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

Reserved on 3rd June, 2021

Pronounced on 7th July, 2021

I.A. 2084/2021 in

\+ CS(COMM) 69/2021

FMC CORPORATION & ANR. ..... Plaintiffs

Through: Mr. Sandeep Sethi, Sr. Adv. with Mr. Sanjay Kumar, Ms. Arpita Sawhney, Mr. Arun Kumar Jana, Mr. Harshit Dixit and Mr. Priyash Sharma, Advs.

versus

BEST CROP SCIENCE LLP & ANR ..... Defendants

Through: Mr. Gopal Subramanium, Sr. Adv. with Dr. Shilpa Arora,, Mr. Siddharth Chopra, Ms. Sneha Jain, Dr. Amitavo Mitra, Dr. Victor Vaibhav Tandon, Ms. Shruti Jain, Ms. Hima Lawrence, Mr. Jayavardhan Singh, Advs.

I.A. 15352/2019 in

\+ CS(COMM) 611/2019

FMC CORPORATION & ANR. ..... Plaintiffs

Through: Mr. Sandeep Sethi, Sr. Adv. with Mr. Sanjay Kumar, Ms. Arpita Sawhney, Mr. Arun Kumar Jana, Mr. Harshit Dixit and Mr. Priyash Sharma, Advs.

versus

NATCO PHARMA LIMITED ..... Defendant

Through: Mr. J. Sai Deepak, Mr. Guruswamy Nataraj, Mr. Avinash K Sharma, Mr. R. Abhishek and Mr. Ankur Vyas, Advs.

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

J U D G M E N T

% 07.07.2021

1. This judgment disposes of IA 15352/2019 in CS(Comm) 611/2019 and IA 2084/2021 in CS(Comm) 69/2021. The captioned application has, in each case, been filed by the common plaintiff FMC Corporation (who would be referred to, in this judgment, as "the plaintiff"), against the defendant Natco Pharma Ltd in CS(Comm) 611/2019 and against the defendant Best Crop Science LLP in CS (Comm)69/2021, under Order XXXIX Rules 1 and 2 of the Code of Civil Procedure, 1908 (CPC).

2. In each case, the plaintiff asserts its product patent IN 201307 ("IN'307", in short) and its process patent IN 213332 ("IN'332", in short), which relate to the product Chlorantraniliprole (also known as "CTPR") and the process for the preparation thereof. The plaintiff alleges that the defendants are proposing to infringe the suit patents by manufacturing and releasing, in the market, their own CTPR products, even while the suit patents continue to be alive and without obtaining any license from the plaintiff. Injunction, against the defendants from doing so has, therefore, been sought in the plaints.

3. The applications under Order XXXIX of the CPC, which this judgment disposes of, seeks interim injunction against the infringement of the suit patents by the defendants.

4. For ease of reference, discussion in this judgment, would pertain principally to the facts relevant to CS (Comm) 611/2019 and IA 15352/2019, preferred therein. As such, the expression "defendant" would refer to the defendant in CS (Comm) 611/2019, i.e. Natco Pharma Ltd.

A. Re. IN'307

Facts

5. The plaintiff sets up the following case in the plaint:

(i) The plaintiff applied to the Patent Office in India, on 17th May, 2005, for grant of patent in respect of CTPR, of which the plaintiff claimed to be the inventor. The date of publication of the application, under Section 11A[1] of the Patents Act, 1970

[1] The relevant sub- sections of Section 11A read thus:

"**11A. Publication of applications –**

(1) Save as otherwise provided, no application for patent shall ordinarily be open to the public for such period as may be prescribed.

(2) The applicant may, in the prescribed manner, request the Controller to publish his application at any time before the expiry of the period prescribed under sub- section (1) and subject to the provisions of sub- section (3), the Controller shall publish such application as soon as possible.

(3) Every application for patent shall, on the expiry of the period specified under sub- section (1), be published, except in cases where the application –

was declared as 30th September, 2005, and priority dates[2] relatable to applications US 60/311, 919; US 60/324, 128; and US 60/369, 661, were declared as 13th August, 2001, 21st September, 2001 and 2nd April, 2002. The title of the application was "Arthropodicial Anthranilamides".[3]

(ii) The application was subsequently allowed, resulting in grant, to the plaintiff, of the suit patent IN'307, covering 15

(a) in which secrecy direction is imposed under section 35; or
(b) has been abandoned under sub- section (1) of section 9; or
(c) has been withdrawn three months prior to the period specified under sub- section (1)."

"Prescribed" is defined, under Section 2(u) as, in cases other than those relating to proceedings before the High Court or the IPAB, "prescribed by rules made under this Act".

Rule 24 of the Patents Rules, 2003, stipulates the period, under Section 11A (1) as 18 months from the date of filing of the application or the priority date of the application, whichever is earlier.

Rule 24A requires the applicant to file a request for publication, under Section 11A(2) in Form 9.

[2] Section 7 (1) of the Patents Act requires every application for a patent to be only for one invention. Subsections (1A) and (1B) of Section 7 read thus:

"(1A) Every international application under the Patent Cooperation Treaty for a patent, as may be filed designating India shall be deemed to be an application under this Act, if a corresponding application has also been filed before the Controller in India.
(1B) The filing date of an application referred to in sub- section (1A) and its complete specification processed by the patent office as designated office or elected office shall be the International filing date accorded under the Patent Cooperation Treaty."

"Priority date" is defined, in Section 2(w) as having "the meaning assigned to it by section 11".

Subsections (1) and (6) (the interceding sub- sections being irrelevant for the purposes of the present case) of Section 11 read thus:

"**11. Priority dates of claims of a complete specification –**
(1) There shall be a priority date for each claim of a complete specification.
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(6)In any case with sub-sections (2), (3), (3A), (4) and (5) do not apply, the priority date of a claim shall, subject to the provisions of section 137, be the date of filing of the complete specification."

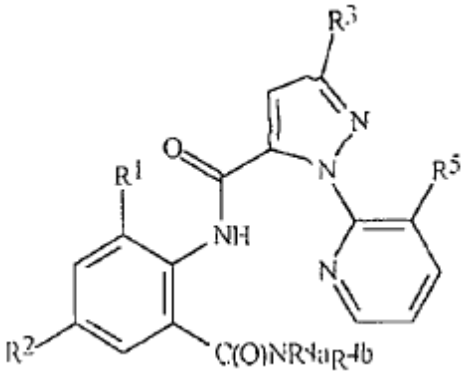
"The date of filing of the complete specification" in cases where, for the same invention, international applications for grant of patent had earlier been filed by the applicant, or by its predecessor in interest, necessarily had to be reckoned in accordance with sub- sections (1A) and (1B) of Section 7.

[3] Section 10(1) of the Patents Act requires every specification to "describe the invention and shall begin with a title sufficiently indicating the subject matter to which the invention relates."

claims.[4] Of these, the plaintiff submits that CTPR was covered by Claims 1 to 6 and 8 to 10, particularly Claims 1, 8 and 9, and was specifically exemplified as the tenth compound in Claim 8. Of these,

a) Claim 1 was a Markush structure[5], and read thus:

> "A compound selected from Formula 1 or an *N*-oxide thereof



wherein

R^1 is CH_3, F, Cl or Br;
R^2 is F, Cl, Br, I or CF_3;
R^3 is CF_3, Cl, Br or OCH_2CF_3;
R^{4a} is C_1-C_4 alkyl;
R^{4b} is H or CH_3; and
R^5 is Cl or Br;

or an agriculturally suitable salt thereof."

b) the tenth compound in Claim 8 was described thus:

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[4] Section 10(4) stipulates that "every complete specification shall –
(a) fully and particularly described the invention and its operation or use and the method by which it is to be performed;
(b) disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection; and
(c) end with a claim of claims defining the scope of the invention for which protection is claimed;
(d) be accompanied by an abstract to provide technical information on the invention:"

[5] "Markush claims", or claims covering "Markush structures", which are common in patents for chemical entities, whether agricultural or pharmaceutical, are molecular structures which "cover a group of compounds, which disclose the possibility of individual permutations and combinations that can run into several million (if not more) structurally diverse compounds." [as defined in ***Astrazeneca AB v. Intas Pharmaceuticals, 2020 (84) PTC 326 (Del)***]

"A compound as claimed in claim 1 that is selected from the group:

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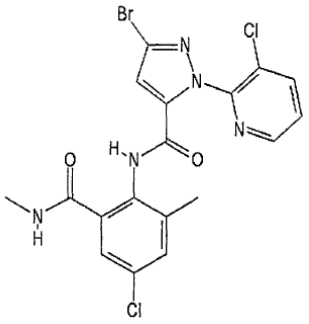
the compound of Formula 1 wherein R^1 is CH_3, R^2 is Cl, R^3 is Br, R^{4a} is CH_3, R^{4b} is H and R^5 is Cl;", and

c) Claim 9 read as under:

"A composition for controlling invertebrate pest comprising a biologically effective amount of a compound as claimed in claim 1 and at least one additional component selected from the group consisting of surfactants, solid diluents and liquid diluents."

(iii) CTPR, which bears the chemical structure



stands specifically exemplified in Example 6 of the Complete specifications of the suit patent, as granted, which reads as under:

"EXAMPLE 6

Preparation of 3 - bromo - *N* - [4 - chloro - 2 - methyl - 6 - [(methylamino) carbonyl] phenyl] - 1 - (3 - chloro - 2- pyridinyl) - 1*H* - pyrazole - 5- carboxamide

> To a solution of 2 - [3 - bromo - 1 - (3 - chloro - 2 - pyridinyl) - 1*H* - pyrazol - 5 - yl] - 6 - chloro - 8 - methyl - 4*H* - 3,1 - benzoxazin - 4 - one (i.e. the benzoxazinone product of Example 5, Step E) (0.20 g, 0.44 mmol) in tetrahydrofuran was added methylamine (2.0 M solution in THF, 0.514 mL, 1.02 mmol), and the reaction mixture was heated to 60°C for 90 minutes and then cooled to room temperature. The tetrahydrofuran solvent was evaporated under reduced pressure, and the residual solid was triturated with ether, filtered, and dried to afford the title compound, a compound of the present invention, as a solid (40 mg), m.p. 162-164° C."

(iv) Thus, the Markush structure, along with the necessary radicals to be substituted therein, the method of preparation and the actual and precise molecular structure and formula of CTPR, stands specifically claimed in the suit patent IN'307. CTPR is, additionally, one of 148 compounds specifically exemplified in the suit patent. The defendant does not dispute this position. The plaintiff claims that the 3-substituted-2-pyridyl ring, with two substituents on the phenyl ring, results in compounds with superior insecticidal activity. This superior insecticidal activity is also explained under the head "Biological Examples of the Invention", in the suit patent. The plaint asserts that the compounds disclosed in the suit patent IN'307 are first of a kind, novel anthranilic diamide insecticides which are ryanodine receptor activators. CTPR, it is asserted, activates the ryanodine receptor in the pest by stimulating the release of calcium from the sarcoplasmic reticulum of its muscle cells, resulting in impaired regulation, paralysis and

death. The superior and selective action of these insecticides against the ryanodine receptor in pests also results in low mammalian toxicity.

