejudice to the above, it is submitted that IN 625 is vulnerable to challenge because of the plaintiffs having breached the provisions of Section 8 of the Act and, hence, had opened IN 625 to revocation under Section 64(1)(m). The requirements of Section 8 are mandatory. The provisions of this section oblige the applicant to keep the Indian Patent Office informed about the status of all corresponding foreign patent applications, which are filed in respect of the same or substantially the same invention *qua* which patent is sought.

xxii. Under the provisions of Section 8, the applicant is required to disclose details with regard to grant, refusal or abandonment of any foreign application. Subsection (1) of Section 8 requires an applicant to file, on its own, all material particulars including office actions and examination reports issued by foreign patent offices. This obligation becomes inescapable under subsection (2) of Section 8 where the patent examiner calls for information concerning examination report and office action issued by foreign patent offices.

xxiii. In the instant case, the plaintiffs supressed the office actions/examination reports dated 30.07.2002 issued by the USPTO concerning US 117 which corresponds to IN 625. In the said examination report, the USPTO had expressly found, in relation to US 117, that the subject matter claimed therein was fully disclosed in US 126 which corresponds to IN 147. In this context, it is important to note that the plaintiffs, *via* their response dated 19.08.2002, voluntarily offered to limit the term of US 117

[equivalent to IN 625] to that of US 126 [equivalent to IN 147] which expired on 04.10.2020. The methodology adopted, which, in USA, is known as a "terminal disclaimer", prevented the rejection of application preferred for grant of US 117 on the ground of obviousness and double patenting.

xxiv. US 117 was granted on 20.09.2002 by the USPTO only upon acceptance of the terminal disclaimer offered by the plaintiffs. The plaintiffs ought to have disclosed, on their own, the said information in consonance with Section 8(1) of the Act. The plaintiffs did not do so. The plaintiffs failed to furnish this information even when the Indian Patent Office, *vide* its first examination report [FER] dated 12.10.2007, issued in relation to IN 625, sought the information. [See: Serial no. 13 of FER dated 12.10.2007] The plaintiffs, instead, furnished copies of the European patent. [See: Plaintiffs response dated 08.10.2008] The plaintiffs' response that since the patent in the USA had already been granted, there was no statutory obligation cast on them under Section 8 of the Act to submit office actions issued by USPTO, is contrary to the intent of Section 8 [See: ***Chemtura Corporation vs. Union of India (UOI) and Ors***., 2009 (41) PTC260(Del)]

xxv. The assertion of the plaintiffs that they had furnished the information concerning the corresponding US patent along with their letter of 10.01.2005 is incorrect since the said letter did not enclose either the non-final rejection letter issued by USPTO dated 30.07.2002 or the terminal disclaimer dated 19.07.2002. This omission was deliberate. The omission was material as it would have alerted the Indian Patent Office to raise a prior claiming objection which would have constrained the patentee to amend IN 625 to a patent of addition under Section 54 of the Act. In other

words, IN 625 would, then, have a validity period which would terminate with the tenure of IN 147 i.e. 02.10.2020.

xxvi. The submission advanced on behalf of the plaintiffs that termination disclaimer is only an obviation and not an admission of obviousness/double patenting based on the judgement rendered in ***Quad Environment vs. Union Sanitary***, 946 F2d 870 does not appear to be in line with the current thinking in USA. [See: ***Festo Corp. vs. Shoketsu Kinzoku***, 535 U.S 722 (2002); and **SimpleAir, Inc. vs. Google LLC**, Appeal Number: 16-2738, United States Court of Appeals for the Federal Circuit].

xxvii. The admissions made in the plaint, in at least 18 paragraphs, i.e. paragraph numbers 2, 3, 16, 22, 26, 28, 53, 54, 56, 70, 71, 73, 76, 77, 79, 83, 84, 87, 88 and the prayer clause [i.e. 101] that DAPA is covered by both suit patents would propel the Court to dismiss the interlocutory application in view of the express language of Section 53(4) and Section 13(1)(b) and Section 64(1) of the Act. In support of this plea, that is, DAPA is covered by the claims made in the genus patent i.e. IN 147 reference is also made to Form 27 filed by the plaintiffs between 2015-2019 with the Indian Patent Office in relation to IN 147. Form 27 supports the plea of the defendants that even according to the plaintiffs DAPA is covered by IN 147.

xxviii. Besides this, a perusal of PTE applications dated 06.03.2014 filed for the corresponding patents i.e. US 117 and US 126 would show that the plaintiffs have identified the "approved product" for which the PTE was being sought as Farxiga [the generic name being DAPA]. It is emphasised that while PTE of US 117 was filed by the plaintiffs, the similar application i.e. PTE dated 06.03.2014 *qua* US 126 was kept back.

xxix. In this context, it was submitted that the PTE filed in respect of US 126 *inter alia* states at internal page 12 that claims 1-8 and 14-28 "read on" the product DAPA. This clearly demonstrates that even according to the plaintiffs DAPA is covered by US 126 and, therefore, is also covered by Indian genus patent i.e. IN 147. It is in the backdrop of these PTE applications that USPTO required the plaintiffs to elect, between one of the two patents for grant of PTE *vide* its final notice of election dated 15.06.2020. The record would show that on 10.07.2020 plaintiffs elected US 117 and, therefore, US 117 was granted PTE. It is also relevant to note that before US FDA, *qua* US 126 along with other US patents, the plaintiffs have stated that it covers DAPA which, by logical corollary, would also stand covered by IN 147.

xxx. In this context, it is important to note the plaintiffs stand *vis-à-vis* an entity going by the name Zydus Pharmaceuticals USA, in an action filed by them against the said entity in the District Court of Delaware, wherein, one of the patents asserted was US 126 [equivalent to IN 147]. In paragraphs 28, 29, and 31 to 33 of the complaint which was the subject matter of the aforementioned action, it is averred that Zydus Pharmaceutical USA's application to the US FDA to market DAPA tablets would infringe at least claims 1 and 26 of US 126 if approval is granted before the expiry of the said patent. It is important to bear in mind that Claim 1 of US 126 is identical to Claim 1 of IN 147 and claim 26 of IN 147 claims the same structure as Claim 27 of US 126.

xxxi. Given these admissions, not only should the interlocutory application be dismissed but also the suit as no trial would be required. These admissions trigger the bar contained in Section 53 (4) of the Act which *inter alia* states that on expiry of the term of the patent, the subject matter covered by the said patent shall not be entitled to any protection. The

admissions in the plaint and other documents show that DAPA is covered by IN 147 which expired on 02.10.2020 and, therefore, no further protection can be given to DAPA through the route of the species patent i.e. IN 625.

xxxii. Section 53(4) which was introduced in the Act pursuant to the 2002 amendment sought to protect abuse by the patentee of its monopoly rights by resorting to double patenting. It is in this context that extension of protection of subject matter which is covered by an expired patent is not countenanced by the Statute.

xxxiii. Section 53(4) along with Section 107A of the Act was introduced to balance the interest of public in lieu of extension of patent term to 20 years for patents across the board for all inventions. Section 107A, in this spirit, facilitates timely entry of generic drugs by exempting certain activities such as research and development and obtaining regulatory approvals from the pale of infringement actions. The purpose being that manufacturers of generic drugs should be in a position to commence their activities immediately upon the expiry of the patent in the interest of the public at large. These statutory safeguards were put in place to balance its international commitment under the Agreement on Trade-Related Aspects of Intellectual Property Rights [in short "TRIPS agreement"] as against India's obligation to protect the health of its citizens. [See: Doha declaration on the TRIPS agreement and Public Health dated 14.11.2001].

xxxiv. In this context, it was emphasized that when Section 13(1)(b) is read with Section 64(1)(a) of the Act, it would show that it allows the examiner to invoke anticipatory prior art even where the claim made in another complete specification filed in India is dated before or has a priority date

earlier than the patent application placed before him for examination to ascertain whether the invention of the subject matter is the same.

A. In other words, unlike other grounds of anticipation which require prior publication of documents sought to be used as anticipatory prior art Section 13(1)(b) makes an exception. There is, in fact, no statutory exception or defence provided to anticipation by prior claiming. Therefore, once it is established [and, in this case, admitted by the plaintiffs] that DAPA is covered by the claims of genus patent IN 147, the plaintiffs cannot be heard to say that anticipation by prior claiming is not established under Section 64(1)(a) of the Act since DAPA, while being covered by the claims of IN 147 only because it is not disclosed by the said patent.

B. It is important to note that for a defendant to establish prior claiming, it is not important to show that the prior art contained in the prior patent is identical to the impugned claim in the impugned patent. All that the defendant has to establish is that the subject matter claimed that the impugned patent falls within the scope or is covered by the prior claim of the prior patent. In the facts of the instant case since the prior claim of IN 147 such as 1, 14 to 26 being broader, encompass within their scope, the entire principal claim of the impugned patent i.e. IN 625, it renders the entire principal claim of IN 625 vulnerable to revocation.

C. Significantly, Section 64(1)(a) read with Section 13(1)(b) of the Act only requires coverage of the subject matter by a prior claim, there being no requirement of disclosure whatsoever. This, though, is without prejudice to the submission of the defendants that DAPA is, in fact, disclosed in IN 147. If this position is held to be true,

then, the stand taken by the plaintiff that DAPA is covered but not disclosed will not help its cause. In this regard, it has to be borne in mind that Section 11 of the Act requires that every claim of a patent is based on a matter which is fairly disclosed.

xxxv. In the instant case, preferred embodiments leading to DAPA form structure claimed in claims 1, 14, 15 and 26 are expressly set out in internal pages 29 and 33 of the complete specification of IN 147 wherein ethyl for the alkyl group and chlorine for halogen are specifically captured as most preferred embodiments. Therefore, not only is DAPA covered by claims of IN 147, as is admitted by the plaintiffs, the said claims are, as indicated above, supported by the disclosure of the specification.

xxxvi. IN 625 is also vulnerable on the ground of prior publication. This is evident if one were to read section 64(1)(e) along with Section 13(2) of the Act. In the instant case, IN 625 is liable to be revoked on the ground of lack of novelty due to prior publication of WO2001/27128 [in short "WO'128"] which is the PCT equivalent of the genus patent IN 147. WO'128 was published on 19.04.2001 whereas the priority date of IN 625 admittedly is 20.05.2002.

xxxvii. A careful perusal of WO'128 with IN 625 would show that the written description qua the background of respective purported inventions is identical. A perusal of the detailed description of two documents would also show that in large swathes they are identical and is, therefore, a classic case of cut, copy, paste. Besides this, the description of preferred embodiments substituents possible combinations with other pharmaceutical ingredients and suggestive doses are all identical. What is ironical and also similar is: that there is a complete absence of any

example concerning actual pharmaceutical formulation containing purportedly novel compounds in either document. There is, in both documents, a complete absence of any data relating to efficacy let alone significant enhancement of efficacy or indeed any activity whatsoever.

xxxviii. The balance of convenience is in favour of the defendants since they would be manufacturing their drug in India which would generate employment and align with the policies of Government of India i.e. Make in India. The plaintiffs, on the other hand, would be importing their product for marketing in India.

xxxix. The plaintiffs are guilty of misrepresentation and concealment. The plaintiffs have concealed relevant facts from the Indian Patent Office at the time of filing patent application for IN 625 including the following.

- The plaintiffs already hold a valid patent which discloses the sale compound i.e. DAPA;
- As per the plaintiffs' own admission, IN 625 is part of a catalogue of patents including IN 147, therefore, it was incumbent on the plaintiffs to disclose the same to the examiner
- The Plaintiffs have failed to disclose material particulars of their corresponding US patents which is violative of Section 8(2) of the Act.
- The plaintiffs failed to disclose the non-final rejection letter issued by USPTO dated 30.07.2002 and the terminal disclaimer dated 19.07.2002 field in response thereto to the said objection.

xl. The plaintiffs have failed to demonstrate irreparable injury. Irreparable injury is understood to be an injury which is not monetarily compensable.

