$~ (Original Side)

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

\+ CS(COMM) 76/2021, CC(COMM) 8/2021, I.A. 2298/2021
I.A. 2299/2021 & I.A. 13391/2021

PHARMACYCLICS LLC & ANR. ..... Plaintiffs
Through: Mr. Pravin Anand, Ms. Archana Shanker, Mr. Dhruv Anand, Ms. Udita Patro, Ms. Kavya Mammen, Ms. Sampurnaa Sanyal, Advs.

versus

HETERO LABS LIMITED & ORS. ..... Defendants
Through: Ms. Rajeshwari H., Adv. Mr. Harish Vaidyanathan Shankar, CGSC with Ms. S. Bushra Kazim & Mr. Karan Chibber, Advs.

\+ W.P.(C)-IPD 3245/2021 & CM APPL. 9916/2021

LAURUS LABS LIMITED ..... Petitioner
Through:

Versus

UNION OF INDIA & ORS. ..... Respondents
Through: Ms. Rajeshwari H., Adv.Mr. Harish Vaidyanathan Shankar, CGSC with Ms. S. Bushra Kazim & Mr. Karan Chibber, Advs.
Mr. Pravin Anand, Ms. Archana Shanker, Mr. Dhruv Anand, Ms. Udita Patro, Ms. Kavya Mammen, Ms. Sampurnaa Sanyal, Advs. for Respondent No.2

+ CS(COMM) 709/2019, I.A. 18051/2019, I.A. 18491/2019, I.A. 3219/2020, I.A. 11421/2021, I.A. 11422/2021, I.A. 13388/2021, I.A. 13851/2021 & I.A. 16992/2021

PHARMACYCLICS, LLC & ANR. ..... Plaintiffs
Through: Mr. Sudhir Chandra, Senior Counsel with Mr. Pravin Anand, Ms. Archana Shanker, Mr. Dhruv Anand, Ms. Udita Patro, Ms. Kavya Mammen, Ms. Sampurnaa Sanyal, Advs.

versus

NATCO PHARMA LIMITED ..... Defendant
Through: Mr. G. Natray, Mr. Avinash Kumar & Mr. Ankur Vyas, Advs.

+ CS(COMM) 342/2020, I.A. 7332/2020, I.A. 7333/2020, I.A. 8761/2021, I.A. 10504/2021, I.A. 13390/2021, I.A. 15713/2021, I.A. 16039/2021 & I.A. 16040/2021

PHARMACYCLICS LLC & ANR. ..... Plaintiffs
Through: Mr. Dayan Krishnan, Senior Counsel with Mr. Pravin Anand, Ms. Archana Shanker, Mr. Dhruv Anand, Ms. Udita Patro, Ms. Sampurnaa Sanyal, Advs.

versus

BDR PHARMACEUTICALS INTERNATIONAL PVT LTD & ORS. ..... Defendants
Through: Mr. G. Natray, Mr. Avinash Kumar & Mr. Ankur Vyas, Advs.

+ CS(COMM) 451/2020, I.A. 9360/2020, I.A. 1906/2021 & I.A. 8742/2021

PHARMACYCLICS LLC & ANR. ..... Plaintiffs
Through: Ms. Manisha Singh, Mr. Abhai Pandey, Mr. Varun Sharma & Mr. Gautam Kumar, Advs.
Mr. Pravin Anand, Ms. Archana Shanker, Mr. Dhruv Anand, Ms. Udita Patro, Ms. Sampurna Sanyal, Advs.

Versus

SHILPA MEDICARE LIMITED & ANR. ..... Defendants
Through:

\+ CS(COMM) 571/2020 & I.A. 12649/2020, I.A. 12650/2020 & I.A. 13389/2021

PHARMACYCLICS LLC & ANR. ..... Plaintiffs
Through: Mr. Dayan Krishnan, Senior Counsel with Mr. Pravin Anand, Ms. Archana Shanker, Mr. Dhruv Anand, Ms. Udita Patro, Ms. Sampurnaa Sanyal, Advs.

versus

ALKEM LABORATORIES LTD ..... Defendant
Through: Mr. G. Natraj, Mr. Avinash Kumar & Mr. Ankur Vyas, Advs.

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

J U D G M E N T

% 21.12.2023

1. This is a batch of six suits and one writ petition. The writ petition, filed by Laurus Labs Ltd ("Laurus" hereinafter) challenges

judgment dated 29 September 2020 passed by the Intellectual Property Appellate Board ("the IPAB"). The suits allege infringement, by the respective defendants, of Indian Patent 262968 (IN'968, also referred to as "the suit patent"). The controversy, on merits, is identical in all the suits.

2. This judgment decides the applications for interim relief filed in the writ petition of Laurus and the six suits filed by Pharmacyclics LLC. They are IA 2298/2021 in CS (Comm) 76/2021, IA 9360/2020 in CS(COMM) 451/2020, IA 18051/2019 in CS (Comm) 709/2019, IA 7332/2020 in CS (Comm) 342/2020, IA 12649/2020 in CS (Comm) 571/2020 and CM APPL. 9916/2021 in W.P.(C) 3245/2021. For the sake of convenience, I am treating CS (Comm) 709/2019 as the lead case. The decision on IA 18051/2019 would apply, *mutatis mutandis*, to all other IAs. This is but obvious as the decision on the prayer for restraint against exploitation of the suit patent, whichever way it goes, would apply *in rem*, not *in personam*.

Facts

3. The suit patent, which is registered in favour of the Plaintiff 1, covers "Inhibitors of Bruton's Tyrosine Kinase" and claims, in Formula 4, the drug Ibrutinib. Plaintiff 2, Johnson & Johnson Private Limited, an Indian affiliate of Janssen Biotech, Inc, is the exclusive

licensee of Plaintiff 1. Ibrutinib is commercially sold by the plaintiffs under the registered trademark IMBRUVICA.

4. The present suit was instituted as a *quia timet* action, anticipating launch, in the market, by the defendants, of Ibrutinib, without any license from the plaintiff.

5. When this suit came up for preliminary hearing on 19 December 2019, the defendants submitted that they had already launched the infringing product in the market. In the circumstances, while issuing notice on the present application, this Court directed the defendants to disclose the date of commencement of marketing of Ibrutinib by them, and the quantum of sales of the said product effected till then. The defendants were also directed to file, before this Court, the sales of the impugned product as effected by them on a quarterly basis.

6. The plaintiff, however, filed IA 18491/2019, also under Order XXXIX Rules 1 and 2 of the Code of Civil Procedure, 1908 (CPC), disputing the defendants' contention that the impugned product had been launched in the market. On 24 December 2019, this Court recorded the said submission and issued notice in IA 18491/2019, returnable for the date already fixed.

7. The defendants, in their written statement filed by way of response to the plaint, did not dispute the fact that they were intending to launch Ibrutinib in the market. They, however, invoked Section 107(1)[1] read with Section 64[2] of the Patents Act, 1970, to question the

[1] **107. Defences, etc. in suits for infringement. –**
(1) In any suit for infringement of a patent, every ground on which it may be revoked under Section 64 shall be available as a ground for defence.

[2] **64. Revocation of patents. –**
(1) Subject to the provisions contained in this Act, a patent, whether granted before or after the commencement of this Act, may, be revoked on a petition of any person interested or of the Central Government or on a counter-claim in a suit for infringement of the patent by the High Court on any of the following grounds, that is to say,—
(a) that the invention, so far as claimed in any claim of the complete specification, was claimed in a valid claim of earlier priority date contained in the complete specification of another patent granted in India;
(b) that the patent was granted on the application of a person not entitled under the provisions of this Act to apply therefor;
(c) that the patent was obtained wrongfully in contravention of the rights of the petitioner or any person under or through whom he claims;
(d) that the subject of any claim of the complete specification is not an invention within the meaning of this Act;
(e) that the invention so far as claimed in any claim of the complete specification is not new, having regard to what was publicly known or publicly used in India before the priority date of the claim or to what was published in India or elsewhere in any of the documents referred to in Section 13;
(f) that the invention so far as claimed in any claim of the complete specification is obvious or does not involve any inventive step, having regard to what was publicly known or publicly used in India or what was published in India or elsewhere before the priority date of the claim;
(g) that the invention, so far as claimed in any claim of the complete specification, is not useful;
(h) that the complete specification does not sufficiently and fairly describe the invention and the method by which it is to be performed, that is to say, that the description of the method or the instructions for the working of the invention as contained in the complete specification are not by themselves sufficient to enable a person in India possessing average skill in, and average knowledge of, the art to which the invention relates, to work the invention, or that it does not disclose the best method of performing it which was known to the applicant for the patent and for which he was entitled to claim protection;
(i) that the scope of any claim of the complete specification is not sufficiently and clearly defined or that any claim of the complete specification is not fairly based on the matter disclosed in the specification;
(j) that the patent was obtained on a false suggestion or representation;
(k) that the subject of any claim of the complete specification is not patentable under this Act;
(l) that the invention so far as claimed in any claim of the complete specification was secretly used in India, otherwise than as mentioned in sub-section (3), before the priority date of the claim;
(m) that the applicant for the patent has failed to disclose to the Controller the information required by Section 8 or has furnished information which in any material particular was false to his knowledge;

validity of the suit patent on the ground of prior publication, anticipation and lack of obviousness in view of the disclosure, in Patent WO 2005/037836, of the compound (1-[(3R)-3-[8-amino-1-(4-penoxyphenyl)-imidazo [1,5-a] pyrazin-3-y]-1-piperidinyl]-2-propen-1-one). As such, this Court proceeded to frame issues on 7 February, 2020, including, among them, issues regarding the validity of the suit patent in the light of the objections regarding anticipation by prior claiming, publication and obviousness, raised by the defendants.

8. During the pendency of the suit, a post-grant opposition, filed against the suit patent by Laurus Labs Ltd ("Laurus" hereinafter), was allowed by the Joint Controller of Patients & Designs ("the Joint Controller"), resulting in revocation of the suit patent. In the circumstances, the defendants moved IA 3219/2020 under Order VII Rule 11 of the CPC, seeking rejection of the plaint. This Court was, however, informed on 6 March 2020 that the plaintiffs had preferred an appeal against the decision of the Joint Controller, to IPAB. In the circumstances, this Court adjourned the matter, instead of dismissing it.

(n) that the applicant contravened any direction for secrecy passed under Section 35 or made or caused to be made an application for the grant of a patent outside India in contravention of Section 39;
(o) that leave to amend the complete specification under Section 57 or Section 58 was obtained by fraud;
(p) that the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention;
(q) that the invention so far as claimed in any claim of the complete specification was anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere.

9. Thereafter, during the pendency of these proceedings, the aforenoted appeal (OA/46/2020/PT/DEL) came to be allowed by the IPAB by its judgment dated 29 September 2020.

10. A primary contention, advanced by learned Senior Counsel for the plaintiffs – primarily by Mr. Dayan Krishnan – is that, once the validity of the suit patent thus stands upheld by the IPAB, a *prima facie* case against exploitation of the suit patent by the defendants exists.

11. It would be appropriate to examine this contention at the outset, before proceeding to the rival submissions on merits as, if a view regarding the validity of the suit patent has already been taken by the IPAB, and the challenge to the present suit, by the defendants, is only on the ground of invalidity of the suit patent, Mr. Dayan Krishnan may be correct in his submission that a case for interim injunction is made out even for that reason alone – unless, of course, this Court decides to stay the IPAB order. Before, however, proceeding to the order of the IPAB, and its impact on the present application, a brief view of the rival stands, on merits, is necessary.

12. So far as the plaintiffs are concerned, it contends that, as the suit patent is valid and subsisting and claims Ibrutinib, and as Ibrutinib is, admittedly, manufactured and sold by the defendants under various brand names, the defendants are infringing the suit patent.

13. The PCT application for the invention titled "Inhibitors of Bruton's Tyrosine Kinase", claiming the drug Ibrutinib was initially filed by Plaintiff 1 on 28 December 2006. The suit patent, therefore, claims priority from US 60/826720 (US' 720) dated 22 September 2006 and US 60/828590 (US'590) dated 6 October 2006. The National Phase Application in India was filed on 12 March 2009 and the suit patent came to be granted on 25 September 2014. The suit patent is valid for 20 years w.e.f. 28 December 2006 and is, therefore, due to expire only in 2026.

14. Relevant passages from the "field of the invention", "background of the invention" and "detailed description of the invention" may be reproduced thus:

> "[0002] Described herein are compounds, methods of making such compounds, pharmaceutical compositions and medicaments containing such compounds, and methods of using such compounds and compositions to inhibit the activity of tyrosine kinases.
>
> [0003] Bruton's tyrosine kinase (Btk), a member of the Tec family of non-receptor tyrosine kinases, is a key signalling enzyme expressed in all hematopoietic cells types except lymphocytes and natural killer cells, Btk plays an essential role in the B-cell signaling pathway linking cell surface B-cell receptor (BCR) stimulation to downstream intracellular responses."

> "[0005] Described herein are inhibitors of Bruton's tyrosine kinase (Btk). Also described herein are irreversible inhibitors of Btk. Further described are irreversible inhibitors of Btk that form a

covalent bond with a cysteine residue on Btk. Further, described herein are irreversible inhibitors of other tyrosine kinases. wherein the other tyrosine kinases share homology with Btk by having a cysteine residue (including a Cys 481 residue) that can form a covalent bond with the irreversible inhibitor (such tyrosine kinases are referred herein as "Btk tyrosine kinase cysteine homologs"). Also described herein are methods for synthesizing such irreversible inhibitors, methods for using such irreversible inhibitors in the treatment of diseases (including diseases wherein irreversible inhibition of Btk provides therapeutic benefit to a patient having the disease). Further described are pharmaceutical formulations that include an irreversible inhibitor of Btk.

[0006] Compounds described herein include those that have a structure of any of Formula (A), Formula (B), Formula (C), or Formula (D) and pharmaceutically acceptable salts, solvates, esters, acids and prodrugs thereof. In certain embodiments, isomers and chemically protected forms of compounds having a structure represented by any of Formula (A), Formula (B), Formula (C), or Formula (D) are also provided.

Detailed description-

"[00163] The methods described herein include administering to a subject in need a composition containing a therapeutically effective amount of one or more irreversible Btk inhibitor compounds described herein. Without being bound by theory, the diverse roles played by Btk signalling in various hematopoietic cell functions, e.g. B-cell receptor activation, suggests that small molecule Btk inhibitors are useful for reducing the risk of or treating a variety of diseases affected by or affecting many cell types of the hematopoetic lineage including, e.g., autoimmune diseases, heteroimmune conditions or diseases, inflammatory diseases, cancer (e.g., B-cell proliferative disorders), and thromboembolic disorders. Further, the irreversible Btk inhibitor compounds described herein can be used to inhibit a small subset of other tyrosine kinases that share homology with Btk by having a cysteine residue (including a Cys 481 residue) that can form a covalent bond with the irreversible inhibitor. See, e.g., protein kinases in FIG, I. Thus, a subset of tyrosine kinases other than Btk are also expected to be useful as therapeutic targets in a number of health conditions.