(v) IN'307 is a subsisting patent, the life of which would expire on 13th August, 2022 (reckoning 20 years from 13th August, 2002, when the patent was granted). No pre-grant or post-grant opposition, to the suit patent, was filed by anyone, including the defendant. The plaint also asserts that counterparts of the suit patent had been granted in more than 40 countries, in all of which they continue to subsist till date, Colombia being the sole jurisdiction where the equivalent of the suit patent was invalidated.

(vi) IN'332, which was the process patent, was filed on 8th January, 2004, published on 15th December, 2006 and granted on 27th December, 2007. Priority dates were claimed, in respect of the claims in IN'332 as 13th August, 2001, 21st September, 2001 and 2nd April, 2002, on the basis of US 919, US 128 and US 661 respectively. The title of the patent was "A process for preparing a compound of Formula 1". It is not in dispute that the process for making CTPR is covered by IN'332. The plaintiff asserts that Claim 1 in IN'332 discloses the process for preparation of CTPR, whereas Claims 2 to 22 disclose the processual steps for arriving at the reactants used in Claim 1.

IN'332 would remain alive till 13th August, 2022, reckoning 20 years from 13th August, 2002.

(vii) No pre-grant or post-grant opposition was filed in relation to IN'332. Moreover, the counterparts of IN'332 had been granted patents in over 40 countries, in none of which have they been revoked or invalidated.

(viii) Having thus set out the specifics of the suit patents IN'307 and IN'332, the plaint adverts to IN 204978 ("IN'978" in short) which, fundamentally, forms the focus of controversy in the present case. IN'978 contains a Markush formula, from which the compounds in Formula 1 of IN'307 are asserted to be a novel and inventive selection. The plaint acknowledges that CTPR falls within the scope of the numerous compounds, and is in the class of anthranilamides, included in the Markush formula, disclosed and claimed in the patent IN'978, but asserts, with equal emphasis, that CTPR is not specifically disclosed in IN'978 and that no person skilled in the art would be able to synthesise CTPR based on the claim and disclosure in IN'978.

(ix) Reliance is placed, in the plaint, on the declaration filed with the U.S. Patent and Trademarks Office (USPTO), during the prosecution of US'836, the counterpart in the US of IN'307. The declaration refers to tests conducted, to compare the compounds claimed and disclosed in IN'307, with their closest

counterparts disclosed in IN'978. These tests indicated superior insecticidal activity of the compounds disclosed in IN'307 *vis-à-vis* their closest counterparts disclosed in IN'978.

(x) As such, the plaint asserts that a person skilled in the art would not arrive at CTPR from Formula 22 in IN'978 without human intervention and ingenuity and application of hindsight knowledge.

(xi) IN'307 stands worked in India, as CTPR is duly registered with the Central Insecticide Board under Section 9(3) of the Insecticides Act, 1968[6], for (i) "Chlorantraniliprole technical for import, (ii) Chlorantraniliprole 18.5 % w/w SC for indigenous manufacture which is marketed by the plaintiff under the brand name CORAGEN®, and (iii) Chlorantraniliprole 0.4% GR for indigenous manufacture which is marketed by the plaintiff under the brand name

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[6] "**9. Registration of insecticides:**

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(3) On receipt of any such application for the registration of an insecticide, the Committee may, after such enquiry as it deems fit and after satisfying itself that the insecticide to which the application relates conforms to the claims made by the importer or by the manufacturer, as the case may be, as regards the efficacy of the insecticide and its safety to human beings and animals, register [on such conditions as may be specified by it] and on payment of such fee as may be prescribed, the insecticide, allot a registration number thereto and issue a certificate of registration in token thereof within a period of twelve months from the date of receipt of the application:

Provided that the Committee may, if it is unable within the said period to arrive at a decision on the basis of the materials placed before it, extend the period by a further period not exceeding six months:

Provided further that if the Committee is of opinion that the precautions claimed by the applicant as being sufficient to ensure safety to human beings or animals are not such as can be easily observed or that notwithstanding the observance of such precautions the use of the insecticide involves serious risk to human beings or animals, it may refuse to register the insecticide."

FERTERRA®." The application of the plaintiff for substituting M/s FMC India Pvt. Ltd., the affiliate company of Plaintiff No. 1 in India, as the current registrant of these insecticides, stands approved by the Central Insecticides Board and Registration Committee on 4th October, 2019.

(xii) As such, the plaintiff claims the exclusive rights to manufacture, use, market or sell CTPR in India. No third party can manufacture, sell or distribute CTPR in India without a valid license from the plaintiff.

(xiii) In October 2019, the plaintiff claims to have learnt of the imminent launch, by the defendant, of a CTPR product, which would infringe the suit patents IN'307 and IN'332. An application for "improved process for the preparation of anthranilimide derivatives" has also been filed by the defendant before the Indian Patent Office. This application allegedly provides for an improved process for preparation of CTPR. Any manufacture of CTPR, by such allegedly novel process would result in infringement of IN'307, which, as already noted hereinbefore, specifically claims CTPR in Claim 8.

(xiv) The plaint also adverts to a suit filed by the defendant under Section 34 of the Specific Relief Act, 1963, before the City Civil Court, Hyderabad, ("the Hyderabad suit" in short). It is asserted, in the plaint, that the said suit is an abuse of process of law and is jurisdictionally incompetent.

6. The plaint, thus, seeks a permanent injunction against infringement, by the defendant, of the suit patents IN'307 and IN'332. The present application seeks interlocutory directions in that regard. The prayer clause in the application reads as under:

> "17. In light of the foregoing, it is most humbly prayed that the following interim reliefs may be granted by this Hon'ble Court
>
> (i) An order of *ex parte ad interim* injunction restraining all the Defendant, its directors, employees, officers, servants, agents and all others acting for and on their behalf from manufacturing, using, selling, distributing, advertising, exporting, offering for sale, and in any other manner, directly or indirectly, dealing in any product that infringes the claimed subject matter of the Plaintiff's Indian Patent No 201307, including the product CHLORANTRANILIPROLE;
>
> (ii) An order of *ex parte ad interim* injunction restraining Defendant, its directors, employees, officers, servants, agents and all others acting for and on their behalf from using, directly or indirectly, any of the processes claimed under Indian Patent No. 213332; and
>
> (iii) Any other Order(s) as this Hon'ble Court may deem fit and proper in the facts and circumstances of the case."

Rival Stands

7. A detailed written statement has been filed by the defendant. Arguments, in this matter, continued over several days, with the plaintiff initially being represented by Mr. Pravin Anand and, later, by

Mr. Sandeep Sethi, learned Senior Counsel, instructed by Mr. Sanjay Kumar. Mr. J. Sai Deepak, learned Counsel, addressed arguments on behalf of the defendant.

(i) Copious written submissions running into several pages, with accompanying charts and other materials have been filed. They are so exhaustive, and cover the arguments advanced at the Bar by the learned Counsel so comprehensively, that it is not necessary to refer to the contents of the written statement or replication.

(ii) Given the nature of the controversy, it would be appropriate to set out, seriatim, each of the grounds on which the defendant contests the suit and the response of the plaintiff thereto, side by side. This is because the entire case of the defendant is premised on Section 107(1) of the Patents Act[7], which permits the raising, in defence to an allegation of patent infringement, of every ground on the basis of which the plaintiff's suit patent may be revoked. As such, the case of the defendant is not that it does not propose to launch CTPR products in India, as would infringe IN'307 but, rather, that IN'307 is itself an invalid patent, and is liable to be revoked.

(iii) Patent rights are, classically, statutory and territorial in nature. Unlike trademark rights, which also draw sustenance

[7] **"107. Defences, etc., in suit 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."

from common law, the right to grant of patent, as well as the rights to have an infringing patent revoked, must emanate from the Patents Act. Section 64 of the Patents Act provides for the grounds on which a patent may be revoked. Of the various grounds enumerated therein, those which the defendant, in the present case, seeks to invoke, may, for ready reference, be reproduced as under:

> "**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 by the Appellate Board or on a counter-claim in a suit for infringement of the patent by the High Court on any of the following grounds, that is to say –
>
> (a) that the invention, so far as claimed in any claim of the complete specification, was claimed in a valid claim of the earlier priority date contained in the complete specification of another patent granted in India;
>
> *****
>
> (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;
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> *****
>
> (k) that the subject of any claim of the complete specification is not patentable under this Act;"

(iv) In this context, Mr. Sai Deepak has also emphasized the position that the defendant, in order to succeed in a defence against the challenge of infringement, is only required to put up a credible challenge, which would suffice to show that the suit patent is *vulnerable*. The moment a credible challenge, which discloses vulnerability of the suit patent to revocation is made out by the defendant, Mr. Sai Deepak would contend, the plaintiffs' case for an interlocutory injunction has necessarily to fail. In this context, Mr. Sai Deepak relies on the judgment of a Division Bench of this Court in ***F. Hoffman-La Roche v. Cipla***[8].

(v) Learned Senior Counsel for the plaintiff, fairly, does not dispute the position, in law, that if the defendant is able to make

[8] **2009 (110) DRJ 452 (DB)**

out a credible case of vulnerability of the suit patent to revocation, no interlocutory injunction, against infringement (or, more properly, exploitation) of the suit patent, can be granted.

(vi) Given the fact that the defendant does not dispute its intent to manufacture and market CTPR, and essentially seeks to assail the validity of the suit patent IN'307, it would be appropriate to examine, seriatim, the contentions of the defendant, *vis-à-vis* the response of the plaintiff thereto.

8. Non-assertion, by the plaintiff, of IN'978:

8.1 Mr. Sai Deepak has emphasised the fact that the plaintiff has not chosen to assert IN'978, or any Claim therein including Claim 22. Mr. Sethi, learned Senior Counsel for the plaintiff, on the other hand, is categorical that his client is not asserting IN'978 in the present proceedings, which are limited to asserting IN'307 and IN'332.

8.2 To my mind, this is essentially a non-issue. It is for the plaintiff to decide what it chooses to assert. The plaintiff has asserted IN'307 and IN'332, and the task of this Court is to examine the merits of the said assertion. That the plaintiff has not chosen to assert, in these proceedings, IN'978, quite obviously cannot amount to any kind of an acknowledgement, on the plaintiff's part, regarding the vulnerability of IN'978 to challenge or revocation – which is why I regard this as a

non-issue in the present proceedings. According to the plaintiff, IN'978 neither claims, nor discloses, CTPR and does not, therefore, in any manner invalidate IN'307 or any of the claims therein including Claim 1. In view of this stand, no occasion, obviously, arose for the plaintiff to assert IN'978.