There is no presumption *qua* irreparable injury where the validity of a patent has not been tested in litigation. [See: ***Nutrition 21 vs. The United States of America***, US 930 F.2d 867] This principal is important for cases in India as there is no presumption of validity in India as provided in Section 13(4) of the Act.

xli. There are at least two entities i.e. Sun and Abbott which have obtained a license *qua* IN 625. The packaging of the two products which are used by Sun and Abbott establish this fact. Therefore, the plaintiffs, clearly, have not sought market exclusivity but have shown willingness to monetise the patent *via* licensing. The logical sequitur of this would be that the royalty payable by the aforementioned licensees could provide a reasonable basis to assess the damages if the plaintiffs were to finally succeed in the instant actions. [See: ***Polymer Technologies, Inc. vs. Bridwell***, 103 F.3d 970, 974 (Fed.Cir.1996); ***T.J. Smith and Nephew Ltd. vs. Consolidated Medical Equip. Inc.***, 821 F.2d 646; and ***Dynamic Mfg. Inc. vs. Craze***, No. 97–1165, 1998 WL 241201]

xlii. The defendants being large enterprises who possess financial wherewithal and are not fly by night operators would be able to pay damages if proved under the law.

xliii. Furthermore, without prejudice to the contentions made hereinabove, interim injunction ought to be denied to the plaintiffs given the considerations of the public interest.

xliv. The plaintiffs and their aforementioned licensees [i.e. Sun and Abbott] are marketing DAPA under various brand names such as FORXIGA, XIGDUO, OXRA, GLADEPA and various fixed dose combinations at Rs. 54.4 for a 5-milligram dose and Rs. 57.29 for a 10-milligram dose. Thus, a strip of 14 tablets would cost, *qua* the aforesaid dosages, between

Rs. 761.60 and Rs. 802.90 respectively. The cost per patient *vis-à-vis* plaintiffs' drug in the market would range approximately between Rs. 1523.20 and Rs. 1605.80. As against this, the defendants propose to sell their drugs for Rs. 13.90 for 5-milligram and Rs. 17.50 for a 10-milligram dose. Thus, a strip comprising of 14 tablets would have a price range of Rs. 194.60 and Rs. 245 respectively. Thus, the drugs manufactured by the defendants would lay a financial burden on a patient that would range between Rs. 490 and 554.50 per month. The difference in percentage would be approximately 250%.

xlv. More importantly, in the present times when the Coronavirus pandemic is prevalent, the probability of a diabetic person being afflicted with the virus is exponentially high.

Rejoinder arguments on behalf of the plaintiffs: -

9. In the rejoinder, the plaintiffs were led by Mr. Harish Salve, learned senior counsel, who addressed arguments, in some detail, with regard to two aspects:

a. First, the true and correct ratio of the ***Novartis*** judgement.

b. Second, the applicability of Section 53(4) of the Act to the instant case.

10. In respect of the first aspect, Mr. Salve drew my attention to various paragraphs of the ***Novartis*** judgement to demonstrate that the said judgement concerned, essentially, the applicability and interpretation of Section 3(d) of the Act [along with the explanation appended thereto] in the context of facts obtaining in that case. It was sought to be pointed out by Mr. Salve that Novartis before the Supreme Court had *inter alia* contended that beta crystalline imatinib mesylate was a new invention *qua* which there were no teachings in the earlier patent i.e. the Zimmerman patent.

10.1 It was pointed out that Novartis had argued that while imatinib-in-free-base was claimed in the Zimmerman patent, there were no teachings in the Zimmerman patent on how to prepare imatinib mesylate from the former and that there was no mention of polymorphism or crystalline structure in the said patent.

10.2 Mr. Salve endeavoured to demonstrate that it was, in this context, that one of the arguments, which was advanced on behalf of Novartis was that while imatinib mesylate was covered by the Zimmerman patent, it was not disclosed therein and that coverage or claim in a patent was distinct from the disclosure made in a patent.

10.3 In other words, the boundary laid out by the claim for coverage is permitted to be wider than disclosure or enablement or teaching in a patent. It was sought to be pointed out that in ***Novartis*** case, on facts, the Supreme Court found that the US Board of Patent Appeals had noticed that the Zimmerman patent taught the person skilled in the art how to use imatinib – a compound of formulae 1 or a pharmaceutically acceptable salt thereof in a pharmaceutical composition for treating tumours or a method of treating warm-blooded animals suffering from a tumoral disease.

10.4 Apart from this, as pointed out by Mr. Salve, the Supreme Court had also noticed the fact that in an article published in a journal going by the name Cancer Research and Nature Medicine [which was co-authored by several persons including Jurg Zimmerman], there was a detailed discussion about anti-tumoral properties of imatinib and its methanesulfonate salt i.e. imatinib mesylate. My attention was drawn also to the fact that the Court noticed yet another article published in the aforementioned journal in which there was a discussion about imatinib designed to inhibit Abl Protein-Tyrosine Kinase in Vitro and in Vivo by a 2-phenulaminopyrimidine derivative.

10.5 Mr. Salve, thus, submitted that it was in this background that the Supreme Court concluded that imatinib mesylate was not a new product and that it was a known substance seen in the Zimmerman patent. Furthermore, Mr. Salve pointed out that the Supreme Court said that for imatinib mesylate to be construed as a new product i.e. an invention it should have features which involved technical advance over existence knowledge and would make invention not obvious to the person skilled in the art.

10.6 In short, Mr. Salve submitted that the observations made in paragraphs 118 and 119 of the ***Novartis*** case concerning coverage and disclosure have to be understood in this context. According to Mr. Salve, what was emphasized was that Novartis was not able to prove *inter alia* therapeutic efficacy of its claimed invention. It was emphasized that what the Court disapproved was, perhaps, clever drafting of descriptions and specifications which, then, are used as a ploy to extend the validity period of the patent.

10.7 According to Mr. Salve, the Court did not do away with the Markush structure which is what the plaintiffs are relying upon in the instant case and that this aspect is evident if one were to carefully peruse the observations made in paragraph 134 of the ***Novartis*** case.

10.8 As regards, Section 53(4) of the Act, Mr. Salve contended that it had no application to the facts obtaining in the instant case.

11. Mr. Sudhir Chandra, learned senior counsel, in rejoinder, concentrated on the aspects concerning balance of convenience apart from what was stated in the opening by him which was recorded in my order dated 01.10.2020.

12. Mr. Anand also made submissions in rejoinder and submitted an additional note of written submissions to counter the arguments raised by the defendants and also distinguish the judgements cited by the defendants in

support of their case.

Analysis and reasons: -

13. I have heard the matter, at some length, on 9 dates running into several hours. Counsels on both sides have relied upon a plethora of documents, pleadings, written submissions and judgements in support of their respective stand. I have attempted to capture the significant parts of the submissions advanced on both sides.

13.1 To my mind, what is important, at this juncture, is to bear in mind the stage of the proceedings and, therefore, contextualise the submissions and pleadings bearing this aspect in mind.

14. Given this backdrop, let me begin by noticing certain facts over which there is no dispute.

i. First, the actions concern two patents i.e. the genus patent i.e. IN 147 and the species patent i.e. IN 625.

ii. Second, the aforementioned patents have corresponding patents in the USA i.e. US 126 [which is the genus patent] and US 117 [which is the species patent]

iii. Third, the Indian genus patent i.e. IN 147 expired on 02.10.2020.

iv. The Indian species patent i.e. IN 625 expires on 15.05.2023.

v. The prayers made in the suit actions including the captioned interlocutory applications seek injunction against purported infringement of not only IN 147 but also of IN 625. The suit actions were filed on 30.09.2020 i.e. two days prior to expiry of validity period of IN 147 which, as indicated above, ended on 02.10.2020.

vi. Before the USPTO, the plaintiffs filed a terminal disclaimer which, in sum, meant that the validity period of the corresponding US patent i.e.

US 126 [US genus patent] and US 117 [US species patent] would end on the same date. The terminal disclaimer was filed by the plaintiffs as an objection had been raised by the USPTO *qua* non-obviousness/double patenting. The plaintiffs, of course, claim that such applications are filed in the normal course in the USA to obviate objections raised by the USPTO and that this step cannot be construed as an admission of the objection *qua* obviousness and double patenting raised by USPTO.

vii. Apart from the plaintiffs, DAPA is being marketed with the permission of the plaintiffs by two entities namely Sun and Abbott. The brand names, under which DAPA is being marketed, are FORXIGA, XIGDUO, OXRA, GLADEPA. The defendants claim that Sun and Abbott are plaintiffs' licensees whereas the plaintiffs assert that these entities are only their distributors. This fact is noted only in the context of the argument advanced that damages if any caused, are compensable. This aspect of the matter will be discussed by me in the latter part of the judgement.

15. Thus, given the aforesaid broad points of reference, it would be important to deal, in the very first instance, with the issue as to whether or not, at this stage, I am required to ascertain the validity of IN 625 by conducting a mini-trial. In other words, would it suffice from the defendants' point of view, given the fact that the actions are at the stage where the plaintiffs are seeking a preliminary injunction, to demonstrate that they have raised a credible challenge to IN 625?

15.1 In this context, on behalf of the defendants, it was argued that a patent is valid only till such time it is challenged and, therefore, there is no presumption as to its validity. It was emphasized that a challenge could be raised both, at the pre and post-grant of a patent, and also by way of revocation or counter-claim.

15.2 The plaintiffs, on the other hand, have sought to bring to fore the fact that

because there has been no challenge to the suit patents either by way of pre or post-grant challenge or even by way of revocation or counter-claim, up-until 2020, is the very reason why this Court should not countenance arguments which seek to raise doubts *qua* the validity of the suit patents.

15.3 The plaintiffs argue that although given the scheme of the Act, there are various stages at which validity of a patent can be challenged, it does not follow that there is a presumption as to the invalidity of the patent. Mr. Chandra, in this context, had cited the following judgements.

a) Order dated 15.03.2018, passed in CS (COMM) 737/2018, titled ***Pfizer Inc. and Ors. vs. Nagesh Palepu and Ors.***; and
b) Judgement dated 09.07.2015, passed in CS(OS) 442/2013, titled ***Telefonaktiebolaget LM Ericsson (PUBL) vs. Mercury Electronics & Anr.***

16. Given the arguments and counter-arguments, it would be helpful if one were to look to the scheme of the Act.

16.1 Section 25(1) accords leeway to oppose grant of a patent once an application for the said purpose has been published. The grounds on which opposition can be filed are set out in subclause (a) to (k) of Subsection (1) of Section 25 of the Act.

16.2 Subsection (2) of Section 25 of the Act allows a person who is interested in opposing the patent granted by the Controller by giving notice to him in the prescribed manner on one or more grounds referred to in clause (a) to (k) of the said subsection. However, the notice of opposition has to be given at any time after the grant of the patent but before the expiry of the period of one year from the grant of the patent. Pertinently, both under subsection (1) and (2), the grounds of opposition are restricted to those referred to in the respective sub-clauses.

16.3 Section 48 sets out the rights of the patentee subject to other provisions

contained in the Act and conditions specified in Section 47. The section, broadly, gives a right of exclusivity to the patentee whereby he can exclude third parties from acts of making ["act of using" in a process patent], using, offering for sale, selling or importing for the purposes indicated herein before, that product ["that process" in the case of process patent] in India as long as they do not have the consent of the patentee.

16.4 Section 64 of the Act confers a right revocation of a patent. Thus, any person interested [or the Central Government] can seek revocation of a patent by either moving the appellate board constituted under the Act or by filing a counter-claim in an infringement suit filed before the High Court. This apart, Section 105 confers an independent right to file a declaratory suit for non-infringement.

16.5 Pertinently, the grounds of revocation are set out in subclause (a) to (q) of subsection (1) of Section 64 of the Act. Besides this, there are special provisions for seeking revocation of patent or amendment of complete specification conferred on the Central Government in matters relating to atomic energy.

16.6 Likewise, Central Government can also seek revocation of a patent in the public interest if it believes that the patent or the mode in which it is exercised is mischievous to the State or generally prejudicial to the public, *albeit*, after giving the patentee an opportunity of being heard in the matter.

17. Therefore, what is clear [and something which is conceded by both sides as noticed above], a challenge can be laid either at the stage when an application is moved for grant of a patent, *albeit*, after its publication or after its grant, although, within the timeframe provided in the relevant provision or even by seeking revocation by moving the appellate board or by way of a counterclaim in the infringement suit.

