2024:DHC:1716

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

Reserved on: 3 July 2023
Pronounced on: 1 March 2024

\+ CS(COMM) 29/2023, I.A. 907/2023

KUDOS PHARMACEUTICALS LIMITED & ORS.
..... Plaintiffs
Through: Mr. Praveen Anand, Ms.Vaishali Mittal, Mr.Siddhant Chamola, Ms.Pallavi Bhatnagar, Mr.Hersh Desai and Mr.Shivang Sharma, Advs.

versus

NATCO PHARMA LIMITED ..... Defendant
Through: Mr. J. Sai Deepak, Mr. G. Natraj, Ms. Harshita Agarwal and Ms. Varsha Jhavar, Advs.

\+ C.O.(COMM.IPD-PAT) 1/2023, I.A. 153/2023

NATCO PHARMA LIMITED ..... Plaintiff
Through: Mr. J. Sai Deepak, Mr. G. Natraj, Ms. Harshita Agarwal and Ms. Varsha Jhavar, Advs.

versus

KUDOS PHARMACEUTICALS LIMITED & ANR.
..... Defendants
Through: Mr. Praveen Anand, Ms.Vaishali Mittal, Mr.Siddhant Chamola, Ms.Pallavi Bhatnagar, Mr.Hersh Desai and Mr.Shivang Sharma, Advs. for D-1
Mr. Piyush Beriwal, Adv. for D-2

CORAM:
HON'BLE MR. JUSTICE C. HARI SHANKAR

2024:DHC:1716

J U D G M E N T

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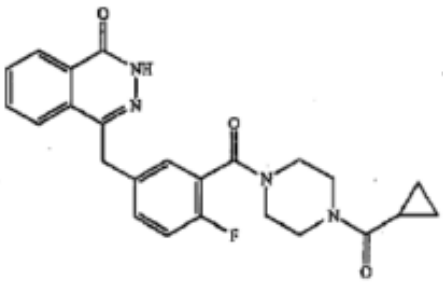
I.A. 907/2023 in CS(COMM) 29/2023

1. Kudos Pharmaceuticals Ltd. ("Kudos" hereinafter) is the registered proprietor of Indian Patent IN 228720 (IN' 720) (hereinafter referred to as "the suit patent"), issued on 12 March 2004 for a period of 20 years. The patent certificate was granted for an invention entitled "Phthalazinone derivative".

2. Claim I of the suit patent read thus:

> "1. A Phthalazione derivative of the following formula.
>
> 
>
> Or isomers, salts or solvates thereof.

3. The application for grant of Suit Patent was filed in India on 31 August 2005 with a priority date of 12 March 2003. It was granted by the Indian Patent Office (IPO) on 10 February 2009.

4. There has been no pre-grant or post-grant opposition to the suit patent. It is only after the present suit was filed that the defendant Natco Pharma Limited ("Natco" hereinafter) filed CO (COMM.IPD-

PAT) 1/2023 under Section 64(1)[1] of the Patents Act, 1970 ("1970"), seeking revocation of the suit patent.

5. The compound claimed in Claim I of the suit patent has been assigned the IUPAC name "Olaparib".

6. There is no dispute that, even while the suit patent continues to remain alive and subsisting, Natco has manufactured and sold its own generic version of Olaparib under the brand name BRACANAT.

7. This, contends Kudos, amounts to infringement of the suit patent. Kudos has, therefore, instituted the present suit before this Court seeking a decree of permanent injunction, restraining Natco

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[1] **64. Revocation of patent-**

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

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

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(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;

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(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;

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(*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;

from manufacturing or selling or otherwise dealing with any product with Olaparib, either under the brand name BRACANAT or otherwise.

8. Olaparib, it may be noted, is an oral poly (ADP- ribose) polymerase (PARP) inhibitor, used for treating various forms of cancer. It is stated that, by inhibiting PARP, Olaparib preferentially kills cancer cells. The mechanics by which Olaparib acts as an anti-cancer drug are not of particular significance, insofar as the present decision is concerned.

9. Along with the suit, the plaintiff has filed IA 907/2023 under Order XXXIX Rules 1 and 2 of the Code of Civil Procedure, 1908 (CPC), seeking an interlocutory injunction restraining the defendants from manufacturing or selling Olaparib, under any brand name, pending disposal of the present suit.

10. This judgment disposes of the said IA 907 of 2023 and I.A. 153/2023 in C.O.(COMM.IPD-PAT) 1/2023.

A prefatory note

11. In para 15 of the report in ***Astrazeneca v. Intas***[2], the Division Bench of this Court has entered the following cautionary note, in the matter of passing of interlocutory orders in intellectual property matters:

> "15. Supreme Court, in order dated 16th August, 2017 in Civil Appeal No. 18892/2017 titled ***AZ Tech (India)*** **v.** ***Intex***

[2] **(2021) 87 PTC 374 (DB)**, hereinafter referred to as "**Astrazeneca-I**"

> ***Technologies (India) Limited***, commented on the disturbing trend, of the orders of disposal of applications for interim relief in Intellectual Property Rights matters governing parties for a long time, with exhaustive judgments, virtually on merits of the suit, being written and expressed the need for addressing the said malady. In fact, *suo moto* Writ Petition (Civil) No. 8/2017 titled ***Re : Case Management of Original Suits***, was initiated in pursuance to the said order and in which proceedings this Court informed the Supreme Court of the remedial measures being taken."

12. More recently, the Supreme Court, in ***Pernod Ricard India Pvt. Ltd. v. United Spirits Ltd***[3], echoed the above sentiment in the following words:

> "At the insistence of counsel for the petitioner, we clarify that it is well settled proposition of law that decisions on interlocutory applications are only made to protect rival interests pending suit. Somehow the interim applications itself are treated as final decision but it is not so. In all such cases, interim arrangements should be made and the trial should proceed rather than to spend time only on interlocutory applications. That protects the petitioner against the apprehension that the impugned judgment may be cited in other Court qua petitioner's cases of a similar nature."

13. The present order is passed on an interlocutory application under Order XXXIX of the CPC. All that the Court has to see, therefore, is whether there is a *prima facie* case in favour of the plaintiff, whether the refusal of interim relief would result in irreparable loss to the plaintiff, and which way the balance of convenience would lie. A threadbare analysis of the entire dispute, and findings which partake of a final expression of opinion on all issues in controversy, is neither justified, nor even appropriate, at this stage.

[3] Order dated **6 September 2023 in SLP (C) 17674/2023**

14. Arguments in this case extended over several days. Written submissions have also been tendered by both sides, with the submissions of the plaintiff extending to 53 pages. If I were to return findings on every issue argued, and on every plea urged, hardly anything would survive for consideration in the suit.

15. The attempt is, therefore, to ensure that this order conforms to the discipline of Order XXXIX of the CPC.

Rival Contentions

16. I have heard Mr. Pravin Anand, learned counsel for Kudos, and Mr. J. Sai Deepak, learned counsel for the Natco at exhaustive length.

Submissions of Mr. Pravin Anand

17. Mr. Pravin Anand advanced the following submissions to justify his prayer for interlocutory injunction:

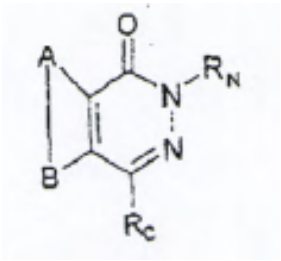
(i) Olaparib is specifically disclosed and claimed in Claim I of the suit patent IN'720.

(ii) During the life of the suit patent and till the filing of C.O. (COMM.IPD-PAT) 1/2023, there has been no pre-grant or post-grant opposition to the suit patent, which stands granted in as many as 61 countries.

(iii) The first act of infringement of the suit patent, by Natco, has taken place when the suit patent is in the 19th year of its life. The suit patent is, therefore, an old patent and is, therefore, *prima facie* entitled to be treated as valid, strong and liable to be enforced against third party infringers.

(iv) Olaparib was also *covered* by IN 245218 (IN'218) registered in favor of the plaintiff which expired on 25 October 2021 titled 'Substituted Benzyl Phthalazinones'.

(v) Claim I in IN'720 was as under :

> "WE CLAIM:
> A compound of the formula :
>
> 
>
>
> Or an isomer, salt, solvate, chemically protected form, and prodrug thereof, wherein :
> A and B together represent an optionally mono-substituted, fused aromatic ring: Rc is -CH2-RL;
> RL is phenyl substituted by a substituent selected from the group consisting of :
> C3-20 heterocyclyl; esler; amido; ureido; sulfonamino; and acyloxy and optionally further substituted; and
> RN is hydrogen."

This is a Markush claim which covers, depending on the selected substitutions from the suggested substitutions provided in the claim, a large number of compounds – worked out in the

written submission of the plaintiff as in the range of 93600 million. This figure is not disputed by Natco. One among these is Olaparib.

(vi) Thus, IN'218 neither claims nor discloses Olaparib. Olaparib is merely one of the millions of compounds which fall within the broad Markush coverage of Claim I in IN'218.

(vii) The specifications in IN'218 do not contain the necessary teaching to guide a person skilled in the art to synthesize Olaparib.

(viii) Natco is admittedly manufacturing and selling Olaparib. Olaparib is specifically disclosed and claimed in the suit patent IN'720. The fact that Natco is infringing the suit patent, therefore, stands admitted.

(ix) Natco has not cleared the way before infringing the suit patent. It has not filed any pre or post grant opposition to the suit patent. C.O. (COMM.) IPD-PAT 1/2023 has also been filed by Natco only after the present suit was instituted by Kudos. The very fact that Natco chose to launch its own generic version of Olaparib, admittedly infringing the suit patent, without, in the first instance, clearing the way, entitles Kudos to interlocutory injunction.

(x) Clearing the way, moreover, would require Natco not to just to file a revocation petition challenging the suit patent, but also to succeed in its challenge. For the proposition that the very act of infringing of the suit patent without Natco having first clear the way entitles Kudos to an interim injunction, Mr. Anand relies on para 87 of the report in ***Merck Sharp and Dohme Corporation v. Glenmark Pharmaceuticals***[4] passed by the Division Bench of this Court, the decision of the UK High Court ***Actavis v. Lilly***[5] and on the decision of the UK Court of Appeal in ***Novartis AG v. Hospira***[6]**.**

(xi) While it is true that, to justifiably oppose a prayer for interim injunction, the defendant in a patent infringement suit is only required to set up a credible challenge to the validity of the suit patent, it cannot be said that Natco has set up such a challenge.

(xii) In ***F. Hoffman La Roche v. Cipla Ltd***[7] and ***Intex Technologies (India) Ltd. v. Telefonaktiebolaget L.M. Ericsson***[8], a credible challenge has been identified as one which is strong, and which is not fanciful or moonshine. In assessing whether a challenge is credible, the Division Bench in both these decisions has held that the fact that the inventor had been granted a patent for his invention after thorough scrutiny by the

[4] **(2015) 63 PTC 257**, hereinafter referred to as "**Merck**".
[5] **2015 EWHC 1955**
[6] **2013 EWCA (Civ) 583**
[7] **(2009) 40 PTC 125(DEL)**, hereinafter referred to as "**Roche-I**".
[8] **2023 SCC OnLine Del 1845,** hereinafter referred to as "**Intex**".

Indian Patent Office was a relevant factor which had to be accorded due weightage.

(xiii) The fact that no pre-grant or post-grant opposition had been filed to the suit patent, till Natco decided to file a revocation petition in the 19th year of the life of the suit patent is also a recognition of the validity of the suit patent and a factor which entitles Kudos to interim injunction, applying the law laid down by the House of Lords in ***American Cyanamide v. Ethicon Ltd***[9]**.**

(xiv) On the erroneous presumption that coverage implies disclosure, Natco was seeking to incorrectly contend that Olaparib stood disclosed in IN'218. In actual fact, coverage and disclosure are distinct and different concepts. Coverage does not imply disclosure. The fact that coverage and disclosure are different and distinct stand acknowledged by the Supreme Court in its judgment in ***Novartis AG v. UOI***[10] as well as by the Division Bench of Court in para 11.18.7 of its decision in ***FMC Corporation v. Natco Pharma Ltd.***[11] and by this Bench in ***Novartis AG v. Natco Pharma Ltd***[12]**.**

(xv) Disclosure of a chemical compound in a patent is done only through an individual identification of that compound in the patent document by its chemical name, chemical structure,

[9] **1975 UK HL 1**
[10] **(2013) 6 SCC 1**
[11] **2023 SCC OnLine Del 106**, hereinafter referred to as "**FMC-I**".
[12] **(2023) SCC OnLine Del 106,** hereinafter referred to as "**Novartis-I"**

chemical formula, IUPAC name etc. Reliance is placed, for this purpose, on paras 283 and 329 of the judgment of the Federal Court of Australia in ***Eli-Lilly and Co. Ltd. v. Apotex Pty Ltd***.[13]

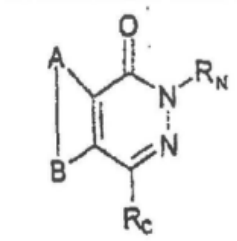
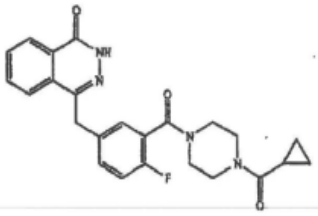
(xvi) In ***FMC-I***, the Division Bench held that disclosure of a compound in a genes patent cannot be presumed.