8.3 Nothing, therefore, turns, in my opinion, on the fact that the plaintiff has not asserted IN'978 in the present proceedings. Nor can this fact assist the case of the defendant. It would be for the defendant to establish, independently, that IN'307 is vulnerable, whether on the ground of IN'978 or on any other ground.

9. Presumptive validity of a granted patent – Section 13(4)

9.1 Mr. Sai Deepak submits, relying on Section 13(4) of the Patents Act[9], that the statutory dispensation as it obtains in this country with respect to patents does not envisage any presumptive validity of a patent, on it being granted. He relies, for the purpose, on ***Bishwanath Prasad Radhey Shyam v. Hindustan Metal Industries***[10]**.** Mr. Sai Deepak, in fact, carries the argument to the point of submitting that any decision, of this Court or any other Court, which presumes a

[9] "**13. Search for anticipation by previous publication and by prior claim –**

*****

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

[10] **(1979) 2 SCC 511**

patent to be valid because it has been granted, is *per incuriam*, in view of para 32 of ***Bishwanath Prasad Radhey Shyam***[10].

9.2 Disregarding of judicial precedents on the ground that they are *per incuriam* is not a decision which is to be lightly taken, as it compromises consistency and certainty in the law. Having said that, it is equally true that the judgment of a Court, which is contrary to a decision by a hierarchically superior Court, is *per incuriam*, if it proceeds in ignorance of the earlier decision or consciously enunciates the law contrary thereto without distinguishing the decision.

9.3 A plain reading of para 32 of ***Bishwanath Prasad Radhey Shyam***[10] reveals that Mr. Sai Deepak is not correct in his submission. The Supreme Court has not, in the said paragraph, disturbed, in any manner, the presumption of validity of a granted patent. It merely states that "the grant and sealing of the patent, or the decision rendered by the Controller in the case of opposition, does not *guarantee* the validity of the patent, which could be challenged before the High Court on various grounds in revocation or infringement proceedings". To this proposition, there can obviously be no cavil. There is, however, an obvious etymological difference between a "guarantee of validity" and a "presumption of validity". Grant of patent cannot, obviously, guarantee its validity; else, a granted patent would become immune from challenge. It is inconceivable that such a contention could even be urged, far less countenanced. Mr. Sethi submits that, while grant of a patent does not guarantee its validity,

there is, to an extent that the defendant assailing the patent would have to produce cogent material to support the challenge, a presumption that, in the absence of a credible challenge, the patent is valid. Mr. Sethi has also drawn my attention to judgments which have taken the fact that a patent was granted as a point in favour of its validity.

9.4 Section 13(4), too, does not deal with presumption of validity of a granted patent. It states that "the examination and investigations required under section 12 and this section shall not be deemed in any way to warrant the validity of any patent". The expression used here is, once again, "warrant" which, etymologically, is akin to the expression used by the Supreme Court, i.e. "guarantee". Grant of patent, or the extent to which the application for such grant has been subjected to examination, investigation or scrutiny prior to the grant, cannot and does not either guarantee or warrant its validity. Mr. Sethi is, however, correct that, once the patent is granted, the onus to make out a credible challenge to its validity would rest squarely on the defendant.

9.5 I do not deem it necessary to devote any further time to this aspect, as it is nobody's case that, merely by a patent being granted, the Court can avoid examining the merits of the challenge to its validity. In any event, as I am proceeding to examine the contentions of Mr. Sai Deepak on merits, the issue of presumed validity

consequent on grant of a patent need not burden this judgment any further.

10. Standard of challenge

10.1 Mr. Sai Deepak contends that, at the interlocutory stage, the defendant is not required to prove, to the hilt, the invalidity of the suit patent. The defendant is only required to set up a credible challenge to the vulnerability of the suit patent. Mr. Sethi, for the plaintiff, does not dispute this position. He, however, refers me to the judgment of Dr. S. Muralidhar, J. (as he then was), sitting singly, in ***Strix v. Maharaja Appliances***[11], which delineates the "standard of credibility" of the challenge which the defendant is required to pose, to the validity of the suit patent.

10.2 The plaintiff in ***Strix***[11] asserted a patent granted in respect of a liquid heating vessel with certain special characteristics, and alleged infringement of the patent by the defendant. One of the principal defences to the challenge, as raised by the defendant, was that the plaintiff's patent was earlier taught by a European patent which, therefore, constituted prior art and divested the plaintiff's patent of novelty. Without entering into the niceties of the challenge, suffice it to state that this Court found that the invention patented by the European patent was different from the subject matter of the suit patent asserted by the plaintiff and that, therefore, the European patent

[11] **2009 SCC OnLine Del 2825**

could not be regarded as, *prima facie*, prior art which taught the plaintiff's invention. Paras 21 to 23 of the report alone are relevant and may, therefore, be reproduced as under:

> "**21.** The essential difference between the product manufactured using the Strix patent and the product made using the European Patent is this: the Strix patent product is a temperature control device which is linked to the element itself and, therefore, when the element reaches a certain temperature, the circuit is broken, and the device is switched off. This prevents the overheating of the element itself. Therefore, even if there is no liquid in the vessel and the vessel is switched on, the element will not get damaged on account of overheating. As far as the European Patent is concerned, its mechanism operates by the temperature control device sensing the temperature of the liquid and not of the element. If there is no liquid in the vessel, the sensor will not get activated and therefore the overheating of the element cannot be avoided thus leading to it being damaged. It cannot, therefore, prima facie be said that the Strix Patent is not an inventive step over the European Patent and, therefore, is not patentable as such. Of course, these are only tentative views at an interlocutory stage. A final view will be taken by the Court, at the end of the trial, upon an independent assessment of the evidence, uninfluenced by this order.
>
> **22.** It was contended by learned counsel for the Defendant that at an interlocutory stage, the Defendant should be held to have discharged its burden of raising a 'credible challenge' to the validity of the Plaintiff's patent by merely pointing out the existence of the European Patent. This court is unable to agree. *In order to raise a credible challenge to the validity of a patent, even at an interlocutory stage, the Defendant will have to place on record some acceptable scientific material, supported or explained by the evidence of an expert, that the Plaintiff's patent is prima facie vulnerable to revocation. The burden on the Defendant here is greater on account of the fact that there was no opposition, pre-grant or post-grant, to the Plaintiff's patent.* In ***Beecham Group Ltd v. Bristol Laboratories Pty Ltd (1967-68) 118 CLR 618*** and ***Australian Broadcasting Corporation v. O'Neill (2006) 229 ALR 457*** it

was held that *the defendant alleging invalidity bears the onus of establishing that there is "a serious question"* to be tried. In ***Hexal Australia Pty Ltd. v. Roche Therapeutics Inc. 66 IPR 325*** it was held that *where the validity of a patent is raised in interlocutory proceedings, "the onus lies on the party asserting invalidity to show that want of validity is a triable question."*

23. In the instant case, the prior art cited by the Defendant, i.e. the European Patent, is not even prima facie a prior art that teaches the Plaintiff's invention. It works on a very different principle. Further, the Defendant has been unable to show that the Chinese supplier from whom it is purchasing the infringing product, holds a patent for it. It is not even the Defendant's case that the said product per se does not infringe the Plaintiff's patent. The only defence is that the Plaintiff's patent lacks novelty and its validity is vulnerable on the ground of obviousness. This, for the reasons already discussed, has not even prima facie been established by the Defendant. It is not possible to agree with the contention that the Plaintiff's patent is a mere trade variant of a known product. The Plaintiff has been able to *prima facie* show that it has been validly granted the patent which appears to be an inventive step in comparison with the prior art cited by the Defendant, viz., the European Patent. There is no merit in the contention that in terms of Section 3(f) of the Act, the patent ought not to have been granted since the invention is a mere re-arrangement of known elements. In the considered view of this court, such a contention cannot be accepted on a mere averment by the Defendant. *The Defendant will have to place on record some scientific literature supported by some credible expert opinion to show even prima facie that the Defendant's product is a mere re-arrangement of already known products.* This burden has not been discharged by the Defendant."

(Emphasis supplied)

10.3 ***Strix***[11] has been followed, by this Court, in various decisions, including ***Sandeep Jaidka v. Mukesh Mittal***[12], ***Telefonaktiebolaget LM Ericsson v. Intex Technologies***[13], ***Bristol-Myers Squibb Co. v. J.D. Joshi***[14] and ***Telefonktiebolaget LM Ericsson v. Lava International Ltd***[15].

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

10.5 I cannot understand ***Strix***[11] as, however, in every case, requiring the defendant to provide expert evidence to support its credible challenge. The observation, in the said decision, that the defendant, in that case, had not produced any expert evidence to demonstrate the

[12] (2014) 211 DLT 401
[13] 2015 (62) PTC 90 (Del)
[14] 2015 (64) PTC 135 (Del)
[15] 2016 (67) PTC 596 (Del)

similarity between the invention patented by the European patent and the invention claimed in the suit patent has, necessarily, to be understood in the context of the facts before this Court. As the distinction between the subject matter of the European patent and the subject matter of the suit patent was found to essentially relate to the technical characteristics of the invention, this Court opined that, in the absence of any technical expert evidence produced by the defendant, it could not be said that the defendant had discharged the onus, cast on it, to show that the suit patent was vulnerable to challenge. It would, however, be perfectly open to the defendant, in a given case, to make out a credible challenge to the vulnerability of the suit patent on the basis of other material, without having to necessarily take recourse to expert evidence. While, therefore, being unable to agree with Mr. Sethi that, no expert evidence having been produced by the defendant in the present case, it could not be said that the defendant had not raised a credible challenge, it still remains to be assessed whether, in fact, a credible challenge to the vulnerability of the suit patent IN'307, in the present case, has been raised by the defendant, on the grounds urged by it.

11. Disclosure *vis-à-vis* invalidity on the ground of obviousness

11.1 Mr. Sai Deepak advances, principally, three contentions to support his submission that CTPR was disclosed by the genus patent, i.e., Claim 22 in IN'978. These are:

(i) that Section 11(2)(b)[16] of the Patents Act creates a presumption of the existence of a disclosure in a patent to which the priority date has been assigned,

(ii) that the plaintiff had admitted, in the plaint, "coverage" of CTPR by the genus patent, and the Supreme Court, in ***Novartis AG v. U.O.I.***[17], has clearly held that there can be no dichotomy, or distinction, between "coverage" and "disclosure" in a patent; ergo, acknowledgement of coverage amounts to an acknowledgement of disclosure, and

(iii) that, in fact, the preferred embodiments, forming part of the Complete Specification of Claim 22 in IN'978, when applied to the Markush structure claimed therein, "*led to* CTPR".