18. All this, points in the direction that the interested third parties can lay challenge to an invention which is the subject matter of either the patent application or the patent at various stages. The clearest indication of the

legislative intent is embedded in subsection (4) of Section 13. Section 13 is a provision which empowers the examiner before whom an application for grant of patent is placed to make investigations to ascertain if a patent is anticipated by previous publication and/or by a prior claim.

18.1 In this context, subsection (4) makes it clear that examination and investigations required under Section 12 or Section 13 shall not be deemed, in any way, to warrant *inter alia* the validity of the patent. In other words, even when the patent crosses the threshold of examination by the patent office, it does not, as per the Statute, warrant its validity. Therefore, quite clearly, irrespective of when the challenge is laid, the challenger [i.e. the person interested] can put the patent in jeopardy. [See: ***Bishwanath Prasad Radhey Shyam vs. Hindustan Metal Industries***[1], (1979) 2 SCC 511]

18.2 Thus, till the time the patent is invalidated i.e. revoked, the patentee has the right to exclude third parties. Therefore, the observations made in ***Pfizer Inc. and Ors.*** case and ***Telefonaktiebolaget LM Ericsson (PUBL)*** case cannot, in my view, be read in a manner whereby they roil against express provisions of the statute.

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

i. First, there is a period of overlap between the genus patent i.e. IN 147 and the species patent i.e. IN 625. The defendants, in this case, chose

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[1] This extract is taken from ***Bishwanath Prasad Radhey Shyam vs. Hindustan Metal Industries***, (1979) 2 SCC 511 at page 521.

"***32.*** *It is noteworthy that the grant and sealing of the patent, or the decision rendered by the Controller in the case of opposition, does not guarantee the validity of the patent, which can be challenged before the High Court on various grounds in revocation or infringement proceedings. It is pertinent to note that this position viz. the validity of a patent is not guaranteed by the grant, is now expressly provided in Section 13(4) of the Patents Act. 1970. In the light of this principle, Mr Mehta's argument that there is a presumption in favour of the validity of the patent, cannot be accepted.*"

to wait [in line with arguments advanced in their defence of the suit actions] till such time the validity period of the genus patent i.e. IN 147 expired.

ii. Second, as indicated above, the scheme of the Act does not foreclose the right of the defendants in defence to an infringement action to question the validity of the patent. Section 107 of the Act, expressly confers a right on the defendants to raise, in defence, in an infringement suit, all those grounds on which the patent can be revoked under Section 64 of the very same Act. Therefore, the judgement in ***Bristol-Myers Squibb Company and Ors vs. J.D. Joshi and Ors.***, MANU/DE/1889/2015, if read in context, would demonstrate that it has not emasculated the right of the defendant, as conferred under the Act, to challenge the validity of the patent. The presumption of validity exists only till such time the patent is challenged - a challenge which is credible and no further. In my opinion, if the plaintiffs' argument was to be accepted, then, it would have to be held that the older the patent, the stronger the firewall. Such an interpretation, in my view, would be contrary to the plain words of the Statute.

19. The next question which arises for consideration is: at the stage of preliminary injunction, what is the threshold that the challenger has to meet? In other words, is the challenger required to demonstrate that the patent is invalid or is the challenger required to establish that the patent is vulnerable and that the validity is not vexatious.

19.1 This issue came up for consideration before a Division Bench of this Court in ***F. Hoffmann-LA Roche Ltd. & Anr. vs. Cipla Ltd.***, 2009 (110) DRJ 452 (DB), wherein, the Court clearly set out the judicial standard which ought to operate at the preliminary injunction stage. The Court, in no uncertain terms,

stated that validity of a patent is required to be looked at the stage of trial.

19.2 However, at the stage of preliminary injunction all that the defendant is required to demonstrate is that she/he has made a credible challenge or that the patent is vulnerable and that validity is not vexatious. The relevant observations made by the Division Bench in this behalf are extracted hereafter.

> "***53***. ***The plea of the plaintiff that since there is a multi-layered, multi-level examination of the opposition to the grant of patent it should accorded the highest weightage, is not entirely correct***. *The contention that there is a heavy burden on the defendant to discharge since it has to establish that it has a stronger prima facie case of the plaintiff is contra indicated of the decisions in the context of Section 13(4). Reference may be made to the decisions in Biswanath Prasad Radhey Shyam v. Hindustan Metal Industries, AIR 1982 SC 1444 : PTC (Suppl)(1) 731 (SC), Standipack Pvt. Ltd. v. Oswal Trading Co. Ltd., AIR 2000 Del 23 : 1999 PTC (19) 479 (Del), Bilcare Ltd. v. Amartara Pvt. Ltd., 2007 (34) PTC 419 (Del), Surendra Lal Mahendra v. Jain Glazers, (1979) 11 SCC 511. In Beecham Group Ltd. v. Bristol Laboratories Pty Ltd., (1967-1968) 118 CLR 618 and Australian Broadcasting Corporation v. O'Neill, (2006) 229 ALR 457 it was held that the defendant alleging invalidity bears the onus of establishing that there is "a serious question" to be tried on that issue. In Hexal Australai Pty Ltd. v. Roche Therapeutics Inc., 66 IPR 325 it was held that where the validity of a patent is raised in interlocutory proceedings, "the onus lies on the party asserting invalidity to show that want of validity is a triable question." In Abbot Laboratories v. Andrx Pharmaceuticals Inc. (decision dated 22nd June 2006 of the U.S. Court of Appeals for the Federal Circuit 05-1433) the Court of Appeals followed its earlier ruling in Helifix Ltd. v. Blok-Lok Ltd. 208 F.3d 1339 where it was held (at 1359): "**In resisting a preliminary injunction, however, one need not make out a case of actual invalidity. Vulnerability is the issue at the preliminary injunction stage, while validity is the issue at trial. The showing of a substantial question as to invalidity thus requires less proof than the clear and convincing showing necessary to establish invalidity itself." (emphasis supplied) In Erico Int'll Corprn v. Vutec Corprn (U.S. Court of Appeals for the Federal Circuit, 2007-1168) it was held that the "defendant must put forth a substantial question of invalidity to show that the claims at issue are vulnerable.**"*
>
> ***54.*** *In the present case, the grant of a patent to the plaintiffs for Erlotinib Hydrochloride as a mixture of Polymorphs A and B will not ipso facto entitle them to an interim injunction if the defendant is able to satisfy the court that there is a serious question to be tried as to the validity of the patent.* ***The use by the learned Single Judge of the expressions "strong credible challenge", "arguable case" or that the defendants claim being not unfounded, cannot be termed as vague and inconsistent since they convey the same meaning in the context of the strength of the defendant's challenge***.
>
> ***55.*** *The question before this Court is when can it be said that the defendant has raised a credible challenge to the validity of a patent held by the plaintiff in an infringement action? During the course of the argument it was suggested by counsel that the challenge had to be both strong and credible. Also, the defendant resisting the grant of injunction by challenging the validity of the patent is at this stage required to show that the patent is "vulnerable" and that the challenge raises a "serious substantial question" and a triable issue. Without indulging in an exercise in semantics, the Court when faced with a prayer*

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

[Emphasis is mine]

19.3 This view has been reiterated in ***Natco Pharma vs. Bear Healthcare LLC***, 2019 80 PTC 131 [See: paragraphs 17 to 21]; and ***Natco Pharma vs. Bristol Myers Squibb Holding***, 263 (2019) DLT 622 [See: paragraphs 34 and 35].

19.4 The reliance by the plaintiffs on ***Telefonaktiebolaget LM Ericsson (PUBL)*** case is, in my view, misplaced as that case concerned decision on the issue as to which of the contesting parties should be burdened with proving a particular issue. Interestingly, the Court, while distinguishing the judgement rendered in ***TEN XC Wireless Inc. & Anr. vs. Mobi Antenna Technologies (Shenzhen) Co. Ltd.***, 2011 SCC OnLine Del 4648 : (2012) 187 DLT 632 made the following observations.

10. Reliance on Bishwanath (supra) and Ten XC Wireless (supra) by the learned counsel for the defendants is also misplaced. In fact, Bishwanath was premised on Section 13(4) of the Patents Act, according to which there is no presumption of validity of a patent only to the extent that no liability shall be incurred by the Central Government or any other officer thereof in connection with the grant of patent. ***In Ten XC Wireless, no presumption was drawn in favour of the patent only for the purposes of an interim injunction and not for onus of proof****.*

[Emphasis is mine]

19.5 Likewise, a perusal of the order in ***Pfizer Inc. and Ors.*** case shows that the defendants in that case did not make any submission as to how the challenge raised by them *qua* the patent-in-issue was credible. It is in this context, that the Court granted the injunction. Pertinently, this order was passed when the suit

was listed for issuance of summons and notice in the interlocutory application. The defendants, obviously, at that stage had no chance of showing to the Court that there was a credible challenge to the patent-in-issue. The Court left that window open by observing as follows.

> "*... Of course, this would not debar the defendants to raise a substantial, tenable and credible challenge in its pleading.*"

19.6 This judgement is distinguishable as in the instant suit actions the defendants have raised a credible challenge as discussed hereafter.

19.7 Similarly, ***J.D. Joshi*** case is distinguishable as the Court came to a *prima facie* conclusion that the plaintiffs had a valid patent and the defences raised did not enable it, at that juncture, to doubt the validity of the patent. [See: paragraph 88 in ***J.D. Joshi***] Such is not the position in the present case.

ARE THE SUIT PATENTS VULNERABLE?

20. The challenge to the species patent i.e. IN 625 is, broadly, laid on the following five grounds.

i. First, since IN 147 expired on 02.10.2020 and according to the admissions made by the plaintiffs in various paragraphs of the plaint that DAPA is covered in the suit patents, in particular, in the genus patent i.e. IN 147, it cannot be protected in terms of Section 53(4) of the Act.

ii. Second, IN 625 is vulnerable to revocation under Section 64(1)(a) read with Section 13(1)(b) of the Act on the ground of lack of novelty in view of prior claiming by the genus patent i.e. IN 147.

iii. Third, IN 625 is vulnerable to revocation under Section 64(1)(e) of the Act on the ground of lack of novelty due to prior publication of WO'128 which is the PCT equivalent of the genus patent i.e. IN 147.

iv. Fourth, IN 625 is vulnerable to revocation under Section 64(1)(f) of the Act as it lacks inventive step as provided in Section 2 (1) (ja) i.e. lacks

technical advance or economic significance and is obvious to a person skilled in the art.

v. Lastly, IN 625 is vulnerable to revocation under Section 64(1) of the Act in view of the failure of the plaintiffs to make full and fair disclosure as required under Section 8 of the Act.

21. Insofar as the first aspect is concerned, let me quote the relevant extracts from some of the paragraphs in the plaint.

CS (COMM) 410/2020

"*16. The Plaintiffs' suit patents IN 205147 [genus patent] and IN 23 5 625 [species patent]* ***cover*** *the Plaintiffs' drugs comprising inter alia its invention DAPAGLIFLOZIN, which are made available by the Plaintiff under the brands FORXIGA, XIGDUO, XIGDUO XR, XIGDUO IR, QTERN.*

xxx **xxx** **xxx**

V. THE PLAINTIFFS' SUIT PATENTS

22. ***DAPAGLIFLOZIN falls within the scope of the Plaintiffs Indian Patent Numbers IN 205147; IN 235625****. …*

36. 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 which specifically claims said compound as well as pha11naceutically acceptable salts, stereoisomers, or prodrug esters thereof. Further, claim 2 of the suit paten t IN '625 claims pharmaceutical 32 compositions prepared using DAP AGLIFLOZIN. The Plaintiffs have filed a copy of the complete specification and granted claims of IN '625 in the present proceedings and are not extracting the above claims for the sake of brevity.*"

[Emphasis is mine]

21.1 There are several other paragraphs, for instance, paragraphs nos. 56 and 86 of the plaint filed in CS (COMM) 410/2020, wherein, a similar averment has been made by the plaintiffs.

21.2 The fact that IN 147 has been worked commercially in India cannot be disputed if one were to peruse Form 27 filed by the plaintiffs in consonance with the provisions of Section 146(2) read with Rule 131 of The Patent Rules, 2003 [in short "Rules"].

21.3 The fact that PTE applications were moved for the extension of the term

of US 117 is not in dispute. It is not in dispute that both applications concerned the drug Farxiga which is the brand name for the compound DAPA. The documents on record show that the USPTO informed the plaintiffs *via* AstraZeneca Medimmune through "notice of final determination and requirement for election" that they needed to elect one of the two PTE's. The relevant extract from the aforementioned communication is set forth below.