(xvii) The Supreme Court, in its judgment in ***Biswanath Prasad v. Hindustan Metal Industries***[14] and the US Court of Appeals in ***Fujikawa v. Wattanasin***[15] hold that the issue of disclosure of a patent in specifications is a question of fact, which has to be proved by clear and convincing evidence.

(xviii)There is a difference between coverage and claiming. The fact that Olaparib is covered under the overall Markush claim in IN'218 does not result in Olaparib being vulnerable to invalidity on the ground of prior claiming.

(xix) In order for a claim in a patent to be invalided on the ground of prior claiming, the invention in the two claims must be identical. The Markush Claim I in IN'218 is clearly different from Claim I in the suit patent which specifically claims and discloses Olaparib. This has been sought to be demonstrated thus:

[13] **2013 FCA 214,** hereinafter referred to as "**Eli Lilly**".
[14] **(1979) 2 SCC 511**
[15] **29 USP Q. 2d 1895**

Invention of the genus patent IN '218	Invention of the species patent IN '720
	

In the genus patent IN'218, though millions of compounds could be synthesized from the Markush Claim I, only 265 compounds were exemplified, and Olaparib was not one amongst them. In order for a claim in a species patent to be invalidated on the ground of prior claim in the genus patent, the disclosure in the genus patent must be enabling; in other words, it must enable a person skilled in the art to arrive at the species patent from the teachings which it provides. Reliance is placed, for this purpose, on ***The General Tire and Rubber Co. Ltd. v. Firestone Tyre and Rubber Co. Ltd.***[16]

(xx) There can be no question of double patenting or prior claiming where the scope of earlier and later patent is different.

(xxi) In order to support his contention that the mere coverage of the claim in the species patent, in the overall Markush structure in the genus patent does not invalidate the species patent on the ground of prior claiming, Mr. Anand relies on para 63.2 to 63.6 of ***Novartis-I***, paras 12.5, 12.7 & 12.18 of the judgment of this Bench in ***FMC Corporation v. Best Crop***

[16] **(1971) FSR 417**

Science LLP[17] and paras 191, 192 and 195 of ***Novartis AG v. Natco Pharma Ltd.***[18], paras 10.5 to 10.8 of ***Astrazeneca v. Torrent***[19] and paras 26 to 30 of the Judgment of the UK Court of Appeal in ***Dr. Reddy's Laboratories (UK) Ltd. v. Eli Lilly and Co. Ltd***[20]**.**

(xxii) If Natco's submissions were to be accepted, it would invalidate all selection patents, which are recognized in this country. Natco was seeking to contend that all species patents were patents of addition under Section 34[21] and had, therefore, necessarily to terminate with the genus patent. This was a seriously flawed submission, and went against the well-recognized theory of selection patents. Selection patents were valid subject to their satisfying the three factor test, postulated in ***Re. I.G. Farbenindustrie A.G.'s Patents***[22], followed by this Court in its decision in ***FMC-I.***

(xxiii)The suit patent could not be treated as a patent of addition under Section 54[23] of the Patents Act, as was sought to be

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[17] **(2021) 87 PTC 217,** hereinafter referred to as "**FMC-II**"
[18] **(2021) SCC OnLine Del 5340,** hereinafter referred to as "**Novartis-II"**
[19] **(2020) 275 DLT 361,** hereinafter referred to as "**Astrazeneca-II"**
[20] **(2010) RPC 9**
[21] **34. No anticipation if circumstances are only as described in sections 29,30, 31 and 32-** Notwithstanding anything contained in this Act, the Controller shall not refuse to grant a patent, and a patent shall not be revoked or invalidated by reason only of any circumstances which, by virtue of section 29 or section 30 or section 31 or section 32, do not constitute an anticipation of the invention claimed in the specification.
[22] **(1930) 47 RPC 289 (Ch D)**
[23] **54. Patents of addition-**
(1) Subject to the provisions contained in this section, where an application is made for a patent in respect of any improvement in or modification of an invention described or disclosed in the complete specification filed therefor (in this Act referred to as the "main invention") and the applicant also applies or has applied for a patent for that invention or is the patentee in respect thereof, the Controller may, if the applicant so requests, grant the patent for the improvement or modification as a patent of addition.

contended by Natco. A patent of addition was filed with respect to minor improvements over an invention described or disclosed in an earlier patent. Olaparib is neither described nor disclosed in the genus patent IN'218. Moreover, Olaparib was not a mere improvement over the genus patent but constitutes an entirely new invention.

(xxiv) The reliance on Section 53(4)[24] of the Patents Act, by Natco is also misplaced. Natco was seeking to contend that, by operation of Section 53(4), the expiry of the genus patent IN'218 resulted *ipso facto* in falling, into the public domain all subject matter covered by the genus patent even if it was neither claimed nor disclosed in it. This was a fundamentally misplaced submission. The protection available under Section 53(4) was as much available to the species patents as to the genus patent. It is well-settled that multiple patents can cover the same product. In such a case, the expiry of genus patent does not result automatically into expiry of the species patents or evisceration of the protection available under Section 53(4) to the species patent.

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(2) Subject to the provisions contained in this section, where an invention, being an improvement in or modification of another invention, is the subject of an independent patent and the patentee in respect of that patent is also the patentee in respect of the patent for the main invention, the Controller may, if the patentee so requests, by order, revoke the patent for the improvement or modification and grant to the patentee a patent of addition in respect thereof, bearing the same date as the date of the patent so revoked.

(3) A patent shall not be granted as a patent of addition unless the date of filing of the application was the same as or later than the date of filing of the application in respect of the main invention.

(4) A patent of addition shall not be granted before grant of the patent for the main invention.

[24] **53. Term of Patent-**

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(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.

(xxv) This was clear from the expression "notwithstanding anything contained in any other law for the time being in force", with which Section 53(4) commences. The Patents Act could not be treated as "other law" for the purposes of Section 53(4). While, therefore, Section 53(4) had supervening application over other laws, it was nonetheless subject to the Patents Act and, especially, to Sections 19, 91(1) and 141 (1) thereof. Reliance was placed, for the interpretation "any other law" on the judgment of the Supreme Court in ***P. Virudhachalam v. Management of Lotus Mills***[25] . The correct interpretation to be placed on Section 53 (4) was, therefore, that all compounds *disclosed* by the genus patent would be open to the public upon its expiry. Inasmuch as Olaparib was not specifically disclosed in the genus patent IN'218, the expiry of IN'218 did not render Olaparib available in the public domain for anyone to exploit.

(xxvi) A plea that Olaparib was disclosed in the Russian Genus Patent RU'865 was also incorrect. Natco was seeking to contend that RU'865 – which was the Russian equivalent to IN'218 – also claimed a medicament used to treat cancer via PARP inhibition. The reliance on RU'865 was, however, misplaced as RU'865 did not disclose that any drug, let alone Olaparib, commercially emerged from RU'865.

[25] **(1998) 1 SCC 650**

(xxvii) Natco had sought to rely on the Form 27s filed by Kudos, for the genus patent IN'218 and the species patent IN'720. The filing of Form 27 did not amount to any kind of admission that Olaparib was specifically disclosed in both the patents. One product can conceivably be covered by several patents and several patents could cover a single commercial product. This position stands statutorily recognized by Sections 3(d), 19, 88(3), 91 and 141 of the Patents Act. The amended form 27 requires all patentees to file a single Form 27 for multiple patents, provided all patents are related or worked through one product. As such, the fact that one Form 27 had been filed both for species patent IN'720 and genus patent IN'218 did not constitute any admission that both disclosed Olaparib. They were merely related patents, as genie and species patents respectively.

(xxviii) Similarly, the Patent Term Extension (PTE) application filed by Kudos in respect of Australian Patent AU 2001295789 (AU'789) – which corresponded to the Indian genus Patent IN'218 – was completely irrelevant and did not constitute any admission that Olaparib was disclosed in the genus patent. The Patents Act in Australia provides PTEs to account for delay which could occur when obtaining regulatory approvals for pharmaceuticals. Reliance has been placed, in this context, on Sections 70 to 79A of the Australian Patents Act 1990. The above legal position stands exposited by this Court in paras 67, 67.1 and 67.2 of its judgment in ***Novartis-I***.

(xxix) In PCT application WO 2021/224381 of Kudos, there was an inadvertent statement that Olaparib was disclosed in WO'976, which corresponded to the genus patent IN'218. Immediate corrective steps had been taken by Kudos to rectify this error and it now stands clarified that Olaparib was described in WO'976, which corresponds to IN'720, the species patent. That this was an error is also manifested from the fact that Kudos applied for several other patents related to Olaparib, referring to WO'976 as the patent which described Olaparib. Specific instances in this regard have been provided.

(xxx) The challenge to the validity of the suit patent IN'720 on the ground that it suffered from insufficiency of disclosure under Section 64(1)(h) was not one which could be examined by the court at an interlocutory stage. It was a question of fact, not a question of law, and would have to be decided only once evidence was led and Kudos was granted an opportunity to cross examine its witnesses. Reliance is placed, for this purpose, on the judgment of this Court in ***Communication Components Antenna Inc v. Mobi Antenna Technologies (Shenzen) Co. Ltd.***[26] and on Terrell on the Law of Patents.

(xxxi) Natco's reliance on Section 8(2) to the Patents Act, *vis-à-vis* the omission on Kudos part to reveal details of the Patent Applications filed before the Japanese Patent Office (JPO),

[26] **Manu/DE/0946/2022**

corresponding to the suit patent IN'720 during the time of prosecution of the application resulting in its grant, before the Indian Patent office, was also unsustainable. Reliance has been placed, in this context, on a letter written to Kudos by its Agent on 14 December 2007, informing Kudos of the Section 8 objection raised by the IPO and requesting Kudos to supply the search and examination report for corresponding patent applications filed in the US and Europe. Such an inadvertent, unintentional error would not amount to violation of Section 8(2) so as to disentitle the patentee to interlocutory relief. Reliance has been placed, in this context, on paras 27 and 28 of the judgment of the Division Bench of this Court in ***Sukesh Bahl v. K. Philips Electronics***[27] and paras 123 to 125 of ***F. Hoffman La Roche Ltd v. Cipla Ltd***[28]**.** In any case the Kudos stood to gain nothing by suppressing the patent applications filed before the Japanese Patent Office (JPO), as both applications had been granted.

(xxxii) Natco's contention that the suit patent IN'720 suffered from lack of inventive step, as it had not demonstrated any technical advance of Olaparib over prior art, was contrary to the very words of Section 2(1) (ja) of the Patents Act, which defined "inventive step" as meaning "a feature of an invention that involves technical advance 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".

[27] **2015 SCC OnLine Del 2313**
[28] **148 (2008) DLT 598** (hereinafter referred to as "**Roche-II**")

As such, technical advance over prior art is not a mandatory pre-requisite for an inventive step to be found to be involved in a patent claim. Economic significance of the product related to the claim would also suffice to make out an inventive step. Olaparib definitely possesses economic significance over prior art. It is sold over 90 countries, used for the treatment of multiple tumour types, and is a certified blockbuster drug, with sales revenues of over USD 2.3 billion in 2021. In 2016, the US FDA had granted "breakthrough therapy" status to Olaparib for treatment of metastatic prostate cancer. The very definition of a therapy as breakthrough indicated that it possessed substantial improvement over existing therapy. Mr. Anand places reliance on literature explaining the concept of a breakthrough therapy.

(xxxiii) It is only if the suit patent were to lack in inventive steps, as envisaged by Section 2(1) (ja), that it could be said to be vulnerable to invalidity on the ground of prior claiming. Inasmuch as Olaparib could not be said to lack in inventive step over prior art, the suit patent was not vulnerable to invalidity for want of obviousness.

(xxxiv) In order to be valid, a claim for patenting an invention was not required to demonstrate superiority of the invention over prior art. All that was required to be shown was that the invention satisfies the test of novelty, non-obviousness and utility.

(xxxv) In view of the fact that the genus patent IN'218 did not contain the teaching to lead a person skilled in the art to synthesize Olaparib, as the compound claimed in Claim I of the species patent in IN'720, from the Markush formula claimed in Claim I of the genus patent, and it was possible to synthesize Olaparib from the Markush claim in the genus patent only by cherry-picking the substituents from the several suggested substitutions in Claim I, and substituting them on the Markush radicals by employing hindsight reconstruction, it was clear that the Olaparib could not be said to be disclosed, much less claimed, in Claim I of the genus patent IN'218.

For all these reasons, among others, Mr. Anand submits that, as the fact of infringement is indisputable, and as Natco has not succeeded in setting up a credible challenge to the suit patent, indicating that it is vulnerable to invalidity, Kudos is entitled to an interlocutory injunction as sought.

