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

% **Date of Decision: 06th May, 2019**

\+ CS(COMM) 1169/2018 & I.As. 13934/2018, 15885/2018

EISAI CO. LTD. & ANR. ..... Plaintiffs

Through: Mr.Sudhir Chandra, Senior Advocate with Mr.Pravin Anand, Ms.Archana Sanker, Mr.Dhruv Anand, Ms.Vidisha Garg, Ms.Udita Patro and Mr.Nischay Mall, Advocates for plaintiffs

versus

SATISH REDDY & ANR. ..... Defendants

Through: Mr.Saikrishna Rajagopal, Ms.Sneha Jain, Mr.Devvrat Joshi, Mr.Amitavo Mitra and Ms.Garima Sawhney, Advocates

CORAM:
HON'BLE MR. JUSTICE J.R. MIDHA

J U D G M E N T

I.A. 13934/2018

1. The plaintiffs have instituted this suit for permanent injunction for restraining the defendants from manufacturing, selling, distributing, exporting or offering for sale of any product that infringes the plaintiffs' patent No. 215528 including *Lorcaserin* or any of its pharmaceutically acceptable salts including *Lorcaserin Hydrochloride* (hereinafter referred to as 'LH') and *Lorcaserin Hydrochloride Hemihydrate* (hereinafter referred to as 'LHH'). The plaintiffs are also seeking damages, accounts and costs from the defendants. In I.A. 13934/2018, the plaintiffs are seeking interim injunction against the defendants.

2. The defendants appeared before this Court on the very first date i.e. 08th October, 2018 to oppose the injunction. The relevant portion of the order dated 08th October, 2018 is reproduced hereunder:

> *"5. Issue notice. Learned counsel for the defendant accepts notice.*
> 6. *Learned counsel for the plaintiff presses for an interim injunction against the defendants. Learned counsel for the plaintiff submits that the defendant has not yet launched their product in India.*
> 7. *Learned counsel for the defendant submits that the defendants have received the marketing approval and the product is likely to be launched in January, 2019. Learned counsel for the defendant, however, submits that plaintiff is not entitled to injunction as the plaintiff has not worked out their patent in India. Reliance is placed on Division Bench judgment of this Court in* ***Franz Xaver Huemer v. New Yash Engineers*** *1996 (37) DRJ (DB).*
> 8. *Learned counsel for the plaintiff submits that the aforesaid judgment would not help the defendants who have not yet launched their product in India. Reliance is placed on the order dated 14th February, 2017 in* ***Bayer Intellectual Property GMBH v. BDR Pharmaceuticals International Pvt. Ltd.***
> 9. *Since the defendants have not yet launched their product which is likely to be launched in January, 2019, the hearing on the injunction application is deferred till pleadings are completed."*

3. The defendants have filed the written statement to which the plaintiffs have filed their replication. Both the parties have filed their respective documents and have also carried out the admission/denial of the documents.

Plaintiffs' Case

4. Plaintiff No.1, a Japanese Pharmaceutical Company, is an exclusive licensee of Indian Patent No. 215528 whereas plaintiff No. 2 is the patentee in respect of the aforesaid patent. Plaintiff No.2 claims to have invented a

man-made molecule named *Lorcaserin*, not found in nature, around the year 2001. The plaintiff researched and conducted clinical trials and studies for next eight years on over 8,000 patients. The Phase-III studies were concluded in 2010. The cardio vascular trials were concluded in 2018 on over 12,000 patients to establish the safety of *Lorcaserin*. *Lorcaserin* has been studied on over 20,000 patients over the last 15 years. The plaintiffs claim to have spent almost 18 years and a cost of approximately 1 billion dollars to develop *Lorcaserin* molecule and in conducting clinical trials to commercialize the same.

5. Plaintiff no.2 obtained patents in over 65 jurisdictions and the said patent has not been revoked in any country. In 2006, WHO recognized *Lorcaserin* to be a new molecule. From 2010 to 2018, the plaintiff carried out the mandatory requirements of US Food and Drug Administration (USFDA). Marketing approvals have been granted in six countries namely USA, South Korea, Taiwan, Israel, Brazil and Mexico.

6. The plaintiff applied for patent in India on 23rd September, 2004 in pursuance to which patent No.215528 was granted on 27th February, 2008 for the period of 20 years i.e. from 11th April, 2003 till 10th April, 2023. There were no pre-grant oppositions, no post-grant oppositions, no revocations and in pursuant suit, no counter-claim has been filed. The suit patent has thus existed undisturbed on the register for more than 10 years. The plaintiffs have applied for the marketing approval which is yet to be granted. The plaintiffs have already completed the critical steps towards regulatory approval for its drug product in India. The plaintiffs expect the marketing approval to be granted by March, 2019.

7. By virtue of grant of the suit patent no. IN215528, the plaintiffs have the exclusive right to prevent any third party from the act of making, using, offering for sale, exporting or importing the subject matter of the suit patent and all its pharmaceutically acceptable salts and solvates or hydrates, including LHH, as claimed in the suit patent (in particular by Claims 38 and 39) up to 10th April, 2023.

8. In late August, 2018, the plaintiffs found that the defendants were planning to commercialize *Lorcaserin* in Indian market. Further online search revealed that the defendants have filed a US patent application for LH being US patent application No.14/141, 112. The plaintiffs further found that the defendants approached the Subject Expert Committee (SEC) for permission to manufacture and market LH in India. The defendants were subsequently granted such permission in the SEC meeting of 28th August, 2018. The plaintiffs promptly filed the present lawsuit on 5th October, 2018.

9. According to the plaintiffs, the defendant's product LHH infringes the plaintiffs' patent No.215528 which covers *Lorcaserin* and its pharmaceutically acceptable salts, including LHH, which are specifically claimed in Claims 38 and 39. According to the plaintiffs, to obtain its marketing approval in India, the defendants have piggy-backed on the data generated by the plaintiffs who have spent millions of dollars by carrying out more than 18 different studies. As opposed to this, the defendants have carried out limited bioequivalence studies with reference to the plaintiffs' drug.

10. The suit patent is a Basic patent which discloses:

(i) Manufacture of 54 compounds ($5HT_{2c}$ receptor modulators), including *Lorcaserin* (specifically disclosed in Example 26 at page 63 and claimed in Claims 38 and 39 at page 100).

(ii) Claims 38 and 39 specifically claim *Lorcaserin* and all its pharmaceutically acceptable salts and hydrates. *Lorcaserin* is the first of its kind selective $5HT_{2c}$ Receptor Agonist used in the treatment of obesity. It binds to receptors in the hypothalamus and activates them leading to feeling of satiety.

(iii) At pages 29 and 30, the patent specification discusses possibility of salts being made of the compounds of the invention (including that of *Lorcaserin*) with various acids, including hydrochloric acid. Further formations of solvate forms of the compounds of the present invention are also disclosed.

