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

% Reserved on: 23rd, October, 2020
Decided on: 18th November, 2020

\+ **I.A. 6931/2020 (under Order XXXIX Rule 1 and 2 CPC)**
in
CS(COMM) 323/2020

ASTRAZENECA AB & ANR. ..... Plaintiffs
Represented by: Mr.Pravin Anand, Ms.Vaishali Mittal, Mr.Siddhant Chamola, Mr.Rohin Koolwal, Ms.Devyani Nath, Mr.Souradeep Mukhopadhyay, Advocates.

versus

TORRENT PHARMACEUTICALS LTD. ..... Defendant
Represented by: Mr.Sandeep Sethi, Sr. Advocate with Mr.S.Majumdar, Mrs.Suhrita Majumdar, Mr.Dominic Alvares, Mr.Afzal B. Khan and Mr.Samik Mukherjee, Advocates.

\+ **I.A.7399/2020 (under Order XXXIX Rule 1 and 2 CPC)**
I.A.9484/2020 (under Order XXXIX Rule 4 CPC-by defendant)
in
CS(COMM) 346/2020

ASTRAZENECA AB & ANR. ..... Plaintiffs
Represented by: Mr.Pravin Anand, Advocate with Ms.Vaishali Mittal, Mr.Siddhant Chamola, Mr.Rohin Koolwal, Ms.Devyani Nath, Mr.Souradeep M., Advocates.

versus

MICRO LABS LIMITED. ..... Defendant
Represented by: Mr.C.S.Vaidyanathan, Sr.Advocate Ms.Bitika Sharma, Mr.Adarsh Ms.Namrita Kochar, Ms.Nitya Sharma,

Mr. Devanshu Khanna, Ms.Vrinda Pathak, Mr.Akshay Nagarajan, Advocates.
Mr.J.Sai Deepak, Advocate

\+ **I.A. 8940/2020 (under Order XXXIX Rule 1 and 2 CPC)**

in

CS(COMM) 414/2020

ASTRAZENECA AB & ANR. ..... Plaintiffs

Represented by: Mr.C.Aryama Sundaram, Sr.Advocate with Mr.Pravin Anand, Ms.Vaishali Mittal, Mr.Siddhant Chamola, Mr.Rohin Koolwal, Ms.Devyani Nath and Mr.Souradeep Mukhopadhyay, Advocates.

versus

ZYDUS HEALTHCARE LTD. & ANR. .... Defendants

Represented by: Mr.C.S.Vaidyanathan, Sr.Advocate with Ms.Bitika Sharma, Mr.Adarsh Ramanujjan, Ms. Namrita Kochhar, Ms.Vrinda Pathak, Mr.Lakshay Kaushik and Ms.Nitya Sharma, Advocates.

\+ **I.A. 8991/2020 (under Order XXXIX Rule 1 and 2 CPC)**

in

CS(COMM) 418/2020

ASTRAZENECA AB & ANR. ..... Plaintiffs

Represented by: Mr.Pravin Anand, Ms.Vaishali Mittal, Mr.Siddhant Chamola, Mr.Rohin Koolwal, Ms.Devyani Nath, Mr.Souradeep Mukhopadhyay, Advocates.

versus

ERIS LIFESCIENCES LTD. .... Defendant

Represented by: Mr.C.S.Vaidyanathan, Sr.Advocate with Ms.Rajeshwari H., Mr.Tahir

A.J., and Mr.Praveen Singh, Advocates.

\+ **I.A. 8997/2020 (under Order XXXIX Rule 1 and 2 CPC)**
in
CS(COMM) 419/2020

ASTRAZENECA AB & ANR. ..... Plaintiffs
Represented by: Mr.Pravin Anand, Ms.Vaishali Mittal, Mr.Siddhant Chamola, Mr.Rohin Koolwal, Ms.Devyani Nath, Mr.Souradeep Mukhopadhyay, Advocates.

versus

USV PVT. LTD. .... Defendant
Represented by: Mr.C.S.Vaidyanathan, Sr.Advocate with Mr.J.Sai Deepak, Mr.G.Natrajan and Mr.Avinash Sharma, Advocates.

\+ **I.A. 9075/2020 (under Order XXXIX Rule 1 and 2 CPC)**
I.A.9316/2020 (under Order XXXIX Rule 4 CPC-by defendant)
in
CS(COMM) 426/2020

ASTRAZENECA AB & ANR. ..... Plaintiffs
Represented by: Mr.Sudhir Chandra, Sr. Advocate with Mr.Pravin Anand, Ms.Vaishali Mittal, Mr.Siddhant Chamola, Mr.Rohin Koolwal, Ms.Devyani Nath and Mr.Souradeep Mukhopadhyay, Advocates.

versus

MSN LABORATORIES PVT. LTD. .... Defendant
Represented by: Mr.J. Sai Deepak, Mr.G.Natarajan and Mr.Avinash Sharma, Advocates.

% Reserved on: 6th November, 2020
Decided on: 18th November, 2020

+ **I.A.10168/2020 (Under Order XXXIX Rule 4 CPC-by defendant)**
in
CS(COMM) 323/2020

ASTRAZENECA AB & ANR. ..... Plaintiffs
Represented by: Mr. Pravin Anand and Mr.Siddhant Chamola, Advocates.

versus

TORRENT PHARMACEUTICALS LTD. ..... Defendant
Represented by: Mr. Afzal B. Khan, Advocate with Mr. Samik Mukherjee, Advocate for applicant.

CORAM:
HON'BLE MS. JUSTICE MUKTA GUPTA

Brief Facts of the Plaintiffs:

1.1 By the present suits, the plaintiffs have sought decree of permanent injunction against the defendants and their employees and agents including third parties, for restraining them from manufacturing, selling, online retailing of the products comprising of the compound Dapagliflozin thereby infringing the patent owned by the plaintiffs being IN 235625 (in short, IN 625) besides damages and rendition of accounts in respect of the infringement of the patents IN 205147 (in short, IN 147) and IN 625.

1.2 By the present applications, the plaintiffs seek a temporary injunction restraining the defendants from manufacturing, selling, retailing etc. the compound Dapagliflozin thereby infringing the plaintiffs' patent IN 625, rendition of accounts and an ex parte relief in terms thereof. Since interim injunctions were granted in CS(COMM) 323/2020, CS(COMM)

CS(COMM) 426/2020 and CS(COMM) 346/2020, applications under Order XXXIX Rule 4 CPC have been filed therein.

1.3 The defendants in the present suits are Torrent Pharmaceuticals Ltd. (in short 'Torrent'), Micro Labs Limited (in short "Micro Labs'), Zydus Healthcare Ltd.(in short 'Zydus'), ERIS Lifesciences Ltd. (in short 'ERIS'), USV Pvt. Ltd. (in short 'USV') and MSN Laboratories Pvt. Ltd. (in short 'MSN').

1.4 Plaintiff No.1 Astrazeneca AB is a company organized and existing under the laws of Sweeden operating as a subsidiary of Astrazeneca PLC. Plaintiff No.2 Astrazeneca Pharma India Limited is a company incorporated under the laws of India and an Indian subsidiary of Astrazeneca marketing pharmaceutical products in the domestic market. By the suit patent IN 235625 (in short IN '625) which is the species patent of IN 205147 the genus patent, plaintiffs claim to have invented the pharmaceutical composition i.e. Dapagliflozin which is a molecule having the chemical formula (2S, 3R, 4R, 5S, 6R) -2-[4-Chloro-3-(4-ethoxybenzyl)phenyl]-6-(hydroxymethyl)tetrahdro-2H-Pyran-3,4,5-triol.

1.5 According to the plaintiff Dapagliflozin has proven to be an effective Sodium-Glucose co-Transporter 2 (in short SGLT2) inhibitor indicated for managing diabetes mellitus type 2. SGLT2 protein is a transporter protein majorly responsible for the reuptake of the glucose in the proximal tubule, thus playing a crucial role in maintaining a balance between the levels of glucose excretion as well as plasma glucose level by modulating what proportion of sugar filtered by the kidneys gets reabsorbed in the blood plasma. In view of Dapagliflozin working in reduction in re-absorption of the glucose, the same has turned out to be very effective in control of

diabetes and diabetic complication such as retinopathy, neuropathy, nephropathy, wound healing and related diseases. The plaintiff's distributor in India, namely Sun Pharma Laboratories Limited and Abbott Healthcare Private Limited make drugs comprising of Dapagliflozin, such as OXRA, OXAMET, OXMET IR, OXRAMET XR and GLEDEPA, GLEDEPA MET IR and GLEDEPA MET XR.

1.6 Plaintiff No.1 is the registered holder of the patent IN '147 having the title *'A C-ARYL GLUCOSIDE'* wherein the plaintiffs claimed the Markush structure which covered numerous compounds and based on various permutations and combination, quadrillion compounds could be prepared. The relevant bibliographic chart of the genus patent is as under:-

Application Number	IN/PCT/2002/00433/MUM	Genus Patent
Applicant Name	AstraZeneca AB	
PCT International Filing Date	October 02, 2000	
Priority date	October 12,1999	
S.11A Publication Date	March 18, 2005	
Date of Grant	March 15, 2007	
Date of Patent Expiry	October 02, 2020	

1.7 Plaintiff No.1 is also the registered holder of species patent IN '625 "*A COMPOUND (2S, 3R, 4R,5S,6R)-2(4-CHLORO-3(4-ETHOXYBENZYL) PHENYL)-6 (HYDROXYMETHL) TETRAHYDRO-2H-PYRAN-3, 4, 5-TRIOL AND COMPOSITION COMPRISING THE SAME*", which was prepared after further research and development and received on assignment

from Bristol Myers Squibb Company. The bibliographic details thereof are as under:-

Application Number	3573/DELNP/2004	Species patent
Applicant Name	AstraZeneca AB	
Date of Filing	November 16, 2004	
PCT International Filing Date	May 15, 2003	
Priority Date	May 20, 2002	
Publication Date (u/s 11A)	April 01, 2005	
Date of Grant	July 09, 2009	
Date of Patent Expiry	May 15, 2023	

1.8 According to the plaintiff the suit patent is valid in approximately 60 countries worldwide. It is the case of the plaintiff that IN '625 is a valid and subsisting patent and neither any pre-grant nor post-grant opposition was filed thereto except a post-grant opposition copy received by the plaintiff on 16th May, 2020 filed by the defendant/ TORRENT seeking revocation of the patent almost 11 years of the grant of the patent.

1.9 Since the defendants challenged the validity of the suit patent, learned counsels for the defendants addressed the arguments at length in the first instance which was replied by the learned counsels for the plaintiffs. Arguments on behalf of the parties were addressed on number of dates on day to day basis.

Contentions of Mr.C.S.Vaidynathan, Sr.Counsel on behalf of ZIDUS, ERIS and USV:-

2.1 Contention of Mr. C.S. Vaidyanathan, learned Senior Counsel for the defendants is that contrary to the claim of the plaintiffs, a prima facie case showing invalidity of the suit patent IN 625 is made out in favour of the defendants, the balance of convenience also lies in favour of the defendants. In case, an injunction is granted, the defendants would suffer an irreparable loss and that public interest also demands that no injunction be granted. According to the learned Senior counsel for the defendants, the plaintiffs could not have been granted the suit patent IN '625 as a specie patent but could have been granted as a patent of addition only. In the pleadings plaintiffs claim that IN '625 is covered under the genus patent IN '147 i.e. under its Markush Structure but IN '625 which claims Dapagliflozin was not disclosed in IN '147. This argument of the plaintiffs cannot be accepted as claim cannot be larger than the disclosure. This finding has already been returned by the Supreme Court in the decision reported as (2013) 6 SCC 1 *Novartis AG Vs. Union of India and Ors.* Further, this argument of the plaintiffs is hit by Section 10 of the Patents Act. Even as per the definitions under Sections 2(j) and 2(1)(ja) of the Patents Act, the species patent cannot be held to be an invention or an inventive step involving technical advancement. Further, the defendants have placed on record affidavits of expert and at this stage, the defendants are not relying upon the affidavit of Dr. Sanjay Desai, who is an employee of the defendants but on the affidavit of Dr. Bipin Pandey, an independent witness who is Ph.D. in Organic Chemistry from IIT Kanpur. In his affidavit, Dr. Bipin Pandey has stated that on going through examples of IN '147, it is clear from Example 11, 12,

70, 71 and 72 that halogen, preferably chlorine atom is a preferred substituent for R1 and for R4, O-lower alkyl is a preferred compound. Thus, the selection of R4 as ethoxy (-OEt group) will not be an undue burden to a skilled person. As per this affidavit, the compound Dapagliflozin is disclosed and claimed in IN 147 and preparation of compound as per example 12 can be considered to be the closest analog to Dapagliflozin, the only difference between the two being an-OEt (Et = ethyl groups, a lower alkyl) in Dapagliflozin instead of an -OMe (Me=methyl group, a lower alkyl) in example 12.

2.2 Learned Senior counsel for the defendants further contends that though no affidavit of an expert was filed with the plaint, plaintiffs have filed the affidavit of Mr.William N. Washburn, who is the co-author and inventor of Dapagliflozin as an additional document filed on 6th October, 2020. However, the said witness deals with the objections of Natco Pharma Limited only i.e. Dapagliflozin does not demonstrate increased efficacy and the compound is obvious and anticipated. Hence, the affidavit by this witness is of no use as it does not deal with the issue that the specie patent is already disclosed in the genus patent.

2.3 Learned Senior counsel for the defendants further states that the suit patent is also invalid for non-compliance of Section 8 as neither before the Indian Patent Office while seeking the patent IN 625 nor before this Court, the plaintiffs have disclosed that in the corresponding US patent, an objection was raised by the US Patent Office on 25th July 2002 stating that the claims 1 to 17 of the corresponding US patents were rejected under the judicially created Doctrine of Double Patenting unless a timely terminal disclaimer was filed to overcome an actual or provisional rejection. In

response to this objection by the US Patent Office, the plaintiffs filed their terminal disclaimer on 14th August, 2002, therefore accepting that any patent granted on the said application shall be enforceable only for enduring such period as that of the prior genus patent US No. 6, 414, 126 (in short US '126). Based on the terminal disclosure application plaintiffs were granted the species patent US '6515117 (in short US '117) equivalent to IN '625. In view of concealment of this document before the Indian Patent Office, the Indian Patent Office did not have the complete record to form an opinion thereon and hence, the suit patent IN 625 is invalid. Therefore, the defendants have raised a credible defence of invalidity under Section 64 of the Patents Act and not merely a triable issue, hence, there is no prima facie case made out in favour of the plaintiff.

2.4 Further, the plaintiffs are bound by the admissions made in respect of the claims made in the Orange Book and Form 27 besides the admission before the US Patent Office while seeking terminal disclaimer.

2.5 It is further contended that the balance of convenience also lies in favour of the defendants and in case, an injunction is granted, the defendants would suffer an irreparable loss. It is stated that as per the pleadings the only grievance of the plaintiffs is that the defendants have not taken a licence. Thus, the ultimate claim of the plaintiffs is by way of royalty. The plaintiffs are selling the drug with the compound Dapagliflozin by importing the same and has given licence to two companies i.e. Sun Pharmaceuticals and Abbot India Ltd. A perusal of the sales figures of the plaintiffs in para 68 of the plaint would show that half of the sales of the plaintiffs are through import and half through licences. Thus, even if the plaintiffs succeed in the suit, they would be entitled to the royalty and the defendants are ready and

willing to submit their accounts before this Court. The defendants are already selling the compound Dapagliflozin from 3rd October, 2020 and if injuncted, would suffer an irreparable loss. The medicines sold by the defendants is much cheaper in comparison to that of the plaintiffs and hence, public interest also requires the drug being made available for Diabetic patients, at lower prices.

2.6. Reliance of the learned counsel for the plaintiffs on the earlier interim orders and decree passed by this Court is misconceived for the reason, in none of those suits, challenge to the validity of the suit patent was argued before this Court. Reliance is also placed on the decisions reported as 1994(56) DLT 673 *Ravi Raj Gupta vs Acme Glass Mosaic Industries*, AIR 1996 Cal 367 *Hindustan Lever Limited v. Godrej Soaps Limited and Others*, 2010 (167) DLT 6 *Glaverbel S.A v. Dave Rose & Ors.*, 2014 (59) PTC 234 *Sandeep Jaidka v Mukesh Mittal*, 2010 FC 46 *Biovail Corporation & Depomed, Inc. & The Minister of Health & Apotex Inc.* (Federal Court of Canada), (1979) 2 SCC 511 *Bishwanath Prasad Radhey Shyam v. Hindustan Metal Industries*, 2009 (110) DRJ 452 *Hoffman La Roche v. Cipla* (DB), MIPR 2014 (3) 0004 *3M Innovative Properties Company v. Venus Safety Health Pvt. Ltd.*, [2005] UKHL 59 *Synthon Case (decision of the House of Lords in Synthon BV (Appellants) v. Smithkline Beecham plc (Respondents)*, [1995] RPC 255 *Glaverbel SA v. British Coal Corporation*, , MIPR 2014 (3) 0004*3 M Innovative Properties Company v. Venus Safety Health Pvt. Ltd.*.