18. Inasmuch as the defendant has, undisputedly, manufactured and sold generic Olaparib during the life of the suit patent, the fact of "infringement" of the suit patent by the defendant, as understood *stricto sensu*, cannot be disputed either. Mr. Sai Deepak, however, invokes Section 107, read with clauses (a), (d), (e), (f), (j), (k) and (m) of Section 64(1) of the Patents Act to defend the charge of infringement, and the reliefs sought by Kudos on that basis. He also submits that, for defending an allegation of infringement, and

successfully opposing a prayer for interlocutory injunction, a defendant is only required to put forward a "credible challenge", demonstrating the suit patent to be vulnerable to invalidity on one or the other grounds envisaged by Section 64(1). His submissions, according to him, meet that standard.

19. To save time and space, I propose to decide this application by dealing, seriatim, with the various points of defence raised by Mr. Sai Deepak, *vis-à-vis* the submissions of Mr. Pravin Anand in that regard. In doing so, aspects which involve detailed examination of facts and which, therefore, would merit an exhaustive analysis after both sides are given an opportunity to lead evidence, are not being addressed, adhering to the discipline of ***Astrazeneca-I*** and ***Pernod Ricard***. I shall, however, note the said issues towards the conclusion of this order.

The consideration of credible challenge

20. Mr. Sai Deepak seeks to contend that the defendant is only required to raise a credible challenge to the vulnerability of the suit patent in order to succeed in its defence against infringement.

21. There is no dispute about this legal position.

22. However, it is necessary to understand what "credible challenge" means. In this context, this court has held, in para 19 of

FMC-II, paras 178 and 231 to 233 of ***Novartis I*** and para 129 of ***Novartis II*** thus:

FMC-II

"19**.** Thus, the challenge, posed by the defendant to the validity of the plaintiff's patent need not be such as to demonstrate, conclusively, the invalidity thereof. It is sufficient if the defendant is able to make out a case of the suit patent being vulnerable to revocation under the Patents Act. This vulnerability has, however, to be demonstrated by way of a credible challenge. The onus would be on the defendant, therefore, to establish the credibility of the challenge raised by it. The challenge cannot be incredible, fanciful, or moonshine. It must not strain the sinews of acceptability. There can, however, needless to say, be no fixed standard on the basis of which the credibility of the challenge can be assessed. It would be for the Court, in each case, therefore, to ascertain, for itself, whether the challenge raised by the defendant, to the validity of the suit patent, is, or is not, credible."

Novartis I

"178**.** The challenge in this regard must be credible. Credibility indicates that, on the face of the challenge, it must merit favourable consideration. A credible challenge occupies a higher pedestal than a challenge, which is merely worthy of consideration.

xxxxx

231**.** Before closing the discussion, I wish to enter a final observation. There appears, *prima facie*, to me, to be a fundamental misconception relating the concepts of a "credible challenge" and of "vulnerability". The submissions advanced by the defendant seem to have been predicated on the premise that the slightest shadow of doubt, which could be cast on the suit patent, was sufficient to constitute a credible challenge, exposing its vulnerability to revocation. This proposition, according to me, is completely misconceived. Para 28 of the report in *Bishwanath Prasad Radheyshyam*recognises the fact that, prior to grant of a patent, especially for a pharmaceutical product, a thorough study is normally undertaken by the Patent Office, regarding the validity of the patent as sought. When an infringer seeks to defend infringement on the ground that the patent that he infringes is invalid, the onus, to prove such invalidity heavily lies on him. This standard has to be met, when applying the principle of "credibility". Repeated attempts were made to convince me that

any and every ground that the defendant sought to raise, and for which a cast iron response from the plaintiff was not immediately forthcoming, was sufficient to establish vulnerability of the suit patent to revocation. Revocation is a drastic act, and a patent, once granted, cannot be treated as easily vulnerable to revocation. Even if, *prima facie*, a ground for revocation is made out, as is noted in *Merck* v. *Glenmark*, revocation is not automatic, but remains a matter of discretion, for the patent authority. The grant of such discretion is itself a pointer to the legislative intent that, before revoking a patent, the authority is required to satisfy itself, that, all considerations having been mould in mind, revocation is absolutely necessary. Vulnerability to revocation has also to be judged on the same standard. It is only when, judged on that standard, a credible challenge to the validity of the patent as vulnerable to revocation is made out, that an infringer can escape the consequences of infringement. The standard is, therefore, high, rather than low.

232**.** This would especially be so in a situation, as in the present case, the infringer never choose to challenge the suit patent either at pre-grant or at post-grant stage, by filing oppositions. The defendants have not, therefore, "cleared the way", before exploiting the suit patent. Mr. Sai Deepak sought to contend that, by deferring the release of their Eltrombopag Olamine, till the expiry of the term of IN 176, the defendants had sufficiently cleared the way. Mr. Hemant Singh has disputed this contention, and I confess that I agree with him. IN 161 was granted as far back as on 27th March, 2009. It has remained in force for 12 years. The defendants have neither chosen to launch any pre-grant or post-grant, opposition to IN 161. Nor have they filed any proceedings before the patent office or the IPAB, to cancel or suspend the registration granted to IN 161. Rather, even while IN 161 continues to remain valid, the defendants have, without blinking an eyelid, sought to exploit the subject matter of the said patent, i.e. EO. That they have done so with the full awareness that EO is specifically claimed in IN 161, is not disputed. Clearly, therefore, the defendants have, by their attitude, as well as by failing to clear the way before exploiting the suit patent, IN 161, exposed themselves to an interlocutory injunction.

233**.** It is only when they have been "caught in the act", as it were, that the infringer defendants, unable to dispute the charge of infringement on facts, seek to question the validity of the suit patent. While Section 64, undoubtedly, allow them to do so, the challenge has to be credible, not incredible. The defendants, in the present case, neither launched any pre-grant nor any post-grant, opposition to IN 161. They have not initiated any proceeding

before IPAB or any other authority, for revocation, cancellation or removal of the suit patent from the register of patents. In such circumstances, the holder of the suit patent would ordinarily be entitled to an injunction against continued infringement. Absent any *prima facie* case of vulnerability of the suit patent to revocation on the ground of invalidity, therefore, injunction cannot be refused, once infringement is established."

Novartis II

"129**.** *In fact, Natco has, in its submissions, completely glossed over the most important query which it would have to answer, in order to set up even a credible challenge to the validity of the suit patent, vis-à-vis a Markush prior art. The suit patent could be said to be vulnerable to invalidity, vis-à-vis known Markush prior art, only if it is established, cumulatively, that*

(i) from the known prior art, it is possible to arrive at the suit patent, by effecting suggested substitutions in the Markush formula claimed in the prior art, from the substitutions suggested therein, and

(ii) the Markush prior art contains the requisite teaching, as would suggest the substitutions which are to be so made in order to arrive at the suit patent."

23. Thus, the onus to establish that the challenge raised by it is credible, is on the respondent. A credible challenge, as Mr. Pravin Anand has correctly submitted, is a challenge which is not incredible, fanciful, or moonshine, and must *prima facie* be acceptable. On its face, the challenge must merit favorable consideration. It is not enough for the defendant to raise a challenge which is worthy of consideration. The challenge must be more than that; it must partake of the character of *prima facie* acceptability. "credibility", even by itself, connotes a fairly high standard. In examining whether the challenge raised is credible, a relevant consideration is the fact that the Patent Office has, after a thorough study, found the patent to be valid

and capable of being granted. In ***Merck***, the Division Bench of this Court held that, even if a ground for revocation of a granted patent was made out, revocation was not an inevitable sequitur, but that the patent authority retained discretion in that regard. The same standard has to be adopted while examining vulnerability to revocation. The standard of credibility is, therefore, a high standard, not a low standard, as is commonly understood.

II. The decision in ***Astrazeneca-I***

24. Mr. Sai Deepak laid great stress on the decision in ***Astrazeneca-I.*** According to him, the view taken by this Bench in ***FMC-II, Novartis-I*** and ***Novartis-II*** can no longer be followed after the decision of the Division Bench in ***Astrazeneca-I***. As against this, Mr. Pravin Anand points out that, when the judgment of this Bench in ***FMC-II*** was cited before the Division Bench in ***Astrazeneca-I***, the Division Bench did not overrule the decision, but only distinguished it on the ground that, in ***FMC-II***, only the specie patent was asserted by the plaintiff whereas, in ***Astrazeneca-I***, both genus and specie patent were asserted.

25. Mr. Sai Deepak submits that the observation that, in ***FMC-II***, the specie patent alone was asserted, whereas, in ***Astrazeneca-I***, both genus and specie patent were asserted, was merely a closing observation of the Division Bench in ***Astrazeneca-I***, and to accord that closing observation pre-eminence over all other findings of the Division Bench would be a lopsided approach. He submits that the

closing observation regarding the judgment of this Bench in ***FMC-II*** does not dilute the rigour of the rest of the judgment in ***Astrazeneca-I***, or take away its precedential value. The findings in the decision, he submit, apply on all fours to the facts at hand, and are directly contrary to the view expressed by this Bench in ***FMC-II***, ***Novartis-I*** and ***Novartis-II.*** All those findings cannot, he submit, be overlooked merely because of the closing observation differentiating the decision in ***FMC-II*** from the facts which were before the Division Bench.

Effect of reference, in ***Astrazeneca-I***, to the decision in ***FMC-II***

26. In so submitting, Mr. Sai Deepak overlooks the fact that, had the Division Bench felt that the view expressed by this Bench in ***FMC-II*** was wrong, the easiest thing would have to be to overrule it. Indeed, that would be the only natural course of action which the Division Bench would ordinarily have followed. The Division Bench did not, however, do so, and it would, therefore, be overreaching the decision of the Division Bench if one were to read ***Astrazeneca-I*** as overruling ***FMC-II.*** It appears, *prima facie*, incongruous if an interpreter of a judgment were, in the process of interpreting, to rewrite the judgment as doing what the author of the judgment could have done, but did not choose to do.

27. The Division Bench, therefore, *consciously* refrained from overruling the view of this Bench in ***FMC-II.*** The words used by the Division Bench are of stellar significance. The Division Bench observes:

> "51. The counsel for the appellants/plaintiffs, on 12th July, 2021 mentioned the matter, to draw attention to judgment dated 7th July, 2021 in applications for interim relief in CS(COMM) No. 69/2021 and CS(COMM) No. 661/2019 titled ***FMC Corporation v. Best Crop Science LLP***. *In taking the view aforesaid, we have considered the said judgment also, in which infringement of one patent only was claimed*."
>
> (Emphasis supplied)

28. Nothing, in my considered opinion, could be plainer. The Division Bench was specifically shown the decision of this Bench in ***FMC-II***. The Division Bench noted that, in arriving at its view, *it had also considered* the decision of this Bench in ***FMC-II***. *After considering the decision of this Bench in* ***FMC-II***, the Division Bench propounded the view that it did, and the identifying and distinguishing feature of the judgment of this Bench in ***FMC-II*** is, clearly, from the italicised words in para 52 of the report in ***Astrazeneca-I***, *the fact that, in* ***FMC-II****, only the specie patent was asserted, whereas, in* ***Astrazeneca-I****, Astrazeneca asserted both the genie and specie patent, contending that the impugned invention of Intas infringed both patents*. It is *because of this distinguishing feature* that the Division Bench in ***Astrazeneca-I,*** without disturbing the decision of this Bench in FMC, held as it did. That much, according to me, is clear from para 52 of ***Astrazeneca-I.***

29. It would, therefore, be folly, according to me, for any hierarchically subordinate Court, or Bench, to *interpret* the decision of the Division Bench in ***Astrazeneca-I*** as overruling ***FMC-II***, or even as disapproving the view expressed therein.

Assuming Mr Sai Deepak's contention to be correct – Discussion in main body of the decision in ***Astrazeneca-I***

30. Even if one were to go along with Mr. Sai Deepak's submission, and advert to the body of the ***Astrazeneca-I*** decision, one finds that the Division Bench has proceeded almost entirely on the consideration that Astrazeneca had, in its suit, asserted both the genus and the specie patents. It is helpful, in this context, to vivisect the ***Astrazeneca-I*** decision into its individual components, as that would help a great deal in understanding what the Division Bench went on to hold. For this purpose, the para numbers to which I allude are the para numbers of the report in the SCC OnLine journal.

31. Astrazeneca, in its suit, asserted two patents; IN 205147 (IN' 147) and IN 235625 (IN'625). On the basis thereof, Astrazeneca sought an injunction against Intas manufacturing or otherwise dealing in Dapagliflozin ("DAPA"). The facts of the case are not of much significance, and are contained in paras 1 to 14 of the report.

32. The Division Bench proceeds, in para 16 of the report, to enumerate the contentions of learned Counsel for Astrazeneca. Thereafter, paras 17 to 21, the Division Bench observes thus:

> "17. Though ordinarily we would have recorded the arguments of the counsels for the respondent(s)/defendant(s) also but need therefor is not felt in the facts of the present case since during the hearing itself, we entertained doubts/reservations as spelled out herein below, and which doubts *inter alia* also form the defence of the respondent(s)/defendant(s).

