IN THE HIGH COURT OF HIMACHAL PRADESH, SHIMLA

COMS No. 09 of 2023 a/w COMS No. 02 of 2024, Counter Claim (COMS) No. 01 of 2024 in COMS No. 09 of 2023 and Counter Claim (COMS) No. 07 of 2024 in COMS No. 02 of 2024

OMP No. 409 of 2023 in COMS No. 09 of 2023

Reserved on: 03.05.2024

Decided on: 30.05.2024

Civil Suit (COMS) No. 09 of 2023

(1) Boehringer Ingelheim International GmbH 55216, Ingelheim am Rhein Germany

Through its Power of Attorney Holder

(2) Boehringer Ingelheim (India) Pvt. Ltd. Unit No. 202 and part of Unit No. 201, Second Floor, Godrej 2, Pirojsha Nagar, Estern Express Highway, Vikhroli (E), Mumbai-400079, India.

Thrugh its Power of Attorney Holder

……Plaintiffs.

-Versus-

(1) Eris Lifesciences Limited, Second Floor, Office No. 287/A, Block-B, Motia Plaza, Hadbast No. 205, Pragna, Dharmapur, Suraj Majra Labana, Baddi, Solan, Himachal Pradesh-173205.
Through its Managing Director
Also at:
Amingaon, North Guwahati, Distt. Kamrup-781031 (Assam)

Through its Managing Director

Also at:

AF-10 Kanchan Pharma House, National Highway No. 8, Aslali, Ahmedabad-382427, Gujarat

Through its Managing Director

…….Defendant.

Civil Suit (COMS) No. 02 of 2024

(1) Boehringer Ingelheim International GmbH 55216, Ingelheim am Rhein Germany
Through its Power of Attorney Holder

(2) Boehringer Ingelheim (India) Pvt. Ltd. Unit No. 202 and part of Unit No. 201, Second Floor, Godrej 2, Pirojsha Nagar, Estern Express Highway, Vikhroli (E), Mumbai-400079, India.

Through its Power of Attorney Holder

……Plaintiffs.

-Versus-

(1) Eris Lifesciences Limited, Second Floor, Office No. 287/A, Block-B, Motia Plaza, Hadbast No. 205, Pragna, Dharmapur, Suraj Majra Labana, Baddi, Solan, Himachal Pradesh-173205.

Through its Managing Director
Also at:

Eris Lifesciences Limited
Amingaon, North Guwahati, Distt. Kamrup-781031 (Assam)

Through its Managing Director

Also at:

Eris Lifesciences Limited
AF-10 Kanchan Pharma House, National Highway No. 8, Aslali, Ahmedabad-382427, Gujarat

Through its Managing Director

…..Defendant.

Coram
The Hon'ble Mr. Justice Ajay Mohan Goel, Judge.

Whether approved for reporting?[1]

For the plaintiffs: Mr. Ashok Aggarwal, Senior Advocate and Mr. Vinay Kuthiala Senior Advocate, with Dr. Sanjay Kumar, M/s Arpita Sawhney, Atul Jhingan, Priyansh Sharma and Jitesh Prakash Gupta, Advocates, for the plaintiffs in COMS No. 09 of 2023 and COMS No. 02 of 2024 and for Non-Counter Claimants in Counter Claim (COMS) No. 01 of 2024 in COMS No. 09 of 2023 and Counter Claim (COMS) 07 of 2024 in COMS No. 02 of 2024.

For the defendant(s): Mr. Chander Lall, Senior Advocate, with M/s Bitika Sharma, Shradha Karol, Abhineeta Chaturvedi, Vrinda Pathak and Mr. Vaibhav Singh Chauhan, Advocates, for the defendant in COMS No. 09 of 2023 and COMS No. 02 of 2024 and for the Counter Claimant in Counter Claim (COMS) No. 01 of 2024 in COMS No. 09 of 2023 and Counter Claim (COMS) No. 07 of 2024 in COMS No. 02 of 2024.

Ajay Mohan Goel, Judge *(Oral):*

OMP No. 409 of 2023 in COMS No. 09 of 2023

By way of this application filed under Order XXXIX, Rules 1 and 2 read with Section 151 of the Code of Civil Procedure, 1908, the applicants/plaintiffs (hereinafter referred to as 'the plaintiffs') have prayed for the following relief during the pendency of the suit:-

> *"Restrain the respondent by itself, its directors, licensees, stokiest and distributors, agents and/or anyone claiming through any of*

[1] *Whether reporters of the local papers may be allowed to see the judgment?*

them, jointly and severally from infringing the patent rights of applicant No. 1 under Indian Patent No. 268846 by launching, advertising, making, using, offering for sale, selling, importing and/or exporting the medicinal product, Empagliflozin in any form whatsoever including Empagliflozin API, Empagliflozin formulation, "Empagliflozin Tablets", "Empagliflozin + Metformin Hydrochloride Tablets" and/or "Empagliflozin + Linagliptin Tablets" or any "generic version" thereof or any product sold under the trade mark(s)/name(s) "Linares-E" or any other trade mark/name, whatsoever, or any other product covered by the subject patent granted by the Controller of Patents on September 18, 2015 in favour of applicant No.1."

2. The suit filed by the plaintiffs is for a decree of permanent prohibitory injunction, restraining the defendant from infringing the patent owned by applicant/plaintiff No. 1 as also other consequential reliefs mentioned therein.

3. The case of the plaintiffs/applicants is that plaintiff/applicant No. 1 is a Company organized and existing under the laws of Germany. It is the owner of Indian Patent No. 268846 (hereinafter referred to as 'the subject patent' or 'IN 846'). Applicant No. 2 has the permission of the Drugs Controller General of India, to import and market on Form 45 under Rules 122-A, 122-D and

122-DA of the Drugs and Cosmetics Rules, 1945, “Empagliflozin Tablet”, “FDC of Empagliflozin +Metformin Hydrochloride Tablets” and FDC of “Empagliflozin 10mg/25mg +Linagliptin 5mg/5mg film coated tablets”, which are the formulation of the drug “Empagliflozin” which is the International Non-proprietary Name (INN) of the pharmaceutical drug covered by the subject patent of applicant No. 1. It is further the contention of the applicants that applicant No. 1 is one of the world’s 20 leading pharmaceutical companies. It is a full member of the European Federation of Pharmaceutical Industries and Associations (EFPIA). In the year 2020, it achieved net sales of above 19.6 billion Euros and its Research and Development expenditure for human pharmaceuticals in the year 2020 amounted to 3.3. billion Euros, corresponding to around 22.8% of its human pharma net sales. The focus of the plaintiff-Company is upon researching, developing, manufacturing and marketing new medications of high therapeutic value for human and veterinary medicine. As part of R & D activities for innovative drugs, the company focuses primarily on the therapeutic area of cardiovascular disease, respiratory diseases, diseases of the central nervous system, metabolic diseases, virological diseases and oncology. Applicant No. 1 is stated to be owner of plethora of patents worldwide, including the subject patent. It conducts its pharmaceutical business in India through applicant No. 2, which

holds a licence to import and market the product covered by the subject patent. The subject patent was granted in favour of applicant No. 1 on September 18, 2015 under Section 43 of the Patents Act, 1970 under IN '846 for pharmaceutical product entitled "GLUCOPYRANOSYL SUBSTITUTED BENZENOL DERIVATIVES, DRUGS CONTAINING SAID COMPOUNDS, THE USE THEREOF AND METHOD FOR THE PRODUCTION THEREOF", as disclosed in its patent application for a term of 20 years. According to the applicants, said patent is currently valid. The annuities have been regularly paid in respect of the same and as a result of which, by virtue of Section 48 of the Patents Act, 1970, applicant No. 1 has the exclusive right to prevent third parties, who do not have consent, from the act of making, using, offering for sale, selling and importing for those purposes any product whatsoever covered by the subject patent in India. "Empagliflozin Tablet", "Empagliflozin +Metformin Hydrochloride Tablets" and "Empagliflozin + Linagliptin Tablets" covered by the subject patent were introduced and launched in the Indian market under the brand name "JardianceR/Jardiance Duo" and "Glyxambi" in the years 2015 and 2018, respectively and the plaintiffs thereafter have an active presence in India. According to the plaintiffs, none filed any pre-grant opposition or post-grant opposition against the subject patent, including the non-applicant, which establishes the quality and strength of the subject patent. In

order to take undue advantage of the success of the product in issue, just before launch of the infringing product(s) in the Indian market, in the month of October, 2021, Dr. Reddy's Laboratories Limited alongwith MSN Laboratories Limited filed a revocation petition before the High Court of Delhi bearing number C.O. (COMM.IPD-PAT) No. 3 of 2021, which is still pending adjudication.

4. According to the plaintiffs, in terms of the provisions of the Patents Act, after the grant of the patent, a patentee gets, for a term of twenty years from the date of filing of the International Patent Application under the Patent Cooperation Treaty (PCT), an exclusive right to prevent third parties, who do have the consent of the patentee from the act of making, using, offering for sale, selling and/or importing the patented product in India.