Contentions of Mr.Sandeep Sethi, Sr.Counsel on behalf of TORRENT:-

3.1 In addition to the contentions in respect to the invalidity of the suit patent on the ground of disclosure in the genus patent, admissions of

plaintiffs in the pleadings, orange book and Form 27 filed by plaintiffs, learned Senior counsel for the Torrent has taken two other substantial objections one being the non-compliance of Section 8(1) and 8(2) of the Patents Act and second being the fact that in view of the plaintiff not having deposited its renewal fee the plaintiff's suit patent lapsed and in the absence of the same being republished in the Gazette, the plaintiff as on date does not have a valid and subsisting patent IN '625.

3.2 According to learned counsel for the defendant the basic requirements under Section 8(1) of the Patents Act are that the applicant shall file along with his application or subsequently within the period prescribed as referred under Rule 12 of the Patents Rule, firstly, a statement setting details of any application for patent being prosecuted in any country outside India in respect of the same or substantially the same invention and secondly, an undertaking that up to the date of grant of patent in India, the applicant would keep the Controller informed in writing, from time to time of detailed particulars as required under Section Clause 8 in respect of every other application relating to the same or substantially the same invention filed in any country outside India subsequently to the filing of the statement referred to hereinabove. Thus under Section 8(1) the obligation on the applicant does not depend upon any inquiry from the Controller but such an obligation arises at the time of filing the patent application itself and continues till the grant of the patent. Under Section 8(2) an obligation is cast on the applicant from the time of filing the application till the grant or refusal of the patent that if the Controller requires the applicant to furnish details, as may be prescribed, relating to the processing of any application in any country outside India, the applicant shall furnish to the Controller information

available to him within such period as may be prescribed.

3.3 According to learned Senior counsel for the defendant, the plaintiff has violated the mandate of both Section 8(1) and 8(2) of the Patents Act inasmuch as the plaintiff filed an application as continuation in part-application to the US genus patent US '126 which was granted as US '117 equivalent to the suit patent IN '625. The plaintiffs however did not file the objection of the USPTO which rejected the claim of the plaintiff in continuation in part-application, giving him an option for filing a terminal disclaimer wherein the plaintiff opted to file an application for terminal disclaimer. By merely giving the date and number of granted genus patent and the species patent granted as a continuation in part, the plaintiff's requirement of a complete disclosure before the Indian Patent Office in respect of the disclosure of objections raised by the USPTO and the plaintiff offering to convert the same to a terminal disclosure is not met. The plaintiff was under an obligation to disclose these facts under Section 8(1) and in any case on being required to furnish the details by the Controller under Section 8(2) the relevant documents were required to be submitted before the Indian Patents Office. Thus, the plaintiff consciously suppressed the fact that the US equivalent of IN '625 was objected to on the ground of double patenting, a concept equally prescribed under the Indian law. Further, the plaintiff also did not disclose the rejection of the Columbian equivalent of IN '147.

3.4 Reliance is placed on the Ayyangar Committee's report in respect of the interpretation of Section 8 of the Act, particularly in respect of the patent of addition. Reliance is also placed on the decision in MANU/DE/1880/2009 *Chemtura Corporation Vs. Union of India & Ors.*;

MANU/DE/2785/2014 *Sukesh Behl v. Koninklijke Phillips Electronics*; (2015) SCConline Del 13619 *F. Hoffmann-La Roche Ltd. v. Cipla Ltd.*

3.5 The second objection of Torrent to the validity of the suit patent is in respect of the suit patent having lapsed for want of paying the renewal fee. It is stated that even if the renewal fee was paid belatedly, the suit patent was required to be republished and could not have restored once it had lapsed. According to the defendant suit patent was published on 31st July, 2009 and the date of recordal was 27th January, 2010. The plaintiff was required to pay the accumulated renewal fee within three months i.e. 27th April, 2010, however, though due to the lapse of the patent office no payment of renewal fee was made, the patent lapsed on 27th April, 2010. On 27th April, 2011 the plaintiff filed a petition under Rule 137 of the Patents Rule 2003 to keep the patent alive which was allowed by the Patent Office on 4th July, 2011. On 15th May, 2020 the defendant filed a representation before the Patent office challenging the severe irregularity which representation was dismissed on 13th July, 2020. The Patent office not only noted that the renewal fees was not paid but also noted that the patent had not been published in the post-grant journal and directed the publication within 15 days. In this regard proceedings between the plaintiff and defendant are pending in a writ petition, however for the purposes of the present suit contention of the defendant is that the suit patent having lapsed once, it could not have been restored without an application under Section 60/61 of the Patents Act read with Rule 84 to 86 of the Patents Rules and without the patent being published. The suit patent according to the defendant Torrent has thus lapsed and is invalid. Reliance is placed on the decision in (2014) 15 SCC 360 *Alloys Wobben & Anr. v. Yogesh Mehra &*

Ors.

Contentions of Mr.S.Majumdar, Counsel on behalf of TORRENT

4.1 Mr. S. Majumdar, learned counsel on behalf of Torrent further submits that the suit patent IN '625 is hit by anticipation due to prior claiming. He states that there is a distinction between anticipation by prior claiming and anticipation by prior publication. For a suit patent to be revoked under Section 64(1)(a) no prior publication is required. However, if there is a prior patent for the same invention, no second patent can be granted. Even the definition of invention under Section 2(1)(j) of the Act provides that invention means a new product or process involving an inventive step and capable of industrial application. Therefore, the invention should be either a product or a process and consequently there is bound to be a conflict.

4.2 A perusal of the specification of the species patent IN '625 as against the genus patent IN '147 reveals that no disclosure at all which amounts to added matter not disclosed in the genus patent with respect to the compound Dapagliflozin exists. Further, mere details of synthesis being the process for making Dapagliflozin does not show any advantage possessed by the purported selected member of the species patent IN '625 over the genus patent. A hindsight analysis may be impermissible in obviousness but is not applicable to an objection of prior claiming and anticipation.

4.3 Relying upon the decision in (1970) R.P.C.; No.10 *Ethyl Corporation (Cook's) Patent*, it is contended that just as in cases of anticipation and obviousness, a claim is bad if it includes something within it which is shown to be old or obvious, so also in prior claim by analogy if a latter claim includes something already claimed in an earlier claim it is prima facie bad

until amended. Based on the three typical instances of conflict between a prior claim cited therein it is contended that a narrower latter claim which falls wholly within the broader areas of the disclosure of an earlier published prior document is hit by anticipation unless the patentee of the latter invention can show that he has selected an area from the prior broad disclosure which gives advantages beyond or different from those disclosed by the prior document. It is thus contended that the concept of selection patent necessitates that the advantage possessed by the selected member must be clearly disclosed in the specification of the species patent.

4.4 Reliance is also placed on the decision in (2006) SCA 1194 *Apotex Vs. Sanofi* wherein the established principle in the context of anticipation were laid down in (930) 47 RPC 289 *Re I.G. Farbenindustrie A.G.* it is contended that Dr. Washburn's affidavits cannot be treated as disclosure in the specification and the said affidavit being an opinion of the inventor it cannot be relied upon at this stage without the same being tested on the anvil of cross-examination.

4.5 Relying upon the decision in *Simpleair, Inc. Vs. Google LLC*, it is stated that a terminal disclaimer is a strong clue that a patent examiner and, by concession, the applicant, through the claims in the continuation lacked a patentable distinction over the parent. It is further stated that grant of a patent does not lead to any presumption of validity as provided under Section 13(4) of the Patents Act.

Contentions of Mr.J.Sai Deepak, Counsel on behalf of MSN and USV

5.1 Though in the opening argument Mr.J. Sai Deepak, learned counsel for the defendants MSN and USV took the plea of disclosure of the

pharmaceutical composition Dapagliflozin in IN '147 i.e. Dapagliflozin was disclosed prior to IN '625 the species patent and hence the same is invalid, however in the rejoinder argument learned counsel for the defendant also argued vulnerability of IN '625 on the ground of prior claiming in view Section 13(1)(b) read with Section 64(1)(a) of the Patent Act, on the basis of prior publication in terms of Section 13(2) read with Section 64(1)(e) of the Act and obviousness under Section 64(1)(f) of the Patents Act.

5.2 It is contended that IN '625 is liable to be revoked under Section 64(1)(a) read with Section 13(1)(b) and Section 107 of the Act. Section 13(1)(b) requires the patent examiner to investigate the subject matter claimed under examination in a patent application to see if any claim of another complete specification filed in India, having a priority date earlier than the filing date of complete specification in the subsequent application. Since IN '147 has an earlier priority date than IN '625, therefore IN 625 is anticipated by prior claiming within the meaning of Section 13(1)(b) to the extent it too claims Dapaglifozin. The significance of Section 13(1)(b) read with Section 64(1)(a) is that unlike other grounds of anticipation which require prior publication of the document sought to be used as anticipatory prior art, Section 13(1)(b) expressly permits the use of only an Indian Patent application or Indian patent which was published subsequent to the priority date of the challenged patent but has a priority date earlier than the challenged patent. The object of the provision is to ensure that no patent applicant takes the Patent Office for a ride by filing multiple patent applications covering the same subject matter. Under Section 64(1)(a) read with 13(1)(b) only coverage of the subject matter by a prior claim is required and there is no requirement of disclosure whatsoever. Therefore, the plea of

the plaintiffs that IN '147 only covers Dapagliflozin but does not expressly disclose is of no help or consequence to the plaintiff and in view of the prior claiming of Dapagliflozin in the claims of IN'147 the consequences in terms of Section 64(1)(a) must follow, whether or not Dapagliflozin is disclosed in IN '147. This submission of the defendant is without prejudice to the submission that Dapagliflozin is disclosed in IN '147.

5.3 The suit patent IN '625 is also liable to be revoked in terms of Section 13(2) read with Section 64(1)(e) of the Patent Act on the grounds of lack of novelty due to prior publication of WO2001/27128 which is PCT equivalent of the genus patent IN '147. WO2001/27128 was published on 19th April, 2001 whereas the priority date of IN '625 is 20th May, 2002.

5.4 The detailed descriptions of IN '625 matches with the descriptions of WO '128. WO '128 discloses C-aryl glucosides which are inhibitors of Sodium dependent glucose transporters found in the intestine and kidney (SGLT2). It is submitted that in Korea the concerned authority i.e. the Korean IP Tribunal and Appellate Board invalidated KR 101021752, equivalent to the species patent IN '625, based on WO '128 on the ground of lack of novelty. Further, WO 128 is also relevant to challenge the alleged inventive step of IN '625 i.e. IN '625 is obvious in the light of the claims and disclosure of IN '147, based on the state of art on its priority date.

5.5 Leaned counsel reiterates the arguments in relation to concealment under Section 8 of the Act and relies upon the decision in *Chemtura Corporation (supra)* and *Maj. (Retd.) Sukesh Behl & Anr. Vs. K. Philip Electronics*.

5.6 It is further contended that since the US species patent application resulting in grant of US '117 was filed as a continuation-in-part application,

which is akin to a patent of addition under Section 54 of the Patents Act, the term of the two Indian patents i.e. IN '147 and IN '625 should also be the same and IN '625 ought to be treated as a patent of addition and consequently expired on 2nd October, 2020. Further, the plaintiffs also did not submit before the Indian Patent Office, the rejection of the Colombian equivalent of IN '147 and thus suppressed material facts.

5.7 According to Mr. Sai Deepak, learned Advocate appearing on behalf of USV and MSN since the defendant launched its product after expiry of IN '147 on 2nd October, 2020, the same did not amount to infringement and it actually constitutes sufficient "clearing of the way". Since IN '147 claims Dapagliflozin and its composition, on expiry of IN '147 the defendants were entitled to use the information contained in such patent without legal bar or hindrance and the same does not amount to infringement. Under Section 13(4) of the Patents Act a patent enjoys no presumptive validity despite having been granted as held in 1979 (2) SCC 511 *Bishwanath Prasad Radhey Shyam Vs. Hindustan Metal Industry*. Since the defendant has laid credible challenge to the validity of the suit patent and the challenge being not vexatious as held by the Division Bench in *F. Hoffman La Roche & Anr. (supra*) 2009 (110) DRJ 452 (DB), the plaintiff is not entitled to any interim injunction.

5.8 According to the defendant as a matter of fact a case is made out for summary dismissal of the suit under Order XIII-A CPC even without a trial based on the documents of the plaintiff. In view of the own admission of the plaintiffs on 2nd October, 2020 the plaint is required to be rejected under Order VII Rule 11 CPC in terms of Section 53(4) of the Act. Further, while the plaintiff filed along with the suit, the grant of Patent Term Extension

(PTE) by the USPTO to US '117, they did not file the application for (PTE) filed by the plaintiffs before USPTO in respect of US '126. Further, pursuant to the final notice for election on 10th July, 2020 the plaintiffs elected US '117 for grant of PTE, as a consequence of which only US '117 was granted the PTE. Also the plaintiff submitted before the USFDA that US '126 which is equivalent to IN '147' covers Dapagliflozin. Moreover, Dapagliflozin is covered at least by the claims, 1, 14, 15 & 26 of the genus patent IN '147', as asserted by the plaintiffs in infringement proceedings against the third parties in the US, in particular claim suit filed against Zydus Pharmaceuticals (USA) Inc on 1st May, 2018. It is thus contended that in view of the repeated admissions of the plaintiff that Dapagliflozin is covered within the scope of the claims of the genus patent IN '147 the bar under Section 53(4) of the Patents Act is triggered.

5.9 It is contended that not only have the defendants demolished the plaintiff's claim of a prima facie case, even the balance of convenience and irreparable harm lies in favour of the defendant because it would be both in the interest of the public as also the rights of the defendants that no interim injunction is granted and the interim injunction granted in the case of MSN is vacated.

Contentions of Ms. Rajeshwari, Counsel on behalf of ERIS

6.1 Addressing further arguments Ms. Rajeshwari, Advocate, learned counsel for ERIS contends that IN '625 is not a valid patent as the compound Dapagliflozin is disclosed and thus anticipated by WO2001/027128 (WO '128 which is the international publication of IN '147). It is stated WO '128 is a prior art published prior to the priority date

of IN '625. The contention of the plaintiff that IN '147 was published only after 2005 and not a prior art is incorrect, since IN '147 was published as WO '128 prior to the priority date of IN '625 and thus acts as prior art. It is stated that WO '128 discloses several C-aryl glucoside compounds and also provides a list of preferred compounds. Within the class of these preferred compounds is one where R5a is lower alkyl; which could be thus methyl, ethyl, propyl, etc. Further, R^1 is a halogen preferably chlorine or fluorine. Thus, Dapagliflozin is one of the compounds which is embraced within the disclosure of WO '128.

6.2 Referring to the decision in r*e Petering* (301 F.2d 676) it is contended that even in case of markush, the publication would be deemed to describe the individual compound even though it did not spell out the compounds embraced by that markush. It is sufficient if a person of ordinary skill in the art is able to arrive at the compound using the prior art specification and his knowledge and there is no requirement under the Patents Act for the prior art to disclose the claimed compound by structure and formula. Reliance is placed on the decision in 1972 RPC 457 *General Tire & Rubber Company Vs. Firestone & Ors*. to determine whether the claims at hand are disclosed by prior art by using the infringement test.

6.3. Relying upon the admissions of the plaintiffs wherein the plaintiffs claim infringement of IN '147 by the defendant by manufacturing and selling Dapagliflozin, in the Orange Book plaintiffs list US '126 (equivalent to IN '147) as one of the patents and notified the world at large that it would be infringed if Dapagliflozin was made. Plaintiffs filed identical working statements in Form-27 for IN '147 and IN '625 listing Dapagliflozin as the compound which has worked. Plaintiffs also filed Patent Term Extension

(PTE) in respect of US '126 claiming that Dapagliflozin is disclosed therein.

6.4 IN '625 has failed as a selection patent in terms of the principles governing the grant of genus – species patents laid down in *Re: I.G. Farbenindustrie A.G.* (1930) 47 RPC 289. It is submitted that therefore a selection patent must demonstrate "substantial advantage" or "technical advancement". Further, data in support of the "technical advancement" must be present in the specification. In the present case IN '625 has miserably failed to provide even a bare minimal statement of "substantial advantage" or "technical advancement" with respect to the compound Dapagliflozin and in comparison with the compounds of IN '147. Therefore, IN 625 does not qualify as a selection patent or a species patent.

6.5 Plaintiff has relied upon the affidavit of Dr. Washburn, the inventor, to wriggle out of the lack of novelty, however the specifications as demonstrated in the affidavit cannot cure the defect of lack of proper disclosure of inventive steps in the original patent application of IN '625.

6.6 Relying upon the decision in *Astrazeneca AB Vs. TevaUK Limited* it is stated that "clear the way" doctrine is not applicable while granting or refusing injunction. Thus the plaintiffs have not made out a prima facie case in their favour. The balance of convenience also lies in favour of the defendants and if an injunction is granted not only the defendants would suffer an irreparable loss, public interest would also suffer.

