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

***Reserved on: 01.02.2023***
***Date of decision: 05.07.2023***

\+ **CS(COMM) 343/2019 & I.As. 8878/2019, 9685/2019, 1178/2022**

BAYER HEALTHCARE LLC ..... Plaintiff
Through: Mr. Pravin Anand, Mr. Dhruv Anand, Ms. Udita Patro, Ms. Swati Jain, Advs.

versus

NATCO PHARMA LIMITED ..... Defendant
Through: Mr. J. Sai Deepak, Mr. G. Nataraj, Mr. Avinash K. Sharma, Mr. Shashikant Yadav, Mr. Rahul Bhujbal, Ms. Harshita Agarwal, Ms. Garima Joshi, Advs.

\+ **CS(COMM) 660/2022 & I.As. 15573/2022, 15574/2022, 1432/2023, 1848/2023**

BAYER HEALTHCARE LLC ..... Plaintiff
Through: Mr. Pravin Anand, Mr. Dhruv Anand, Mr. Devinder Singh Rawat, Ms. Udita Patro, Ms. Swati Jain, Advs.

versus

MSN LABORATORIES PRIVATE LIMITED ..... Defendant
Through: Mr. G. Nataraj, Mr. Avinash K. Sharma, Mr. Shashikant Yadav, Mr. Rahul Bhujbal, Ms. Harshita Agarwal, Ms. Garima Joshi, Advs.

**CORAM:**
**HON'BLE MR. JUSTICE NAVIN CHAWLA**

**J U D G M E N T**

**I.A. 8878/2019 in CS(COMM) 343/2019**
**I.A. 15573/022 in CS(COMM) 660/2022**

1. The present applications are being taken up together for consideration as they relate to the claim of the plaintiff to an order of *interim* injunction against the defendants based on the same patent, being Indian Patent No.240207 (hereinafter referred to as the 'Suit Patent'), that covers and claims a molecule, which is claimed to be a new chemical entity, *4{4-[3-(4-chloro-3-trifluoromethylphenyl)-ureido]-3-fluorophenoxy}-pyridine-2-carboxylic acid methylamide*, which has been assigned an International Non-proprietary Name ('INN'), REGORAFENIB.

**CASE OF THE PLAINTIFF**

2. The plaintiff is a part of the Bayer Group of Companies ('the Group'), the Holding Company being Bayer AG. The Group conducts its business in the healthcare sector through the plaintiff, which is involved in research, development, manufacturing and marketing products for the prevention, diagnosis and treatment of diseases.

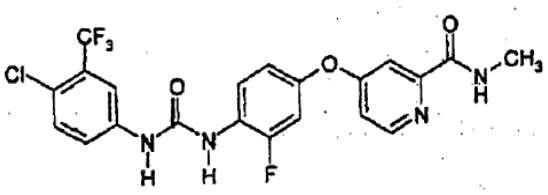
3. As mentioned hereinabove, the plaintiff claims that the suit patent covers and claims a molecule, being a new chemical entity, that is, 4{4-[3-(4-chloro-3-trifluoromethylphenyl)-ureido]-3-fluorophenoxy}-pyridine-2-carboxylic acid methylamide, which has been granted INN, REGORAFENIB.

4. The bibliographic details of the suit patent are given below:

*"a) Indian Patent No.: 240207*
*b) Patentee: Bayer HealthCare LLC*
*c) Indian Application No.: 402/DELNP/2006*
*d) Date of filing in India: 23rd January, 2006*
*e) Date of publication u/s 11A: 24th August, 2007*
*f) Date of filing of international application: 22nd July, 2004*
*g) PCT Application No.: PCT/US04/023500*
*h) Priority application nos. and dates:*

- *US 60/489,102 (23-Jul-2003)*
- *US 60/540,326 (02-Feb-2004)*

*i) Date of grant: 29th April, 2010*
*j) Title: A FLUORO SUBSTITUTED OMEGA-CARBOXYARYL DIPHENYL UREA COMPOUND OR A SALT, OR AN ISOLATED STEREOISOMER THEREOF*
*k) Drug covered: REGORAFENIB (WHO INN Nomenclature) - used for treatment of Metastatic colorectal cancer and advanced gastrointestinal stromal tumors.*
*l) No. of claims: 9*
*m) Claims claiming / covering Regorafenib: Specifically claimed in Claims 1 and 3.*
*n) The suit patent discloses the compound REGORAFENIB, its preparation and characterization in Example 1, The HCl salt of Regorafenib is exemplified in Example 2, the Mesylate salt in Example 3, the Phenyl sulphonate salt in Example 4 and the Biological assays to demonstrate the biological activity of REGORAFENIB are provided in Examples 5 to 11.*
*o) IUPAC name of REGORAFENIB: 4{4-[3-(4-chloro-3- trifluoromethylphenyl)-ureido]-3-fluorophenoxy)-pyridine-2-carboxylic acid methyl amide*
*p) Structure of REGORAFENIB: As provided at internal page 13, page 47 (Example 1) and page 58 (Claim 1):*



5. In the plaint, it is averred that the Suit Patent is a valid and subsisting patent in India, and has a term of 20 years from 22.07.2004. The aforesaid patent was neither opposed in a pre-grant opposition nor in a post-grant opposition by any member of the public or interested party in India. The plaintiff claims that the counterparts of this patent have been granted in more than 80 countries, and in none of these jurisdictions has the patent been revoked or invalidated.

6. The plaintiff states that the patent family in India, which covers and/or claims REGORAFENIB and its formulations (in addition to the Suit Patent), include Indian Patent Applications 187/DELNP/2010 (divisional patent application of the Suit Patent), 1628/DELNP/2009 (polymorph or monohydrate form of REGORAFENIB), and 8948/DELNP/2012 (process for preparation of REGORAFENIB).

7. The plaintiff further discloses that the two revocation petitions against the Suit Patent, being ORA/41/2014/PT/DEL filed by Natco Pharma Limited, that is, the defendant in CS (COMM) 343/2019, and ORA/9/2022/PT/DEL filed by BDR Pharmaceuticals International Private Limited, are currently pending adjudication.

8. The plaintiff has also been granted what it claims is a genus patent, IN 215758 for 'CARBOXYARYL SUBSTITUTED DIPHENYL UREAS' with a filing date of 12.01.2000, which was published on 20.07.2000. Its bibliographic details are given as follows:-

| | |
|---|---|
| ***Patent No.*** | ***IN 215758*** |
| ***Title*** | *"Carboxyaryl Substituted Diphenyl Ureas"* |
| ***Application Number*** | *IN/PCT/2001/00799/MUM* |
| ***International Filing Date*** | *12.01.2000* |

| | |
|---|---|
| ***PCT Application No.*** | *PCT/US2000/00648* |
| ***PCT Application No.*** | *WO/2000/042012 published on 20.07.2000* |
| ***Priority(ies)*** | *1. US 60/115,877 (13.01.1999)*<br>*2. US 60/257,266 (25.02.1999)*<br>*3. US 09/425,228 (22.10.1999)* |
| ***National Phase Entered*** | *05.07.2001* |
| ***Sec. 11A Publn. Date*** | *04.03.2005* |
| ***Claim amended*** | *27.09.2007* |
| ***Date of Grant*** | *03.03.2008* |
| ***Date of Expiry*** | *12.01.2020* |
| ***Inventors*** | ***RIEDL, Bernd***<br>***DUMAS, Jacques***<br>*KHIRE, Uday*<br>*LOWINGER, Timothy*<br>*SCOTT, William J.*<br>*SMITH, Roger*<br>*MONAHAN, Mary-Katherine*<br>*NATERO, Reina*<br>*RENICK, Joel*<br>*SIBLEY, Robert N.* |
| ***Admitted Foreign Equivalents by Bayer*** | *US 7,351,834* |

9. The plaintiff further claims that IN'758 is a genus patent covering vast number of compounds. The plaintiff states that REGORAFENIB is not specifically disclosed in the genus patent by way of either a chemical name, chemical formula, or chemical structure, however, it is technically covered within the generic scope of the numerous compounds included in the Markush Formula disclosed in the patent. The plaintiff claims that a person skilled in the art would not have recognized REGORAFENIB from this genus patent and further, there is no specific claim in the said genus patent pertaining to REGORAFENIB.

10. The plaintiff further states that an *inter partes* review was filed by a third party, Fustiball LLC, against the grant of the US equivalent

of the Suit Patent, that is, US 8637553 ('US '553'), on the ground that the said patent was anticipated and made obvious in view of the earlier granted genus patent, i.e., US 7351834 (the equivalent of IN '758), however, the US Patent Trial and Appeal Board (' US PTAB'), vide its order dated 08.02.2017, denied the Petition seeking *inter partes* review, and held that the equivalent of the Suit Patent, that is, US '553, had been validly granted and was in no manner anticipated or made obvious by the genus patent, US '834.

11. The plaintiff states that the plaintiff applied for and obtained an import license through its India affiliate, Bayer Pharmaceuticals Pvt. Ltd., on 01.07.2014, and has been selling REGORAFENIB under the brand name '*STIVARGA*®' in countries such as the United States, countries of the European Union, China and Japan, and is also selling the same under the brand names '*NUBLEXA'* and '*RESIHANCE'* in India since 2015. The plaintiff states that these are oral, prescription anticancer medication approved by the US Federal Drug Administration ('FDA') for people with cancer such as colon or rectal cancer ('CRC'), a rare stomach, bowel or oesophageal cancer known as Gastrointestinal Stromal Tumour ('GIST'), and a type of liver cancer called Hepatocellular Carcinoma ('HCC'). The plaintiff states that REGORAFENIB works not only by hindering the signals that tell cancer cells to multiply, thus, slowing the cancer from spreading to other parts of the body, but it is also effective in stopping the creation of new blood vessels that feed cancer cells.

12. The plaintiff states that REGORAFENIB's commercially branded drug *'STIVARGA®'* has obtained an Orphan Drug

Designation in the USA. It claims that REGORAFENIB has increased the overall length of time of a patient's life and has delayed worsening of the disease in patients.

13. The plaintiff, on the above submissions, seeks an interim injunction against the defendants from infringing the Suit Patent of the plaintiff.

## CASE OF THE DEFENDANTS IN THEIR RESPECTIVE WRITTEN STATEMENTS

14. The defendants state that the Suit Patent, that is, IN '207, is already disclosed in IN '758, as the salts and the compositions as claimed in the Suit Patent are already set out in the genus patent.

15. The defendants state that the plaintiff had prior knowledge of the compound REGORAFENIB at the time of filing of genus patent IN '758. The defendants submit that at the time of filing, the genus patent captured numerous compounds under its formula, however, later during prosecution, many such compounds, including REGORAFENIB, were deleted by the plaintiff by amending the description of IN '758. The defendants submit that this was done to claim compounds already disclosed in the genus patent. Moreover, due to such deletion, the said compounds entered into the public domain and became *publici juris.*

16. The defendants state that the plaintiff had also filed an application seeking extension of the patent term of the equivalent of the genus patent IN '758, that is, US '834, at the US Patent and Trademark Office, wherein the plaintiff has specifically admitted that the compound REGORAFENIB is claimed and covered by US' 834.