5. Non-applicant is a publicly listed Indian Pharmaceutical Company, which is also engaged in marketing of infringing product, Empagliflozin and Linagliptin Tablets 25 mg/5mg sold under the brand name "Linares-E". As per the plaintiffs, this product is covered by the subject patent and the defendant/non-applicant is carrying on business for gain within the territorial jurisdiction of this Court. It is further the case of the plaintiffs that they were able to lay hand on the infringing product manufactured and marketed by the defendant under the brand name "Linares-E". According to the plaintiffs, manufacturing, marketing, selling, using, offering for sale and/or

exporting of the infringing product under the brand name of “Linares-E” covered by the subject patent, is an infringement of the exclusive right of the applicants in the subject patent and as the defendant/non-applicant is marketing, selling and offering for sale the infringing product within the territorial jurisdiction of this Court, therefore, there is an urgency to restrain the non-applicant from infringing the subject patent by marketing, selling, using and offering for sale etc. the infringing product. It is also the contention of the plaintiffs that they have been vigilant in protecting their rights in the medicinal produce covered by the subject patent and have initiated the legal proceedings against various parties who have infringed their patent and details thereof are given in Para-28 of the application. It is mentioned in this para that this Court in three Civil Suits filed by the plaintiffs, has passed restraint orders against the infringers therein and in favour of the plaintiffs. Reference has also been made to the orders passed by the District Court of Vadodara and the Court of learned Additional District Judge (Commercial) Dehradun at Uttarakhand, which Courts as per the applicants, have passed orders in favour of the plaintiffs.

6. It is further averred in the application that if defendant/non-applicant is allowed to manufacturer and/or sell the drug in issue, it will not only infringe the subject patent, but also completely defeat the purpose of subject patent. It is further averred

in the application that the companies who incur huge investments will be left bereft of protection, if the infringers who do not carry out R & D on their own, are allowed to indulge in dishonest practices. As per the plaintiffs/applicants, w.e.f. 18.09.2015, the plaintiffs/applicants have an exclusive right to make, use, offer for sale, sell, import and/or export the product covered by the subject patent and the act of the defendant/non-applicant of infringing the subject patent was causing a substantial financial hardship to the plaintiffs/applicants and as they were having a *prima facie* case in their favour, therefore, non-grant of injunction in their favour during the pendency of the Civil Suit would cause irreparable harm and injury to the applicants.

7. Defendant/non-applicant opposes the prayers made in the application. According to the defendant, plaintiffs/applicants have failed to discharge the burden to establish a prima facie case of infringement of subject patent by the defendant. As per the defendant, there is no presumption of validity of old patent and for a granted patent in India, be it a new or old patent, there is no presumption of validity. Third party Dr. Reddys Laboratories is stated to have filed a revocation petition against the suit patent, which belies the contention of the plaintiffs that the suit patent is unchallenged. According to the defendant, non-filing of a pre-grant or post grant opposition does not precludes the defendant-Company

from raising a credible challenge to the subject patent either in the reply and also in Counter Claim to the infringement suit initiated by the plaintiffs and the defendant-Company has a statutory right to raise all defence including every ground of revocation available under Section 64 of the Patents Act and, therefore, as the defendant-Company has only to raise a credible challenge to the grant of patent and not to establish invalidity thereof at the stage of interim injunction, it is doing so. As per the defendant, a credible challenge to the validity of the suit patent is made out in view of the following prior art documents:-

"a. WO2001027128 (D1); (Dapagliflozin Genus); &

b. WO2003099836 (D2) (Dapagliflozin Species)"

As per the defendant, the invention in the suit patent lacks inventive step, as the alleged invention is obvious to a person skilled in the art (hereinafter referred to as POSA). It is further the contention of the defendant that Glucopyranosyloxy-Substituted Aromatic Groups and the preparation thereof and their possible activity as SGLT2 inhibitors are known from the prior art. It is also the contention of the defendant that the plaintiffs have not approached the Court with clean hands and they have suppressed material fact that the suit patent has been revoked in China and said revocation, assumes importance in view of the fact that some of the prior arts are the same on which the defendant is placing reliance. It is further the

contention of the defendant that there is no balance of convenience in favour of the plaintiffs nor irreparable injury shall be caused to them if injunction is not granted in their favour pending the decision of the suit, for the reason that the plaintiffs are selling the drug @ Rs.886 per strip (Rs.86 per tablet), whereas, the defendant is selling the same @ Rs.250/- per strip (Rs.25 per tablet). Thus, owing to the huge price difference, the defendant-Company's drug is more accessible to the public at a reasonable price. At the stage of interim injunction, access to affordable medicines and public interest are important factors, which cannot be overlooked. As per the defendant, diabetes is a lifestyle disease, in which a patient is required to consume medicines throughout his life, as opposed to having a one -time cure, therefore, it is imperative that medicines are accessible to pubic at affordable costs, which demonstrates that balance of convenience is in favour of the defendant. It is further the contention of the defendant-Company that it was already in the market under the trademark 'LINARIS-E' when the suit was filed. The patients are already being prescribed the medicine in issue, which is being consumed by them and, therefore, an order of injunction would disrupt the continuity of drug consumption and create difficulties for the patients. As the product in question is a pharmaceutical drug and many patients would shift to the more accessible, cost effective drug of the defendant-Company, therefore

also, the balance of convenience is also in favour of the defendant-Company. It is also the stand of the defendant that if the plaintiffs are able to establish injury/infringement, then also, the plaintiffs can be compensated monetarily and, therefore, the so called loss is not irreparable. As per the defendant, the plaintiffs have already licenced its patent to three entities, namely, (a) Torrent Pharmaceuticals Limited; (b) Lupin Limited and (c) Cipla Limited and, therefore, have put a monetary value on it and this fact was also concealed by the plaintiffs. On these grounds, according to the defendant, the plaintiffs are not entitled for any interim injunction.

8. By way of rejoinder filed to the reply, the plaintiffs/applicants have reiterated the contentions raised in the application and denied the stand taken by the defendant/non-applicant in the reply. The plaintiffs have denied the contention of the defendant that the plaintiffs have failed to prove the infringement of the subject patent. It is mentioned in the rejoinder that the very fact that the defendant has admitted that it had launched the infringing product, at the time when the suit was filed demonstrates that the defendant was practicing the suit patent by manufacturing, using, offering for sale the product covered by the suit patent and this also demonstrates that the defendant was infringing the suit patent. According to the plaintiffs, there is a complete misreading of the statutory provisions of the Patents Act by the defendant and

onus to prove the credible challenge to the validity of the subject patent was squarely on the defendant and the plaintiffs had already demonstrated that there was a valid patent in its favour, which was being infringed by the defendant. Further, according to the plaintiffs, the price of the drug was not relevant for the purpose of the adjudication of the application for the reason that defendant had copied the patented product of the plaintiffs and taken undue advantage of the R&D of the said party and copied the product at lower price to gain undue sympathy at the cost of someone else's intellectual property rights, which cannot be allowed to continue. According to the plaintiffs, they have been able to make out a clear case for the grant of interim relief, as they have proved that they have a valid patent in their favour, which is being infringed by the defendant and that the patented drug has a large market and, therefore, if the infringing product will be permitted to be sold at a lower price, the ill effect upon the plaintiffs will be long term and unqualifiable. It is also the contention of the plaintiffs that manufacturing of the drug by the defendant without the consent of the plaintiff is good enough to establish the violation of the Section 48 of the Patents Act, more so, in the light of the fact that there was no denial of infringement. It is also mentioned in the rejoinder that the suit patent has been granted in favour of the plaintiffs by more than 70 countries worldwide. The corresponding patent was granted

in China and was invalidated, wherein a re-trial petition has been filed before the Supreme People's Court of the People's Republic of China, which is pending. It is also the stand of the plaintiffs that the prior art relied upon by the defendant has been part of examination proceedings in all countries, including before the major Patent Offices. The grant of a suit patent is based on technical expertise of the patent examiners, who have not casted any doubt on the validity and inventiveness of the suit patent. The patent protection is territorial and governed by respective patent laws of each of the countries. The patent law is peculiar to each country and as such, the same cannot be followed in a blanket manner, as has been the attempt of the defendant. The corresponding patents have been granted by all major countries around the world rather than keeping an eye on just one country where the matter is sub judice and interim cannot be denied to the plaintiffs for the following factors:-

"(a) The suit patent is old and established;

(b) The subject matter disclosed is extremely useful and successful;

(c) The product covered by the suit patent is in the Indian market since 2015;

(d) No pre-grant opposition;

(e) No post-grant opposition;

(f) No revocation (except as stated above);

(g) Granted in 70 countries, including major Patent judisdictions;

(h) No application for a voluntary license made by the defendant; and

(i) No application for a compulsory license filed by the defendant."