> "*ASTRAZENECA MEDIMMUNE*
> *One Med.Immune Way*
> *Gaithersburg MD 20878*
>
> *In Re: Patent Term Extension*
> *Application for*
> *U.S. Patent No. 6,515,117*
> *June 15, 2020*
>
> *A determination has been made that U.S. Patent No. 6,515,117, claims of which cover the human drug product and methods of using the human drug product known by the tradename* ***FARXIGA~ (dapagliflozin)****, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 5 years.*
>
> **xxx xxx xxx**
>
> *Applicant also has applied for patent term extension of U.S. Patent No. 6,414,126 based on the regulatory review period for the human drug product,* ***FARXIGA® (dapagliflozin)****, of NDA 202293.*
>
> *When patent term extension applications are filed for extension of the terms of different patents based upon the same regulatory review period for a product, the certificate of extension is issued to the patent having the earliest date of issuance unless applicant elects a different patent. In the absence of an election by applicant within one month of the date of this notice, and in accordance with 37 CFR L785(b), the application for patent term extension in the above-identified patent will be denied. Accordingly, the application for patent term extension of the patent having the earlier date of issuance will be granted. A certificate of extension will be issued to U.S. Patent No. 6,414,126, for 5 years. In the absence of such request for reconsideration and if U.S. Patent No. 6,515.117 is elected, the Director will issue to the applicant a certificate of extension, under seal, for a period of 5 years in U.S. Patent No. 6,515, 117.*
>
> **xxx xxx xxx**
>
> *Upon issuance of the certificate of extension, the following information will be published in the*
> *Official Gazette:*
> *U.S. Patent No.: 6,515,117*
> *Granted: February 4, 2003*
> *Original Expiration Date2: October 4, 2020*
> *Applicant: Ellsworth et al.*
> *Owner of Record: AstraZeneca AB*
> *Title: C-Aryl Glucoside SGL T2 Inhibitors and Method*
> *Product Trade Name: FARXIGA® (dapagliflozin)*
> *Term Extended: 5 years*

Expiration Date of Extension: October 4, 2025"

[Emphasis is mine]

21.4 It is in response to the aforesaid notice that election was made seeking an extension of US patent 117 from the date of its expiration which was 04.10.2020 for 5 years i.e. till 04.10.2025. The response gave up the request made in the PTE application filed *qua* US patent 126. This is evident from the following extract taken from the communication issued in that behalf.

"***RESPONSE TO NOTICE OF FINAL DETERMINATION AND REQUIREMENT FOR ELECTION***

In response to the Notice of Final Determination and Requirement for Election dated June 15, 2020, pursuant to 35 U.S.C. § 156(c)(4), ***Applicant hereby elects the Certificate of Extension to be issued to U.S. Patent No. 6,515,117 for a period of 5 years from the date of expiration and not for U.S Patent No. 6,414,126 in connection*** *with the patent term extension filed for the approved pharmaceutical product* ***FARXIGA® (dapagliflozin)****.*"

[Emphasis is mine]

21.5 Likewise, in an infringement action filed against Zydus Pharmaceuticals (USA) Inc., in the US district court for the District of Delaware, *inter alia* assertions have been made by Astra Sweden that grant of approval by the US FDA for its 5mg and 10 mg DAPA tablets which are generic versions of the drug sold under the brand name Farxiga would infringe at least claim no. 1 and claim no. 26 of US patent 126. Claim no. 1 and 26 of US patent 126 is identical to/or similar in structure to claim no. 1 and 27 of corresponding claims made in IN 147.

21.6 Therefore, the fact that both in the pleadings and in the aforementioned documents, there is a definitive assertion that DAPA is covered in both the genus patents granted in USA and India i.e. US 126 and IN 147 cannot be disputed. The plaintiffs, however, submit [and an averment to that effect has been made in paragraph 28 of the plaint], that while DAPA is covered in IN 147, it is not disclosed. The plaintiffs rely upon the Markush structure in support of their plea.

21.7 Markush structure or Markush claim/group is a methodology employed

by a patent drafter to select a particular element of the invention wherein all elements share a common characteristic. Thus, a patent drafter who does not use a Markush claim/group would be required to write a series of alternate dependent claims claiming use of each of the elements selected from the group. In a nutshell, Markush claim allows a patent drafter to condense a multitude of alternate dependent claims into one single claim[2].

21.8 The argument advanced on behalf of the plaintiffs that coverage does not necessarily include disclosure is founded on the Markush claim/group. It is also contended by the plaintiffs that the judgement of the Supreme Court did not close this gap between what is covered and that which is disclosed. The emphasis, in this behalf, was laid on paragraph 134 of the ***Novartis*** case. This argument though was apart from the other features of the ***Novartis*** case which were sought to be highlighted to establish that case was distinguishable on facts from those obtaining in the instant suit actions.

21.9 Mr. Vaidyanathan, on the other hand, relied upon portions of the Novartis case to demonstrate that in the very least what is claimed is certainly disclosed; although according to him, the observations in paragraph 118 and 119 of the ***Novartis*** case obliterate the distinction between coverage and disclosure. In support of this plea, Mr. Vaidyanathan pointed out the submissions advanced by the counsel for Novartis before the Supreme Court to the effect that imatinib mesylate which was covered in the Zimmerman patent was not disclosed – a submission which was ultimately rejected by the Supreme Court.

22. In my view, the fact that the plaintiffs have taken out an infringement action both for IN 147 and IN 625 is a sufficient clue, at least at this juncture, that DAPA is claimed in both suit patents. It seems incongruous to me that a patent holder can take out an infringement action for a patent and yet aver it is

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[2] See: Eric, ***Markush Claims, what are they, when should I use one, and how do I use one?*** Jafari Intellectual Property Law (June 2014), Available at: https://www.jafarilawgroup.com/markush-claims-use-one-use-one/, last accessed on 26.10.2020 at 16:00 hours.

not disclosed.

22.1 This is especially so as under our Act the "complete specification" provision encapsulated in various subclauses of subsection (4) of Section 10 require setting out by an applicant who seeks grant of patent to fully and particularly describe the invention and its operation or use and the method by which it is performed, disclose the method of performing the invention which is known to her/him and for which she/he is entitled to claim protection and end with a claim or claims defining the scope of the invention. [See: Section 10(4)(a) to (c)] The applicant is also required to provide an abstract of technical information *qua* the subject invention. The claim or claims forming part of complete specification *inter alia* are required to be "fairly based on the matter disclosed in the specification" [See: Section 10(5) of the Act].

22.2 Therefore, in my view, the defendants' submission that IN 625 should be revoked on account of prior claiming under the provisions of Section 64(1)(a) of the Act has substance, at least at this stage.

22.3 What lends credence to this plea are the provisions of Section 13 (1) (b) of the Act which require the examiner to ascertain as to whether the application referred to him for investigation under Section 12 adverts to an invention which is anticipated by a prior claim. Section 13 (1) (b), simply put, allows an examiner to make use of an Indian patent application or an Indian patent which, though published, after the impugned patent bears a priority date which is earlier than the impugned patent. The fact that the said patent was published after the impugned patent does not come in the way of the investigation carried out by the examiner.

22.4 In the present case, the Indian genus patent i.e. IN 147 bears the priority dates 12.10.1999 and 05.04.2000 whereas the Indian species patent i.e. IN 625 bears 20.05.2002 as its priority date. For the purposes of Section 64(1)(a) this ingredient is sufficient. Therefore, as long as the defendant can establish that the inventions so far claimed in any claim of the complete specification [in this case

IN 625] was claimed in a valid claim of an earlier priority date contained in the complete specification of another patent [i.e. IN 147] – a ground for revocation is made out.

22.5 I must indicate that the plaintiffs, in support of their submission, have cited the judgement rendered by the English Court of Appeal in ***Daikin Kogyo Co. Ltd. (Shingu and Another's) Application***, (1974) R.P.C. 18. This was a case where grant of process patent was opposed on the grounds of prior claim and insufficiency of description. The specification related to a process for making tetrafluoroethylene [TFE] by pyrolysis of chlorodifluoromethane [CDM] with water vapour. Furthermore, it was specifically asserted that the invention insofar as claimed in Claim 2 of the application in suit is claimed in Claim 21 of the opponent's patent.

22.6 The Court ultimately concluded that the process claimed differed in terms of steps and features. One specific feature that the Court noticed was that surface to volume ratio had to be less than 130 reciprocal metres, a feature which was not contained in example 2 of the cited patent. The Court noted that the reaction zone was such that the surface to volume ratio was over 130. Importantly, the Court based its decision on an earlier judgement rendered in ***Kromshroder's Patent*** [1960] R.P.C. 75. The Court of Appeal also noted the judgement rendered in ***Merck & Co. (Macek's) Patent***, [1967] R.P.C. 157 which was a case of revocation based on prior claiming. Pertinently, the Court of Appeal did not, in any manner, dilute the ratio of the ***Merck & Co. (Macek's)*** case. The facts in ***Merck & Co. (Macek's)*** case reveal that 4 claims of the letters patent in the suit read as follows.

> "*The four claims of the letters patent in suit read as follows :*
> *1. A composition having enhanced bactericidal activity comprising novobiocin in combination with at least one other antibiotic selected from the following, namely, penicillin, tetracycline, oxytetracydine, chlortetracycline, streptomycin, chloramphenicol, bacitracin, neomycin, spiramycin, streptothricin and grisein.*
> *2. A composition as claimed in claim 1 in which the antibiotics are incorporated in a solid carrier.*
> *3. A composition as claimed in claim 1 in which the antibiotics are incorpora- ted in a*

parenteral liquid.
4. A composition as claimed in claim 1 in which the antibiotics are incorpora- ted in an ointment vehicle."

22.7 Noticing the aforementioned claims, the Court observed that Claim 1 is comprehensive which permits alternative additions to novobiocin which alternative additions consist of one or more of the named antibiotics. According to the Court, it was a convenient submission of what, in effect, were number of separate claims to different compositions of which some would relate to compositions having two ingredients and some to three or more ingredients.

22.8 The Court went on to re-write the claim to make plain this differentiation. The patentees contended [an aspect which was noticed by the Court] that such notional dismemberment of their claim necessarily involved destruction of the generality of the inventive step and, thus, deprived them of the real differentiation between what they sought to protect and that which was cited as prior document. The Court, in this background, made the following pertinent observations.

"*They point to the phraseology of section 14 of the Patents Act, 1949. wherein the ground of objection is set out, and urge that the phrase "the invention so far as claimed in any claim" should be construed to mean the inventive step taken by the patentee to the full extent to which the claim covers it and not to the area of the monopoly which the claim confers.* ***They seek to support their contention by pointing to the emphasis laid upon the phrase by the judgment of the Court of Appeal in the Kromschroder ease; and referer.ee to the report shows that, without actually defining its precise significance****, the court took it to require that the invention claimed in the later patent should be the subject of a distinct claim to protection in the earlier patent, and to justify rejection of the plea of prior claiming where "the invention in question is only covered or comprehended by the claim as being a part or integer (however important) of some wider combination or arrangement which and which alone is the subject matter of the claim." (See page 82, lines 27 to 30.)*
s*The 1949 Act introduced this phrase 44 the invention so far as claimed in any claim" not only in section 14 (l)(c) but elsewhere in the Act and in particular in section 14(1)(b) (prior publication), section 14(l)(d) (prior user) and section 14(l)(e) (obviousness). The acceptance of the principle of multiple priorities required some such introduction, so that it cannot be assumed that Parliament in phrasing the alteration as it did was intending 5 to do more than to adjust the Act to accord with this principle. It would be a matter of surprise if, in purporting to do this, the legislature had made a fundamental alteration in the principles by which the validity of claimed monopolies has hitherto been determined.*

xxx **xxx** **xxx**

> ***<u>There would appear to be no ground for construing the phrase "the invention so far as claimed in any claim" in different senses in the sub-divisions of section 14(1), so that, if the cited prior claim on its fair construction can be seen to grant as a manner of manufacture that which the later claim on its fair construction would re-monopolise, the objection of prior claiming is established, and this despite the inclusion in the later claim of variants of the manner of manufacture to which no objection can properly be raised</u>***. *The later circumstance will of course be of concern in the determination of the relief to be accorded if and when the plea is established, but it cannot shield a vulnerable embodiment of the invention claimed from attack on the ground of preclaiming any more effectively than it can from the other objections available at the opposition stage.*"
>
> [Emphasis is mine]

22.9 In my view, the facts in the instant suit action are closer to those which obtain in ***Merck & Co. (Macek's)*** case. As noticed above, in the ***Daikin Kogyo*** case, the Court found that the features were different.