The plaintiff has also represented US '834 in the Orange Book as the patent claiming and covering REGORAFENIB.

17. The defendants also challenge the lack of novelty as well as inventive step in the Suit Patent based on the prior disclosure in IN '758 as well as WO 00/42012 (WO '012), which is the parent PCT for IN '758.

18. They claim that there is a substantial overlap between the Suit Patent and WO2000/041698 (WO '698) as WO '698 contains practically the same teaching as WO '012, albeit it contains repetition in its structure.

19. The defendants submit that the plaintiff had entered into an agreement with a company called Onyx Pharmaceuticals Inc. in USA in or about 1994 with the aim of developing compounds having activity against proteins in the RAF pathway. The same led to the development of SORAFENIB. The defendants claim that the plaintiff did not notify Onyx Pharmaceuticals about Fluoro Sorafenib. Onyx Pharmaceuticals filed a complaint case no. 3:03-cv-021 34-MHP dated 15.05.2009 in the United States District Court, Northern District of California, praying for a declaration that the Fluoro Sorafenib compound be treated as a collaboration compound and Onyx Pharmaceuticals be entitled to a share in the profits from the sale of such Fluoro compound by the plaintiff. The said dispute was settled between the parties, and the plaintiff agreed to pay certain royalties to Onyx Pharmaceuticals in respect of the compound Fluoro Sorafenib. The defendants claim that the above sequence of events show that the plaintiff was aware of the Fluoro Sorafenib as far back as 1998, that is prior to the filing of the patent

application no. 60/115,877 in the United States (as provisional application) on 13.01.1999.

20. The defendants claim that REGORAFENIB being disclosed in the patent- IN '758, which expired on 12.01.2020, any corresponding protection to REGORAFENIB also expired on the same date, and no injunction can be granted against the defendants.

**SUBMISSIONS OF THE LEARNED COUNSEL FOR THE PLAINTIFF**

21. The learned counsel for the plaintiff submits that the Suit Patent is a unique one in-as-much as it was not opposed by the defendant or any other person either through a pre-grant opposition or a post-grant opposition, despite a three years' window between the publication date under Section 11A of the Patents Act, 1970 (in short, 'the Act') (24.08.2007) and the date of grant (29.04.2010). The Suit Patent has existed on the register for more than 12 years, and has been granted in 80 countries of the world.

22. He submits that in 2009, the WHO assigned an INN to the chemical molecule covered and disclosed by the Suit Patent, in clear recognition of the fact that this compound is not found in nature or known.

23. The learned counsel for the plaintiff further submits that the genus patent, IN'758, corresponds to US Patent US'834 and PCT WO'012, and does not anticipate REGORAFENIB or render it obvious. He submits that WO'012 was cited as a prior art in the First Examination Report issued by the Indian Patent Office (hereinafter referred to as the 'IPO') in respect of the Suit Patent. It was also cited in the International Search Report (ISR) issued in respect to the PCT application of the Suit Patent

(WO'961) as 'Category A' document, that is, a document which defines the state of the art and which is not to be considered to be of particular relevance, and not as a 'Category X' document, which is of particular relevance for novelty, or a 'Category Y' document, which is of particular relevance for inventive step determination. The Suit Patent was granted only after the genus patent was considered by the IPO.

24. The learned counsel for the plaintiff makes extensive reference to the US PTAB decision in ***Fustiball LLC v. Bayer Healthcare LLC,*** to submit that the US PTAB has found that the genus patent did not expressly disclose the Suit Patent and that the Markush formula given in the genus patent covers billions of compounds.

25. The learned counsel for the plaintiff submits that even otherwise, an examination of the genus patent would show that it exemplifies 103 compounds, 90 of which have an unsubstituted central ring; 8 have central ring with CI as a substitute; 5 have $CH_3$ substitution on the central ring, however, none have F as a substituent on the central ring. The genus patent does not give any biological activity data or $IC_{50}$ values in respect of any of the compounds. It, therefore, has no teaching for a Person Skilled in the Art (hereinafter referred to as the "POSA") to make REGORAFENIB obvious.

26. Placing reliance on ***Eisai Co. Ltd. and Another v. Satish Reddy and Another,*** 2019 SCC OnLine Del 8496; ***Novartis AG & Anr. v. Natco Pharma Limited,*** 2023 SCC OnLine Del 106; ***Dr. Reddy's (UK) Ltd. v. Eli Lilly and Co. Ltd.***, 2010 RPC 9; **Terrell on Law of Patents, para 9-132; Manual of Patent Office Practice and Procedure (India)**, Version 01.11; and ***FMC Corporation & Anr. v. Best Crop. Science LLP & Anr***., 2021 SCC OnLine Del 3647, he

submits that merely because the plaintiff has applied for a patent separately for a specific species of the genus, it does not mean that that the species patent cannot be granted or is invalid.

27. He also submits that the defendant, that is Natco Pharma Limited, in its own patent application, WO 2017/125941 A1, titled "*An Improved Process for the Preparation of Regorafenib*", admits that the first disclosure of REGORAFENIB was made in the Suit Patent.

28. On the point of lack of inventiveness, the learned counsel for the plaintiff submits that 'POSA' with respect to Section 64(1)(h) of the Act would not possess the calibre of an inventor and would not arrive at the Suit Patent from the genus patent by applying directness and non-usage of their creative faculties. He submits that defendants have not given any 'lead compound' analysis and not explained as to how they selected Sorafenib; how they identified the modifications needed to be made thereto and at what position and where. He submits that all this could only have been possible by way of a HINDSIGHT ANALYSIS, with due knowledge of the REGORAFENIB structure, which is impermissible in law. In this regard, he relies on ***F. Hoffmann-La Roche Ltd. & Anr v. Cipla Ltd,*** 2015 SCC OnLine Del 13619; and ***Eli Liliy and Company Limited v. Apotex Pty Ltd***, [2013] FCA 214.

29. He submits that the Suit Patent shows technical advancement over the genus patent, as REGORAFENIB is a multi-kinase inhibitor, and moreover, it is used in the treatment of and is directed at multiple diseases, unlike the compound disclosed in the genus patent. The advancement has also been acknowledged amongst the scientific community. Placing reliance on ***Knoll Pharmaceutical v. Teva***

***Pharmaceuticals,*** *367 F.3d. 1381;* and ***Genetic Institute v. Norvatis,*** *655 F.3d. 1391*, he submits that post-grant evidence on the improvement offered can be taken into account by the Court.

30. On the question of the plaintiff's admission that REGORAFENIB is covered under the genus patent US' 834, the learned counsel for the plaintiff submits that the public knowledge of REGORAFENIB came only with the publication of WO '012, the species patent was subsequently applied for. He submits that at the time of seeking the patent term extension of US '834 in 2012, REGORAFENIB was known, and it was known that it is covered by the Markush Structure A-D-B disclosed in US '834. He submits that the statement was accordingly made under US Law. He submits that the statements made subsequently shall have no effect on the claims of the plaintiff. In this regard, he relies on the judgement of the Division Bench of this Court in ***F. Hoffmann-La Roche Ltd. & Anr.*** (supra).

31. He further states that there is a marked difference between 'coverage' and 'disclosure' under the patent. 'Coverage' of compounds under the genus patent does not mean that the same have been 'disclosed' or that they cannot be protected under a separate patent application. In support, he places reliance on the judgement of the Supreme Court in ***Novartis AG v. Union of India & Others***, (2013) 6 SCC 1, ***FMC Corporation & Anr.*** (supra); and on ***Novartis AG & Anr. v. Natco Pharma Limited*** (supra).

32. On the deletion of the Markush Claim in the genus patent, the learned counsel for the plaintiff submits that such deletion was carried out by the plaintiff subsequent to applying for the Suit Patent and,

therefore, such deletion would not mean that REGORAFENIB has fallen into the public domain.

33. On the litigation with Onyx Pharmaceuticals Inc., the learned counsel for the plaintiff states that the plaintiff and Onyx Pharmaceuticals Inc. have already settled their disputes. He submits that Onyx Pharmaceuticals Inc. has agreed not to question the validity of ownership of the plaintiff in the Suit Patent in any jurisdiction.

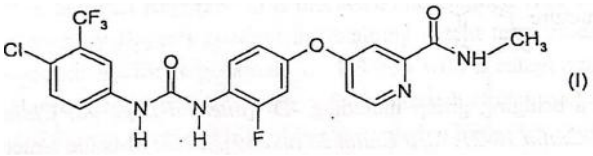
34. On the question of whether the plaintiff has lost protection in respect of REGORAFENIB in Europe, he submits that the plaintiff's European Patent is still valid and subsisting in Europe. He submits that EP 1793824, the patent which has been declared invalid, relates to a different invention which deals in new pharmaceutical compositions containing REGORAFENIB and is, thus, irrelevant to the challenge to the validity of the Suit Patent.

**SUBMISSIONS OF THE LEARNED COUNSELS FOR THE DEFENDANTS**

35. The learned counsels for the defendants submit that the Suit Patent is anticipated by prior publication, and is liable to be revoked under Section 64(1)(e) of the Act, as the genus patents WO'012 and US '834 discloses and claims REGORAFENIB. They submit that the present suit is a case of patent evergreening. They explain the same as under[1]:-

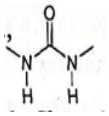
> *"9. Regorafenib, the product asserted in the present Suit has the following structure:*

[1] From the written submissions filed by the defendant in CS (COMM) 660/2022



*WO'012 & US'834 discloses (and claims) Regorafenib as follows:*

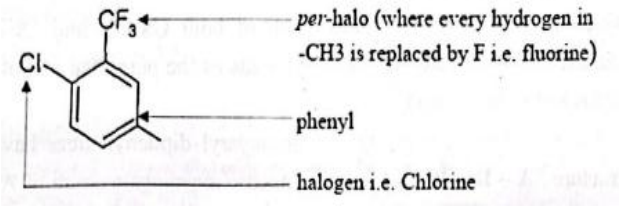
*10. WO'012 defines D as -NH-C(O)-NH-, i.e.*



*[internal page 2, line 29; internal page 89, Claim 1, line 6; internal page 100, Claim 38, line 23; internal page 103, Claim 39, line 6; numerous compound examples from pages 41 et seq.). In fact, this is the only definition for D in WO'012 and US'834.*

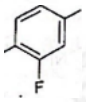
*11.WO'012 defines B, inter alia, as a substituted heteroaryl group having up to 30 carbon atoms which is bound directly to D. The number of hetero atoms, i.e., N, O or S is stated to be 0 as well, i.c., the heteroatom is absent. This leads to substituted "aryl" since "hetero" is 0 (zero). The substitutions shown in WO'012 include halo and per-halo. "halo" is halogen which includes Chlorine i.e., Cland Fluorine i.e., F [internal page 3, lines 6-8; internal page 5, bottom of page, defining aryl as phenyl: internal page 89, Claim 1, lines 12-14; internal pages 95-96, Claim 6-8 which expressly state that B can be a phenyl substituted by a halogen including per-halo substitutions; internal pages 101-102, Claim 38, definition of B; internal pages 103-104, Claim 39 which expressly states that B is a substituted phenylwhere the substitution can be halo and/or per-halo].*