18. *Our doubts stemmed from, the appellants/plaintiffs averring and pleading manufacture and sale by the respondent(s)/defendant(s) of DAPA to be in infringement of two patents i.e. IN 147 and IN 625.* It was felt, that if DAPA was not disclosed and/or known at the time of seeking patent IN 147 or US equivalent thereof and was invented only subsequently and patent thereof obtained in IN 625 or US equivalent thereof, there could be no infringement by respondent(s)/defendant(s) of IN 147 by manufacturing and/or selling DAPA. Conversely, *once the appellants/plaintiffs claimed infringement of IN 147 also, it necessarily followed that DAPA was subject matter thereof and once it was the subject matter thereof, how it could be the subject matter of subsequent patent IN 625*.

19. It was thus enquired from the counsel for the appellants/plaintiffs, that if the patent IN 147 was/is not of DAPA, *how could the appellants/plaintiffs in the suits from which these appeals arise, claim infringement by the respondent(s)/defendant(s) of IN 147 also, by manufacturing DAPA.* It was further enquired, *whether not from the factum of the appellants/plaintiffs, in the suits from which these appeals arise, having claimed infringement by the respondent(s)/defendant(s) of both, IN 147 as well as IN 625, the appellants/plaintiffs are deemed to have admitted DAPA as the subject matter of both, IN 147 and IN 625.*

20. We, at this stage, spell out the thought process behind the aforesaid query.

21. In our opinion, with respect to one invention, there can be only one patent. *The appellants/plaintiffs herein however, while claiming one invention only i.e. DAPA, are claiming two patents with respect thereto, with infringement of both, by the respondent(s)/defendant(s). The same alone, in our view, strikes at the very root of the claim of the appellants/plaintiffs and disentitles the appellants/plaintiffs from any interim relief.*"

(Emphasis supplied)

33. Paras 25 to 28, 31, 32, 36, 43 and 45 of the report proceed to observe thus:

"25. With "invention", as defined in the statute, forming the core of a patent and the appellants/plaintiffs in their suits having claimed only one invention i.e. DAPA, as subject matter of both

the patents, we wondered whether there could be two patents with respect to the same invention and proceeded to examine the two patents, to decipher the invention claimed in each.

26. IN 147 sets out the field of invention as under:

"The present invention relates to C-aryl glucosides which are inhibitors of sodium dependent glucose transporters found in the intestine and kidney (SGLT2) and to a method for treating diabetes, especially type II diabetes, as well as hyperglycemia, hyperinsulinemia, obesity, hypertriglyceridemia, Syndrome X, diabetic complications, atherosclerosis and related diseases, employing such C-aryl glucosides alone or in combination with one, two or more other type antidiabetic agent and/or one, two or more other type therapeutic agents such as hypolipidemic agents".

27. IN 625 sets out the field of invention as under:

"The present invention relates to C-aryl glucosides which are inhibitors of sodium dependent glucose transporters found in the intestine and kidney (SGLT2) and to a method for treating diabetes, especially type II diabetes, as well as hyperglycemia, hyperinsulinemia, obesity, hypertriglyceridemia, Syndrome X, diabetic complications, atherosclerosis and related diseases, employing such C-aryl glucosides alone or in combination with one, two or more other type antidiabetic agent and/or one, two or more other type therapeutic agents such as hypolipidemic agents".

28. As would immediately be obvious from above, there is complete identity, without any difference whatsoever, between the field of invention as set out in the two patents i.e. IN 147 and IN 625. For IN 625 to be with respect to a 'new product' involving an inventive step i.e. a feature involving a technical advance as compared to existing knowledge including of IN 147 or having economic significance and which was not anticipated by earlier publication or use including of IN 147, to say the least, we expected the description of the field of invention in IN 625 to describe the technical advancement and/or the difference in efficacy, from that in IN 147.

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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 for 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 therefor.

32. As far as the arguments of the counsel for the appellants/plaintiffs, of DAPA being only covered and not disclosed in IN 147 and being disclosed for the first time in IN 625, and of DAPA being not obvious from and capable of being anticipated from IN 147 are concerned, we are also of the opinion that once the appellants/plaintiffs, in the plaints in their suits claimed the action of the respondent(s)/defendant(s) of manufacturing medicines having DAPA as their ingredient to be an infringement of both IN 147 and IN 625, the appellants/plaintiffs are deemed to have admitted DAPA to be the invention subject matter of both, IN 147 and IN 625. Without DAPA being disclosed in IN 147, there could be no patent with respect to DAPA in IN 147 and which was being infringed by the respondent(s)/defendant(s) by manufacturing drugs/medicines with DAPA as ingredient.

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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 the respondent(s)/defendant(s) 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.

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43. However, under the Indian regime, patent is to be sought and granted with respect to a new product or process. "Product" is not defined in the Act. The said word is thus deemed to have been used in the Act, as commonly understood. "Product" is understood as something that is made to be sold, usually something that is produced by an industrial process or, less commonly, something that is grown or obtained through farming. However, the arguments of the appellants/plaintiffs before us make out IN 147 to be a discovery/invention of a group of formulations, which was capable, with further research, of acting as a drug/medicine for inhibiting re-absorption of sugar in kidneys. The appellants/plaintiffs, on the basis thereof could not have manufactured any drug/medicine and have not pleaded any drug/medicine manufactured post IN 147 and thus it *prima facie* appears, could not have restrained any other person who discovered DAPA, even if from IN 147. In fact we wondered, why the appellants/plaintiffs have pleaded and claimed infringement by the respondent(s)/defendant(s) of both, IN 147 and IN 625. Though in response to our query aforesaid, we expected the appellants/plaintiffs to confine their claim for infringement to IN 625 only but the appellants/plaintiffs stuck to their stand of the respondent(s)/defendant(s) being also in infringement of IN 147. It is obvious therefrom that the appellants/plaintiffs have no legs to stand on, by claiming infringement of IN 625 only, without also claiming infringement of IN 147. However, as held in the impugned judgment/order dated 2nd November, 2020, the question of the respondent(s)/defendant(s), by working DAPA, infringing IN 147 could arise only if DAPA was disclosed in IN 147. If DAPA was disclosed in IN 147, even if better disclosed in IN 625, cannot enjoy two rounds of 20 years of protection, when the legislative policy is to grant protection for a period of one term of 20 years only.

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45. We, at least at this stage are unable to, in the face of the aforesaid pleadings of the appellants/plaintiffs themselves, find any difference between IN 147 and IN 625. The appellants/plaintiffs themselves are found to be pleading DAPA to have been disclosed generally in IN 147 and specifically in IN 625. In the face of the said pleading, no case for injuncting the respondent(s)/defendant(s) during the pendency of the suits is made out. As aforesaid, we entertain doubt as to the very basis of the claim of the appellants/plaintiffs, as noted in the judgment/order dated 2nd November, 2020 identifying the key question in the dispute to

be "whether the compound-in-issue i.e. Dapagliflozin [in short "DAPA"] which, according to the plaintiffs, is covered in IN 147 stands disclosed both, in law as well as on facts".

34. In the face of the afore-extracted passages, it would be facile to even suggest that the simultaneous assertion, by Astrazeneca, of the genus patent IN'147 and the species patent IN'625, resulting in the allegation that the manufacture and sale, by Intas, of dapagliflozin infringed both the genus and the species patents, did not play a predominant role in the Division Bench holding as it did. In para 18, the Division Bench holds that, by simultaneously claiming infringement of the genus and the species patent, Astrazeneca had admitted that DAPA was the subject matter of both patents. In para 21, it is observed, even more significantly, that Astrazeneca was "*claiming two patents...with infringement of both*". This act of Astrazeneca in claiming both the genus and the species patent through DAPA, and alleging infringement of both patents by Intas, was found by the Division Bench to strike at the very root of the claim of Astrazeneca, disentitling it to any interim relief. The simultaneous assertion by Astrazeneca of the genus and the species patent, and the consequent allegation that the manufacturer of DAPA by Intas had infringed both patents, was found by the Division Bench, in para 32 of the report, to amount to a deemed admission, by Astrazeneca, that DAPA was the "invention subject matter" of both the genus and the species patents. By thus claiming the manufacture and sale of DAPA by Intas as infringing the genus and the species patents, the Division Bench observed that Astrazeneca had impliedly acknowledged the disclosure of DAPA in the complete specifications both of the genus and the

species patent. Thus, the act of Astrazeneca, in alleging the manufacture and sale of DAPA by Intas to be infringing the genus as well as the species patent, was found to foreclose Astrazeneca from maintaining any stand that the genus patent did not disclose DAPA.

35. This position is even more prominently underscored in para 36 of the report, in which the Division Bench holds that if the case of Astrazeneca were that DAPA was not disclosed in the genus patent, though 80 other compounds were disclosed, DAPA could not have blamed the manufacture and sale of DAPA by Intas, to be infringing the genus patent IN'147. Para 39 of the report again emphasizes the view of the Division Bench, that, if the genus patent IN'147 did not disclose DAPA, AstraZeneca could not have claimed the manufacture and sale of DAPA by Intas to be infringing IN'147. The concluding observation in para 39 specifically holds that the act of Astrazeneca in pleading infringement of the genus patent IN'147 as well as the species patent IN'625 had, at least at the interlocutory stage, to be treated as an admission, by Astrazeneca, of DAPA being a known substance, while obtaining the genus patent.

36. Para 43 of the report gives voice to the concern, of the Division Bench, as to why Astrazeneca had pleaded and claimed infringement, by Intas, of both the genus and the species patents. Significantly, the paragraph goes on to observe that, when the Division Bench had queried Astrazeneca in that regard, it was expected that Astrazeneca would confine their claim of infringement only to the species patent – *which is what Kudos has done in the present case*. The obvious

sequitur is that, had Astrazeneca restricted its claim of infringement to the species patent, instead of alleging infringement of the genus and species patent both, the outcome of the judgment would have been different. The submission of Mr. Sai Deepak that the ultimate decision in ***Astrazeneca-I*** would not be different even if Astrazeneca had asserted only the species patent, instead of asserting genus and species patents both, is, therefore, clearly unsustainable, in the light of the observations in para 43 of ***Astrazeneca-I***.

37. The insistence, by Astrazeneca, to continue to plead infringement by Intas, of the genus patent IN'147 as well as the species patent IN'625 was found to be defeating the case that Astrazeneca was seeking to set up.

38. Practically, the entire reasoning of the Division Bench of this Court in ***Astrazeneca-I***, therefore, revolves around the fact that Astrazeneca was pleading infringement, by DAPA, of the genus patent IN'147 as well as the species patent IN'625. This assertion of simultaneous infringement of both the genus and the species patents was found to completely defeat the case of Astrazeneca. Perhaps, most significantly, in para 43, the Division Bench observed that Astrazeneca might have had a case, had it restricted its claim of infringement to the species patent, rather than claiming infringement of both the genus and the species patents.

39. In the present case, there is no dispute that Kudos has claimed infringement only of the species patent IN'720 and has claimed no

infringement of the genus patent IN'218. The above observations of the Division Bench in ***Astrazeneca-I***, particularly in conjunction with the manner in which the Division Bench sought to distinguish the judgment of this court in ***FMC-II***, clearly indicates that, in a case where the species patent alone is asserted, and no infringement of the genus patent is pleaded, the decision in ***FMC-II*** would continue to hold the field.

40. In fact, far from ***Astrazeneca-I*** overruling ***FMC-II,*** or ***FMC-II*** being no longer good law after the decision in ***Astrazeneca-I***, my understanding is that, *in a case where a species patent alone is asserted,* ***Astrazeneca-I*** *upholds the decision in* ***FMC-II*** *as representing the correct legal position. The decision in* ***Astrazeneca-I*** *having been upheld by the Supreme Court by dismissal of the SLP, in a case where the species patent alone is asserted, the correct legal position would be the position taken by this Court in* ***FMC-II***.

III. Individual grounds of challenge raised by Mr. Sai Deepak

41. The individual grounds of challenge raised by Mr. Sai Deepak in the present case are all covered by the earlier decisions of this bench in ***FMC-II***, ***Novartis-I*** and ***Novartis-II***. Though appeals may have been preferred against these decisions, I have not been informed of any interlocutory order having been passed, staying their operation.

42. I deem it necessary, therefore, only to allude to the relevant passages from the decisions of this bench in ***FMC-II***, ***Novartis-I*** and

Novartis-II, which address the issues raised by Mr. Sai Deepak, *vis-à-vis* the facts which arise in the present case, rather than re-analyze the legal position *ab initio*.

IV. <u>The coverage v. disclosure conundrum and the challenge on the ground of obviousness and lack of inventive step – Section 64(1)(f)</u>

43. The aspect of whether coverage and disclosure are the same, or whether coverage implies disclosure, has to be decided on the basis of the judgment of the Supreme Court in ***Novartis AG***, as the Supreme Court has specifically alluded to the point. Howsoever one may interpret or understand ***Novartis AG***, it is not permissible for any court, lower in the judicial hierarchy to the Supreme Court, to allow its judicial peregrinations to take it outside ***Novartis AG*** of that decision, when dealing with the aspect of coverage *vis-à-vis* disclosure.