[00164] In some embodiments, the methods described herein can be used to treat an autoimmune disease, which includes, but is not limited to, rheumatoid arthritis, psoriatic arthritis, osteoarthritis, Still's disease, juvenile arithritis, lupus, diabetes, myasthenia gravis, Hashimoto's thyroiditis, Ord's thyroiditis. Graves' disease Sjogren's syndrome, multiple selerosis, Guillain-Barre Syndrome, acute disseminated encephalomyelitis, Addison's disease, opsoclonus-myoclonus syndrome, ankylosing spondylitisis, antiphospholipid antibody syndrome, aplastic anemia, autoimmune hepatitis, coeliae disease. Goodpasture's syndrome, idiopathic thrombocytopenic purpura, optic neuritis, scleroderma, primary biliary cirrhosis. Reiter's syndrome, Takayasu's arteritis, temporal arteritis. warm autoimmune hemolytic anemia, Wegener's granulomatosis, psoriasis, alopecia universalis, Behcet's disease, chronic fatigue, dysautonomia. endometeriosis, interstitial cystitis, neuromyotonia, scleroderma, and vulvodynia.

[00165] In some embodiments, the methods described herein can be used to treat heteroimmune conditions or diseases, which include, but are not limited to graft versus host disease, transplantation, transfusion, anaphylaxis, allergies (e.g., allergies to plant pollens, latex, drugs, foods, insect poisons, animal hair, animal dander, dust mites, or cockroach calyx), type I hypersensitivity, allergic conjunctivitis, allergic rhinitis, and atopic dermatitis,

[00166] In further embodiments, the methods described herein can be used to treat an inflammatory disease, which includes, but is not limited to asthma, inflammatory, bowel disease, appendicitis, blepharitis, bronchiolitis. bronchitis, bursitis, cervicitis, cholangitis, cholecystitis, colitis, conjunctivitis, cystitis, dacryoadenitis, dermatitis, dermatomyositis, encephalitis, endocarditis, endometritis, enteritis, enterocolitis, epicondylitis, epididymitis, fasciitis, fibrositis, gastritis, gastroenteritis, hepatitis, hidradenitis suppurativa, laryngitis, mastitis, meningitis, myelitis myocarditis, myositis. nephritis, oophoritis, orchitis, osteitis, otitis, pancreatitis, parotitis, pericarditis, peritonitis, pharyngitis, pleuritis, phlebitis, pneumonitis, pneumonia, proctitis, prostatitis, pyelonephritis, rhinitis, salpingitis, sinusitis, stomatitis, synovitis, tendonitis, tonsillitis, uveitis, vaginitis, vasculitis, and vulvitis.

[00167] In yet other embodiments, the methods described herein can be used to treat a cancer, e.g. B-cell proliferative

disorders, which include, but are not limited to diffuse large B cell lymphoma, follicular lymphoma, chronic lymphocytic lymphoma, chronic lymphocytic leukemia. B-cell prolymphocytic leukemia, lymphoplasmacytic lymphoma/Waldenström macroglobulinemia, splenic marginal zone lymphoma, plasma cell myeloma, plasmacytoma, extranodal marginal zone B cell lymphoma, nodal marginal zone B cell lymphoma, mantle cell lymphoma, mediastinal (thymic) large B cell lymphoma, intravascular large B cell lymphoma, primary effusion lymphoma, burkitt lymphoma/leukemia, and lymphomatoid granulomatosis.

[00176] The Btk inhibitor compounds described herein are selective for Btk and kinases having a cysteine residue in an amino acid sequence position of the tyrosine kinase that is homologous to the amino acid sequence position of cysteine 481 in Btk. See. e.g. kinases in FIG. 1. Inhibitor compounds described herein include a Michael acceptor moiety.

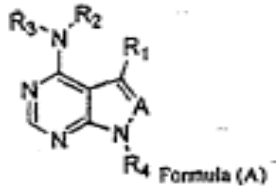
[00181] Irreversible Btk inhibitor compounds can used for the manufacture of a medicament for treating any of the foregoing conditions (e.g. autoimmune diseases, inflammatory diseases, allergy disorders, B-cell proliferative disorders, or thromboembolic disorders).

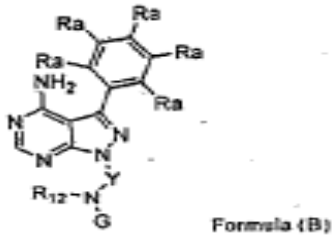
[00183] In one embodiment, the irreversible Btk inhibitor compound selectively and irreversibly inhibits an activated form of its target tyrosine-kinase (e.g. a phosphorylated form of the tyrosine kinase). For example, activated Btk is transphosphorylated at tyrosine 551. Thus, in these embodiments the irreversible Btk inhibitor inhibits the target kinase in cells only once the target kinase is activated by the signalling events.

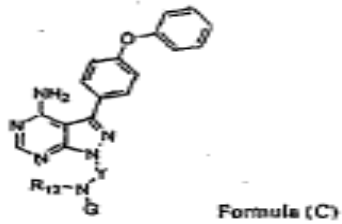
[00184] Described herein are compound of any of Formula (A), Formula (B), Formula (C), or Formula (D). Also described herein are pharmaceutically acceptable salts, pharmaceutically acceptable solvates, pharmaceutically active metabolites and pharmaceutically acceptable prodrugs of such compounds. Pharmaceutical compositions that include at least one such compound or a pharmaceutically acceptable salt, pharmaceutically acceptable solvate, pharmaceutically active metabolite or pharmaceutically acceptable prodrug of such compound, are provided. In some embodiments, when compounds disclosed herein contain an oxidizable nitrogen atom, the nitrogen atom can be converted to an N-oxide by methods well known in the art. In

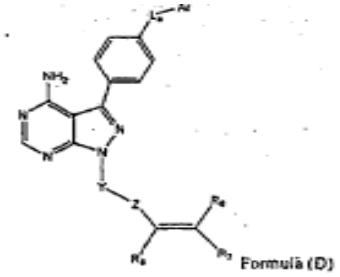
certain embodiments, isomers and chemically protected forms of compounds having a structure represented by any of Formula (A), Formula (B), Formula (C), of Formula (D) are also provided."

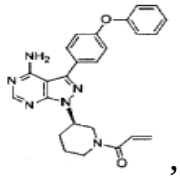
15. Formulae (A) to (D), to which para 00184 makes reference, were thus provided in the complete specifications:









16. Ibrutinib is claimed in Claim 1 of the suit patent. Its chemical structure is  , and its IUPAC/chemical name is l-[(R)-3-[4-Amino-3-(4-phenoxyphenyl)- 1H-pyrazolo [3,4-d]pyrimidin-1-yl] piperidin-1-y1]prop-2-en-l-one.

17. That the defendants in these suits manufacture and sell – or intend to manufacture and sell – Ibrutinib, is not in dispute. That they do so without any licence or authority from the plaintiffs is also not in dispute. As in many such cases, the defendants do not plead that their acts are not, strictly speaking, infringing of the suit patent. They rely, instead, on Section 107(1) read with Section 64 of the Patent Act. Their defence is, therefore, predicated on alleged invalidity of the suit patent.

18. As already noted, the invalidity of the suit patent is, however, not being tested for the first time. Laurus filed a post grant opposition before the Indian Patent Office (IPO), seeking revocation of the suit patent on 24 July 2019.

19. By order dated 4 March 2020, the Joint Controller allowed the post grant opposition and revoked the suit patent as obvious to an ordinary person skilled in the art and, therefore, as lacking any

inventive step vis-à-vis prior art. That order was, however, set aside by the IPAB *vide* judgment dated 29 September 2020.

20. As the defendants are contesting these suits only on the ground of invalidity of suit patents, and the validity of the suit patents stands affirmed by the judgment dated 29 September 2020 of the IPAB, Mr. Dayan Krishnan, learned Senior Counsel appearing for some of the plaintiffs, argues that a *prima facie* case *ipso facto* stands made out in the plaintiffs' favour.

21. This submission is contested by Mr. J. Sai Deepak, who led arguments on behalf of defendants, on the ground that the Chairman of the IPAB, who authored the judgment dated 29 September 2020, was not competent to hold office. He was, according to Mr. Sai Deepak, *coram non judice.*

22. The tenure of the Chairman of the IPAB, he submits, had expired on 21 September 2019 and he was continuing to hold office on the basis of certain interim orders passed by the Supreme Court. The Supreme Court ultimately held, *vide* judgment dated 27 November 2020 read with clarification dated 12 February 2021, that the tenure of the Chairman of the IPAB in fact had ended on 21 September 2019. Thus, submits Mr. Sai Deepak, all orders passed by the learned Chairman after 21 September 2019 were *non est.* Mr. Dayan Krishnan, in response to this submission, invokes the *de facto*

doctrine. Mr. Sai Deepak, never the man to cede an inch where there exists a case worth contesting, submits that the *de facto* doctrine is not applicable in the facts of this case.

23. For the purposes of the present application, which only requires this Court to examine the issue *prima facie*, I am certainly not inclined to revisit the findings of the IPAB. To the extent the IPAB has upheld the validity of the suit patent, a *prima facie* case must be held to exist in favour of the plaintiff. This, however, is undoubtedly subject to the submission of Mr. Sai Deepak that the judgment of the IPAB is null and void as the learned Chairman was not competent to hold office. That aspect would be dealt with by and by.

24. If, however, Mr. Sai Deepak has advanced any submissions, assailing the validity of the suit patent, beyond those which were considered by the IPAB, those submissions undoubtedly have to be taken into consideration.

25. Thus, primary issues arise for examination before me, which may be framed thus:

(i) What is the value of the judgment dated 29 September 2020 passed by the IPAB ? Is it null and void, as Mr. Sai Deepak would seek to contend, or is it saved by the *de facto* doctrine, as submitted by Mr. Dayan Krishnan?

(ii) Has Mr. J. Sai Deepak advanced any contention beyond those which were considered by the IPAB, which make out a *prima facie* case for denial of interlocutory injunction as sought by the plaintiffs ?

26. Re. Issue (i) - Value of the judgment of the IPAB and applicability of the *de facto* doctrine

26.1 On 21 September 2019, Manmohan Singh, J., the Chairman of the IPAB, demitted office on completion of his tenure.

26.2 The International Association for Protection of Intellectual Property ("the IAPIP") preferred WP (C) 1439/2019 before the Supreme Court. The writ petition was tagged with other writ petitions which challenged the constitutional validity of the Tribunal, Appellate Tribunal and other Authorities (Qualification, Experience and other Conditions of Service of Members) Rules, 2020 ("the 2020 Rules"), headed by WP (C) 804/2020 (***Madras Bar Association v. U.O.I.***). That batch came to be disposed of, by the Supreme Court, by judgment dated 27 November 2020[3].

26.3 During the pendency of the said proceedings, the tenure of all incumbent members of all tribunals was continued by interim orders passed by the Supreme Court from time to time – particularly order dated 16 September 2020 – till 31 December 2020.

[3] **(2021) 7 SCC 369**

26.4 MA 2219/2020 was filed by the IAPIP in WP (C) 1439/2019, praying that, till a new Chairperson of the IPAB was appointed, Manmohan Singh, J. be permitted to continue as Chairman. In other words, the IAPIP sought extension of the interim orders earlier passed, which came to an end on 31 December 2020, till a new Chairperson was appointed to the IPAB.

26.5 MA 2219/2020 was dismissed, by the Supreme Court, by judgment dated 12 February 2021[4]. The opening paragraph of the judgment is, however, of significance:

> "This judgement will dispose of an application by which directions are sought that till a new chairperson of the Intellectual Property Appellate Board (hereinafter referred to as "the board" or "IPAB") is appointed, the incumbent (whose *tenure had been extended* by interim orders of this court, up to 31.12.2020) should continue to function as Chairperson."
>
> (Emphasis supplied)

As already noted, the judgment ultimately dismissed MA 2219/2020.

26.6 The Supreme Court, in its judgment dated 12 February 2021, noted the fact that Manmohan Singh, J., had continued to function as Chairman of the IPAB under various interim orders passed from time to time in ***Madras Bar Association***. Specific notice is taken, in para 5 of the judgment, of the order dated 16 September 2020, thus:

> "5. Learned Counsel relied upon the said judgment. It was argued that the orders made by this Court during the pendency of

[4] **International Association for Protection of Intellectual Property v. U.O.I., (2021) 4 SCC 519**

> that case, till final judgment, i.e. dated 27th of November, 2020 protected the tenures of all incumbent tribunal members and their chairpersons. Specific reliance was placed upon the order dated 16th September 2020, which had extended the tenure of office of all incumbent members of all tribunals, to 31st December, 2020. The applicant also urged that it is essential that there is continuity and that taking into consideration the workload of the board, it is absolutely essential that it is headed by a properly qualified chairperson."

26.7 Clearly, the Supreme Court, in its judgment dated 12 February 2021, did not expressly undo the effect of its interim orders, passed in ***Madras Bar Association***, extending the tenure of the incumbent members of all tribunals till 31 December 2020, or set the clock back.

26.8 What, then, is the status of orders passed by Manmohan Singh, J., as Chairman of the IPAB, between 21 September 2019 and 31 December 2020? The order dated 29 September 2020, on which the plaintiffs in these suits relies, is one such order.

26.9 Mr. Dayan Krishnan submits that all such orders are saved by the *de facto* doctrine. He relies on ***Gokaraju Rangaraju v. State of A.P.***[5] He submits that the Supreme Court, while rendering its judgment dated 12 February 2021 in ***International Association for Protection of Intellectual Property***, was well aware of the fact that the tenure of Manmohan Singh, J. had been continued under orders passed by the Supreme Court itself. It did not pass any orders nullifying all judicial acts done by Manmohan Singh, J., during the

[5] **(1981) 3 SCC 132**

period of such continuance. The *de facto* doctrine squarely applies in such a case. Its application is excepted only to a usurper or an intruder, and Manmohan Singh, J., obviously was neither. The applicability of the doctrine was not excepted in a case in which the incumbent demitted office on superannuation. Mr. Dayan Krishnan cited, in this context, paras 3, 4, 7 and 13 of a judgment of the High Court of Patna in ***Sunity Pandey v. Sri Kant Prasad Shrivastava*** [6].

26.10 Mr. Sai Deepak contends that all the orders passed by Manmohan Singh, J., during the aforesaid twilight period perish with the judgment dated 31 December 2020. According to him, every judicial order passed by Manmohan Singh, J. after 21 September 2019 has been rendered null and void. The Supreme Court having held, in its judgment dated 12 February 2021, that Manmohan Singh, J's term of office as Chairman of the IPAB had come to an end on 21 September 2019, and having not passed any orders protecting judicial acts done by Manmohan Singh, J., thereafter, all such acts stand nullified. He places especial reliance on para 23 of the judgment in ***International Association for Protection of Intellectual Property***, which reads thus:

> "23. Another argument urged by the applicant was that the Finance Act, 2017 had inserted Section 89A of the TM Act, (introduced by Section 161 of the former Act) which states that the tenure of office and maximum age of retirement would be governed by the terms of the said Finance Act and, consequently, the pre-existing tenure and age limits did not apply. Undoubtedly, the purport of Section 89A was to overbear or supersede the pre-

[6] **1997 (1) BLJ 803**

existing age and tenure limits (the existing tenure and age limits have been indicated in Section 86 of the TM Act). However, the Finance Act merely stipulates the potential maximum age limits and tenure limits. In the case of Chairpersons, the maximum age limit prescribed was seventy years (by virtue of second proviso to Section 184[1]). However, by virtue of the first proviso to Section 184(1), members or chairpersons could be appointed "for such term as specified in the Rules made by the Central Government but not exceeding five years from the date on which he enters upon his office". Thus, the outer limit of the tenure was five years. As noticed earlier, the Central Government had fixed the tenure of chairperson of the board to be three years. By the time this Rule was held unconstitutional, the tenure of the incumbent holding office of chairperson, of the board ended, on 21.09.2019. The final judgment in Rojer Mathew, could not have per se been applied to the facts of this case. The applicant's contentions in this regard are of no avail; it is after the judgment in Madras Bar Association (supra) that the tenure has been mandated to be five years. It is to be noticed that even the 2020 Rules did not prescribe the maximum tenure; it rather confined the tenure to four years. In the facts of this case, even if that were to be applied-assuming such a course to be available, the four-year period too ended on 21.09.2020. It is important to notice that the changes brought about in the tenure and age limits were not only through the Schedule to the Finance Act, 2017, but also through its substantive provisions-Sections 156 to 182.5 These provisions introduced changes relating to tenure and age limits for members and chairpersons of 19 tribunals (including the Income Tax Appellate Tribunal; Securities Appellate Tribunal, Competition Commission of India, CESTAT, Railway Claims Tribunal, Central Administrative Tribunal, Debt Recovery Tribunal, Debt Recoveries Appellate Tribunals, the IPAB-i.e. the Board, in this case, etc.). All these provisions, much like Section 89A of the TM Act, aligned Parliamentary intention to legislate uniform tenure limits and maximum age for members and chairpersons. Therefore, Section 89A is only part of the entire legislative design. However, that has no bearing on the circumstances of the present case."