Further, as per the plaintiffs, defendant has failed to raise a credible challenge against the subject patent. According to the plaintiffs, the grant of Patent Certificate, prima facie, amount to validity thereof and the prior art documents do not in any manner further the case of the defendant vis-à-vis validity of the suit patent. It is denied by the plaintiffs that Empagliflozin is embraced by the broadest generic claim of WO'128. According to the plaintiffs, Empagliflozin is a highly potent inhibitor of the SGLT2 (EC50 1-3 nM) with high selectivity for SGLT 2 over SGLT1. The selectivity of Empagliflozin (-2500) is higher than the selectivity of Dapagliflozin (about 1200) and the compound of Example 12 of WO'128 (about 900) and superior to the compounds in the prior art. Therefore, in view of the improved selectivity Empagliflozin has a technical advancement over WO'128. It is also the stand of the plaintiffs that economic significance is established by the net sales of the drugs. As per the plaintiffs, term of the suit patent expires on March 11,2025 and has not been subjected to any pre-grant or post-grant opposition under Sections 25(1) and 25(2) of the Patents Act. Suit patent, IN '846 specifically discloses and covers a New Chemical Entity having an International Non-Proprietary Name (INN) Empagliflozin (WHO INN) and the

IUPAC name “(2S, 3R,4R,5S,6R)-2-{4-chloro-3-{{4-{(3S)-oxolan-3-yl}oxyphenyl}methyl}phenyl}-6-(hydroxmethyl)oxane-3,4,5-triol”. The compound, Empagliflozin is an active pharmaceutical ingredient of the drug, Jardiance R, which has been approved for the treatment of type 2 diabetes mellitus in 110 countries. It is used as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus, and to reduce the risk of cardiovascular death in adult patients with type 2 diabetes mellitus and established cardiovascular disease (USFDA). Empagliflozin is an inhibitor of the sodium co-transporter-2 (SGL T2). SGL T2 inhibitors are a new class of glucose-lowering agents developed for the treatment of type 2 diabetes mellitus, which has a mechanism of action that is independent of pancreatic beta-cell function or the degree of insulin resistance. By inhibiting the SGLT 2, the glucose reabsorption in the kidney is blocked, such that an excess of glucose is excreted via the urine resulting in a lowering of the blood glucose level. The SGL T2 is found almost exclusively in the proximal tubules of nephronic components in the kidneys. SGL T2 accounts for about 90 percent of glucose reabsorption into the blood. Empagliflozin inhibits SGL T2 selectively.

9. Learned Senior Counsel appearing for the plaintiffs argued that in the present case, in view of the fact that there is a valid patent registered in favour of plaintiff No. 1 under the Patents

Act, 1970 and as the defendant is infringing the patent of the plaintiffs by manufacturing and marketing the product which is covered under the subject patent, the plaintiffs having a *prima facie* case in their favour, are entitled for the interim relief. He submitted that in view of the fact that on one hand, there is a valid patent registered in favour of plaintiff No. 1-Company, whereas, the defendant happens to be a rank infringer, the balance of convenience is also in favour of the plaintiffs and, therefore, in these circumstances, in case the interim protection is not granted to the plaintiffs during the pendency of the suit, the plaintiffs shall suffer irreparable loss.

10. On the other hand, learned Senior Counsel appearing for the defendant submitted that in a patent case, interim cannot be prayed on the grounds that have been urged on behalf of the plaintiffs. He submitted that it is settled law that in case at the stage of interim, the defendant is able to raise successfully the plea that the patent is “vulnerable”, then no interim is to be granted. He submitted that validity of the patent is to be tested during the course of the trial, but for the purpose of testing an application filed under Order XXXIX, Rules 1 and 2 of the Code of Civil Procedure, this Court has to see as to whether the patent of the plaintiffs is “vulnerable” or not. He further submitted that in the present case, the subject patent is “vulnerable” on the following grounds:-

(a) the subject patent is not a result of any inventive step, but is a copy of prior art;

(b) that same patent of the plaintiffs was invalidated by the Court of competent jurisdiction, i.e., Supreme People's Court of the People's Republic of China and this fact has been concealed by the plaintiffs, who thus have not approached the Court with clean hands; and

(c) affidavit of an expert (Dr. Prabuddha Ganguli) would demonstrate that the subject patent is not a result of any inventive step, but it is a copy of prior art.

11. I have heard learned Senior Counsel for the parties and have also gone the pleadings.

12. There is no dispute qua the fact that the subject patent is duly registered under the Patents Act in favour of plaintiff No. 1-Company. The subject patent was granted to the plaintiffs on 18th September, 2015. The international filing date of the subject patent is 11th March, 2005 and the expiry date of the subject patent is 11th March, 2025. On the other hand, the defendant admittedly does not have any patent qua the infringing product. It is also a matter of record that no pre-grant or post-grant challenge was laid to the application filed by the plaintiffs for the registration of the parent.

13. Learned Senior Counsel for the defendant submitted that because the defendant has not laid any pre-grant or post-grant

opposition to the patent application of plaintiff No. 1-Company, this does not mean that the defendant is precluded from raising the issue of “vulnerability” of the subject patent at this stage before the Court. The Court concurs with the submission made by learned Senior Counsel for the defendant. Therefore, the issue as to whether the defendant has been able to demonstrate that the subject patent is “vulnerable” shall be decided by the Court, taking into consideration this aspect of the matter.

14. Before proceeding further, it is relevant to refer to the broad principles as stand enunciated by Hon’ble Supreme Court of India as well as other Courts while dealing with the matters relating to infringement of Patent in General and an application filed under Order XIII, Rule 1 and 2 of the Civil Procedure Code on the ground of infringement of the Patent.

15. In **M/s Bishwanath Prasad Radhey Shyam** vs. **Hindustan Metal Industries**, (1979) 2 Supreme Court Cases 511, Hon’ble Supreme Court has been pleased to hold that grant and sealing of the patent, or the decision rendered by the Controller in the case of opposition, does not guarantee the validity of the patent, which can be challenged before the High Court on various grounds in revocation or infringement proceedings. Hon’ble Supreme Court further held that the ‘validity of a patent is not

guaranteed by the grant', was also expressly provided in Section 13(4) of the Patents Act, 1970.

16. Hon'ble Supreme Court of India in **Dalpat Kumar and Another** vs. **Prahlad Singh and Others**, (1992) 1 Supreme Court Cases 719 has held that it is settled law that the grant of injunction is a discretionary relief and exercise thereof is subject to the Court satisfying that (1) there is a serious disputed questions to be tried in the suit and that an act, on the facts before the Court, there is probability of his being entitled to the relief asked for by the plaintiff/defendant; (2) the Court's interference is necessary to protect the party from the species of injury. In other words, irreparable injury or damage would ensue before the legal right would be established at trial' and (3) that the comparative hardship or mischief or inconvenience which is likely to occur from withholding the injunction will be greater than that would be likely to arise from granting it. In para-5 of the judgment, Hon'ble Apex Court has been further pleased to hold as under:-

> *"5. Therefore, the burden is on the plaintiff by evidence aliunde by affidavit or otherwise that there is "a prima facie case" in his favour which needs adjudication at the trial. The existence of the prima facie right and infraction of the enjoyment of his property or the right is a condition for the grant of temporary injunction. Prima facie case is not to be confused with*

prima facie title which has to be established, on evidence at the trial. Only prima facie case is a substantial question raised, bona fide, which needs investigation and a decision on merits. Satisfaction that there is a prima facie case by itself is not sufficient to grant injunction. The Court further has to satisfy that non-interference by the Court would result in "irreparable injury" to the party seeking relief and that there is no other remedy available to the party except one to grant injunction and he needs protection from the consequences of apprehended injury or dispossession. Irreparable injury, however, does not mean that there must be no physical possibility of repairing the injury, but means only that the injury must be a material one, namely one that cannot be adequately compensated by way of damages. The third condition also is that "the balance of convenience" must be in favour of granting injunction. The Court while granting or refusing to grant injunction should exercise sound judicial discretion to find the amount of substantial mischief or injury which is likely to be caused to the parties, if the injunction is refused and compare it with that it is likely to be caused to the other side if the injunction is granted. If on weighing competing possibilities or probabilities of likelihood of injury and if the Court considers that pending the suit, the subject-matter should be maintained in status quo, an injunction would be issued. Thus the Court has to exercise its

sound judicial discretion in granting or refusing the relief of ad interim injunction pending the suit."

17. The principles in general being followed for the purpose of grant of injunction in Patent matters as they stand summarized in ***Ten XC Wireless Inc. and Others*** **vs.** ***Mobi Antenna Technologies (Shenzhen) Co. Ltd.,*** *2011 SCC Online Delhi 4648 are as under:-*

"(i) The registration of a patent per se does not entitle the plaintiffs to an injunction. The certificate does not establish a conclusive right.

(ii) There is no presumption of validity of a patent, which is evident from the reading of Section 13(4) as well as Sections 64 and 107 of the Patents Act.

(iii) The claimed invention has to be tested and tried in the laboratory of Courts.

(iv) The Courts lean against monopolies. The purpose of the legal regime in the area is to ensure that the inventions should benefit the public at large.

(v) The plaintiff is not entitled to an injunction if the defendant raises a credible challenge to the patent. Credible challenge means a serious question to be tried. The defendant need not make out a case of actual invalidity. Vulnerability is the issue at the preliminary injunction stage whereas the validity is the

issue at trial. The showing of a substantial question as to invalidity thus requires less proof than the clear and convincing showing necessary to establish invalidity itself.