23. The plaintiffs also cited the decision of U.S. Court of Customs and Patent Appeals [CCPA] rendered *in* ***Application of Virgil W. Vogel and Paul W. Vogel***, 422 F.2d 438 (C.C.P.A. 1970) in support of their stand.

23.1 This appeal arose from a decision of the Patent Office Board of Appeals whereby rejection of claims 7, 10 and 11 in the appellant's patent application for "Process of Preparing Packaged Meat Products for Prolonged Storage" was affirmed. In this case, the sole ground of rejection of claims 7, 10 and 11 was that they were unpatentable over appellant's co-pending patented claims in Vogel et al in view of Ellies.

23.2 It was typically a double patenting type of rejection. The CCPA viewed the matter from two angels. First, was it the same invention i.e. identical subject matter? Second, whether the claim in the application, defined merely an obvious variation of an invention disclosed and claimed in the patent. Insofar as the first aspect was concerned, the CCPA observed as follows.

> "*The first question is: Is the same invention being claimed twice? The answer is no. The patent claims are limited to pork. Appealed claims 7 and 10 are limited to meat, which is not the same thing. Claims 7 and 10 could be infringed by many processes which would not infringe any of the patent claims. Claim 11 is limited to beef. Beef is not the same thing as pork.*"

23.3 As regards the other aspect which is whether the appeal claim defined merely an obvious variation of the invention disclosed, the CCPA noted that the appeal Claim 11 recited beef which did not read on the pork process disclosed and claimed in the patent. The CCPA, thus, concluded that Claim 11 did not define merely an obvious variation of the pork process. It found that the specific time and temperature consideration concerning pork might not apply to beef. Accordingly, it held that Claim 11 did not present any kind of double patenting situation. However, in the case of Claim 10, it made the following pertinent observations.

> "*Appealed claim 10, supra, will now be considered. It recites a process to be performed with "meat." "Meat" reads literally on pork. The only limitation appearing in claim 10 which is not disclosed in the available portion of the patent disclosure is the permeability range of the packaging material; but this is merely an obvious variation as shown by Ellies. The answer to the second analysis question, therefore, is yes, and the claim is not allowable in the absence of a terminal disclaimer. The correctness of this conclusion is demonstrated by observing that claim 10, by reciting "meat," includes pork. Its allowance for a full term would therefore extend the time of monopoly as to the pork process. It is further noted that viewing the inventions in reverse order, i. e. as though the broader claims issued first, does not reveal that the narrower (pork) process is in any way unobvious over the broader (meat) invention disclosed and claimed in the instant application. The same considerations and result apply to claim 7.*
> *The decision of the board is affirmed as to claims 7 and 10 and reversed as to claim 11.*"

24. Furthermore, *qua* the arguments advanced on behalf of the plaintiffs that DAPA, though, covered in IN 147, was not disclosed therein, is answered, to my mind, by the judgement of the United Kingdom Supreme Court [UK SC] in ***Regeneron Pharmaceuticals Inc (Respondent). vs. Kymab Ltd. (Appellant)***, (2020) UKSC 27 [Majority view 4:1].

24.1 This was a case where a dispute related to two patents obtained by Regeneron Pharmaceuticals Inc. [RPI] with a priority date of 16.02.2001 and each with substantially the same disclosure to justify different claims. The two patents were briefly referred to as "287 patent" and "163 patent". The 163 patent was divisional of 287 patent.

24.2 The challenge to the validity arose because RPI alleged infringement by

Kymab Ltd. of Claim 1 in 163 patent and Claim 5 and 6 of 283 patent by offering to the pharmaceutical industry its own transgenic mouse i.e. "Kymouse" with reverse chimeric locus some of which included the whole of the human variable segments in both the heavy and the light chain loci. The UK SC was faced with a challenge to the aforementioned patents which sought to confer monopoly over the creation of a range of transgenic mouse.

24.3 The Court observed that "***in order to patent an inventive product the patentee must be able to demonstrate (if challenged) that a skilled person can make the product by the use of teachings disclosed in the patent coupled with common general knowledge which is already available at the time of priority date without having to undertake undue experimental burden or apply any inventiveness on their own***". This requirement, according to the UK SC, is labelled as sufficiency. Applying this test, the Court culled out certain principles which are set out in paragraph 56 of the judgement. A couple of principles that the Court adverted to reads as follows.

> "*iii) Patentees are free to choose how widely to frame the range of products for which they claim protection. But they need to ensure that they make no broader claim than is enabled by their disclosure.*
> *iv) The disclosure required of the patentee is such as will, coupled with the common general knowledge existing as at the priority date, be sufficient to enable the skilled person to make substantially all the types or embodiments of products within the scope of the claim. That is what, in the context of a product claim, enablement means.*
> *v) A claim which seeks to protect products which cannot be made by the skilled person using the disclosure in the patent will, subject to de minimis or wholly irrelevant exceptions, be bound to exceed the contribution to the art made by the patent, measured as it must be at the priority date.*
> *vi) This does not mean that the patentee has to demonstrate in the disclosure that every embodiment within the scope of the claim has been tried, tested and proved to have been enabled to be made. Patentees may rely, if they can, upon a principle of general application if it would appear reasonably likely to enable the whole range of products within the scope of the claim to be made. But they take the risk, if challenged, that the supposed general principle will be proved at trial not in fact to enable a significant, relevant, part of the claimed range to be made, as at the priority date.*"

25. Applying these principles, it would have to be said that the arguments of the plaintiffs that DAPA was not claimed in IN 147 seem to be untenable at this

stage. The ***Regeneron Pharmaceuticals*** decision, in my opinion, has a greater persuasive value than the decisions rendered in ***Eli Lily, Apotex***, 2010 FCA 214 and ***Dr. Reddy's Laboratories (UK) Ltd vs. Eli Lilly and Co Ltd.*** (2009) EWCA 1362 cited on behalf of the plaintiffs, which are, distinguishable on facts.

25.1 It must be stated that it was portrayed on behalf of the plaintiffs that the genus patent i.e. IN 147 ringfenced certain compounds which were disclosed only when the species patent i.e. IN 625 was granted, which would, essentially, mean that the written description/complete specification of IN 147 covered DAPA but did not disclose it. To my mind, such written descriptions/specifications would be flawed as it would prevent third parties from carrying out research in future. The Federal Court, in an *en banc* decision in ***Ariad Pharmaceuticals, Inc. vs. Eli Lilly and Company***, 598 F.3d 1336, made some pertinent observations in this behalf.

> "*The written description requirement also ensures that when a patent claims a genus by its function or result, the specification recites sufficient materials to accomplish that function—a problem that is* *1353 *particularly acute in the biological arts.5* See Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, 1, "Written Description" Requirement, *66 Fed.Reg. 1099, 1105–1106 (Jan. 5, 2001). This situation arose not only in* Eli Lilly *but again in* University of Rochester v. G.D. Searle & Co., Inc., *358 F.3d 916 (Fed.Cir.2004).* In Rochester, *we held invalid claims directed to a method of selectively inhibiting the COX–2 enzyme by administering a non-steroidal compound that selectively inhibits the COX–2 enzyme.* Id. *at 918. We reasoned that because the specification did not describe any specific compound capable of performing the claimed method and the skilled artisan would not be able to identify any such compound based on the specification's function description, the specification did not provide an adequate written description of the claimed invention.* Id. *at 927–28. Such claims merely recite a description of the problem to be solved while claiming all solutions to it and, as in Eli* Lilly *and Ariad's claims, cover any compound later actually invented and determined to fall within the claim's functional boundaries—leaving it to the pharmaceutical industry to complete an unfinished invention.*
>
> *Ariad complains that the doctrine disadvantages universities to the extent that basic research cannot be patented. But the patent law has always been directed to the "useful Arts," U.S. Const. art. I, § 8, cl. 8, meaning inventions with a practical use,* see Brenner v. Manson, 383 U.S. 519, 532–36, 86 S.Ct. 1033, 16 L.Ed.2d 69 (1966). Much university research relates to basic research, including research into scientific principles and mechanisms of action, see, e.g., Rochester, 358 F.3d 916, and universities may not have the resources or inclination to work out the practical implications of all such research, i.e., finding and identifying compounds able to affect the mechanism discovered. That is no failure of the law's interpretation, but its

intention. Patents are not awarded for academic theories, no matter how groundbreaking or necessary to the later patentable inventions of others. "[A] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." Id. *at 930 n. 10 (quoting* Brenner, *383 U.S. at 536, 86 S.Ct. 1033). Requiring a written description of the invention limits patent protection to those who actually perform the difficult work of "invention"—that is, conceive of the complete and final invention with all its claimed limitations—and disclose the fruits of that effort to the public.*

That research hypotheses do not qualify for patent protection possibly results in some loss of incentive, although Ariad presents no evidence of any discernable impact on the pace of innovation or the number of patents obtained by universities. But claims to research plans also impose costs on downstream research, discouraging later invention. The goal is to get the right balance, and the written description doctrine does so by giving the incentive to actual invention and not "attempt[s] to preempt the future before it has arrived." Fiers, *984 F.2d at 1171. As this court has repeatedly stated, the purpose of the written description requirement is to "ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's* *1354 *contribution to the field of art as described in the patent specification."* Rochester, *358 F.3d at 920 (quoting* Reiffin v. Microsoft Corp., *214 F.3d 1342, 1345 (Fed.Cir.2000)). It is part of the* quid pro quo *of the patent grant and ensures that the public receives a meaningful disclosure in exchange for being excluded from practicing an invention for a period of time.* Enzo, *323 F.3d at 970.*"

26. In my opinion, given the aforesaid discussion, a credible defence to the infringement action is set up by the defendants.

27. This takes me to the other aspect i.e. challenge laid to IN 625 on the ground that it was anticipated by what was published or publicly known from IN 147. Concededly, the PCT publication date of IN 147 is 19.04.2001 which is well before, as noted above, the priority date of IN 625, that is, 20.05.2002. It is contended on behalf of the defendants that since DAPA is both claimed and "fully and particularly described" as required under Section 10(4)(a) of the Act as a part of its complete specification, there is a credible case that DAPA was known and, therefore, vulnerable under Section 64(1)(e).

27.1 In this behalf, reference was made to the judgement of the Supreme Court in ***Monsanto Company vs. Coromandel Indag Products***, (1986) 1 SCC 642. It was contended on behalf of the defendants that the expression publicly known is to be understood from the point of view of a person engaged in the pursuit of knowledge of the patented product which in this case would be a man of science dealing with organic/medicinal chemistry.

27.2 Thus, based on the comparison of written descriptions of WO'128 and IN 625, it was contended that to the man of science of ordinary skill but otherwise interested in the field of organic/medicinal chemistry having reasonable experience, DAPA was not new and was known prior to the priority date of IN 625.

27.3 In support of this contention, the counsel of the defendants laid stress on the fact that the person skilled in the art, ultimately, would filter down to a small class of compounds since the prior publication set out a series of preferred claims. Thus, according to the defendants, even if the prior art referred to infinite number of molecules, a person skilled in the art would be able to narrow it down to 8 molecules. In support of this submission, the defendants have, to a large extent, relied upon the affidavit of their expert witness i.e. one, Dr. Stephen F. Martin.

27.4 The plaintiffs, on the other hand, have relied upon an affidavit of one, Dr. Easwaran dated 18.10.2020 to contend that WO'128 which is the PCT equivalent of the suit patent IN 147 would have structures which would cover millions of compounds and, therefore, going by the Markush formula they would have to be taken down and made one by one. This would take a lifetime. It was also contended that substitutions indicated by Dr. Martin, such as, A, CH-2, R1 had no obvious logic and, therefore, could only be carried out by hindsight wisdom.