*12.Thus, the definition of B includes phenyl group with one halo i.e., chlorine (CI) substitution and one per-fluoro substitution as shown below:*

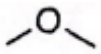



*13. WO'012 defines A as a substituted moiety of up to 40 carbon atoms of the formula -L-(M-LI)q where L is defined as a 6-membered cyclic structure bound directly to D. WO'012 further states that when B is substituted, L is also substituted, and that the substitutions include halogen [internal page 3, lines 1-5, internal page 4, lines 12-14: respective portions of Claim 1, 38 and 39].*

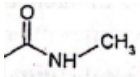
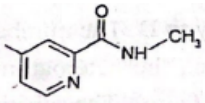
*14. Thus, L is the structure*




*15. M is defined as a bridging group including -O- [internal page 95, Claim 3: internal page 97, Claim 18-21; also Claim 38 and 39] Thus, M is the structure:*

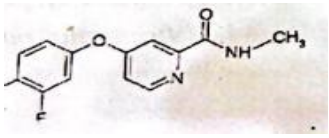



*16. L1 is defined as a substituted cyclic moiety of at least 5 members, and optionally substituted by -C(O)Rx [internal page 3, lines 1-5, 9&10; Claim 1, 38 and 39 respective portions]Rx is defined as -NRaRb where Ra and Rb are defined as being independently hydrogen or a carbon-based moiety of up to 30 carbon atoms [internal page 3, lines 18-23].*

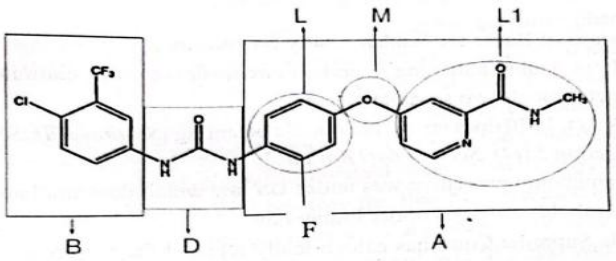
*17. Thus, -C(O)Rx is the structure*  *and L1 is the structure: i.e. substituted puridinyl.* 

*18. The fact that LI is substituted pyridinyl is in WO'012 [Claim 12-17 for example).*

*19. Thus, L-(M-LI) is the structure:*



*20. In sum and substance, WO'012 & US'834 [and IN'758 before it was amended] disclosed and claimed Regorafenib in the definition of A-D-B as depicted below:"*




36. They submit that the plaintiff, while extending its patent term for US '834, admitted that the claims thereof, which uses the Markush Structure A-D-B, includes REGORAFENIB sold as Stivarga. They submit that the inclusion of REGORAFENIB in US '834 in the Orange Book in the US is also an evidence of the fact that the plaintiff has admitted to the disclosure of the REGORAFENIB in US '834. They submit that therefore, the plaintiff cannot now renege out of its own admissions.

37. The learned counsels submit that the reliance of the plaintiff on the grant of US'533, the US species patent equivalent to the Suit Patent, despite being tested against US'834, that is, the genus patent, is ill-founded. They submit that the US Law permits claiming the same product through two separate patents in certain cases, which is impermissible under Indian Law, specifically under Section 3(d), 13(1)(b) read with Sections 53(4) and 64(1)(a) of the Act.

38. The learned counsels for the defendants further submit that the plea of difference between "disclosure" and "coverage" in a patent, has been considered by this Court in ***Astrazenca AB & Anr. v. Intas Pharmaceuticals Ltd.***, *MANU/DE/1939/2020;* and ***Astrazenca AB & Anr. v. Intas Pharmaceuticals Ltd.***, 2021 SCC OnLine Del 3746 (which was upheld by the Supreme Court vide order dated 21.07.2022 in SLP(C) no. 15650-15658 of 2021). They submit that, therefore, this artificial distinction between the two, sought to be contended by the plaintiff, is liable to be rejected.

39. The learned counsels for the defendants submit that the claims in the Suit Patent lack any inventive step. They submit that WO '012 expressly teaches REGORAFENIB. The Suit Patent does not disclose any technical problem associated with compounds of the genus patent nor it offers any advantages over the same. Placing reliance on Section 2(1)(ja) and Section 64(1)(f) of the Act, they submit that the test for assessment of whether there is any inventive step in cases where there is commonality of inventorship, is identifying the purported problem in the prior art and the alleged solution the Suit Patent offers. They submit that both these ingredients are missing in the Suit Patent. They submit that this lacuna cannot be filled by filing a post-filed data before this Court. They place reliance on ***Astrazenca AB & Anr. v. Intas Pharmaceuticals Ltd.*** (supra) in support.

40. They submit that in Colombia and Argentina, the corresponding species applications were rejected for lack of any inventive step and based on WO'012. This fact has also been concealed by the plaintiff in the plaint.

41. They submit that the plaintiff had filed a divisional application from IN'758, which is IN'1633 with exactly the similar set of claims as IN'758 in the A-D-B Markush format. This evidently includes not only Sorafenib but also Regorafenib. The IPO had rejected IN'1633 on 19.05.2022 *inter alia* on the ground that it does not meet the requirements of Section 2(1)(j) of the Act.

42. They submit that the European Patent Office Board of Appeal, in relation to another one of the plaintiff's applications in Europe for a composition containing REGORAFENIB [EP 05792486.2, later published as EP 1793824 (EP'824)], has held that not just the composition in question therein, but REGORAFENIB itself lacks an inventive step over WO'012 and that there are sufficient teachings in WO'012 to reach REGORAFENIB for POSA.

43. The learned counsels for the defendants submit that the plaintiff's Patent Term Extension application contains a positive affirmation that US'834 claims REGORAFENIB. Placing reliance on ***Novartis*** (supra) and ***Hoffman La Roche*** (supra), they submit that the statements made in a foreign jurisdiction are relevant to assess the scope of a purported invention. They submit that in view of Section 8(1) and 8(2) of the Act, these details should have been disclosed by the plaintiff in the prosecution of its application for the Suit Patent. They rely on ***Chemtura Corporation v. Union of India,*** *2009 SCC OnLine Del 2634* in support of their submission.

44. The learned counsels for the defendants submit that the plaintiff deleted the description and claims qua REGORAFENIB in IN'758 and effectively surrendered the same to the public. They submit that it

is axiomatic that once an invention is disclaimed, it cannot be subsequently reclaimed. In support they place reliance on ***Boehringer Ingelheim International GMBH v. Controller of Patents & Anr.***, *2022 SCC OnLine Del 3777.*

45. The learned counsels for the defendants submit that the settlement of the dispute raised by Onyx Pharmaceuticals shows that REGORAFENIB had been developed by the plaintiff in collaboration with Onyx Pharmaceutical and under the earlier agreement. The terms of the settlement have intentionally not been disclosed by the plaintiff.

46. The learned counsels for the defendants state that the grant of a patent in other jurisdictions is immaterial since even an Indian patent does not have presumption of validity due to Section 13(4) of the Act. They submit that at the stage of deciding an application for *interim* injunction, the Court must look at whether the defendant has raised a credible challenge to the vulnerability of the patent. In this regard, they rely on ***B.P. Radhey Shyam v. Hindustan Metal Industries***, (1979) 2 SCC 511; and ***F. Hoffman La-Roche Ltd. and Ors.*** (supra).

47. The defendants also submit that there is no substantial basis to grant an *interim* injunction against the defendants, as the plaintiff's case does not pass the trinity test as enumerated in ***NATCO Pharma v. Bristol Myers Squibb Holdings Ireland Unlimited Company and Ors.***, 2019 SCC OnLine Del 9164.

## ***PROSECUTION HISTORY OF CS(COMM) No.343/2019***

48. This Court by its *ad interim* order dated 05.07.2019, while issuing summons in the suit, passed the following interim order:

> *"20. Till the next date of hearing, there shall be an interim order, in terms of order dated 31st May, 2019 in* ***Sterlite Technologies Ltd.*** *supra, copy of which, for convenience, is annexed to this order, restraining the defendant from infringing the Indian Patent No.IN 240207."*

49. The defendants, being aggrieved of the same, challenged the same by way of an appeal, being FAO(OS) (Comm) no.158/2019. The Division Bench of this Court, vide its judgment dated 11.07.2019, set aside the *ad interim* order dated 05.07.2019 passed by the learned Single Judge of this Court, primarily on the ground that the three important elements for the grant of an *interim* injunction had not being reflected in the said order and the order lacked clarity. The Court directed that the *status quo* as on 05.07.2019 shall be maintained by the defendants. The Division Bench further directed that the application seeking *interim* relief shall be decided afresh by the learned Single Judge after hearing the parties.

**PROSECUTION HISTORY OF CS(COMM) 660/2022**

50. While arguments in CS (COMM) 343/2019 were being addressed, the plaintiff filed CS (Comm) 660/2022 against the defendant therein, claiming infringement of the Suit Patent by the defendant therein.

51. On 22.09.2022, when the suit was listed before this Court, the learned counsel for the defendant therein stated that the defendant has not yet launched its product and undertakes to maintain *status quo* in that regard till there is a decision on the *interim* applications filed in the suit. The said order continues till date.

**ANALYSIS AND FINDINGS**

***Preface***

52. At the outset, it is important to note that the defendants have not alleged non-infringement of the Suit Patent in either of the suits. Their defence in the suits is primarily founded on their claim of the invalidity of the Suit Patent.

53. The Defendant- Natco Pharma, has also raised a preliminary objection on the maintainability of the suit by claiming that this Court lacks the territorial jurisdiction and that the Court ought to wait for the decision of the learned City Civil Court in Hyderabad. However, the learned counsel appearing for the defendant-Natco Pharm did not press the said preliminary objection for the purposes of the present applications, reserving the right of the defendant to do the same at a later stage.