(vi) At this stage, the Court is not expected to examine the challenge in detail and arrive at a definite finding on the question of validity of the patent. That will have to await at the time of trial. However, the Court has to be satisfied that a substantial, tenable and credible challenge has been made.

(vii) The plaintiff is not entitled to an injunction, if the patent is recent, its validity has not been established and there is a serious controversy about the validity of the patent."

18. Recently, the Hon'ble Division Bench of Delhi High Court in FAO(OS) (COMM 178/2021 and CM Nos.46299/2021, 46300/2021, 46301/2021, 46302/2021, 19118/2022, 19119/ 2022 and 30850/2022, titled as ***Natco Pharma vs. Novartis AG and Anr.,*** decided on 24.04.2024, on the point of Standard of Challenge to validity at interim stage has been pleased to hold as under:-

"39. At the outset, it is relevant to note that there is no presumption of validity of a patent by virtue of the same being granted by the Patent Office. Thus, the fact that the examiners have conducted necessary investigations prior to the grant of patent does

not render a patent immune from challenge to its validity. The contention that there was no pre-grant or post-grant opposition to IN'161 and therefore, Natco has to cross a very high threshold to assail the validity of the patent, is unmerited. The Act expressly enables a challenge to the validity of a patent at various stages. Section 25(1) of the Act enables any person to challenge the grant of a patent after the application for the patent has been published. This is, essentially, in aid of the examination process 6. In terms of Section 25(2) of the Act, an interested person can challenge the grant of a patent on the grounds as set out in the said sub-section, subject to the said challenge being raised within a period of one year from the date of publication of the patent. Section 64(1) of the Act also enables a person to file a petition for revocation of a patent on the grounds as set out in Section 64(1) of the Act. In terms of Section 64(1) of the Act, any person interested, or the Central Government is entitled to apply for revocation of the patent, either, by way of a petition or by way of a counter-claim in a suit for infringement on the grounds as set out in Section 64(1) of the Act. Additionally, in terms of Section 105 of the Act, any person is entitled to institute a suit for declaration, that the use by him of any process, or the making, use or sale of any article by him

does not, or would not constitute infringement of a claim of a patent.

40. It is also material to note that there is no statutory provision similar to Section 31 of the Trade Marks Act, 1999, which posits a statutory presumption of validity on grant of a patent. It is also relevant UCB Farchim Sa v. Cipla Ltd. & Ors.: 2010 SCC OnLine Del 523 to refer to Section 13(4) of the Act, which expressly provides that the investigation required under Section 12 of the Act - the pre-grant investigations and inquiries leading to the grant of patent - does in any way warrant the validity of any patent.

41. Absent any statutory presumption and given the scheme of the Act, which enables challenge to the validity of a patent at several stages, there is neither any presumption as to the validity of a patent nor renders the patent immune for challenge to its validity.

42. Thus, in an action for infringement of a patent, defence as to the invalidity of the patent on the grounds as provided in Section 64(1) of the Act, is available to the defendant. The court is required to examine the challenge with an open mindset and not from the standpoint of an assumption that the patent is validly granted.

43. Unless there is no real prospect of the defendant to succeed in its challenge and

an appropriate application to allow the action is made prior to framing of issues, the questions as to the validity of the patent asserted, are required to be determined at the trial. However, at the stage of interim relief, the defendant has to establish its assertion that its defence is not insubstantial and sets out a credible challenge to the validity of the patent. The defendant is not required to establish that the patent is invalid, it has to merely show that the patent is vulnerable. If the challenge raised to the validity is substantial, the threshold standard for resisting an interim injunction in this regard - subject to other relevant considerations -would be met. In this context, it is relevant to refer to the decision of the Division Bench of this Court in F. Hoffmann-LA Roche Ltd. & Anr. v. Cipla Ltd.7. In the said case, the Division Bench had rejected the contention that the defendant had a heavy burden to discharge and would have to establish a stronger prima facie case than the plaintiff. The Division Bench had also not accepted the contention that since there is a multi-level examination of opposition to the grant of patent, it ought to be accorded the highest weightage. The relevant extract of the said decision is set out below:

"53. The plea of the plaintiff that since there is a multi- layered, multi-level examination of the opposition to the grant of patent it should accorded the highest weightage, is not entirely correct. The contention that there is a heavy

burden on the defendant to discharge since it has to establish that it has a stronger prima facie case of the plaintiff is contra indicated of the decisions in the context of Section 13(4). Reference may be made to the decisions in Biswanath Prasad Radhey Shyam v. Hindustan Metal Industries, (1979) 2 SCC 511 : AIR 1982 SC 1444 : Supp (1) PTC 731 (SC), Standipack Pvt. Ltd. v. Oswal Trading Co. Ltd., AIR 2000 Del 23 : (1999) 19 PTC 479 (Del), Bilcare Ltd. v. Amartara Pvt. Ltd., (2007) 34 PTC 419 (Del), Surendra Lal Mahendra v. Jain Glazers, 1980 SCC OnLine Del 219. In Beecham Group Ltd. v. Bristol Laboratories Pty Ltd., (1967-1968) 118 CLR 618 and Australian Broadcasting Corporation v. O'Neill, (2006) 229 ALR 457 it was held that the defendant alleging invalidity bears the onus of establishing that there is "a serious question" to be tried on that issue. In Hexal Australai Pty Ltd. v. Roche Therapeutics Inc., 66 IPR 325 it was held that where the validity of a patent is raised in interlocutory 2009 SCC OnLine Del 1074 proceedings, "the onus lies on the party asserting invalidity to show that want of validity is a triable question." In Abbot Laboratories v. Andrx Pharmaceuticals Inc. (decision dated 22nd June 2006 of the U.S. Court of Appeals for the Federal Circuit 05-1433) the Court of Appeals followed its earlier ruling in Helifix Ltd. v. Blok-Lok Ltd. 208 F.3d 1339 where it was held (at 1359): "In resisting a preliminary injunction, however, one need not make out a case of actual invalidity. Vulnerability is the issue at the preliminary injunction stage, while validity is the issue at trial. The showing of a substantial question as to invalidity thus requires less proof than the clear and convincing showing necessary to establish invalidity itself." (emphasis supplied) In Erico Int'll Corprn v. Vutec Corprn (U.S. Court of Appeals for the Federal Circuit, 2007- 1168) it was held that the "defendant must put forth a substantial question of invalidity to show that the claims at issue are vulnerable."

54. In the present case, the grant of a patent to the plaintiffs for Erlotinib Hydrochloride as a mixture of Polymorphs A and B will not ipso facto entitle them to an interim injunction if the defendant is able to satisfy the court that there is a serious question to be tried as to the validity of the patent. The use by the learned Single Judge of the expressions "strong credible challenge", "arguable case" or that the defendants claim being not unfounded, cannot be termed as vague and inconsistent since they convey the same meaning in the context of the strength of the defendant's challenge.

55. The question before this Court is when can it be said that the defendant has raised a credible challenge to the validity of a patent held by the plaintiff in an infringement action? During the course of the argument it was suggested by counsel that the challenge had to be both strong and credible. Also, the defendant resisting the grant of injunction by challenging the validity of the patent is at this stage required to show that the patent is "vulnerable" and that the challenge raises a "serious substantial question" and a triable issue. Without indulging in an exercise in semantics, the Court when faced with a prayer for grant of injunction and a corresponding plea of the defendant challenging the validity of the patent itself must enquire whether the defendant has raised a credible challenge. In other words, that would in the context of pharmaceutical products, invite scrutiny of the order granting patent in the light of Section 3(d) and the grounds set out in Section 64 of the Patents Act, 1970. At this stage of course the Court is not expected to examine the challenge in any great detail and arrive at a definite finding on the question of validity. That will have to await the trial. At the present stage of considering the grant of an interim injunction, the defendant has to show that the patent that has been granted is vulnerable to challenge. Consequently, this Court rejects the contentions

of the plaintiffs on this issue and affirms the impugned judgment of the learned Single Judge"

44. It is also relevant to refer to the decision of the learned Single Judge of this Court in Astrazeneca AB & Anr. v. Intas Pharmaceuticals Ltd.8. In the said case, the learned Single Judge rejected the contention that since the suit patents were old, they should be presumed to be valid. The learned Single Judge did so for two reasons. First, the learned Single Judge found - much like in the present appeal where it is the stated case that ELT-O is covered under both IN' 176 and the suit patent IN' 161 - that there was an overlap in the genus patent and the species patent. And second, that the presumption of validity exists only till such time the patent is challenged and the challenge is credible. The relevant extract of the said decision is set out below:

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

i. First, there is a period of overlap between the genus patent i.e. IN 147 and the species patent i.e. IN 625. The defendants, in this case, chose to wait [in line with arguments advanced in their defence of the suit actions] till such time the

validity period of the genus patent i.e. IN 147 expired.

ii. Second, as indicated above, the scheme of the Act does not foreclose the right of the defendants in defence to an infringement action to question the validity of the patent. Section 107 of the Act, expressly confers a right on the defendants to raise, in defence, in an infringement suit, all those grounds on which the patent can be revoked under Section 64 of the very same Act. Therefore, the judgment in Bristol-Myers Squibb Company v. J.D. Joshi, 2015 SCC OnLine Del 10109, if read in context, would demonstrate that it has not emasculated the right of the defendant, as conferred under the Act, to challenge the validity of the patent. The presumption of validity exists only till such time the patent is challenged - a challenge which is credible and no further. In my opinion, if the plaintiffs' argument was to be accepted, then, it would have to be held that the older the patent, the stronger the firewall. Such an interpretation, in my view, would be contrary to the plain words of the Statute."