28. Having heard arguments of both sides on this aspect of the matter, in my view, while counsel for the defendants, based on the affidavit of Mr. Martin, did try to convey that a person skilled in the art could iterate the claims and arrive at 8 molecules based on prior publication and not hindsight, this is an aspect which would be required to be tested in a trial. Therefore, on this score, the defendants' defence, at this stage, in my opinion, does not inject vulnerability.

29. This brings me to the ground for revocation taken under Section 64(1)(f) i.e. that IN 625 is vulnerable as it does not involve any "inventive step". It is

required to be noticed that the expression "inventive step" has been defined under Section 2(1)(ja) as follows.

> "*(ja) "inventive step" means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art;*"

29.1 A plain reading of the definition would show that it has two parts to it and both are inextricably linked with the other. In other words, if a patentee is unable to measure up to the ingredients of either of the two parts, the invention claimed is not construed under the Act as an inventive step.

29.2 First part involves patentee to show that the invention claimed in any claim involves "technical advance" as compared to the existing knowledge or has "economic significance" or both. The second part of the definition alludes to the fact that the invention should not be obvious to the person skilled in the art.

29.3 A comparison of the complete specifications/descriptions of Indian genus patent i.e. IN 147 and Indian species patent i.e. IN 625 shows that there is no technical advance of the latter over the former. This is clearly evident if one were to peruse the following extracts from Indian genus patent i.e. IN 147 and Indian species patent i.e. IN 625.

Extracts from Indian Patent 147 [internal page number 11 of the complete specification]	**Extracts from Indian Patent 625 [internal page number 7 of the complete specification]**
… The compound of formula I possesses activity as inhibitors of the sodium dependent glucose transporters found in the intestine and kidney of mammals and is useful in the treatment of diabetes and the micro- and macrovascular complications of diabetes such as retinopathy, neuropathy, nephropathy, and wound healing. …	… The compound of formula I possesses activity as inhibitors of the sodium dependent glucose transporters found in the intestine and kidney of mammals and is useful in the treatment of diabetes and the micro- and macrovascular complications of diabetes such as retinopathy, neuropathy, nephropathy, and wound healing. …

29.4 The plaintiffs sought to get over this by seeking to rely upon Dr. Washburn's affidavit of April 2020 which was filed on 12.10.2020 to show technical advance. The data pertaining to technical advance is set out in Dr.

Washburn's affidavit under the following broad headings.

> "***A. Enhanced selectivity for SGLT2 versus SGLT1***
> ***B. Enhanced ability to reduce blood glucose at 5 hours after oral administration to diabetic STZ rats (short-term animal model)***
> ***C. Enhanced ability to reduce plasma glucose over a 15-day period after oral administration to ZDF rats (longer-term animal model)***"

29.5 Based on the data set out in the affidavit, Dr. Washburn made the following conclusions.

> **"***29. In my opinion, the increased selectivity and the reduction of glucose levels obtained with dapagliflozin compared to Example 12 of WO '128 in the STZ and ZDF rat models were surprising and unexpected.*
> *30. In my opinion, the glucose reductions in STZ and ZDF rats are particularly surprising considering that, in the in vitro experiments, the SGLT2 inhibitory potential (EC50) of dapagliflozin was seemingly similar to the SGLT2 inhibitory potential of Example 12 of WO '128.*"

30. In my opinion, if this information was not available at the time the application for grant of patent was filed, then, this cannot be taken into account, at this juncture, by the plaintiffs in support of their plea that IN 625 involved an inventive step. There is no clue in IN 625 of an unknown technical effect on its priority date. Dr. Washburn's affidavit, who professes to be the co-inventor of DAPA, could have come to the rescue of the plaintiffs to demonstrate technical advance if, at least a seed of that nature had been planted in IN 625, on its priority date.

30.1 The plaintiffs' argument that post filing data relating to the invention is admissible is based on two grounds.

i. First and foremost, the applicant may not be fully aware of the advances and properties of the subject invention, in this case, the compound DAPA, on the priority date. In this behalf, it is stated that DAPA's properties for treatment of heart failure came to be known only subsequently.

ii. Second, there is no requirement in law that all properties, advantages, and characteristics should be stated on the filing date of the patent application.

In support of their plea, the plaintiffs relied upon ***Genetics institute, LLC, vs. Novartis vaccines***, 655 F.3d 1291 (2011); and ***Knoll Pharm. Co. vs. Teva Pharms. USA, Inc.***, 367 F.3d 1381, 1385. It was argued that the plaintiffs had complied with the best code rule as engrafted in Section 10(4) of the Act which is qualified by the expression "known to the applicant". It was also contended that they had satisfied the examiner on the aspect of inventive step and factually the examiner had raised no such objection in his examination report of October 2007. The plaintiffs also sought to contend that they met the plausible unknown technical effect test as formulated in ***Generics (UK) Limited vs. Yeda Research and Development Company Limited***, (2017) EWHC 2629 (Pat).

30.2 In this context, I may refer to the judgement in ***Generics (UK) Limited vs. Yeda Research and Development Company Limited***, (2017) EWHC 2629 (Pat) cited on behalf of the defendants. In this case, Generics, which was the claimant, sought revocation of a European patent [entitled low-frequency glatiramer acetate therapy] of which the defendant i.e. Yeda was the registered proprietor and a third party [i.e. Teva] was the exclusive licensee. One of the issues which arose for consideration before the Court concerned the lack of inventive step for want of technical contribution and insufficiency.

30.3 On behalf of Generics, it was contended that the claimed inventions made no technical contribution to the art and, therefore, did not involve inventive steps as summarized in another judgement i.e. ***Generics (UK) Ltd vs Yeda Research and Development Co Ltd,*** [2013] EWCA Civ 925 Alternatively, it was argued that the technical contribution was insufficient as per principles summarised by Kitchin LJ in ***Idenix Pharmaceuticals Inc vs. Gilead Sciences Inc***, [2016] EWCA Civ 1089. The Court after discussing the issue made the following crucial observations.

> *197.* ***In case this case goes further, I must briefly address the Defendants' reliance upon evidence which post-dates the priority date of the Patent. It is***

common ground that such evidence can only be relied upon to confirm the existence of a technical effect which is plausible in the light of the specification and the skilled person's common general knowledge, and not to establish the existence of a technical effect for the first time.

[Emphasis is mine]

30.4 Therefore, what emerges is this: that post priority date evidence which has been furnished in Dr. Washburn's affidavit to show technical advance can only be taken into account to confirm the existence of technical effect which is found embedded in the specification of IN 625 and is capable of being understood by a skilled person having common general knowledge and not to rely upon the same to establish its effect for the first time.

30.5 The plaintiffs have not been able to demonstrate, at least at this stage, the existence of such technical effect in the specifications. The plaintiffs' argument that the examiner should have been conscious of the inventive step objection or that evidence of technical advance could be placed before the Court even at this juncture fails to take into account the plain language of Section 64(1)(f) read with Section 2 (1)(ja) of the Act. The defendants are entitled, as noted above, to submit, in support of their challenge, that there is no demonstrable technical advance as on the date of priority of IN 625.

30.6 Whether or not the examiner raised this issue, the defendants are certainly entitled to raise the same in defence to an infringement action. The plaintiffs' submissions, to my mind, would only buttress the stand of the defendants that there is a credible challenge to IN 625. The reference by the plaintiffs to some of the attributes which, according to them, are referred to in IN 625 does not demonstrate, at least at this stage, technical advance.

31. On the last aspect, which is, as to whether the plaintiffs failed to make a complete disclosure in terms of Section 8 of the Act, the following facts need to be noticed.

i. The plaintiffs had, *vide* a letter dated 10.01.2005, filed the corresponding US patent with the Indian Patent Office. The Indian

Patent Office, while issuing its first examination report on 12.10.2007, against serial no. 13 concededly sought the following information.

ii. In response thereto, the plaintiffs on 08.10.2007, stated the following.

"*Regarding paragraph 13 of the official letter, we have the honour to submit herewith copies of the EPO decision to grant and the EP granted patent, which in turn meets with the requirement of Section 8(2)*"

iii. Clearly the plaintiffs did not provide to the Indian Patent Office, the office action/examination report dated 30.07.2002 issued by the USPTO in connection with US 117 which corresponds to IN 625. In the examination report of 30.07.2002, the USPTO *inter alia* stated the following.

"*1. Claims 1-17 are rejected under the judicially created doctrine of double patenting over claims 14-30 of U. S. Patent No. 6,414,126 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent. The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows:*

Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are directed towards glucoside structures characterized by specific stereochemistry and further these compounds are characterized by biaryl substitution (SGLT2 inhibitor compounds), their pharmaceutical acceptable salts and a method of treatment of diabetes employing an SGLT2 Inhibition (i.e. C-Aryl glucoside compounds) which encompass the invention cited in claims in 14-30 of '126 which are directed toward the (SGLT2 inhibitor compounds), their pharmaceutical composition and a method of treatment of diabetes with an SGLT2 inhibitor.

The issued patent '126 differ from the present application in that it does not include the acetyl derivatives of glucoside structures characterized by specific stereochemistry in a C-Aryl glucoside compounds (22 claim 17).

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See In re Schneller, 397 F.2d 350, 158 USPQ 210 (CC)A 1968). See also MPEP 804."

iv. It is in response to the same that the plaintiffs, on 19.08.2002 voluntarily sought to limit the term of US 117 [equivalent to IN 625] to the date when the US genus patent 126 was to expire. It was only after terminal disclaimer was filed by the plaintiffs, which was accepted by USPTO, that US 117 was granted on 20.09.2002, *albeit*,

with the caveat that it would expire on the same date as the US genus patent i.e. US 126. This information was not furnished to the Indian Patent Office.

31.1 In this behalf, the plaintiffs contend that the Indian Patent Office was aware of the fact that the continuation- in- part application had been moved before the USPTO which, according to the plaintiffs, would have indicated to the Indian Patent Office that the corresponding US patent was to terminate on the same date.

31.2 Second, the fact that USPTO had already granted patents, it was not incumbent upon the plaintiffs to file the examination reports generated by the USPTO. It was also contended that the error, if any, was *bona fide* and, therefore, could not lead to revocation under Section 64(1)(m) of the Act. In support of their plea, the plaintiffs placed reliance on judgement dated 07.11.2014, passed in FAO (OS) No. 16/2014, titled ***Maj. (Retd.) Sukesh Behl & Anr. vs. Koninklijke Phillips Electronics***.

32. In my view, the judgement in ***Chemtura Corporation vs. Union of India (UOI) and Ors***., 2009 (41) PTC 260 (Del) sets the tone as to what all needs to be provided to the patent office when a prospective patentee seeks grant of patent.

32.1 In the instant actions, specific details were sought by the Indian Patent Office concerning search and examination report. What was submitted by the plaintiffs to the Indian Patent Office *via* the letter dated 10.01.2005 were the corresponding US patents and not the examination reports. It is not denied by the plaintiffs that the examination report dated 30.07.2002 issued by the USPTO *qua* US species patent 117 was not furnished.

32.2 It is also not denied by the plaintiffs that their response of 19.08.2002, whereby, the validity period of US 117 was voluntarily aligned with the US genus patent i.e. US 126 was not placed before the Indian Patent Office. These

were vital documents which ought to have been furnished to the Indian Patent Office.

32.3 The submission advanced on behalf of the plaintiffs that the terminal disclaimer is an obviation and not an admission of obviousness is not an answer to the provisions of Section 8(2) of the Act which is mandatory. Assuming, under the USA patent law, it is construed as an obviation, even then, in my view, it was incumbent upon the plaintiffs to furnish the examination report of the USPTO. As to what would have followed from there, would obviously be within the ken of the examiner at the Indian Patent Office. The scope of Section 8 of the Act has been captured in ***Chemtura Corporation*** case. The relevant observations are replicated hereafter for the sake of convenience.