***Principles to be applied at the interim stage***

54. ***In B.P. Radhey Shyam*** (supra), the Supreme Court has held that the grant of a patent or a decision rendered by the Controller in the course of prosecution thereof, does not guarantee the validity of the patent, and it can be challenged before the High Court on various grounds in the revocation or the infringement proceedings. Presumption in favour of the validity of a patent cannot be accepted. The Supreme Court held that:

> *"32. It is noteworthy that the grant and sealing of the patent, or the decision rendered by the Controller in the case of opposition, does not guarantee the validity of the patent, which can be challenged before the High Court on various grounds in revocation or infringement proceedings. It is pertinent to*

> *note that this position viz. the validity of a patent is not guaranteed by the grant, is now expressly provided in Section 13(4) of the Patents Act, 1970. In the light of this principle, Mr. Mehta's argument that there is a presumption in favour of the validity of the patent, cannot be accepted"*
>
> *(Emphasis Supplied)*

55. In ***F. Hoffmann-LA Roche Ltd. & Anr v. Cipla Limited***, 2008 SCC OnLine Del 382, a learned Single Judge of this Court has held that the challenge to the validity of the patent is one of the grounds that can be taken by a Defendant in defence to a patent infringement suit. In the said judgement, it has also been clarified that at the interim stage, the challenger only needs to show that the challenge is a credible challenge. The relevant observations in the said judgement are as under:-

> *"**69.** What then is the correct approach where a defendant challenges the validity of a patent? Here too, decided cases provide valuable guidance. At the stage of considering an application for interlocutory injunction, the defendant has to show that its challenge is a genuine one and not vexatious or set up to merely play for time [Ref. TJ Smith and Nephew Ltd. v. 3M United Kingdom, PLC (1983) RPC 92 and Quantel v. Shima Seiki, 1990 (RPC) 436]. An almost identical line of reasoning, i.e. existence of a substantial question, raised by the Defendant, during interlocutory proceedings, has been favoured in the United State Courts, exemplified in the following extract of a recent judgment by Rader, J., speaking for the US Court of Appeals for the Federal Circuit in Erico International Corpn. v. DOC's Marketing Corporation, 2008 U.S. App. Lexis 3439 (19.2.2008):*
>
> *"Validity challenges during preliminary injunction proceedings can be successful, that*

> *is, they may raise substantial questions of invalidity, on evidence that would not suffice to support a judgment of invalidity at trial.' Amazon.com, Inc., 239 F.3d at 1358. In other words, a defendant need not prove actual invalidity. On the contrary, a defendant must put forth a substantial question of invalidity to show that the claims at issue are vulnerable. Thus, a showing of [11] a substantial question of invalidity requires less proof than the clear and convincing standard to show actual invalidity. Id."*
>
> ***70**. To summarize, on the issue of interlocutory injunctions:*
>
> *(i) In patent infringement actions, the Courts should follow the approach indicated in American Cyanamid, by applying all factors;*
>
> *(ii) The Courts should follow a rule of caution, and not always presume that patents are valid, especially if the defendant challenges it;*
>
> *(iii) The standard applicable for a defendant challenging the patent is whether it is a genuine one, as opposed to a vexatious defence. Only in the case of the former will the Court hold that the defendant has an arguable case."*
>
> *(Emphasis supplied)*

56. In appeal against the above, a Division Bench of this Court {(2009) 40 PTC 125 (Del)} reiterated that the unlike the Trade Marks Act which raises *prima facie* presumption of validity, the Patent Act contemplates multiple challenges to the validity of a patent. Mere registration of the patent does not guarantee its resistance to subsequent challenges. Such challenge can be in form of a counter-claim in a suit on the grounds set out in Section 64 of the Act. The Court specifically rejected the plea that since there is a multi-layered and multi-level examination of the application to the grant of patent, it should be accorded the highest weightage. The Court also rejected the

submission that there is a heavy burden on the defendant to discharge in case the defendant challenges the validity of the patent. It held that at the *interim* stage, the defendant is only to show a serious question to be tried on the invalidity of the patent, and the same requires lesser proof than at the stage of the final adjudication. It was held as under:-

> *"**53.** The plea of the plaintiff that since there is a multi-layered, multi-level examination of the opposition to the grant of patent it should accorded the highest weightage, is not entirely correct. The contention that there is a heavy burden on the defendant to discharge since it has to establish that it has a stronger prima facie case of the plaintiff is contra indicated of the decisions in the context of Section 13(4). Reference may be made to the decisions in Biswanath Prasad Radhey Shyam v. Hindustan Metal Industries, AIR 1982 SC 1444 : PTC (Suppl)(1) 731 (SC), Standipack Pvt. Ltd. v. Oswal Trading Co. Ltd., AIR 2000 Del 23 : 1999 PTC (19) 479 (Del), Bilcare Ltd. v. Amartara Pvt. Ltd., 2007 (34) PTC 419 (Del), Surendra Lal Mahendra v. Jain Glazers, (1979) 11 SCC 511. In Beecham Group Ltd. v. Bristol Laboratories Pty Ltd., (1967-1968) 118 CLR 618 and Australian Broadcasting Corporation v. O'Neill, (2006) 229 ALR 457 it was held that the defendant alleging invalidity bears the onus of establishing that there is "a serious question" to be tried on that issue. In Hexal Australai Pty Ltd. v. Roche Therapeutics Inc., 66 IPR 325 it was held that where the validity of a patent is raised in interlocutory proceedings, "the onus lies on the party asserting invalidity to show that want of validity is a triable question." In Abbot Laboratories v. Andrx Pharmaceuticals Inc. (decision dated 22nd June 2006 of the U.S. Court of Appeals for the Federal Circuit 05-1433) the Court of Appeals followed its earlier ruling in Helifix Ltd. v. Blok-Lok Ltd. 208 F.3d 1339 where it was held (at 1359):"In resisting a preliminary*

> *injunction, however, one need not make out a case of actual invalidity. Vulnerability is the issue at the preliminary injunction stage, while validity is the issue at trial. The showing of a substantial question as to invalidity thus requires less proof than the clear and convincing showing necessary to establish invalidity itself." (emphasis supplied) In Erico Int'll Corprn v. Vutec Corprn (U.S. Court of Appeals for the Federal Circuit, 2007-1168) it was held that the "defendant must put forth a substantial question of invalidity to show that the claims at issue are vulnerable."*

57. From the above, the following principles applicable to consideration of an application seeking *interim* injunction can be culled out:-

(a) Section 107 of the Act provides that in any suit for infringement of a patent, every ground on which the patent may be revoked under Section 64 of the Act shall be available as a ground for defence;

(b) The fact that the patent is old, that is, granted a long time back, and/or that there was no challenge to the same prior to its grant or thereafter, are not relevant circumstances. There is no presumption on the validity of the patent;

(c) The defendant, in opposition to the prayer for interim relief made by the plaintiff, is only to show vulnerability of the patent in question. The defendant is not to prove actual invalidity of the patent.

58. In view of the above principles, the submission of the learned counsel for the plaintiff that as the subject patent had not been objected to at the pre-grant or the post-grant stage, and is old,

therefore, a presumption to its validity should be drawn, cannot be accepted. Independent of the above circumstances, it has to be determined whether the defendants have been able to raise a credible challenge to the validity of the patent.

***Genus v. Species Patent***

59. From the submissions noted hereinabove, it would be evident that the primary dispute between the parties revolves around what is now understood as a conflict between a Genus and a Species Patent. The plaintiff claims that REGORAFENIB was not disclosed or anticipated in PCT'648/US'834/WO'012, it was merely covered by it, as it exemplified 103 compounds, 90 of which had an unsubstituted central ring; 8 had central rings with CI as a substitute; 5 had $CH_3$ substitution on the central ring, however, none had F as a substituent on the central ring. It gave no biological activity data or $IC_{50}$ values in respect of any of the compounds and had no teachings for a POSA to arrive at REGORAFENIB. On the other hand, it is the case of the defendant that PCT'648/US'834/WO'012 covered REGORAFENIB when it claimed that (i)-carboxyaryl diphenyl ureas as purported invention having a Markush structure "A-D-B" and assigned specific meanings to each of A, D, and B. The use of Markush structure covers and provides protection and acts as a disclosure of each combination/compound which falls in the definition.

60. To appreciate the above submissions, some of the provisions of the Act which would be relevant are as under:

> *"2(1)(j) "invention" means a new product or process involving an inventive step and capable of industrial application;*

*2(1)(ja) "inventive step" means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art.*

*xxxxx*

*3(d) The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.*

*Explanation. For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.*

*xxxx*

*10(4) Every complete specification shall-*

*(a) fully and particularly describe the invention and its operation or use and the method by which it is to be performed;*

*(b) disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection;*

*(c) end with a claim or claims defining the scope of the invention for which protection is claimed;*

*(d) be accompanied by an abstract to provide technical information on the invention:*

*Provided that-*

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

*(ii) if the applicant mentions a biological material in the specification which may not be described in such a way as to satisfy clauses (a) and (b), and if such material is not available to the public, the application shall be completed by depositing the material to an international depository authority under the Budapest Treaty and by fulfilling the following conditions, namely:-*

*(A) the deposit of the material shall be made not later than the date of filing the patent application in India and a reference thereof shall be made in the specification within the prescribed period;*

*(B) all the available characteristics of the material required for it to be correctly identified or indicated are included in the specification including the name, address of the depository institution and the date and number of the deposit of the material at the institution;*

*(C) access to the material is available in the depository institution only after the date of the application of patent in India or if a priority is claimed after the date of the priority;*

*(D) disclose the source and geographical origin of the biological material in the specification, when used in an invention.*

*xxxxx*

*13(4) The examination and investigations required under section 12 and this section shall not be deemed in any way to warrant the validity of any patent, and no liability shall be incurred by the Central Government or any officer thereof by reason of, or in connection with, any such examination or investigation or*

*any report or other proceedings consequent thereon.*

*xxxx*

*53(4) Notwithstanding anything contained in any other law for the time being in force, on cessation of the patent right due to non-payment of renewal fee or on expiry of the term of patent, the subject matter covered by the said patent shall not be entitled to any protection.*

***64. Revocation of patents**. - (1) Subject to the provisions contained in this Act, a patent, whether granted before or after the commencement of this Act, may, 149 [be revoked on a petition of any person interested or of the Central Government by the Appellate Board or on a counter-claim in a suit for infringement of the patent by the High Court] on any of the following grounds that is to say-*

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

*(b) that the patent was granted on the application of a person not entitled under the provisions of this Act to apply therefor:*

*(c) that the patent was obtained wrongfully in contravention of the rights of the petitioner or any person under or through whom he claims;*

*(d) that the subject of any claim of the complete specification is not an invention within the meaning of this Act;*

*(e) that the invention so far as claimed in any claim of the complete specification is not new, having regard to what was publicly known or publicly used in India before the priority date of the claim or to what was*

*published in India or elsewhere in any of the documents referred to in section 13:*

*(f) that the invention so far as claimed in any claim of the complete specification is obvious or does not involve any inventive step, having regard to what was publicly known or publicly used in India or what was published in India or elsewhere before the priority date of the claim:*

*(g) that the invention, so far as claimed in any claim of the complete specification, is not useful;*

*(h) that the complete specification does not sufficiently and fairly describe the invention and the method by which it is to be performed, that is to say, that the description of the method or the instructions for the working of the invention as contained in the complete specification are not by themselves sufficient to enable a person in India possessing average skill in, and average knowledge of, the art to which the invention relates, to work the invention, or that it does not disclose the best method of performing it which was known to the applicant for the patent and for which he was entitled to claim protection;*

*(i) that the scope of any claim of the complete specification is not sufficiently and clearly defined or that any claim of the complete specification is not fairly based on the matter disclosed in the specification;*

*(j) that the patent was obtained on a false suggestion or representation;*

*(k) that the subject of any claim of the complete specification is not patentable under this Act;*