44. In ***FMC-II***, this Court has analyzed the decision in ***Novartis AG*** threadbare, para by para. The conclusion that this Court has arrived is contained in paras 81 to 84 of the decision, which may be reproduced thus:

> "81. Paras 118, 119 and 134 of the decision in *Novartis* have, in my view, to be understood in the light of paras 114 and 116, which set out the submissions advanced, before the Supreme Court, by learned Senior Counsel Mr. Subramanium and Mr. Andhiyarujina. Though the submissions of learned Senior Counsel were, as they necessarily had to be, advanced in the light of the factual controversy before the Supreme Court, the propositions advanced were general in nature, and the findings of the Supreme Court, as contained in paras 118, 119 and 134 also, in my opinion, equally omnibus. What was contended, by learned Senior Counsel, as recorded in paras 114 and 116 of the report, was that "the scope of

coverage is distinct from the scope of disclosure in a patent". This argument stands reiterated, in the same para (para 116) - "that coverage that is granted in respect of a patent is not always co-extensive with what is disclosed in the patent". In the light of the Zimmerman invention, learned Senior Counsel contended that "the patent may be entitled to larger coverage than what is specifically disclosed in it". The teaching in the patent, it was contended, lay "in the disclosure/specification that supports the claim", which "describes the invention". Dealing with these submissions, the Supreme Court held, in para 119 of the report, that "the dichotomy… 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, (seemed) to strike at the very root of the rationale of the law of patent". The words "in *a* patent", as used by the Supreme Court, indicated of the intent of the Supreme Court to be expounding the law in general terms, and not limited to the Zimmerman patent, or the suit patent before it. In fact, a bare reading of para 118 of the report in ***Novartis AG*** makes it clear that the Supreme Court has expressed its view with respect to patents in general. The opening sentence of para 119 of the report is a proposition couched in absolute terms and, in my respectful opinion, it would be folly, on the part of this Court, to restrict those observations to the facts of ***Novartis AG***.

82. According to the Supreme Court (and at the cost of repetition), any dichotomy, sought to be drawn between coverage or claim, and disclosure or enablement or teaching, in a patent, struck at the very root of the rationale of patent law. Obviously, the Supreme Court has disapproved, in no uncertain terms, of any dichotomy being sought to be drawn between coverage and disclosure.

83. Having said that, etymologically, "dichotomy" is not the same as "distinction". The Supreme Court has not held that coverage and disclosure are the same. Nor has it held that there is no distinction between coverage and disclosure. Choosing its words with precision, the Supreme Court has held that there is no "dichotomy" between "coverage" and disclosure". "Dichotomy" is defined, in the Oxford Dictionary, as "a division or contrast between two things that are or are being represented *as being opposed or entirely different*". In holding that there can be no dichotomy between coverage or claim, on the one hand, and disclosure or enablement or teaching, on the other, the Supreme Court has not, therefore, held that they are identical. Accepting the submission of Mr. Sai Deepak would require this Court to place, in the first sentence in para 119 of the report in ***Novartis AG***, the word "dichotomy" with "distinction" or "difference". That, I am

afraid, I cannot do. Apparently, in fact, the Supreme Court has, in disapproving the existence of any "wide gap" between coverage and disclosure, clarified that it merely disapproved of any dichotomy between these concepts, and was not seeking to hold that the concepts were identical.

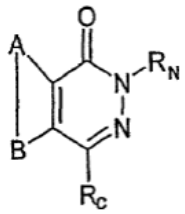
84**.** Indeed, the judgement of the Supreme Court, read thus, would be in entire accord with the covenants of the Patents Act, which make repeated reference, in more than one provision, to "disclosure". Clearly, the framers of the Patents Act did not envisage the "claim" or "coverage" of the claim, to be identical to "disclosure". Nor, for that matter, has the Supreme Court so held. What was being sought to be contended, before the Supreme Court, by learned Senior Counsel was that, though the specific claim in the Zimmerman patent covered Imatinib with its pharmaceutically acceptable salts, and though Imatinib Mesylate was a pharmaceutically acceptable salt of Imatinib and, therefore, covered by the Zimmerman Patent, it was, nevertheless, not disclosed by it. Such an argument, if accepted, would amount to holding that there was *complete dichotomy* between "coverage" and "disclosure", with no connection between the two. It would amount to holding that, while examining what was disclosed in a patent, the authority, or the Court concerned, was to remain oblivious to the coverage of the patent. Such a dichotomy, which would result in a "wide gap" between coverage and disclosure was, in terms, disapproved by the Supreme Court. If, however, there was clear coverage of a product in the claim (as was found to exist in the Zimmerman Patent, qua Imatinib Mesylate), it would be difficult for the patent holder to assert, before the Court, that, despite such coverage, the claim did not disclose the product. That, in my view, is what ***Novartis AG*** holds. It does not pronounce that coverage and disclosure are identical or synonymous terms, in patent law. The submission, by Mr. Sai Deepak, to that effect cannot, therefore, be accepted."

45. It cannot, therefore, be said that coverage is the same as disclosure or that, by accepting coverage of the impugned product by the genus patent, the plaintiff also admits disclosure.

46. A bare glance at the Markush structure claimed in Claim I of the genus patent IN'218, *vis-à-vis* the chemical structure of Olaparib as claimed in Claim I of the species patent IN'720, makes it apparent

that Olaparib cannot be said to have been disclosed in the genus patent.

47. Natco's pleadings in this regard are admittedly to be found in paras 89 to 106 of the written statement filed by way of response to the present plaint, which read thus:

> "89. The following submissions are made without prejudice to the foregoing averments as well as subsequently following submissions under other grounds of revocation.
>
> 90. It is submitted that the claims of IN'720 lack inventive step and/or are obvious in view of the following prior art, when taken independently or in any combination:
>
> ***Teachings of WO'576***
>
> 91. WO'576 discloses the preparation of specific product claimed in IN'720. *The specific portions of the complete specification of WO'576 specifically teaches and also categorically suggests the the specific substitutions in the Markush structure of WO'576 which result in Olaparib claimed in IN'720.* For the purpose of convenience, the specific portions of the complete specification of WO'576 are reproduced below:
>
> WO'576 discloses the following compound
>
> 
>
>
> wherein
>
> A-B, R_N and RC can be optionally substituted.
>
> **Substitution of A-B**
>
> Page 5 of the complete specification states the second aspect of the present invention wherein

A and B together represent an optionally substituted, fused aromatic ring

At Page 7 of the complete specification describes aromatic ring as follows:

The term "aromatic ring" is used herein in the conventional sense to refer to a cyclic aromatic structure, that is, a cyclic structure having delocalised n-electron orbitals.

Page 7 and Page 8 of the description:

In one group of preferred embodiments, ***the aromatic group comprises a single aromatic ring****, which has five or six ring atoms, which ring atoms are selected from carbon, nitrogen, oxygen, and sulphur, and which ring is optionally substituted. Examples of these groups include* ***benzene****, pyrazine, pyrrole, thiazole, isoxazole, and oxazole.*

Substitution of RC

R_C is $-CH_2-R_L$;

Substitution of RL

R_L is optionally substituted phenyl

At Page 19 of the description:

R_L is preferably a ***benzene ring****, naphthalene, pyridine or 1,3-benzodioxole, and more preferably a* ***benzene ring***

When ***R_L is a benzene ring, it is preferably substituted****. The one or more substituents may be selected from: C_{1-7} alkyl, more preferably methyl, CF_3; C_{5-20} aryl; C_{3-20} heterocyclyl; halo,* ***more preferably fluoro****; hydroxy; ether, more preferably methoxy, phenoxy, benzyloxy, and cyclopentoxy; nitro; cyano****; carbonyl groups****, such as carboxy ester and* ***amido****; amino (including sulfonamide), more preferably $-NH_2$, -NHPh, and cycloamino groups, such as morpholino; acylamido including ureido groups, where the acyl or amino substituent is preferably phenyl, which itself is optionally fluorinated; acyloxy; thiol; thioether; sulfoxide; sulfone.*

On page 15 of the complete specification preferred substituents of the benzene ring when ***R_L is phenyl*** is given and includes:

Amido *(carbamoyl, carbamyl, aminocarbonyl, carboxamide) :* ***-C***

(=0)NR[1]R[2], *wherein R^1 and R^2 are independently amino substituents, as defined for amino groups. Examples of amido groups include, but are not limited to, -C(=0)NH_2, -C(=0)$NHCH_3$, -C(=0)$N(CH_3)_2$, - C(=0) $NHCH_2CH_3$, and -C(=0)$N(CH_2CH_3)_2$, as well as amido groups in which* ***R^1 and R^2, together with the nitrogen atom to which they are attached, form a heterocyclic structure*** *as in, for example, piperidinocarbonyl, morpholinocarbonyl, thiomorpholinocarbonyl, and* ***piperazinocarbonyl.***

Substitution of RN

92. The specific disclosures in WO'576 regarding these particular substitutions provides the teaching, suggestion and motivation and also makes it obvious for a person skilled in the art to reach to the desired product i.e., Olaparib claimed in IN'720.

93. It is pertinent that there is nothing in IN'720 which would show any technical advancement or economic significance over the disclosure of WO'576 – given the substantial identity of the respective disclosures (as outlined above under prior publication and relied on for purposes of brevity as if reproduced herein).

94. Given that the dosages, the modes of formulation and even the concentration of active in formulation are identical, IN'720 is woefully lacking in any material which would show the purported inventive step of the claims that were granted. It is in fact equally pertinent that Olaparib, i.e.,Compound 168 of IN'720 actually lacks supporting disclosure to show that it has the same benefits of IC50 values or potentiating growth factor values as the remaining compounds of that document, let alone better values than the compounds disclosed in WO'576. Simply put, IN'720 lacks any seed material to support the claim of inventive step over WO'576.

95. It is therefore submitted that IN'720 must be rejected alone on the ground of lack of inventive step and/or obviousness based on WO'576 alone.

Teachings of WO 2002/014090

96. Yet another prior art on the basis of which IN'720 lacks inventive step is WO'090. The details of WO'090 are as follows:

Title of the Invention	Amino-Phthalazinone Derivatives Active as Kinase Inhibitors,

	Process For their Preparation and Pharmaceutical Composition Containing them
Date of filing	July 30, 2002
Date of effective filing	July 30, 2002
Date of priority	Aug 07, 2001 (US)
Date of publication	Feb 20, 2003
Name of applicant	Pharmacia (IT)

97. The application was published on 20.02.2003 i.e., before the earliest priority dated of IN'720 and hence, is prior art for IN'720.

98. The cited prior art relates to the amino phthalazinone derivatives active as Kinase inhibitors. Page 4 Placitum 16 of WO'090 states:

> *The present invention provides a method for treating diseases caused by and/or associated with an altered protein kinase activity, by administering to a mammal in need thereof an effective amount of an amino-phthalazinone derivative represented by formula (I):*
>
> *wherein the relevant teaching is as follows:*
>
> ***Ra and Rb** are, each independently, a **hydrogen atom** or a group,*
> ***R2 is a hydrogen atom** or it is a group, optionally further substituted **m is 0** or an integer from 1 to 3;*
>
> ***R1** is hydrogen or an **optionally substituted group** selected from*
> *alkyl, cycloalkyl, cycloalkylalkyl, aryl, **arylalkyl**, heterocyclyl or*
> *heterocyclylalkyl*

Page 31 placitum 35 defines arylalkyl group as:

*arylalkyl group such as, for instance**, the benzyl group**, by working*
according to conventional methods.

Page 10 placitum 4 further describes the substitution of benzyl group as:
***optionally substituted in any of the free positions by one or more groups**, for instance 1 to 6 groups, selected from: **halogen**, nitro, oxo groups (=0) , carboxy, cyano, alkyl, perfluorinated alkyl, alkenyl alkynyl, cycloalkyl, aryl, heterocyclyl, a ino groups and derivatives thereof such as, for instance, alkylamino, dialkylamino, arylamino, diarylamino, ureido, alkylureido or arylureido; **carbonylamino** groups and derivatives thereof such as, for instance, formylamino, **alkylcarbonylamino**, alkenylcarbonylamino, arylcarbonylamino, alkoxycarbonylamino.*

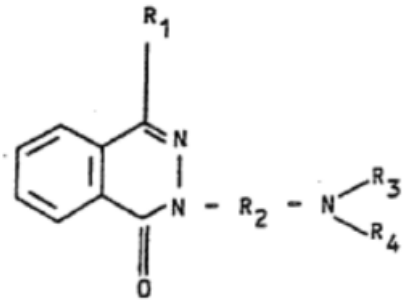
99. The above disclosure of WO'090 not only teaches but also suggests the specific substitutions described above. For a person of skill in the art, this also provides the motivation to try and practice the substitutions taught and suggested in WO'090 since the cited document also relates to providing anti-tumour compounds. The difference if any resides in that WO'090 suggests and additional substitution of an amino on the benzene ring. There is however, nothing to suggest that the unsubstituted phthalazinone would be ineffective or is not preferred. In any event, even this differential is overcome when WO'090 and WO'576 are read together – which would provide a phthalazinone derivative without the additional amino substitution on the benzene ring. There is sufficient motivation to read the two documents together since both in essence relate to phthalazinone derivatives and both purportedly provide compounds with anti-tumoral activity. When the teaching of WO'090 is read together with the teachings of WO'576, there is sufficient, teaching, suggestion and motivation which renders the claims of IN'720 and in particular Olaparib obvious for a person of skill in the art. On the above-mentioned ground, IN'720 lacks inventive step and is obvious to a person of skill in the art.