11.2 Apropos contention (iii), Claim 22 of IN'978 is reproduced as under:

> "A compound of Formula 1, its *N*-oxides and agriculturally suitable salts

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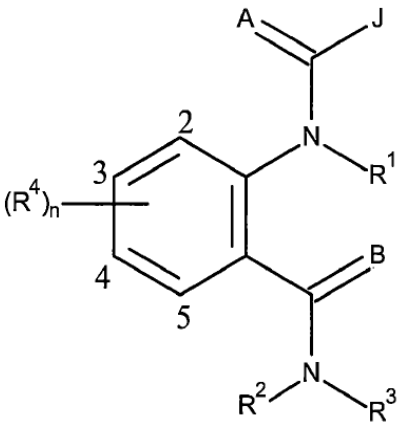
[16] "**11. Priority dates of claims of a complete specification –**
(1) There shall be a priority date for each claim of the complete specification.
(2) Where a complete specification is filed in pursuance of a single application accompanied by –
*****
(b) a specification which is treated by virtue of a direction under sub-section (3) of section 9 as a provisional specification, and the claim is fairly based on the matter disclosed in the specification referred to in clause (a) or clause (b), the priority date of that claim shall be the date of the filing of the relevant specification."

[17] **(2013) 6 SCC 1**



wherein

A and B are independently **O** or S;

each J is independently a phenyl or naphthyl group substituted with 1 to 2 R^5 and optionally substituted with 1 to 3 R^6;

or each **J is independently a 5-or 6-membered heteroaromatic ring** or an aromatic 8-,9- or 10- membered fused heterobicyclic ring system wherein each ring or ring system is **optionally substituted with 1 to 4 R^7**;

n is 1 to 4;

R^1 is H; or C_1-C_6 alkyl, C_2-C_6 alkenyl, C_2-C_6 alkynyl or C_3-C_6 cycloalkyl each optionally substituted with one or more substituents selected from the group consisting of halogen, CN, NO_2, hydroxy, C_1-C_4 alkoxy, C_1-C_4 alkylthio, C_1C_4 alkylsulfinyl, C_1-C_4 alkylsulfonyl, C_2-C_4 alkoxycarbonyl, C_1-C_4 alkylamino, C_2-C_8 dialkylamino and C_3-C_6 cycloalkylamino; or

R^1 is C_2-C_6 alkylcarbonyl, C_2-C_6 alkoxycarbonyl, C_2-C_6 alkylaminocarbonyl, C_3- C_8 dialkylaminocarbonyl or C(=A)J;

R^2 is H, C_1-C_6 alkyl, C_2-C_6 alkenyl, C_2-C_6 alkynyl, C_3-C_6 cycloalkyl, C_1-C_4 alkoxy, C_1-C_4 alkylamino, C_2-C_8

dialkylamino, C_3-C_6 cycloalkylamino, C_2-C_6 alkoxycarbonyl or C_2-C_6 alkylcarbonyl;

R^3 is H; C_1-C_6 alkyl, C_2-C_6 alkenyl, C_2-C_6 alkynyl, C_3-C_6 cycloalkyl, each optionally substituted with one or more substituents selected from the group consisting of halogen, CN, NO_2, hydroxy, C_1-C_4 alkoxy, C_1- C_4 haloalkoxy, C_1-C_4 alkylthio, C_1-C_4 alkylsulfinyl, C_1-C_4 alkylsulfonyl, C_2-C_6 alkoxycarbonyl, C_2-C_6 alkylcarbonyl, C_3-C_6 trialkylsilyl, and a phenoxy ring optionally substituted with one to three substituents independently selected from the group consisting of C_1-C_4 alkyl, C_2-C_4 alkenyl, C_2-C_4 alkynyl, C_3-C_6 cycloalkyl, C_1-C_4 haloalkyl, C_2-C_4 haloalkenyl, C_2-C_4 haloalkynyl, C_3-C_6 halocycloalkyl, halogen, CN,NO_2, C_1-C_4 alkoxy, C_1-C_4 haloalkoxy, C_1-C_4 alkylthio, C_1-C_4 alkylsulfinyl , C_1-C_4 alkylsulfonyl, C_1-C_4 alkylamino, C_2-C_8 dialkylamino, C_3-C_6 cycloalkylamino, C_3-C_6 (alkyl) cycloalkylamino, C_2-C_4 alkylcarbonyl, C_2-C_6 alkoxycarbonyl, C_2-C_6 alkylamino carbonyl, C_3-C_8 dialkylaminocarbonyl or C_3-C_6 trialkylsilyl; C_1-C_4 alkoxy; C_1-C_4 alkylamino; C_2-C_8 dialkylamino; C_3-C_6 cycloalkylamino; C_2-C_6 alkoxycarbonyl or C_2-C_6 alkylcarbonyl; or

R^2 and R^3 can be taken together with the nitrogen to which they are attached to form a ring containing 2 to 6 atoms of carbon and optionally one additional atom of nitrogen, sulfur or oxygen, said ring may be optionally substituted with 1 to 4 substituents selected from the group consisting of C_l-C_2 alkyl, halogen, CN, NO_2 and C_1-C_2 alkoxy;

each **R^4 is independently H, C_1-C_6 alkyl,** C_2-C_6 alkenyl, C_2-C_6 alkynyl, C_3-C_6 cycloalkyl, C_1-C_6 haloalkyl, C_2-C_6 haloalkenyl, C_2-C_6 haloalkynyl, C_3-C_6 halocycloalkyl, **halogen,** CN, NO_2, hydroxy, C_1-C_4 alkoxy,C_1-C_4 haloalkoxy, C_1-C_4 alkylthio, C_1-C_4 alkylsulfinyl, C_1-C_4 alkylsulfonyl, C_1-C_4 haloalkylthio , C_1-C_4 haloalkylsulfinyl , C_1-C_4 haloalkylsulfonyl, C_1-C_4 alkylamino, C_2-C_8 dialkylamino, C_3-C_6 cycloalkylamino, or C_3-C_6 trialkylsilyl; or

each R^4 is independently phenyl, benzyl or phenoxy, each optionally substituted with C_1-C_4 alkyl, C_2-C_4 alkenyl, C_2-C_4 alkynyl, C_3-C_6 cycloalkyl, C_1-C_4 haloalkyl, C_2-C_4 haloalkenyl,

C_2-C_4 haloalkynyl, C_3-C_6 halocycloalkyl, halogen, CN, NO_2, C_1-C_4 alkoxy, C_1-C_4 haloalkoxy, C_1-C_4 alkylthio, C_1- C_4 alkylsulfinyl, C_1-C_4 alkylsulfonyl, C_1-C_4 alkylamino, C_2- C_8 dialkylamino, C_3-C_6 cycloalkylamino, C_3-C_6 (alkyl)cycloalkylamino, C_2-C_4 alkylcarbonyl, C_2-C_6 alkoxycarbonyl, C_2-C_6 alkylaminocarbonyl, C_3-C_6 dialkylaminocarbonyl or C_3- C_6 trialkylsilyl;

each R^5 is independently C_1-C_6 haloalkyl , C_2-C_6 haloalkenyl, C_2-C_6 haloalkynyl, C_3-C_6 halocycloalkyl, C_1-C_4 haloalkoxy, C_1-C_4 alkylthio, C_1-C_4 alkylsulfinyl, C_1- C_4 alkylsulfonyl, C_1-C_4 haloalkylthio, C_1-C_4 haloalkylsulfinyl, C_1-C_4 haloalkylsulfonyl , CN, NO_2, C_1-C_4 alkylamino , C_2-C_8 dialkylamino, C_3-C_6 cycloalkylamino, C_2-C_6 alkylcarbonyl, C_2-C_6 alkoxycarbonyl, C_2-C_6 alkylaminocarbonyl, or C_3-C_8 dialkylaminocarbonyl;

or

$(R^5)_2$ attached to adjacent carbon atoms can be taken together as -OCF_2O-, -CF_2CF_2O-, or -OCF_2CF_2O-;

each R^6 is independently H, halogen, C_1-C_6 alkyl, C_2-C_6 alkenyl, C_2-C_6 alkynyl, C_3-C_6 cycloalkyl, C_1-C_4 alkoxy or C_2-C_4 alkoxycarbonyl; or

each R^6 is independently a phenyl, benzyl, phenoxy, 5- or 6-membered heteroaromatic ring or an aromatic 8-, 9- or 10 membered fused heterobicyclic ring system, each ring optionally substituted with one to three substituents independently selected from the group group consisting of C_1-C_4 alkyl, C_2-C_4 alkenyl, C_2-C_4 alkynyl, C_3-C_6 cycloalkyl, C_1-C_4 haloalkyl, C_2-C_4 haloalkenyl, C_2-C_4 haloalkynyl, C_3-C_6 halocycloalkyl, halogen, CN, NO_2, C_1-C_4 alkoxy, C_1-C_4 haloalkoxy, C_1-C_4 alkylthio, C_1-C_4 alkylsulfinyl, C_1-C_4 alkylsulfonyl, C_1-C_4 alkylamino, C_2-C_8 dialkylamino, C_3-C_6 cycloalkylamino, C_3-C_6 (alkyl)cycloalkylamino, C_2- C_4 alkylcarbonyl, C_2-C_6 alkoxycarbonyl, C_2-C_6 alkylaminocarbonyl, C_3-C_6 dialkylaminocarbonyl or C_3-C_6 trialkylsilyl;

each R^7 is independently H, C_1-C_6 alkyl, C_2-C_6 alkenyl, C_2-C_6 alkynyl, C_3-C_6 cycloalkyl , **C_1-C_4 haloalkyl,** C_2-C_6 haloalkenyl, C_2-C_6 haloalkynyl, C_3-C_6 halocycloalkyl, **halogen,** CN, CO_2H, $CONH_2$, NO_2, hydroxy, C_1-C_4 alkoxy, **C_1-C_4 haloalkoxy,** C_1-C_4 alkylthio, C_1-C_4 alkylsulfinyl, C_1-C_4 alkylsulfonyl, C_1-C_4 haloalkylthio, C_1-C_4 haloalkylsulfinyl, C_1-C_4 haloalkylsulfonyl, C_1-C_4 alkylamino, C_2-C_8 dialkylamino, C_3-C_6 cyc1oalkylamino, C_2-C_6 alkyl carbonyl, C_2-C_6 alkoxycarbonyl, C_2-C_6 alkylaminocarbonyl, C_3-C_8 dialkylaminocarbonyl, C_3-C_6 trialkylsilyl; or

each **R^7 is independently a phenyl, benzyl, benzoyl, phenoxy or 5- or 6-membered heteroaromatic ring or an** 8-, 9- or 10- membered fused heterobicyclic ring system, **each ring optionally substituted with one to three substituents independently selected from the group consisting of** C_1-C_4 alkyl, C_2-C_4 alkenyl, C_2-C_4 alkynyl, C_3-C_6 cyloalkyl, C_1-C_4 haloalkyl, C_2-C_4 haloalkenyl, C_2-C_4 haloalkynyl, C_3-C_6 halocycloalkyl, **halogen,** CN, NO_2, C_1-C_4 alkoxy, **C_1**-C_4 haloalkoxy, C_1-C_4 alkylthio, C_1-C_4 alkylsulfinyl, C_1-C_4 alkylsulfonyl, C_1-C_4 alkylamino, C_2-C_8 dialkylamino, C_3-C_6 cycloalkylamino, C_3-C_6 (alkyl)cycloalkylamino, C_2-C_4 alkylcarbonyl, C_2-C_6 alkoxycarbonyl, C_2-C_6 alkylaminocarbonyl, C_3-C_8 dialkylaminocarbonyl or C_3-C_6 trialkylsilyl;

provided that

(i) at least one R^4 and at least one R^7 are other than H;

(ii) J is other than an optionally substituted 1,2,3-thiadiazole;

(iii) when J is an optionally substituted pyridine and R^2 is H, R_3 is other than H or CH_3;

(iv) when J is an optionally substituted pyridine, then R^7 cannot be $CONH_2$, C_2-C_6 alkylaminocarbonyl or C_3-C_8 dialkylaminocarbonyl; and

(v) when J is an optionally substituted pyrazole, tetrazole or pyrimidine, then R^2 and R^3 cannot both be hydrogen."