11. There exists a *prima facie* case of infringement of the suit patent, in favour of the plaintiff, especially in view of the following factors:

(i) The defendants are infringing their patent as *Lorcaserin* forms the major portion of LH and LHH cannot be made without using *Lorcaserin*. The defendants cannot manufacture their product without infringing the patents in the first place. Reliance is placed on ***MERCK v. Glenmark*** (2015) 223 DLT 454:

> *"75. ...It has come on record that Sitagliptin forms the major portion of Sitagliptin Phosphate Monohydrate. ...use of Sitagliptin free base alone in Sitagliptin Phosphate Monohydrate tablet by the defendant itself amounts to infringement of the suit patent."*

(ii) The defendants have admitted that their drug is covered by the plaintiffs' patent in the statement dated 14th January, 2019 of Mr.

Girish Parhate, Director of the Defendant for Indian Drug Regulations Affairs, recorded as part of the Order on the said date:

> *"I say that the defendant disclosed in their application dated 29th June, 2016 that the drug in question is covered by the plaintiffs' patent No. IN 215528".*

(iii) The defendants had complete knowledge of the plaintiffs' patent for *Lorcaserin* in 2014, when the defendants applied for its US patent application 2014/0187538A1. The defendants have clearly admitted in the said application that the PCT application corresponding to the suit patent i.e. WO2003/086306 discloses *Lorcaserin*. The defendants' aforesaid application further discloses Formula I, which is LH:

> *"Various processes for the preparation of compound of Formula I, its related salts, enantiomers and intermediates have been reported in WO 2003/086306…."*

WO2003/086306 is the PCT application corresponding to the suit patent.

(iv) Admission by the defendants in the pre-grant opposition filed against the plaintiff's pending Indian Patent Application No. 311/KOLNP/2009 for LHH on page 8 paras 20-23 of the pre-grant opposition filed by the defendants, in which the defendants clearly admit that in PCT application WO2003/086306 (suit patent) there is explicit and unambiguous disclosure of hydrochloride salt of *Lorcaserin* and method of preparing thereof.

12. The balance of convenience for the grant of interim injunction lies in favour of the plaintiffs as the defendants has evidently not "*cleared the way"*

before going ahead with obtaining a marketing approval for launch of the infringing product. Though the defendants are attempting to take the defense that the suit patent is invalid, it has till date, even though the suit patent has been on the Patent Office record for more than 10 years, not taken any steps to seek invalidation of the suit patent or seek a declaration of non-infringement.

13. The plaintiffs shall suffer irreparably if the injunction is not granted. On the other hand, the defendants, as per their own admission, obtained manufacturing approval on 22nd October, 2018 and had not commenced the manufacturing of the drug at the time of filing of the present suit. An injunction against the defendants would not cause them any harm or injury as the infringing drug of the defendants are not yet in the market.

14. Reliance is placed on ***Merck v. Glenmark***; 2015 (63) PTC 257 [Del][DB] in which the Division Bench of this Court held that:

> *"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. This is more so where Glenmark today argues that MSD ought to have disclosed international patent applications for SPM and Sitagliptin plus Metformin since they were the "same or substantially the same" as the suit patent under Section 8. That is Glenmark"s stated position. Such being the state of things, it is surely reasonable for Glenmark to detect the possibility to challenge, when a US patent application for SPM filed by it was opposed by MSD. Despite this, Glenmark released the drug without initiating revocation proceedings under the Act, which is also a right vested in*

Glenmark that would have obviated the need for the interim arrangement we are today considering. This does not mean that Glenmark's right to question the validity of the patent in an infringement is affected, but the manner of challenge is a relevant factor against it at the interim stage. As Justice Jacob noted in both Smithkline Beecham cases (supra):

> *"I remain of the same opinion that I was in the Generics case. Where litigation is bound to ensue if the defendant introduces his product he can avoid all the problems of an interlocutory injunction if he clears the way first. That is what the procedures for revocation and declaration of non-infringement are for."*
>
> *(Emphasis Supplied)*

15. Reliance is also placed on the following paragraph of ***Merck v. Glenmark*** (*supra*) to demonstrate that the non-grant of an injunction in a strong case of infringement would lead to irreparable injury to the Plaintiff:

> *'This leads us to the second principle, which is whether the Court can overlook the public interest in maintaining the integrity of the patent system itself, so that a legitimate monopoly is not distorted. As this Court noted in Bayer Corporation and Ors. v. Cipla, Union of India (UOI) and Ors., 162 (2009) DLT 371 "[i]f, after a patentee, rewarded for his toil - in the form of protection against infringement - were to be informed that someone, not holding a patent, would be reaping the fruits of his efforts and investment, such a result would be destructive of the objectives underlying the Patents Act. The Court must be mindful - especially in a case where a strong case of infringement is established, as here - there is an interest in enforcing the Act. It may be argued that despite this no injunction should be granted since all damages from loss of sales can be compensated monetarily ultimately if the patentee prevails. This argument though appealing, is to be rejected because a closer look at the market forces reveal that the damage can in some cases be irreparable.*

> *This in turn leads to the third principle, which is where an infringer is allowed to operate in the interim during the trial, it may result in a reduction in price by that infringer since it has no research and development expenses to recoup - most revenue becomes profit. The patentee however can only do so at its peril. Importantly, prices may not recover after the patentee ultimately prevails, even if it is able to survive the financial setback (or "hit") during the interim, which may take some time. The victory for the patentee therefore should not be pyrrhic but real."*
>
> *(Emphasis Supplied)*

16. The defendants have taken three main defenses in the Written Statement. The first contention of the defendants is that they are not infringing the suit patent as the patent does not cover LHH, which is what the defendants have obtained a marketing approval for. The defendants' primary argument is that the plaintiffs have made certain admissions in reply to oppositions filed by a third party against the plaintiffs' subsequent patent applications concerning LHH, which show that the plaintiffs' patent does not disclose LHH.

17. According to the plaintiffs, the above contention is completely fallacious as it ignores the well-established concepts of basic and improvement patents. The plaintiffs rely on ***I. G. Farbenindustrie A.G.'s Patents;*** (1930) 47 RPC 289 at page 321:

> *"It may be observed that chemicals patents in recent years have consisted of two sharply divided classes. The first class is that of patents based on what may be described as an originating invention, that is, the discovery of a new reaction or a new compound. Such patents may be called for brevity "originating patents". The second class comprises patents (the so-called selection patents) based on a selection of related compounds such as the homologues*

> *and substitution derivatives of the original compounds which presumably have been described in general terms and claimed in the originating patent."*

18. The suit patent is in the nature of an originating/genus patent and the various subsequent patent applications were for improvement/selection inventions, which specifically discloses and claims a particular '*species'* of the genus patent, i.e. the *hydrochloride hemihydrate* form. Merely because the plaintiffs have applied for a patent separately for a specific *species* of the genus disclosed in the suit patent, does not mean that the *species* patent cannot be granted or that the *species* patent would not fall within the coverage of the genus patent (i.e. the suit patent in the present case).