19. As I have already mentioned hereinabove, the test which the defendant has to cross to deny the plaintiffs the interim relief during the pendency of the Civil Suit is that the subject patent is "vulnerable". This Court reiterates that it understands the difference between "vulnerability" and "validity", i.e., to say that at this stage this Court is not venturing into the issue as to whether subject patent is valid or not and only thing which this Court would decide is as to whether the defendant has been able to lay a "credible challenge" to the subject patent by demonstrating that the

subject patent is “vulnerable” on three grounds urged in this regard by learned Senior Counsel appearing for the defendant or not.

20. The contention of the defendant as submitted by learned Senior Counsel is that the subject patent lacks inventive steps as compared to the prior art documents. The main argument of the defendant revolves around the aspect of vulnerability of the plaintiff’s patent on account of obviousness [Section 64(1)(f)] and on account of lack of therapeutic efficacy [Section 64(1)(k) r/w 3(d)]. As per the defendant, the suit patent is not an invention within the meaning of Section 2(j) and there is no inventive step within the meaning of Section 2(1)(ja). In addition, there is no enhancement of therapeutic efficacy and the patent is hit by Section 3(d) of the Patents Act, 1970. The defendant has cited the following prior arts:-

“A. *WO2001027128-Dapa 1; and*

B WO2003099836 –Dapa 2”

As per the defendant, Dapa 1- a Markush patent- provides 80 exemplified examples. Of these, the starting point is example 12 (provided in the specification of Dapa 1). The only difference between example 12 of Dapa 1 and Dapa 2 is the substitution at one position from **Ethoxy** to **Methoxy**. A Person skilled in the art, after a combined reading of Dapa 1 and Dapa 2, would be motivated to make substitutions at the same position. The specification of the impugned patent shows no technical advance over Dapa patents.

The specification of Dapa 1 clearly states that SGLT 2 inhibitors are helpful in normalizing blood sugar. Dapa 1 was the first invention to state that SGLT 2 inhibition is helpful for controlling diabetes and thus SGLT 2 inhibitors got the name Gliflozins. Suit patent teaches exactly what Dapa 1 taught and that there is no technical advance. Technical advancement needs to be shown from the patent specification. Thus, the arguments of the defendant on the aspect of vulnerability of plaintiffs' patent are on account of obviousness and also on account of therapeutic efficacy.

21. The specifications of Dapa 1 clearly stated that SGLT 2 inhibitors are helpful in normalizing blood sugar. Dapa 1 was the first invention to state that SGLT 2 inhibition is helpful for controlling diabetes and thus SGLT 2 inhibitors got the name Gliflozins. According to the defendant, the suit patent teaches what Dapa 1 taught and that there is no technical advance and the technical advancement needs to be shown from the patent specification and since a POSA would be motivated to make structural changes at the same position to come to compounds showing similar activity vis-à-vis Dapa 1 and the suit patent, therefore, the subject patent is nothing but an ever greening of the earlier existing art and such patent is vulnerable. Its contention is that as far as the subject patent is concerned, Methoxy in example 12 of Dapa 1 has been replaced by tetrahydrofuranyloxy (THF) in the subject patent. According to the

defendant, in Dapa 2 Astra Zeneca attempted to do exactly the same and this was held to be obvious by the High Court of Delhi in Astrazeneca AB and another Vs. Torrent Pharmaceuticals Ltd., 2020 SCC Online Del. 1446. As per the defendant, the inventive step and technical advance has to have its genesis in the patent specification and the plaintiffs were required to state in the specification how suit patent has a technical advance over Dapa and as the subject patent failed to do so, therefore, the same is vulnerable.

22. It has also been argued on behalf of the defendant that the application for grant of interim is liable to be rejected on the ground that the plaintiffs have not approached the Court with clean hands. It is contended by the defendant that the same patent of plaintiff No. 1 having been invalidated by the Supreme People's Court of the People's Republic of China, having been concealed in the plaint itself deserves dismissal of the application. According to the defendant, as the plaintiff did not approach the Court with clean hands, therefore, no indulgence can be shown to the plaintiffs. To substantiate this argument, reliance has been placed on the following judgments:-

> *"1. Freebit As Vs. Exotic Mile Private Limited, FAO (OS) (COMM) 15/2024 and CAV43/2024 and CM Nos. 5698/2024, 5699/2024 & 5700/2024.*
>
> *2. Natco Pharma Vs. Navartis AG and anr. FAO (OS) (COMM) 178/2021 and CM Nos. 46299/2021,*

46300/2021, 46301/2021, 46302/2021, 19118/2022, 19119/2022 and 30850/2022."

The defendant has also referred to the affidavit filed by an expert Dr. Prabuddha Ganguli and argued that the expert has clearly held that there is no inventive step involved in the subject patent and the same is an ever greening of an already exiting patent and thus, as the defendant has demonstrated the vulnerability as far as the subject patent is concerned, therefore, the application for grant of interim injunction is liable to be dismissed.

23. On the other hand, the contention of the plaintiffs is that the so called ever greening of an existing patent by plaintiff No. 1-Company is incorrect. According to the plaintiffs, there is an inventive step involved over and above the existing arts and, therefore, it cannot be said that the subject patent is an ever greening of an already existing patent. Empagliflozin is a highly potent SGLT2 inhibitor (EC50 1-3 nM) and has a high selectivity for SGLT2 over SGLT1. The selectivity of Empagliflozin (>2500) is higher than the selectivity of Dapagliflozin (around 1200) which in turn has a higher selectivity than the compound of Example 12 (around 900) of IN '147. Therefore, in view of the improved selectivity, Empagliflozin has a technical advancement over Dapagliflozin (WO '836/IN '625) and over the Example 12 of WO '128/ IN '147. In addition, further compounds covered by the claims of IN '846 including, but not limited to compounds of claims 1 and

claim 4 corresponding to Example 2; claim 1 according to the compound of Example 10; claim 1 and claim 2 corresponding to Example 21; claim 1 and claim 3 corresponding to Example 22 are potent SGLT2 inhibitors and selective for SGLT2 as opposed to SGLTI (over 900 times more selective). In particular like Empagliflozin, the compound of claim 4 (Example 2), which is the R-diastereomer of Empagliflozin, has a higher selectivity for SGLT2 over SGLT1 than Dapagliflozin and even more than the compound of Example 12 of IN '147. Also, the compounds of the claims 2 and 3 (Examples 21 and 22), which bear a methyl substituent at the central phenyl ring, have a better selectivity for SGLT2 over SGLT 1 than the respective compound of Example 8 of IN '147. It also stands urged on behalf of the plaintiffs that there was a specific mention of the existing prior arts in the application that was submitted by the plaintiffs for registration of its patent and, thus, there was no concealment of any fact from the statutory authorities. The fact that the patent was granted in favour of the plaintiff-Company thereafter, itself is demonstrative of the fact that the subject patent is not an ever greening of an already existing patent. It is also the contention of the plaintiffs that the factum that the subject patent is registered under the jurisdiction of more than 70 countries worldwide is also an indicator of the fact that the subject patent is not vulnerable patent and simply because the jurisdiction of one country has invalidated

the patent of the plaintiff-Company, this does not render the patent to be vulnerable as compared to the number of countries, which have registered the subject patent of the plaintiff-Company, vis-à-vis one country which has invalidated it. It cannot said that invalidation by one country will tilt the balance of convenience in favour of the defendant by any stretch of imagination.

24. Similarly, with regard to the affidavit of the expert, the contention of the plaintiffs is that there is an affidavit of the expert of the plaintiffs also, which stands filed by it in other proceedings and otherwise also, the so called affidavit of the expert is based on the material which was provided by the defendant to the expert, who obviously submitted the affidavit on the terms as were dictated by the defendant.

25. Be that as it may, on the issue of obviousness, the primary contention of the defendant is that the subject patent does not contain any technical advancement and it is just an ever greening of Dapa 1, primarily the substitution of Methoxy by tetrahydrofuranyloxy (THF), which cannot be said to be an inventive step. The contention of the defendant is that the substitution of Methoxy by tetrahydrofuranyloxy (THF) does not amount to an inventive step, which enhances therapeutic efficacy. To substantiate this fact, reliance has been placed on the affidavit of its expert.