*(l) that the invention so far as claimed in any claim of the complete specification was secretly used in India, otherwise than as mentioned in sub-section (3), before the priority date of the claim;*

*(m) that the applicant for the patent has failed to disclose to the Controller the information required by section 8 or has furnished information which in any material particular was false to his knowledge;*

*(n) that the applicant contravened any direction for secrecy passed under section 35 or made or caused to be made an application for the grant of a patent outside India in contravention of section 39;*

*(o) that leave to amend the complete specification under section 57 or section 58 was obtained by fraud.*

*(p) that the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention;*

*(q) that the invention so far as claimed in any claim of the complete specification was anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere.*

*(2) For the purposes of clauses (e) and (f) of sub-section (1)-*

*(a) no account shall be taken of 153 personal document or secret trial or secret use; and*

*(b) where the patent is for a process or for a product as made by a process described or claimed, the importation into India of the product made abroad by that process shall constitute knowledge or use in India of the invention on the date of the importation, except where such importation has been for the purpose of reasonable trial or experiment only.*

*(3) For the purpose of clause (l) of sub-section (1) no account shall be taken of any use of the invention-*

*(a) for the purpose of reasonable trial or experiment only; or*

*(b) by the Government or by any person authorised by the Government or by a Government undertaking, in consequence of the applicant for the patent or any person from whom he derives title having communicated or disclosed the invention directly or indirectly to the Government or person authorised as aforesaid or to the Government undertaking; or*

*(c) by any other person, in consequence of the applicant for the patent or any person from whom he derives title having communicated or disclosed the invention, and without the consent or acquiescence of the applicant or of any person from whom he derives title.*

*(4) Without prejudice to the provisions contained in sub-section (1) a patent may be revoked by the High Court on the petition of the Central Government, if the High Court is satisfied that the patentee has without reasonable cause failed to comply with the request of the Central Government to make, use or exercise the patented invention for the purposes of Government within the meaning of section 99 upon reasonable terms.*

*(5) A notice of any petition for revocation of a patent under this section shall be served on all persons appearing from the register to be proprietors of that patent or to have shares or interests therein and it shall not be necessary to serve a notice on any other person."*

61. In the Modern Law of Patents by Judge Fysh, 2nd Edition, it is stated as under:

*"**2.117** A Markush group claim' is used to define a family of compounds by defining the structure that is common to the whole family (the letter 'R' being commonly used to represent the alternatives). The advantage of such a claim is that it removes the need to*

*include a claim for each individual type of compound and claims, the advantage given by the whole group.*

***2.118*** *The EPO has held by implication that a product can be defined by a generic formula' and that such a product will anticipate products which are claimed in a more specific manner. Where a generic formula cannot be used to accurately describe the whole group it can be made more specific by including particular characteristics such as melting point, molecular weight and so forth.*

***2.119*** *It has been stated that a class of compounds which is defined only by a general structure with at least two variable groups' does not anticipate each individual compound which would result from the compound. This raises the issue of what happens where the invention is a particular compound and the prior art discloses a family of compounds with a general formula including the particular compound but not explicitly describing it; in such a case the invention is novel. If the invention claimed is a group of compounds (rather than a particular compound) however; the invention lacks novelty.*

***2.120*** *In any event, at the EPO at least, it is necessary for there to be a direct and unambiguous disclosure of a particular compound for it to be anticipated. There is no specific case law discussing the acceptability of Markush claims in English law, but they are clearly allowed in practice."*

62. *Terrell on the Law of Patents*, while dealing with the difference between the scope of claim and disclosure in paragraph 9-132 states that *'Merely because it is possible to envisage an embodiment which falls within the scope of a claim does not mean that such an embodiment (or any particular feature thereof) is disclosed by the*

*specification and claim. Not everything which is merely encompassed by a patent is necessarily disclosed by it.'*

63. In the Manual of Patent Office Practice and Procedure, published by the office of the Controller General of Patents Design and Trademarks, it is stated that a generic disclosure in the prior art may not necessarily take away the novelty in a specific disclosure. The onus of proving that the 'applied for' patent is not anticipated by prior art is on the applicant. In its 'Guidelines For Examination of Patent Applications in the Field of Pharmaceuticals', it is stated as under:

> *"1. Often broad (generic) patent claims are drafted covering a family of a large number (sometimes thousands or millions) of possible compounds. The so-called 'Markush claims' refer to a chemical structure with plurality of functionally equivalent chemical groups in one or more parts of the Compound. The Markush claims are drafted to obtain a wide scope of protection encompassing a large number of compounds whose properties might not have-been tested, but only theoretically inferred from the equivalence with other compounds within the claim. Quite often the Markush claims generate confusion regarding the novelty, non-obviousness and industrial applicability of a group of compounds covered within the sald Markush formula. Also, the Markush claims may invoke the question of sufficiency and plurality of distinct group of inventions surrounding such claims."*

64. It further states that in case of Markush formulae, it is to be checked from the prior art whether compounds disclosed specifically in the prior are of such structure so that they can unambiguously take away the novelty of the compound(s) in the subsequent patent. If the

compounds of prior art disclosed specifically do not take away the novelty of the compounds in question, then the generic disclosure in the prior art may still be cited for the purpose of inventive step.

65. It further explains the concept of 'implicit disclosure' and 'inherent anticipation', as under:-

> *"7.4* ***Implicit disclosure:*** *The lack of novelty must normally be clearly apparent from the explicit teaching of the prior art. However, since the prior art is read through the eyes of the person skilled in the art, the implicit features of a document may also be taken into account for determining novelty. Thus, if the person skilled in the art would read a disclosure as including a particular feature without it being specifically mentioned, it would be considered an implicit feature of that disclosure and lack of novelty may be implicit in the sense that, in carrying out the teaching of the prior document, the skilled person would inevitably arrive at a result falling within the terms of the claim. Therefore, if the said prior art discloses the claimed subject-matter in such implicit manner that it leaves no doubt in the mind of examiner as to the content of the prior art and the practical effect of its teaching, an objection regarding lack of novelty should be raised.*
>
> *7.5* ***Inherent anticipation:*** *Sometimes the prior art may inherently disclose the subject matter of an invention. In one case before the IPAB, it was held that" patent is invalid for anticipation if a single prior art reference discloses each and every limitation of the claimed invention. The prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating prior art. It is not necessary that inherent anticipation requires that a person of ordinary skill in the art at the time would have recognized the inherent*

*disclosure. But it is necessary that the result is a necessary consequence of what was deliberately intended in the invention".”*

66. In ***Novartis AG v. Union of India & Ors.*** (supra), the Supreme Court has held that the amendment/addition made in Section 3(d) of the Act is meant specifically to deal with the chemical substances, and more particularly pharmaceutical products. It sets up a second tier of qualifying standards for chemical substance/pharmaceutical products in order to leave the door open for true and genuine inventions but, at the same time, to check any attempt at repetitive patenting or extension of the patent term on spurious grounds. It was held that a reading of Section 2(1)(j), 2(1) (ja) and Section 3(d) of the Act would show that different standards for qualifying as an ‘invention’ have been set up for medicines and drugs and other chemical substances, with the threshold of the invention being higher. It was held that to say that the coverage in a patent might go much beyond the disclosure seems to negate the fundamental rule underlying the grant of patent. Under the scheme of patent, a monopoly is granted to a private individual in exchange of the invention being made public so that at the end of the term, the invention may belong to the people at large, who may be benefited by it. The court rejected the submission that the boundary laid out by the claim for coverage is permissible to be much wider than the disclosure/enablement/teaching in a patent. The court held as under:

*“**87**. We are clearly of the view that the importance of the amendment made in section 3(d), that is, the addition of the opening words in the substantive provision and the insertion of explanation to the substantive provision,*

*cannot be under-estimated. It is seen above that, in course of the Parliamentary debates, the amendment in section 3(d) was the only provision cited by the Government to allay the fears of the Opposition members concerning the abuses to which a product patent in medicines may be vulnerable. We have, therefore, no doubt that the amendment/addition made in section 3(d) is meant especially to deal with chemical substances, and more particularly pharmaceutical products. The amended portion of section 3(d) clearly sets up a second tier of qualifying standards for chemical substances/pharmaceutical products in order to leave the door open for true and genuine inventions but, at the same time, to check any attempt at repetitive patenting or extension of the patent term on spurious grounds.*

***88.**. We have so far seen section 3(d) as representing "patentability", a concept distinct and separate from "invention". But if clause (d) is isolated from the rest of section 3, and the legislative history behind the incorporation of Chapter II in the Patents act, 1970, is disregarded, then it is to see section 3(d) as an extension of the definition of "invention" and to link section 3(d) with clauses (j) and (ja) of section 2(1). In that case, on reading clauses (1) and (ja) of section 2(1) with section 3(d) it would appear that the Act sets different standards for qualifying as "inventions" things belonging to different classes, and for medicines and drugs and other chemical substances, the Act sets the invention threshold further higher, by virtue of the amendments made in section 3(d) in the year 2005.*

*xxxx*

***118**. The submissions of Mr. Andhyarujína and Mr. Subramanium are based on making a distinction between the coverage or claim in a patent and the disclosure made therein. The submissions on behalf of the appellant can be summed up by saying that the boundary laid*

> *out by the claim for coverage is permissible to be much wider than the disclosure/enablement/teaching in a patent.*
>
> ***119**. The dichotomy that is sought to be drawn between coverage or claim on the one hand and disclosure or enablement or teaching in a patent on the other hand, seems to strike at the very root of the rationale of the law of patent. Under the scheme of patent, a monopoly is granted to a private individual in exchange of the invention being made public so that, at the end of the patent term, the invention may belong to the at large who may be benefited by it. To say that the coverage in a patent might go much beyond the disclosure thus to negate the fundamental rule underlying the grant of patents.*
>
> *xxxx*
>
> ***134**. However, before leaving Hogan and proceeding further, we would like to say that in this country the law of patent, after the introduction of product patent for all kinds of substances in the patent regime, is in its infancy. We certainly do not wish the law of patent in this country to develop on lines where there may be a vast gap between the coverage and the disclosure under the patent; where the scope of the patent is determined not on the intrinsic worth of the invention but by the artful drafting of its claims by skillful lawyers, and where patents are traded as a commodity not for production and marketing of the patented products but to search for someone who may be sued for infringement of the patent."*

67. In ***AstraZeneca AB*** (supra), a learned Single Judge of this Court examined this concept of Genus versus Species Patent, and held as under:

> *"**25.1**. It must be stated that it was portrayed on behalf of the plaintiffs that the genus patent i.e. IN 147 ringfenced certain*

*compounds which were disclosed only when the species patent i.e. IN 625 was granted, which would, essentially, mean that the written description/complete specification of IN 147 covered DAPA but did not disclose it. To my mind, such written descriptions/specifications would be flawed as it would prevent third parties from carrying out research in future. The Federal Court, in an en banc decision in Ariad Pharmaceuticals, Inc. vs. Eli Lilly and Company, MANU/USFD/0442/2010: 598 F.3d 1336, made some pertinent observations in this behalf.*