(The emphasized words in Claim 22, as extracted hereinabove, have been emphasized by the defendant to denote the substitutions effected, by it, on the Markush moiety of Claim 22, which, according to the defendant, would "lead" a person skilled in the art to CTPR.)

11.3 Para 102 of the written submission seeks to demonstrate how CTPR is "included within the scope" of Claim 22 of IN'978, thus:

"102. It is submitted that the carrying out of the substitutions highlighted above show that the compound of Formula I includes within its scope Chlorantraniliprole when

A and B are O

R^1 is H

R^2 is H

R^3 is C_1-C_6 alkyl (in this case CH_3 which is C_1 alkyl, represented by NH - in Formula I)

R^4 is independently C_1-C_6 alkyl (in this case CH_3 which is C_1 alkyl) or halogen (in this case chlorine i.e. Cl), with the substitutions being at the 5 and 3 positions respectively

and n is 1 to 4 (in this case 2 which falls in the range of "1 to 4")

and J is independently a 5-or 6-membered heteroaromatic ring optionally substituted with 1 to 4 R^7

where each R^7 is independently halogen (in this case Bromine i.e. Br) or each R^7 is independently 6-membered heteroaromatic ring, each ring optionally substituted with one

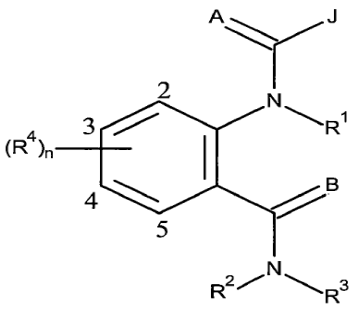
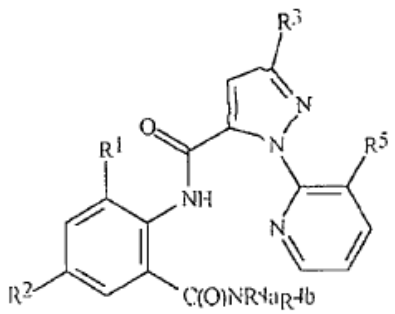
to three substituents independently selected from the group consisting halogen (Chlorine <u>in this case</u>).

<u>leads directly</u> to the structure of Chlorantraniliprole."

(Italics contained in the written statement of the defendant; underscoring supplied)

11.4 Further, Mr. Sai Deepak has attempted to demonstrate that the Markush formula in Claim 22 of IN'978 sufficiently discloses CTPR, so as to enable a person skilled in the art to synthesise the latter from the former. This has been sought to be explained, in a tabular format, in para 103 of the written statement, thus:

"It is further submitted that apart from a direct anticipation by prior claiming of Chlorantraniliprole, the broad Markush structure given in IN'307 in Claim 1 is also covered and encompassed wholly by the disclosure of Claim 22 of IN'978. The two claims are reproduced in the Table below with the relevant portions highlighted by the use of underlined and bold characters.

IN'978 - Claim 22	**IN'307 - Claim – edited to ensure correlation of substitutions**
A compound of Formula 1, its N-oxides and agriculturally suitable salts  Formula-I	A compound selected from Formula 1 or an N-oxide thereof 

wherein **A and B** are independently **O** or S; Each J is independently a phenyl or naphthyl group substituted with 1 to 2 R^5 and optionally substituted with 1 to 3 R^6; or each **J is independently a 5-or6-membered heteroaromatic ring** or an aromatic 8-,9- or 10-membered fused heterobicyclic ring system wherein each ring or ring system is **optionally substituted with 1 to 4 R^7**; **R^1 is H**; or C_1-C_6 alkyl, C_2-C_6 alkenyl, C_2-C_6 alkynyl or C_3-C_6 cycloalkyl each optionally substituted with one or more substituents selected from the group consisting of halogen, CN, NO_2, hydroxy, Cγ-C_4 alkoxy, C_1-C_6 alkylthio, C_rC_4 alkylsulfinyl, CC_4 alkylsulfonyl, Q_2-C_4 alkoxycarbonyl, C_1-C_4 alkylamino, C_2-C_8 dialkylamino and C_3-C_6 cycloalkylamino; or R^1 is C_2-C_6 alkylcarbonyl, C_2-C_6	Wherein **(A and B in the respective positions in Figure 1 are O)** **(J from Formula I of IN'978 is a 5-membered heteroaromatic ring** **optionally substituted with one or more R7 where each R7 is independently halogen (i.e. Br) or a 5 or 6-membered heteroaromatic ring substituted by halogen i.e. CI).** **(this is shown as -NH)**

alkoxycarbonyl, C_2-C_6 alkylaminocarbonyl, C_3-C_8dialkylaminocarbonyl or C(=A)J; **R² is H, C_1-C_6 alkyl**, C_2-C_6 alkenyl, C_2-C_6 alkynyl, C_3-C_6 cycloalkyl, C_1-C_4 alkoxy, C_1-C_4 alkylamino, C_2-C_6 dialkylamino, C_3-C_6 cycloalkylamino, C_2-C_6 alkoxycarbonyl or C_2-C_6 alkylcarbonyl; **R³ is** H; **C_1-C_6 alkyl,** C_2-C_6 alkenyl, C_2-C_6 alkynyl, C_3-C_6 cycloalkyl, each optionally substituted with one or more substituents selected from the group consisting of halogen, CN, NO_2, hydroxy, C_1-C_4 alkoxy, C_1-C_4 haloalkoxy, C_1-C_4 alkylthio, C_r-C_4 alkylsulfinyl, C_1-C_4 alkylsulfonyl, C_2-C_6 alkoxycarbonyl, C_2-C_6 alkylcarbonyl, C_3-C_6 trialkylsilyl, or a phenoxy ring optionally substituted with one to three substituents independently selected from the group consisting of C_1-C_4 alkyl, C_2-C_4 alkenyl, C_2-C_4 alkynyl, C_1-C_6 cycloalkyl, C_1-C_4 haloalkyl, C_2-C_4 haloalkenyl, C_2-C_4 haloalkynyl, C_3-C_6 halocycloalkyl, halogen, CN,NO_2, C_1-C_4 alkoxy, C_1-C_4 haloalkoxy, C_1-C_4 alkylthio, C_1-C_4 alkylsulfinyl, C_1-C_4 alkylsulfonyl, C_1-C_4 alkylamino, C_2-C_8	R^{4b} is H or CH_3 R^{4a} is C_1-C_4 alkyl;

dialkylamino, C_3-C_6 cycloalkylamino, C_3-C_6 (alkyl) cycloalkylamino, C_2-C_4 alkylcarbonyl, C_2-C_6 alkoxycarbonyl, C_2-C_6 alkylaminocarbonyl, C_3-C_8 dialkylaminocarbonyl or C_3-C_6 trialkylsilyl; C_1-C_4 alkoxy; C_1-C_4 alkylamino; C_2-C_8 dialkylamino; C_3-C_6 cycloalkylamino; C_2- C_6 alkoxycarbonyl or C_2-C_6 alkylcarbonyl; or R^2 and R^3 can be taken together with the nitrogen to which they are attached to form a ring containing 2 to 6 atoms of carbon and optionally one additional atom of nitrogen, sulfur or oxygen, said ring may be optionally substituted with 1 to 4 substituents selected from the group consisting of C_1-C_2 alkyl, halogen, CN, NO_2 and C_1-C_2 alkoxy; **n is 1 to 4**; each **R^4 is independently** H**, C_1-C_6 alkyl,** C_2-C_6 alkenyl, C_2-C_6 alkynyl, C_3-C_6 cycloalkyl, C_1-C_6 haloalkyl, C_1-C_6 haloalkenyl, C_2-C_6 haloalkynyl, C_3-C_6 halocycloalkyl,**halogen,** CN, NO_2, hydroxy, C_1-C_4 alkoxy,C_1-C_4 haloalkoxy, C_1-C_4 alkylthio, C_1-C_4 alkylsulfinyl, C_1-C_4 alkylsulfonyl, C_1-C_4 haloalkylthio , C_1-C_4 haloalkylsulfinyl , C_1-C_4	R^1 is CH_3, F, Cl or Br; R^2 is F, Cl, Br, I or CF_3; (when n in Formula I of IN'978 =2)

haloalkylsulfonyl, C_1-C_4 alkylamino, C_2-C_8 dialkylamino, C_3-C_6 cycloalkylamino, or C_3-C_6 trialkylsilyl; or each R^4 is independently phenyl, benzyl or phenoxy, each optionally substituted with C_1-C_4 alkyl, C_2-C_4 alkenyl, C_2-C_4 alkynyl, C_3-C_6 cycloalkyl, C_1-C_4 haloalkyl, C_2-C_4 haloalkenyl, C_2-C_4 haloalkynyl, C_3-C_6 halocycloalkyl, halogen, CN, NO_2, C_1-C_4 alkoxy, C_1-C_4 haloalkoxy, C_1-C_4 alkylthio, C_1- C_4 alkylsulfinyl, C_1-C_4 alkylsulfonyl, C_1-C_4 alkylamino, C_2-C_6 dialkylamino, C_3-C_6 cycloalkylamino, C_3-C_6 (alkyl)cycloalkylamino, C_2-C_4 alkylcarbonyl, C_2-C_6 alkoxycarbonyl, C_2-C_6 alkylaminocarbonyl, C_3-C_6 dialkylaminocarbonyl or C_3-C_6 trialkylsilyl; each R^5 is independently C_1-C_6 haloalkyl , C_2-C_6 haloalkenyl, C_2-C_6 haloalkynyl, C_3-C_6 halocycloalkyl, C_2-C_4 haloalkoxy, C_1-C_4 alkylthio, C_1-C_4 alkylsulfinyl, C_1- C_4 alkyl sulfonyl, C_1-C_6 haloalkylthio, C_1-C_4 haloalkylsulfinyl, C_1-C_4 haloalkylsulfonyl , CN, NO_2, C_1-C_4 alkoxycarbonyl, C_1-C_4 alkylamino , C_2-C_8 dialkylamino, C_3-C_6 cycloalkylamino, C_2-	