Contentions of Mr.C.A. Sundaram, Sr.Counsel, Mr. Sudhir Chandra, Sr.Counsel and Mr.Pravin Anand, Counsel on behalf of the Plaintiffs-

7.1 In the initial arguments, case of the defendants was that Dapagliflozin was disclosed in IN'147, thus invalid, however, in rebuttal arguments the

defendants particularly, the defendants in MSN and USV also challenged the validity of the suit patent due to anticipation, prior claiming and obviousness. Learned counsels for the plaintiffs contend that infringement of IN‘625 is not the issue in the present suits for the reason the defendants agree that in case this Court finds IN‘625 to be valid, the product being manufactured and sold by the defendants infringes the plaintiffs’ suit patent. As noted above in the initial arguments, as against the claim of the plaintiff that genus patent IN ‘147 covers Dapagliflozin vide the species patent IN‘625 discloses the compound, the case of the defendants was that Dapagliflozin was not only covered but disclosed in IN‘147.

7.2 It is the case of the plaintiffs that IN‘147 relates to a different invention from that disclosed in IN’625, the former is the base structure or core, which can have variables at specific positions and the probable permutations thereof can run into millions. The invention in IN‘147 is a Markush structure common to all compounds which it covers and they all have common properties namely SGLT2 inhibition to prevent glucose re-absorption in the kidneys. However, IN‘625 discloses a specific compound ‘Dapagliflozin’ which has proved to be the winning candidate and a successful drug for Diabetes Type-2 mellitus having regard to efficacy, toxicity and other drug like properties. The defence of anticipation as taken by defendants in MSN and USV is inapplicable since the genus patent IN‘147 has been cited as a prior art but the said patent does not disclose Dapagliflozin by name or chemical formula or chemical structure. Out of the 80 examples disclosed in IN‘147, Dapagliflozin is not one of them.

7.3 It is contended that the defendants in their pleadings have clearly admitted that Dapagliflozin was first disclosed in US‘117, particularly, MSN

while filing its applications for their respective patents in the year 2014 and 2018 as also Zydus Cadila that Dapagliflozin was first disclosed in US‘117, equivalent to IN ‘625, the suit patent. Disclosure is a question of fact and disclosure of an invention in a prior art document alone destroys novelty of the subsequent patent for the said invention making it vulnerable to invalidity. Even in the decision in *Novartis* (supra) Supreme Court notes that there is a distinction between disclosure and coverage however, it is cautioned that the gap between the two should not be wide. Therefore, coverage cannot be deemed to be disclosure. The so called admissions used by the plaintiffs in Form-27 in India or the orange book or patent term extension in US etc. nowhere states that Dapagliflozin was disclosed in genus patents US‘126 or IN‘147.

7.4 Though none of the defendants have attacked the validity of IN‘147 however, in rejoinder arguments, indirectly the validity of IN '147 is also sought to be challenged on the basis of Markush formula by relying upon passages in *Novartis* (supra). The importance of Markush Structure was highlighted by the Division Bench of this Court in the decision reported as 2015 (63) PTC 257 (Del) *Merck Sharp and Dohme Corporation & Ors. vs. Glenmark Pharmaceuticals* wherein the genus patent was noted to claim all pharmaceutically acceptable salts of Sitaglptin as a Markush claim. Further even in *Novartis* (supra) the Supreme Court did not disapprove of the Markush structure of Zimmerman patent for Imatinib Mesylate. The Patent Office Manual also recognizes the validity of Markush structures and states that any species residing within the genus can be said to be anticipated only if it is unambiguous and specifically disclosed in the genus. It is not only the plaintiffs but the defendants and other similarly placed companies who

have been applying and have been granted patents for the Markush claim. IN‘147 covers the basic core, structure, scaffold (pharmacophore) showing three rings, one sugar and two phenyl, connected to each other in a certain way, and having multiple variables on specific positions of the two phenyl rings. If the total number of permutations are worked out, then several millions of compounds are covered by this basic core. Out of this basic core only 80 compounds were synthesized and identified in the genus patent specification in IN‘147, which can be treated as disclosed in IN‘147. On the expiry of the genus patent on 2nd October, 2020, only the inventive concept of the basic, core structure and the disclosed 80 examples went into the public domain and no further. In patent bargain in return for the disclosure of certain invention, the inventor gets a period of monopoly. The requirements of disclosure are provided under Sections 10(4) (b) read with Sections 11(3), 11(3A), 11(4) of the Act and since Dapagliflozin was not disclosed in IN‘147 it cannot go into public domain. In *Merck vs. Glenmark*, CS (OS) 586/2013, this Court has already held that multiple patents can cover a single product as is also evident from Sections 19, 91(1) and 141 (4) of the Patents Act. If a third party manufactures or sells the product before the expiry of the patent, the same would amount to infringement.

7.5 The decision in Novartis (supra) was based on the peculiar facts of that case wherein a finding of fact had been arrived at by the US Board of Appeals that Imatinib Mesylate was disclosed in Zimmerman patent. In the present case, there is no such finding of any Board, Tribunal or Court. Reliance is placed on the decision reported as 2013 FCA 214 *Eli Lilly vs. Apotex* wherein it was held that disclosure of a chemical compound takes

place when it is identified by reference to its chemical structure, name or IUPAC name.

7.6 In *Novartis* (supra) Supreme Court was dealing with the question whether the beta crystalline form of Imatinib Mesylate was an invention or not. In the said case the claim of invention was in two steps i.e. Imatinib to Imatinib Mesylate and Imatinib Mesylate to its beta-crystalline form. In view of the clear disclosure of the compound methane sulphonic acid of Imatinib in the Zimmerman patent and the claim expressly including Imatinib and its pharmaceutically acceptable salts, including Imatinib Mesylate Supreme Court held that since Imatinib Mesylate was disclosed in the Zimmerman patent thus there was no error in declining grant of patent to the beta crystalline form of Imatinib Mesylate.

7.7 Bar under Section 3(d) also does not apply to Dapagliflozin as it is neither a salt, ether, esters or polymorph of the compounds in IN‘147 unlike in *Novartis* (supra) where the beta crystalline was hit by Section 3(d) being a polymorph, thus requiring enhanced therapeutic efficacy. The therapeutic efficacy of Dapagliflozin over example 12 of IN‘147 has been duly explained by Dr.Washburn, the inventor, in his affidavit, that is, the enhanced ability of absorbtion of blood sugar 25%; plasma sugar 58%, 1.7 times selective of SGLT2 over SGLT1 Further, example 12 of In '147 never became a drug and has no known efficacy as it was never tested in humans. Dapagliflozin was synthesized in the year, 2001 after the priority date of IN‘625. All these factors clearly show that Dapagliflozin was not disclosed in example 12 of IN‘147.

7.8 Plea of the defendants in the rejoinder arguments that IN‘625 is invalid based on prior claiming under Section 64(1) (a) of the Indian Patents

Act is also fallacious. This oral submission of the defendants is contrary to the written pleadings of the defendants. Plaintiffs' response to the plea of double patenting or prior claiming under Section 13 (1) (b) taken by the defendants is that firstly there is no law in India on the question of double patenting and secondly prior claiming under Section 13 (1) (b) read with Section 64 (1) (a) requires that the invention as claimed in IN'625 should have been claimed in a complete specification having a priority date earlier to IN'625. The law of prior claiming requires two conditions; firstly that only claims have to be compared and secondly that the invention in the two claims is the same. Reliance is placed on the decisions reported as *Daikin Kogyo Co. Ltd*. and *application of Virgil W. Vogel*

7.9 On the issue of obviousness, the plaintiffs have already filed the affidavits of Dr. Washburn, the inventor and another affidavit of Dr. Eswaran. Affidavit of Dr. Bipin Pandey has been filed by the defendants which was relied upon by the defendants during the course of arguments, besides the affidavit of Dr. Tiwary. As per the plaintiffs evidence, a person of ordinary skill in the art on seeing IN'147 could not reach Dapagliflozin unless he was motivated by hindsight. Plaintiff's affidavits explain that the drilling down of 80 examples to a most preferred list by reference to Formula-1B and by referring to the conspicuity of the explanations given for Examples 1–15 and by reference to the fact that detailed manufacturing processes appear to be appended only to Examples 1-15 is a faulty methodology. Further, Formula-1B can have millions of possible permutations and defendants armed with hindsight arguments urges the logic to reach Dapagliflozin. As a matter of fact, the general knowledge prevalent at the time actually taught away from the use of ethoxy and preferred

methoxy as having superior qualities and thus the defendants cannot rely upon Example 12.

7.10 Drug discovery is not a drawing of a molecular structure on a paper but a complex task of pharmaceutical research involving synthesizing tens of thousands of compounds, testing them for their physical, chemical and biological properties, determining their best solubility, absorption through most appropriate salts, determining the best processes, researching their efficacy, safety and toxicity in vitro and then on animal models and once they show promise, then clinical trials on phase-1, 2 and 3 to study the pharmacokinetics and pharmacodynamics. Typically it takes ten years to research and one or two USD billions.

7.11 Rebutting the arguments of learned counsel for the defendants that the specifications in IN‘625 are the same as IN‘147 hence no technical advancement is specified in IN‘625, reply of the plaintiffs is that on the date of priority even the inventor may not be fully aware of the advantages and the properties of the invention. For example the instant drug Dapagliflozin was brought as SGLT2 inhibitor and for diabetes type -2 mellitus but with further treatments it has shown excellent properties for treatment of heart failure as well. Thus there cannot be and there is no requirement of law that all the properties, advantages and characteristics of the invention should be stated on the filing date of the patent application. Further post filing data with the inventor have also been held to be admissible in an attack on infringement in a suit. Reliance is placed on the decision reported as 655 F 3rd 1291 (2011) *Genetics Institute LLC vs. Novartis Vaccines* and 367 F.3d 1381, 1385 *Knoll Pharm Co. vs. Teva Pharms. USA, Inc*. If the application discloses the basic properties or utilities, the same satisfies the three

elements of novelty, utility and non-obviousness as noted in *Application of Walter Lorenz and Gerhard Schrader*, 333 F.2d 908 (C.C.P.A. 1964).

7.12 Under Section 10(4) Patents Act it is sufficient if the inventor discloses the best method known to the inventor even though at that stage it may not know all its advantages, benefits or special characteristics. Section 2(1) (ja) of the Patents Amendment Act, 2005 is unique to Indian law and this requirement does not exist in other jurisdictions like USA etc. The specifications of IN‘625 clearly state that large population suffers from Type-2 Diabetes which are expected to be solved by SGLT2 inhibition in the kidneys, it being a novel, safe and orally active anti-diabetic agent with less side effects, the known product was Phlorizin inhibited SGLT which had adverse effects. Various prior art documents disclose compounds that inhibit SGLT2 however, the specific compound of Formula-1 in IN‘625 possesses SGLT2 activity and is useful for the treatment of diabetes.

7.13 Section 53(4) starts with 'Notwithstanding anything in any other law', so it does not preclude other Sections of the Patents Act. Therefore, Section 53(4) relating to Term of Patent has to be reconciled with Sections 19(1), 88(3), 91 and 141 which relate to multiple patents covering a single product.

7.14 In respect of the application for terminal disclosure filed by the plaintiff before the US Patent Office in its species patent US‘117 though the claim of the defendants is that the same amounts to an admission that the patentee itself sought that the species patent was obvious and did not merit separate protection beyond US‘126, it is important to note the backdrop in which terminal disclaimer was filed in USA which made no practical difference to the plaintiff’s right with respect to Dapagliflozin in USA. In USA the plaintiff filed the species patent US‘117 as a continuation in part

application to the genus patent US‘126 and as per the US law MPEP 201.08 the basic requirement of a continuation in part application filed during the lifetime of an earlier non-provisional application is that it repeats substantial portion or all of the earlier non-provisional application besides additional matter not disclosed in the said earlier non-provisional application. Thus disclosure of additional matter is a prerequisite to entertain a continuation in part application. The moment, the US Patent Office accepted the application of the plaintiff as a continuation in part application, it is deemed that in the species patent there were further disclosures which were not there in the genus patent. Since the priority dates of US‘117 and US ‘126 were the same and would have expired on the same date, hence filing of the terminal disclaimer did not prejudice the plaintiffs. Further as held in 946 F2d 870 *Quad Environmental Technologies Corporation vs. Union Sanitary District Apt*. that agreeing to a terminal disclaimer is not an admission or acquiescence regarding invalidity on the ground of obviousness.

7.15 The plaintiffs have been able to clearly show compliance of Section 8(1) of the Patents Act when Form-3 was filled up along with necessary requirements on 16th November, 2004, 10th January, 2005 and 1st January, 2009 followed by the documents on 17th December, 2009. Specific particulars of the corresponding patent registration in USA, i.e. US‘117 were provided by the patentee of its own volition. The first page of the complete specification of the application for IN ‘625 before the Indian patent office itself mentions that its corresponding patent in USA was filed as a continuation in part application of the genus patent. In respect of non-compliance under Section 8(2) of the Patents Act it is submitted that the test is whether the examiner got full opportunity to examine the non-obviousness

of IN‘625. Since all material particulars in this regard were placed including the plaintiffs arguments on non-obviousness made through responses dated 8th October, 2008 the examiner was duly satisfied. In any case, there has been substantial compliance of requirement of Section 8(2) of the Patent Act. Reliance is placed on *Quad Environmental Technologies* (supra) and 884 F.3d 1160 *Simple Air vs. Google LLC* and Patentee’s response dated 8th October, 2008.

7.16 The objection of the US patent office is not an order or a finding but a mere objection. The decision to file a terminal disclaimer by the plaintiff was not motivated by any acknowledgment or acceptance that US‘117 was obvious in the face of US‘126 but only an obviation strategy which has been clarified in the decision in *Quad Environmental Technologies* (supra). Further even this Court in *Sukesh Behl vs. Philips* (supra) and *Merck vs. Glenmark* (supra) held that the issue of Section 8 is not the be all and end all of a temporary injunction claim, while adjudicating the issue of prima facie case for infringement of patent and the Court is only required to look at the issue broadly while deciding a temporary injunction claim.

7.17 Claim of the defendants that IN‘625 ought to have been registered as a patent of addition in view of the plaintiff having filed a continuation in part application in respect of its species patent US‘117 with the genus patent US‘126 so that both the patents co-terminated is fallacious for the reason it is the choice of the applicant to trade off an inquiry as to obviousness with co-terminus conditions under Sections 56 and 55 of the Patents Act and if the applicant is confident in the case of new molecule that it would withstand attack of obviousness, it need not seek a patent of addition. There is a difference between a continuation in part application and patent of

addition application for the reason the continuation in part application pre-supposes an additional disclosure in the said application. Defendants' reliance on the decisions reported as 2018 EWCA Civ 671 *Regeneron vs. Kymab* and 598 F.3d 1336 *Ariad vs. Eli Lily* is misconceived as Regeneron had applied for patents covering hybrid structures known as Reverse Chimeric Locus, which contained only a small part of human genetic element, however it had actually patented mice regardless of the amount of human genetic material. The Court held that the patent suffered from insufficiency and therefore, was invalid. Similarly in *Ariad* (supra) it was a biotechnology patent relating to methods only, not involving any Markush formula, and it was held to suffer from a descriptiveness issue.

7.18 Contention of defendants relying upon *Idenix Pharmaceuticals vs. Gilead*, 2018-1691 (CAFC) dated 30th October, 2019 citing the analogy with blaze marks on tress to contend that IN 625 patent is invalid for want of sufficiency also does not hold good in the facts of the present case as in *Gilead* (supra) the defendant attacked the patent for lack of enablement and failure to meet the written description requirement. There are no such flaws in the suit patent claim. The plaintiffs having made out a prima facie case, the balance of convenience also lies in favour of the plaintiff and the plaintiffs will suffer an irreparable loss in case no injunction is granted to the plaintiffs.

7.19 Adverting to facts relating to Zydus it is stated that Zydus manufactured and launched the drug Dapagliflozin under the brand name DAPAGLYN on 2nd October, 2020, released a large stock of Dapagliflozin to various stockiest, distributors in different cities of Gujarat. The product of Zydus reveals that it was manufactured in September, 2020. Zydus

neither filed a pre-grant nor a post-grant revocation petition challenging the suit patent. It is the case of the plaintiffs that the defendants were in clear knowledge of the plaintiffs' right in the species patent IN'625 as in the year 2018 the plaintiffs instituted a suit in the US District Court, Delaware against the defendants US company. Further Zydus in its own patent application in India and USA has admitted that Dapagliflozin was disclosed in the plaintiffs' species patent US'117 equivalent to IN'625. Even the defendant's patent application in USA for amorphous form of Dapagliflozin was rejected on the grounds of disclosure in US'117.