*"The written description requirement also ensures that when a patent claims a genus by its function or result, the specification recites sufficient materials to accomplish that function--a problem that is particularly acute in the biological arts. (See Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, "Written Description" Requirement, 66 Fed. Reg 1099, 1105, 1106 (Jan. 5, 2001)). This situation arose not only in Eli Lilly but again in University of Rochester v. G.D. Searle & Co., Inc., MANU/USFD/0128/2004 : 358 F.3d 916 (Fed. Cir. 2004). In Rochester, we held invalid claims directed to a method of selectively inhibiting the COX-2 enzyme by administering a non-steroidal compound that selectively inhibits the COX-2 enzyme. Id. at 918. We reasoned that because the specification did not describe any specific compound capable of performing the claimed method and the skilled artisan would not be able to identify any such compound based on the specification's function description, the specification did not provide an adequate written description of the claimed invention. Id. at 927- 28. Such claims merely recite a description of the problem to be solved while claiming all solutions to it and, as in Eli Lilly and Ariad's claims, cover any compound later actually invented and determined to fall within the claim's functional boundaries--leaving it to the pharmaceutical industry to complete an unfinished invention.*

*Ariad complains that the doctrine disadvantages universities to the extent that basic research cannot be patented. But the patent law has always been directed to the "useful Arts," U.S. Const. art. 1, § 8, cl. 8, meaning inventions with a practical use, see Brenner v. Manson, MANU/USSC/0208/1966: 383 U.S. 519, 532-36 86 S.Ct. 1033 16 L.Ed.2d 69 (1966). Much university research relates to basic research, including research into scientific principles and mechanisms of action, see, e.g., Rochester, MANU/USFD/0128/2004: 358 F.3d 916, and universities may not have the resources or inclination to work out the practical implications of all such research, i.e., finding and identifying compounds able to affect the mechanism discovered. That is no failure of the law's interpretation, but its intention. Patents are not awarded for academic theories, no matter how groundbreaking or necessary to the later patentable inventions of others. "[A] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." Id. at 930 n. 10 (quoting Brenner, MANU/USSC/0208/1966: 383 U.S. at 536 86 S.Ct. 1033). Requiring a written description of the invention limits patent protection to those who actually perform the difficult work of "invention"--that is, conceive of the complete and final invention with all its claimed limitations--and disclose the fruits of that effort to the public.*

*That research hypotheses do not qualify for patent protection possibly results in some loss of incentive, although Ariad presents no evidence of any discernable impact on the pace of innovation or the number of patents obtained by universities. But claims to research plans also impose costs on downstream research, discouraging later invention. The goal is to get the right balance, and the written description doctrine does so by giving the incentive to actual invention and not*

*"attempt[s] to preempt the future before it has arrived." Fiers, 984 F.2d at 1171. As this court has repeatedly stated, the purpose of the written description requirement is to "ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification." Rochester, 358 F.3d at 920 (quoting Reiffin v. Microsoft Corp., 214 F.3d 1342: 1345 (Fed. Cir. 2000)). It is part of the quid pro quo of the patent grant and ensures that the public receives a meaningful disclosure in exchange for being excluded from practicing an invention for a period of time. Enzo, 323 F.3d at 970."*

*xxxxx*

***29.*** *This brings me to the ground for revocation taken under Section 64(1)(f) i.e. that IN 625 is vulnerable as it does not involve any "inventive step". It is required to be noticed that the expression "inventive step" has been defined under Section 2(1)(ja) as follows.*

*xxxxx*

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

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

*xxxxx*

***35.3****. India, it appears, brought in certain amendments to balance the interests of the inventors as also those of her citizens. The insertions inter alia of Sections 2(1)(1),*

*2(1)(ja), and 2(1)(1); Section 3(d); Section 8; Section 10(5); Section 53; and Section 107(A) were a step in that direction. The trade-off, it appears, was between uniformly increasing the validity of patents including those which were granted for drugs for 20 years as against the right of the local industries to be able to work the to provide the fruits of the invention to its citizenry at reasonable prices and to embed skills locally.*

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

68. In an appeal filed against the above judgment, the Division Bench of this Court observed as under:

*"**30**…… When the inventor is the same, the tests aforesaid, in our opinion, cannot be in the context of "person ordinarily in the art" but have to be of the "person in the know". The enquiry, in such a situation, has to be guided by, whether the inventor, while writing first patent, knew of the invention claimed in the subsequent patent.*

***31.** The Patents Act, though protects the rights and interests of inventors, but for a limited period, whereafter the monopoly of the patentee ceases and comes to an end and the invention with respect to which patent was granted, falls in public domain i.e. open all to practice and reap benefit of. A patent, vide Section 48 of the Act, confers a right on the*

*patentee of a product patent, as DAPA is, to, during the life of the patent, prevent others from making, using, offering for sale, selling or importing, the new product with respect whereto patent is granted. The life of a patent is limited, whereafter, notwithstanding the new product having been invented by the patentee, patentee no longer has exclusive right to make, use or offer for sale the same and anyone else interested can also make, use or offer for sale the said new product invented by the patentee, without any interference from the patentee. If patents with respect to the same invention can be granted more than once, successively in time, the same will negate the legislative intent of limiting the life of the patent and enable the patentee to prevent others from making, using or offering for sale, the new product invented by the patentee, till the time patentee successively keeps on obtaining patent therefore.*

*xxxxx*

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

***35****……. All these provisions show that the patent once granted, is complete, disclosing to world at large the product with respect whereto patent is granted from a mere reading whereof, anyone else, but for the exclusivity granted to the patentee, can manufacture the product for patent is granted. Section 84 titled "Compulsory Licences", empowers the Controller of Patents to grant compulsory*

*licence of patent, enabling the person other than the patentee or whom the patentee has permitted to work the patent, to also work the patent. The said section is indicative of, patent, particularly the specifications therein, being self-sufficient to enable working thereof by others, even without the assistance of the patentee.*

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

*xxxxxx*

***38**. Section 10(5) of the Patents Act, in our view, permitted the appellants/plaintiffs to obtain IN 147 with respect to a group of Inventions, as many as 80 according to the appellants/plaintiffs clearly and succinctly disclosed in the specifications thereof, forming a single inventive step, with the new product of each of the 80 compounds subject matter thereof having the effect as claimed in the description of the field of invention therein. Section 10(5) obviated the need for the appellants/plaintiffs to apply for and obtain separate patents with respect to each of the said 80 compounds specifically disclosed. Section 10(5), in our view also empowers and enables an inventor/patentee to sue for infringement, a person, who merely by making a slight change in the group of inventions*

*relating to a single inventive step subject matter of such a patent, claims his product to be different. Thus, in the facts of the present case, even though none of the 80 compounds disclosed in the specifications of IN 147 have ethoxy, but Section 10(5) would have enabled the appellants/plaintiffs to claim that merely from substitution of 'ethoxy' for 'methoxy' disclosed in one of the 80 compounds, it could not be contended that there was no infringement, inasmuch as it was a part of the single inventive step, subject matter of IN 147 and both 'ethoxy' and 'methoxy' being lower alkyls'. That, in our view, is the reason for the appellants/plaintiffs, in the suits from which these appeals arise, claiming infringement not only of IN 625 but also of IN 147--the inventive step being subject matter of IN 147 only and which could not in law again be the inventive step of subsequent patent IN 625.*

***39**. Rather, according to the arguments of the counsel for the appellants/plaintiffs, IN 147 was with respect to mere discovery of a scientific principle or formulation of an abstract theory or was a mere presentation of information and qua which under Sections 3(c) and 3(n) respectively, no patent could be granted. However, not only was the patent obtained but also infringement thereof claimed in the suits from which these appeals arise, admitting DAPA to be the new product subject matter of IN 147. If IN 147 did not disclose DAPA and specifications thereof did not describe DAPA or the best method of industrially manufacturing DAPA, there could be no infringement of IN 147 from action of the respondent(s)/defendant(s) making and selling medicines/drugs with DAPA as ingredient thereof. The provisions afore noticed of the Patents Act, in our view, do not permit a patent to be granted with respect to the important stage in the inventive process and at which stage there is no product capable of industrial application, even if having technical advancement as compared to the*

> *existing knowledge. The appellants/plaintiffs on the other hand, as aforesaid, not only claimed patent IN 147 at the "breakthrough" stage, when according to them DAPA was not even known but even after obtaining patent IN 625 with respect to DAPA, by suing the respondent(s)/defendant(s) have pleaded infringement of IN 147 also. At least at this stage the same has to be treated as an admission of DAPA being known while obtaining IN 147.*
>
> *xxxxx*
>
> ***47**. To hold, that an inventor, merely on the basis of his work, research, discovery and prior art, but which has not yielded any product capable of commercial exploitation, is entitled, by obtaining patent thereof, to restrain others from researching in the same field, would in our view, not be conducive to research and development and would also be violative of the fundamental duties of the citizens of this country, enshrined in Article 51A of the Constitution of India, to develop the scientific temper and a spirit of inquiry. The same will enable busy bodies to, by walking only part of the mile, prevent others also from completing the mile."*

69. In ***FMC Corporation and Ors v. GSP Crop Science Private Limited***, 2022/DHC/004849, a coordinate bench of this Court has held:

> *"31. Thus, in the opinion of this Court, filing of such multiple patents for different aspects of the same product with an intention to extend the initial monopoly in some form or the other, would not be permissible. It is this very abuse that Section 3(d), mandatorily required disclosures under S.10 and other provisions of the Act, intend to curb.*
> *32. Undoubtedly, multiple patents can be filed for different aspects of a particular product, if the tests for novelty, inventive steps and*

> *industrial applicability are satisfied and the inventions are patentable. However, serial patenting in order to 'Evergreen' a particular monopoly, is not permissible.*
> *33. This would also clearly constitute an abuse of the patenting system and curb legitimate manufacture and sale of such products in India, especially if most of the patents/inventions are not being worked. The effort to extend the monopoly beyond the permissible period of 20 years in this manner is contrary to law as held by the Supreme Court in* ***Novartis AG v. Union of India, AIR 2013 SC 1311****"*

70. In ***FMC Corporation v. Best Crop Science LLP & Ors.*** (supra), a learned Single Judge of this Court reiterated that at the stage of the consideration of an application praying for an *interim* order, the challenge posed by the defendant to the validity of the plaintiff's patent need not be such so as to demonstrate conclusively the invalidity thereof, and that it would be sufficient if the defendant is able to make out a case of the Suit Patent being vulnerable to revocation under the Act. On facts, the Court, unlike the present case, found that there was no admission by the plaintiff of the chemical compound being either covered or disclosed by the previous patent. The Court held that it is not open to the party to contend that though a chemical compound was claimed/covered by the prior patent, it was not disclosed thereby.