26. On the other hand, the stand of the plaintiffs is that Empagliflozin is a highly potent SGLT2 inhibitor (EC50 1-3 nM) and has a high selectivity for SGLT2 over SGLT1. The selectivity of Empagliflozin (>2500) is higher than the selectivity of Dapagliflozin (around 1200) which in turn has a higher selectivity than the compound of Example 12 (around 900) of IN '147. Therefore, in view of the improved selectivity, Empagliflozin has a technical advancement over Dapagliflozin (WO '836/IN '625) and over the Example 12 of WO '128/ IN '147. In addition, further compounds covered by the claims of IN '846 including, but not limited to compounds of claims 1 and claim 4 corresponding to Example 2; claim 1 according to the compound of Example 10; claim 1 and claim 2 corresponding to Example 21; claim 1 and claim 3 corresponding to Example 22 are potent SGLT2 inhibitors and selective for SGLT2 as opposed to SGLTI (over 900 times more selective). In particular like Empagliflozin, the compound of claim 4 (Example 2), which is the R-diastereomer of Empagliflozin, has a higher selectivity for SGLT2 over SGLT1 than Dapagliflozin and even more than the compound of Example 12 of IN '147. Also, the compounds of the claims 2 and 3 (Examples 21 and 22), which bear a methyl substituent at the central phenyl ring, have a better selectivity for SGLT2 over SGLT 1 than the respective compound of Example 8 of IN '147.

27. It is a matter of record that the prior art being relied upon by the defendant was referred to in the application that was filed by the plaintiffs for the registration of the trademark. The reference thereof is in the application that was filed by the plaintiffs in Form 2 as per Section 10 of the Patents Act and Rule-13 framed thereunder. The relevant portion thereof is reproduced hereinbelow:-

> *"In the literature, compounds which have an inhibitory effect on the sodium-dependent glucose cotransporter SGLT2 are proposed for the treatment of diseases, particularly diabetes. Glucopyranosyloxy-substituted aromatic groups and the preparation thereof and their possible activity as SGLT2 inhibitors are known from published International applications WO 98/31697, WO 01/27128, WO 02/083066, WO 03/099836, WO 2004/063209, WO 2004/080990, WO 2004/013118, WO 2004/052902, WO 2004/052903 and US application US 2003/0114390."*

28. There is no dispute on the issue that published International Application WO 01/27128, refers to DAPA 1 and published International Application WO 03/099836, refers to DAPA 2. The application was scrutinized by the Statutory Authorities, whereafter, the patent was granted. Though the grant of patent per se does not amount to issuance of a certificate qua its validity, but

fact of the matter still remains that it not as if the patent was obtained by the plaintiffs by concealing prior publications relating to DAPA 1 and DAPA 2, which is the main and only argument of defendant on Obviousness. Now, as per the plaintiffs, the subject patent is an improvement over the existing prior act as it contains an inventive step, whereas, this is denied by the defendant. In other words, as per the defendant, there is no inventive step in the subject patent and it is an ever greening of the existing art.

29. This Court is of the considered view that whether or not substitution of Methoxy by tetrahydrofuranyloxy (THF) etc. has enhanced the therapeutic efficacy or not, is an issue which has to be decided at the stage of adjudicating the validity of the patent. I have already observed hereinabove that in the application that was filed by plaintiff No. 1 for registration of the patent, there was a reference of Dapa 1 and Dapa 2 as SGLT2 inhibitors. Therefore, as from the date of fling of the application, this fact is in public domain since then. For the purpose of holding that the patent is vulnerable, this Court cannot, at this stage, return a finding that the substitution of Methoxy by tetrahydrofuranyloxy (THF) etc. was nothing but an ever greening of the existing art. This is the stand of the defendant, which it has to prove. The defendant cannot be permitted to say that its allegation is enough to render the subject patent vulnerable. Even, the affidavit filed by the expert which has been placed on record by

the defendant cannot be read so as to hold at this stage that the subject patent stands rendered vulnerable on the basis of the contents of the affidavit, because the veracity of the affidavit is yet to be established, which is subject to cross-examination of the expert witness by the plaintiffs. This Court cannot lose sight of the fact that the affidavit filed by the expert is at the behest of the defendant. The affidavit is neither a publication nor it was in existence prior to the filing of this Civil Suit. In a suit of infringement, ordinarily, no defendant would admit the allegations. But obvious, it will deny the contentions of the plaintiff that the defendant is infringing its patent. In view of the statutory provisions, as they exist in the Patent Act, such a defendant would take all the defences as are available to it in law. Availability of these defences and defendant harping upon them, has to be kept in mind by the Court while deciding an application under Order 39, Rules 1 and 2 of the Code of Civil Procedure. This is more so for the reason that in a case of infringement under the Patents Act, at the stage of interim, the Court has to consider the factum of “credible challenge”, if any, laid by the defendant to the patent of the plaintiff or the aspect of vulnerability qua the subject patent. The Court therefore has to be careful that until and unless there is material on record, more than mere allegations, a powerfully put defence *per se*, in the absence of a *prima facie* satisfaction of the Court, cannot bound the Court to not grant the interim injunction.

30. Now, I will deal with the ground that the plaintiffs have not approached this Court with clean hands and they have suppressed the material facts from the Court. The contention of the defendant is that same patent of plaintiff No. 1, which was registered in China, was invalidated by the Competent Court of law in China and this fact was concealed by the plaintiff from this Court. Learned Senior Counsel for the defendant submitted that this act and conduct of the plaintiffs alone, disentitles them from grant of any interim relief. Learned Senior Counsel referred to judgment dated 14.12.2023, passed by the learned Single Judge of High Court of Delhi in Freebit AS Vs. Exotic Mile Private Limited, CS (COMM) 884/2023, I.As. 25074/2023, 25075/2023, 25076/2023 and 25077/2023 as also judgment 31.01.2024, passed by the Hon'ble Division Bench of Delhi High Court in *Freebit As Vs. Exotic Mile Private Limited, FAO (OS) (COMM) 15/2024 and CAV43/2024 and CM Nos. 5698/2024, 5699/2024 & 5700/2024* to substantiate his contention.

31. Learned Single Judge of Delhi High Court in ***Freebit AS Vs. Exotic Mile Private Limited*** *(supra)* has held as under:-

> *"29. As per the High Court of Delhi Rules Governing Patent Suits, 2022, (hereinafter, 'Patent Suit Rules') it is necessary, to the extent possible, for a plaint to include details of corresponding foreign patent applications, as well as information relating to any orders passed by a Court or Tribunal concerning the same or substantially similar*

invention as asserted in the suit. The relevant extracts from the Patent Suits Rules are set out below:

"3. Content of Pleadings
A. Plaint
The Plaint in an infringement action shall, to the extent possible, include the following aspects:
….
(iv) Brief summary of international corresponding applications/patent(s) and grant thereof including details of worldwide protection for the invention;
(v) Brief prosecution history of the suit patent(s);
(vi) Details of any challenge to the suit patent(s) and outcome thereof;
(vii) Details of orders, if any, passed by any Indian or international court or tribunal, upholding or rejecting the validity of the suit patent or a patent which is for the same or substantially the same invention;"

30. Further, Order XI Rule 1 CPC, as amended by the Commercial Courts Act, 2015,obligates the Plaintiff filing suit, to file all documents which would have a bearing on the suit. The said Rule specifies that the Plaintiff even has a duty to file those documents, which are adverse to the case of the Plaintiffs. Therefore, overall, the said Rule mandates comprehensive disclosure by a Plaintiff, to ensure that all relevant information is available to the Court, for a fair adjudication. The relevant extract of the said rule is set out below:

"ORDER XI DISCLOSURE, DISCOVERY AND INSPECTION OF DOCUMENTS INSUITS BEFORE THE COMMERCIAL DIVISION OF A HIGH COURT OR ACOMMERCIAL COURT
1. Disclosure and discovery of documents. -
(1) Plaintiff shall file a list of all documents and photocopies of all documents, in its power, possession, control or custody, pertaining to the suit, along with the plaint, including: -
(a) documents referred to and relied on by the plaintiff in the plaint;

(b) documents relating to any matter in question in the proceedings, in the power, possession, control or custody of the plaintiff, as on the date of filing the plaint, irrespective of whether the same is in support of or adverse to the plaintiff's case…."

31. The above set of rules show that at the time of filing of the suit, a basic enquiry ought to be made, if there are corresponding patents internationally, and if any of them have been rendered invalid by any Court or Tribunal.

32. In the present suit, however, a bare perusal of paragraph 19 of the plaint shows that in respect of some of the countries, where the suit patent has either been revoked, refused, abandoned, lapsed, have been shown as either pending or granted……

…. …. ….

36. In Satish Khosla v. M/s. Eli Lilly Ranbaxy Ltd. [MANU/DE/0763/1998: 71 (1998)DLT 1 (DB)], the ld. Division Bench of this Court has underscored the importance of candour and forthrightness in instituting legal proceedings. It Is Incumbent upon a Plaintiff that approaches the Court to approach the Court with 'clean hands', a principle that mandates the full disclosure of all relevant and material facts. This disclosure is not limited to facts that bolster a party's case but extends to all information that could potentially aid in a comprehensive and fair adjudication of the dispute. The duty of disclosure encompasses not only the submission of all documents pertinent to the current litigation but also an obligation to inform the Court of any previous litigations between the parties, any previous litigations concerning the suit patent, along with their respective outcomes.