Teachings of EP 0289881

100. EP'881 relates to 2-aminoalkyl-4-benzyl-1-(2H)-phthalazinone derivatives and was published on 09.11.1988. It is therefore prior art for IN'720. EP'881 describes compounds which are useful as antiasthmatic, antiallergic, Paf-antagonistic (Paf = platelet activating factor, mediator, which triggers asthma inter alia) and leukotriene-inhibition. The EPO machine-translated copy of EP'881 is filed in the proceedings.

Page 1 of EP'881 states:

"….a process for preparing basic substituted phthalazinone of the general formula



*in which **R1** represents an aryl or **aralkyl** radical optionally substituted in the nucleus, R2 represents a divalent straight or branched aliphatic chain having at least 2 and at most 5 carbon atoms, and R3 and R4 denote low molecular weight alkyl groups which, together with the nitrogen, may be members of a heterocyclic ring, or their salts or quaternary ammonium compounds. For these compounds, a histaminolytic (antihistamine) effect, spasmolytic and local anaesthetic effect is specified.*

*The radical **R1 is preferably** in the 4-position of the phenyl ring; **occurring C1-C6-alkyl groups**, C1-C6-alkoxy groups, alkenyl groups or alkynyl groups can be straight or branched, in particular these radicals consist of 1-4 or, if they are unsaturated, of 3-4 C atoms.*

If R3 is an alkenyl or alkynyl group, there is at least one saturated C atom between the unsaturated bond and the nitrogen. The unsaturated bond is preferably in the 2,3-position or 3,4-position.

The C3-C8-cycloalkyl radical is in particular the cyclopentyl radical or cyclohexyl radical.

If R3 represents a phenyl-C1-C6-alkyl radical, this may be mono -,di-or trisubstituted by the stated radicals. The alkyl part of this phenylalkyl radical preferably consists of one, two or three C atoms and may optionally also be branched.

The alkylene bridge Alk can be straight or branched and preferably consists of two, three or four C atoms. If this alkylene bridge contains Alk a double bond, it is isolated from the group NR2 R3 if R2 is hydrogen (ie, not conjugated to this group). Preferably, at least one saturated carbon atom is located between such a double bond and the two nitrogen bonds.

Particularly favourable effects have, for example, those compounds where the radicals R1 to R3, Alk have the following meanings: R1 = fluorine, chlorine or bromine, in particular in the 4-position, preferably fluorine in the 4-position; R2 = C1-C6-alkyl, preferably methyl; R3 = phenyl-C1-C6-alkyl, optionally substituted as indicated.

The ***substituents of the phenyl-C1-C6-alkyl radical are*** *preferably C1-C4-alkyl groups (in particular methyl) or a* ***halogen*** *(for example Cl,* ***F****) or C1-C4-alkoxy groups (in particular methoxy groups). The substituents in the phenyl part of this phenylalkyl radical are preferably in the 2-position, 3-position, 4-position or 2,4-position. Occurring alkyl, alkoxy, alkanoyloxy, alkanoylamino or alkoxy alkyl groups may be straight or branched.Alkyl or alkoxy radicals preferably consist of 1 to 4 C atoms, the alkanoyl radicals preferably consist of 2 to 4 C atoms.*

101. The teachings of EP'881 suggest similar structure of phthalazinone derivatives and also suggests towards the substitution of phenyl at R1 which is further substituted with a halo group (one of which is F) as preferred. Hence, if such teachings of EP'881 are read with the teachings of WO'576 and/or WO'090, it clearly suggests and teaches towards what is claimed as an "invention" IN'720, thus rendering claims 1 and 2 of IN'720 obvious for a person of skill in the art. Hence, on the basis of the teachings of EP'881 read with above cited arts, IN'720 is obvious and lacks inventive step.

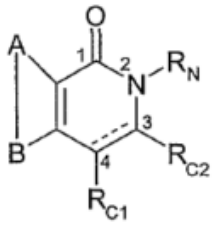
Teachings of WO 2002/090334

102. Another prior art on the basis of which IN'720 lacks

inventive step is WO'334. The present Patent has also been filed by the same entity i.e., Kudos Pharmaceuticals and even has at least two common inventors.

103. It is respectfully submitted that, on the basis of specific disclosure in WO'334, IN'720 lacks inventive step. For the perusal of this Hon'ble court, the specific teachings of WO'334 which results in the final product claimed in IN'720 is reproduced herein:

The complete specification at page no. 5 reproduces the following compound



wherein:

A-B together represent an optionally substituted aromatic ring One of the RC_1 and RC_2 is $-CH_2-R_L$ and other of RC1 and RC_2 is H R_L is optionally substituted Phenyl; and

R_N is hydrogen

On page 17 placitum 20 onwards, Further preferences of substitution is discussed as:

It is preferred that only one of RC1 And RC2 is represented by $-L-R_L$, and the other of RC1 and R_{C2} is H

<u>On Page 17 Placitum 25</u>
The fused aromatic ring(s) represented by -A-B- preferably consist of solely carbon ring and thus may be Benzene, naphthalene and is more preferably Benzene.

<u>On page 17 placitum 31</u>

RN is preferably selected from hydrogen.

<u>On Page 18 placitum 28</u>

*R_L is preferably C_{5-20} aryl, and more **preferably a benzene** ring, naphthalene, pyridine, 1,3-benzodioxole or furan.*

When RL is a benzene ring, it is preferably substituted. The one or more substituents may be selected from: C_{1-7} alkyl, more preferably methyl, CF_3; C_{5-20} aryl, C_{3-20} heterocyclyl; ***halo, more preferably fluoro;*** *hydroxy; ether, more preferably methoxy, phenoxy, benzyloxy, and cyclopentoxy; nitro; cyano; carbonyl groups, such as carboxy, ester and* ***amido;*** *amino (including sulphonamide), more preferably -NH_2, -NHPh, and cycloamino groups, such as morpholino; acylamido, including ureido groups, where the acyl or amino substituents is preferably phenyl, which itself is optionally fluorinated; acyloxy; thiol; thioether; sulphoxide; sulphone*

On Page 14 placitum 8 amido group is explained as:

Amido *(carbamoyl, carbamyl, aminocarbonyl, carboxamide) :* ***-C (=0)NR_1R_2,*** *wherein R^1 and R^2 are independently amino substituents, as defined for amino groups. Examples of amido groups include, but are not limited to, -C(=0)NH_2, -C(=0)$NHCH_3$, -C(=0)$N(CH_3)_2$, -C(=0) $NHCH_2CH_3$, and -C (=0)N $(CH_2CH_3)_2$, as well as amido groups in which* ***R^1 and R^2, together with the nitrogen atom to which they are attached, form a heterocyclic structure*** *as in, for example, piperidinocarbonyl, morpholinocarbonyl, thiomorpholinocarbonyl, and* ***piperazinocarbonyl*** *.*

104. It is respectfully submitted that the only difference that WO'334 shows is the specific substitution of Nitrogen (N) at RC2. If the teachings of WO'334 are read together with WO'576, it makes it obvious for the person skilled in the art to reach Olaparib now claimed in IN'720.

105. It is further submitted that such specific disclosure regarding the substitutions and the fact that the application has been filed by the same applicant and have at least 2 common inventors clearly shows that the product claimed in IN'720 was always within the knowledge of Plaintiff 1 and that the filing IN'720 was an attempt at protecting an import monopoly and evergreening of patent protection for Olaparib.

106. On the basis of above disclosures in the above cited prior arts read alone or in combination, it is respectfully submitted that IN'720 lacks inventive step and/or is obvious."

48. A bare reading of the afore-extracted paragraphs from the written statement of Natco indicates that Natco is arriving at chemical structure of Olaparib, in the case of each of the referred prior art inventions, by choosing select radicals out of the several suggested substitutions in the complete specifications of the prior art patents. *There is not a whisper of an averment, in the written statement, to justify such preferential selection.* By way of example, when Natco picks the amido radical out of a choice of "carbonyl groups, such as carboxy, ester and amido", or carbylamino and its alkylcarbylamino derivative out of a choice of "alkylamino, dialkylamino, arylamino, diarylamino, ureido, alkylureido or arylureido; carbonylamino groups and derivatives thereof such as, for instance, formylamino, alkylcarbonylamino, alkenylcarbonylamino, arylcarbonylamino, alkoxycarbonylamino", the written statement does not indicate *why* Natco chooses to make *that particular choice*. Nor does it contain anything to indicate that the teachings in the suggested prior arts would lead a person skilled in the art to *make that particular selection*. The exercise undertaken by Natco is, therefore, clearly an exercise of hindsight reconstruction, armed with prior knowledge of the necessary radicals which are to be substituted onto the Markush Claim I of the genus patent IN'218 in order to arrive at claim I of the species patent IN'720, by cherry-picking the appropriate radicals for substitution. Such hindsight operation, *prima facie*, demolishes the plea, of Natco that Claim I in the suit patent is obvious from the genus patent, or, for that reason, that the species patent is vulnerable to invalidity on the ground of want of inventive step, under Section 64(1)(f) of the Patents Act.

49. Indeed, if Olaparib were so obvious from the suggested prior arts, there is no explanation why it took 19 years, after the genus patent had been granted, for Natco to synthesize Olaparib. Even as an old patent, which has weathered 19 years of uninfringed existence, therefore, the suit patent is entitled to protection.

V. Re. allegation of anticipation by prior claiming – Section 64(1)(a)

48. Section 64(1)(a) has also come up for analyses by this Court in ***FMC-II***, and paras 107 and 109 to 112 of the said decision may in this context be thus reproduced:

> **"**107**.** Section 64(1)(a) provides, as a ground for revoking a patent already granted, claiming, of the invention claimed in the claim of the said patent, in a valid claim of earlier priority date, contained in the complete specification of another patent granted in India. The statutory preconditions, for this clause to apply as a ground for alleging invalidation of the suit patent, are that (i) the invention claimed in the claim, under consideration, of the suit patent, was claimed in another valid claim, (ii) said valid claim was of earlier priority date and (iii) said valid claim was contained in the complete specification of another patent granted in India (for ease of reference, "the prior patent"). A defendant who seeks to allege invalidity, or vulnerability, of a suit patent, under Section 64(1)(a), therefore, predicates his case on the premise that the prior patent was valid. An allegation that the prior patent was invalid is fatal to any challenge to the validity of the suit patent under Section 64(1)(a). The defendant in the present case, in asserting vulnerability of IN'307 as having been anticipated by prior claiming in Claim 22 of IN'978, therefore, has to accede to the validity of Claim 22 of IN'978.
>
> *****
>
> 109**.** CTPR is the "invention… claimed in Claim 1 of the complete specification" in IN'307, i.e. the suit patent. The "valid

claim of earlier priority date" in the prior patent, for the purposes of Section 64(1)(a), as alleged by Mr. Sai Deepak, is Claim 22 of IN'978. Section 64(1)(a) would, therefore, render the suit patent vulnerable if CTPR is, *prima facie*, claimed in Claim 22 of IN'978.

110. I have already held, hereinabove, that CTPR is *not* claimed, or even disclosed, in Claim 22 of IN'978. Claim 22 of IN'978 claims a Markush moiety. It is possible to travel from said Markush moiety to Claim 1 in IN'307, or to CTPR, only by cherry picking select radicals out of the innumerable choices provided in the complete specifications accompanying Claim 22 of IN'978, for substitution on said Markush moiety. Save and except for demonstrating how, by substituting such select radicals, it is possible to move from the Markush moiety in Claim 22 of IN'978 to Claim 1 of IN'307, or to CTPR, the defendant has, in its written statement, not indicated any teaching or guidance, available in the complete specifications of IN'278, as would guide a person skilled in the art to pick the select radicals and substitute them on the Markush moiety in Claim 22 of IN'978, so as to "lead" him to CTPR. Neither CTPR, nor the Markush formula claimed in Claim 1 of IN'307, is obvious from the disclosure provided in Claim 22 of IN'978.