7.20 Qua the defendant MSN case of the plaintiffs is that on coming to know that the defendants are manufacturing and launching Dapagliflozin, plaintiff issued a legal notice on 6th October, 2020 and filed the instant suit. MSN has neither filed a pre-grant nor a post-grant opposition till the filing of the suit. In January, 2018 the defendant's US company submitted multiple ANDA applications recognizing the plaintiffs' right in Dapagliflozin and undertook that it will not launch any infringing generic drug until the expiry of the plaintiff's US patents till 2025. Further the defendant's own patent applications in India, in the years 2014 and 2015, one application in European Union (EU) in October, 2016 and two applications in USA one of which was filed on 28th November, 2018 as well as its PCT application filed in 2015 states that Dapagliflozin and its process for the preparation were first disclosed in US'117. The defendant's patent applications in India, EP and USA have been rejected in view of US'117. Though defendant MSN relies upon its 2016 application however, as noted above in its application in the year 2018 before the USPTO defendant MSN

again reaffirmed its position that Dapagliflozin was first disclosed in US'117.

7.21 Defendant Eris is selling the pharmaceutical composition Dapagliflozin manufactured by MSN who had made admissions over the years that Dapagliflozin was first disclosed in US'117. On learning about the defendants' action the plaintiffs issued a cease and desist letter on 3rd October, 2020 which was replied by the defendant on the same day at 11.00 PM wherein the defendant confirmed that it has launched the drug with the pharmaceutical composition Dapagliflozin under the brand name UDAPA. Thereafter, the defendant hurriedly filed the revocation petition against the plaintiffs' patent on 4th October, 2020 however, the said patent petition has not been acted upon by the IPAB as yet and nor has the plaintiff received any information in this regard.

7.22 Defendant Micro Labs applied for and was granted manufacturing approval of Dapagliflozin from the Drugs Authority, Tamil Nadu and when the plaintiffs learnt about the same they filed an application under Right to Information Act, 2005 which was objected to by the defendant stating that no such information should be provided. The defendant made an application before the National Pharmaceutical Pricing Authority (NPPA) requesting to fix the price for generic versions of Dapagliflozin as well as its combination with Metformin, where the defendant stated that they would manufacture and market the said drug. Initially this request was rejected by NPPA however, in September, 2020 NPPA claimed that price fixation had no linkage with the plaintiff. As per the plaintiff, the fixation of price does not entitle the defendant to actually release the infringing product in the market and violate the plaintiffs' right in the suit patent.

7.23 Plaintiffs thus contend that from the facts as noted it is evident that defendant MSN, Micro Labs, Eris, USV and Zydus have not cleared the way before launching the drug.

7.24 In respect of Torrent, it may be noted that the defendant in its Form-24 dated 17th June, 2020 filed before the patent office admitted having acquired marketing approval for drug Dapagliflozin therefore the plaintiff filed the suit wherein a statement was made on behalf of the defendant on 14th August, 2020 that the defendant would not commercialized the product until 2nd October, 2020 and before the said undertaking expired, this Court restrained the defendant from launching the drug by infringing the plaintiffs product till the next date of hearing before this Court which order has continued. The plaintiff and defendant Torrent are embroiled in multiple litigations. Firstly the defendant filed a representation dated 15th May, 2020 before the patent office challenging the species patent of the plaintiff which was published in July, 2011 on the patent office website. This representation was dismissed vide order dated 13th July, 2020 by the patent office. From this application the plaintiff got to know that the defendant had filed a revocation petition against IN 625 on 20th February, 2020. Further Torrent filed a post grant opposition before the patent office on 16th May, 2020, eleven years after the grant of the patent and atleast nine years since the factum of grant of patent was published on the patent office website, the defendant also filed a writ petition before W.P. (C) No.3470/2020 seeking removal of IN 625 from the patent register on the grounds taken in the revocation petition, the post grant opposition and the representation. The writ petition was disposed of vide order dated 11th June, 2020 whereafter Torrent filed a further petition before the patent office in Form-24 on 17th

June, 2020 followed by a second writ petition being W.P. (C) No.5187/2020 before this Court which is pending hearing. Plea of Torrent in the writ petition is that no renewal fee having been deposited, the patent lapsed and without fresh publication the patent could not have been revived.

ANALYSIS & REASONS:

Construction of claim & Disclosure of Dapagliflozin in IN '147

8.1 Main challenge to the validity of the suit patent IN '625 by all the defendants is on the ground of prior disclosure and anticipation by prior claiming in IN '147. These grounds would normally arise in most of the cases of grant of genus patent and the species patent as substantial portion of the claim/claims in a species patent are bound to be imbibed in the claims of the genus patent. In India and abroad, grant of patents for Markush claim and the selection claim i.e. the genus and species patents is legally permissible. To ascertain whether IN '625 is disclosed or claimed in IN '147, claims in the two patents are required to be compared.

8.2 Division Bench of this Court in the decision reported as 2015 (225) DLT 391 *F. Hoffman-La Roche vs. Cipla Ltd.,* dealing with the construction of claim held:-

> *66. Before we apply the aforenoted legal position to the facts of the instant case we need to discuss the legal position concerning construction of claims. In the decision reported as MANU/MH/0064/1969 : AIR 1969 Bombay 255 FH & B v. Unichem Laboratories it was held that specifications end with claims, delimiting the monopoly granted by the patent and that the main function of a Court is to construe the claims without reference to the specification; a reference to the specification being as an exception if there was an ambiguity in the claim. Claims must be read as ordinary English sentences without incorporating into them extracts from body of specification or*

changing their meaning by reference to the language used in the body of the specification. In a recent decision in FAO (OS) No. 190/2013 Merck v. Glenmark the Division Bench held that claim construction to determine the coverage in the suit patent has to be determined objectively on its own terms with regard to the words used by the inventor and the context of the invention in terms of the knowledge existing in the industry. Abandonment of an application cannot remove what is patented earlier nor can it include something that was excluded earlier and that a patent is construed by the terms used by the inventor and not the inventors subjective intent as to what was meant to be covered. Merely because an inventor applies for a latter patent that is already objectively included in a prior patent, but which inventor subjectively feels needs a separate patent application, doesn't mean it is to be taken at face value and therefore neither Section 3(d) or abandonment of subsequent patent application can be used to read into terms of prior application, which has to be construed on its own terms. In the decision reported as 415 F. 3d 1303 Edward H. Phillips v. AWH Corporation it was held that claims have to be given their ordinary and general meaning and it would be unjust to the public, as well as would be an evasion of the law, to construe a claim in a manner different from plain import of the terms and thus ordinary and customary meaning of the claim term is the meaning of the term to a Person Of Ordinary Skill in the Art as of effective date of filing of the patent application. In case of any doubt as to what a claim means, resort can be had to the specification which will aid in solving or ascertaining the true intent and meaning of the language employed in the claims and for which the court can consider patent prosecution history in order to understand as to how the inventor or the patent examiner understood the invention. The Court recognized that since prosecution is an ongoing process, it often lacks clarity of the specification and thus is less useful for claim construction. The Court also recognizes that having regard to extrinsic evidence such as inventor testimony, dictionaries and treaties would be permissible but has to be resorted to with caution because essentially extrinsic evidence is always treated as of

lesser significance in comparison with intrinsic evidence. In the decision reported as 457 F.3.1284 (United States) Pfizer v. Ranbaxy the Court held that the statements made during prosecution of foreign applications are irrelevant as they are in response to unique patentability requirements overseas. The Court also held that the statement made in later unrelated applications cannot be used to interpret claims of prior patent. In the decision reported as 1995 RPC 255 (UK) Glaverbel SA v. British Coal Corp the Court held that a patent is construed objectively, through the eyes of a skilled addressee. The Court also held that the whole document must be read together, the body of specification with the claims. But if claim is clear then monopoly sought by patentee cannot be extended or cut down by reference to the rest of the specification and the subsequent conduct is not available to aid the interpretation of a written document.

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

> *"(i) Claims define the territory or scope of protection (Section 10(4)(c) of the Patents Act, 1970.*
>
> *(ii) There is no limit to the number of claims except that after ten claims there is an additional fee per claim (1st Schedule of the Act).*
>
> *(iii) Claims can be independent or dependent.*
>
> *(iv) The broad structure of set of claims is an inverted pyramid with the broadest at the top and the narrowest at the bottom (Manual of Patents Office - Practice and procedure).*
>
> *(v) Patent laws of various countries lay down rules for drafting of claims and these rules are used by Courts while interpreting claims.*
>
> *(vi) One rule is that claims are a single sentence defining an invention or an inventive concept.*
>
> *(vii) Different claims define different embodiments of same inventive concept.*

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

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

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

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

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

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

(xiv) At the beginning of an infringement action the Courts in the United States conduct what is known as a 'Markman hearing' to define the scope of the claims or to throw light on certain ambiguous terms used in the claims. Although this is not

technically done in India but functionally most Judges will resort to a similar exercise in trying to understand the scope and meaning of the claims including its terms. "

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

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

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

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

(a) Comprising;

(b) Consisting;

(c) Consisting essentially of;

(d) Having;

(e) Wherein;

(f) Characterised by;

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

Further some terms are close ended such as 'consisting of, i.e. in a claim of three elements, 'A', 'B' and 'C' a defendant would infringe if he has all three elements. In case the defendant adds a fourth element 'D' he would escape infringement.

(xvi) Each claim has a priority date so that in a group of claims in a specification you could have multiple priority dates. This only means that if a patent application with certain priority date and claims was followed by another application with different claims and different priority dates, then if they were consolidated or cognate with another application, each claim would retain the original priority date [Section 11(1)]."

8.3 Even at the stage of interim injunction, construction of the claim by the Court, to verify its coverage is fundamental as held by the Division

Bench of this Court in *Merck Sharp and Dohme Corporation Vs. Glenmark (supra*). It was held that the coverage depends on the nature of the claims made and enabling disclosures specified by the patentee in its "Complete Specification" under Form 2 of the Act. The word used to describe the claims – as read by a person of ordinary skill in the art – determine the breadth of the monopoly granted by the patent, for which the substantive and indeed substantial rights under Section 48 of the Act are triggered. Noting the free base of Sitagliptin, the Division Bench observed that the patent was "directed to pharmaceutical compositions comprising these compounds and the use of these compounds and compositions". The issue required to be decided by the Court was as to how far these compositions can be subsumed with the "core" of the patent, without precise enabling disclosures; in other words, how elastic can the Court read the claim to be.

8.4 The Division Bench held that the term "composition" used in the specifications was intended to encompass a product comprising the specified ingredients in the specified amount as well as any product which results, directly or indirectly, from combination of the specific ingredients in the specified amounts. Such a term in relation to pharmaceutical composition, is intended to encompass a product comprising the active ingredients and the inert ingredients that make up a carrier as well as any product which results, directly or indirectly, from combination, complexation or aggregation of any two or more ingredients or from disassociation. The Division Bench also noted the limitations that the issues involved required a minute examination of the patent claim and its disclosure, prior art, subsequent application and the nature of Glenmark product which the Court cannot engage at the stage of interim hearing and should be left to the stage of full trial with pleading

and expert evidence, therefore, in determining whether a prima facie case exists, a mini trial is not required to be resorted to. The Division Bench thus noted that from the various examples which disclose the free base structure of Sitagliptin besides several known compounds and several methods for preparing the said compounds, the invention therein was that the compound created through Schemes 1 to 5 are used in Scheme 6 to reach the Sitagliptin free base, which is the essence of invention in the case. Case of Glenmark was that the patent does not disclose the Sitagliptin free base but only the Sitagliptin HCL salt.

8.5 The Division Bench in *Merck Sharp and Dohme (supra*) reiterated the Wands test to determine sufficiency or enablement of disclosure which provides: (1) the quantity of experimentation necessary (2) the amount of direction or guidance presented. (3) the presence or absence of working examples (4) the nature of the invention (5) the state of the prior art (6) the relative skill of those in the art (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

8.6 After applying the test laid down as noted above, the Division bench came to the conclusion that Sitagliptin free base was disclosed in the suit patent, as opposed to a salt form, whether phosphates, hydrochlorides or any other. The Court also noted that Glenmark does not dispute that free base was required to be transformed into a salt form before it could be administered to the patients. Rejecting the arguments of Glenmark that no free base was disclosed, this Court also noted that in each of the specifications Sitagliptin is found as the free base without any attached form and that the Court has to look to the invention in the case and read the claim literally. The claims must not be imaginary and must not leave anything

unarticulated that requires further research by those skilled in the art. Nor was there any principle that patent specifications be interpreted in favour of validity where an ambiguity exists. The Court noted that to constitute prior disclosure of an invention, the matter relied upon as prior art must disclose subject matter which, if performed, would necessarily result in infringement of the patent. Noting Section 10(4)(b) of the Patents Act, the Division Bench arrived at the conclusion that though Sitagliptin HCL salt was disclosed specifically in Example 7, however the phosphate salt was not disclosed leading to the clear inference that the specified salt was unknown to the inventor at the time or perhaps even if known was not disclosed.

8.7 Dealing with a markush claim and a subsequent species claim, in Model law of Patent, 2nd Edition, Consultant Editor –Judge Fysh, notes:

> "*A Markush group claim is used to define a family of compounds by defining the structure that is common to the whole family (the letter R being commonly used to represent the alternatives). The advantage of such a claim is that it removes the need to include a claim for each individual type of compound and claims, the advantage given by the whole group.*
> *The EPO has held by implication that a product can be defined by a generic formula and that such a product will anticipate products which are claimed in a more specific manner.*
> *It has been stated that a class of compounds which is defined only by a general structure, with at least two variable groups does not anticipate each individual compound which would result from the compound. This raises the issue of what happens where the invention is a particular compound and the prior art discloses a family of compounds, with a general formula including the particular compound but not explicitly describing it; in such a case the invention is novel. If the invention claimed is a group of compounds (rather than a particular compound) however; the invention lacks novelty.*"
>
> *(Emphasis supplied)*

8.8 In *Re I.G. Farbenindustrie A.G. (supra)* the principles governing grant of genus and species patent were laid down as under:

> *"Three general propositions may, however, I think, be asserted as true:- First, a selection patent to be valid must be based on some substantial advantage to be secured by the use of the selected members. (The phrase will be understood to include the case of a substantial disadvantage to be thereby avoided.) Secondly, the whole of the selected members must possess the advantage in question. Thirdly, the selection must be respect of a quality of a special character which can fairly be said to be peculiar to be selected group. The first proposition is plain (see the statement of Mr. Justice Parker in Clyde Nail Co. Ld. V. Russell, (1916) 33 R..C. 291, at p. 306). I will add that this condition must not be assimilated with the doctrine of utility as applied to an originating patent. In such a patent there may well be invention without utility. In a selection patent the condition that there must be a substantial advantage attributable to the use of the selected members in inherent in the so-called invention…*
>
> *… I must add a word on the subject of the drafting of the specification of such inventive step, that it is necessary for the patentee to define in clear terms the nature of the characteristic which he alleges to be possessed by the selection for which he claims a monopoly….*
>
> *… I will summarise the conclusion at which I have arrived by saying that in a selection patent the inventive step lies in the selection for a useful and special property or characteristic adequately defined; and this is the proposition which has to be kept in mind in considering the application to amend and the Petition for revocation".*"
>
> *(Emphasis supplied)*

8.9 Thus the principles which emerge from the decision in *I.G. Farbenindustrie A.G. (supra)* for a selection patent to be valid are:

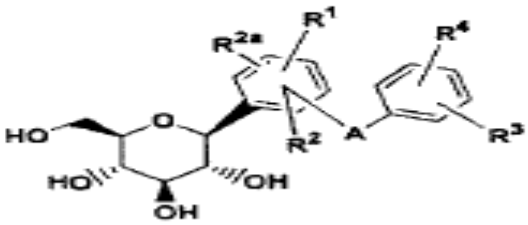
> *"(i) There must be a "substantial advantage" to be secured or disadvantage to be avoided by the use of the selected*

members of the species patent as compared to the non-selected members of the genus patent;
(ii) The whole of the selected members of the species patent must possess the substantial advantage in question;
(iii) Selection must be in respect of a quality of a special character peculiar to the selected members (i.e. as compared to the non-selected members of the genus patent);
(iv) The patent specification qua the selection patent must disclose the "substantial advantage" or "unexpected advantage" possessed by the "selected members" and compared to the non-selected members of the genus patent."

8.10 It is thus established that both a markush formula with number of variables can be granted a valid patent besides a selection patent which though covered under the markush formula is not disclosed clearly and unambiguously in the markush formula. As noted above, one of the four conditions laid down in *I.G. Farbenindustrie A.G.* case for the selection patent to be valid are that the selection patent must show substantial advantage or avoid disadvantage by use of the selected members of the species patent as compared to the non-selected members of the genus patent. It is the case of the plaintiffs that by the markush formula, the pharmaceutical composition Dapagliflozin was not arrived at much less manufactured or marketed. Thus the pharmaceutical composition Dapagliflozin specifically disclosed in claim 1 and 2 of IN '625 clearly shows a substantial advantage and hence it cannot be held that Dapagliflozin is disclosed in IN '147. Further as noted in *Merck Sharp and Dohme* (supra), a phosphate salt of Sitagliptin cannot be deemed to be disclosed in the Sitagliptin free base or the HCL salt thereof, in the present case a compound with ethoxy substitution instead of a methoxy as the lower alkyl group cannot be interpreted to read disclosure of Dapagliflozin in IN '147.