26.11 According to Mr. Sai Deepak, the *de facto* doctrine applies only where the office of the incumbent itself is disbanded by operation of law and not in case such as the present in which the incumbent was

wrongfully (as is specifically alleged, in writing, in para 4(c)(viii) of the consolidated written submissions of Mr. Sai Deepak) continuing in office beyond superannuation, contrary to the law. In the present case, he submits, the post of Chairperson IPAB was disbanded after the issuance of the judgment dated 24 September 2020. Mr. Sai Deepak also cites ***Central Bank of India v. Bernard***[7], which excepts the applicability of the *de facto* doctrine to a usurper in office. A person who continues in office after retirement, he submits, is a usurper. Mr. Sai Deepak also places reliance on the judgments of the High Court of Patna in ***Sunity Pandey*** and ***Shrikant Prasad Shrivastava v. State of Bihar***[8].

26.12 To my mind, the issue is elementary. It would be preposterous to hold that the continuance in office of Manmohan Singh, J., which was in accordance with interim orders passed by the Supreme Court in ***Madras Bar Association***, was "wrongful", or that he was holding office as a "usurper". Compliance with orders passed by the Supreme Court cannot be regarded as wrongful. The submission, of Mr. Sai Deepak, that a person who continues in office after retirement does so as a usurper, and that his continuance in office is illegal, mistakes the wood for the trees. As a general principle, it may be unexceptionable; but, in a case in which the person continues in office under orders passed by a judicial forum – in this case, none

[7] **(1991) 1 SCC 319**
[8] **1997 (1) BLJ 204**

less than the Supreme Court – he is, quite obviously, neither a usurper, nor continuing illegally, or even wrongfully, in office.

26.13 *De hors* the *de facto* doctrine and its applicability, the judgment dated 12 February 2021 in ***International Association for Protection of Intellectual Property*** clearly observes that the interim orders of the Supreme Court in ***Madras Bar Association*** *extended the tenure* of incumbent members of all tribunals, including the Chairman, IPAB. The import is obvious. The interim orders of the Supreme Court were not intended at gratuitously permitting the members of the tribunals to continue in office, subject to the final outcome of the petitions. *Their tenures were extended*. "Tenure" is defined by the Supreme Court in ***Dr L.P. Agarwal v. U.O.I.***[9] and ***Yashwant Singh Kothari v. State Bank of Indore***[10] as the "term during which *an office is held*". The situation was clarified still further in ***Dr P. Venugopal v. U.O.I.***[11]:

> " "Tenure" means a term during which the office is held. It is a condition of holding the office. Once a person is appointed to a tenure post, *his appointment to the said post begins when he joins and it comes to an end on the completion of tenure unless curtailed on justifiable grounds*. Such a person does not superannuate, he only goes out of the office on completion of his tenure."
>
> (Emphasis supplied)

Extension of tenure, therefore, *ipso facto* implies extension of the tenure during which the incumbent holds office. Where such

[9] **AIR 1992 SC 1872**
[10] **1993 Supp 2 SCC 592**
[11] **(2008) 5 SCC 1**

extension is by orders passed by the Supreme Court, he obviously holds office under authority of law. By no means is he a usurper.

26.14 Besides, the *de facto* doctrine, as explained in ***Gokaraju Ramaraju***, also concludes the controversy. The Supreme Court held thus, in the said decision:

> "4. We are unable to agree with the submissions of the learned Counsel for the appellants. The doctrine is now well-established that "the acts of the officers de facto performed by them within the scope of their assumed official authority, in the interest of the public or third persons and not for their own benefit, are generally as valid and binding, as if they were the acts of officers de jure (***Pulin Behari v. King-Emperor***[12]). As one of us had occasion to point out earlier "the doctrine is founded on good sense, sound policy and practical expedience. It is aimed at the prevention of public and private mischief and the protection of public and private interest. It avoids endless confusion and needless chaos. An illegal appointment may be set aside and a proper appointment may be made, but the acts of those who hold office de facto are not so easily undone and may have lasting repercussions and confusing sequels if attempted to be undone. Hence the de facto doctrine" (*vide* ***Immedisetti Ramkrishnaiah Sons v. State of A.P.***[13]).
>
> 5. In ***Pulin Behari*** , Sir Asutosh Mookerjee, J. noticed that in England the de facto doctrine was recognised from the earliest times. The first of the reported cases where the doctrine received judicial recognition was the case of ***Abbe de Fontaine***[14] decided in 1431. Sir Asutosh Mookerjee noticed that even by 1431 the de facto doctrine appeared to be quite well known and, after 1431, the doctrine was again and again reiterated by English Judges.
>
> 6. In ***Milward* v. *Thatcher***[15], Buller, J. said:
> "The question whether the judges below be properly judges or not, can never be determined, it is sufficient

[12] (1912) 15 Cal LJ 517, 574 : 16 IC 257 : 16 Cal WN 1105 : 13 Cri LJ 609
[13] AIR 1976 AP 193
[14] 1431 Year Book 9 H 6 Fol 32
[15] [(1787) 2 TR 81, 87 : 100 ER 45]

> if they be judges de facto. Suppose a person were even criminally convicted in a Court of Record, and the Recorder of such Court were not duly elected, the conviction would still be good in law, he being the judge de facto."

7. In ***Scadding* v. *Lorant***[16], the question arose whether a rate for the relief of the poor was rendered invalid by the circumstance that some of the vestry men who made it were vestry men de facto and not de jure. The Lord Chancellor observed as follows:

> "With regard to the competency of the vestry men, who were vestry men de facto, but not vestry men de jure, to make the rate, Your Lordships will see at once the importance of that objection, when you consider how many public officers and persons there are who were charged with very important duties, and whose title to the office on the part of the public cannot be ascertained at the time. You will at once see to what it would lead if the validity of their acts, when in such office, depended upon the propriety of their election. It might tend, if doubts were cast upon them, to consequences of the most destructive kind. It would create uncertainty with respect to the obedience to public officers and it might also lead to persons, instead of resorting to ordinary legal remedies to set right anything done by the officers, taking the law into their own hands."

8. Some interesting observations were made by the Court of Appeal in England in ***Re James***[17] (*An Insolvent*). Though the learned Judges constituting the Court of Appeal differed on the principal question that arose before them namely whether "the High Court of Rhodesia" was a British Court, there did not appear to be any difference of opinion on the question of the effect of the invalidity of the appointment of a judge on the judgments pronounced by him. Lord Denning, M.R., characteristically, said:

> "He sits in the seat of a judge. He wears the robes of a judge. He holds the office of a judge. Maybe he was not validly appointed. But, still, he holds the office. It is the office that matters, not the incumbent.... So long as the man holds the office,

[16] **[(1851) 3 HLC 418 : 15 Jur 955 : 10 ER 164 (HL)]**
[17] **[(1977) 2 WLR 1 : (1977) 1 All ER 364 (CA)**

and exercises it duly and in accordance with law, his orders are not a nullity. If they are erroneous they may be upset on appeal. But, if not, erroneous they should be upheld."

Lord Denning then proceeded to refer to the ***State of Connecticut* v. *Carroll***[18] decided by the Supreme Court of Connecticut, ***Re Aldridge***[19] decided by the Court of Appeal in New Zealand and ***Norton* v. *Shelby County***[20] decided by the United States Supreme Court. Observations made in the last case were extracted and they were:

"Where an office exists under the law, it matters not how the appointment of the incumbent is made, so far as the validity of his acts are concerned. It is enough that he is clothed with the insignia of the office, and exercises its powers and functions.... The official acts of such persons are recognised as valid on grounds of public policy, and for the protection of those having official business to transact."

9. Scarman, L.J., who differed from Lord Denning on the question whether the High Court of Rhodesia was a British Court appeared to approve the view of Lord Denning, M.R. in regard to the de facto doctrine. He said:

"He (Lord Denning) invokes the doctrine of recognition of the de facto judge, and the doctrine of implied mandate or necessity. I agree with much of the thinking that lies behind his judgment. I do think that in an appropriate case our courts will recognise the validity of judicial acts, even though they be the acts of a judge not lawfully appointed or derive their authority from an unlawful Government. But it is a fallacy to conclude that, because in certain circumstances our courts would recognise as valid the judicial acts of an unlawful court or a de facto judge, therefore, the court thus recognised is a British Court."

10. The de facto doctrine has received judicial recognition in the United States of America also. In ***State* v. *Gardner*** (Cases on Constitutional Law by McGonvey and Howard, Third Edition, p. 102) the question arose whether the offer of a bribe to a City Commissioner whose appointment was unconstitutional was an offence. Bradbury, J. said:

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[18] **(1871) 38 Conn 449**
[19] **(1893) 15 NZLR 361**
[20] **(1886) 118 US 425 : 30 L Ed 178**

"We think that principle of public policy, declared by the English courts three centuries ago, which gave validity to the official acts of persons who intruded themselves into an office to which they had not been legally appointed, is as applicable to the conditions now presented as they were to the conditions that then confronted the English judiciary. We are not required to find a name by which officers are to be known, who have acted under a statute that has subsequently been declared unconstitutional, though we think such officers might aptly be called de facto officers."

11. In ***Norton* v. *Shelby County***[21] Field, J., observed as follows:

> "The doctrine which gives validity to acts of officers de facto whatever defects there may be in the legality of their appointment or election is founded upon considerations of policy and necessity, for the protection of the public and individuals whose interests may be affected thereby. Offices are created for the benefit of the public, and private parties are not permitted to inquire into the title of persons clothed with the evidence of such offices and in apparent possession of their powers and functions. For the good order and peace of society their authority is to be respected and obeyed until in some regular mode prescribed by law their title is investigated and determined. It is manifest that endless confusion would result, if in every proceeding before such officers their title could be called in question."

12. In Cooley's *Constitutional Limitations*, Eighth Edition, Volume 2, p. 1355, it is said:

> "An officer de facto is one who by some colour or right is in possession of an office and for the time being performs its duties with public acquiescence, though having no right in fact. His colour of right may come from an election or appointment made by some officer or body having colorable but no actual right to make it; or made in such disregard of legal requirements as to be ineffectual in law; or made to

[21] **(1871) 38 Conn 449**

> fill the place of an officer illegally removed or made in favour of a party not having the legal qualifications; or it may come from public acquiescence in the qualifications; or it may come from public acquiescence in the officer holding without performing the precedent conditions, or holding over under claim of right after his legal right has been terminated; or possibly from public acquiescence alone when accompanied by such circumstances of official reputation as are calculated to induce people, without inquiry, to submit to or invoke official action on the supposition that the person claiming the office is what he assumes to be. An intruder is one who attempts to perform the duties of an office without authority of law, and without the support of public acquiescence.
>
> No one is under obligation to recognise or respect the acts of an intruder, and for all legal purposes they are absolutely void. But for the sake of order and regularity, and to prevent confusion in the conduct of public business and in security of private rights, the acts of officers de facto are not suffered to be questioned because of the want of legal authority except by some direct proceeding instituted for the purpose by the State or by some one claiming the office de jure, or except when the person himself attempts to build up some right, or claim some privilege or emolument, by reason of being the officer which he claims to be. In all other cases the acts of an officer de facto are as valid and effectual, while he is supposed to retain the office, as though he were an officer by right, and the same legal consequences will flow from them for the protection of the public and of third parties. There is an important principle, which finds concise expression in the legal maxim that the acts of officers de facto cannot be questioned collaterally."

13. In *Black on Judgments* it is said:

"A person may be entitled to his designation although he is not a true and rightful incumbent of the office, yet he is no mere usurper but holds it under colour of lawful authority. And there can be no question that judgments rendered and other acts performed by such a person who is ineligible to a judgeship but who has

nevertheless been duly appointed, and who exercises the power and duties of the office is a de facto judge, and his acts are valid until he is properly removed."

14. The de facto doctrine has been recognised by Indian courts also. In ***Pulin Behari*** Sir Asutosh Mookerjee, J. after tracing the history of the doctrine in England observed as follows:

> "The substance of the matter is that the de facto doctrine was introduced into the law as a matter of policy and necessity, to protect the interest of the public and the individual where these interests were involved in the official acts of persons exercising the duties of an office without being lawful officers. The doctrine in fact is necessary to maintain the supremacy of the law and to preserve peace and order in the community at large. Indeed, if any individual or body of individuals were permitted, at his or their pleasure, to collaterally challenge the authority of and to refuse obedience to the Government of the State and the numerous functionaries through whom it exercised its various powers on the ground of irregular existence for defective title, insubordination and disorder of the worst kind would be encouraged. For the good order and peace of society, their authority must be upheld until in some regular mode their title is directly investigated and determined."

15. In ***P.S. Menon* v. *State of Kerala***[22] a Full Bench of the Kerala High Court consisting of P. Govindan Nair, K.K. Mathew and T.S. Krishna-moorthy Iyer, JJ., said about the de facto doctrine:

> "This doctrine was engrafted as a matter of policy and necessity to protect the interest of the public and individuals involved in the official acts of persons exercising the duty of an officer without actually being one in strict point of law. But although these officers are not officers de jure they are by virtue of the particular circumstances, officers, in fact, whose acts, public policy requires should be considered valid."

[22] **AIR 1970 Ker 165, 170 (FB) : ILR (1969) 2 Ker 391**

16. In the judgment under appeal Kuppuswami and Muktadar, JJ., observed:

> "Logically speaking if a person who has no authority to do so functions as a judge and disposes of a case the judgment rendered by him ought to be considered as void and illegal, but in view of the considerable inconvenience which would be caused to the public in holding as void judgments rendered by judges and other public officers whose title to the office may be found to be defective at the later date. Courts in a number of countries have, from ancient times evolved a principle of law that under certain conditions, the acts of a judge or officer not legally competent may acquire validity."

17. A judge, de facto, therefore, is one who is not a mere intruder or usurper but one who holds office, under colour of lawful authority, though his appointment is defective and may later be found to be defective. Whatever be the defect of his title to the office, judgments pronounced by him and acts done by him when he was clothed with the powers and functions of the office, albeit unlawfully, have the same efficacy as judgments pronounced and acts done by a judge de jure. Such is the de facto doctrine, born of necessity and public policy to prevent needless confusion and endless mischief. There is yet another rule also based on public policy. The defective appointment of a de facto judge may be questioned directly in a proceeding to which he be a party but it cannot be permitted to be questioned in a litigation between two private litigants, a litigation which is of no concern or consequence to the judge except as a judge. Two litigants litigating their private titles cannot be permitted to bring in issue and litigate upon the title of a judge to his office. Otherwise so soon as a judge pronounces a judgment a litigation may be commenced for a declaration that the judgment is void because the judge is no judge. A judge's title to his office cannot be brought into jeopardy in that fashion. Hence the rule against collateral attack on validity of judicial appointments. To question a judge's appointment in an appeal against his judgment is, of course, such a collateral attack.