> "***Non-compliance with Section 8***
>
> *36. Section 8 of the Act is titled 'Information and undertaking regarding foreign applications'. 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 the statement and undertaking to be filed in terms of Section 8 (1) of the Act will be in Form 3. Prior to the making of the present Rules in 2003, the earlier relevant Rule was Rule 13 which was to the same effect with slight changes in Form 3.*
>
> **xxx xxx xxx**
>
> *40.* ***As far as Section 8(2) is concerned, the Controller on his own may also require the applicant to furnish details "relating to the processing of the application in a country outside India, and in that event the applicant shall furnish to the Controller information available to him within such period as may be prescribed." That requirement is mandatory as has been further emphasised by the wording of Section 64(1) (j)*** *["that the applicant has failed to disclose to the Controller the information required by Section 8 or has furnished information which in any manner was false to his knowledge"] which indicates the non-compliance with such directive of the Controller as a ground for the revocation of the patent. The obtaining of a patent, "on a false suggestion or representation" is a further ground of revocation under Section 64 (1) (m).*
>
> **xxx xxx xxx**
>
> *43. It is not possible to agree with the submission of Mr. Shanti Bhushan that the search and the examination report is required to be furnished only if it has resulted in*

the allowing of the Plaintiff's claim by the Patent Office in a foreign country. The word "including" only means that the Plaintiff has to additionally furnish the search and the examination report where applications have been allowed. It was incumbent on the Plaintiff therefore to furnish to the Controller of Patents any search or/and examination report that may have been issued by the Patent Office either in US or Europe as on the date of their reply i.e. 17th October 2005. What is significant is that initially by the letter dated 17th October 2005 to the Patent Controller, the Plaintiff did not adhere to the requirements of paras 7 and 8 at all. Later after the telephonic conversation it submitted that a letter dated 19th October 2005 where it simply stated that "there has been no further development subsequent to Form 3 which was filed at the time of filing the application in India." This statement, as will be seen hereafter, was not true.

xxx **xxx** **xxx**

45. ***It is not possible to accept the submission, made by referring to the Halsbury's Laws of England, that since the omission to furnish particulars is not serious enough to affect the grant of the patent, it did not impinge on its validity. Section 64 (1) (j) and (m) indicate to the contrary. Further under Section 43 (1) (b) a patent can be granted only when the application has been found not to be contrary to any provision of the Act. It cannot be said that the omission to comply with the requirement of Section 8 (2) was not serious enough to affect the decision of the Controller to grant the patent to the Plaintiff.*** *The information, if provided, would have enlightened the Controller of the objections raised by the US patent office and the extent to which the Plaintiff had to limit its claims to the torus shape of the compression spring, which was a key feature of the subject device. Had the Controller been informed of the Plaintiff's own patent No.3932005 dated 13th January 1976, he would have been called upon to examine if that patent taught the use of a toroidal shape of a compression member and whether therefore the subject device was an inventive step within the meaning of the Act.*

xxx **xxx** **xxx**

48. Under the amended Section 48 (1) of the Act, the patent granted shall, where the subject matter of the patent is a product, give the patentee the exclusive right to prevent third parties, who do not have his consent, from the act of making, using, offering for sale, selling or importing for those purposes that product in India. Likewise, where the subject matter of the patent is a process, the patentee would have the exclusive right to prevent third parties, who do not have his consent, from the act of using that process, as well as from the act of using, offering for sale, selling or importing any product obtained directly by that process in India. The change is therefore, that under the amended Section 48 a right is given to the patent holder Plaintiff, to prevent third parties from making, selling or offering for sale, the product for which such patent has been granted without the prior consent of the patent holder. ***The amended Section 48, however, does not in any manner change the position as regards the validity of the patent itself. It would still be vulnerable to challenge in terms of Section 13 (4) read with Sections 64 and 107 of the Act. A similar conclusion has been arrived at in Bajaj Auto Ltd. v. TVS Motor Company Ltd. (supra)****.*

49. This Court holds that for the aforementioned reasons, in view of the prima facie non-compliance by the Plaintiff with the requirement of Sections 8 (1)(b) and 8(2) of the Act, the ground for revocation as contained in Section 64 (1) (m) is prima

facie attracted. ..."

[Emphasis is mine]

32.4 The reliance placed on behalf of the plaintiffs on a judgement of the Division Bench i.e. in ***Maj. (Retd.) Sukesh Behl*** case, in my view, misses a vital distinction between this case and the judgement rendered in ***Chemtura Corporation*** case. In this context, it is required to be noticed that the judgement in ***Maj. (Retd.) Sukesh Behl*** case was rendered in the context of Order XII Rule 6 of the Code of Civil Procedure, 1908 [in short "CPC"] whereas the judgement in ***Chemtura Corporation*** case was foregrounded in the provisions of Order XXXIX Rule 1 and 2 of the CPC [See paragraph 39 in ***Maj. (Retd.) Sukesh Behl*** case].

32.5 Furthermore, in ***Maj. (Retd.) Sukesh Behl*** case, the Court ruled that because the power to revoke patent was discretionary [on account of the expression 'may' inserted in subsection (1) of section 64 of the Act], a decision in the matter could be reached only after a trial in view of absence of an unequivocal and/or unambiguous admission by the plaintiff in that case.

32.6 A careful perusal of the facts found in ***Maj. (Retd.) Sukesh Behl*** case would show that the plaintiffs' attorney while furnishing information concerning foreign applications had missed out some part of the information. However, the plaintiffs' attorney on their own, albeit after a lapse of time, had filed a letter with the Indian Patent Office whereby the information which was missed out was furnished. In the letter, it was indicated that the documents received by the attorney had some part of the information incorporated on the reverse side of the said documents. It was stated that the paralegal who was assisting the attorney had inadvertently left out the said information.

32.7 Construing these facts, the Court ruled that it was not a case of a clear and unambiguous admission, thus, triggering the provisions of Order XII Rule 6 of the CPC. Pertinently, the Court agreed with the judgement rendered in ***Chemtura Corporation*** case that the provisions of Section 8 were mandatory.

32.8 As indicated above, the plaintiffs in support of their submission that filing of terminal disclaimer was only an obviation and not admission of obviousness and double patenting had relied upon the judgement of the US Federal Court in ***Quad Environment vs. Union Sanitary***, 946 F2d 870. The defendants, on the other hand, relied upon the judgement of the US Supreme Court in ***Festo Corp. vs. Shoketsu Kinzoku***[3], 535 U.S 722 (2002); and another judgement of the US Court of Appeals for the Federal Circuit **SimpleAir, Inc. vs. Google LLC**, Appeal Number: 16-2738, United States Court of Appeals for the Federal Circuit.

32.9 A perusal of these judgements would show that while terminal disclaimers are not treated as admissions, they are taken into account to ascertain the prosecution history of the patent i.e. the reason as to why the patentee chose to narrow down its claim. Thus, while terminal disclaimer filed by a patentee is not treated as a complete bar against the defence of non-obviousness, depending on facts, it can operate as estopped by conduct.

33. The point to be stressed here is that under our Act, was the examiner under the Indian Patent Office not entitled to know as to what was the prosecution history of the plaintiffs *qua* the corresponding patents in US. In my opinion, the answer to this has to be in the affirmative. ***Chemtura Corporation*** case, while interpreting the provisions of Section 8 of our Act, in a sense, in its own language, brings to fore this seminal point.

33.1 Therefore, to my mind, as to whether or not the Court would, ultimately, revoke the suit patents for failure to furnish information, as sought for by the

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[3] "… *When the patentee is unable to explain the reason for amendment, estoppel not only applies but also "bar[s] the application of the doctrine of equivalents as to that element." Ibid. These words do not mandate a complete bar; they are limited to the circumstance where "no explanation is established." They do provide, however, that when the court is unable to determine the purpose underlying a narrowing amendment—and hence a rationale for limiting the estoppel to the surrender of particular equivalents—the court should presume that the patentee surrendered all subject matter between the broader and the narrower language*."

Indian Patent Office, would be ruled upon after the trial. It, nevertheless, is an important factor to be taken into account at a preliminary injunction stage; at which point, the Court exercises equitable jurisdiction.

34. This brings me to the arguments raised concerning the balance of convenience, and irreparable harm. In my view, if, as held by me above, the defendants have been able to set up a credible challenge and/or establish, at least at the preliminary injunction stage, the vulnerability of the suit patents, even if the balance of convenience is in favour of the plaintiffs, the injunction cannot be granted.

34.1 On the other hand, if the plaintiffs had established a strong *prima facie* case for grant of a preliminary injunction, they would still have to satisfy the Court as to whether or not balance of convenience was in their favour and that denial of interim relief would cause irreparable damage. In this background, let me examine the rival contentions made on behalf of the parties before me.

34.2 The plaintiffs claim that the Indian genus patent i.e. IN 147 survived its full validity period and the Indian species patent i.e. IN 625 is in 18th year of its lifecycle. The plaintiffs' product is being sold in India since 2015 at reasonable prices. The defendants, according to the plaintiffs, should be asked to "clear the way" as contemplated in ***Merck Sharp and Dohme Corporation and Ors. vs. Glenmark Pharmaceuticals***, MANU/DE/0852/2015 by following any of the following rules i.e.

i. Seeking voluntary license;

ii. Seeking compulsory license;

iii. Filing revocations;

iv. Filing pre-grant opposition and post-grant opposition; and

v. Filing a declaratory action for non-infringement.

34.3 The suit patents i.e. IN 147 and IN 625 were published in 2005 and were

granted nearly 13 and 11 years ago respectively. Besides this, the plaintiffs have obtained injunctions in several pending suit actions which have been instituted in this Court. Furthermore, if the injunction is not granted, it would destroy the plaintiffs' market *qua* their product. Besides this, doctors have expressed concerns about the quality of the products that the defendants may launch. It is also contended that the damages are difficult to compute. Monetary compensation, according to the plaintiffs, will not be adequate. It is emphasized that the plaintiffs are interested in a real and not a pyrrhic victory by having their rights enforced under the Act.

34.4 The defendants, on the other hand, say that the plaintiffs' suit actions are abusive which are intended to re-monopolise their rights that admittedly came to an end on 02.10.2020. It is emphasized by the defendants that grant of an injunction would not only impact the defendants' rights to enter the market but would deprive the public at large to obtain their drug at relatively cheap prices. It is contended that since the plaintiffs are interested in licensing their product to third parties, the damage if any caused is compensable in monetary terms in accordance with the mandate of the law.

34.5 As against this, if an injunction is granted, the opportunity lost by the defendants to market their products cannot be quantified in monetary terms. Therefore, even from the point of restitution, the balance tilts in favour of the defendants.

35. Having considered the case from the point of view of facets involving balance of convenience and irreparable harm, it has to be stated that the fact that a challenge has been laid at the stage when the plaintiffs seek to enforce their rights under the patents would not propel the Court [as indicated above] to grant an injunction if the challenge is credible.

35.1 The provisions of the Act do not provide any shield of inviolability. This principle is true not only in India but jurisdictions across the world. In no country, a mere grant of a patent by the patent offices' guarantees their validity.

It is important to remember that grant of monopoly to the inventor, which is necessary for her/him to recoup investments and/or derive profits from her/his inventions, comes with a *quid pro quo* as noticed in paragraph 38 of Report on the Revision of the Patents Law by Shri Justice N. Rajagopala Ayyangar (September, 1959). Paragraph 38 reads thus:

> "*38.* ***I have already set out the considerations which are said to constitute the quid pro quo for the grant of the patent monopoly, namely; (1) the working of the invention within the country so as to result in the establishment in the country of a new industry or an improvement of an existing industry which would profitably employ the labour and capital of the country and thus increase the national wealth, and (2) disclosure to the public of the invention and the manner of its working so that on the expiry of the life of the patent the public are enabled to work the invention themselves and in competition with each other****. Where the patentee has no intention of working the invention in this country either because he considers that this is not profitable or because he prefers to expand the production in his home country so as to achieve there greater efficiency and more production or is otherwise not interested in working the invention in India, the grant of the Indian patent might tend to improve the economy of the patentee's home country but offers little advantage to us.* ***Unless therefore the law provides for measures to be taken to compel the patentees to work the invention within the country, and these measures are effective to achieve their purpose, the social cost involved in the grant of the patent is not offset by any benefit to the community.*** *As regards the possible advantage which might result by disclosure it should be noted that most of the inventions patented by foreigners in this country are also patented abroad and the theory therefore that but for patent protection the invention would have been worked in secret and that the public would have been deprived of the knowledge of the invention has no relevance in the case of the large majority of patents granted in India. As neither of the above considerations seems to be present in the case of patents granted to foreign nationals which are not worked in this country the cost to the community by the grant of the patents is unrelieved by any positive advantage by way of an increase of technical skill or of national wealth.*"

[Emphasis is mine]

35.2 The recommendations made therein were a precursor to the enactment of the Patents Act, 1970. The judgement of the Supreme Court in detail captures the reasons for the passing of the more recent amendment Acts i.e. 2002 Amendment Act and the 2005 Amendment Act. Broadly, India sought to make amendments *via* the said amendments Acts to meet its obligation under TRIPS which formed part of the agreement which established the World Trade Organisation [WTO].