8.11 IN '147 seeks patent for a group of compounds as noted in the 26 claims with number of permutations and combinations of which claim 1 is as under:

A C-aryl glucoside having the structure

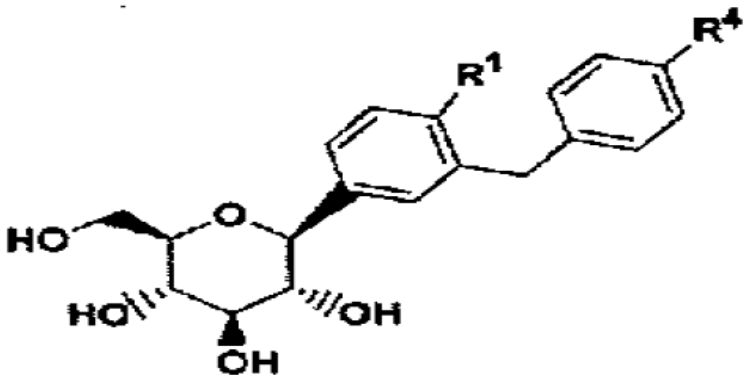


wherein R^1, R^2 and R^{2a} are independently hydrogen, OH, OR^5, alky1, CF_3, $OCHF_2$, OCF_3, SR^{5i} or halogen, or two of R^1, R^2 and R^{2a} together with the carbons to which they are attached can form an anelated five, six or seven membered carbocycle or heterocycle which may contain 1 to 4 heteroatoms in the ring which are N, O, S, SO, and/or SO_2; R^3 and R^4 are independently hydrogen, OH, OR^{5a}, OAryl, OCH_2, Aryl, alkyl, cycloalkyl, CF_3, $-OCHF_2$,-OCF_3, halogen, -CN, $-CO_2R_{5b}$,$-CO_2H$, COR^{6b}, -CH (OH) R^{6c}, -CH (OR^{5h}) R^{6d},- $CONR^6R^{6a}$, $NHCOR^{5c}$, $-NHSO_2R^{5d}$, $-NHSO_2$Aryl, Aryl, $-SR^{5e}$, SOR^{5f}, $-SO_2R^{5g}$, $-SO_2$Aryl, or a five, six or seven membered heterocycle which may contain 1 to 4 heteroatoms in the ring which are N, O, S, SO, and/or SO_2, or R^3 and R^4 together with the carbons to which they are attached form an anelated five, six or seven membered carbocycle or heterocycle which may contain 1 to 4 heteroatoms in the ring which are N, O, S, SO, and/or SO_2; R^5, R^{5a}, R^{5b}, R^{5c}, R^{5d}, R^{5e}, R^{5f}, R^{5g}, R^{5h} and R^{5i} are independently alky; R^6, R^{6a}, R^{6b}, R^{6c} and R^{6d} are independently hydrogen, alkyl, aryl, alkyaryl or cycloalkyl, or R^6 and R^{6a} together with the nitrogen to which they are attached from an anelated five, six or seven membered heterocycle which

may contain 1 to 4 heteroatoms in the ring which are N, O, S, SO, and/or SO_2, A is O, S, NH, or (CH_2)n where n is O-e, or a pharmaceutically acceptable salt, stereoisomer, or prodrug ester thereof; with the proviso that where A is (CH_2)n where n is O, 1, 2 or 3 or A is O, and at least one of R^1, R^2, and R^{2a} is OH or OR^5, then at least one of R^1, R^2, and R^{2a} is CF_3, OCF_3,-CN, -CO_2R^{5b}, CH (OR^{5h}) R^{6d}, CH(OH) R^{6c}, COR^{6b}, -$NHCOR^{5c}$, -$NHSO_2R^{5d}$, -$NHSO_2$Aryl, Aryl, -SR^{5e},-SOR^{5f}, -SO_2Aryl.

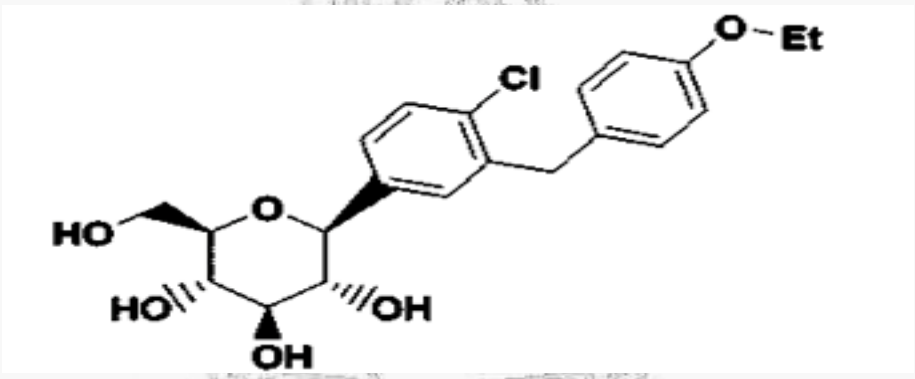
8.12 There are in total 26 claims in the application for which IN '147 was granted. Claim No.1 is noted above. Claims-1 to 5 are further claims wherein substitution of primarily 'A' has been given with various permutation and combinations. Claim-6 is a wide claim wherein not only substitution of 'A' has been provided but of R^1, R^2, R^{2a} also with specified claims thereof at Serial Nos.7, 8, and 9. Claim-10 gives certain specific structure of claim-3 whereas claim-11 gives a specified structure of Claim-1, wherein 'A' is CH_2 and various options for R^1, R^2, R^{2a} and R^3 have been given. Claim-12, 13 and 14 give structures of claim-1. Claim-15, 16 and 17 provide for the pharmaceutical compositions of Claim-1 and Claim-16. Claim-18 is a combination of Claim-17 with an antibiotic agent. Claim-19 provides the composition along with various anti diabetic agents such as Metformin, Glytburide etc. Claim-20 gives weight ratio of the anti diabetic agent as claimed in Claim-17 whereas Claim-21 describes the composition in Claim-16 along with an anti obesity agent. Claim-22 describes the various anti obesity agents in Claim-21. Claim-23 describes various lipid lowering agents in Claim-16. Claim-24 also describes the various lipid lowering agent in Claim-23. Claim-25 describes SGLT2 inhibitor weight ratio to lipid lowering agent in Claim-23. Claim-26 describes the

composition as claimed in any of the proceeding claims wherein SGLT2 inhibitors compound has a structure:



8.13 Claim of the plaintiff in patent IN '625 is as under:

(2S,3R,4R,5S,6R)-2-(4-Chloro-3-(4ethoxybenzyl)phenyl) (hydroxymethyl) tetrahydro-2H-pyran-3,4,5-triol having the structure



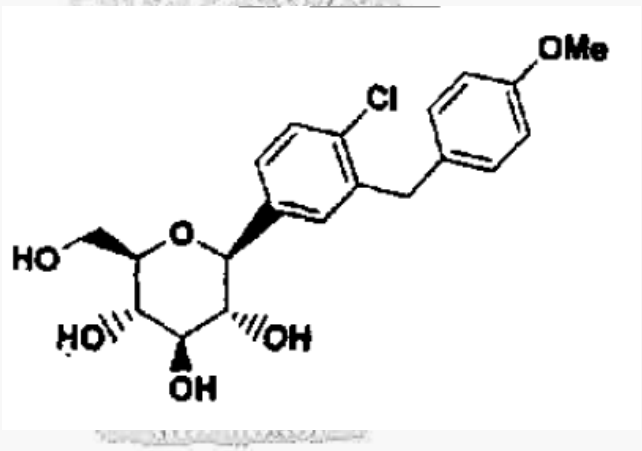
or a pharmaceutically acceptable salt, a stereoisomer thereof, or a prodrug ester thereof. A pharmaceutical composition as and when prepared by using the compound as defined in Claim 1 and a pharmaceutically acceptable carrier of the kind such as herein described.

8.14 Case of the plaintiffs is that though IN '147 the genus patent covers Dapagliflozin, however it nowhere discloses Dapagliflozin and the same is specifically disclosed in the species patent IN '625. According to the

plaintiff IN ‘147 discloses only 80 exemplified compounds and Dapagliflozin is not one amongst these 80 compounds. Even claim 1 of IN ‘147 i.e. markush structure has 22 variables and therefore markush structure itself contains a large number of substituents.

8.15. According to the defendant example 12 of the IN‘147 discloses the compound claimed in IN‘625. Example 12 of IN ‘147 gives five methods of preparation of 5-Bromo-2-chloro-4’-methoxydiphenylmethane. The five methods of preparation of example 12 result in the following structure:

“Example 12



8.16 A reading of example 12 would indicate that out of the Halogens, chorine has been identified as the preferred halogen however, in Example-12 all the procedures relate to methoxy substitution and not to ethoxy. In the entire Example 12 of IN '147 there is no teaching in favour of ethoxy. Thus based on the decisions noted above and reading of the claims in IN '147 and IN '625 it is clear that IN '147 comprises of a group of claims belonging to a family, and even the closest Example 12 in IN '147 discloses methoxy benzophenone as the ingredient of the compound and there is no disclosure of a compound with ethoxy group as in Dapagliflozin. Thus, as held by the

Division Bench in *Merck Sharp Dohme vs. Glenmark* (supra) that though Sitagliptin HCL salt was disclosed but not the phosphate salt in the present case though the compound with methoxy salt was disclosed but not with ethoxy. Further substantial improvement in IN '625 is attributable from the fact that the drug Dapagliflozin came only under IN '625 and not under IN '147 though it gave various options for SGLT2 inhibitors but not Dapagliflozin. Also as per the tests laid down in *I.G. Farbenindustrie A.G* (supra) Dapagliflozin the product of the claim in IN '625 shows a substantial advantage over the claims in IN '147 as no viable drug could be manufactured from the claims in IN '147, even though the compounds thereof depicted SGLT2 properties.

Whether Admission of Coverage in IN '147 amounts to Disclosure

9.1 Case of the defendants is that since the plaintiffs have admitted in their pleadings and applications that Dapagliflozin is covered by IN '147 and there being no distinction between coverage and disclosure as per the decision of the Supreme Court in *Novartis* (supra) the suit patent IN '625 is invalid having been disclosed in IN '147.

9.2 In the case of *Novartis*, (supra) Novartis had filed an application seeking patent for the beta crystaline form of Imatinib Mesylate. Though the Zimmermann Patent was for Imatinib, however no patent for Imatinib Mesylate was sought by Novartis and it sought patent only for the beta crystaline form of Imatinib Mesylate. The grant of beta crystaline form of Imatinib Mesylate to Novartis was rejected by the IPAB returning a clear finding of fact that Imatinib Mesylate was disclosed in the Zimmermann Patent for Imatinib.

9.2 Before proceeding to analyse the distinction between coverage and

disclosure it would be appropriate to note the relevant paragraphs of the decision in *Novartis* as under:

> *"105. From the above discussion it would be clear that the drug Gleevec directly emanates from the Zimmermann Patent and comes to the market for commercial sale. Since the grant of the Zimmermann Patent, the appellant has maintained that Gleevec (that is, Imatinib Mesylate) is part of the Zimmermann Patent. It obtained drug approval for Gleevec on that basis. It claimed extension of the term of the Zimmermann Patent for the period of regulatory review for Gleevec, and it successfully stopped NATCO Pharma Ltd. from marketing its drug in UK on the basis of the Zimmermann Patent. Not only the appellant but the US Board of Patent Appeals, in its judgment granting patent for beta crystalline form of Imatinib Mesylate, proceeded on the basis that though the beta crystalline form might not have been covered by the Zimmermann Patent, the Zimmermann Patent had the teaching for the making of Imatinib Mesylate from Imatinib, and for its use in a pharmacological compositions for treating tumours or in a method of treating warm-blooded animals suffering from a tumoral disease. This finding was recorded by the US Board of Patent Appeals, in the case of the appellant itself, on the very same issue that is now under consideration. The appellant is, therefore, fully bound by the finding and cannot be heard to take any contrary plea.*
>
> *xxx*
>
> *112. That Imatinib Mesylate is fully part of the Zimmermann Patent is also borne out from another circumstance. It may be noted that after the Zimmermann Patent, the appellant applied for, and in several cases obtained, patents in the US not only for the beta and alpha crystalline forms of Imatinib Mesylate, but also for Imatinib in a number of different forms. The appellant, however, never asked for any patent for Imatinib Mesylate in non-crystalline form, for the simple reason that it had always maintained that Imatinib Mesylate is fully a part of the Zimmermann Patent and does not call for any separate patent.*
>
> *113. We thus find no force in the submission that the development of Imatinib Mesylate from Imatinib is outside the*

Zimmermann Patent and constitutes an invention as understood in the law of patent in India.

xxx

118. The submissions of Mr Andhyarujina and Mr Subramanium are based on making a distinction between the coverage or claim in a patent and the disclosure made therein. The submissions on behalf of the appellant can be summed up by saying that the boundary laid out by the claim for coverage is permissible to be much wider than the disclosure/enablement/teaching in a patent.

119. The dichotomy that is sought to be drawn between coverage or claim on the one hand and disclosure or enablement or teaching in a patent on the other hand, seems to strike at the very root of the rationale of the law of patent. Under the scheme of patent, a monopoly is granted to a private individual in exchange of the invention being made public so that, at the end of the patent term, the invention may belong to the people at large who may be benefited by it. To say that the coverage in a patent might go much beyond the disclosure thus seem to negate the fundamental rule underlying the grant of patents.

120. In India, Section 10(4) of the Patents Act, 1970 mandates:

> *"10.Contents of specifications.—(1)-(3) ****
>
> *(4) Every complete specification shall—*
>
> *(a) fully and particularly describe the invention and its operation or use and the method by which it is to be performed;*
>
> *(b) disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection; and*
>
> *(c) end with a claim or claims defining the scope of the invention for which protection is claimed;*
>
> *(d) be accompanied by an abstract to provide technical information on the invention:*

Provided that—

(i) the Controller may amend the abstract for providing better information to third parties; …"

And, Section 10(5) provides as under:

"10. (5) The claim or claims of a complete specification shall relate to a single invention, or to a group of inventions linked so as to form a single inventive concept, shall be clear and succinct and shall be fairly based on the matter disclosed in the specification."

121. The UK Patents Act, 1977, in sub-sections (2), (3) and (5) of Section 14, provides as under:

*"14.Making of an application.—(1)-(1-A) ****

(2) Every application for a patent shall contain—

(a) a request for the grant of a patent;

(b) a specification containing a description of the invention, a claim or claims and any drawing referred to in the description or any claim; and

(c) an abstract,

but the foregoing provision shall not prevent an application being initiated by documents complying with Section 15(1) below.

(3) The specification of an application shall disclose the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the art.

***

(5) The claim or claims shall—

(a) define the matter for which the applicant seeks protection;

(b) be clear and concise;

(c) be supported by the description; and

(d) relate to one invention or to a group of inventions which are so linked as to form a single inventive concept."

122. Further, Section 112(a) of the Title 35 of the US Code provides as under:

> *"35 U.S.C. § 112 [Recall that it is on the basis of this provision that the US Board of Patent Appeals had held in the case regarding the appellant's claim for patent for beta crystalline form of Imatinib Mesylate that "in light of 35 U.S.C. § 282, therefore, we may presume that the specification of the Zimmermann Patent teaches any person skilled in the art how to use Imatinib, or a pharmaceutically acceptable salt thereof,…".]*
>
> *(a) In general.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention."*

123. Terrell on Law of Patents (17th Edn., 2011) in Chapter 9: "Construction of the Specification and Claims", under the heading "Principles equally applicable to infringement and validity" states:

> *"9.05.—Section 125(1) defines an 'invention' as (unless the context otherwise requires) that specified in a claim of the specification, and both validity (see Sections 1 to 4 and 72 of the Act) and infringement (see Section 60) are to be tested by reference to the 'invention'. It is, of course, a fundamental principle that the construction of a claim is the same whether validity or infringement is to be considered; no patentee is entitled to the luxury of an 'elastic' claim which has a narrow meaning in the former case but a wide meaning in the latter. Under English procedure, infringement and validity are normally litigated at the same time and therefore the court is astute to avoid such a result. …"*
>
> *(emphasis supplied)*

124. Chisum on Patents: A Treatise on the Law of Patentability, Validity, and Infringement (Vol. 3-6-2007) in chapter "Adequate Disclosure" notes:

> *"§ 7.03. — The enablement requirement*
>
> *Since 1790, the patent laws have required that the inventor set forth in a patent specification sufficient information to enable a person skilled in the relevant art to make and use the invention.*
>
> *The 'invention' that must be enabled is that defined by the particular claim or claims of the patent or patent application. This is consistent with the general principle of patent law that the claim defines the invention for purposes of both patentability and infringement."*

125. Nevertheless, both Mr Andhyarujina and Mr Subramanium strenuously argued that the coverage or the claim, and the disclosure or the teaching, have different parameters in a patent, and that the former may have an extended boundary within which disclosure or teaching may be confined to a narrower extent. In support of the submission, Mr Andhyarujina relied upon a decision of the Court of Appeal in A.C. Edwards Ltd. v. Acme Signs & Displays Ltd. [1992 RPC 131] and another of the High Court of Justice, Chancery Division, Patent Court in Astellas Pharma Inc. v. Comptroller General of Patents [2009 EWHC 1916 (Pat)] .