18. We do not agree with the submission of the learned Counsel that the de facto doctrine is subject to the limitation that the defect in the title of the judge to the office should not be one traceable to the violation of a constitutional provision. The contravention of a constitutional provision may invalidate an

appointment but we are not concerned with that. We are concerned with the effect of the invalidation upon the acts done by the judge whose appointment has been invalidated. The de facto doctrine saves such acts. The de facto doctrine is not a stranger to the Constitution or to the Parliament and the legislatures of the States. Article 71(2) of the Constitution provides that acts done by the President or Vice-President of India in the exercise and performance of the powers and duties of his office shall not be invalidated by reason of the election of a person as President or Vice-President being declared void. So also Section 107(2) of the Representation of the People Act, 1951 (43 of 1951) provides that acts and proceedings in which a person has participated as a member of Parliament or a member of the legislature of a State shall not be invalidated by reason of the election of such person being declared to be void. There are innumerable other Parliamentary and State legislative enactments which are replete with such provisions. The twentieth amendment of the Constitution is an instance where the de facto doctrine was applied by the constituent body to remove any suspicion or taint of illegality or invalidity that may be argued to have attached itself to judgments, decrees, sentences or orders passed or made by certain District Judges appointed before 1966, otherwise than in accordance with the provision of Article 233 and Article 235 of the Constitution. The twentieth amendment was the consequence of the decision of the Supreme Court in ***Chandra Mohan* v. *State of U.P***[23] that appointments of District Judges made otherwise than in accordance with the provisions of Articles 233 and 235 were invalid. As such appointments had been made in many States, in order to pre-empt mushroom litigation springing up all over the country, it was apparently thought desirable that the precise position should be stated by the constituent body by amending the Constitution. Shri Phadke, learned Counsel for the appellants, argued that the constituent body could not be imputed with the intention of making superfluous amendments to the Constitution. Shri Phadke invited us to say that it was a necessary inference from the twentieth amendment of the Constitution that, but for the amendment, the judgments, decrees etc. of the District Judges appointed otherwise than in accordance with the provisions of Article 233 would be void. We do not think that the inference suggested by Shri Phadke is a necessary inference. It is true that as a general rule the Parliament may be presumed not to make superfluous legislation.

[23] **AIR 1966 SC 1987 : (1967) 1 SCR 77**

The presumption is not a strong presumption and statutes are full of provisions introduced because *abundans cautela non nocet* (there is no harm in being cautious). When judicial pronouncements have already declared the law on the subject, the statutory reiteration of the law with reference to particular case does not lead to the necessary inference that the law declared by the judicial pronouncements was not thought to apply to the particular cases but may also lead to the inference that the statute-making body was mindful of the real state of the law but was acting under the influence of excessive caution and so to silence the voices of doubting Thomases by declaring the law declared by judicial pronouncements to be applicable also to the particular cases. In ***Chandra Mohan*** *case* this Court had held that appointments of District Judges made otherwise than in accordance with Article 233 of the Constitution were invalid. Such appointments had been made in Uttar Pradesh and a few other States. Doubts had been cast upon the validity of the judgments, decrees etc. pronounced by those District Judges and large litigation had cropped up. It was to clear those doubts and not to alter the law that the twentieth amendment of the Constitution was made. This is clear from the Statement of Objects and Reasons appended to the Bill which was passed as Constitution (20th Amendment) Act, 1966. The statement said:

> "Appointments of District Judges in Uttar Pradesh and a few other States have been rendered invalid and illegal by a recent judgment of the Supreme Court on the ground that such appointments were not made in accordance with the provisions of Article 233 of the Constitution.... As a result of these judgments, a serious situation has arisen because doubt has been thrown on the validity of the judgments, decrees, orders and sentences passed or made by these District Judges and a number of writ petitions and other cases have already been filed challenging their validity. The functioning of the District Courts in Uttar Pradesh has practically come to a standstill. It is, therefore, urgently necessary to validate the judgments, decrees, orders, and sentences passed or made heretofore by all such District Judges in those States...."

19. In our view, the de facto doctrine furnishes an answer to the submissions of Shri Phadke based on Section 9 of the Criminal Procedure Code and Article 21 of the Constitution. The judges who rejected the appeal in one case and convicted the accused in

> the other case were not mere usurpers or intruders but were persons who discharged the functions and duties of judges under colour of lawful authority. We are concerned with the office that the Judges purported to hold. We are not concerned with the particular incumbents of the office. So long as the office was validly created, it matters not that the incumbent was not validly appointed. A person appointed as a Sessions Judge, Additional Sessions Judge or Assistant Sessions Judge, would be exercising jurisdiction in the Court of Session and his judgments and orders would be those of the Court of Session. They would continue to be valid as the judgments and orders of the Court of Session, notwithstanding that his appointment to such Court might be declared invalid. On that account alone, it can never be said that the procedure prescribed by law has not been followed. It would be a different matter if the constitution of the court itself is under challenge. We are not concerned with such a situation in the instant cases. We, therefore, find no force in any of the submissions of the learned Counsel."

26.15 The overarching consideration of public interest has, therefore, to inform the interpretation and application of the *de facto* doctrine. The Supreme Court did not limit or restrict, in any way, the discharge of functions by the members of the various tribunals whose tenures were extended. The orders passed by Manmohan Singh, J., in his capacity as the Chairman of the IPAB, between 21 September 2019 and 31 December 2020, were, therefore, passed under lawful colour of authority, as he continued to hold office in accordance with the directives of the Supreme Court. Applying ***Gokaraju***, therefore, the *de facto* doctrine clearly legitimizes them.

26.16 Besides the fact that Mr Sai Deepak's stand is, even in law, not correct, acceptance of his contention would result in a situation of chaos, as every judicial decision taken by Manmohan Singh, J., for the

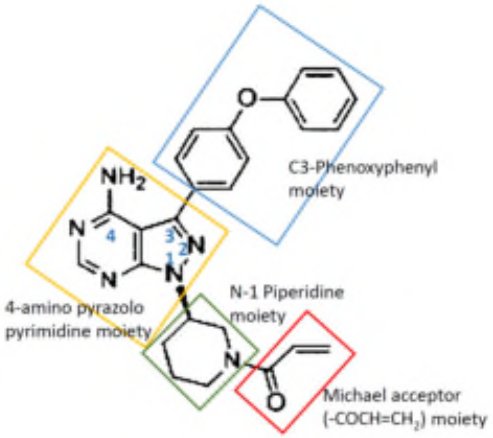
entire period of nearly a year and a quarter after 21 September 2019 would stand invalidated. The law frowns on interpretations which consign the legal position to a state of flux or uncertainty. Given the fact that he was functioning as Chairman under orders of the Supreme Court, there is no justification to invalidate all judicial acts performed by him during the said period. Doing so would also, in my view, be perilously in the teeth of Article 144 of the Constitution of India, which requires all civil and judicial authorities in the territory of India to act in aid of the Supreme Court. The intent of the Supreme Court in allowing members of the tribunals to continue in office was obviously to ensure that the administration of justice continued unimpaired. It would ill behove this Court, therefore, to hold that all judicial acts of such members, during the period of their continuance in office, are invalid and *non est*.

26.17 Mr. Sai Deepak's contention that the consequence of the judgment dated 12 February 2021 in ***International Association for Protection of Intellectual Property*** was that all judgments and orders passed by Manmohan Singh J. after 21 September 2019 were rendered *non est* cannot, therefore, be accepted.

26.18 The plaintiffs are, therefore, within its rights in relying on the IPAB judgment dated 29 September 2020. The extent to which the said judgment would further the case of the plaintiffs has, of course, to be assessed.

27. <u>The order dated 4 March 2020 of the Joint Controller</u>

27.1 To understand the objections raised by Laurus to the validity of the suit patent before the Joint Controller, it is first necessary to understand the chemical structure of Ibrutinib itself. The chemical structure of Ibrutinib comprises four distinct moieties, as under:



27.2 Ibrutinib may, therefore, be regarded as comprising a core 4-amino pyrazolo pyrimidine moiety – which the plaintiffs call the Ibrutinib "nucleus" – with the following three substituents at positions 1, 2, 3 and 4 (in the structure shown above):

(i) N at position 1 attached to the N-1 piperidine ring  with the Michael acceptor attached to the N on the piperidine ring,

(ii) an unattached N at position 2,

(iii) a phenoxy phenyl group attached to the C at position 3, and

(iv) an amino group -NH_2 attached to the C at position 4.

27.3 The post grant opposition filed by Laurus was allowed by the Joint Controller, *vide* his order dated 4 March 2020, on the ground that Ibrutinib was obvious to a person skilled in the art from the prior art documents cited by Laurus and was, therefore, lacking in inventive step.

27.4 Laurus predicated its challenge to the suit patent on clauses (b), (e), (f) and (g) of Section 25(2)[24] of the Patents Act, by alleging that Ibrutinib is lacking in novelty, lacking in inventive step, not patentable by virtue of Section 3(d) and insufficiently described in the complete specifications of the suit patent.

27.5 The Joint Controller rejected the challenge predicated on clauses (b), (f) and (g) of Section 25(2), but upheld the challenge bsed

[24] (2) At any time after the grant of patent but before the expiry of a period of one year from the date of publication of grant of a patent, any person interested may give notice of opposition to the Controller in the prescribed manner on any of the following grounds, namely:—

*****

(b) that the invention so far as claimed in any claim of the complete specification has been published before the priority date of the claim—

(i) in any specification filed in pursuance of an application for a patent made in India on or after the 1st day of January, 1912; or

(ii) in India or elsewhere, in any other document:

Provided that the ground specified in sub-clause (ii) shall not be available where such publication does not constitute an anticipation of the invention by virtue of sub-section (2) or sub-section (3) of Section 29;

*****

(e) that the invention so far as claimed in any claim of the complete specification is obvious and clearly does not involve any inventive step, having regard to the matter published as mentioned in clause (b) or having regard to what was used in India before the priority date of the claim;

(f) that the subject of any claim of the complete specification is not an invention within the meaning of this Act, or is not patentable under this Act;

(g) that the complete specification does not sufficiently and clearly describe the invention or the method by which it is to be performed;

on clause (e). He held, therefore, that Ibrutinib was lacking in any inventive step – in other words, that it was "obvious" to a person skilled in the art – from the prior art cited by Laurus.

27.6 The rejection, by the Joint Controller, of the challenge of Laurus predicated on clauses (b), (f) and (g) of Section 25(2) was never challenged.

27.7 The challenge under Section 25(2)(c) was premised on the following prior art documents:

(i) WO2002/080926 (WO'926),

(ii) US 2004/0006083 (US'083),

(iii) WO 2004/100868 (WO'868),

(iv) Andrew F. Burchatet et al, Bioorganic & Medicinal Chemistry, 2002, 12 (Andrew *et al* 2002), and

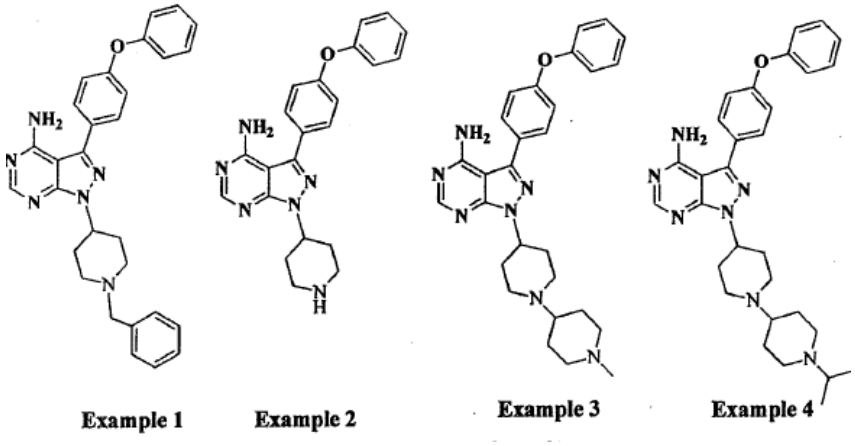
(v) Robert A. Copeland, Evaluation of Enzyme Inhibitors in Drug Discovery, 2005.

27.8 Regarding the prior art documents cited by Laurus, Laurus' submissions, and the findings of the Joint Controller, were as under:

(i) <u>Re. WO2002/080926 (WO'926)</u>

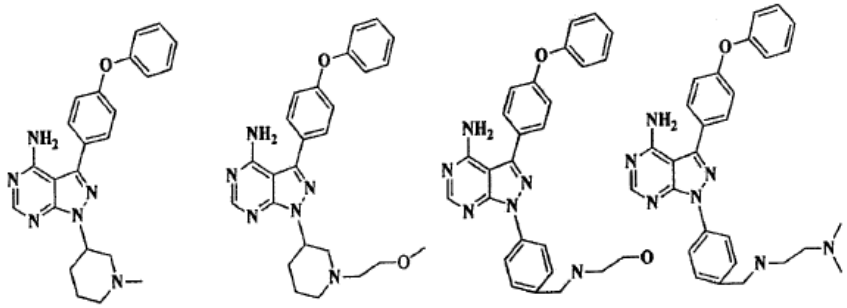
Laurus contended that this patent described various protein tytrosine kinase inhibitors and that the preferred

compounds in the patent were those in which, on the core 4-amino pyrazolo pyrimidine moiety, the phenoxyphenyl moiety was substituted at the third and the piperidine moiety was substituted at the first place. Some relevant compounds were cited thus:



(ii) Re. US 2004/0006083 (US'083):

This patent was also stated to disclose various tyrosine kinase inhibitors, including potential Btk inhibitors. They all had the 4-amino-pyrazolo-[3,4] pyrimidine core with substitutions at positions 1 and 3, to result in Ibrutinib like compounds. The following relevant compounds were disclosed by this patent:



(iii) Re. WO 2004/100868 (WO'868) and Andrew F. Burchatet et al, Bioorganic & Medicinal Chemistry, 2002, 12 (Andrew *et al* 2002)

These, too, were stated to disclose a patent with the 4-amino-pyrazolo-pyrimidine core, with many of the disclosed compounds containing phenoxyphenyl based with piperidine or other heterocyclic substitutions. The compounds were stated to show significant Lck inhibitory activity.

(iv) Re. Robert A. Copeland, Evaluation of Enzyme Inhibitors in Drug Discovery, 2005 ("Copeland", hereinafter)

Laurus contended that Copeland disclosed, which was said to disclose irreversible enzyme inactivators, and contained the requisite teaching to instruct a person skilled in the art to attach the Michael receptor to the N-piperidinyl moiety.