111. The defendant appears to be aware of this legal position, as is apparent from the assertion, in para 21 of the written submissions filed by the defendant that "Claim 22 of IN'978 encompasses within its scope the entire principal claim, Claim 1 of the impugned patent IN'307, thereby rendering the entirety of the principal claim of IN 307 vulnerable to revocation". The correctness of this argument of the defendant appears to be somewhat doubtful and, in fact, also appears to be contrary to the contention, of Mr. Sai Deepak, that the words used in Section 13(1)(b) have to be strictly construed. While advancing this contention, the defendant has introduced two new concepts, which find no place in Section 13(1)(b), viz. the concepts of "scope" and "coverage". Section 13(1)(b) clearly applies where a claim in the suit patent "is *claimed* in any claim of any other complete specification". It does not make any reference either to the scope of the claim or the coverage of the claim. What is required therefore, *prima facie*, is comparison of the claims, not whether the claim in the suit patent is covered by or within the scope of the claim in the genus patent. This position is also conceded by the defendant, in its written submissions, by accepting that, ordinarily, a challenge of anticipation by prior claiming has to be decided on a claim-to-claim comparison. The defendant would seek to contend that, in the present case, this exercise is obviated because of the admission - as the defendant would perceive it - by the plaintiff, in

its plaint and replication, of the coverage of CTPR in Claim 22 of IN'978. No such admission is, as already held here in before, discernible from the paragraphs on which the defendant seeks to place reliance. A claim-to-claim comparison, even as per the defendant is, therefore, necessary, in order to examine the applicability of Section 64(1)(a) - or, for that matter, Section 13(1)(b) - to the facts of the present case. Such comparison, when undertaken, does not make out a prima facie case that these provisions apply.

112. The defendant has made a strained effort to justify invocation of Section 13(1)(b)/64(1)(a) by contending that, even if Claim 1 in IN'307 includes variants which were outside the scope of Claim 22 in IN'978, the former claim was, nonetheless, rendered *prima facie* vulnerable to the extent it fell within the scope of Claim 22 of IN'978, i.e. to the extent it claimed CTPR. Neither Section 13(1)(b), nor Section 64(1)(a), in my considered opinion, lends itself to such an interpretation. All that these provisions require the Court - or authority before whom the challenge to the validity is raised - to do is to assess whether the invention, insofar as it has been claimed in the suit patent, was, or was not, claimed in the prior patent. CTPR, directly or indirectly, is not *claimed* in Claim 22 of IN'978. The highest that the defendant can assert, at least at this juncture, is that CTPR, as an arthropodicidal anthranilamide, falls within the broader Markush coverage of Claim 22 of IN'978. In the discussion here in before, I have already opined that the sequitur of any such *coverage* cannot be that CTPR has been *claimed* in Claim 22 of IN'978."

49. As has been correctly contended by Mr. Pravin Anand, a plea of vulnerability of invalidity on the ground of anticipation by prior claiming can successfully be raised *only if the claim in the suit patent has been claimed in a patent of an earlier priority date. There must, therefore, be identity of claims*. Para 16 of the written submissions filed by Mr. Sai Deepak, it is asserted, in this regard, thus:

"16. From the above it is clear that anticipation by prior claiming u/Sec. 64(1)(a) is dependent on reasonable construction of the claim to assess the scope of its coverage in respect of a product but is in no way contingent on specific disclosure of the product in the complete specification. After all, what the patentee can assert against third parties in the form of a sword must be equally available to the third parties as a shield to defend themselves

> against the patentee's claim of infringement. Any other interpretation of the statutory scheme would defeat the manifest legislative intent and that too in a critical realm such as the pharmaceutical industry. The concept of enabling disclosure may at best be applicable with respect to the ground of anticipation by prior publication, but not in the context of anticipation by prior claiming since Sec. 64(1)(a) is meant to act as a fetter on the patentee's ability to evergreen its right to sue based on the claim and is therefore not contingent on the scope or specificity of the disclosure. Therefore, to apply the test of enabling disclosure in the context of 64(1)(a) is to foist on it one of the possible standards which may be applicable to Sec. 64(1)(e)."

50. The assertions in the afore-extracted passage from the written submissions of Mr. Sai Deepak, in my view, is based on a fundamentally erroneous legal premise.

51. Mr. Sai Deepak seeks to contend that a claim of vulnerability of the suit patent to invalidity on the ground of anticipation by prior claiming "is dependent on reasonable construction of the claim to assess *the scope of its coverage* in respect of a product, but is in no way contingent on specific disclosure of the product in the complete specification". It is further sought to be contended that specificity of disclosure may be a relevant test for Section 64(1)(e), but cannot be regarded as a relevant test for Section 64(1)(a) of the Patents Act.

52. The view expressed by me in ***FMC-II***, as already extracted hereinabove, compels me to disagree with Mr. Sai Deepak's submissions. In my view, Section 64(1)(a) is clear and categorical in the words it uses. It states that the invention, *so far as claimed* in the suit patent, *has to have been claimed in a valid claim* of earlier priority date for the suit patent to be regarded as vulnerable to

invalidity on the ground of anticipation by prior claiming. *There has, therefore, to be identity of claims. The claim asserted in the suit patent, must have been claimed in a complete specification relating to a patent of earlier priority date.* Then, and only then, can a plea of invalidity on the ground of anticipation by prior claiming be successfully laid.

53. A claim is even more specific than a disclosure. On a plain claim to claim comparison, it is clear that Olaparib, as Claim I in the suit patent IN'720, has never been claimed in any earlier patent to which Mr. Sai Deepak draws attention. The Markush structure claimed in Claim I of the genus patent IN'218 certainly cannot be said to claim Claim I in the suit patent IN'720. As such, no *prima facie* case of anticipation by prior claiming can be said to exist.

Reliance on Form 27s, PTE applications by Kudos in Australia and Korea and Eurasian patent EU 006300 and Russian patent RU 2755865

54. Mr. Sai Deepak has sought to place reliance on the Forms 27 filed by Kudos in respect of IN'720 and IN'218, the PTE applications filed by Kudos in Australia and Korea and the identity of the Eurasian and Russian equivalents of alleged identity of the claims in Russian patent RU'865 with the claims in IN'720.

55. I do not see how this Court, in exercise of its jurisdiction under Order XXXIX Rules 1 and 2 of the CPC, can delve into such depth of detail. It is true, this Court has, in earlier decisions, done so.

However, in view of the note of caution sounded by the Supreme Court in ***Pernod Ricard***, I am of the opinion that some kind of rethink is necessary on this aspect. There is no denying the fact that orders on applications filed in pharma patent cases for interim relief often go into such depth of details that practically nothing remains for adjudication in the suit. This may not be an acceptable way of proceeding.

56. Particularly when dealing with a challenge to the validity of the suit patent on the ground of anticipation by prior claiming, once the Court finds, on facts, by claim to claim comparison, that there is *no* anticipation by prior claiming, statements made in other jurisdictions, or in documents filed by the plaintiffs elsewhere, cannot *make out* a case of anticipation by prior claiming, even at the *prima facie* stage. ought not to legitimately form part of the consideration. The plaintiffs would have, during the course of trial, every opportunity to explain the circumstances in which such statements were made, and before grant of such opportunity, where a *prima facie* clear case of lack of anticipation of prior claiming is made out, the matter must rest there, when dealing with an Order XXXIX Rule 1 and 2 applications.

57. I have nonetheless reproduced, in this regard, the defence raised by Mr. Anand to the various points raised by Mr. Sai Deepak, and for the purposes of adjudicating the present Order XXXIX Rule 1 and 2 applications, suffice it to state that the challenges have not been left unanswered. The response by Mr. Praveen Anand raises, at the very least, triable issues. When, on a claim to claim comparison, no case of

anticipation of prior claiming is found to exist, it cannot be said that the defendant has raised a credible challenge on that ground.

VI. Re. Anticipation by prior publication – Section 64(1)(e)

58. Anticipation by prior publication has also been dealt with, by this Bench, in its decisions in ***FMC-II*** and ***Novartis I***. Paras 117 to 118, 124 to 128 and 133 of ***FMC-II*** and para 222 of ***Novartis I*** may, in this context, be reproduced thus:

From FMC-II

"117**.** Section 64(1)(e) states where the invention, so far as claimed in the suit patent, is not new, having regard to either (i) what was publicly known or publicly used in India before the priority date of the claim in the suit patent or (ii) what was published in India or elsewhere in any of the documents referred to in Section 13. Unlike Section 64(1)(a), therefore, which is a self-contained provision, Section 64(1)(e) refers us back to Section 13. Sub-sections (1)(a) and (2) of Section 13 are relevant, and maybe reproduced thus:

> "**13. Search for anticipation by previous publication and by prior claim -**
>
> (1) The examiner to whom an application for a patent is referred under section 12 shall make investigation for the purpose of ascertaining whether the invention so far as claimed in any claim of the complete specification -
>
> (a) has been anticipated by publication before the date of filing of the applicant's complete specification in any specification filed in pursuance of an application for a patent made in India and dated on or after the 1st day of January, 1912;
>
> *****
>
> (2) The examiner shall, in addition, make investigation for the purpose of ascertaining, whether the invention, so far as claimed in any claim of the complete specification, has been anticipated by publication in India or elsewhere in any document other than those mentioned in subsection (1)

before the date of filing of the applicant's complete specification."

118. Whether under clause (1)(a) or (2), what Section 13 requires is publication of the invention, claimed in the suit patent, in any document, before the date of filing of the complete specification in the suit patent.

xxxxx

124. Section 64(1)(e) starts with the words "that the invention so far as claimed in any claim of the complete specification is not new". This necessarily refers us back to the definition of "new invention" in clause (l) of Section 2 as meaning "any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e., the subject matter has not fallen in public domain or that it does not form part of the state of the art". "Anticipation", when used in the Patents Act, has its own peculiar legal connotation. Though "anticipation", *per se*, is not separately defined, Section 13 provides for anticipation only by prior publication or by prior claim. Section 64(1)(e) deals with the liability of a patent to revocation on the ground of anticipation by prior publication. In order for anticipation by prior publication to constitute the basis for revoking a patent under Section 64(1)(e), it is necessary that, consequent to such anticipation, the patent is no longer "new"; which in other words, the invention patented thereby has lost its character as a "new invention", by reason of anticipation by prior publication. Section 64(1)(e), therefore, requires satisfaction of two indicia, viz. (i) that there has been anticipation by prior publication and (ii) as a consequence, the invention cannot be treated as a "new invention". This is counterbalanced by the definition of "new invention", which envisages absence of novelty either on account of anticipation by publication, or on account of use. We are not, in the present case, concerned with loss of novelty on account of prior use of the invention in the suit patent, i.e. CTPR, no such case having been pleaded by the defendant. The defendant pleads loss of novelty on the ground of anticipation by prior publication.

125. Section 64(1)(e) is, on a plain reading, somewhat peculiarly - and significantly - worded. The words "before the priority date of the claim" succeeds the first part of the clause, i.e. the words "what was publicly known or publicly used in India". No such caveat as to time follows the latter part of Section 64(1)(e), which deals with publication in India or elsewhere in any of the documents referred to in Section 13. Three circumstances are, therefore, contemplated,

in Section 64(1)(e) as divesting the invention in the suit patent of novelty, viz. (i) public knowledge in India before the priority date of the claim in the suit patent, (ii) public usage in India before the priority date of the claim in the suit patent and (iii) publication in India or elsewhere in any of the documents referred to in Section 13. Section 64(1)(e) does not, therefore, envisage publication of the invention in India or elsewhere in any of the documents referred to in Section 13 *prior to the priority date of the claim in the suit patent*. The reference, by Mr. Sethi, to the priority date of the suit patent, does not, therefore, appear to be appropriate, in view of the manner in which Section 64(1)(e) has been crafted by the legislature.

126. That does not, however, mean that the circumstance of prior publication, envisaged in the second part of Section 64(1)(e), is completely open ended, with no *terminus ad quem*. What, then, is the *terminus ad quem*, for the purposes of prior publication under Section 64(1)(e)? The legislature has not deemed it appropriate to provide a *terminus ad quem* for the latter part of Section 64(1)(e), which deals with the prior publication, apparently because this part of the clause is to be read in conjunction with Section 13, which provides the appropriate *terminus ad quem*, in clauses (1)(a) and (2), which have already been reproduced hereinabove, and which envisage anticipation by prior publication. The *terminus ad quem* provided in respect of anticipation by prior publication, in clauses (1)(a) and (2) of Section 13, *is the "date of filing of the applicant's complete specification", and not the priority date of the suit patent*. The priority date of the suit patent is, therefore, *prima facie* irrelevant for the purposes of vulnerability on the ground of anticipation by prior publication, Section 64(1)(e) read with Section 13 of the Patents Act. What has to be seen is whether, prior to the date of filing of the complete specification in the suit patent, *the invention, i.e. CTPR in the present case*, was published in India or elsewhere in any document.

127. Can there be publication of a patent, relating to an invention without disclosure of the invention in the patent?

128. Publication involves making known to the public the patent application. Every application is required to disclose the invention for which it relates. Sub-section (4) of Section 10 of the Patents Act[4] (already reproduced above) specifically requires disclosure, in the complete specification of the patent, not only of the invention, its operation or use and the method by which it is to be performed, but also its claims defining the scope of the invention for which protection is claimed. In order, therefore, for the defendant to be

able to successfully allege that CTPR was published in US'424 and US'357 (being the US equivalent of EP'508), the defendant would have to establish that CTPR was disclosed in these patents."

xxxxx

133. Neither of these patents claims, or discloses, CTPR. Besides, they are pharmaceutical patents, relating to pharmaceutical products for therapeutic administration. There is also substance in Mr. Sethi's contention that these are also Markush claims, and cannot, therefore, be said to "teach" synthesising of CTPR. I am unable, prima facie, to convince myself that CTPR stands claimed, or disclosed, in these patents. Sans any claim or disclosure of CTPR, it cannot be said that CTPR was published either in US'424 or US'357 (or, therefore, in EP'508)."