19. Grant of a subsequent patent, which is an improvement invention, does not take the said forms out of the first/basic patent, which in the present case is the suit patent. If the subsequent patent is granted, the pharmaceutical product in such a case gets covered by two patents and an infringer making the pharmaceutical patent would infringe two patents. For this, reliance is placed upon ***Extract from Pharmaceutical Patent Law by John R*, *Thomas***.

20. The plaintiffs further rely on the decision of the Court of Appeals for England and Wales in ***Dr. Reddy's Laboratories (UK) Ltd. v Eli Lily***, 2010 RPC 9. In this case, *Dr.Reddy* sought revocation of *Eli Lily's* patent from *Olanzapine* drug, stating that the patent of *Eli Lily* was not novel on the ground that it was disclosed in a previous patent which disclosed a general formula. The Court while rejecting the revocation petition of *Dr.Reddy* held the following:

> *"First then, the a priori considerations apart from case-law. An old question and answer runs as a follows: "Where does a wise man hide a leaf? In a forest." It is, at least*

> *faintly, ridiculous to say that a particular leaf has been made available to you by telling you that it is in Sherwood Forest. Once identified, you can of course see it. But if not identified you know only the generality: that Sherwood Forest has millions of leaves."*

21. The above passage shows that even though a genus patent exists, a second subsequent patent can be granted for a '*species'* present in the genus patent. Reliance is placed on ***Merck v. Glenmark*** (Supra) and ***Roche v. Cipla*** (65) PTC 1 (Del) (DB)**.**

22. The plaintiffs' pleadings before the Patent Office have been reproduced/relied upon by the defendants in their written submissions in a misleading manner.

23. As regards the second contention of the defendants that the plaintiffs have not worked out the suit patent in India, it is submitted that the said contention is fallacious for the following reasons:

(i) In case of non-working, the remedy provided under Sections 83 and 84 of the Patents Act, 1970 is for the defendants to seek a compulsory License. The defendants instead of applying for either a voluntary license or a compulsory License, on its own volition decided to go ahead and seek a marketing approval from the DCGI's office by relying upon the data of the plaintiffs.

(ii) It is well-established that non-working (especially in case of a patent for a pharmaceutical product) cannot have a bearing on the rights of a patentee under Section 48 of the Patents Act, 1970. The case which discusses non-working and its consequences in cases of pharmaceuticals patents, is ***Cipla v. Novartis;*** 2017 (70) PTC 80 [DB] which holds that non-working of a patent does not have any

bearing on Section 48 of the Patents Act, 1970 which lays down the Exclusive Rights of a Patentee.

> *"It is immediately clear that the provisions of section 83 do not curtail or circumscribe the rights of the patentees under Section 48, except in the background of compulsory licenses…"*

(iii) The cases cited by the defendants are not applicable in the present case as they relate to mechanical patents. The regulatory regime governing pharmaceutical products is far more stringent and it takes a lot of effort and time for a company to ensure that its product is ready, through multiple testing's/clinical trials for regulatory approval.

(iv) The case of ***Franz Xaver Huemer v. New Yash Engineers****; AIR* 1997 Del 79 related to a special kind of loom which was vital for the textile industry of the country and which would affect the economy of the country, thereby seriously affecting the market and economy. The Court in the said case found that if the plea for injunction was accepted then it would seriously affect the market and economy conditions in our country inasmuch as it would enable a mechanical device invented abroad (or in India) to be registered in India and kept unused thereby excluding public of its benefits and at the same time preclude the similar device being produced or used in our market or industry.

(v) In the present case, the plaintiffs applied for marketing approval which will be granted within a period of next two-three months and therefore, ***Franz Xaver*** (*supra*) is totally distinguishable in the facts of the present case.

(vi) In each of the cited cases, the defendants' products were already out in the market. Moreover, there have been significant changes in the compulsory licensing regime under Sections 83 and 84 of the Patents Act, as a result of the amendment to the Patents Act in 2005. All the cases cited are prior to 2005.

(vii) The plaintiff has gradually taken preparatory steps to commercialize the LHH product in India and is expected to receive final regulatory approval by end of March, 2019. Thus, the question of non-working is completely moot and irrelevant, especially since the defendants' product itself is not in the market.

24. The last contention raised by the defendants is that the suit patent is invalid. It is submitted by the plaintiffs, that the defendants arguments on the validity of the suit patent in view of Section 3(d), is completely baseless. The suit patent is a novel and inventive compound (new chemical entity) and does not fall under Section 3(d) of the Indian Patents Act. For Section 3(d) to apply, the following two criteria have to be satisfied:

(i) The claimed invention is a new form of a known substance or a derivative of a known substance; and

(ii) The said known substance should have known efficacy. In other words, it is not enough for Section 3(d) to be attracted to show that there is some known compound in the prior art which allegedly bears some structural resemblance to the claimed compound. There is no known substance at the prior date of the instant application. The compounds of the present invention are structurally different from the compounds disclosed in the cited references. Further, the compounds as claimed in the present invention are not a salt, ester, ether or

polymorph or derivative of any known compound that has known efficacy. Reliance is placed on para 105 of the ***Merck v. Glenmark*** (*supra*) in which it was observed as follows:

> *"It is worth pointing out here that the biological activity of a molecule and its utility as a medicine is completely dependent on the structure as a whole. That is, each part of the molecule makes some contribution to the overall biological effect".*

Defendants' case

25. The plaintiffs have suppressed various facts which disentitle them from interim injunction. The plaintiffs have suppressed the fact that they have not worked the suit patent in India till date despite the passage of more than 15 ½ years of the life of the patient, which disentitle the plaintiffs to the relief of interim injunction. The non-working of the suit patent disentitle the plaintiffs from any interim relief. The plaintiffs' assertion that they will launch in March, 2019 is misleading. The plaintiffs have admittedly applied for approvals only in November, 2018 and December, 2018. As per statutory timelines prescribed by Drugs and Cosmetics Act, 1940, it takes around 12-18 months from the time of application to obtain approvals for launching a product. In this regard, defendants have filed an affidavit of Mr. Girish Parhate, Director (Regulatory Affairs) of defendants' company on timelines for grant of regulatory approvals. Thus, as per the statutory timelines, the plaintiffs would not be in a position to launch by March, 2019, which is just 6 months from date of application. In this regard, defendants have relied upon working statements from 2011-2017 of suit patent. Reliance is placed on ***Franz Xaver Huemer v. New Yash Engineers*** (Supra); ***Glaverbel S.A. v.***

Dave Rose., 2010 (43) PTC 630 (Del); ***Sandeep Jaidka v Mukesh Mittal***, 2014 SCC OnLine 2970.

26. The plaintiffs are also disentitled to any equitable relief in light of the deliberate suppression of the various admissions made by the plaintiff No.2 before the Indian Patent Office (IPO) as also before the European Patent Office (EPO), which are completely contrary to the assertions, which have been made in the instant suit. Most importantly, the admissions by the plaintiff no.2 before the IPO and the EPO clearly establish that LH and LHH are outside the scope of the suit patent. Thus, by the plaintiffs' own admissions, it is evident that the suit patent cannot be used to assert or restraint the defendant No.2 from manufacturing and selling *Lorcaserin Hydrochloride* or *hemihydrate* of *lorcaserin* salt and thus, no case of infringement is made out.