C_6 alkylcarbonyl, C_2-C_6 alkoxycarbonyl, C_2-C_6 alkylaminocarbonyl, or C_3-C_8 dialkylaminocarbonyl; or $(R^5)_2$ attached to adjacent carbon atoms can be taken together as –OCF_2O-, -CF_2CF_2O-, or OCF_2CF_2O-; eachR^6 is independently H, halogen, C_1-C_6 alkyl, C_2-C_6 alkenyl, C_2-C_6 alkynyl, C_3~ C_6 cycloalkyl, C_1-C_4 alkoxy or C_2-C alkoxycarbonyl; or each R^6 is independently a phenyl, benzyl, phenoxy, 5- or 6-membered heteroaromatic ring or an aromatic 8-, 9- or 10 membered fused heterobicyclic ring system, each ring optionally substituted with one to three substituents independently selected from the group group consisting of alkyl, C_2-C_4 alkenyl, C_2-C_4 alkynyl, C_3-C_6 cycloalkyl, C_1-C_4 haloalkyl, C_1-C_4haloalkenyl, C_2-C_4 haloalkynyl, C_3-C_6 halocycloalkyl, halogen, CN, NO_2, C_1-C_4 alkoxy, C_2-C_6 haloalkoxy, C_rC alkylthio, C_1-C_4 alkylsulfinyl, C_1-C_4 alkylsulfonyl, C_1-C_4 alkylamino, C_2-C_8 dialkylamino, C_3-C_6 cycloalkylamino, C_3-C_6 (alkyl)cycloalkylamino, C_2-C_6 alkylcarbonyl, C_2-C C_1-C_4	

alkoxycarbonyl, C_2-C_6 alkylaminocarbonyl, C_3-C_6 dialkylaminocarbonyl or C_3-C_6 trialkylsilyl;	
each R^7 is independently H, C_1-C_6 alkyl, C_{2-6} alkenyl, C_2-C C_1-C_6 alkynyl, C3-C6 cycloalkyl , **C_1-C_4 haloalkyl,** C_2-C_6 haloalkenyl, C_2-C_6 haloalkynyl , C_3-C_6 halocycloalkyl, **halogen,** CN, CO_2H, $CONH_2$, NO_2, hydroxy, C_1-C_6 alkoxy, **C_1-C_4 haloalkoxy,** C_1-C_4 alkylthio, C_1-C_4 alkylsulfinyl, C_1-C_4 alkylsulfonyl, C_1-C_4 haloalkylthio, C_1-C_4 haloalkylsulfinyl, C_1-C_4 haloalkylsulfonyl, C_1-C_4 alkylamino, C_2-C_8 dialkylamino, C_3-C_6 cycloalkylamino, C_2-C_6 alkyl carbonyl, C_2-C_6 alkoxycarbonyl, C_2-C_6 alkylaminocarbonyl, C_3~C_8 dialkylaminocarbonyl, C_3-C_6 trialkylsilyl; or	**(from Formula I of IN'978 - where J is a 5- or 6-membered heteroaromatic ring substituted by R_7 where R_7 is equal to R3 of IN'307)** where R^3 is CF_3, Cl, Br, or OCH_2CF_3
each **R^7 is independently** a phenyl, benzyl, benzoyl, phenoxy or 5- or **6-membered heteroaromatic ring** 8-, 9- or 10- membered fused heterobicyclic ring system, **each ring optionally substituted with one to three substituents independently selected from the group consisting of** C_1-C_4 alkyl, C_2-C_4	6-membered ring substituted by R^5 which is Cl or Br

alkenyl, C_2-C_4 alkynyl, C_3-C_6 cyloalkyl, C_1-C_4 haloalkyl, C_2-C_4 haloalkenyl, C_1-C_4 haloalkynyl, C_3-C_6 halocycloalkyl, **halogen,** CN, NO_2, C_1-C_4 alkoxy, **C_1**-C_4 haloalkoxy, CI-C4 alkylthio, C_1-C_4 alkylsulfinyl, C_1-C_4 alkylsulfonyl, C_1-C_4 alkylamino, C_2-C_8 dialkylamino, C_3-C_6 cycloalkylamino, C_3-C_6 (alkyl)cycloalkylamino, C_2-C_4 alkylcarbonyl, C_2-C_4 alkoxycarbonyl, C_2-C_6 alkylaminocarbonyl, C_3-C_8 dialkylaminocarbonyl or C_3-C_6 trialkylsilyl; provided that (i) at least one R^4 and at least one R^7 are other than H; (ii) J is other than an optionally substituted 1,2,3-thiadiazole; (iii) when J is an optionally substituted pyridine and R^2 is H, R_3 is other than H or CH_3; (iv) when J is an optionally substituted pyridine, then R^7 cannot be $CONH_2$, C_2-C_6 alkylaminocarbonyl or C_3-C_8 dialkylaminocarbonyl; (v) when J is an optionally substituted pyrazole, tetrazole or pyrimidine, then R^2 and R^3 cannot both be hydrogen.	

11.5 Mr. Sethi submits, *per contra*, that neither can the Markush structure claimed in Claim 1 in IN'307, nor can CTPR itself, be said to be disclosed in Claim 22 in IN'978. He submits that a person skilled in the art would not be able to arrive at CTPR from the embodiments or suggestions provided in Claim 22 in IN'978, without cherry picking selective radicals for substitution in the Markush moiety disclosed in the said Claim. This, he submits, is precisely what the defendant has done, in arriving at CTPR from the disclosure in Claim 22 in IN'978. In examining whether the genus patent taught, or disclosed the specie patent, Mr. Sethi submits that the approach has to be one of a person ordinarily skilled in the art. Such a person was required to be non-inventive and incapable of creative inputs. For this purpose, Mr. Sethi cites ***General Tire & Rubber Co. v. Firestone Tyre & Rubber Co.***[18], ***Eli Lilly v. Zenith Goldline Pharmaceuticals***[19] and ***Bishwanath Prasad Radhey Shyam***[10].

11.6 Claim 22 in IN'978, submits Mr. Sethi, is a Markush claim covering millions of compounds. Such a Markush claim does not, in any manner, disentitle patenting of any select compound, not disclosed in the Markush claim, but within the coverage thereof. This, he submits, is the entire concept of genus and specie patents, for which statutory sanction is also to be found in Section 10(5) of the Patents Act[20], which permits patenting of an inventive concept

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[18] **(1972) RPC 457 @ 486**
[19] **471 F. 3d. 1369 (Fed. Cir. 2006)**
[20] "**10. Content of specifications –**

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(5) The claim or claims of a complete specification shall relate to a single invention, or to a group of inventions linked so as to form a single inventive concept,

covering a group of interlinked inventions. Patents, he submits, may legitimately be granted to selection inventions, derived from the vast number of compounds covered by the Markush coverage in the genus patent. No embodiment in IN'978, Mr. Sethi submits, teaches CTPR, and the defendant, too, has not referred to any specific embodiment or embodiments in that regard. For this proposition, Mr. Sethi relies on the decision of the Chancery Division of the High Court of UK in ***In re. I. G. Farbenindustrie A.G.'s Patents***[21]. For the proposition that individual specie patents may be granted to compounds which fall within the coverage of the genus patent, Mr. Sethi cites the judgment, dated 8th December, 2015 of the Division Bench of this Court in ***F. Hoffmann-La Roche Ltd v. Cipla Ltd***[22], the judgments of Single Benches of this Court in ***Eisai Co. Ltd v. Satish Reddy***[23] and ***Bristol Myers Squibb Holdings v. Emcure Pharmaceuticals Ltd***[24]**,** the decision of the US Court of Appeals in ***Eli Lilly & Co. v. Zenith Goldline Pharmaceuticals***[19], the decision of the UK High Court in ***Dr Reddy's Laboratories (UK) Ltd v. Eli Lilly & Co. Ltd***[25], the decision of the UK Court of Appeals in ***Dr Reddy's Laboratories (UK) Ltd v. Eli Lilly & Co. Ltd***[26] and the decision of the Supreme Court of Canada in ***Apotex Inc. v. Sanofi-Synthelabo Canada Inc.***[27]**.**

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shall be clear and succinct and shall be fairly based on the matter disclosed in the specification."

[21] **(1930) 47 RP 289**
[22] Rendered in RFA (OS) 92/2012
[23] **2019 (79) PTC 568 (Del)**
[24] Order dated 12th December, 2019 in CS (Comm) 684/2019
[25] **(2008) EWHC 2345 (Pat)**
[26] **(2009) EWCA 1362**
[27] **(2008) 3 SCR 265**

11.7 ***Novartis***[17], submits Mr. Sethi, has no application for a variety of reasons. Firstly, ***Novartis***[17] deals with the issue of patentability of the invention claimed by Novartis AG, the appellant before the Supreme Court, in the light of Section 3(d)[28] of the Patents Act. In a case where the Court is approached on the issue of patentability, by the applicant-plaintiff whose application for patent has been refused, the onus to establish patentability, points out Mr. Sethi, is on the aggrieved applicant-plaintiff. As against this, in case of an infringement challenge, where the defendant pleads vulnerability of the granted patent, the onus is on the defendant to show that the patent is vulnerable to challenge. Secondly, the Supreme Court proceeded, in that case, on its initial finding that the genus patent constituted prior art, whereas, in the present case, IN'978 does not, in his submission, constitute prior art for Claim 1 in IN'307 or for CTPR. Thirdly, the Supreme Court found that there was, in the genus patent, clear disclosure of the salt constituting the specie patent, within the claim of the genus patent, as the genus patent included "Imatinib and its pharmaceutically acceptable salts", and Imatinib Mesylate, the β-crystalline form of which was the subject matter of dispute, was a pharmaceutically acceptable salt of Imatinib. Fourthly, Mr. Sethi

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[28] "**3. What are not inventions –**
The following are not inventions within the meaning of this Act, –
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(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.
Explanation. – For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy;"

submits that, while ***Novartis***[17] was a decision essentially predicated on Section 3(d), that provision does not come in for consideration at all, in the present case, as CTPR, according to the plaintiff, is neither claimed nor disclosed in IN'978. *Arguendo* and without prejudice, Mr. Sethi submits that ***Novartis***[17] did not hold, as Mr. Sai Deepak would seek to contend, that there was no distinction between coverage and disclosure. All it held was that no "wide gap" could be said to exist, between these two concepts in Indian patent law. Nor, submits Mr. Sethi, has the Supreme Court ultimately held, in ***Novartis***[17], that the specie patent could not be granted. For all these reasons, according to Mr. Sethi, the decision in ***Novartis***[17] cannot advance the case of the defendant.