126. Mr Gopal Subramanium strongly relied upon the decision of the United States Court of Customs and Patent Appeals in Hogan, In re [Hogan, In re, 559 F 2d 595 (CCPA 1977)] in support of his contention.

xxx

132. It needs to be noted here that even in the US, Hogan [Hogan, In re, 559 F 2d 595 (CCPA 1977)] represents a decision given in the context of the special set of facts and circumstances of the litigation over polypropylene. In later decisions, the Federal Circuit appears to have drastically narrowed Hogan case's [Hogan, In re, 559 F 2d 595 (CCPA 1977)] scope as a precedent. In Plant Genetic Systems, N.V. v. DeKalb Genetics Corpn. [315 F 3d 1335, 1341 (Fed Cir 2003)] the effect of Hogan [Hogan, In re, 559 F 2d 595 (CCPA

1977)] was considerably constricted and its effect is virtually eliminated in Chiron Corpn. v. Genentech Inc. [363 F 3d 1247, 1257 (Fed Cir 2004)] Since Chiron [363 F 3d 1247, 1257 (Fed Cir 2004)], the Federal Circuit has not referred to Hogan [Hogan, In re, 559 F 2d 595 (CCPA 1977)] in any of its cases that involved claims to a genus where a single species was enabled.

xxx

134. However, before leaving Hogan [Hogan, In re, 559 F 2d 595 (CCPA 1977)] and proceeding further, we would like to say that in this country the law of patent, after the introduction of product patent for all kinds of substances in the patent regime, is in its infancy. We certainly do not wish the law of patent in this country to develop on lines where there may be a vast gap between the coverage and the disclosure under the patent; where the scope of the patent is determined not on the intrinsic worth of the invention but by the artful drafting of its claims by skilful lawyers, and where patents are traded as a commodity not for production and marketing of the patented products but to search for someone who may be sued for infringement of the patent.

135. In light of the discussions made above, we firmly reject the appellant's case that Imatinib Mesylate is a new product and the outcome of an invention beyond the Zimmermann Patent. We hold and find that Imatinib Mesylate is a known substance from the Zimmermann Patent itself. Not only is Imatinib Mesylate known as a substance in the Zimmermann Patent, but its pharmacological properties are also known in the Zimmermann Patent and in the article published in the Cancer Research journal referred to above. The consequential finding, therefore, is that Imatinib Mesylate does not qualify the test of "invention" as laid down in Section 2(1)(j) and Section 2(1)(ja) of the Patents Act, 1970."

(Emphasis supplied)

9.3 Supreme Court in para 105 of the report noted that US Board of Patents Appeal gave a clear finding that Imatinib Mesylate was disclosed as a pharmaceutical preparation in the Zimmermann Patent for Imatinib and

based on that finding of fact, Supreme Court held that Imatinib Mesylate having been disclosed in the Zimmermann Patent, beta crystaline form of Imatinib Mesylate could not have been granted a species patent. A finding of fact that the Zimmerman Patent had the teachings for the making of Imatinib Mesylate from Mesylate and for its use in a pharmacological compositions for treating tumours was also noted by the Supreme Court. Further, Novartis never sought any patent for Imatinib Mesylate though it sought for its beta crystaline form and other forms of Imatinib. In view of these findings of fact already arrived at by US Board of Patent Appeals, Supreme Court rejected the claim that Imatinib Mesylate is a new product and outcome of an invention beyond the Zimmermann Patent. However, Supreme Court noted a caution saying that the law of patent in India is in its infancy and it would not like the same to develop where there is a vast difference between coverage and disclosure. This observation of the Supreme Court clearly notes the distinction between coverage and disclosure and thus it would have to be determined on the facts of each case whether the species patent is merely covered by the Markush claim or is disclosed in the same.

9.4 Both sides have filed the affidavits of the experts including the plaintiff's inventor Dr.Washburn, however since these witnesses are yet to be cross-examined, at this stage this Court can form no prima facie opinion based on the affidavits of these experts as the averments in the respective affidavits are diametrically opposite.

9.5 Applying the tests as noted in *Novartis* (supra) to the facts of the present case and on claim construction it is evident that in the claim specifications of IN '147 the composition of Dapagliflozin is not mentioned

and the general properties of markush claim with various permutations and combinations were mentioned. Further the plaintiffs did not apply for drug approval based on IN '147 but based on IN '625, though plaintiffs' claim infringement of IN '147 as well being the markush structure. Hence this Court is of the prima facie opinion that Dapagliflozin is not disclosed in IN '147, as further research and experimentation on IN '147 was required to arrive at IN '625.

Anticipation by Prior Claiming:

10.1 Learned counsels for the defendants have challenged the validity of the suit patent on the ground of anticipation by prior claiming even if not a case of anticipation by prior publication. Section 10(4) of the Patents Act provides for the complete specification of the claims which requires that the specifications must fully and particularly describe the invention, its operation or use and the method by which it has to be performed, disclose the best method of performing the invention which is known to the applicant and for which it is entitled to claim protection and end with a claim defining the scope of invention for which protection is claimed. It is thus stated that since DAPAGLIFLOZIN is claimed in IN‘147, it is liable to be revoked under the provisions of Section 64(1) (a) of the Patents Act.

10.2 Learned counsels for the defendants have relied upon the decision in *Ethyl Corporation* (supra) to contend that if a later claim includes something already claimed in an earlier claim, it is prima facie bad until amended. In *Ethyl Corporation* (Supra) the Court considered three typical instances where conflict in claims arises; firstly, where the earlier claim lies wholly within the area of the later claim; secondly, where the areas of the earlier

and later claims are not co-terminus but overlap; and thirdly, where the earlier claim is broader than and includes within it the area covered by the later claim. According to learned counsels for the defendants, the present case falls in the third category. The test laid down to decipher prior claiming in the third category, that is, in the case of a selection patent was indicated as,

> "*This test is derived by analogy from the position of a so called "selection" patent. In a "selection' case the position is that there is a narrower later claim which falls wholly within the broader area of the disclosure of an earlier published prior document. In such case there will be anticipation unless the patentee of the later invention can show that he has selected an area from the prior broad disclosure which gives advantages beyond or different from those disclosed by the prior document. Provided the strict rules for validity laid down in I. G. Farbenindustrie's Patents (1930) 47 R.P.C. 289, and other cases are observed, there is no reason why the claim in the later selection patent should not be valid.*"

10.3 In *Apotx vs. Sanofi* (supra) relied upon by the learned counsels for the defendants, to overcome an objection of prior publication for a selection patent, the tests as laid down in *I.G. Farbenindustrie A.G.* (supra) were reiterated.

10.4 In *Merck & Company (Macek's) patent*, the Appeal Tribunal was dealing with four claims of the later patent in the suit, that is, (1) A composition having enhanced bactericidal activity comprising novobiocin in combination with at least one other antibiotic selected from the following, namely, penicillin, tetracycline, oxytetracycline, 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 incorporated in a parenteral liquid. (4) A composition as claimed in claim 1 in which the antibiotics are incorporated in an ointment vehicle. The Appeal Tribunal applying the principle of law applicable in prior claiming cases noted that it was not in dispute that the incorporation of antibiotics in carriers of the types specified in claims 2 to 4 was so well known on the date of application so as not to contribute an inventive merit. It was thus held that the claim inventions can be regarded as covered by Claim-1 which was of a comprehensive type permitting of alternative additions to novobiocin which alternative additions consists of one or more of the named antibiotics. It is in relation to this claim that the appeal tribunal held that the objection of prior claiming has been established.

10.5 However, in *Daikin Kogyo Co. Ltd*. (supra) relied upon by learned counsel for the plaintiffs, it was held that if an earlier claim is wider in its scope than a later claim and there is no separate claim in the earlier specification restricted to the subject matter of the later claim, the claimant of the earlier claim cannot assert that he has made a prior claim to the subject matter of the later claim. *Daikin Kogyo Co. Ltd.* (Supra) thus holds that the later claim should not be subsumed in the earlier wider scope as a separate claim. In *Daikin Kogyo* (Supra) the English Court of Appeal was dealing with the grant of process patent wherein the specifications related to a process for making tetrafluoroethylene [TFE] by pyrolysis of chlorodifluoromethane [CDM] with water vapour. It was thus a case of process patent and the Court concluded that the process claimed was different in its features.

10.6 Section 64 (1) (a) of the Patent Act provides that the patent may be vulnerable to revocation due to prior claiming as under:

> *64 Revocation of patents. -*
> *(1) Subject to the provisions contained in this Act, a patent, whether granted before or after the commencement of this Act, may, [be revoked on a petition of any person interested or of the Central Government by the Appellate Board or on a counter-claim in a suit for infringement of the patent by the High 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 India;*

10.7 Thus as per Section 64(1) (a) of the Patent Act if the subsequent claim was claimed in a valid claim of earlier priority date contained in the complete specification of another patent granted, the same would be vulnerable to revocation. Thus the only issue to be determined is whether the species claim of the complete specifications is contained in the complete specifications of the earlier genus claim.

10.8 This Court while dealing with constructions of claims has already held that though various SFLT2 inhibitors alongwith the properties of SGLT2 inhibitors were disclosed and claimed in IN '147 but the specific compound Dapagliflozin was neither claimed nor disclosed in IN '147 as this compound with a ethoxy combination was revealed after further research and development resulting in the claim in IN'625. Hence IN '625 is prima facie not liable to be revoked on the ground of prior claiming.

Admissions by the Plaintiff in Form 27 and Orange Book

11.1 Case of the defendants is that the plaintiffs having admitted in their

Form-27 in respect of IN ‘147 that it worked through the drug Forxiga, the plaintiff cannot now turn around and take the plea that the pharmaceutical composition dapagliflozin was not disclosed in IN ‘147.

11.2 It may be noted that till the year 2014 the plaintiff in respect of its genus and species patent in the US and the genus and species patent in India uniformly stated that the patent had not worked. Only after marketing approvals of the drugs Forxiga that is pharmaceutical composition of Dapagliflozin was granted to the plaintiff in Form-27 in respect of both the genus and species patent, the plaintiff stated that the patent had worked through the drug Forxiga. It is not the case of the plaintiffs that Dapagliflozin is not covered by the genus patent and once plaintiff claimed that Dapagliflozin is covered by the genus patent it was required to submit Form 27 indicating that patent worked through the subsequent pharmaceutical composition Dapagliflozin resulting in the drug Forxiga. The admission of the plaintiff in the Orange Book also was after the drug approval pursuant to IN '625 was granted.

11.3 Further, there are specific admissions of the defendants. Defendant in CS(COMM) 426/2020 i.e. MSN Laboratories Private Limited which is also the manufacturer for the defendants in CS(COMM) 418/2020 and CS(COMM) 419/2020 in its application seeking registration of the patent in respect of the crystalline/ amorphous form of Dapagliflozin in the years 2014 and 2018 categorically stated that Dapagliflozin was first disclosed in US '117 i.e. IN ‘625, even though defendant MSN claims that in its 2016 application it stated that Dapagliflozin was disclosed in US '126. Further, Cadila Zydus, which is the parent company of ZYDUS Healthcare, the defendant in CS(COMM) 414/2020 also in its application seeking patent in

respect of amorphous/ crystalline form pleaded that Dapagliflozin was first disclosed in US ‘117 i.e. IN ‘625.

11.4 As noted above, there can be some gap between coverage and disclosure and the extent of disclosure in the prior act is required to be determined on the facts of each case, plaintiffs statements that the patent had worked through Forxiga as against specific admissions of defendants that Dapagliflozin was first disclosed in US '117 i.e. IN '625 cannot be read as admissions of disclosure by plaintiff of Dapagliflozin in IN '147.

Obviousness:

12.1 Case of the defendants is that the claim in IN '625 is obvious to a person with ordinary skill in the art whereas according to the plaintiffs there was no motivation in Example 12 to proceed with the said example and then substitute methyl to ethyl group and further convert it to ethoxy, from the 80 examples resulting in a number of permutations and combinations and thus the claim in the suit patent is not obvious.

12.2 In the decision 2019 UKSC 15 *Actavis Group PTC EHF and others vs. ICOS Corporation and another*, it was observed that even if prior art comprises of an infinite number of starting point every prior art is deemed to be suggestive to the person skilled in the art. The only exception being that the identification/selection is based on an unknown technical effect and 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.

12.3 Considering the legal effect of generic and specific descriptions of isoalloxazine constructions in Karrer Patent, the Court in 301 F.2d 676 *Re Petering* held as under:

> *"Next we consider the legal effect of the generic and specific descriptions of isoalloxazine structures in the Karrer patent. The generic formula of Karrer, "wherein X, Y, Z, P and R' represent either hydrogen or alkyl radicals, R a side chain containing an OH group," encompasses a vast number and perhaps even an infinite number of compounds since there is no express limit on the size of the alkyl group or the structure and size of R. Even though appellants' claimed compounds are encompassed by this broad generic disclosure, we do not think this disclosure by itself describes appellants' invention, as defined by them in any of the appealed claims, within the meaning of 35 U.S.C. § 102(b). However, there is more than this broad generic disclosure in Karrer. As set forth supra, Karrer discloses certain specific preferences for X, Y, Z, P, R and R' through his series of preferred R groups and his eight specific isoalloxazines. Keeping in mind that the Karrer patent is a publication addressed to those of ordinary skill in this art, it is our opinion that the pattern of Karrer's specific preferences in connection with his generic formula constitutes a description of a definite and limited class of compounds which may be defined with reference to the Karrer generic formula as follows: where X, P and R' are hydrogen, where Y and Z may be hydrogen or methyl, and where R is a member selected from the group consisting of $-CH_2OH$, $-CH_2CH(OH)CH_2OH$, $-CH_2CH_2OH$ $-CH_2(CHOH)_3CH_2OH$ and $-CH_2(CH\ OH)_4CH_2OH$.*
>
> *We think the Karrer patent, as a printed publication, describes to one skilled in this art not only the broad class but also this much more limited class within that broad class, and we think it is immaterial that Karrer did not expressly spell out the limited class as we have done here. It is our opinion that one skilled in this art would, on reading the Karrer patent, at once envisage each member of this limited class, even though this skilled person might not at once define*

in his mind the formal boundaries of the class as we have done here.

A simple calculation will show that, excluding isomerism within certain of the R groups, the limited class we find in Karrer contains only 20 compounds. However, we wish to point out that it is not the mere number of compounds in this limited class which is significant here but, rather, the total circumstances involved, including such factors as the limited number of variations for R, only two alternatives for Y and Z, no alternatives for the other ring positions, and a large unchanging parent structural nucleus. With these circumstances in mind, it is our opinion that Karrer has described to those with ordinary skill in this art each of the various permutations here involved as fully as if he had drawn each structural formula or had written each name. Although isomerism within certain of the R groups will increase the total number of compounds in this limited class, in our opinion, this fact is immaterial in this case because we think that one with ordinary skill in this art, with the 20 Karrer compounds before him, would also have before him those subspecies which involve standard well known isomerism within an R group. For these reasons, we hold that each compound within the limited class in Karrer, as defined supra, has been described in a printed publication within the meaning of 35 U.S.C. § 102(b), and that it is of no moment that each compound is not specifically named or shown by structural formula in that publication."

12.4 Division Bench of this Court in *F. Hoffmann-La Roche Ltd. v. Cipla Ltd.* (supra) laid down the following steps to be conducted to determine obviousness/lack of inventive,:

"Step No. 1 To identify an ordinary person skilled in the art,

Step No.2 To identify the inventive concept embodied in the patent,

Step No.3 To impute to a normal skilled but unimaginative ordinary person skilled in the art what was common general

knowledge in the art at the priority date.

Step No.4 To identify the differences, if any, between the matter cited and the alleged invention and ascertain whether the differences are ordinary application of law or involve various different steps requiring multiple, theoretical and practical applications,

Step No.5 To decide whether those differences, viewed in the knowledge of alleged invention, constituted steps which would have been obvious to the ordinary person skilled in the art and rule out a hide side approach."

12.5 This Court in CS(COMM) 27/2020 titled as "*Bristol-Myers Squibb Holdings Ireland Unlimited Company & Ors. Vs. BDR Pharmaceuticals International Pvt. Ltd. & Anr.*" culled out the principles governing the field to determine whether an invention is obvious or not as under:

"(i) A hindsight reconstruction by using the patent in question as a guide through the maze of prior art references in the right way so as to achieve the result of the claim in the suit, is required to be avoided.

(ii) The patent challenger must demonstrate the selection of a lead compound based on its promising useful properties and not a hindsight driven search for structurally similar compounds.