27. European Counterpart of LHH is EP1838677. As per Examination Report dated 25th March, 2008 issued by the European Patent Office (EPO) during the prosecution of the said patent, the Examiner had raised an objection that LHH lacks inventive step in light of the suit patent. In the response dated 19th May, 2008 filed by the plaintiff no.2 to this examination report, the plaintiff no.2 has categorically admitted that the suit patent describes preparation of the free base of *Lorcaserin* and there is no teaching or suggestion of the corresponding *hydrochloride hemihydrate*.

28. Plaintiff No.2 has filed a separate patent application for LH (311/KOLNP/2009) (hereinafter referred to as '311 Application'). A pre-grant opposition has been filed by a third party (Symed Labs Ltd.). On 02nd May, 2018, plaintiff No.2 filed a reply to the Symed's pre-grant opposition

wherein plaintiff No.2 has categorically asserted and admitted that LH is distinct from the compound claimed in the suit patent.

29. Plaintiff No.2 has also filed a separate patent application for the *hemihydrate* of *Lorcaserin* salt i.e. for crystalline Form 3 R *enantiomer* of LH (2296/KOLNP/2007) (hereinafter referred to as '2296 Application').

30. Plaintiff No.2 has filed another separate patent application for the same *hemihydrate* of *Lorcaserin* salt i.e. for crystalline Form 3 R *enantiomer* of LH (1208/KOLNP/2012) (hereinafter referred to as '1208 Application').

31. The plaintiffs, in the response dated 09th April, 2012 to the First Examination Report (FER), in '2296 Application', asserted and admitted that the suit patent does not provide any teaching, suggestion or motivation for a person skilled in the art to specifically select the *hemihydrate* of *Lorcaserin* salt.

32. The plaintiffs, in the response dated 15th January, 2018 to the FER dated 27th April, 2017 in '1208 Application' have also categorically asserted and admitted that the suit patent does not provide any teaching, suggestion or motivation for a person skilled in the art to specifically select the *hemihydrate* of *Lorcaserin* salt.

33. Plaintiff No.2 has filed a reply dated 16th April, 2018 to pre-grant opposition filed by third party (Symed Labs) in '2296 Application' wherein plaintiff no.2 has categorically admitted that the *hemihydrate* of *Lorcaserin* salt is not anticipated by the suit patent.

34. Considering that the defendant No.2's approvals from the Directorate General of Health Services are for LHH, which was not anticipated or obvious or covered or disclosed (and thus is, in no way, enabled) by the suit

patent, no relief can be granted to the plaintiffs in relation to LHH, and the defendant no.2 is not infringing the suit patent.

35. A patent cannot be used to injunct a product that is not taught, motivated, suggested, disclosed, enabled or covered by the patent. Patent monopoly is granted to an 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 derive benefits from it. Mere claims, without an enabling disclosure, cannot be sustained. The patent must - as a *quid pro quo* for the grant of monopoly - enable a Person of Ordinary Skill in the Art (POSA) to work the invention as claimed. What is covered by a patent can only be limited to what is disclosed in the patent. Such disclosure has to be such as to enable a POSA to make the invention. If such disclosure is lacking, the invention will not be covered by the patent. Coverage cannot go beyond disclosure. Reliance is placed on ***Novartis AG v. Union of India*** 2013 (6) SCC 1, ***Merck Sharp & Dohme Corporation v.Glenmark Pharmaceuticals Ltd.,*** (2015) SCC OnLine Del 8227 (DB).

36. This suit patent does not teach, suggest, or motivate of the POSA to make LH or LHH. It does not disclose or enable LH or LHH. Thus, suit patent cannot cover LH or LHH and cannot be asserted to injunct sale of LH or LHH. The defendants' LHH product cannot infringe the suit patent either. Claim 1 of the suit patent discloses a *Markush* structure which covers thousands, if not millions, of compounds. *Lorcaserin* is one such compound. Admittedly, *Lorcaserin* is oil, which, in the context of pharmaceuticals, is difficult to process, handle and formulate. Claim 38 generally covers all pharmaceutically acceptable salts and hydrates of *Lorcaserin*. As per plaintiffs, at least 1620 salts of *Lorcaserin* can be made from the general

disclosures made in the suit patent. However, pertinently neither LH/LHH salt nor the process for making LH/LHH salt has been disclosed in the suit patent. Since the defendants' product is LHH and not *Lorcaserin*, and since the suit patent does not cover LH / LHH, the defendants' product does not infringe the suit patent. The suit patent discloses 31 acids as general examples of acids that may be used to make "*pharmaceutically acceptable salt*s" of Lorcaserin. Unlike the ***Merck's*** (*supra*) case where certain acids were specifically disclosed as 'preferred acids' thereby providing necessary motivation to POSA to make the salt, the plaintiffs have specifically and categorically admitted before the Patent Office that LH / LHH is not taught, suggested or motivated from the suit patent. When the Indian Patent Office raised an objection during the prosecution of the Plaintiffs' application for LHH (2296/KOLNP/2007) on the ground that LHH is obvious from the suit patent, the plaintiffs' itself admitted that there is nothing in the suit patent that teaches, motivates or suggests to a POSA to specifically select or make LH/LHH from the general examples of acids disclosed in the suit patent. On the contrary, the plaintiffs' own position is that the *Lorcaserin* disclosed in the suit patent is distinct from LH, which is a specific salt form of a specific compound that has been claimed by plaintiffs in a separate subsequent application 311/KOLNP/2009.

37. It is important to highlight that the plaintiffs are taking contradictory stands – asserting before this Court that LH / LHH are covered and disclosed in the suit patent, and specifically asserting before the Patent Office that LH/LHH are distinct and different from *Lorcaserin*/suit patent and are not taught, suggested or motivated by the suit patent. While in principle a single product may be covered by different patents, a patentee cannot keep shifting

its stand in litigation before a Court and in prosecution before the Patent Office. It is reiterated that the plaintiffs have been changing their position as per their convenience - while on the one hand they are asserting before this Court that the suit patent can be asserted to injunct a LH or LHH, on the other hand they have taken a categorical position in various replies to pre-grant oppositions and to FER before the Patent Office that LH and LHH are not taught, suggested or motivated, and thus not covered by the suit patent. Reliance is placed on ***Merck Sharp & Dohme Corporation v. Glenmark Pharmaceuticals Ltd.,*** (2015) 223 DLT 454 and ***F.Hoffman-La Roche v. Cipla*** , 2009 110 DRJ 452 (DB).

38. The suit patent is invalid and liable to be revoked on various grounds. The plaintiffs have asserted Claims 1, 2, 6, 7, 11, 12, 31, 36, 38, 39, 56 and 59 to 67 of the suit patent in the instant case to impose liability against the defendants. In particular, it is the plaintiffs' case that Claims 38 and 39 of the suit patent claims *Lorcaserin* and all its pharmaceutically acceptable salts, *solvates* and *hydrate*, including LHH. All the said claims are invalid and liable to be revoked in light of Sections 64(1)(d), 64(1)(e), 64(1)(f), 64(1)(k), 64(1)(j) and 64(1)(o).