27.9 The Joint Controller noted, in the opening paragraphs of his discussion on the aspect of inventive step in the suit patent vis-à-vis prior art, that the contention of the plaintiffs that all the compounds disclosed in the prior art patents were Lck inhibitors, and not Btk inhibitors, was correct. However, the prior art had to be seen as a whole, and all prior arts referred to the proteins as under the general tyrosine kinase family. The Joint Controller placed reliance on the following recital in the complete specifications of the suit patent:

> "Further described are irreversible inhibitors of Btk that form a covalent bond with a cysteine residue on Btk. Further described herein are irreversible inhibitors of other tyrosine kinases, wherein the tyrosine kinases share homology with Btk by having a cysteine residue (including a Cys 481 residue) that can form a covalent bond with the irreversible inhibitor (such tyrosine kinases are referred herein as "Btk tyrosine kinase cysteine homologs").
>
> [0163] Further, the irreversible Btk inhibitor compounds described herein can be used to inhibit a small subset of other tyrosine kinases that share homology with Btk by having a cysteine residue (including a Cys 481 residue) that can form a covalent bond with the irreversible inhibitor. See e.g. protein kinases in FIG. 1. Thus, a subset of tyrosine kinases other than Btk are also expected to be useful as therapeutic targets in a number of health conditions.
>
> [0039] In another aspect are methods for modulating, including irreversibly inhibiting the activity of Btk or other tyrosine kinases, wherein the other tyrosine kinases share a homology with Btk by having a cysteine residue (incuding a Cys 481 residue) that can form a covalent bond with at least one irreversible inhibitor described therein, in a mammal comprising administering to the mammal at least once an effective amount of at least one compound having the structure of any of Formula (A), Formula (B), Formula (C) or Formula (D)."

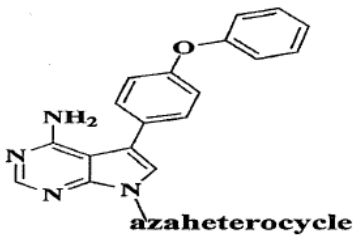
Figure 1, referred to in para [00163] of the complete specifications is the following:

#	473	474	475	476	477	478	479	480	481	482	483
BTK	I	T	E	Y	M	A	N	G	C	L	L
BMX	V	T	E	Y	M	A	R	G	C	L	L
TEC	V	T	E	F	M	E	R	G	C	L	L
TXK	V	T	E	F	M	E	N	G	C	L	L
ITK	V	F	E	F	M	E	H	G	C	L	S
EGFR	I	T	Q	L	M	P	F	G	C	L	L
ErbB2	V	T	Q	L	M	P	Y	G	C	L	L
ErbB4	V	T	Q	L	M	P	H	G	C	L	L
JAK3	V	M	E	Y	L	P	S	G	C	L	R
BLK	V	T	E	Y	L	P	S	G	C	L	L
LCK	I	T	E	Y	M	E	N	G	S	L	V
LYN	I	T	E	Y	M	A	K	G	S	L	L
SYK	V	M	E	M	A	E	L	G	P	L	N

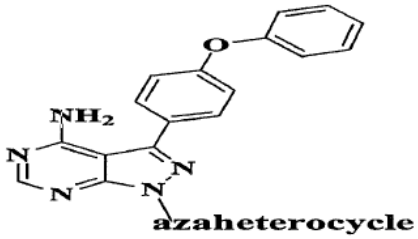
27.10 The Joint Controller observed that, in Figure 1, the plaintiff had shown how Btk protein had homology with other tyrosine kinases including Lck. As such, the plaintiff itself appeared to state, in the complete specifications of the suit patent, that the suit patent was claiming inhibitor compounds which not only inhibited Btk but could also be expected to inhibit other homologous tyrosine kinases of which Lck was one. The crystalline structure of Btk was known. Btk contained a cysteine residue in its ATP binding domain/kinase domain. *As Lck and Btk admittedly had similar structures with cysteine residue, the notion that Lck inhibitors were likely to act as Btk inhibitors was not without any basis*. As such, the submission of the plaintiff that Lck and Btk were totally unrelated and that prior art regarding Lck was required to be rejected was not acceptable, as it

was contrary to the complete specifications of the suit patent. Laurus was, therefore, entitled to rely on prior are pertaining to compounds which acted as Lck inhibitors.

27.11 Andrew et al 2002 described compounds with the 4-amino-pyrazolo-[3,4] pyrimidine core, which were synthesised and evaluated as Lck inhibitors. The Joint Controller referred to the following examples of two such compounds:



Compound 1

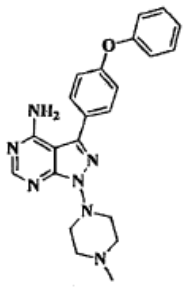


Compound 2

27.12 Of these, Compound 1 had the pyrrolopyrimidine core whereas Compound 2 had the pyrazolopyrimidine core. In each case, the core had N-methyl piperazine appended to a cyclohexyl group at position 1 and the phenoxy-phenyl moiety at position 3. Studies conducted by Laurus indicated that Compound 2 was more therapeutically effective than Compound 1. This was because the phenoxy-phenyl moiety position at 3 occupied the lipophilic pocket in the Lck protein ribose thereby increasing potency. Thus, Compound 2 was found to be more efficacious. As there were only two such compounds in Andrew et al 2002, there was no reason why a person skilled in the art would not select the more efficacious Compound 2 which had a

pyrazolopyrimidine core. Similarly, the placement of the phenoxy-phenyl moiety at position 3 was also logical for a person skilled in the art, as it was shown to be beneficial and responsible for increasing potency.

27.13 The Joint Controller, therefore, opined that a person looking to make an effective compound would, therefore, be expected to retain the phenoxy-phenyl moiety on the pyrazolopyrimidine core. He further observed that Andrew et al, after tests on Compounds 1 and 2, found that, as the ribose pocket of the Lck protein was occupied by N-methyl piperazine, it was important to substitute the N-methyl piperazine group at position 1, resulting in the following compound:



Thus, the inference that substitution of the N-methyl piperazine moiety, at Position 1 of the 4-amino-pyrazolo-[3,4] pyrimidine core would facilitate oral dosing and enable efficacy of the compound, could not be ignored.

27.14 As against this, the plaintiffs sought to contend that, while Ibrutinib had a piperidine moiety attached to N at position 1, the

compound disclosed in Andrew et al had a cyclohexyl group at position 1 to which N-methyl piperazine was appended. Andrew et al, it was submitted, did not contain any teaching, leading a person skilled in the art to substitute the cyclohexyl group combined with N-methyl piperazine at position 1 of the 4-amino-pyrazolo-[3,4] pyrimidine core with a simple piperidine ring.

27.15 Apropos this submission, the Joint Controller observed that the advisability of attaching the cyclohexyl group with N-methyl piperazine at first position to the 4-amino-pyrazolo-[3,4] pyrimidine core was essentially because the substituted cyclohexyl moiety occupied the ribose pocket. As such, a person skilled in the art would search for similar nitrogen based heterocyclic groups, structurally similar to the cyclohexyl group which could occupy the ribose pocket as N-methyl piperazine did. These were few in number. The piperidinyl group was frequently used in the prior art as in WO'868. The Joint Controller also observed that it was common knowledge that the piperidinyl group was closely similar to the cyclohexyl group which was already present in Andrew *et al*.

27.16 As substitution with cyclohexyl with attached N-methyl piperazine was already suggested in Andrew et al, and the piperidinyl group was found within the compounds in other prior arts, also of Abbot, it was possible to expect a replacement of the cyclohexyl N-methyl piperazine moiety with piperidine and expect anti-tyrosine

kinase activity. This was an obvious step which a person skilled in the art would take.

27.17 With regard to the attachment of the Michael acceptor to the piperidine moeity in Ibrutinib, the Joint Controller held that all mechanisms of irreversible engime inactivation were based on covalent modification of the engime and, therefore, displayed slow binding kinetics. For this purpose, incorporation of the Michael acceptor, to bind to covalently inactive cystine residues in the target engime had already entered human clinical trials for the treatment of rhinovirus infection and canceer. These found place in the Copeland article which showed the incorporation of the Michael acceptor group to obtain irreversible kinase inactivators in at least EKB-569 and CI-1033. Thus, the fact that adding of a Michael acceptor to the main compound was possible and that success could be achieved, could be gathered from the Copeland article. This constituted sufficient teaching to a person skilled in the art.

27.18 Thus, by combining elements from WO'926, US' 083 and WO'868 with the teachings contained in Andrew et al 2002 and the Copeland article, the Joint Controller held that the suit patent which claimed Ibrutinib was invalid for lack of inventive step vis-a-vis prior art.

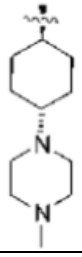
28. Judgment of the IPAB

28.1 The IPAB set aside the decision of the Joint Controller, *vide* its judgment dated 29 September 2020. The decision of the Joint Controller to analogise Lck and Btk was found to be fundamentally flawed. The IPAB found that the complete specifications of the suit patent did not at any point treat Lck and Btk as analogous or homologous. In fact, *Lck and Btk were distinct and different, as Btk had a cysteine residue at the 481 position whereas Lck had a serine residue at the corresponding 481 position. This was apparent from Figure 1*.

28.2 The IPAB held that, to arrive at a finding that there was lack of inventive step, the prior art and the suit patent were required to be analogous. The prior arts chosen by Laurus were not analogous to the suit patent and no finding of want of inventive step could be based thereon.

28.3 Insofar as the compounds disclosed in Andrew *et al* were concerned, the IPAB observed that the findings of the Joint Controller were contradictory. At one point, the Joint Controller stated that the ribose pocket of the Lck protein was filled up with the cyclohexyl group with N-methyl piperazine and, at another, that it was occupied by the N-methyl piperazine moiety alone.

28.4 The finding of the Joint Controler that a person skilled in the art would, from the prior art, be led to substitute the N-methyl piperazine moiety in Andrew *et al* with the piperadine group which figured the suit patent, was also found to be without any basis. These two moieties were fundamentally different:

Cyclohexyl ring appended with N-methyl piperazine as seen in compounds 1 and 2 of Andrew et al.	**Piperidinyl substitution**
	

28.5 Thus, the cyclohexyl ring appended with N-methyl piperazine and piperidinyl moieties were fundamentally different. No one could treat them as interchangeable in the absence of empirical studies. In medicinal chemistry, a small change in a structure of a compound could have a drastic effect on its activity.

28.6 Similarly, it could not be said that the Copeland article taught the modification, even to a person skilled in the art, of attaching a Michael acceptor to the N-1 piperidine moiety. The mere fact that there were some compounds suggested in Copeland which used a Michael acceptor, could hardly be a ground to state that a person

skilled in the art would invariably be led to attach a Michael acceptor to the N-1 piperidine moiety so as to lead him to Ibrutinib.

28.7 Having noted these facts, the IPAB concluded thus:

> "18.6 Firstly, whether the invention was a combination of hitherto known features is based on "hindsight analysis" and we are not inclined to accept it. Even after the hindsight analysis and permutations/combinations, the person skilled in the art could not reach the subject matter of the present invention. Even if we consider for a while the contention of the Learned Controller, Hon'ble Supreme Court laid down the following criteria for assessing "inventive step" which will be very appropriate in this situation. In M/s. Bishwanath Prasad Radhey Shyam v. M/s. Hindustan Metal Industries[25], *"It is important that in order to be patentable an improvement on something known before or a combination of different matters already known, should be something more than a mere workshop improvement; and must independently satisfy the test of invention or an 'inventive step'. To be patentable the improvement or the combination must produce a new result, or a new article or a better or cheaper article than before. The combination of old known integers may be so combined that by their working interrelation they produce a new process or improved result. Mere collection of more than one integers or things, not involving the exercise of any inventive faculty, does not qualify for the grant of a patent."* Hence, once the Learned Controller comes to conclusion *that invention consists merely a combination of known features, which does not give rise to an inventive technical advance,* whether it was judged that this combination is more than a mere workshop improvement or whether the new combination satisfies the test of inventiveness on its own? [Emphasis added]. The order of the Learned Controller is silent on these aspects.
>
> 18.7 The Learned Controller concludes in his decision dated 04/03/2020 *"Having considered all the submissions made by the applicant/patentee during the hearing as well as*

[25] **AIR 1982 SC 1444**

submissions made by the opponent and also in view of the above circumstances and observations, I hereby conclude that the instant granted claims are obvious to a ordinary person skilled in the art therefore lack of inventive step over cited prior art documents.....” [Emphasis added].

18.8 It is worth mentioning here that the concept of “ordinary” person skilled in the art is not available in the Indian Patent Act, 1970. The determination of “inventive step” as envisaged in the Patents Act under section 2(1)(ja) clearly stipulates “person skilled in the art”. The adjective “ordinary” does not find mention with “person skilled in the art” in the entire Patent Act, 1970. That is why the test of “inventive step” as envisaged in the “Manual of Patent office Practice and Procedure 2019” finds its basis in the Hon’ble Supreme court judgment in ***Bishwanath Prasad Vs. Hindustan Metal Industries***.

18.9 The concept of “person skilled in the art” is often confused with the concepts of *“a person in India possessing average skill in, and average knowledge”* as provided in of section 64(h) quoted below:

> *“(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;”*

18.10 The requirement of *“a person in India possessing average skill in, and average knowledge of, the art to which the invention relates, to work the invention”* is for determining the “sufficiency of disclosure’ by proving “workability” of invention and it is different than that of ascertaining the patentability requirements such as determination of “inventive step” of an invention which requires “person skilled in the art”. In absence of any definition of this term in the Patents Act,

1970, the definition provided in Bishwanath Prasad Vs. Hindustan Metal Industries as *"a competent craftsman (or engineer as distinguished from a mere artisan)"* is adopted in said Manual. The relevant portion of the Judgment of Hon'ble Supreme court in Bishwanath Prasad Vs. Hindustan Metal Industries is quoted below:

18.11 *Another test of whether a document is a publication which would negative existence of novelty or an "inventive step" is suggested, as under:*

> *"Had the document been placed in the hands of a competent draftsman (or engineer as distinguished from a mere artisan), endowed with the common general knowledge at the "priority date", who was faced with the problem solved by the patentee but without knowledge of the patented invention, would he have said, "this gives me what I want?" (Encyclopedia Britannica; ibid). To put it in another form: "Was it for practical purposes obvious to a skilled worker, in the field concerned, in the state of knowledge existing at the date of the patent to be found in the literature then available to him, that he would or should make the invention the subject of the claim concerned?" [Halsbury, 3rd Edn., Vol. 29, p. 42 referred to by* ***Vimadalal, J. of Bombay High Court in Farbwerke Hoechst & B. Corporation v. Unichem Laboratories***[26] *" [Emphasis added]*

18.12 On the issue of inventive ingenuity of the invention, we have analyzed the contentions of either party, analysed the prior arts and the order of the Learned Controller and arrived at the conclusion that the Learned Controller could not have arrived at the present findings without the "hindsight analysis". The "alleged ordinary person skilled in the art" as the Learned Controller conceived, could not have visualised the chemical substitutions such as replacing Cyclohexane at position 1 of Andrew's compound with Piperidine, let alone obtaining the compound of the impugned invention with Michael acceptor.

[26] **AIR 1969 Bom 255 (Bom HC)**

18.13 This case is, therefore, a clear case of 'hindsight analysis' as mentioned above. The pharmaceutical Guidelines are quite clear on hindsight analysis when it says *"The 'obviousness' has to be strictly and objectively judged. To judge obviousness objectively, the skilled person needs to eliminate the hindsight analysis...."* This approach is against the spirit of the law. As stated earlier, one of the significant analysis while determining the inventive step is "*v. Viewed without any knowledge of the alleged invention as claimed do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of inventive ingenuity*?". Even Bishwanath Prasad Vs. Hindustan Metal Industries held that "Had the document been placed in the hands of a competent craftsman (or engineer as distinguished from a mere artisan), endowed with the common general knowledge at the 'priority date', who was faced with the problem solved by the patentee but without knowledge of the patented invention, ..." [Emphasis added] In the instant appeal it is observed that every effort by the alleged "ordinary person skilled in the art" is done to reach to the invention having full knowledge of the invention.