(iii) There should be no teachings away from the patent in question in the prior art.

(iv) Mere structural similarity cannot form the basis of selection of lead compound in a prior art and the structural similarity in the prior art document must give reason or motivation to make the claim composition.

(v) Though mosaic of prior art documents may be done in order to claim obviousness, however, in doing so, the party claiming obviousness must be able to demonstrate not only the prior art exists but how the person of ordinary skill in the art would have been led to combine the relevant components from the mosaic of prior art.

(vi) It has to be borne in mind, small changes in structures can have unpredictable pharmacological effects and thus, structural similarity alone is not sufficient to motivate to selection of the lead compound.

(vii) Though it would be tempting to put together a combination of prior arts but this requires a significant degree of hindsight, both in selection of relevant disclosures from these documents and also in disregarding the irrelevant or unhelpful teachings in them."

12.6 From the decisions as noted above, it is clear that there is a difference between the subsequent claim being disclosed in the prior art and the subsequent claim being obvious. For a claim to be obvious the person skilled in the art has to move forward from the teachings of the prior art to arrive at the subsequent claim, however, in the case of disclosure of the subsequent claim in the prior art, the subsequent claim should be so embedded in the prior art that it is evident to even a layman. Thus there is a difference in the degree of teachings in the prior art to constitute disclosure or obviousness in relation to the subsequent claim.

12.7 According to the plaintiff there is no motivation to look at Example 12 when 80 examples have been given of which Examples 1 and 2 were synthesized on a large scale, there is no motivation to change methyl group, there are no teachings towards substitution with ethoxy, efficacy data of Example 12 was not known, the teaching of IN '147 were to have hydrogen on central phenyl ring and no ethoxy on the distal phenyl in any of the 80 examples. As noted above, for preparation of the structure in Example 12, four methods have been noted and in the said example though methoxy was used and even though there was no teaching towards ethoxy, there were no teachings even away from ethoxy. Both ethoxy and methoxy being lower

alkyl, a person with ordinary skill in the art would have been motivated to bring this single change of substitution of methoxy to ethoxy to find out if predictable results ensue. Consequently, this Court is of the prima facie opinion that the suit patent is vulnerable on the grounds of obviousness in view of Example 12 of IN '147.

12.8 Undoubtedly, the objection of US Patent office is neither an order nor a finding and the decision of the plaintiff to file a terminal disclaimer cannot be treated as an admission that the later filed invention claim is obvious, as held in *Quad Environmental Technology (supra*) In *Simple Air Inc. Vs. Google LNC* the US Court of Appeal reiterated this proposition, however held that the terminal disclaimer though not an admission of obviousness would still be relevant to that enquiry and by filing a terminal disclaimer a patent applicant waives potentially valuable right. It was held that a terminal disclaimer is a strong clue that a patent examiner and, by concession, the applicant, sought the claim in continuation lacked the patentable distinction over the parents, however that strong clue does not give rise to a presumption that a patent subject to a terminal disclosure is patentably indistinct from its parents. Hence no presumption of lack of patentability is available on filing of a terminal disclosure; the lack of patentability would thus have to be decided on the facts of each case on the grounds of invalidity available.

Section 8(1) and 8(2) of the Act:-

13.1 Mr. Sandeep Sethi, Learned Senior counsel appearing for the defendant TORRENT claims that the suit patent is invalid in view of non-compliance of Section 8. According to him Section 8(1) mandates that the

plaintiff while filing his application must disclose details of all applications filed by it either alone or jointly in India or outside in respect of the same or substantially the same claim. According to the defendant since the plaintiff did not file the details and documents relating to claiming a terminal disclaimer in respect of US '147 before the US Patent Office, pursuant to the Objection of double patenting raised by the USPTO thereby giving option to the plaintiff of either rejection or to seek terminal disclaimer resulting in the consequent terminal disclaimer dated 19th August, 2002, the suit patent is invalid in view of non-compliance of the mandatory provisions of Section 8 of the Patents Act**.** According to the learned counsel, the plaintiffs not only failed to comply with Section 8(1) of the Act but also Section 8(2) as the Indian Patent Office specifically sought details regarding search and/or examination report as referred to in Rule 12(3) in respect of same or substantially the same invention filed in all the major patent offices such USPTO, EPO, and JPO etc., however despite furnishing an undertaking the plaintiffs only supplied the documents in relation to EPO and did not furnish documents including the objection of double patenting raised by USPTO and the consequential seeking of terminal disclaimer.

13.2 In response to the defendant's arguments learned counsel for the plaintiffs submits that a bare reading of Section 8(1) discloses that only applications which were being prosecuted are required to be filed and when the application in respect of IN '625 was filed before the Indian patent office, the US patent '117 had already been granted. Hence there is no non-compliance of Section 8(1) of the Patents Act. It is further stated that along with the application filed for grant of IN '625, plaintiffs gave the complete list of its patents applied for and granted all over the world which amounted

to sufficient compliance of Section 8 of the Patents Act.

13.3 Section 8 of the Patents Act reads as under:

> *"8. Information and undertaking regarding foreign applications. -*
> *(1) Where an applicant for a patent under this Act is prosecuting either alone or jointly with any other person an application for a patent in any country outside India in respect of the same or substantially the same invention, or where to his knowledge such an application is being prosecuted by some person through whom he claims or by some person deriving title from him, he shall file along with his application or subsequently [within the prescribed period as the Controller may allow]]-*
>
> *(a) a statement setting out detailed particulars of such application; and*
>
> *(b) an undertaking that,[33] [upto the date of grant of patent in India], he would keep the Controller informed in writing, from time to time, of [detailed particulars as required under] clause (a) in respect of every other application relating to the same or substantially the same invention, if any, filed in any country outside India subsequently to the filing of the statement referred to in the aforesaid clause, within the prescribed time.*
>
> *(2) At any time after an application for patent is filed in India and till the grant of a patent or refusal to grant of a patent made thereon, the Controller may also require the applicant to furnish details, as may be prescribed, 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.*"

13.4 Learned counsel for the defendant Torrent relies on the *Ayyangar Committee's Report* pursuant whereof Section 8 was introduced in the Patents Act. The relevant portion of the report reads as under:

"350. In addition to the documents set out in Clause 7 (2) it would be useful to require the applicant to furnish the following further information. The majority of the applicants for patents in India are foreign nationals and in several cases the application in India is for the same or substantially the same invention as that for which an application for patent has already been made by them in other countries. It would be of advantage therefore if the applicant is required to state whether he has made any application for a patent for the same or substantially the same invention as in India in any foreign country or countries, the objections, if any, raised by the Patent Offices of such countries on the ground of want of novelty or unpatentability or otherwise and the amendments directed to be made or actually made to the specification or claims in the foreign country or countries upto the date of acceptance of the application. This matter acquires added importance by reason of the change which I have suggested in the content of the publications which should constitute anticipation to deprive an invention of novelty. As publication abroad before the relevant date would also constitute anticipation, this information would be of great use for a proper examination of the application.

351. I would further suggest a provision for ensuring that the applicant keeps the Controller informed of any further foreign applications made and of the orders made on such applications after the date of the Indian application. Naturally this would have to be in the form of an undertaking to be filed by the applicant.

355. To secure compliance with this provision as to the disclosure of information regarding foreign applications for the same invention, I am adding to Clauses 21 and 37 words to include failure to communicate information in possession of an applicant, as constituting a ground of opposition and revocation respectively.

13.5 In *F. Hoffmann-La Roche Ltd. v. Cipla Ltd*. (supra), the Division Bench of this Court dealing with Section 8 of the Patents Act held:

"125. Thus though as a general rule if a consequence is provided then the rule has to be interpreted as mandatory however in the present case the consequence itself is not mandatory because of use of the word 'may' in Section 64(1). This issue came up for consideration before Division Bench of this Court in Maj.(Retd.) Sukesh Behl (supra) wherein this Court held that though it is mandatory to comply with the requirement under Section 8(1) of the Patents Act and non-compliance of the same is one of the grounds for revocation of the patent under Section 64(1)(m), however the use of the word 'may' in Section 64(1) itself indicates the intention of the legislature that the power conferred thereunder is discretionary and consequently it is necessary for the Court to consider the question as to whether omission on the part of the applicant was intentional or whether it was a mere clerical and bona-fide error.

126. Having held that Section 64(1) is directory in nature and thus non-compliance of Section 8 would not automatically result in revocation of the patent, we need to note the further distinction between a mandatory rule and a directory rule. In the decision reported as (1980) 1 SCC 403 Sharif-Ud-Din v. Abdul Gani Lone the Supreme Court noting the distinction between a mandatory rule and the directory rule held that while the former must be strictly observed, in the case of the latter substantial compliance may be sufficient to achieve the object regarding which the rule was enacted.

127. The doctrine of substantial compliance is a judicial invention, equitable in nature, designed to avoid hardship in cases where a party does all that can reasonably be expected of it, but failed or faulted in some minor or inconsequent aspects which cannot be described as the "essence" or the "substance" of the requirements. Like the concept of "reasonableness", the acceptance or otherwise of a plea of "substantial compliance" depends on the facts and circumstances of each case and the purpose and object to be achieved and the context of the prerequisites which are essential to achieve the object and purpose of the rule or the regulation. (See (2011) 1 SCC

236 Commissioner of Central Excise, New Delhi v. Hari Chand Shri Gopal).”

13.6 In *Merck Sharp & Dohme* (supra), the Division Bench of this Court in relation to non-compliance of Section 8 in Paras 72, 73 and 76 noted Glenmark’s allegations that MSD did not comply with its obligation under Section 8 of the Act to disclose patent application made for the “same or substantially the same invention” or subsequent international application for these compounds either. Referring to Section 64(1)(m) the Division Bench noted that failure to comply with Section 8 is a ground for revocation of the patent however reiterated the discretionary element consequent upon a patent applicant’s failure to comply with Section 8 as under:

“"37. In the present case, it is no doubt true that it is mandatory to comply with the requirements under Section 8(1) of the Patents Act and noncompliance of the same is one of the grounds for revocation of the patents under Section 64(1)(m).

However, the fact that the word "may" is used in Section 64(1) itself indicates the intention of the legislature that the power conferred thereunder is discretionary. The mere fact that the requirement of furnishing information about the corresponding foreign applications under Section 8(1) is mandatory, in our opinion, is not the determinative factor of the legislative intent of Section 64(1). We found that the language of Section 64(1) is plain and unambiguous and it clearly confers a discretion upon the authority/Court while exercising the power of revocation. The interpretation of the FAO (OS) 190/2013 Page 64 provisions of Section 64(1) as discretionary, in our considered opinion, does not result in absurdity nor in any way effect the rigour of the mandatory requirements under Section 8 of the Act.

38. Therefore, we are of the view that though any violation of the requirement under Section 8 may attract Section

64(1)(m) for revocation of the patent, such revocation is not automatic."

An important element in this discussion is that at an interlocutory stage, when the Court merely takes a broad look at the prima facie nature of the case, rejection of the claim for temporary injunction on the basis of such facial understanding regarding non-disclosure of Section 8 would be drastic. The possibility cannot be entirely ruled out, in cases where breach of the provision is patent and manifest. In other cases, resting the decision not to grant interlocutory relief (a powerful interim order, given the length of a patent infringement trial) entirely based on infraction of Section 8 can operate harshly - possibly even cause irreparable harm in itself. The non- disclosure of 5948/DELNP/2005 (Sitagliptin Phosphate Monohydrate), 1130/DELNP/2006 (Sitagliptin Phosphate Anhydrate), 2710/DELNP/2008 (Sitagliptin plus Metformin) is thus prima facie insufficient, in the opinion of this Court, for revocation under Section 64(1)(m).”

13.7 In *Chemtura Corporation Vs. Union of India & Ors*. MANU/DE/1880/2009 learned Single Judge of this Court dealing with Section 8 held that in view of the facts of the case a credible challenge to the validity of the suit patent was raised which was required to be examined during the course of trial, thus the plaintiff was not entitled to the relief of interim injunction. This Court held:

“18. It was pointed out that unaware of the serious objections on the basis of cited prior arts raised by the US and European Patent authorities, the Indian patent authority granted the plaintiff the patent for the subject device with minimal amendments. Claim No. 2 was merged in Claim No. 1 and the subsequent claims were re-numbered by the plaintiff. The Defendants point out that the First Examination Report (FER) dated 20th October 2004 of the Controller of Patents in India raised some insignificant objections without even citing a single prior art whereas the US and European authorities had cited several closely similar patents based on which the plaintiff was

compelled to restrict its claims to the toroidal/torus shape of the compression spring. In para 8 of the requirements communicated with the PER the Controller sought information on the details regarding the search and/or examination report including claims of the applications allowed, as referred to in Rule 12(3) of the Patents Rules 2003 (Rules.) in respect of same or substantially same inventions filed in any one of the major patent offices, such as USPTO, EPO and JPO etc., along with appropriate translation where applicable. This had to be furnished within a period of 30 days.

19. In response thereto, the plaintiff by its letter dated 14th October 2005 did not specifically reply to para 8 of the requirements while maintaining that all the remaining requirements had been complied with. It appears that telephonic discussions took place between the Patent Examiner and the plaintiff's representative between 15th and 19th October 2005. This resulted in a further letter dated October 19, 2005 by the plaintiff to the Patent Examiner. In the said letter the plaintiff's attorneys stated that that there has been no further development subsequent to the Form 3 which was filed at the time of filing the application in India. The requirement in this regard may be withdrawn. According to Defendants 2, 3 and 4 this statement was false since between 21st June 2001 when the Form 3 was filed and October 19, 2005 when the aforementioned letter was written, the US Patent Authorities had issued a rejection letter of 26th July 2001 stating that they were not satisfied with the amendments made by the plaintiff to its claims. By June 12, 2002 the claims were amended at least five times because the plaintiff failed to overcome the closely similar prior art citations of the US Patent Office. These facts were withheld from the Controller of Patents in India. Likewise the examination details of the applications before the European Patent Office were also not brought to the notice of the Controller of Patents in India.

24. It is pointed out by Mr. Shanti Bhushan that in terms of the requirement under Section 8 of the Act read with Rules and the corresponding Form 4 in force on the date of making the patent application, the plaintiff had only to furnish information

about the filing of patent applications elsewhere. Those details were in fact furnished. With reference to the requirement of furnishing the information as asked for by the Controller in Clause 8 of the letter dated 20th October 2004, it is submitted that only where a claim has been accepted and patent granted, there would be a need for the plaintiff to furnish to the Controller of Patents, the search and examination reports of the corresponding authorities of the countries where the patent was granted. However, as on that date i.e. 15th October 2005 no grant of patent had been made by either the US Patent Office or the European Patent Office. Therefore there was full compliance with the requirement of Clause 8. It is stated that there was no false information given or suppression of relevant information by the plaintiff.

25. It is further pointed out by Mr. Shanti Bhushan that the search report available at that point of time was the international search report which was in fact furnished to the Controller of Patents. The word status. in Form 3 only required the plaintiff to indicate whether the application for patent in a country outside India was pending, allowed or dismissed. If every stage of the application in a country outside India has to be disclosed to the Controller of Patents, it would make his task impossible and cumbersome. Referring to a Wikipedia printout on the PCT, Mr. Shanti Bhushan states that the filing of the PCT application is to be construed as furnishing the details relating to filing of application in each designated State. Without prejudice to the above contentions Mr. Shanti Bhushan submits that not every suppression of fact or false statement would vitiate the grant of patent. What would have to be seen is whether the suppression of fact had the potential of affecting the grant of patent. In support of this submission, he refers to the Halsbury's Laws of England (Vol.35 page 564) and the decision in Valensi British Radio Corpn 1973 RPC 337.

37. The plaintiff submitted its National Phase Application for grant of patent in respect of side bearing pad assembly corresponding to the PCT Application dated 15th September 2000 to the Controller of Patents in Mumbai on 21st June 2001. Among other documents, it enclosed with the said application

the completed Form 3 and the international search report. That search report merely indicated the filing of a patent action by the plaintiff elsewhere. The International Application indicated the US Application made in 1999 as the prior application. The plaintiff may be right in contending that the Form 3 which was prevalent at that point of time did not contain a column status. and, therefore, all that it was required to inform the Patent Controller was that it had made applications for patent for the same invention in different countries. However, the requirement of the law did not end there. While Section 8(1)(a) of the Act required the applicant to furnish a statement on the applications made in other countries, Section 8(1)(b) required the applicant to give an undertaking that up to the date of grant of patent in India (or as earlier worded up to the date of the acceptance of his complete specification filed in India) the applicant would keep the Controller informed in writing from time to time of detailed particulars as required in Clause (a) in respect of every other application relating to the same or substantially the same invention if any filed in any country outside India subsequent to the filing of the application referred to in the abovesaid clause within the prescribed time. Even under the Form 3 as was prevalent on the date of filing the application, an undertaking had to be given to the effect that up to date of acceptance of the complete specification filed in connection with our abovementioned application, we would keep the Controller informed in writing from time to time of the details regarding the applications for patent filed outside India from time to time for the same or substantially same invention within three months from the date of filing such application. Therefore this did not hinge on the Controller asking for particulars but the applicant keeping the Controller informed from time to time. The expression time to time meant a periodicity of furnishing information akin to updating the Controller on the current status of the applications filed in other countries. It is not, as suggested by the learned Senior counsel for the plaintiff, a mere furnishing of information whether the application is pending or dismissed.