39. The suit patent is invalid in light of Section 3 (d) of Indian Patents Act, 1970. *Lorcaserin* is a *benzazepine* derivative which acts as a modulator of $5HT_{2C}$ receptors that affect feeding behavior by quenching the need to eat. It is an *anorexigenic* (i.e. drug which causes loss of appetite) and is useful as an anti-obesity drug. It is directed towards modulating $5HT_{2C}$ receptors by contacting the receptors with one or more compounds of the invention. There are already products/inventions/compounds known in the prior art which are also *benzazepine* derivatives invented for the same indication -

anorexigenics / treatment of obesity. The plaintiffs were aware that there were already known products in the market invented for treatment of obesity/as *anorexigenics*. *Lorcaserin* is nothing but a new form (*chloro* derivative or positional isomer) of a known substance (specific *benzazepine* derivatives exemplified in the prior patents) and is invalid in light of Section 3 (d) (lack of enhanced therapeutic efficacy). Reliance is placed on ***Novartis AG v. Union of India***, (2013) 6 SCC 1.

40. *Credible Challenge to Validity of the Suit Patent*

The Suit Patent is vulnerable to invalidation. The corresponding US equivalent of the Suit Patent (being US6953787) is already under challenge by two companies in the US viz. Lupin Ltd. / Lupin Pharmaceuticals, Inc. and Teva Pharmaceuticals USA, Inc. The patented invention does not assert any therapeutic efficacy over the known substances from the prior art, and is therefore not patentable by virtue of Section 3(d) of the Patents Act, 1970. The plaintiffs have failed to establish that *Lorcaserin*, which is merely a new form/derivative of, *inter alia*, compounds exemplified in the foreign patents being GB324, CH194 and/or US639, has any enhanced therapeutic efficacy over the said known compounds. The patented invention/suit patent is further liable to be invalidated on account of the following grounds:

(i) It is not an invention and hence is liable to be revoked under Section 64(1)(d) read with Section 2(1)(j) of the Act.

(ii) It lacks novelty/is anticipated in light of GB324 and CH194 and liable to be revoked under Section 64(1)(e) of the Act.

(iii) It lacks inventive step/is obvious in light of GB324, CH194 and US639 and liable to be revoked under Section 64(1)(f) of the Act.

(iv) It is not patentable as it is a mere admixture and is thus liable to be revoked under Section 64(1)(k) read with Section 3(e) of the Act.

(v) It is not patentable as certain claims relate to method of treatment and are thus liable to be revoked under Section 64(1)(k) read with Section 3(i) of the Act.

(vi) The claims under the Suit Patent as well as the leave to amend claims has been obtained by false representation or suggestion or fraud and is thus liable to be revoked under Sections 64(1)(j) and 64(1)(o) of the Act.

41. The defendants are an extremely reputed pharmaceutical company. The defendants' company was founded in 1984 by Dr. Anji Reddy, the recipient of the *Padhma Shri* Award (in 2001) and the *Padham Bhushan* Award (in 2011). It is one of the leading pharmaceutical companies in India. It currently has more than 350 products in India, more than 300 products in emerging markets (which covers about 26 countries), more than 180 products in the US, more than 80 products in Europe, and more than 40 products in Canada. In the last 5 years alone, the defendant company has launched more than 100 products in India (including licensed products). The philosophy of the company is to ensure that affordable medicines are made available with convenience and ease so that patients do not suffer either due to lack of availability of medicines or due to high prices of innovator drugs. Towards this end, the company has established 9 (nine) research centers globally and more than 1200 (one thousand two hundred) research scientists working on various projects. In financial year 2018 alone, the defendant company invested 13% of its sales revenue i.e. approximately USD 281 million, in research and development activities. As per the Biospectrum

Report published in November, 2018, this is the highest investment in research and development activities among Indian companies. Wherever the defendant company believes that a product is covered by a patent; it has entered into a license with the patent owner. For example, defendants have acquired the molecule XP-23829 from *XenoPort*. This drug is a clinical stage new oral entity that has the potential for the treatment of *plaque psoriasis* and may even be developed for relapsing forms of multiple *sclerosis*. The defendants have also acquired a license with the plaintiff No.1 for its molecule E7777, which is an anti-cancer agent. Defendant No.2 has also filed pre-grant oppositions to the 311 application on 29th October, 2018, 2296 application on 06th November, 2018 and the 1208 application on 11th October, 2018**.** Thus, the defendants have the highest respect for patent rights and are very conscious of ensuring that its products do not infringe any patent.

42. Defendant No.2 has undertaken considerable effort and expenses to conduct clinical trials, and has obtained marketing approvals for their product, as against the plaintiffs who are a foreign patent owner/foreign licensee and who have failed, despite passage of more than 15½ years of the life of the patent (almost 11 years from the date of grant of the suit patent) to even file for regulatory approvals, let alone marketing approvals to work or commercially launch the *Lorcaserin* free base or its *enantiomers*, or even LH or the *hemihydrate* form of LH in India. For obtaining marketing approvals for India, clinical trials have to be conducted on Indian patients. The plaintiffs' *BELVIQ* (containing LHH) was approved on 27th June, 2012 in USA. The plaintiffs' claim to have conducted studies in 12,000 patients, however, not a single Indian patient was enrolled in any of these clinical

trials. This clearly shows that the plaintiffs never gave importance to making their product available to the Indian patients. On the other hand, the defendants have undertaken considerable effort and expenses to conduct clinical trials in India, and to obtain marketing approvals for their product:

(i) The defendants have been involved in developing their LHH product since 2013 till 2018.

(ii) The defendants have conducted Phase-III clinical trial on 300 Indian patients and filed 2500+ pages of documents with the DCGI to obtain approvals.

(iii) The defendants have spent about INR 2,00,00,000 (Rupees Two crores) in conducting its Phase-III Clinical trials and Bioequivalence studies and have additionally spent about INR 1,00,00,000 (Rupees One crore) in development of their product.

(iv) The defendants have initiated process for approvals for clinical trials in 2016 and approvals for the trials were granted in November, 2016.