18.14 Further, with regard to analogous prior art, we conclude that an inhibitor compound as described and claimed in IN'968 cannot be generalized in its selectivity and function. We have seen that nowhere in the complete specification of IN'968 that both Lck and Btk are shown analogues. Lck does not share homology with Btk either and hence, the prior art document are considered to be non-analogous. Therefore, the determination arrived at on the issue of 'inventive step' cannot be said to be objectively assessed."

29. With that, I now turn to the interlocutory applications before me.

CM. APPL. 9916/2021 in WP(C) IPD-3245/2021 filed by Laurus Labs

30. Scope of interference

30.1 Laurus has challenged the judgment dated 29 September 2020 of the IPAB by means of WP(C) 3245/2021. Notice stands issued in the writ petition.

30.2 Laurus has also sought, by means of the present miscellaneous petition, a stay of operation of the IPAB judgment. When sitting in judicial review, under Article 226 or 227, over the judgment of a judicial or quasi-judicial authority, the jurisdiction exercised by the writ court is one of certiorari. The boundaries of certiorari jurisdiction stand authoritatively delineated in the following passages from ***Syed Yakoob v. K.S Radhakrishnan***[27]:

> "7. The question about the limits of the jurisdiction of High Courts in issuing a writ of certiorari under Article 226 has been frequently considered by this Court and the true legal position in that behalf is no longer in doubt. *A writ of certiorari can be issued for correcting errors of jurisdiction committed by inferior courts or tribunals: these are cases where orders are passed by inferior courts or tribunals without jurisdiction, or is in excess of it, or as a result of failure to exercise jurisdiction. A writ can similarly be issued where in exercise of jurisdiction conferred on it, the Court or Tribunal acts illegally or in properly, as for instance, it decides a question without giving an opportunity to be heard, to the party affected by the order or where the procedure adopted in dealing with the dispute is opposed to principles of natural justice. There is, however, no doubt that the jurisdiction to issue a writ of certiorari is a supervisory jurisdiction and the Court exercising it is not entitled to act as an Appellate Court.* This limitation necessarily means that findings of fact reached by the inferior Court or Tribunal as result of the appreciation of evidence cannot be reopened or questioned in writ proceedings. An error of law

[27] **AIR 1964 SC 477**

which is apparent on the face of the record can be corrected by a writ, but not an error of fact, however grave it may appear to be. In regard to finding of fact recorded by the Tribunal, a writ of certiorari can be issued if it is shown in recording the said finding, the Tribunal had erroneously refused to admit admissible and material evidence, or had erroneously admitted inadmissible evidence which has influenced the impugned finding. Similarly, if a finding of fact is based on no evidence, that would be regarded as an error of law which can be corrected by a writ of certiorari. In dealing with this category of cases, however, we must always bear in mind that a finding of fact recorded by the Tribunal cannot be challenged in proceedings for a writ of certiorari on the ground that the relevant and material evidence adduced before the Tribunal was insufficient or inadequate to sustain the impugned finding. The adequacy or sufficiency of evidence led on a point and the inference of fact to be drawn from the said finding are within the exclusive jurisdiction of the Tribunal, and the said points cannot be agitated before a writ Court. It is within these limits that the jurisdiction conferred on the High Courts under Article 226 to issue a writ of certiorari can be legitimately exercised.

8. *It is, of course, not easy to define or adequately describe what an error of law apparent on the face of the record means. What can be corrected by a writ has to be an error of law; it must be such an error of law as can be regarded as one which is apparent on the face of the record. Where it is manifest or clear that the conclusion of law recorded by an inferior Court or Tribunal is based on an obvious mis-interpretation of the relevant statutory provision, or sometimes in ignorance of it, or may be, even in disregard of it, or is expressly founded on reasons which are wrong in law, the said conclusion can be corrected by a writ of certiorari. In all these cases, the impugned conclusion should be so plainly inconsistent with relevant statutory provision that no difficulty is experienced by the High Court in holding that the said error of law is apparent on the face of the record. It may also be that in some cases; the impugned error of law may not be obvious or patent on the of the record as such and the Court may need an argument to discover the said error; but there can be no doubt that what can be corrected by a writ of certiorari is an error of law and the said error must, on the whole, be of such a character as would satisfy the test that it is an error of law apparent on the face of the record.* If a statutory provision is reasonably capable of two constructions and one construction has been adopted by the inferior Court or Tribunal, its conclusion may not necessarily or

> always be open to correction by a writ of certiorari. In our opinion, it neither possible nor desirable to attempt either to define or to describe adequately all cases of errors which can be appropriately described as errors of law apparent on the face of the record. Whether or not an impugned error is an error of law and an error of law which is apparent on the face of the record, must always depend upon the facts and circumstances of each case and upon the nature and scope of the legal provision which is alleged to have been misconducted or contravened."
>
> (Emphasis supplied)

30.3 The writ court, therefore, does not sit in appeal over the decision under challenge, passed by the hierarchically lower judicial or quasi-judicial authority. The scope of interference is limited to examining whether there has been an error of jurisdiction in the decision of the authority below or whether the decision is so fundamentally opposed to law as justify interference by way of certiorari. Classically expressed, the scope of judicial review is restricted to the manner in which the decision under challenge has been arrived at, rather than the merits of the decision itself. Of course, if the decision is markedly perverse, or such as no person properly instructed in the law the facts would arrive at, interference would be justified.

30.4 While, thus, the scope of judicial review in a writ petition itself is circumscribed, even more restricted is the scope of an application that seeks stay of the decision under challenge. Stay can be granted only if the considerations of a *prima facie* case, balance of convenience and irreparable loss coalesce.

30.5 Further, at an interim stage, the Court would not ordinarily grant *status quo ante*. The principles for grant of *status quo ante* are analogous to those which govern the grant of interlocutory mandatory injunction in the CPC, in respect of which the decision most often cited is ***Dorab Cawasji Warden v. Coomi Sarab Warden***[28], from which the following passages may be profitably extracted:

> "16. The relief of interlocutory mandatory injunctions are thus granted generally to preserve or restore the status quo of the last non-contested status which preceded the pending controversy until the final hearing when full relief may be granted or to compel the undoing of those acts that have been illegally done or the restoration of that which was wrongfully taken from the party complaining. But since the granting of such an injunction to a party who fails or would fail to establish his right at the trial may cause great injustice or irreparable harm to the party against whom it was granted or alternatively not granting of it to a party who succeeds or would succeed may equally cause great injustice or irreparable harm, courts have evolved certain guidelines. Generally stated these guidelines are:
>
> > (1) The plaintiff has a strong case for trial. *That is, it shall be of a higher standard than a prima facie case that is normally required for a prohibitory injunction.*
> >
> > (2) It is necessary to prevent irreparable or serious injury which normally cannot be compensated in terms of money.
> >
> > (3) The balance of convenience is in favour of the one seeking such relief.
>
> 17. Being essentially an equitable relief the grant or refusal of an interlocutory mandatory injunction shall ultimately rest in the sound judicial discretion of the court to be exercised in the light of the facts and circumstances in each case. Though the above guidelines are neither exhaustive nor complete or absolute rules,

[28] **(1990) 2 SCC 117**

and there may be exceptional circumstances needing action, applying them as prerequisite for the grant or refusal of such injunctions would be a sound exercise of a judicial discretion."

(Emphasis supplied)

31. On merits

31.1 When one examines the judgment of the IPAB in the light of these principles, no case for grant of stay can be said to be made out. While considering Laurus' prayer for stay, the Court has to bear in mind the fact that the decision under challenge is one which reverses, judicially, the decision of the Joint Controller. The IPAB has rendered a well-considered decision, offering cogent and convincing reasons for setting aside the decision of the Joint Controller. There is, in fact, no justifiable explanation, forthcoming in the decision of the Joint Controller, to treat Lck inhibitors as analogous to Btk inhibitors. The reliance, by the Joint Controller, on Figure 1, to which reference is contained in [para 00163] in the complete specifications of the suit patent, is obviously misplaced, as the Joint Controller failed to notice that, at the 481 position, Btk had a cysteine residue whereas Lck had the Serine residue. This is immediately apparent from Figure 1 as reproduced in para 27.9 *supra.* For the Btk protein, the residue at the 481 position is "C", meaning cysteine, and, for the Lck protein, it is "S", meaning serine. Apart from this, there is nothing, in the decision of the Joint Controller, to justify a finding either of analogy or homology between Lck and Btk.

31.2 The principle of homology, in assessing novelty of a granted patent vis-à-vis prior art, is of especial relevance in the case of pharmaceutical patents involving protein nucleotides. Lord Hoffmann, speaking for the House of Lords in ***Kirin-Amgen Inc v Hoechst Marion Roussel Ltd***[29] expounded on the concept thus:

> "33. In the case of a patent specification, the notional addressee is the person skilled in the art. He (or, I say once and for all, she) comes to a reading of the specification with common general knowledge of the art. And he reads the specification on the assumption that its purpose is to both to describe and to demarcate an invention-a practical idea which the patentee has had for a new product or process-and not to be a textbook in mathematics or chemistry or a shopping list of chemicals or hardware. It is this insight which lies at the heart of "purposive construction" ... The purpose of a patent specification, as I have said, is no more nor less than to communicate the idea of an invention.
>
> *****
>
> 46. As techniques improved and amounts of data became more substantial it became possible to do better than ESTs. It was possible to identify from published sequence data full length nucleotide sequences for proteins. Once that is done you can deduce the amino acid sequence of the protein encoded. And you should be able to make it (the details of how do not matter). But, unlike the days of wet-lab techniques (where you knew it at the outset), you do not know what function the protein has.
>
> 47. Even at that stage, however, it is more than reasonable to suppose that it has some biological function after all the body is carrying the gene for it. One can say in general terms that if there is a disease or condition involving a deficiency of the protein then it may be treatable with it. Or if there is a disease or condition caused by overproduction of the protein it may be treatable with an antibody to the protein. So in a very general sense one can say there is probably an application for the protein or its antibodies. As will be seen, however, that is not good enough to make the protein or its antibodies patentable. You have to say something more about

[29] **(2005) 1 All ER 667**

their proposed use than they will probably be useful in medicine, though that is very likely to be so. The question in general is how much more you need to say and how reliable what you say needs to be.

48. *Without in vitro and ultimately in vivo assays, you cannot definitely know what the protein you have discovered actually does. However even before that stage it may, in the case of some proteins, be possible to make an informed guess. This can be done by seeing how closely the amino-acid sequence of your newly identified protein resembles the amino-acid sequence of a known protein or "family" of proteins. You look for homology between your protein and the known protein or family of proteins. If there is some degree of homology and you know or can predict reasonably well what the known family member(s) do then you can hazard a guess that your unknown one does something like it or them.*

49. Of course *how likely it is that your guess will turn out to be true depends on a host of factors, for instance how homologous your protein sequence is to the other protein sequence(s), how specific the action of the known protein or family of proteins is known to be and how specific your surmise as to its function is. No doubt other factors also come into play.*"

(Emphasis supplied)

Characterizing a granted pharmaceutical patent as lacking in inventiveness on the basis of the disclosures contained in a prior art document which deals with a compound which does not react with the protein with which the subject matter of the granted patent reacts, but with a protein which is *homologous* thereto is, therefore, a serious exercise. It involves extensive *in vivo* and *in vitro* studies. It cannot ordinarily be reckoned by a mere glance at structural similarities between the proteins with which the subject matter of the suit patent, and the prior art, react. As the plaintiffs correctly pointed out before

the IPAB, in medical studies, the slightest difference in chemical structure could alter, altogether, the effect of the drug.

31.3 I am unable, given the degree of circumspection that is needed in such matters, to sustain the decision of the Joint Controller to treat prior art compounds which reacted not with Btk but with Lck inhibitors as relevant prior art so as to justify a finding of lack of inventive step in the suit patent. At the very least, the Joint Controller clearly erred in treating Btk and Lck proteins as homologous. The IPAB was, therefore, correct in the view it took.

31.4 Similarly, the basis for the decision of the Joint Controller that a person skilled in the art would, from the teachings in Andrew *et al*, be led to substituting the cyclohexyl group, with N-methyl piperazine attached, with the Piperidinyl group, is completely unconvincing. The two moieties are, as the plaintiff pointed out and the IPAB correctly appreciated, completely dissimilar in structure. Equally, the reliance on Copeland *et al* to hold that a person skilled in the art would, from the teachings in the said article, be persuaded to attach a Michael acceptor to the N-Piperidinyl moiety attached to the 4-amino-pyrazolo-[3,4] pyrimidine core, also fails to satisfy.

31.5 While the amenability of such findings, contained in the judgment dated 29 September 2020 of the IPAB, to judicial review, under Article 226/227 of the Constitution of India is itself highly

questionable, even if it were to be assumed that these findings could sustain a re-examination on merits in such an exercise, it cannot be said that a *prima facie* case for staying the decision of the IPAB is made out. More so, as the effect of a stay would be to restore the *status quo ante* prior to the decision of the IPAB. The IPAB has restored the suit patent, which stood revoked by the Joint Controller. A stay of the said decision would amount to undoing the restoration and reviving the revocation. That would amount to a *status quo ante* at an interim stage. Such an order is normally not to be passed. It is only in the most exceptional of cases, which satisfy the ***Dorab Cawasji Warden*** test that an order of *status quo ante* can be granted at an interim stage. The present case miserably fails to satisfy to reach that standard.

31.6 As such, I am not persuaded to stay the operation of the judgment dated 29 September 2020 of the IPAB in OA/46/2020/PT/DEL.

31.7 CM 9916/2021 filed by Laurus Labs is accordingly dismissed.

IA 18051/2019 [applicable, *mutatis mutandis*, to other IAs under Order XXXIX Rules 1 and 2]

32. Thus, the judgment dated 29 September 2020 of the IPAB has *prima facie* to be treated as correct for the purposes of the applications in the present suits under Order XXXIX Rules 1 and 2 of the CPC,

seeking interlocutory injunction. The decision is one by a high judicial authority which possesses expertise in the realm of intellectual property. The findings in the said decision are well-reasoned and contained in-depth judicial and technical analyses.

33. To the extent the challenge by the defendant, in the present suits, are covered by the grounds for revocation of the suit patents, urged by Laurus Labs, I am not inclined to reinvent the wheel.

34. Learned Senior Counsel for the plaintiffs contended that, the judgment of the IPAB has resulted in a *prima facie* case in the plaintiffs' favour, insofar as the validity of the suit patent is concerned. The defendants have, on merits, sought to defend the present suits only on the premise that the suit patent is invalid. In the light of the judgment of the IPAB, the *prima facie* merits of such a challenge have necessarily to be held to be in favour of the plaintiffs and against the defendants. As such, unless the defendants are able to demonstrate grounds beyond those which were urged before the Joint Controller and, later, before the IPAB, as would result in a credible challenge to the validity of the suit patents, the plaintiffs are entitled to an injunction. So argue learned Counsel for the plaintiffs.