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).

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."

13.8 Learned counsel for the plaintiff points out to the documents filed wherein a tabulated chart has been filed in respect of the details of the application along with the patents granted or not and the date if any in the

various countries. Copy of the Form 3 filed while seeking the suit patent IN '625 by the plaintiff is as under:

FORM 3
THE PATENTS ACT, 1970
[39 OF 1970]
&
THE PATENTS (AMENDMENT) RULES 2006
STATEMENT & UNDERTAKING UNDER SECTION 8
[See Section 8, Rule 12]

We, BRISTOL-MYERS SQUIBB COMPANY, a Delaware Corporation, of P.O. Box 4000, Route 206 and Province Line Road, Princeton, New Jersey 08543-4000, United States of America,

hereby declare:

(iv) that we have made this application No. 3573/DELNP/2004 dated 16.11.2004 alone/jointly made for the same/substantially same invention application[s] for patent in the other countries, the particulars of which are given below:

SEE ANNEXURE

(v) that the rights in the application[s] has/have been assigned to : No one

(vi) that we undertake that up to the date of acceptance of the complete specification by the Controller, we would keep the Controller informed in writing the details regarding corresponding applications for patents filed outside India within three months from the date of filing of such application;

Dated this 1st day of September, 2009.

[SWATI PAHUJA]
OF REMFRY & SAGAR
ATTORNEY FOR THE APPLICANT[S]

सत्यमेव जयते

ANNEXURE

Country	Filing Date	Application Number	Status	Date of Publication	Grant Date	Patent Number
PCT	15-May-2003	PCT/US03/15591	Entered National Phase	4-Dec-2003		
Argentina	16-May-2003	P030101713	Granted	9-Mar-2005	29-May-2009	AR040032B1
Australia	15-May-2003	2003237886	Pending			
Brazil	15-May-2003	PI0311323-0	Pending	15-Mar-2005		
Canada	15-May-2003	2486539	Pending			
Chile	20-May-2003	2003-997	Pending			
China (People's Republic)	15-May-2003	03811353.8	Pending	10-Aug-2005		
China (People's Republic)	15-May-2003	200710108986.4	Pending	26-Dec-2007		
China (People's Republic)	15-May-2003	200910158686.6	Pending			
Colombia	15-May-2003	04115963	Pending	31-Mar-2006		
Croatia	15-May-2003	P20041084A	Granted	30-Jun-2005	23-May-2008	P20041084A
European	15-May-2003	03736643.2	Granted	16-Feb-2005	07-Feb-2007	EP 1 506 211
Georgia	15-May-2003	8537/01-04	Granted		25-Jun-2008	P4403
Gibraltar	13-May-2003	608	Granted		15-Apr-2009	608
Hong Kong	12-Mar-2007	015101975.2	Pending	22-Apr-2005		
Kosovo	6-Oct-2008	195	Pending			
Indonesia	15-May-2003	WO0200402831	Pending	20-Jan-2005		
Israel	15-May-2003	165119	Pending			
India	13-Oct-2008	8616/DELNP/2008	Pending			
India	13-Oct-2008	8561/DELNP/2008	Pending			
India	15-May-2003	3573/DELNP/2004	Pending			
Iceland	15-May-2003	7529	Abandoned			
Japan	15-May-2003	2004-507493	Pending	20-Oct-2005		

Korea, Republic of	15-May-2003	10-2004-7018685	Pending	12-Jan-2005		
Montenegro	17-Sep-2008	P-130/08	Pending			
Malta	13-May-2003	1907	Granted		12-Mar-2004	1907
Mexico	15-May-2003	PA/a/2004/011371	Granted		01-Oct-2007	249731
Malaysia	16-May-2003	PI20031803	Pending			
Norway	15-May-2003	20044915	Pending			
New Zealand	15-May-2003	536605	Pending	31-May-2007		
Pakistan	17-May-2003	0432/2003	Pending			
Peru	20-May-2003	000491-2003	Granted		29-Feb-2008	004908
Philippines	15-May-2003	1-2004-501873	Pending			
Poland	15-May-2003	P-373369	Pending			
Russian Federation	15-May-2003	2004137489	Granted		10-Oct-2008	2337916
Russian Federation	6-Jun-2008	2008122558	Pending			
Serbia	15-May-2003	P-992/04	Pending			
Thailand	19-May-2003	082434	Pending	14-Jun-2007		
Taiwan	14-May-2003	92113121	Granted	11-Jun-2009	11-Jun-2009	1310770
United States	20 May 2002	10/151436	Granted	26-Sept-2002	04-Feb-2003	6515117
Venezuela	15-May-2003	2003-000775	Pending	20-Oct-2005		
Viet Nam	15-May-2003	1-2004-01327	Pending			

13.9 Based on this document learned counsel for the defendant states that the plaintiff was aware of the fact that not only the details of the application for same or substantially the same patent which were being prosecuted were required to be filed but details of the application for same or substantially the same invention for which patents had been granted were also required to be filed in Form 3, as is evident from the plaintiff's ANNEXURE filed with Form 3 in the suit patent as noted above and thus the plea of the plaintiffs that details of application being prosecuted only were required to be filed.

13.10 As per Section 8(1) of the Patents Act, the applicant is required to furnish details of applications being prosecuted either jointly, separately or individually, in respect of same or substantially the same invention in any

country outside India and besides the detailed particulars, an undertaking is also required to be furnished that the Controller will be kept informed in writing, from time to time, of detailed particulars in respect of every other application relating to the same or substantially the same invention, filed subsequently to the filing of the statement within the prescribed time. Form 12 of the Patent Rules also reinforces the said requirement. In the present case the objection of the US Patent Office seeking a terminal disclaimer by the US Patent Office in relation to US '147 was prior to the plaintiff's filing the application in respect of IN '625 in India and the details of the such applications being PCT No.10/151436, alongwith the claim specifications, applied and granted as a continuation in part application was duly informed to the Indian Patent Office. As US '147 had been granted at the time of filling the Indian PCT application No. 3573/DELNP/2004 resulting in IN '625 and the particulars of the US '147 application alongwith the claim were furnished, the same would amount to substantial compliance. Since details of US PCT No.10/151436 were furnished alongwith the claim application details and all further details were also available on the websites, thus deemed to be within the knowledge of the Indian Patent Office, non-furnishing of the objections raised by the USPTO at this stage cannot be held as deliberate concealment and suppression under Section 8(1) of the Act. Plea of Mr. Majumdar, Ld.Counsel for TORRENT that since the computers of the Indian Patent Office were not working in the relevant period, there was no compliance, cannot be attributed to the plaintiffs once the plaintiffs had given the details of all the applications pending as well as granted for same or substantially the same invention.

13.11 Plaintiffs have, however, failed to comply with Section 8(2) of the

Patents Act wherein if the patent's office raises a query, the party is required to mandatorily furnish the replies thereto as undertaken. The Indian Patent Office required the plaintiff to file certain more documents and sought for reply to the various objections and in this regard objection 12 and 13 are relevant which read as under:

> *"12. Details regarding application for Patents which may be filed outside India from time to time for the same or substantially the same invention should be furnished within six months from the date of filing of the said application under Clause (b) of sub section (1) of section 8 and rule 12(1) of Indian Patent Act.*
>
> *13. Details regarding the search and/or examination report including claims of the application allowed, as referred to in Rule 12(3) of the Patent Rule, 2003, in respect of same or substantially the same invention filed in all the major Patent office such as USPTO, EPO and JPO etc., along with appropriate translation where applicable, should be submitted within a period of six months from the date of receipt of this communication as provided under Section 8(2) of the Indian Patents Act."*

13.12 In reply to these including objection at serial No. 13 the plaintiff did not submit any reply to objection No.12, and in response to objection No.13 the plaintiff furnished copies of the EPO decision of grant and the EP granted patent only, which according to the plaintiff met the requirement of Section 8(2) of the Act.

13.13 It is thus clear that despite the fact that the Patent office clearly sought details regarding the search and/or examination report including claim of the application allowed, as referred to in Rule 12(3) of the Patent Rule 2003 in respect of the same or substantially the same invention filed in all major Patent offices such as USPTO, EPO and JPO etc., the plaintiff only

submitted the documents in relation to the EPO and not the USPTO where on an objection being raised the plaintiff sought a terminal disclosure. The plea of the plaintiffs that as in US '117 plaintiffs had filed a continuation in part application, term whereof if granted was with the genus patent and hence filing of a terminal disclaimer had no bearing deserves to be rejected. The issue is not the term of the patent sought by the plaintiffs in US '117 but the fact that an objection of double patenting was raised by US PTO for the same invention, it was required to be brought to the notice of Indian Patent Office, at least after the same was sought by the Indian Patent Office. Hence the plaintiff's having not complied with Section 8(2), the validity of suit patent is vulnerable for non-compliance of Section 8(2) of the Patents Act

Whether the Suit Patent Lapsed for non-filing the renewal fees in time and non-publication thereafter?

14.1 Since the present application can be decided on the other issues raised and in this respect writ petition is already pending consideration, this Court is not dealing with this issue in the present applications.

Clearing the way:

15.1 In *Bristol Myers Squibb company & Ors. Vs. J.D. Joshi & Anr*. a Single Judge of this Court held that old patents have a kind of presumption of validity, and by filing a revocation petition just before expiry is not the manner of clearing the way. Therefore if the party intends to launch the drug in the market knowing fully well that the plaintiff has been granted a suit patent, it must clear the way by filing a revocation petition well in advance.

15.2 Further the Division Bench in *Merck Sharp Dohme* (supra) observed that if a defendant is aware that there may be a possible challenge to its

product, but still chooses to release the drug without first invoking revocation proceedings or attempting to negotiate, that is surely a relevant factor. The defendant's legal right to challenge the patent at any point in time is intact, but that does not mean that this factor cannot determine the interim arrangement.

15.3 In all these suits except TORRENT, none of the defendants filed any revocation petition and straight away launched the drug Sitagliptin on expiry of the validity of IN '147 on 2nd October, 2020. Even TORRENT filed the revocation petition in February, 2020, nearly 15 years after the grant of the patent. Thus the defendants have not cleared the way before launching the drug.

Legal Principles on grant of refusal of injunction

16.1 As this Court is dealing with the applications for interim injunction, as per the test laid down by the Division Bench of this Court in (2009) 40 PTC 125 *F. Hoffman-La Roche vs. Cipla Ltd.,* this Court need not go into actual invalidity of the suit patent but whether the suit patent is vulnerable based on a credible challenge.

16.2 The Division Bench of this Court in the decision reported as *Merck Sharp and Dohme* (supra) laid down the legal principles in respect of grant or refusal of an interim injunction in a patent suit. It was held that the Court cannot go into the issues of patent claim, its disclosure, prior art, subsequent application and the nature of product, which require a minute examination of the facts, which can be dealt after the Court has the benefit of the full trial with pleadings and expert evidence, especially in matters as complicated as pharmaceutical patents. However, since an interim injunction affects party's legal right based on a necessarily incomplete legal finding that may possibly

tilt the other way, so to speak, the other two factors – balance of convenience and presence of an irreparable injury become all the more important. In determining the balance of convenience between the parties and whether an irreparable injury may result, the Division Bench made some observations on the approach to be adopted by the Courts, however cautioned that the equitable principles though guide the exercise of the discretion, to which Courts must be alive, they not limit Judge's discretion in tailoring the decision and the relief on the facts of each case.

16.3 In *Merck Sharp and Dohme* (supra) the Division Bench laid down six equitable principles which are required to be considered; first of which being that the Court must look at the public interest in granting an injunction. One of the major criteria to determine public interest was price difference of the drug and while comparing with, in *Hoffman La Roche* (supra) the price difference was about 300%, in *Merck Sharp and Dohme* (supra), the price difference was not so startling as to compel the Court to infer that allowing Glenmark to sell the drug, at depressed prices would result in increased access.

16.4 The second principle recognized by the Division Bench was that where a strong case of infringement is established, there is an interest in enforcing the Act. The Court also held that the argument that no injunction should be granted since the patentee can be compensated monetarily by damages from loss of sale, though appealing is to be rejected because a closer look at the market forces reveal that the damages in some cases can be irreparable.

16.5 The third principle recognized by the Division Bench was that where an infringer is allowed to operate in the interim during the trial it may result

in reduction in price by that infringer since it has no research and development expenses to recoup and thus revenue received becomes profit. However, the patentee can only do so at his peril and the victory for the patentee therefore should not be pyrrhic but real. The Division Bench noted that irreparable market effect in cases of sole supplier of a product has also triggered the decision in *SmithKline Beecham v. Generics*, (2002) 25(1) IPD 25005, where in granting an interim injunction it was held that damages would not be an adequate remedy for the plaintiff since it was the sole supplier of the product, and the new entrants to the market were likely to cause its prices to go into a downward spiral. On the facts of the case the Division Bench noted that since the price differential between MSD's product and the infringing products is 30%, a significant portion of which is due to custom duty paid by MSD, the balance of convenience clearly was in favour of MSD.

16.6 The Division Bench noted the fourth principle based on the chronology of events and *Glenmark's* decision to release Zita without first challenging Januvia or Janumet. It was noted that undoubtedly the Act creates a right to oppose patents even after grant. However, if a defendant is aware that there may be a possible challenge to its product but still chooses to release the drug without first invoking revocation proceedings or attempting to negotiate, that is surely a relevant factor. The defendant's legal right to challenge the patent at any point in time is intact, but that does not mean that this factor cannot determine the interim arrangement. Based on the decision relied upon it was held that the fact that the patentee was already dealing in the market on the basis of the patent weighed in as a factor in granting the interim injunction and that the defendant has not

cleared the way.

16.7 It was held that ultimately the Court must look at the combination of three primary factors. A strong case can in some instances offset an equal balance of conveniences between the parties and in the said case MSD having established a prima facie case of infringement, an interim arrangement which secures the interest of both the parties and maintains the public interest involved is available, which also ensures that the possibility of irreparable harm to the patentee is removed. The Division Bench thus set aside the order of the learned Single Judge dismissing the application for grant of an interim injunction and issued directions to MSD to file an affidavit that in the event the suit is dismissed MSD would compensate Glenmark for the damage or loss caused, including but not limited to loss of earnings.

CONCLUSION:-

17.1 In view of the discussion aforesaid, since the defendants have prima facie laid a credible challenge to the validity of suit patent on the ground of obviousness and for non-compliance of Section 8(2) of the Act, this Court finds that the plaintiffs have not made out a prima facie case for grant of interim injunction which is declined. The balance of convenience and an irreparable loss even though in favour of the plaintiffs as held in *Merck Sharp Dohme* (supra), the prima facie vulnerability of the validity of the suit patent outweighs these factors. The interim injunction granted in CS(COMM) 323/2020, CS(COMM) 426/2020 and CS(COMM) 346/2020, is vacated. During the pendency of the present suits, defendants are directed to maintain complete accounts of the manufacture, sale and supply of the

products and file in this Court on affidavits statements of such accounts on quarterly basis, duly certified by their auditors with advance copies to the plaintiffs. The Defendants will also file the annual statement of sales of the products duly authenticated by their auditors. The defendants on affidavits will also undertake to pay damages to the plaintiffs as and when directed by the Court and file the list of their assets, both encumbered and unencumbered alongwith their market value, within four weeks.

17.2 Accordingly, I.A. No. 6931/2020 (under Order XXXIX Rule 1 and 2 PC) in CS(COMM) 323/2020, I.A.7399/2020 (under Order XXXIX Rule 1 and 2 CPC) in CS(COMM) 346/2020, I.A. 8940/2020 (under Order XXXIX Rule 1 and 2 CPC) in CS(COMM) 414/2020, I.A. 8991/2020 (under Order XXXIX Rule 1 and 2 CPC) in CS(COMM) 418/2020, I.A. 8997/2020 (under Order XXXIX Rule 1 and 2 CPC) in CS(COMM) 419/2020 and I.A. 9075/2020 (under Order XXXIX Rule 1 and 2 CPC) in CS(COMM) 426/2020 are dismissed and I.A.9484/2020 (under Order XXXIX Rule 4 CPC) in CS(COMM) 346/2020, I.A.9316/2020 (under Order XXXIX Rule 4 CPC) in CS (COMM) 426/2020 and I.A.10168/2020 (Under Order XXXIX Rule 4 CPC) in CS (COMM) 323/2020 are disposed of.

17.3 It is clarified that the observations made hereinabove while ascertaining a prima facie case will have no bearing on the final decision which would be decided after the full trial on its own merit.

(MUKTA GUPTA)
JUDGE

NOVEMBER 18, 2020
ga/akb/vn