Assuming but not conceding that the defendants' product is within the scope of the suit patent, it is submitted that the balance of convenience is in favour of the defendants; the defendants have undertaken considerable effort and expenses to conduct clinical trials and obtain marketing approvals for their product; the defendants had initiated process for approvals for clinical trials in 2016 and approvals for the trials were granted in November, 2016. The plaintiffs, on the other hand, have failed to work the Suit Patent at all or even file for regulatory approvals, despite passage of more than 15½ years of the life of the suit patent or almost 10½ years from the date of grant of the suit patent. The plaintiffs are merely sitting on their patent registration,

thereby stifling further innovation and depriving the Indian public of the critical and useful properties of the suit patent. The plaintiffs have evidently registered the suit patent to the very detriment of the Indian consumers, without any intention to make available the benefits of the suit patent to the Indian public. Assuming but not conceding that the defendants' product is within the scope of the suit patent, it is submitted that grant of an injunction in favour of the plaintiffs, would cause irreparable harm not only to the defendants, but also to the concerned patient pool in India. Admittedly, the plaintiffs have not commercially worked the suit patent in India at all, let alone make it available to satisfy the reasonable requirements of the Indian public or at reasonably affordable prices. Further, the plaintiffs own product as available in other countries is priced at roughly INR 312/- per tablet, whereas the defendants' product is likely to be priced around INR 29/- per tablet. Furthermore, per the plaintiffs' admission, the alleged loss that will be caused to them is that of loss of "substantial sales" and "goodwill and reputation". It is submitted that the plaintiffs have no commercial presence or sales in respect of the suit patent in India, whatsoever. Thus, there can be no loss that cannot be compensated.

43. The plaintiffs have obtained a patent monopoly to purportedly protect their rights but have miserably failed in their corresponding duties and obligations imposed by the Patents Act to satisfy the reasonable requirements of the Indian public, or to make available the patented invention to the Indian public or work the patented invention in India within a reasonable time of the grant of the patent.

44. The loss and harm to public interest, in light of patients of obesity being deprived of access to medicines as a result of the plaintiffs' non-

working and lack of making availability the patented invention and the possible injunction, is incalculable. No final judgment will be able to restitute and compensate such patients. In cases involving pharmaceutical products, particularly life-saving drugs, public interest plays a major factor in deciding grant or rejection of interim relief. As per the plaintiffs own assertion, obesity is a life threatening disorder. Obesity is a rising health concern in India, wherein around 153 million individuals suffer from abdominal obesity and about 135 million individuals suffer from generalized obesity. In fact, as of 2016, India was in the top five most obese countries in the world. Obesity is a major risk factor for Type-II diabetes, hypertension, heart attack, stroke and certain forms of cancer. Thus, there is evident public interest involved herein that far outweighs the Plaintiffs' request for relief. Public interest demands that a life-saving drug like the patented invention ought to be made available to the largest number of people and at affordable prices. The plaintiffs ought not to be permitted to restrain the manufacture and sale of such a life-saving drug under the garb of the suit patent, which the plaintiff anyways itself is not working in India. The public interest in providing access to a life-saving drug at low cost clearly outweighs the public interest in granting a monopoly to the plaintiffs over the said drug.

45. Since the plaintiffs have not made available the patented invention or even worked the patent in India till date, there is no question of any harm, let alone any irreparable harm being caused to them. The alleged loss and irreparable harm that would be caused to the plaintiffs is that of substantial sales and revenue and profits, which is clearly calculable and determinable. In the event, the plaintiffs succeed in the instant case, the loss of sales or

revenue or profit can clearly be compensated based on the defendant No.2's sales records.

46. The plaintiffs have obtained marketing approvals in the US for their product '*BELVIQ',* which purportedly contains *Lorcaserin*, as far back as 27th June, 2012 and commercially launched it in the US in June 2013. Admittedly, plaintiff No.2 entered into a marketing and supply agreement with the plaintiff No.1 as far back as November, 2013, which became an exclusive license arrangement in December, 2016. However, it is evident that not only did the plaintiffs not take any steps, if at all, till November, 2013 to even consider working the suit patent in India, but it is also evident that even after the exclusive rights in the suit patent were acquired by the plaintiff No.1, no steps have been taken till date to work out and exploit the suit patent in India. The plaintiffs cannot be permitted to sit on a patent monopoly and refuse to let the Indian public have the benefit of the patented invention, particularly at reasonably affordable prices. The plaintiff is a squatter of patents. The plaintiffs have asserted that over 65 countries have granted patents for invention claimed in the suit patent. However, despite having patents in more than 65 countries, the plaintiffs have received regulatory approvals in only six countries. Further, out of these six countries, the plaintiffs have launched only in four countries. It has not yet launched in two countries, despite obtaining approvals more than 2 years ago. This clearly establishes that the plaintiff is a squatter of patent who only believes in getting patents but does not intend to exercise them or work them at all in more than 90% of the jurisdictions where it has obtained a patent.

47. The plaintiffs have delayed in approaching this Court. The information about defendants' interest in LHH has been in the public domain

since November/December 2016. Yet, the plaintiffs chose to wait for 2 years till the completion of the clinical trials and grant of approvals to the defendants to try and stifle the defendants' launch at the last moment.

48. The submission of the defendants on the suggestion of withdrawal of defendants' products if or when plaintiffs start marketing their product in India is that LHH is a long-term therapy and once the patients start taking our medicine, withdrawing the medicine not only impacts the credibility of defendants but also has negative psychological impact on the patients. Obesity is a major risk factor for Type-II diabetes, Hypertension, Heart attack, Stroke and some forms of cancer. In India, about 15.3 crores people have abdominal obesity and 13.5 crores people have generalized obesity. There is also a significant increase in the prevalence of obesity in India. In an overweight or obese population, modest weight loss of 5%-10% can improve existing comorbid conditions or reduce the risk of developing new comorbid conditions, including type 2 diabetes mellitus and hypertension. Due to the lack of effective and safe options, a significant proportion of diagnosed obese patients are not prescribed a pharmacotherapy option. According to IMS Rx data, less than 10% of patients diagnosed with obesity are prescribed *Orlistat* to treat obesity, primarily due to side effects of *Orlistat* (Oily spotting on underwear; Fatty or oily stool; Urgent bowel movements). Several anti-obesity drugs introduced in India like *Fenfluramine* (1998); *Dexfenfluramine* (1998); *Sibutramine* (2011); *Rimonabant* (2009), have subsequently been withdrawn due to safety concerns (Year in brackets is DCGI banned year). *Rimonabant* was approved by DCGI in 2007 and banned in 2009 (suicidal tendencies). There is an unmet need of a safe and effective pharmaco-therapeutic agent in the

treatment of patients with obesity to improve outcomes. The defendants have already spent more than five years to bring LHH product to Indian patients. The defendants have spent considerable amount of time, energy & money on development, clinical trials & approval of LHH for India. Now marketing of the product would require further efforts, including detailing to top cardiologist, endocrinologist, dieticians and monitoring the patient response. 'Good Health' is always the defendants' goal. The defendants see medicines not just as molecules, but as means to help patients regain their health. As a leader in the pharmaceutical industry, defendants realize that they have the ethical and moral imperative to ensure good health that can be delivered to those who need it, and to promote wellness among them. Helping patients manage disease better is one of the defendants' goals. They look at business as an opportunity to serve the patients. Thus, defendants would never agree to launch a product for short-term gains if it has negative repercussion on patients.

Examination of defendants under Section 165 of Indian Evidence Act, 1872.