35. <u>Additional material cited by defendants</u>

35.1 Mr. Sai Deepak, learned Counsel for the defendants has placed written submissions on record, common to all the present suits. Apart from relying on the patents and literature cited by Laurus as prior art in the proceedings which culminated in the IPAB judgment dated 29 September 2020, Mr. Sai Deepak places reliance on the following other material:

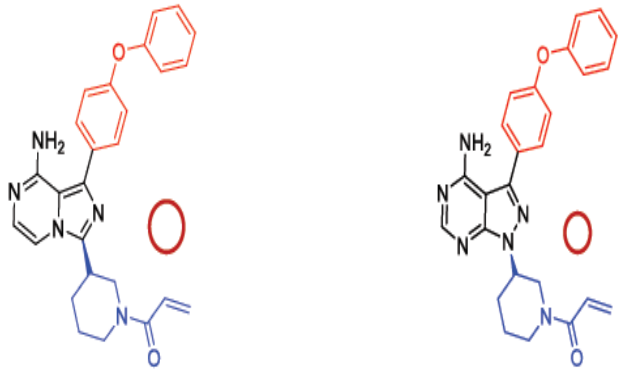
(i) US Patent 7459554 (US' 554)

(a) Mr. Sai Deepak submits that Acerta Pharma B.V., AstraZeneca UK Ltd. and AstraZeneca Pharmaceuticals, as the holders of the US'554 patent, filed a complaint of infringement against the plaintiff, which was settled by the plaintiffs on a "with prejudice" basis. He contends that as the compound claimed in the suit patent is the same product which was covered by US'554, the plaintiff was duty bound to disclose the history of litigation with respect to the patent which involved the plaintiff. Thereafter, in para 5 (vi) and (vii) of his written submissions, dated 14 January 2022, Mr. Sai Deepak contends:

> "vi. Without prejudice to the above, US'554 and its parent document WO'836 (@ page 690 of documents filed by D-3 in CS (Comm) 342 of 2020) disclose the very same compound claimed in the suit patent, namely imidazopyrazine compounds which act as tyrosine kinase inhibitors, including for Bruton's tyrosine kinase. While the

specific compound commercialised out of WO'836 is Acalabrutinib sold by AstraZeneca as Calquence, it does not take away the fact that Ibrutinib is covered and disclosed by US'554. WO'836 not just covers but also discloses an imidazo[1,5-a]pyrazine core whereas Ibrutinib has a pyrazolo[3,4-d]pyrimidine core.

vii. For ease of reference, the respective structures of Acalabrutinib and Ibrutinib are reproduced below:



Compound I (WO'836/ US'554) Acalabrutinib Ibrutinib

The difference between the above two compounds, if any, is immaterial in terms of activity of the respective compounds, their manner of action and efficacy. The respective cores of WO'836 and Ibrutinib both serve the same function – to facilitate binding to and inhibition of a tyrosine kinase, including Bruton's Tyrosine Kinase. The respective cores perform substantially the same function in the same method and to achieve the same result. It is also recognised in the art as far back as mid-2000 before the priority date of IN'968 that imidazopyrazines and pyrrolopyrimidies are chemical equivalents."

(b) A bare glance at the averments contained in the above passages from Mr. Sai Deepak's submissions disclose that it cannot be said, *prima facie*, that a credible

challenge to validity of suit patent has been laid by Mr. Sai Deepak on the basis of US'554. The written submissions admit that the core moiety in the Ibrutinib is pyrazolo-[3,4] pyrimidine, whereas the core moiety in US'554 is imidazo pyrazine. A glance at the molecular structure of the compound claimed in US'554, which is Acalabrutinib and Ibrutinib, itself discloses that the core moiety in the two compounds is different. The averment that the two core moieties perform the same function of facilitating binding an inhibition of a tyrosine kinase may not, by itself, render the two compounds similar or even homologous or analogous. The extent to which the difference in the core moiety affects, or does not affect, its inhibitory activity with the Btk protein, is entirely a matter of conjecture at this stage. At the very least, it is a matter regarding which this Court cannot record a *prima facie* finding one way or the other. It cannot, therefore, be said that Ibrutinib is either covered or disclosed in US'554. Resultantly, the non-disclosure of the litigation pertaining to US'554 can also not be said to amount to material suppression, as would disentitle the plaintiffs to interim relief.

(ii) Article by Pan *et al*

(a) Mr. Sai Deepak also seeks to submit that the suit patent is bad for anticipation on the ground of prior publication. For this purpose, he relies on an Article by Pan *et al*, which is stated to disclose the method of preparation of Ibrutinib. The Pan *et al* article was sent for publication by the predecessor-in-title of the plaintiffs on 8 September 2006, without notice or protective measures. Though the article was published online only on 12 December 2006, the very sharing of the article with a third party without any protective measure, according to Mr. Sai Deepak, undermines any reasonable expectation of confidentiality and amounts to publication within the meaning of the Patents Act. The replication filed by way of response to the written statement of the defendant also does not demonstrate any protective measure or note of confidentiality having been put in place by the predecessor-in-title of the plaintiff before sending the Pan *et al* article for publication to the ChemMedChem Journal.

(b) Mr. Sai Deepak submits that the very sending of the article by Pan *et al* to the ChemMedChem journal on 8 September 2006 without any protective measure restraining further dissemination of the article would itself constitute "publication". He points out that

Sections 29 to 34 of the Patents Act *exclude* certain acts from the ambit of the expression "previous publication" so as to invalidate a granted patent on that ground. The corollary, he submits, is that all other acts would, *ipso facto*, be deemed to amount to "publication".

(c) It is not necessary to refer to the plaintiff's contentions in this regard, as the submission of Mr Sai Deepak is, *ex facie*, not acceptable. There is no presumption in law that if a statute states that A, B and C would not be X, everything other than A, B and C *is* X. The *expressio unius est exclusion alterius* principle recognises that the express *inclusion*, of certain elements, would presume the *exclusion* of the others. The principle is not known to operate in reverse. Mr. Sai Deepak, too, has not cited any judicial authority which would support his contention.

(d) Mr. Sai Deepak's contention is that, while forwarding the article to ChemMedChem, Pan *et al* did not incorporate any confidentiality clause or protective, which effectively "*undermine(d) any reasonable expectation of confidentiality*". In his written submissions, he formulates the proposition thus:

> "The Pan *et al* article was sent for publication by the Plaintiffs' predecessor in title on 08.09.2006 *without any notice of confidentiality or protective*

> *measure* to the journal ChemMedChem. While the said article was published online on 12.12.2006, *the fact that it was shared with a third party without any protective measure effectively undermines any reasonable expectation of confidentiality and amounts to publication* for the purposes of the Patents Act, 1970."

(e) I am unable to agree with Mr. Sai Deepak that the sending of the article by Pan *et al* to the ChemMedChem journal without any confidentiality caveat would amount to "publication" for the purposes of the Patents Act. In ***Bishwanath Prasad Radhey Shyam v. Hindustan Metal Industries***[30], it has been held that "prior public knowledge can be by word of mouth or by publication through books or other media". The Court of Appeals for the Federal Circuit has, in ***James Constant v. Advanced Micro Devices Inc***[31], the following principles find place, with which I entirely agree:

> "[34] The court found that the claims 1, 7, 8, 9, 16, 18, 21, 22 and 23 (including their preambles) were fully anticipated by Exhibit 5, which is a specification sheet for the 2920 that was distributed to the public by Intel in September 1979. Appellant argues that Exhibit 5 was not a printed publication … because there is no evidence in the record to prove that it was actually received by the public before October 14, 1979. *The statutory phrase "printed publication" has been interpreted to mean that before the critical date the reference must have been sufficiently accessible to the public interested in the art; dissemination and public accessibility are the keys to the legal determination whether a*

[30] **(1979) 2 SCC 511**
[31] **848 F. 2d 1560**

prior art reference was "published." ***In re Hall***[32]; ***In re Wyer***[33]. Intel presented extensive uncontroverted evidence of business practice that was sufficient to prove that Exhibit 5 was widely available and accessible to the interested public before October 14, 1979. *Evidence of routine business practice can be sufficient to prove that a reference was made accessible before a critical date.* ***In re Hall****. Accessibility goes to the issue of whether interested members of the relevant public could obtain the information if they wanted to. If accessibility is proved, there is no requirement to show that particular members of the public actually received the information.*

[35] A printed publication must also be enabling. ***In re Donohue***[34]. Constant argues that Exhibit 5 was not enabling because it does not describe a computer program to make the 2920 operational. He contends that in 1979 the 2920 was a novel, sophisticated chip which required a new hardware and software package to program, and argues that one having only ordinary skill in the art would not be able to program and use the 2920. However, Intel has presented uncontroverted evidence that the SP20 kit for programming the 2920 chip was available to the public and on sale before the critical date. Moreover, specific computer programs are irrelevant to the claimed invention. The specification of the '491 patent does not disclose any specific computer programs and does not suggest that a computer program is part of the invention. Such programs are not elements of the claims of the '491 patent. The claims all concern hardware configurations. The disclosure in Exhibit 5 is at least at the same level of technical detail as the disclosure in the '491 patent. If disclosure of a computer program is essential for an anticipating reference, then the disclosure in the '491 patent would fail to satisfy the enablement requirement of 35 U.S.C. § 112, First."

[32] 781 F.2d 897, 899, 228 USPQ 453, 455 (Fed. Cir. 1986)
[33] 655 F.2d 221, 226-27, 210 USPQ 790, 794-95 (CCPA 1981)
[34] 766 F.2d 531, 533, 226 USPQ 619, 621 (Fed. Cir. 1985)

Clearly, therefore, sending the article for publication to a journal is not, *ipso facto*, publication. Publication would take place when the journal publishes the article, thereby making it accessible to the public, which, in this case, admittedly took place on 12 December 2006, later than the priority date of the suit patent which was 22 September 2006.

(f) The concept of "expectation of confidentiality" which Mr. Sai Deepak introduces into the dialogue is foreign to the Patents Act. There is nothing, in the Patents Act, which ordains that any article, or other material, regarding which there is no "expectation of confidentiality" is, for that reason, published, or even deemed to be published. An article is either published, or not published. There is no half-way house. Mr. Sai Deepak's contention, if accepted, would result in a reworking of the law of prior publication, in patents, by requiring that the prior art should not merely have not been published prior to the priority date of the suit patent, but that *it should not have been even sent for publication prior to the said date*. The law cannot, in my view, be stretched that far, in the absence of any statutory or binding precedential foundation.

(g) The suit patent cannot, therefore, be said to have been rendered vulnerable to invalidity for prior publication, because of the Pan *et al* article.

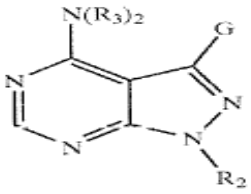
(iii) Though US'083 was examined in the order dated 4 March 2020 as well as in the order 29 September 2020 of the IPAB, and the IPAB has set aside the findings of the Joint Controller that the suit patent was invalid on the ground of obviousness *vis-à-vis* US'083, Mr. Sai Deepak has once again raised the same issue. The averments, in this regard, contained in the written submissions of Mr. Sai Deepak dated 14 January 2022:

> "i. US'083 published on 08.01.2004 relates to and discloses pyrazolopyrimidines for use as tyrosine kinase inhibitors (paragraphs [0001] to [0022]). Bruton's Tyrosine Kinase (Btk) is specifically identified in paragraph [0021] as a tyrosine kinase whose inhibition is sought through the compounds of US'083. It is recognised as being one amongst a class of non-receptor tyrosine kinases which are known since at least 1993. For details, please see Paragraph 95 -102 @Page 56 - 57 of the Written Statement filed by D-3. When the substitutions, all of which are taught in US'083 are carried out, the resultant compound is the compound of Formula 4 of IN'968. US'083 further includes within its scope, racemic-diastereomer mixtures, optical isomers, etc., thereby also encompassing the specific compound of Formula 13 of IN'968, viz., Ibrutinib. It is therefore submitted that IN'968 is squarely anticipated by US'083 and is therefore liable to be held invalid based on this document alone.
>
> ii. Reliance is being placed on the fact that the suit patent is liable to be revoked on grounds of obviousness on the basis of US'554, WO'836 & US'083 as discussed in

paragraphs 94-126 of the Written Statement in CS (Comm.) 342 of 2020."

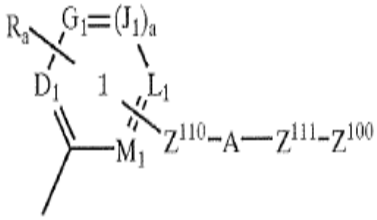
(iv) If one is to consider the above submissions *vis-à-vis* the three prior arts cited by US'083, US'554 and WO'836, it becomes apparent that, if the defendants are able to reach Ibrutinib from the Markush structure claimed in these prior arts, it is only by hindsight analysis. This is apparent from the following explanation provided in the written statement of Defendant 3 in CS (Comm) 342/2020, which seeks to explain how Ibrutinib is obvious from the teachings contained in US'083:

> "95. The Defendant also relies on US Patent Publication US 2004/0006083 (hereinafter US'083; Exhibit 14 to the revocation petition) which was published on 08.01.2004. US'083 relates to and discloses pyrazolopyrimidines which are used as tyrosine kinase inhibitors (paragraphs [0001] to [0022]). Bruton's Tyrosine Kinase (Btk) is specifically identified in paragraph [0021] as a tyrosine kinases whose inhibition is sought through the compounds of US'083. It is recognised as being one amongst a class of nonreceptor tyrosine kinases which are known since at least 1993.
>
> 96. US'083 discloses pyrazolopyrimidines for activity including inhibition of Btk, and provides a Markush structure for such compounds. It is relevant that a Markush structure is a medium of convenience in patent drafting whereby a large number of compounds is covered by a single structure. It is recognised principle in patent law that a Markush structure is a specific disclosure of each compound falling within its metes and bounds.
>
> 97. The Markush structure of the compounds disclosed US'083 is reproduced below for reference (paragraph [0034]):



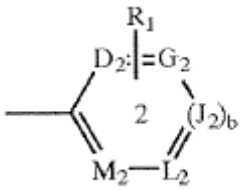
Formula I

US'083 further stipulates that G is a moiety of the following structure (paragraph [0035]):



98. US'083 in paragraph [0036 et seq., goes on to define the various substituents on the moiety G as follows:

- Z^{100} is (paragraph [0036]):

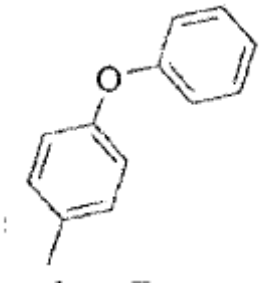


wherein b is 1, D_2, G_2, J_2, L_2 and M_2 are each independently selected from the group consisting of CR_a and N, provided that at least two of D_2, G_2, J_2, L_2 and M_2 arc CR_a (paragraph [0063]). Both R_a and R_1 arc defined as independently being Hydrogen, i.e. H (paragraph [0041]). When these substitutions are carried out the structure for Z^{100} that is obtained is phenyl:

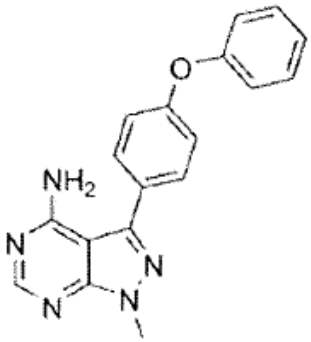
- both Z^{110} and Z^{111} are independently defined as being a covalent bond (paragraphs [0039] and [0040]);
- A is defined as being oxygen viz., O (paragraph [0050]);
- a is 1 and D_1, G_1, J_1, L_1 and M_1 are each independently selected from the group consisting of

CR_a and N, provided that at least two of D_1, G_I, J_1, L_1 and M_1 are CR_a.