71. A reading of the above provisions and judgments would show that for obtaining grant of a patent, the applicant, in its application must succinctly describe the invention and its operation or use and the method by which it is to be performed. It must disclose the best method of performing the invention which is known to the applicant

and for which he is entitled to claim protection, and shall end with a claim or claims defining the scope of the invention for which protection is claimed. The claim or claims of a complete specification shall relate to a single invention, or to a group of inventions linked so as to form a single invention concept. It must be clear and succinct and be fairly based on the matter disclosed in the specification. On expiry of the term of patent, the subject matter 'covered' by the said patent shall not be entitled to any protection. Therefore, what has to be truly determined is whether the product/process claimed in the subsequent patent was 'covered' in the earlier patent. Attempt of ever-greening of the patent is to be discouraged and denounced. It is only truly new product or process involving an inventive step and capable of industrial application, that would be entitled to protection under a subsequent patent.

***Application of the Above Principles to the Facts of the Present Case***

72. It is not disputed by the plaintiff that REGORAFENIB is 'covered' by PCT'648/US'834/WO'012. The learned counsel for the plaintiff, fairly in answer to a query of this Court, stated that a claim of infringement would have been maintainable against the defendant(s) even on basis of IN'758, which is equivalent of PCT'648/US'834/WO'012.

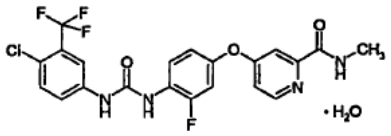
73. The defendants have also drawn my attention to the application seeking Patent Term Extension filed by the plaintiff for US'834, which *inter alia* claims as under:

> ***"(1) A complete identification of the approved product as by appropriate chemical and***

***generic name, physical structure or characteristics; [37C.F.R. § 1.740(a)(1)]***

*The approved product is STIVARGA® (generic name: regorafenib) tablets, 40 mg for oral administration. It is indicated for the treatment of patients with metastatic colorectal cancer (CRC) who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VGEF therapy, and, if KRAS wild type, an anti-EGFR therapy.*

*Regorafenib has the chemical name 4-[4-({[4-chloro-3-(trifluoromethyl) phenyl] carbamoyl} amino)-3-fluorophenoxy]-N-methylpyridine-2-carboxamide monohydrate and the following structural formula:*



*Regorafenib has a molecular formula $C_{21}H_{15}ClF_4N_4O_3 \cdot H_2O$ and a molecular weight of 500.83. Regorafenib is practically insoluble in water, slightly soluble in acetonitrile, methanol, ethanol, and ethyl acetate and sparingly soluble in acetone.*

***(2) A complete identification of the Federal statute including the applicable provision of law under which the regulatory review occurred; [37 C.F.R. § 1.740(a)(2)]***

*Bayer HealthCare Pharmaceuticals Inc. submitted New Drug Application (NDA) 203,085 for STIVARGA® on April 27, 2012, under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. § 355(b)). Regulatory review occurred under section 505 of the FDCA.*

***(3) An identification of the date on which the product received permission for commercial marketing or use under the provision of law under which the applicable regulatory review period occurred; [37 C.F.R. § U40(a)(3)]***

*Bayer HealthCare Pharmaceuticals Inc. received approval of NDA 203,085 under section 505 of the FDCA for commercial marketing of STIVARGA® on September 27,2012.*

***(4) In the case of a drug product, an identification of each active ingredient in the product and as to each active ingredient, a statement that it has not been previously approved for commercial marketing or use under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Virus-Serum-Toxin Act, or a statement of when the active ingredient was approved for commercial marketing or use (either alone or in combination with other active ingredients), the use for which it was approved, and the provision of law under which it was approved; [37 C.F.R. § 1.740(a)(4)]***

*The only active ingredient in STIVARGA® is regorafenib. Regorafenib has not been previously approved for commercial marketing or use under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Virus-Serum-Toxin Act, prior to the approval of NDA 203,085.*

***(5) A statement that the application is being submitted within the sixty day period permitted for submission pursuant to § 1.720(f) and an identification of the date of the last day on which the application could be submitted; [37 C.F.R. § 1.740(a)(5)]***

*This application is being submitted within the sixty day period beginning on the date STIVARGA® first received approval for commercial marketing or use, which period is believed to expire on November 25, 2012. Because the last day of this period falls on a Sunday, the application would still be considered timely if submitted the next succeeding business day, i.e., November 26,2012.*

***(6) A complete identification of the patent for which an extension is being sought by the name of the inventor, the patent number, the date of issue, and the date of expiration; [37 C.F.R. § 1.740(a)(6)]***

*Inventors: Bernd Riedl; Jacques Dumas; Uday Khire; Timothy Lowinger; Williain Scott; Roger A. Smith; Jill E. Wood; Mary-Katherine Monahan; Reina Natero; Joel Renick; and Robert Sibley*

*U.S Patent No.: 7,351,834*
*Issue Date: April 1,2008*
*Expiration Date: January 12,2020*

***(7) A copy of the patent for which an extension is being sought, including the entire specification (including claims) and drawings; [37 C.F.R. § 1.740(a)(7)]***

*A copy of U.S. Patent No. 7,351,834 is attached as Exhibit A.*

***(8) A copy of any disclaimer, certificate of correction, receipt of maintenance fee payment, or reexamination certificate issued in the patent; [37 C.F.R. § 1.740(a)(8)]***

*Terminal disclaimers submitted July 23, 2007 and August 28, 2007 are attached as Exhibit B. A Maintenance Fee Statement showing timely payment of the maintenance fee due at the 4$^{th}$ year is attached as Exhibit C. No certificate of correction or reexamination certificate has been issued for U.S. Patent No. 7,351,834.*

***(9) A statement that the patent claims the approved product, or a method of using or manufacturing the approved product, and a showing which lists each applicable patent claim and demonstrates the manner in which at least one such patent claim reads on:***
***(i) The approved product, if the listed claims include any claim to the approved product;***
***(ii) The method of using the approved product, if the listed claims include any claim to the method of using the approved product; and***

***(iii) The method of manufacturing the approved product, if the listed claims include any claim to the method of manufacturing the approved product; [37 C.F.R. § 1.740(a)(9)]***

*U.S. Patent No. 7,351,834 claims the approved product STIVARGA® and the active ingredient thereof. Specifically, the active ingredient regorafenib is covered by claims 1-12,19-29, and 34, which are reproduced below:*

*1. A compound of Formula I:*

*A—D—B*

*or a pharmaceutically acceptable salt thereof, wherein*

*D is —NH—C(O)—NH—,*

*A is a substituted moiety of the formula:*

*—L-M—$L^1$,*

*wherein L is phenyl, optionally substituted by halogen, up to per-halo, and $W_n$, where n is 0-3;*

*wherein each W is independently selected from the group consisting of $C_1$-$C_5$ linear or branched alkyl, $C_1$-$C_5$ linear or branched haloalkyl up to perhaloalkyl and $C_1$-$C_3$ alkoxy*

*$L^1$ is selected from pyridinyl substituted by -$C(O)R_x$ , and*

*optionally substituted with 1-3 additional substituents independently selected from the group consisting of $R^7$ and halogen;*

*wherein $R_x$, is $NR_aR_b$ and $R_a$, and $R_b$ are*

*A) independently*

*a) hydrogen,*

*b) $C_1$-$C_{10}$ alkyl,*

*c) $C_6$ aryl,*

*d) pyridinyl*

*e) substituted $C_{1-10}$ alkyl,*

*f) substituted $C_6$ aryl,*

*g) substituted pyridinyl*

*h) -phenylpiperazine(pyridinyl),*

*i) -phenylmorpholinyl,*

*j) -ethylmorpholinyl.*

*k) -ethylpiperidyl,*

*1) -methyl pyrrolidinyl,*

*m) -metfiyl tetrahydrofuryl,*

*or*
*n)—$C_2H_4NH$(phenyl);*

*where when $R_a$, and $R_b$ are a substituted group, they are substituted by*
*a) halogen up to per halo,*
*b) hydroxy,*
*c)—$N(CH_3)_2$.*
*d) $C_1$-$C_{10}$ alkyl,*
*e) $C_1$-$C_{10}$ alkoxy,*
*f) halosubstituted $C_{1-6}$ alkyl, or*
*g)—$OSi(Pr\text{-}i)_3$;or*

*B) $R_a$, and $R_b$ together form piperazine or a substituted piperazine with substituents selected from the group consisting of*
*a) halogen,*
*b) hydroxy,*
*c) $C_1$-$_{10}$ alkyl,*
*d) pyridinyl*
*e) $C_1$-$_{10}$ alkoxy,*
*f) $C_6$ aryl,*
*g) halo substituted $C_6$ aryl, and*
*h) N-(4-acetylphenyl);*

*M is selected from the group consisting of oxygen and sulfur; and*

*B is phenyl, substituted with 1-3 substituents independently selected from the group consisting of halogen and $R^7$,*
*and $R^7$ is*

*(a) $C_1$-$C_6$ linear or branched alkyl, optionally substituted with 1-3 halogen substituents; or*
*(b) $C_1$-$C_6$ linear or branched alkoxy.*

*1. A compound as in claim 1 wherein M is oxygen.*

*4. A compound of claim 1 wherein B of Formula I is phenyl, substituted with 1-3 substituents independently selected from the group consisting of chlorine, $C_1$-$C_6$ alkoxy or up to per halo substituted $C_1$-$C_6$ alkyl.*

*5. A compound of claim 2 wherein B of Formula I is phenyl, substituted with 1-3 substituents independently selected from the group consisting of chlorine, $C_1$-$C_6$ alkoxy, or substituted $C_1$-$C_6$ alkyl, substituted by one or more halogen substituents.*

*7. A compound of claim 1, wherein L is phenyl, optionally substituted by halogen up to perhalo.*

*8. A compound of claim 1, wherein L is phenyl, optionally substituted with 1-3 substituents independently selected from the group consisting of halogen and $C_1$-$C_3$ alkoxy.*

*11. A compound of claim 7 wherein M is—O—*

*12. A compound of claim 8 wherein M is—O—*

*19. A compound of claim 2 wherein $R_a$ and $R_b$ are independently hydrogen or $C_1$-$C_6$ alkyl.*

*22. A compound of claim 11 wherein $R_a$, and $R_b$ are independently hydrogen or $C_1$-$C_6$ alkyl.*

*23. A compound of claim 12 wherein $R_a$, and $R_b$ are independently hydrogen or $C_1$-$C_6$ alkyl.*

*24. A compound of Formula I:*

*A—D—B*

*or a pharmaceutically acceptable salt thereof, wherein*

*D is —NH—C(0)—NH—,*
*A is of the formula: —L—M—$L^1$, wherein*

*L is phenyl, optionally substituted with 1-3 substituents independently selected from the group consisting of $C_1$-$C_6$ linear or branched alkyl, $C_1$-$C_6$ linear or branched haloalkyl up to perhalo, $C_1$-$C_3$ alkoxy and halogen;*