From Novartis-I

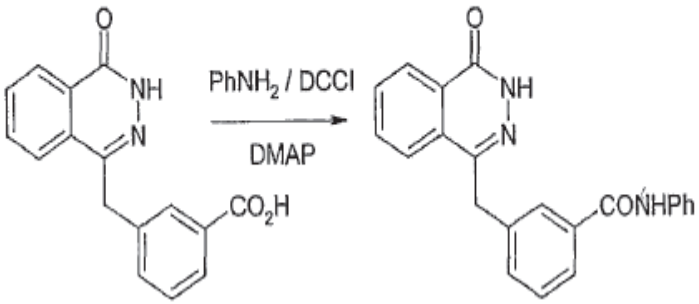
"222. Section 64(1)(e) envisages, as a ground for revocation of a patent, "that the invention so far as claimed in any claim of the complete specification is not new, having regard to what was publicly known or publicly used in India before the priority date of the claim or to what was published in India or elsewhere in any of the documents referred to in Section 13". The plea of vulnerability of the suit patent IN 161 on the ground of anticipation by prior publication, as advanced by Mr. Sai Deepak, is predicated on the latter half of this Clause. Section 64(1)(e) refers back to Section 13. Anticipation by publication finds reference in Clauses (1)(a) and (2) of Section 13. Section 13(1)(a) refers to anticipation by publication of the applicant's complete specifications in any specification filed in pursuance of an application for a patent made in India and does not, therefore, apply to the ground taken by Mr. Sai Deepak. Section 13(2) refers to anticipation by publication of the invention, so far as claimed in any claim of the complete specification, by publication in India or elsewhere in any document before the date of filing of the complete specification of the suit patent. The use of the expression "so far as claimed", in Section 13(2) would, therefore, require identity in the extent of claim contained in the specification in the suit patent and in the specification of the prior art which is cited for the purpose of alleging anticipation by prior publication."

59. In para 126 of ***FMC-II***, this Bench has clearly rejected Mr. Sai Deepak's contention that the *terminus ad quem* for determining anticipation by prior publication is the priority date of the suit patent.

It is held, in the said para, that the priority date of the suit patent is *prima facie* irrelevant, while examining vulnerability on the ground of anticipation by prior publication and that, when Section 64(1)(e) is read with Section 13 of the Patents Act, what has to be seen is whether, prior to the date of filing of the complete specification of the suit patent, the asserted invention was published in India or elsewhere in any document.

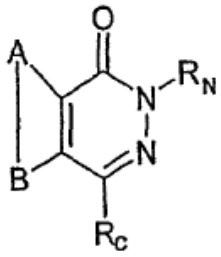
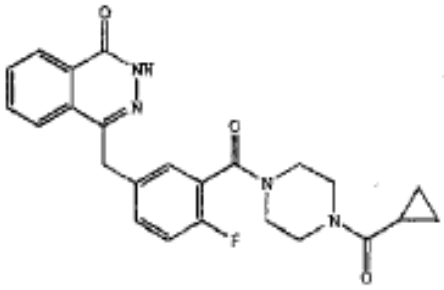
60. Mr. Sai Deepak has placed reliance on the genus patent WO 2002/36576 (WO'576), equivalent to IN'218 to contend that Claim 1 in the suit patent, i.e. Olaparib, stands anticipated by prior publication in WO'576. He relies, for this purpose, on Compound 278 in WO'576, and the process of its synthesis as reflected in the complete specifications in WO'576.

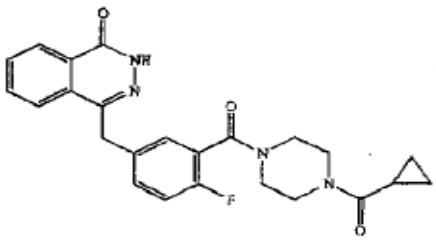
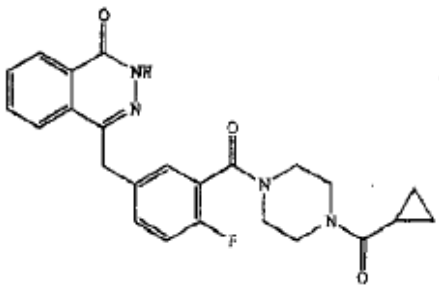
(i) Synthesis of 278

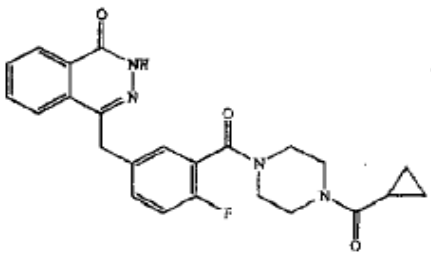


61. It is obvious at a bare glance that the product compound 278 is not Olaparib.

62. Para 83 of the written statement sets out, in a tabular fashion, the manner in which WO'576 allegedly anticipates, by prior publication, Olaparib:

WO'576	IN'720
WO'576 discloses the following Compound  wherein A-B, R_N and R_C can be optionally substituted. Page 4 of the description states the second aspect of the present invention wherein A and B together represent an optionallysubstituted, fused aromatic ringR_C is -CH_2-R_L; R_L is optionally substituted phenyl; and R_N is hydrogen. Substitution of A-B Page 6 of the complete specification describes aromatic ring as follows: The term "aromatic ring" is used herein	IN'720 claims the following Compound 

in the conventional sense to refer to a cyclic aromatic structure, that is, a cyclicstructure having delocalised n-electronorbitals. Page 7 and Page 8 of the description: In one group of preferred embodiments, the aromatic group comprises a single aromatic ring, which has five or six ringatoms, which ring atoms are selectedfrom carbon, nitrogen, oxygen, andsulphur, and which ring is optionallysubstituted. Examples of these groupsinclude benzene, pyrazine, pyrrole,thiazole, isoxazole, and oxazole.	 Compound at the place of A-B (in IN'218) enclosed above shows an aromatic ring i.e., Benzene
Substitution of R_L Page 18 of the description doc: R_L is preferably a benzene ring, naphthalene, pyridine or 1,3- benzodioxole, and more preferably a benzene ringWhen R_L is a benzene ring, it ispreferably substituted. The one or moresubstituents may be selected from: C_{1-7}alkyl, more preferably methyl, CF_3; C_{5-20}aryl; C_{3-20}heterocyclyl; halo, more preferably fluoro; hydroxy; ether, more preferably methoxy, phenoxy, benzyloxy,and cyclopentoxy; nitro; cyano; carbonylgroups, such as carboxy, ester andamido; amino (including sulfonamide),more preferably -NH_2, -NHPh, andcycloamino groups, such as morpholino;acylamido including ureido groupswhere the acyl or amino substituent ispreferably phenyl, which itself	 Compound at the place of RC (inIN'218) shows substitution of $R_L$whereinR_L is selected from amido group andoptionally further substituted withFluorine (F)

isoptionally fluorinated; acyloxy; thiol;thioether; sulfoxide; sulfone.	
On page 15 of the description Preferred substituents of the benzene ring, when $R_L$is phenyl is given, which includes: Amido (carbamoyl, carbamyl,aminocarbonyl, carboxamide) : -C(=0)NR^1R^2, wherein R^1 and R^2 are independently amino substituents, as defined for amino groups. Examples of amido groups include, but are not limitedto, -C(=0)NH_2, -C(=0)$NHCH_3$, - C(=0)$N(CH_3)_2$, -C(=0) $NHCH_2CH_3$, and-C (=0)N $(CH_2CH_3)_2$, as well as amidogroups in which R^1 and R^2, togetherwith the nitrogen atom to which theyare attached, form a heterocyclicstructure as in, for example,piperidinocarbonyl, morpholinocarbonyl, thiomorpholinocarbonyl, and piperazinocarbonyl .	
Substitution of RN *R_N is hydrogen.*	 The substitution at the place of R_N (in IN'218) is **Hydrogen (H)** as stated in the claim of IN'218

63. It is clear, from a bare glance at the manner in which Natco has arrived at the chemical structure of Olaparib from Claim I in WO'576 that there has been cherry picking of substituents. For example,

(i) in the A-B radical in the WO'576 claim, there is no explanation for why the example of benzene has been selected out of the possible substituents of 5- to 6- membered aromatic rings, out of

(a) benzene,

(b) pyrazine,

(c) pyrrole,

(d) thiazole,

(e) isoxazole and

(f) oxazole,

which, too, are merely mentioned as examples, and

(ii) in the $-CH_2-R_L$ substitution, while the description of WO'576 does state that R_L, if a benzene ring, is preferably substituted, there is no explanation for why the halo and carbonyl substituents should be selected in preference to

(a) C_{1-7} alkyl (more preferably methyl),

(b) CF_3,

(c) C_{5-20} aryl,

(d) C_{3-20} heterocyclyl,

(e) hydroxy,

(f) ether (more preferably methoxy, phenoxy, benzyloxy and cyclopentyloxy),

(g) nitro, and

(h) cyano,

among others. Most significantly, perhaps, there is no teaching, in any of the cited prior arts, to lead a person skilled in the art to envision the terminal  cyclopropane substitution.

64. No other prior publication, which publishes Olaparib, has been cited by Mr. Sai Deepak either during oral arguments or in written submissions.

65. No case for anticipation by prior publication is also, therefore, made out.

VII. Section 3(d)[29]

66. Mr. Sai Deepak has also sought to invoke Section 3(d) of the Patents Act to contend that the specifications for Olaparib do not contain any data to indicate enhanced efficacy over the prior art IN'218.

67. The fallacy of the submission is obvious. Section 3(d), to the extent it is at all relevant to the submission of Mr. Sai Deepak, applies only to "new forms" of "known substances". It cannot be said that

[29] **3. What are not inventions**. – The following are not inventions within the meaning of this Act, -

*****

(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

Olaparib is a new form of the Markush Claim I in IN'720. The submission, therefore, merits *prima facie* rejection.

VIII. Section 64(1)(m) read with Section 8[30]

68. On the ground that, while applying for and obtaining the suit patent, Kudos did not disclose the fact that its applications for grant of the same patent JP 2006-505955 and JP 2007-226723 were facing rejection. This, in my opinion, cannot be a basis, in any case, for Kudos to be regarded as *disentitled* to an injunction. At the very least, the matter would be a question of fact, to be decided on the facts of each individual case.

69. Besides, Section 8 requires the patent applicant in India, who is prosecuting an application for a patent in another country outside India in respect of the same invention, to file, along with his application, a statement setting out the particulars of the application. The issue of whether, in a case where the patent is registered, or being prosecuted, in several other jurisdictions, the omission to mention the

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

proceedings before one jurisdiction would invalidate the granted patent altogether is, in my *prima facie* view, highly arguable. Even more arguable would be the question of whether, if the omission is *bona fide*, the patentee, whose patent is admittedly infringed, can be refused an interim injunction.

70. In the present case, Kudos has placed, on record, documents, including correspondences with its patent agent, which, according to it, indicate that the omission to mention the Japanese patents was not deliberate, but was an inadvertent omission on the part of the patent agent. How far this argument would be acceptable is, in my view, a matter which would have to await trial. In any event, in view of the explanation, this cannot be regarded as so overwhelming a factor as would justify rejection of the interim relief that Kudos seeks.

IX. The sequitur

71. As already noted towards beginning of this judgment, several incidental contentions were raised, including IC 50 values, dosage data, anti-cancer PARP inhibition data, and the like, all of which would require a detailed excursion into facts. It would not be justified for this Court to enter into all these areas, once a *prima facie* case has been found to exist in favour of the plaintiff. For the purposes of the present application, it is admitted, in the first place, that the defendant is in fact exploiting the suit patent by manufacturing and selling Olaparib. It is also admitted that this exploitation has take place in the 19th year of the life of the suit patent. No credible case of

vulnerability of the suit patent to invalidity on any of the grounds contained in Section 64 of the Patents Act can be said to have been made out by the Natco. As no credible challenge to the validity of the suit patent has been made out, the prayer for interlocutory injunction has necessarily to be granted.

Conclusion

72. For all the aforesaid reasons, the present application succeeds and is allowed. The defendant shall stand restrained from manufacturing and selling, or in any manner, dealing with Olaparib, either under the brand name BRACANAT or under other brand name, pending disposal of the present suit, so long as the suit patent continues to remain alive and subsisting.

73. I.A. 907/2023 is allowed accordingly.

IA 153/2023 in CO (Comm. IPD-PAT) 1/2023

74. By this application, Natco seeks an interlocutory injunction staying the operation of the suit patent and restraining Kudos from seeking any injunction against Natco exploiting the suit patent.

75. No separate submissions have been advanced in this application. In any event, the outcome of I.A 907/2023 in CS (Comm) 29/2023 would necessarily also determine the outcome of the present applications.

76. Resultantly, I.A. 153/2023 is dismissed.

C.HARI SHANKAR, J

MARCH 1, 2024