35.3 India, it appears, brought in certain amendments to balance the interests of the inventors as also those of her citizens. The insertions *inter alia* of Sections 2(1)(j), 2(1)(ja), and 2(1)(l); Section 3(d); Section 8; Section 10(5); Section 53; and Section 107(A) were a step in that direction. The trade-off, it appears, was between uniformly increasing the validity of patents including those which were granted for drugs for 20 years as against the right of the local industries to be able to work the patent to provide the fruits of the invention to its citizenry at reasonable prices and to embed skills locally.

35.4 This is acutely true when seen in the context of enforcement of patents concerning drugs. The Court has to be vigilant towards attempts of the patentee that aims at evergreening an invention which does not *inter alia* involve an inventive step i.e. technical advance or economic significance. Therefore, depriving the defendants, at this stage, from manufacturing and selling their drugs, when, during the validity period of the genus patent i.e. IN 147 they largely held themselves in check would, in my opinion, not be appropriate, especially, when they have set up a credible challenge to the suit patents.

35.5 What persuades me to decline injunction, in addition to what I have stated above, is also the fact that in this case damages if proved at trial, appear to be compensable. The defendants have averred that the plaintiffs have, possibly, licensed their rights under the suit patents to two entities i.e. Sun and Abbott. The packaging of the products of the drug sold through these entities is indicative of this aspect. The plaintiffs, however, for reasons best known to them have not placed on record the agreements arrived at with these entities in support of their plea. Therefore, it has to be inferred that the said entities are licensees.

35.6 Besides this, the plaintiffs also aver that they are importing their drug into the country. Therefore, the plaintiffs seek to monetize their invention. Thus, at the end of the trial, if they were to succeed, they could be granted damages, if proved, under the law. Thus, as long as a mechanism can be put in place for

securing the recovery of damages by the plaintiffs, it would, at this stage, balance the interest of the parties. [See: ***Dynamic Manufacturing, Inc. vs. David A. Craze, and Miller Industries, Inc.***, 1998 WL 241201]

PUBLIC INTEREST: -

36. The parties have also advanced submissions on the aspect concerning public interest. The plaintiffs have submitted that the quality of the drug could be an issue. The plaintiffs have also contended that the drug sold by them is priced reasonably.

36.1 To my mind, this aspect can be quantitatively verified, to a large extent, if one were to compare the price of the drugs sold by the plaintiffs both, directly and/or indirectly, and the prices at which the defendants seek to offer their drugs.

Price of the plaintiffs' product – 5 mg tablet	Rs. 54.4/-	Price of the INTAS product – 5 mg tablet	Rs. 9.90/-	Price of the ALKEM product – 5 mg tablet	Rs. 13.90/-
Price of the plaintiffs' product – 10 mg tablet	Rs. 57.29/-	Price of the INTAS product – 10 mg tablet	Rs. 11.90/-	Price of the ALKEM product – 10 mg tablet	Rs. 17.50/-
Cost per patient per month of the plaintiffs' product - 5 mg	Rs. 1523.20/-	Cost per patient per month of the INTAS product - 5 mg	Rs. 277.20/-	Cost per patient per month of the ALKEM product - 5 mg	Rs.490/-
Cost per patient per month of the plaintiffs' product - 10 mg	Rs. 1605.80/-	Cost per patient per month of the INTAS product - 10 mg	Rs. 333.20/-	Cost per patient per month of the ALKEM product - 10 mg	Rs.554.4/-

36.2 Clearly the difference in prices of drugs ranges between 250% to 350%. Therefore, as is apparent, if defendants were allowed to manufacture and market

their drugs, it would be far cheaper. Concerns as to quality, at this juncture, appear to be a self-serving argument. The concerned statutory authority can, in my view, adequately deal with this issue if and when such a situation arises.

37. I may also indicate herein that an argument was raised that diabetes is a lifestyle disease and, therefore, the concerns generally expressed by Courts *qua* drugs which are used to treat life-threatening diseases such as Cancer, HIV/AIDS etcetera should not impact this matter.

37.1 The defendants on the other hand have emphasised that diabetes is no longer construed as a lifestyle disease. According to them, given the spread of Coronavirus, diabetes can cause comorbidity in a patient leading to a potentially life-threatening situation.

38. On this aspect, judicial notice needs to be taken of the following figures published by the Government of India and World Health Organisation on diabetes.

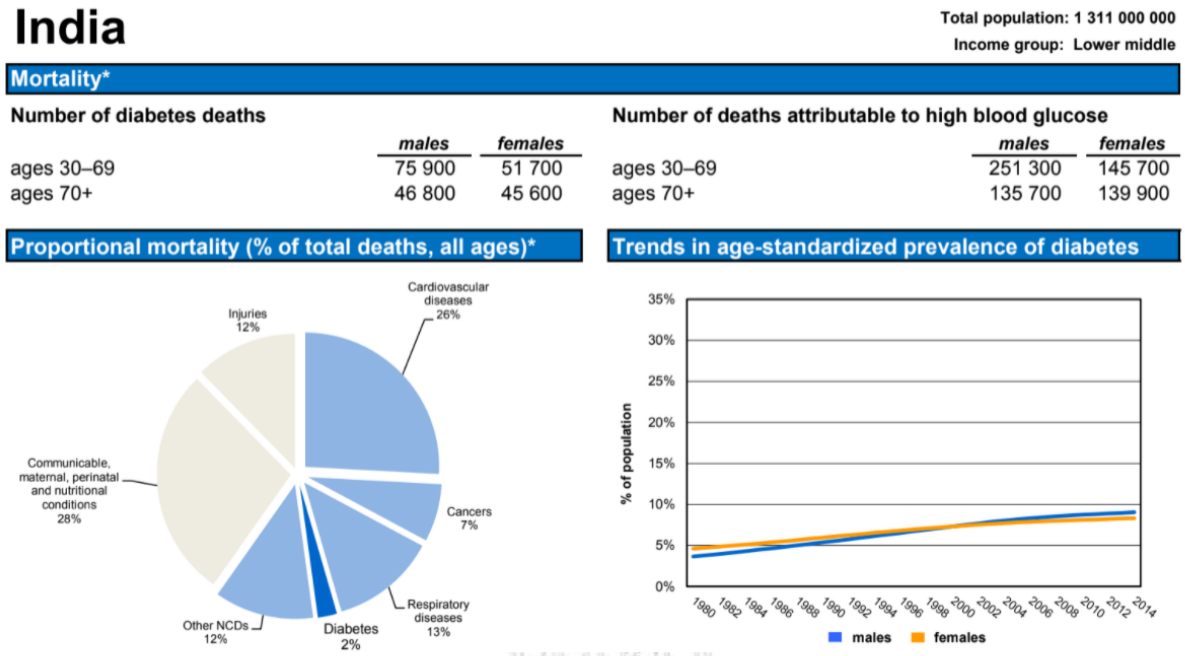
- The National Centre for Disease Control, Directorate General of Health Service, Government of India, in its "Diabetes Special Edition on Occasion of World Health Day 2016" [April 2016][4] has noted thus:

> "*India has 6.51 crore diabetes cases which is second highest number of diabetics in the world and is projected to have 10.9 crore affected persons by 2035.*
>
> **xxx** **xxx** **xxx**
>
> *Diabetes mellitus is a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both. The chronic hyperglycemia of diabetes is associated with long-term damage, dysfunction, and failure of various organs, especially the eyes, kidneys, nerves, heart, and blood vessels.*
>
> **xxx** **xxx** **xxx**
>
> *Type 2 diabetes (non-insulin dependent) is characterised by insulin resistance*

[4] [See: https://ncdc.gov.in/WriteReadData/linkimages/cdalert0616262925183.pdf]

and/ or abnormal insulin secretion. Type 2 diabetes accounts for over 90% and Type 1 accounts for up to 10% of all diabetes."

- The World Health Organisation, in its 'Diabetes Country Profiles, 2016' concerning India, has noted the following.



38.1 Therefore, if one were to bear in mind the aspect concerning price as also the nature of the disease which is sought to be treated by the drug-in-issue, the scales of balance, in my opinion, at this stage, would weigh in favour of the defendants.

39. Before I conclude [and *dehors* what has been observed by me hereinabove], there is literature and scholarly articles available of well-established academicians which point in the direction that the doctrine of double patenting needs to be strengthened.

39.1 Some of the academicians in the US, familiar with patent law, decry the weakening of double patenting doctrine by the Federal Courts in the country by disregarding the earlier view of the US Supreme Court which held that "invention of the genus patent is not determined only by the claims but also by

the embodiments disclosed in the specifications".

39.2 Some of the academicians appear to be of the view [based on the precedents of the US Supreme Court and also some Federal Circuit Court judgements] that it must be presumed that the party with genus patent has invented the full scope of the genus. It is argued that when the same inventor holds a genus patent for a pharmaceutical product, such an inventor should be estopped from obtaining a species patent which is within the scope of genus, whether or not the genus patent constitutes prior art. [See: ***O'Reilly vs. Morse***, 56 U.S. 62, 114 (1853); ***Singer Mfg. Co. vs. Juune Mfg Co.***, 163 U.S. 169 (1896); and ***Schriber-Schroth Co. vs. Cleveland Trust Co.***, 305 U.S. 47 (1938)]

39.3 In this behalf, see the abstract of the article published in Northwestern Journal of Technology and Intellectual Property, Volume 14, Issue 3 (Winter 2017) titled ***Double Patenting: Follow-on Pharmaceutical Patents that Suppress Competition***, authored by Douglas L. Rogers, which is extracted hereafter.

"***ABSTRACT***

> *Prices for pharmaceutical products over the last 10 years have skyrocketed, increasing far more rapidly than the general cost of living. This article argues there should be greater competition for the production of follow-on drugs through the strengthening of the double patenting prohibition: preventing extending exclusive rights beyond the original patent term by dressing up part of that invention as a new one. This prohibition against the same party holding two patents covering the same composition announced by the Supreme Court in the 1800's has been weakened by lower federal courts to (1) only considering the claims and not the rest of the specification in determining if the same invention is being claimed by the inventor in two patents and (2) only applying the prohibition when the earlier patent did not satisfy the technical meaning of "prior art" within §102 of the Patent Act. The rulings weakening the double patenting doctrine have disregarded that the "invention" of a genus patent is not determined only by the claims, but also by the embodiments disclosed in the specification, and under Supreme Court and Federal Circuit precedent it must be presumed that the party with a genus patent has invented the full scope of the genus. These weakening rulings have also disregarded that the double patenting doctrine arises from §101 of the patent statutes, rather than §§102 and 103, which the Federal Circuit models it double patenting test on, often incorrectly concluding there is no double*

patenting. §§102 and 103 serve different purposes than §101. This article argues that when the same inventor holds a genus patent for a pharmaceutical product, it should be estopped from obtaining a patent on a species within the scope of the genus, whether or not the genus patent constitutes prior art. Applying this strengthened double patenting doctrine would increase competition for the development of follow-on pharmaceutical products."

Conclusion: -

40. Thus, for the foregoing reasons I am not inclined to grant an injunction in favour of the plaintiffs and against the defendants. Consequently, the captioned applications are dismissed.

41. The defendants will, however, *via* their respective affidavits, place on record the details, quantum, and value of drug manufactured and sold as also indirect and direct taxes paid in that behalf. This information will be placed on the Court's record every quarter.

41.1 The defendants will also provide details of their assets [encumbered and unencumbered] which would include their location and current market value. The information given in the affidavits will be backed by a certificate of a statutory auditor. The defendants *via* their affidavits will also undertake to pay damages as and when called upon to do so by the Court. These affidavits will be filed within a period of 3 weeks.

CS (COMM) No. 410/2020 & CS (COMM) No. 411/2020

42. List the captioned matters on 15.01.2021.

RAJIV SHAKDHER, J

NOVEMBER 02, 2020

Click here to check corrigendum, if any