11.8 I proceed, now, to address the three grounds raised by Mr. Sai Deepak, on the basis of which it is sought to be contended that CTPR was disclosed in Claim 22 in IN'978. While doing so, *it has to be borne in mind that the plaintiff is not asserting that there is no disclosure in Claim 22 of IN'978. The contention of the plaintiff is that what is disclosed, in Claim 22 of IN'978, is the Markush structure visualised therein, and not CTPR or any moiety on which, by effecting substitutions in keeping with the embodiments provided in the said Claim, a person skilled in the art would be taught how to arrive at CTPR.*

11.9 Viewed thus, Section 11(2)(b) cannot support the conclusion that Mr. Sai Deepak would seek to draw from it. The defendant has,

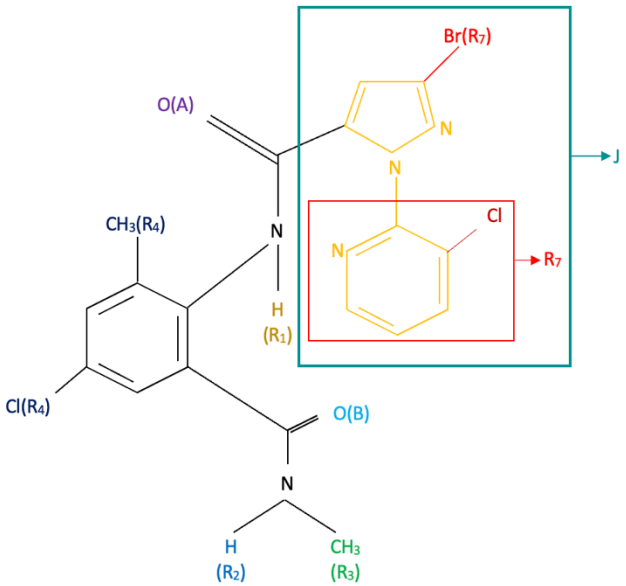
in its written submissions, specifically pointed out that it is not contesting the patentability of a Markush structure or Markush formula, as the Indian Patent Office accepts such applications. The specific submission, in this regard, as it figures in para-28 of the written submissions dated 29th November, 2020, filed by the defendant, reads thus:

> "As regards Markush claims, it is clarified that the Defendant herein has no objection *per se* Markush type claims since they are accepted by the Indian Patent Office. The Defendant's limited argument is that if a Markush claim in an Indian patent or Patent Application with an earlier priority date subsumes within its ambit the specific claim or even a Markush claim of a subsequently filed patent application, then the former anticipates the latter within the meaning of Section 13(1)(b)."

In advancing such an argument, the defendant is, in my view, attempting to run with the hare and hunt with the hounds. Once the defendant accepts that Markush claims are patentable, it no longer remains open to the defendant to rely on Section 11(2)(b) to advance an argument that, as Claim 22 in IN'978 was patented, there must be a presumption of disclosure of CTPR therein. The plaintiff's assertion, *per contra*, is that Claim 22 in IN'978 claimed a Markush structure, which does not claim, teach or disclose CTPR, or the Markush structure claimed in Claim 1 of IN'307, even if CTPR may come within the coverage of Claim 22 in IN'978. Section 11(2)(b) cannot, therefore, advance the case of the defendant.

11.10 Mr. Sai Deepak's second contention, on facts, is that CTPR stands taught by the Markush structure in Claim 22 of IN'978, as,

effecting substitutions in accordance with the embodiments provided in the said Claim itself, it is possible for a person skilled in the art to synthesise CTPR, as well as the Markush moiety claimed in Claim 1 of IN'307. A bare reading of para 102 of the written statement filed by the defendant, juxtaposed with para 101 thereof, clearly reveals the fallacy of this argument. The defendant has, in arriving at CTPR from the Markush structure claimed in Claim 22 of IN'978, clearly cherry picked, in para 102, specific substitutions out of the multifarious options provided in Claim 22 of IN'978, for each variable radical. The various substitutions effected on the Markush structure claimed in Claim 22 of IN'978 by the defendant, in order to arrive at CTPR, may be depicted thus:



The above structure, when seen in juxtaposition with the explanation provided by the defendant in paras 101 and 102 of the written statement, reveals that, on the Markush structure provided in Claim 22

in IN'978, the defendant has effected the following substitutions, choosing from the alternatives provided in the said claim:

(i) for 'A', the defendant has substituted 'O', choosing between 'O' and 'S',

(ii) for 'B', too, the defendant has substituted 'O', choosing between 'O' and 'S',

(iii) for R^1, Claim 22 in IN'978 suggests, as substitutions,

(a) H,

(b) C_1-C_6 alkyl,

(c) C_2-C_6 alkenyl,

(d) C_2-C_6 alkynyl, or

(e) C_3-C_6 cycloalkyl,

for each of which one or more of the following substituents could be chosen,

(i) halogen,

(ii) CN,

(iii) NO_2,

(iv) hydroxy,

(v) C_1-C_4 alkoxy,

(vi) C_1-C_6 alkylthio,

(vii) C_1-C_4 alkylsulfinyl,

(viii) C_1-C_4 alkylsulfonyl,

(ix) C_2-C_4 almoxycarbonyl,

(x) C_1-C_4 alkylamino,

(xi) C_2-C_8 dialkylamino, and

(xii) C_3-C_6 cycloalkylamino,

(f) C_2-C_6 alkylcarbonyl,

(g) C_2-C_6 alkoxycarbonyl,

(h) C_2-C_6 alkylaminocarbonyl,

(i) C_3-C_8 dialkylaminocarbonyl, or

(j) C(=A)J,

from which the defendant has chosen 'H',

(iv) for R^2, Claim 22 in IN'978 suggests, as substitutions,

(a) H,

(b) C_1-C_6 alkyl,

(c) C_2-C_6 alkenyl,

(d) C_2-C_6 alkynyl,

(e) C_3-C_6 cycloalkyl,

(f) C_1-C_4 alkoxy,

(g) C_1-C_4 alkylamino,

(h) C_2-C_6 dialkylamino,

(i) C_3-C_6 cycloalkylamino,

(j) C_2-C_6 alkoxycarbonyl, or

(k) C_2-C_6 alkylcarbonyl,

from which the defendant has chosen 'H',

(v) for R^3, Claim 22 in IN'978 suggests, as substitutions,

(a) H,

(b) C_1-C_6 alkyl,

(c) C_2-C_6 alkenyl,

(d) C_2-C_6 alkynyl,

(e) C_3-C_6 cycloalkyl,

each optionally substituted with one or more of the following:

(i) Halogen,

(ii) CN,

(iii) NO_2,

(iv) hydroxy,

(v) C_1-C_4 alkoxy,

(vi) C_1-C_4 haloalkoxy,

(vii) C_1-C_4 alkylthio,

(viii) C_1-C_4 alkylsulfinyl

(ix) C_1-C_4 alkylsulfonyl,

(x) C_2-C_6 alkylcarbonyl

(xi) C_2-C_6 alkylcarbonyl,

(xii) C_3-C_6 trialkylsilyl, or

(xiii) a phenoxy ring optionally substituted with one to three substituents independently selected from the group consisting of

(a) C_1-C_4 alkyl,

(b) C_2-C_4 alkenyl,

(c) C_2-C_4 alkynyl,

(d) C_1-C_6 cycloalkyl,

(e) C_1-C_4 haloalkyl,

(f) C_2-C_4 haloalkenyl,

(g) C_2-C_4 haloalkynyl,

(h) C_3-C_6 halocycloalkyl,

(i) halogen,

(j) CN,

(k) NO_2,

(l) C_1-C_4 alkoxy,

(m) C_1-C_4 haloalkoxy,

(n) C_1-C_4 alkylthio,

(o) C_1-C_4 alkylsulfinyl,

(p) C_1-C_4 alkylsulfonyl,

(q) C_1-C_4 alkylamino,

(r) C_2-C_8 dialkylamino,

(s) C_3-C_6 cycloalkylamino,

(t) C_3-C_6 (alkyl)cycloalkylamino,

(u) C_2-C_4 alkylcarbonyl,

(v) C_2-C_6 alkoxycarbonyl,

(w) C_2-C_6 alkylaminocarbonyl ,

(x) C_3-C_8 dialkylaminocarbonyl or

(y) C_3-C_6 trialkylsilyl;

(xiv) C_1-C_4 alkoxy;

(xv) C_1-C_4 alkylamino;

(xvi) C_2-C_8 dialkylamino;

(xvii) C_3-C_6 cycloalkylamino;

(xviii) C_2-C_6 alkoxycarbonyl or

(xix) C_2-C_6 alkylcarbonyl; or

(f) R^2 and R^3 can be taken together with the nitrogen to which they are attached to form a ring containing 2 to 6 atoms of carbon and optionally one additional atom of

(a) nitrogen,

(b) sulphur, or

(c) oxygen,

and with optional substitution with 1 to 4 substituents out of

(a) C_1-C_2 alkyl,

(b) Halogen,

(c) CN,

(d) NO_2, and

(e) C_1-C_2 alkoxy,

from which options the defendant chose CH_3 (methyl) as belonging to the C_1-C_6 alkyl group,

(vi) for R^4, Claim 22 in IN'978 suggests, as substitutions on the phenyl ring,

(a) H,

(b) C_1-C_6 alkyl,

(c) C_2-C_6 alkenyl,

(d) C_2-C_6 alkynyl,

(e) C_3-C_6 cycloalkyl,

(f) C_1-C_6 haloalkyl,

(g) C_1-C_6 haloalkenyl,

(h) C_2-C_6 haloalkynyl,

(i) C_3-C_6 halocycloalkyl,

(j) halogen,

(k) CN,

(l) NO_2,

(g) hydroxy,

(h) C_1-C_4 alkoxy,

(i) C_1-C_4 haloalkoxy,

(j) C_1-C_4 alkylthio,

(k) C_1-C_4 alkylsulfinyl,

(l) C_1-C_4 alkylsulfonyl,

(m) C_1-C_4 haloalkylthio,

(n) C_1-C_4 haloalkylsulfinyl,

(o) C_1-C_4 haloalkylsulfonyl,

(p) C_1-C_4 alkylamino,

(q) C_2-C_8 dialkylamino,

(r) C_3-C_6 cycloalkylamino, or

(s) C_3-C_6 trialkylsilyl;