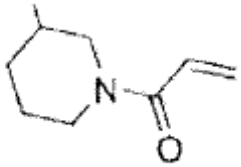
99. It is submitted that when the above substitutions which are taught in US'083 are carried out, the resultant moiety for G is as follows:



100. US'083 also stipulates that R_3 can be H (paragraph [0049]). This leads to the following structure when combined with the structure derived for G, as set out hereinabove:



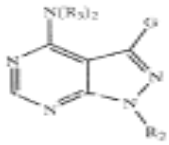
101. US'083 further stipulates in paragraph [0060] that R_2 is a group of the formula -B-E, where B is defined as substituted or unsubstituted azacycloalkyl and E is defined as substituted or unsubstituted alkylcarbonyl. This leads to the following structure for the R2 moiety on the scaffold:



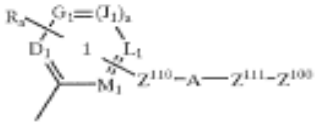
102. It is respectfully submitted that when the substitutions, all of which are taught in US'083 are carried out, the resultant compound is the compound of Formula 4 of IN'968. US'083 further includes within its scope,

> racemic-diastereomer mixtures, optical isomers, etc., thereby also encompassing the specific compound of Formula 13 of IN'968, viz., Ibrutinib. It is therefore respectfully submitted that IN'968 is squarely anticipated by US'083 and is therefore liable to be held invalid based on this document alone.

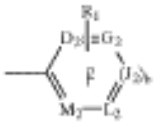
(v) The assertion, in the written submissions of Mr. Sai Deepak, to the effect that "when the substitutions, all of which are taught in US'083 are carried out, the resultant compound is the compound of Formula 4 of IN'968" is facially correct. Where the problem lies, however, is that the paragraphs from the complete specifications in US'083, which are cited by Mr. Sai Deepak, and from the suggestions contained in which the substitutions have been effected on the Markush moiety claimed in US'083, so as to arrive at Ibrutinib, *are not taught in US'083, in the sense that the complete specifications in US'083 do not contain the requisite teachings as would provoke a person's skilled in the art to select those substitutions, from the myriad substitutions contained in US'083 for attaching on to the Markush structure, as would enable him to arrive at Ibrutinib*. This is also clear when one reads the averments in paras 95 to 102 of the written statement of Defendant 3 in CS (Comm) 342/2020 *vis-à-vis* the paragraphs from the complete specifications in US'083 to which the said passages refer. This can be simply explained thus:

(a) As is acknowledged in para 97 of the written statement, the Markush structure in Formula 1 of US'083 is  .

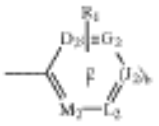
(b) As is clear from the above admitted molecular structure, it has three variables - G, R_2 and R_3.

(c) Para 0035 in US'083 in turn identifies the -G moiety as  .

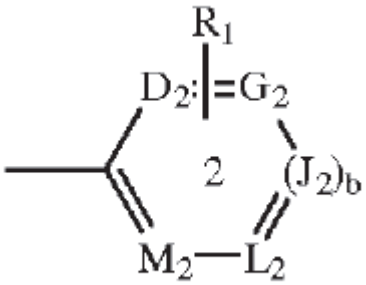
(d) Thus, even for the G moiety, it is defined in terms of a structure which contains at least ten variables, being A, D_1, G_1, J_1, M_1, R_a, Z^{100}, Z^{110} and Z^{111}.

(e) Z^{100} is in turn defined in para 0036 of US'083  , wherein b is 1 and D_2, G_2, J_2, L_2 and M_2 are each independently selected from the group consisting of CR_a.

(f) From the submissions of Defendant 3 which follow in paras 95 to 102 of the written statement in CS (Comm) 342/2020, it would seem to appear that, by

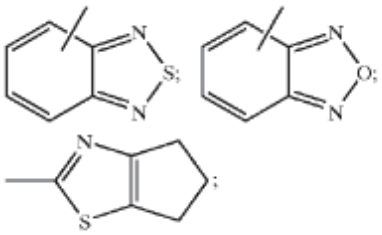
effecting simple substitutions on to the Z^{100} moiety as shown in para 0036 of US'083, it is easily possible to arrive at the G moiety in the Markush structure of US'083. However, matters are not so simple. The G moiety alone contains not just the Z^{100} variable, but, as already noted the further variables A, D_1, G_1, J_1, M_1, R_a, Z^{110} and Z^{111}. Even for Z^{100}, the  moiety is not the only substitution envisaged in US'083. Paras 0036 to 0038 of the complete specifications in US'083 makes this clear from 0036 to 0038:

"[0036] where Z^{100} is



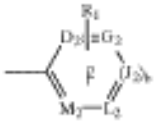
[0037] or a group optionally substituted with R, selected from the group consisting of alkyl, cycloalkyl, pyrrolidinyl; a bicyclic aromatic nitrogen containing heterocycle in which each ring has six atoms such as quinolinyl, quinoxalinyl, quinazolinyl, isoquinolinyl and phthalazinyl; a bicyclic aromatic nitrogen containing heterocycle in which nitrogen is in a bridging position and one aromatic ring has five member and the other

aromatic ring has six members such as imidazo[1,2-a] pyrimidinyl;1H-imidazo[1,2-a] imidazolyl, imidazo[2,1-b],[1,3] thiazolyl, naphthyl, tetrahydronaphthyl; benzothienyl; furanyl; thienyl; benzoxazolyl; benzoisoxazolyl; benzothiazolyl,



[0038] *thiazolyl; benzofuranyl; 2,3-dihydrobenzo-furanyl; indolyl; isoxazolyl, tetrahydropyranyl, tetrahydrofuranyl, piperidinyl, pyrazolyl; pyrrolyl, pyrrolopyridinyl; H-pyridinone; oxazolyl, isothiazolyl, oxadiazolyl; thiadiazolyl; indolinyl; indazolyl; imidazo[1,2-a]pyridinyl; benzoisothiazolyl;1,1-dioxy benzoisothiazolyl; pyrido-oxazolyl; pyrido-thiazolyl, pyrimido-oxazolyl; pyrimido-thiazolyl; and benzimidazolyl."*

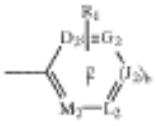
(g) Thus, while choosing the appropriate substituent even for the Z^{100} variable, the person skilled in the art would have before him an option between the

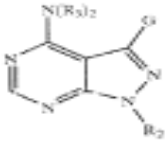


moiety or a group optionally substituted with R where R may be alkyl, cycloalkyl, pyrrolidinyl or a bicyclic aromatic nitrogen containing heterocycle in which each ring has six atoms or a bicyclic aromatic nitrogen containing heterocycle in which nitrogen is in bridging position and one aromatic ring has five

members and the other aromatic ring has six members, with further several suggested substitutions for the six atoms on the first bicyclic aromatic nitrogen containing heterocycle and the various members for the aromatic ring in the second bicyclic aromatic nitrogen containing heterocycle. And this is just Z^{100}!

(h) It is precisely in such a situation that the proscription against "cherry picking of substituents with the benefit of hindsight knowledge" kicks in. The challenger to the validity of the later specie patent, who knows which substituent fits where, cannot plead obviousness from the genus Markush patent merely on the ground that all substituents are suggested in the Markush. He would additionally have to show that the Markush *contains the requisite teaching which indicates, to a person skilled in the art, the appropriate substituent radical to choose, out of the several laid out before him.* It is in attempting to demonstrate *this* that the challenger often stumbles, and the present case is no different. There is no mention, in the submissions of Mr. J. Sai Deepak as to why, instead of selecting a member out of the groups suggested in paras 0037 of

US’083, the persons skilled in the art should choose the  moiety.

(i) This position is replicated in paras 0039 to 0070 of US’ 083. Given the principles of suggested substitutions envisaged in these paragraphs, there are literally millions of compounds which can be synthesized by attaching, to the Markush  Formula 1 structure of US’083, substitutions from those suggested in paras 0035 to 0070 of US’083.

(j) The submissions of Mr. Sai Deepak do not elucidate why, from the teachings in US’083, a person skilled in the art would be led to choose those specific substitutions which would lead him to Ibrutinib, i.e. Formula 4 in the suit patent.

(k) This position is replicated in WO’ 836.

(l) This is precisely what is not permissible, while alleging that a granted patent is vulnerable to invalidity on the ground of obviousness. It is not permissible for the challenger, possessed of hindsight knowledge, to

choose suggested substitutions from the thousands of substitutions available in the complete specifications of the Markush prior art, and, by arriving, by such pick and choose, at the specie patent, allege that the specie patent is bad on the ground of obviousness from prior art.

35.2 On merits, therefore, it cannot be said that Mr. Sai Deepak has been able to make out a case of *prima facie* invalidity of the suit patent, as would make out a credible challenge of its vulnerability. The challenge has to be credible. Credibility requires a fairly high standard to be met. Where the defendants' submissions merely suggest a possibility of the validity of the suit patent as being questionable, it cannot be said that a *credible* challenge has been launched. In the present case, however, the standard of a *possible* challenge to the validity of the suit patent, on the ground of obviousness in the light of US'083 or WO'836, cannot also not be said to have been met.

36. Objections regarding institution of the suits

36.1 Mr. Sai Deepak has also sought to submit that the suits are not properly instituted, as Mr. Pankaj Pahuja, who has signed the plaint on behalf of the plaintiff, is not competent to do so. Mr. Pahuja has signed the plaint in his capacity as Director (Commercial Operations Litigation) of the plaintiff.

36.2 Mr. Pahuja is admittedly the authorised signatory of the plaintiffs. He has filed an affidavit to that effect along with the statement of truth. It is not Mr. Sai Deepak's contention that Mr. Pahuja was not authorised by the plaintiffs to sign and verify the plaint. His contention appears to be that Mr. Pahuja *could not* have been authorised by the plaintiffs to do so. The foundation for this contention is, with respect, shaky. Mr. Sai Deepak appears to be predicating his submission on the LinkedIn profile of Mr. Pahuja which shows him to be the Director (Commercial Operations Litigation) for the plaintiff's counsel. This, according to Mr. Sai Deepak, imbues Mr. Pahuja more with the character of counsel than of client. Mr. Sai Deepak thereafter invokes the judgment of this Court in ***Baker Oil Tools v. Baker Hughes***[35] , to contend that a counsel cannot sign on behalf of his client.

36.3 I am unable to agree.

36.4 Mr. Pahuja is, admittedly, not a lawyer. Mr. Sai Deepak, even while acknowledging this fact, brushes it aside by saying that a higher degree of probity is necessary in commercial matters. The fact remains that Mr. Pahuja is not a lawyer. This, therefore, is not a case in which a counsel is signing on behalf of his client. The client has authorised Mr. Pahuja to sign and verify the documents and prosecute

[35] **(2011) 47 PTC 296 (Del)**

the matter. The genuineness of this authorisation is not in doubt. It is open to the plaintiffs to authorise any person it chooses as its constituted attorney. Mr. Sai Deepak has not been able to refer to any judicial precedent which stands in the way.

36.5 In these circumstances, I am not willing to countenance the objection of Mr. Sai Deepak, predicated on the alleged incompetence of Mr. Pankaj Pahuja to sign and verify the pleadings in these cases, as a ground to refuse injunction.

36.6 Mr. Pahuja, to reiterate, was admittedly authorized by the plaintiffs to verify and sign the plaint. He did so under the authorization given to him. In such a scenario, I am not inclined to refuse injunction, where a case of *prima facie* infringement of the suit patent is found to exist, merely because the defendant has chosen to question whether the plaintiffs *could have authorized* Mr. Pahuja to verify and sign the pleadings. No *prima facie* case of the authorization being invalid has been made out.

The sequitur

37. For the aforesaid reasons, the challenge, by the defendants, in these suits, to the validity of the suit patent is not *prima facie* sustainable. Other technical grounds which have been raised to contest the suit have been found not to be tenable in law.

38. The fact that the defendants are in fact manufacturing and selling Ibrutinib, without a license from the plaintiffs, is not disputed.

39. Where a granted patent is *prima facie* found to be infringed, and is being exploited without a license from the patent holder, the balance of convenience is always in favour of restraining further infringement. I am aware that the drug in question is needed for treating various serious ailments, including cancer. That said, the law sternly prohibits patent infringement, and it may not be possible to argue that considerations of public interest should be allowed to justify infringing drugs to circulate in the market.

40. A patent remains alive only for 20 years, whereafter, it is, in any case, in the public domain. As such, allowing infringement of the suit patent is bound to result in irreparable loss to the plaintiffs.

41. Several other arguments were advanced at the Bar. There were detailed submissions on the integrity of the suit patent as well as challenges to its validity. While deciding the present application, the Court is required to take a *prima facie* view. The Supreme Court has, in its recent order dated 6 September 2023 in ***Pernod Ricard India Pvt Ltd v. United Spirits Ltd***, observed thus:

> "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."

The task of the Court is to assess whether a *prima facie* case for grant of interlocutory injunction has, or has not, been made out and, thereafter, to attempt to expedite the disposal of the suit.

42. In the present case, the judgment dated 29 September 2020 of the IPAB itself makes out a *prima facie* case of validity of the suit patent. At a *prima facie* stage, an interim order would have been justified even on that ground. Nonetheless, I have examined the further submissions advanced by learned Counsel at the Bar, regarding the validity of the suit patent, to the extent that a consideration of the matter under Order XXXIX Rules 1 and 2 of the CPC would justify. Entering into the facto-legal – to coin a word – thicket in any greater depth would convert this into a final judgment in the suit.

43. As judgment in this matter had remained reserved for a considerable period of time, learned Counsel were requested to appear before the Court and state whether they were agreeable to judgment being rendered on the basis of the written submissions tendered as well as oral arguments made at the Bar, or whether they desired that the matter be re-listed for hearing.

44. Learned Counsel *ad idem* agreed, very fairly, to this Court proceeding to pronounce judgment in the matter.

Conclusion

45. For the aforesaid reasons, the following orders are passed:

(i) Pending disposal of CS (Comm) 76/2021, CS (Comm) 709/2019, CS (Comm) 342/2020, CS (Comm) 451/2020 and CS (Comm) 571/2020, the defendants in the said suits shall stand restrained from manufacturing and marketing Ibrutinib.

(ii) IA 2298/2021 in CS(Comm) 76/2021, IA 18051/2019 in CS(Comm) 709/2019, IA 7332/2020 in CS(Comm) 342/2020, IA 9360/2020 in CS(Comm) 451/2020 and IA 12649/2020 in CS(Comm) 571/2020 are allowed accordingly.

(iii) Given the importance of the drug, however, the Court permits the defendants to exhaust the stock available with them, subject to their placing, on affidavit with this Court, prior to releasing said stock in the market, the details of the stock, including Batch Numbers and dates of expiry, within a week from today. Till the affidavit is filed, the stock would not be released or sold.

(iv) The Court is not, however, passing any interdiction in respect of stocks of Ibrutinib manufactured by the defendants which are already in circulation.

(v) CM APPL 9916/2021 in W.P. (C) 3245/2021 is dismissed.

(vi) However, W.P. (C) 3245/2021 is listed for final disposal before the Court on 16 January 2024 at 2.30 pm. Written submissions, not exceeding 10 pages each, shall be filed by each of the learned Counsel in the matter, at least 3 days prior to the date of hearing, after exchanging copies electronically with all other learned Counsel. The case would be taken up at 2.30 pm. Each Counsel shall be allowed 1 hour to argue, and no more. No adjournment shall be granted.

(vii) Trial of these suits has to be expedited. List all these matters, therefore, before the Bench on 16 January 2024, so that the Court could frame a protocol for expediting trial. Learned Counsel may place suggestions on record in that regard.

C. HARI SHANKAR, J.

DECEMBER 21, 2023
dsn/rb