Such transparency is indispensable for ensuring that the Court has a complete and unobscured view of the relevant factual landscape, which is crucial for the fair dispensation of justice. The relevant extract of the said decision is set out below:

> *"15. In S.P. Chengalvaraya Naidu V. Jagannath and Others, MANU/SC/0192/1994: AIR 1994 SC 853 it was held that the Courts of Law are meant for imparting justice between the parties. One who comes to the Court, must come with clean hands. "It can be said without hesitation that a person whose case is based on false-hood has no right to approach the Court. He can be summarily thrown out at any stage of the litigation. A litigant, who approaches the Court, is bound to produce all the documents executed by him which are relevant to the litigation. If he withholds a vital document in order to gain advantage on the other side then he would be guilty of playing fraud on the Court as well as on the opposite party."*
>
> *16. …It is contended by Mr. Oberoi, appearing on behalf of the respondent that the respondent had no intention or motive to suppress the pendency of the earlier application in which the stay was not granted and having disclosed in the plaint that a suit between the parties was pending, it was not relevant or necessary to mention that in the said suit the Court had not granted any stay in its favour. In our view, the arguments are wholly fallacious. A party must come to the Court with clean hands and must disclose all the relevant facts which may result in appreciating the rival contentions of the parties. In our view, a litigant, who approaches the Court, must produce all the documents which are relevant to the litigation and he must also disclose to the court about the pendency of any earlier litigation between the part is and the result thereof.*
>
> *….In our opinion, it was obligatory upon the respondent to disclose to the Court that in the application filed in the earlier suit a similar relief had been claimed, however, the Court had not granted the said relief. In our view, if these facts were before the Court on February 6, 1997 when the second suit came up for hearing before it, may be Hon'ble*

the Single Judge was persuaded not to grant any ex parte stay in favor of the respondent. Moreover, in a suit for specific performance of an agreement to register the agreement of lease, it appears to us that the plaintiff could not claim an injunction which had already been claimed in Suit No. 3064/96. We are, Therefore, of the opinion that the respondent has not come to the Court with clean hands and has also suppressed material facts from the Court with a view to gain advantage in the second suit. This in our view is clearly over reaching the Court."

37. The Supreme Court in Arunima Baruah V. Union of India (UOI)[MANU/SC/7366/2007] emphasised the importance of the maxim "He who comes into equity must come with clean hands." The Supreme Court ruled that suppression of material facts by a party can impact their right to equitable relief. This principle would also be relevant in a suit for patent infringement, where the Plaintiff's failure to disclose revocations or invalidations of corresponding foreign patents of the asserted patent has a material bearing on the case. Such suppression and misrepresentation would undoubtedly affect the Court's willingness to grant equitable relief, as it contradicts the principle of approaching the court with clean hands.

38. Vide judgement dated 29th July, 2010, a Id. Single Judge of this Court, in Charanjit Thukral and Ors. v. Deepak Thukral and Ors. (MANU/DE/1814/2010 2010: DHC:3737) again emphasised that Plaintiffs seeking relief from the Court, whether equitable or otherwise, are obligated to honestly disclose all material facts relevant to a case. Plaintiffs seeking an injunction must inform the Court of all material facts pertinent to their claim for an

injunction. Failure to do so, even under the guise of being unaware of the significance of any omitted facts, is not permissible. Court possesses the inherent authority to deny an injunction if the plaintiff acts in bad faith or withholds any material facts. The relevant extracts of the said decision are set out below:

> "*17. Interim order is passed as a temporary arrangement to preserve the status quo till the matter is decided finally, to ensure that the matter does not become either infructuous or a fate accompli before the final hearing. The purpose of an interlocutory injunction is, to protect the plaintiff against injury by violation of his right for which he could not be adequately compensated in damages recoverable in the action if the uncertainty was resolved in his favour at the trial.*
>
> *18. It is settled principle of law that a person who approaches the Court for grant of relief, equitable or otherwise, is under a solemn obligation to candidly disclose all the material/important facts which has bearing on the adjudication of the issues raised in the case. It is the duty of the party asking for an injunction to bring to the notice of the Court all facts material to the determination of his right to have injunction and it is not an excuse for him to say that he was not aware of the importance of any facts which he has omitted to bring forward. Where plaintiff does not act bonafidely and does not put every material facts before the Court, the Court is within its inherent power to refuse to grant him injunction, even though there might be facts upon which injunction might be granted. Conduct of the plaintiff is very material in bringing the case and disclosing the facts before the Court. plaintiff is required to make fullest possible disclosure of all material facts within his knowledge to the Court and if he does not make that fullest possible disclosure, he cannot obtain any advantage from the*

proceedings and is liable to be deprived of any advantage he might have already obtained by means of the order which has thus wrongly been obtained by him by concealment of material facts."

39. The specific view that suppression and misrepresentation can have a bearing interim injunction application, especially in the context of IP disputes, was upheld by a ld. Single Judge of this Court in Aura Synergy India Ltd. v. New Age False Ceiling Co. Pvt. Ltd., [2016 : DHC : 1109]. The said decision has also been approved by the ld. Division Bench vide judgment dated 18th November, 2016 in Aura Synergy India Ltd. v. New Age False Ceiling Co. Pvt. Ltd., [2016 : DHC : 7530-DB].

40. Further, in FMC Corporation v. GSP Crop Science Private Limited, [2022 SCC OnLine Del 3784], this Court held that 'suppression and misrepresentation' is one of the grounds available to a Defendant to challenge the grant of an interim injunction. Vide judgment dated 5th July, 2023, similar grounds of concealment of documents was cited as one of the factors for denial of interim injunction by the Coordinate Bench of this Court in Bayer Healthcare LLC v. Natco Pharma Limited, [2023 : DHC : 4458].

41. *The ld. Division Bench of this Court in F. Hoffmann-LA Roche Limited v. Cipla Limited, [ILR 2009 Supp (2) Del 551], held that the grant of an interim injunction is not based solely on the*

patent's existence or grant, but needs to take into account the potential challenges to its validity. The relevant extract from the said decision in set out below:

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

42. *In the instant case, apart from the non-disclosure or mis-description of the above facts relating to revocation, invalidation of the*

corresponding patents, there are at least two judgments which seriously impinge upon the validity of the suit patent. The said judgments which discuss in detail the reasons for invalidating the corresponding patents, could not have been held back from the Court and not filed on record. They have been rendered by the US Federal Court of Appeals and the UK Patent court in the following decisions:

- *Freebit AS v. Bose Corporation, decision dated 8th October, 2019 bearing no. 18-2365.*
- *Bose Corporation v. Freebit AS, [2018] EWHC 889 (Pat).*

43. In view of the above facts, clearly, no prima facie case has been established by the Plaintiff, considering that the Defendant has been able to demonstrate that the suit patent, on the strength of which the suit has been initiated is vulnerable to revocation, on account of invalidation as demonstrated by decisions from several jurisdictions across the world. The absence of a prima facie case would be a fundamental barrier to the grant of an interim injunction.

44. Secondly, the balance of convenience is also tilted heavily in favour of the Defendant, especially considering a situation where there are serious assertions regarding the potential revocation of the suit patent, granting an injunction could unduly prejudice the Defendant. This is

particularly relevant if the suit patent is later found to be invalid or revoked, as it would mean that the Defendant was unnecessarily restrained from conducting its business activities.

45. Finally, there is a real possibility of irreparable injury to the Defendant if an injunction is granted in these circumstances. The grant of an injunction based on a potentially revocable or invalid patent could lead to significant losses for the Defendant, which is incapable of being adequately compensated. On the other hand, if the patent is held to be valid after trial monetary amounts can be awarded in the form of damages to the Plaintiff.