49. During the course of hearing dated 21st December, 2018 and 14th January, 2019, this Court examined the officers of the defendants on oath in exercise of the power under Section 165 of the Indian Evidence Act. The statements of the officers recorded by this Court are relevant and are reproduced herein below:-

> *(i) Statement of Girish Parhate, S/o Sh. Sadashiv Parhate, aged 40 years, R/o D0601, Sunway Opus Grand Neville, 3A, Sy.No.162 P, 164, Ameenpur, Hyderabad – 502032:*
>
> *"I am the Director (Regulatory Affairs) of the defendant company and I am briefly aware of this case. I am not aware*

who took the decision to launch the medicine named Lorcaserin Hydrochloride Hemihydrate. I am not aware when the decision was taken. I became aware in July 2016 when I was instructed to apply for regulatory permissions from the competent authorities. There is an internal committee of the defendant headed by Business Strategic Head to take a decision to launch a medicine. Ms.Poonam Raghuvanshi is the head of the Patent Department of the defendant company which examines whether medicine to be launched violates patent of any company. I am aware that the plaintiff has got a patent. I am technically not aware about the difference between the plaintiff's medicine and the defendants' medicine. I am not involved in the development of the medicine and cannot answer how much expenditure has been incurred in developing this medicine. I am also not aware about the number of cases in which defendants are involved relating to the violation of patents."

(Emphasis supplied)

(ii) Statement of, Smitha Ramdas, W/o Mr.Ramdas Manakkote, aged 42 years, R/o F1602, Aparna Sarovar, Nallagandla, Hyderabad:

"I am working as a Director (Intellectual Properties) in the defendant company. An Internal Committee of the defendant took the decision to launch this medicine. My senior is member of that Committee. My senior Ms.Poonam Raghuvanshi is the member of the Committee and I had given inputs to her in this regard. The decision to manufacture this medicine was taken in the year 2015. The defendant company was well aware that the plaintiff has got a patent in respect of the chemical substance. The chemical substance of the plaintiff's medicine and the defendants' medicine are same but according to us the patent of the plaintiff does not contain Lorcaserin Hydrochloride Hemihydrate. We examined the patent of the plaintiff before taking this decision. We conducted the trials on the patients for about 1½ years from 2016 onwards with respect to the medicine in question. I am not involved in the protocol of the clinical trials and cannot give the amounts spent on the clinical trials.

The defendant company has launched a medicine named Ticagrelor which according to the defendant company does not violate the patent of Astra Zeneca. M/s. Astra Zeneca has filed a case against the defendant for violation of the patent. There is an injunction order in that case. I can produce the copy of the order. There are five cases relating to patent in which the defendant company is a party. I can produce the list of those five cases and also copies of the relevant orders. The defendant company's policy is to examine the patent of a medicine and to launch the medicine if the patent of the patentee is not valid."

(Emphasis supplied)

(iii) Statement of Girish Parhate, S/o Sh. Sadashiv Parhate, aged about 40 years, R/o D0601, Sunway Opus Grand Neville, 3A, Sy. No. 162 P, 164,, Ameenpur, Hyderabad-502032:

"I am the Director of the defendant for Indian Drug Regulations Affairs of the defendant company since December, 2015. I am not aware who took the decision to develop the medicine named Lorcaserin Hydrochloride Hemihydrate (herein after referred as 'LHH').

In June 2016, I was instructed by Business Strategic Unit of the defendant to apply for grant of permission for manufacture and marketing of LHH where upon I prepared and submitted an application dated 29th June, 2016 before the Drugs Controller General of India, Directorate General of Health Services. I produce the copy of the application dated 29th June, 2016 which is marked as Ex.C1.

Q.1 In para 3 of the application (Ex.C1) you have stated that the defendant has developed the drugs substance LHH. Please tell who developed this drug substance and when was it developed?

Ans. The drug substance LHH was developed by the Research Development Unit of the defendant during the period 2013 to 2016.

Q.2 Did you disclose to the Drug Controller that the plaintiff already has a patent on this salt?

Ans. I did not disclose in the application that the plaintiff is holding the patent in respect of the drug substance because

there is no provision for such disclosure in the application form. Earlier, there was a column in the application form to disclose the patent but the same was removed in the format of the application and therefore such disclosure was not made.

The drug substance LHH is different from the drug substance in respect of which the plaintiff is having patent. I can produce the earlier form showing the requirement of the patent disclosure as well as the amended format in which the said requirement was omitted. However, I am not technical qualified to tell the difference. I can produce the documents relating to the drug substance namely LHH by the defendant.

The 31st Subject Experts Committee (SEC)- Endocrinology and Metabolisim in its meeting dated 08th November, 2016 permitted the defendant to carry on phase III Clinical Trial. The copy of the approval of the SEC is marked as Ex.C2.

On 06th January, 2017, the defendant received the NOC from the DGHS for conducting Clinical Trial of LHH. The copy of the NOC dated 06th January, 2017 is marked as Ex.C3.

On 24th May, 2017, we informed to Drugs Controller General of India having completed Bio equivalence study of LHH. The copy of the reported dated 24th May, 2017 is marked as Ex.C4.

Q.3 Did you ever inform the Drug Controller of the plaintiff's patent?

Ans. I need to check upto the answer this question.

(Deferred for lunch break)

Examination of Mr.Girish Parhate continued after lunch break.

I have verified from the records with respect to the disclosure of the plaintiff's patent. I say that the defendant disclosed in their application dated 29th June, 2016 that the drug in question is covered by the plaintiff's patent No.IN 215528. I produce the copy of the application dated 29th June, 2016 in which the relevant disclosure is made in item 8 of Form 44. The copy of the complete application dated 29th June, 2016

is marked as Ex.C-4 on which item 8 of Form 44 is marked as Mark-A (Copy of the application dated 29th June, 2016 handed over earlier and marked as Ex.C-1 was without the Form 44 which has now been furnished).

I produce the notification dated 03rd April, 2017 whereby item 8 of Form 44 of the Drug and Cosmetic Rules, 1945 was omitted and therefore, no information relating to the patent of any drug is required to be disclosed by a pharmaceutical company. The notification dated 03rd April, 2017 is marked as Ex.C-5."

(Emphasis supplied)

Findings

50. The plaintiffs have made out a strong prima facie case for grant of interim injunction against the defendants for the reasons given hereunder:-

50.1 Plaintiff No.2 claims to have invented a man-made molecule named *Lorcaserin* around the year 2001. The plaintiff further claims to have researched and conducted clinical trials and studies for the next eight years on over 8,000 patients; Phase-III studies were concluded in 2010; cardio vascular trials were concluded in 2018 on over 12,000 patients to establish the safety of *Lorcaserin*; *Lorcaserin* has been studied on over 20,000 patients over the last 15 years and almost 18 years approximately one billion dollars have been spent in developing *Lorcaserin* molecule and in conducting clinical trials to commercialize the same.

50.2 Plaintiff no.2 obtained patents in over 65 jurisdictions and the said patents have not been revoked in any country. Marketing approvals have been granted in six countries namely USA, South Korea, Taiwan, Israel, Brazil and Mexico. In 2006, WHO recognized *Lorcaserin* to be a new molecule. From 2010 to 2018, the plaintiff carried out the mandatory requirements of US Food and Drug Administration (USFDA).