*L is pyridinyl, substituted by—C(O)$R_x$;*

*wherein $R_x$, is $NR_aR_b$ and $R_a$, and $R_b$ are independently*
*hydrogen,*
*$C_1$-$C_{10}$ alkyl,*
*$C_6$ aryl,*
*pyridinyl, substituted $C_{1-10}$ alkyl,*
*substituted $C_6$ or*
*substituted pyridinyl,*
*where $R_a$, and $R_b$ are a substituted group, they are substituted by halogen up to per halo; and*

*M is selected from the group consisting of oxygen and sulfur*
*and*

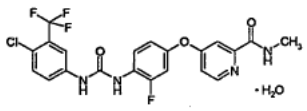
*B is phenyl, substituted with 1-3 substituents independently selected from the group consisting of $R^7$ and halogen;*
*and $R^7$ is*
*(a) $C_1$-$C_6$ linear or branched alkyl, optionally substituted with 1-3 halogen substituents; or*
*(b) $C_1$-$C_6$ linear or branched alkoxy.*

*28. A compound as in claim 24 wherein substituents for B, are selected from the group consisting of up to per halo substituted $C_1$-$C_6$ alkyl and halogen.*

*34. A compound of claim 1 wherein the substituents of B and L are independently selected from the group consisting of methyl, trifluoromethyl, tert-butyl, methoxy, Cl, and F.*

***Demonstration of the manner in which at least one claim reads on the approved product***

*The approved product STIVARGA® contains the active ingredient regorafenib which has the following structural formula:*



*Claim 1 reads on the approved product because regorafenib is a compound of the formula A—D—B, where*
*D is —NH—C(0)—NH—;*
*A is a substituted moiety of the formula: —L—M—$L^1$, where*

*$L^1$ is phenyl substituted by one halogen (specifically, fluorine) and Wn, in which n is 0,*

*$L^1$ is pyridinyl substituted by—C(O)$R_x$, where $R_x$ is $NR_aR_b$, in which $R_a$ and $R_b$ are independently hydrogen and $C_1$-$C_{10}$ alkyl (specifically, methyl);*

*M is oxygen; and*

*B is phenyl, substituted with one halogen (specifically, chlorine) and one $R^7$, where*

*$R^7$ is $C_1$-$C_6$ linear alkyl (specifically, methyl) substituted with 3 halogen substituents (specifically, fluorine).”*

74. A reading of the above application shows that the plaintiff has claimed that US’834 claims REGORAFENIB and even goes on to explain why.

75. The defendants have also drawn my attention to the ‘Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations’, wherein REGORAFENIB has been claimed against US patent US’834.

76. They have also drawn my attention to the rejection of a similar claim of the plaintiff in Columbia and Argentina.

77. The defendants have also drawn my attention to the decision dated 07.09.2021 of the Boards of Appeal of the European Patent Office (EPO) with respect to the EP 1793824, which *inter alia* relying

upon WO'012 (Document 5 therein), revoked the subject patent therein. In the decision, it was *inter alia* observed as under:

> *" 3.2 It is common ground that document (5) represents the closest prior art.*
>
> *Document (5), cited as background art in the application as filed on page 2, line 1, relates to the use of a group of diaryl ureas in the treatment of rafmediated diseases (raf being a serine-threonine kinase), such as cancer, and to pharmaceutical compositions for use in such therapy. It was common ground that regorafenib came under Formula I of document (5). The compounds described under entries 42 and 49 differ from regorafenib only in a substitution on one of the aryl rings (being hydrogen or chlorine instead of fluorine). Information on the substitution by halogens, including fluorine, chlorine, bromine and iodine, can be found on page 4, lines 12 to 14 and page 6, lines 5 to 8. Concerning the formulation of these actives, some general information is given on page 10, line 10 to page 12, line 29. Solid dispersions are not mentioned.*
>
> *Concerning the precise starting point in document (5), the following applies. The Markush formula denominated "Formula (I)" describes the broadest teaching of this document. Indications as to how the substituents may be selected can be found in the specific compounds described in the section "Synthesis of Exemplified Compounds" (starting on page 53) and in Tables 1 to 6. A total of 103 compounds are individualised. Their depiction in Tables 1 to 6 clearly shows which positions for substitution and which substituents are particularly envisaged in order to obtain compounds for the treatment of cancer. Consequently, either Formula (I) or any of the 103 compounds, in particular the closely-related compounds of entries 42 and 49, can be taken as the starting point in the present case.3.5.1 xxxxx*

> *It has been determined under point 3.3.1 above that no surprising effect has been linked to the fluorine substitution that distinguishes regorafenib from some of the compounds exemplified in the closest prior art document (5). It is furthermore common ground that regorafenib comes under the Markush formula defined in document (5). The person skilled in the art, starting from document (5) and aiming at providing a further active agent for the treatment of hyper-proliferative diseases, would have considered any of the compounds, and in particular compounds that are structurally closely related to compounds exemplified in this document. Consequently, the person skilled in the art would have arrived at the claimed compound."*

78. Though the learned counsel for the plaintiff has submitted that the order of the Board of Appeal is in relation to another compound, at least *prima facie* it holds REGORAFENIB was stated to be covered under WO'012.

79. The defendants have also drawn my attention to the history of the prosecution for IN'758. The original application was filed with *inter alia* the following claim:

> *"1. A compound of Formula:*
>
> *A – D- B*
>
> *Or a pharmaceutically acceptable salt thereof, wherein*
>
> *D is –NH-C(O)-NH,*
>
> *A is a substituted money of up to 40 carbon atoms of the formula –L(M-L) where L is a 5 or 6 memberer cyclic structure bound directly to D $L^1$ compromises a substituted cyclic money having at least 5 members. M is a bridging group having at least one atom, q is an integer of from 1-3, and each cyclic structure of L and $L^1$ contains 0-4 members of the group consisting of nitrogen, oxygen and sulphur, and*

> *B is a substituted or unsubstituted, up to tricyclic aryl or heteroary money of up to 30 carbon atoms with at least one 6-member cyclic structure bound directly to D containing 0-4 members of the group consisting of nitrogen, oxygen and sulphur."*

80. Later, however, on an objection of the Controller, the plaintiff deleted the reference to REGROFENIB from the complete specification. Thereafter, the plaintiff filed a divisional application, IN '1633. The defendants have claimed that the said application, however, has been rejected by the IPO on 19.05.2022 for not meeting the criteria laid down in Section 2(1)(j) of the Act.

81. From the above material, the defendants have at least *prima facie* raised a credible defence and challenge to the Suit Patent under Section 64(1)(e) and 64(1)(f) of the Act.

82. Though, the learned counsel for the plaintiff has placed reliance on the order passed by the US PTAB in ***Fustiball LLC*** (supra), in my opinion, at this stage, the same cannot be held sufficient to entitle the plaintiff to a grant of an *interim* injunction as in the said order, it was observed that *'another partes'* is a discretionary power. The Board was influenced to exercise such discretion against the petitioner therein, as it had failed to mention that the US'834 had been cited by the Examiner as prior art and still allowed the claim. The Board, though found that REGROFENIB was not expressly disclosed in the genus patent, it did not concern itself with the question of whether REGROFENIB will be '*covered*' by the genus patent or not?

83. In the present case, what is most relevant is that the plaintiff itself admits in its plaint, as under:

> *"8. In the interest of full disclosure, it would be pertinent to mention that the Plaintiff's sister concern is a proprietor of Indian Patent No. 215758 (IN'758), which is a genus patent covering a vast number of compounds. REGORAFENIB is not specifically disclosed in the genus patent by way of either a chemical name, chemical formula or chemical structure. It is only technically covered within the generic scope of the numerous compounds included in the Markush Formula disclosed in the patent. A person skilled in the art would not have recognized REGORAFENIB from this genus patent. Further, there is no specific claim in the said genus patent pertaining to REGORAFENIB."*
>
> *(Emphasis supplied)*

84. Section 53 of the Act gives the term of Patent. Section 53(4) of the Act specifically provides that on expiry of the term of patent, the subject matter '*covered*' by the said patent shall not be entitled to any protection. The plaintiff having admitted that the Suit Patent is covered by the genus patent, though qualifying such admission by use of the word "technically", whose term has admittedly expired, at least *prima facie* is not entitled to an *interim* order at this stage.

85. What is also relevant is the submission of the learned counsel for the defendants that the subject patent- IN'207 does not disclose any additional advantages over WO'012. They submit that IN'207 does not set out any technical problems associated with the compounds of WO'012. There is no discussion whatsoever in IN'207 on how fluro-substitution present in REGORAFENIB provides any advantages over, say the chloro-substituted carboxyaryl diphenyl urea or even the unsubstituted urea of WO'012. As against this, the plaintiff has now filed documents to claim advantages of compound

covered by the Suit Patent over WO'012, and submits that such post grant evidence be taken into consideration by this Court. Even assuming that such additional evidence can be taken into account at this stage when the grant of patent is in challenge, in my opinion, the submission of the learned counsels for the defendants gives additional grounds to at least reject the prayer for *interim* relief, as the claims of the plaintiff would have to be tested on evidence being led thereon.

86. In view of the above, I find that the plaintiff has been unable to make out a *prima facie* case for grant of an *interim* injunction in its favour.

87. On the issue of balance of convenience and irreparable damage, the other two important ingredients/tests to be made by the plaintiff for grant of an *interim* injunction, in my opinion, the plaintiff has again failed. This is because, if the case of the Plaintiff is proved after trial, they can be appropriately compensated by way of damages. In such a case, damages, if proved at trial, would provide adequate remedy.

88. The public interest would also demand that such injunction be refused inasmuch as it is claimed that there is a huge disparity between the price of the product offered by the plaintiff and the defendant for a disease which is life threatening. In the present case, the Plaintiffs are selling their product at the rate of Rs. 36,995/- by importing the same into India, whereas, the Defendants are manufacturing the product in India and selling the same at a cost of Rs. 9,900/-. Undeniably, the products of the defendants are

significantly cheaper than that of the plaintiffs. Public interest would demand that large segments of population should have relatively easier and affordable access to an anti-cancer drug, which could be the difference between life and death for certain patients. Taking into account the nature of the disease that the drug seeks to provide relief from, affordability plays a major role in its access to wide sections of the public. Therefore, it would not be appropriate to injunct the Defendants from selling the said product, especially when a credible challenge to the patent has been laid and the plaintiff has already enjoyed protection for its full term for IN'758, that is, the genus patent.

89. At the same time, to maintain the balance of convenience, the defendant(s) are directed to maintain complete accounts of manufacture and sale of the products with the subject patent, and file statement of account(s), on affidavit(s), on half yearly basis before this Court.

90. The applications are disposed of with the above directions.

91. It is made clear that any and all observations made hereinabove are only *prima facie* in nature and would not in any manner bind the Court or influence the Court at the time of final adjudication of the suit(s) on merit.

**CS(COMM) 343/2019 & I.As. 9685/2019, 1178/2022**
**CS(COMM) 660/2022 & I.As. 15574/2022, 1432/2023, 1848/2023**

92. List before the Joint Registrar (Judicial) for further proceedings on 23rd August, 2023.

**NAVIN CHAWLA, J.**

**JULY 05, 2023/RN**