46. In Gujarat Bottling Co. Ltd. v. Coca Cola Co. [(1995) 5 SCC 545], the Supreme Court categorically held that since the grant of an injunction is wholly equitable in nature, the conduct of parties have a significant bearing on the grant or non-grant of an interim injunction. The relevant extract of decision is as follows:

> *"In this context, it would be relevant to mention that in the instant case GBC had approached the High Court for the injunction order, granted earlier, to be vacated. Under Order 39 of the Code of Civil procedure, jurisdiction of the Court to interfere with an order of interlocutory or temporary injunction is purely equitable and, therefore, the Court, on being approached, will, apart from other considerations, also look to the conduct of the party invoking the jurisdiction of the*

court, and may refuse to interfere unless his conduct was free from blame. ***Since the relief is wholly equitable in nature, the party invoking the jurisdiction of the Court has to show that he himself was not at fault and that he himself was not responsible for bringing about the state of things complained of and that he was not unfair or inequitable in his dealings with the party against whom he was seeking relief. His conduct should be fair and honest. These considerations will arise not only in respect of the person who seeks an order of injunction under Order 39 Rule 1 or Rule 2 of the Code of Civil Procedure, but also in respect of the party approaching the Court for vacating the ad-interim or temporary injunction order already granted in the pending suit or proceedings****."*

47. *Under such circumstances, in terms of the settled legal position, as also the factual matrix of this case, this Court is of the opinion that the Plaintiff is not entitled to any interim injunction, let alone, ex-parte or ad interim injunction. In addition, the Court is also of the opinion that such conduct cannot be ignored by the Court especially in a case where the Plaintiff ought to come clean and there is specific provisions set out in the various Rules."*

32. The judgment of the learned Single Judge was appealed against. The Hon'ble Division Bench while adjudicating the appeal, vide judgment dated 31.01.2024, passed in ***Freebit AS Vs. Exotic Mile Private Limited (supra)****, FAO (OS) (COMM) 15/2024 and CAV43/2024 and CM Nos. 5698/2024, 5699/2024 & 5700/2024*

upheld the judgment passed by the learned Single Judge and was pleased to hold as under:-

> *"22. It is also material to note that unlike the Trade Marks Act, 1999, where grant of a trademark leads to a presumption of its validity; grant of patent does not lead to any statutory presumption as to its validity. Thus, if a defendant raises a credible challenge to the validity of the patent, the same is relevant for deciding whether any interim orders restraining the defendant rom using the patent in question, is warranted.*
>
> *23. In the present case, the Court had noted that patents corresponding to the suit patent had been invalidated in various countries. In Japan, it had been refused after a trial. As noted above, there is no dispute that the appellant's applications for grant of patent corresponding to the suit patent had been rejected in various countries. The patent has been invalidated in some of the countries as noticed above.*
>
> *24. The respondent had entered appearance to contest the grant of interim relief and had relied upon the decisions rendered in other jurisdiction, refusing and/or invalidating the patent corresponding to the suit patent. In the given circumstances, the Court concluded that the defendants did have a credible challenge to the validity of the suit patent.*
>
> ***The triple test***
>
> *25. Apart from the prima facie case, the learned Single Judge had also found that the balance*

of convenience was in favour of the appellant. According to the appellant, it had licensed the suit patent to an enterprise in India and the third parties in US, Japan and Australia for incorporating the same in their respective earphones. The appellant had also sought damages, which were quantified at 2 crores, on account of alleged infringement of its suit patent. If the appellant succeeds in its action, the appellant can be compensated in terms of money. However, if it was found that the patent was invalid, a grant of injunction restraining the respondent from using the same would have unfairly prejudice the respondent by interdicting its current business. In the given circumstances, the learned Single Judge, after existence of prima facie case, balance of applying the triple test- convenience, and irreparable injury – rejected the appellant's application for interim relief.

26. In Wander Ltd. v. Antox India (P) Ltd.: 1990 Supp SCC 727, the Supreme Court had held as under:

> *"14. The appeals before the Division Bench were against the exercise of discretion by the Single Judge. In such appeals, the appellate court will not interfere with the exercise of discretion of the court of first instance and substitute its own discretion except where the discretion has been shown to have been exercised arbitrarily, or capriciously or perversely or where the court had ignored the settled principles of*

law regulating grant or refusal of interlocutory injunctions. An appeal against exercise of discretion is said to be an appeal on principle. Appellate court will not reassess the material and seek to reach a conclusion different from the one reached by the court below if the one reached by that court was reasonably possible on the material. The appellate court
Would normally not be justified in interfering with the exercise of discretion under appeal solely on the ground that if it had considered the matter at the trial stage it would have come to a contrary conclusion. If the discretion has been exercised by the trial court reasonably and in a judicial manner the fact that the appellate court would have taken a different view may not justify interference with the trial court's exercise of discretion."

27. In the present case, we are unable to accept that the learned Single Judge's exercise of discretion in declining the interim relief is arbitrary, or in ignorance of settled principles of law. Thus, no interference in the impugned judgment is warranted.

28. The appeal is unmerited and, accordingly, dismissed. All pending applications are also disposed of."

33. A perusal of these two judgments demonstrates that firstly there exists High Court of Delhi Rules Governing Patent Suits, 2022 and in terms of these Rules, it is mandatory that a plaint in an infringement action, shall, *inter alia*, include the details of orders, if any passed by any Indian or International Court or Tibunal, upholding or rejecting the validity of the suit patent or a patent which is for the same or substantially the same invention. Not only this, a perusal of the judgment passed by the learned Single Judge of Delhi

High demonstrates that therein the plaintiff mislead the Court by mentioning in the plaint that in respect of some of the countries, where the suit patent has either been revoked, refused, abandoned or lapsed have been shown as either pending or granted. It is in the backdrop of this factual matrix that the learned Single Judge adjudicated on the issue of the plaintiff not approaching the Court with clean hands, which findings of the learned Single were upheld by the Hon'ble Division Bench.

34. Coming to the facts of this case, firstly there are no such Rules governing Patent Suits as far as this Court is concerned. In other words, there are no Patent Rules framed by the High Court, in terms whereof, in a suit for infringement, it is mandatory for the plaintiff to disclose details of orders, if any, passed by any Indian or International Court or Tribunal, upholding or rejecting the validity of the suit patent or a patent which is for the same or substantially the same invention. Now, coming to the provisions of Order XI, Rule 1 of the Code of Civil Procedure, as amended by the Commercial Courts Act, 2015, the plaintiff has a duty to file those documents which are adverse to the case of the plaintiffs. This Court is of the considered view that in the case of infringement of a patent, primarily, the facts to be demonstrated by the plaintiff before the Court are that there is a registered patent in favour of the plaintiffs, which is being infringed by the defendant. If with regard to registration of that particular

patent in India, certain facts stand concealed, then obviously that issue can be considered to be of significance, but the non-disclosure of the factum of the invalidation of the corresponding patent of the plaintiff-Company by the Court of China, cannot be said to be so significant so as to either make this Court believe that this itself renders the subject patent vulnerable or this amounts to concealment of material facts by the plaintiffs. Non-disclosure of the fact that a corresponding patent of the Company, after its registration, was invalidated in China, cannot be said to be such a serious lapse or concealment, of a material fact, so as to call upon this Court to hold that the plaintiffs have not approached the Court with clean hands. In fact, the factum of the suit patent being successfully registered in 70 other countries has not been denied by the defendant. It is also not in dispute that each country has different Set of Laws as far as registration of patents is concerned and registration of a patent by a country gives life to that patent within the jurisdiction of that country only. Even, during the course of arguments, it could not be disputed that registration or invalidation of a patent by a particular country in general has no effect on the registration or invalidation of the same patent in some other country, for the reason that registration and invalidation of patent is governed by the law of that particular country.

35. The contention of the defendant that grant of interim would cause irreparable loss to the Society and in view of the price difference between the product of the plaintiffs and the defendant, no interim be granted to the plaintiffs, can also be not accepted. In the considered view of this Court, the plaintiffs and the defendant are commercial rivals. A commercial rival against whom there is an allegation of infringement of patent cannot be allowed to raise the plea of public interest, in view of the fact that there are enough checks and balances in the Patents Act, 1970 itself to cater the public interest.

36. Chapter XVI of the Patents Act deals with Working of Patents, Compulsory Licences and Revocation and Chapter XVII thereof deals with Use of Inventions for Purposes of Government and Acquisition of Inventions by Central Government. In circumstances of national emergency or in circumstances of extreme urgency and in the case of public non-commercial use, the provisions provided in these Chapters can be resorted to by the Central Government in larger public interest, but fact of the matter remains that this has not been done by the Central Government as far as the subject patent is concerned.

37. In the backdrop of the above discussion, this Court holds that the plaintiffs have been able to prove a *prima facie* case in their favour alongwith balance of convenience, because on one

hand, there is a duly registered subject patent with a successful commercial run in favour of plaintiff No. 1, whereas, on the other hand, defendant does not have any registered patent pertaining to the infringing product. Besides this, in view of the fact that the defendant is manufacturing and selling the infringing product by infringing the suit patent and without the consent of the plaintiffs, therefore, in case the defendant is not restrained from doing so during the pendency of the suit, it obviously will cause irreparable loss to the plaintiffs.

38. Accordingly, in view of the above discussion, as this Court is of the considered view that a case has been made out by the plaintiffs for the grant of interim relief, because the defendant has not been able to establish that the patent is vulnerable, this application is allowed and disposed of with the direction that during the pendency of the Civil Suit, the defendant is restrained by itself, its directors, licensees, stokiest and distributors, agents and/or anyone claiming through any of them, jointly and severally from infringing the patent rights of applicant No. 1 under Indian Patent No. 268846 by launching, advertising, making, using, offering for sale, selling, importing and/or exporting the medicinal product, Empagliflozin in any form whatsoever including Empagliflozin API, Empagliflozin formulation, “Empagliflozin Tablets”, “Empagliflozin + Metformin Hydrochloride Tablets” and/or “Empagliflozin + Linagliptin

Tablets" or any "generic version" thereof or any product sold under the trade mark(s)/name(s) "Linares-E" or any other trade mark/name, whatsoever, or any other product covered by the subject patent granted by the Controller of Patents on September 18, 2015 in favour of applicant No.1.

(Ajay Mohan Goel)
Judge

May 30, 2024
(bhupender)