50.3 Plaintiff No.2 applied for patent in India on 23rd September, 2004 in pursuance to which patent No.215528 was granted on 27th February, 2008 for the period of 20 years from 11th April, 2003 till 10th April, 2023. There were no pre-grant oppositions and no post-grant oppositions. The suit patent has existed undisturbed on the register for more than 10 years.

50.4 The plaintiffs have taken preparatory steps to commercialize the LHH product in India and is expecting final regulatory approvals.

50.5 The plaintiffs' patent No.215528 covers *Lorcaserin* and its pharmaceutically acceptable salts, including LHH. Claims 38 and 39 specifically claim *Lorcaserin* and all its pharmaceutically acceptable salts and hydrates.

50.6 The defendants have admitted in the statement dated 14th January, 2019 of Mr. Girish Parhate, Director (Regulatory Affairs) of the defendant that their drug is covered by the plaintiffs' patent. The relevant portion of the statement is as under:

> *"I say that the defendant disclosed in their application dated 29th June, 2016 that the drug in question is covered by the plaintiffs' patent No. IN 215528".*
>
> *(Emphasis Supplied)*

50.7 The defendants, in their US patent application 2014/0187538A1 admitted that the PCT application corresponding to the suit patent i.e. WO2003/086306 discloses *Lorcaserin*.

50.8 In the pre-grant opposition filed by the defendants against the plaintiffs' pending Indian Patent Application No. 311/KOLNP/2009 for LHH, the defendants admitted that in PCT application WO2003/086306,

(suit patent) there is explicit and unambiguous disclosure of hydrochloride salt of *Lorcaserin* and method of preparing thereof.

50.9 With respect to the defendants' objection that the plaintiffs have made admissions that the plaintiffs' patent does not disclose LHH in reply to oppositions filed by a third party against the plaintiffs' subsequent patent applications concerning LHH, this Court is satisfied with the plaintiffs' explanation that the suit patent is in the nature of an originating/genus patent and the various subsequent patent applications are for improvement/ selection inventions, which specifically disclose and claim a particular '*species'* of the genus patent, i.e. the *hydrochloride hemihydrate* form. Merely because the plaintiffs have applied for a patent separately for a specific *species* of the genus, it does not mean that the *species* patent cannot be granted or that the *species* patent would not fall within the coverage of the genus patent (i.e. the suit patent in the present case). Grant of a subsequent patent, which is an improvement invention, does not take the said forms out of the first/basic patent, which in the present case is the suit patent.

50.10 The plaintiffs have strongly relied upon the admissions of the defendants in the statement made before this Court on 22nd December, 2018 & 14th January, 2019 and the US patent application referred in para 11 above whereas the defendants have strongly relied upon the plaintiffs' admission made in the reply dated 15th January, 2018 and 16th April, 2018. The plaintiffs have satisfactorily explained the aforesaid admissions referred to by the defendants whereas this Court is not satisfied with the explanation of the defendants to their admissions. The admissions of the defendants are sufficient to grant the injunction against the defendants.

50.11 With respect to the defendants' contention that the plaintiffs have not worked out the suit patent in India; the defendants had a remedy to seek a compulsory License under Sections 83 and 84 of the Patents Act, 1970. However, the defendants, instead of applying for either a voluntary license or a compulsory license, decided to go ahead on their own volition and seek a marketing approval. The non-working of a patent particularly for a pharmaceutical product cannot have a bearing on the rights of a patentee under Section 48 of the Patents Act, 1970. Reference be made to ***Cipla v. Novartis;*** 2017 (Supra).

50.12 ***Franz Xaver Huemer v. New Yash Engineers****;* (*Supra*) relied upon by the defendants related to a special kind of loom which was vital for the textile industry of the country and which would affect the economy of the country, thereby seriously affecting the market and economy. The Court, in the said case, found that if the plea for injunction was accepted then it would seriously affect the market and economy conditions in our country inasmuch as it would enable a mechanical device invented abroad (or in India) to be registered in India and kept unused thereby excluding public of its benefit and at the same time preclude the similar device being produced or used in our market or industry. In that case, the defendants' products were already out in the market. Moreover, this case is prior to 2005 and there have been significant changes in the compulsory licensing regime under Sections 83 and 84 of the Patents Act, as a result of the amendment to the Patents Act in 2005.

50.13 The defendants' objections to the validity of the suit patent under Section 3(d) as well as Section 64(1)(d), 64(1)(e), 64(1)(f), 64(1)(j),

64(1)(k), 64(1) (o) read with Section 2(1)(j), 3(e) and 3(i) of the Patents Act cannot be decided without recording of evidence.

51. The balance of convenience for the grant of interim injunction lies in favour of the plaintiffs as the defendants have evidently not "*cleared the way"* before going ahead with obtaining a marketing approval for launch of the infringing drug. The defendants were aware that there may be a possible challenge to its product, but they chose to go ahead to seek the marketing approvals without first invoking revocation proceedings or attempting to obtain a licensee. Where litigation is bound to ensue if the defendants introduce their product, the defendants could have avoided the interlocutory injunction if they had cleared the way first. Reference be made to ***Merck v. Glenmark***; 2015 (63) PTC 257 [Del][DB].

52. The plaintiffs shall suffer irreparably if the injunction is not granted. On the other hand, the defendants obtained manufacturing approval on 22nd October, 2018 and have not commenced the manufacturing of the infringing product. If the defendants are permitted to market its product pending trial, the loss to the plaintiffs cannot be compensated in terms of the money.

53. The Court, at the interim stage, has to take a *prima facie* view of the matter. In that view of the matter, the dissection and analysis of all the submissions is not warranted at this stage.

Conclusion

54. In the facts and circumstances of this case, the application is allowed and the defendants are restrained from making, using, selling, distributing, advertising, exporting, offering for sale, and in any other manner, directly or indirectly dealing in any product that infringes the claimed subject matter of the Plaintiffs' Indian Patent No.215528 or any of the claims thereof

including *Lorcaserin* or *Lorcaserin Hydrochloride*, LHH and any forms thereof till the disposal of the suit.

55. The plaintiffs are entitled to the costs from the defendants. However, the order as to quantum of costs is deferred till the final decision of this suit. Both the parties are directed to submit the actual cost incurred by them. The parties are also directed to submit their estimate of future cost before the commencement of trial so that the parties shall have notice of actual cost that the other side estimate would be incurring in the course of litigation and the parties have an opportunity to take appropriate decision as to manner in which to conduct the litigation. Greater transparency about cost will promote access to justice. This process shall also keep the cost in check and potentially eliminate the need for a detailed assessment at the end as well as dispute as to the amount of the actual cost.

56. The observations made hereinabove are *prima facie* for the purpose of deciding this application and shall not constitute any expression of final opinion on the merits of this case.

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57. List before the Regular Bench as per roster on 04th July, 2019.

J.R. MIDHA, J.

MAY 06, 2019
ds/dk