(t) phenyl,

(u) benzyl or

(v) phenoxy,

each optionally substituted with

(i) C_1-C_4 alkyl,

(ii) C_2-C_4 alkenyl,

(iii) C_2-C_4 alkynyl,

(iv) C_3-C_6 cycloalkyl,

(v) C_1-C_4 haloalkyl,

(vi) C_2-C_4 haloalkenyl,

(vii) C_2-C_4 haloalkynyl,

(viii) C_3-C_6 halocycloalkyl,

(ix) halogen,

(x) CN,

(xi) NO_2,

(xii) C_1-C_4 alkoxy,

(xiii) C_1-C_4 haloalkoxy,

(xiv) C_1-C_4 alkylthio,

(xv) C_1-C_4 alkylsulfinyl,

(xvi) C_1-C_4 alkylsulfonyl,

(xvii) C_1-C_4 alkylamino,

(xviii) C_2-C_6 dialkylamino,

(xix) C_3-C_6 cycloalkylamino,

(xx) C_3-C_6 (alkyl) cycloalkylamino,

(xxi) C_2-C_4 alkylcarbonyl,

(xxii) C_2-C_6 alkoxycarbonyl,

(xxiii) C_2-C_6 alkyl amino carbonyl,

(xxiv) C_3-C_6 dialkylaminocarbonyl or

(xxv) C_3-C_6 trialkylsilyl, with substitutions being permitted at n sites, where n may be 1 to 4, from which the defendant chose n as 2 and CH_3 (as a C_1-C_6 alkyl) and C_l (as a halogen) substitutions on the phenyl ring, and

(vii) for J, Claim 22 in IN'978 suggested, as substitutions,

(a) a 5-membered heteroaromatic ring, or

(b) a 6-membered heteroaromatic ring, or

(c) an aromatic fused heterobicyclic ring system,

in which each ring/ring system is substituted with upto 4 substituents on the ring, each designated as R^7, further suggesting the following substitutions for R^7,

(a) H,

(b) C_1-C_6 alkyl,

(c) C_2-C_6 alkenyl,

(d) C_1-C_6 alkynyl,

(e) C_3-C_6 cycloalkyl,

(f) C_1-C_4 haloalkyl,

(g) C_2-C_6 haloalkenyl,

(h) C_2-C_6 haloalkynyl,

(i) C_3-C_6 halocycloalkyl,

(j) halogen,

(k) CN,

(l) CO_2H,

(m) $CONH_2$,

(n) NO_2,

(o) hydroxy,

(p) C_1-C_4 alkoxy,

(q) C_1-C_4 haloalkoxy,

(r) C_1-C_4 alkylthio,

(s) C_1-C_4 alkylsulfinyl,

(t) C_1-C_4 alkylsulfonyl,

(u) C_1-C_4 haloalkylthio,

(v) C_1-C_4 haloalkylsulfinyl,

(w) C_1-C_4 haloalkylsulfonyl,

(x) C_1-C_4 alkylamino,

(y) C_2-C_8 dialkylamino,

(z) C_3-C_6 cycloalkyllamino,

(aa) C_2-C_6 alkylcarbonyl,

(bb) C_2-C_6 alkoxylcarbonyl,

(cc) C_2-C_6 alkylaminocarbonyl,

(dd) C_3-C_6 dialkylaminocarbonyl,

(ee) C_3-C_6 trialkylsilyl,

(ff) a

(i) phenyl, or

(ii) benzyl, or

(iii) benzoyl, or

(iv) phenoxy, or

(v) 5-membered heteroaromatic ring, or

(vi) 6-membered heteroaromatic ring or

(vii) 8-, 9- or 10- membered fused heterobicyclic ring system,

of which each ring could have 1 to 3 substituents from the following:

(i) C_1-C_4 alkyl,

(ii) C_2-C_4 alkenyl,

(iii) C_2-C_4 alkynyl,

(iv) C_3-C_6 cycloalkyl,

(v) C_1-C_4 haloalkyl,

(vi) C_2-C_4 haloalkenyl,

(vii) C_1-C_4 haloalkynyl,

(viii) C_3-C_6 halocycloalkyl,

(ix) halogen,

(x) CN,

(xi) NO_2,

(xii) C_1-C_4 alkoxy,

(xiii) C_1-C_4 haloalkoxy,

(xiv) C_1-C_4 alkylthio,

(xv) C_1-C_4 alkylsulfinyl,

(xvi) C_1-C_4 alkylsulfonyl,

(xvii) C_1-C_4 alkylamino,

(xviii) C_2-C_8 dialkylamino,

(xix) C_3-C_6 cycloalkylamino,

(xx) C_3-C_6 (alkyl) cycloalkylamino,

(xxi) C_2-C_4 alkylcarbonyl,

(xxii) C_2-C_6 alkoxycarbonyl,

(xxiii) C_2-C_6 alkylaminocarbonyl,

(xxiv) C_3-C_8 dialkylaminocarbonyl, or

(xxv) C_3-C_6 trialkylsilyl,

from which the defendant chose, for J, a 5-membered pyridynyl ring with two substitutions at places 2 and 4, one being a halogen (Br) and the second a 6-membered aromatic ring with one halogen substitution (C_l).

11.11 At a bare glance, it is apparent that the defendant has cherry picked the substitutions at 'A', 'B', 'R^1', 'R^2', 'R^3', 'J' and 'R^7', as well as the radicals for substitutions at the various places on the 5-

membered or 6-membered heteroaromatic rings, out of the multifarious choices provided in Claim 22 in IN'978, so as to arrive at CTPR, or the Markush structure in Claim 1 in IN'307. No explanation for selecting these particular substitutions, out of the several substitutions provided in the Markush claim in IN'978, is forthcoming in the pleadings. It is apparent that these substitutions have been carefully selected so as to arrive at the Markush structure claimed in Claim 1 in IN'307, or at CTPR. Perhaps unwittingly, the pleadings and the written statement as much as acknowledge this fact, by the repeated use of the words "in this case" while referring to the selected substitutions in para 102 (as underscored in para 102 of the written statement as extracted in para 11.3 *supra*). The use of the words "in this case" amount to a tacit acknowledgement of the fact that the substitutions were selected so as to suit "this case", i.e. so as to arrive at CTPR. *Prima facie*, a person skilled in the art would not selectively choose the substitutions unless she, or he, is aware of the fact that, ultimately, CTPR is to be produced. No such effort having been made for all the years during which IN'978 remained valid, and the plaintiff being the first to synthesise CTPR from the Markush moiety claim then disclosed in Claim 22 in IN'978, it is not possible to accept the contention of the defendant that the embodiments provided in Claim 22 in IN'978 would "lead" a person skilled in the art to CTPR. No teaching, so as to enable such a person to synthesise CTPR can, therefore, be said, *prima facie*, to exist in the disclosure provided in Claim 22 in IN'978. It cannot, therefore, be said that

Claim 22 in IN'978 teaches either the Markush structure in Claim 1 in IN'307 or, more particularly, CTPR.

11.12 In ***Herbert Markman v. Westview***[29] (which was followed, by the Division Bench of this Court in ***F. Hoffman La Roche***[8]), it has been held that any analysis of patent infringement entails two steps, the first being determination of the meaning and scope of the allegedly infringed patent claims and the second, comparison of the properly construed claim with the allegedly infringing device. In the present case, Mr. Sai Deepak would contend that Claim 1 of IN'307 infringes Claim 22 of IN'978. There is no gainsaying that both are, in essence, Markush claims. CTPR is specifically exemplified in the specifications accompanying IN'307. There is, equally, no gainsaying that, by effecting substitutions on the Markush moiety as suggested in para 102 of the written statement filed by the defendant, it might be possible to arrive at the Markush moiety claimed in Claim 1 of IN'307 or even at CTPR. That, however, does not end the search. The question to be asked is – *why would a person skilled in the art make the substitutions on the Markush moiety disclosed in Claim 22 of IN'978, out of the several substitutions envisaged in the said claim? Does IN'978 teach, or instruct, a person skilled in the art to effect these particular substitutions in order to achieve the results, or advantages, which CTPR provides?* If the answer to this question is in the affirmative then, possibly, a case of infringement may exist, and Claim 1 in IN'307 might become vulnerable. If, however, the answer

[29] **52 F. 3d. 967**

to this question is in the negative, then, the fact that, by effecting selected substitutions on the Markush moiety disclosed in Claim 22 of IN'978, the defendant has been able to arrive at the Markush moiety claimed in Claim 1 of IN'307, or even at CTPR, would not lead to an inference of infringement or even make out a case of vulnerability, of Claim 1 of IN'307, to revocation.

11.13 No answer to this "why" poser is provided in the written statement filed by the defendant, or in the oral or written submissions of the defendant. I have, therefore, perused, with care, the complete specifications relating to IN'978 and, specifically, Claim 22 therein. I am unable to find, in the complete specifications, any "teaching" which would "lead" (to use the expression employed by the defendant in its written statement) a person skilled in the art to Claim 1 of IN'307 or, further, to CTPR.

11.14 Reference to the principles enunciated in some judicial authorities is, in this context, apposite:

11.14.1 In para 50 of the report in ***Bishwanath Prasad Radhey Shyam***[10], the Supreme Court, while holding that the allegedly infringed invention was *not* novel, but was obvious even from the allegedly infringing invention, opined thus:

> "The patented machine is merely an application of an old invention, known for decades before 1951, for the traditional purpose of scraping and turning utensils, with a slight change in the mode of application, which is no more than a "workshop improvement", a normal development of an

existing manner of manufacture not involving something novel *which would be outside the probable capacity of a craftsman*. The alleged discovery does not lie *outside the track of what was known before*. It would have been obvious to *any skilled worker in the field, in the state of knowledge existing at the date of patent, of what was publicly known or practiced before about this process*, that the claim in question viz., mere addition of a lever and bracket did not make the invention the subject of the claim concerned. There has been no substantial exercise of the inventive power or innovative faculty. There is no evidence that the patented machine is the result of any research, independent thought, ingenuity and skill."

(Emphasis supplied)

11.14.2 In ***Eli Lilly***[19], the Court of Appeal was concerned with an allegation, levelled by Eli Lilly, of infringement, by the defendants before it (collectively referred to, hereinafter, as "Zenith") of its US Patent No 5229 382 (US 382). Zenith alleged US 382 to be invalid, as it was anticipated by an article entitled "4-Piperazinyl-10H-thieno[2,3-b][1,5] benzodiazepines as Potential Neuroleptics", from the Journal of Medicinal Chemistry authored by Jiban K. Chakrabarti *et al* (cited, in the judgement of the Court of Appeals, as "Chakrabarti 1980a"). The following passages, from the decision of the Court of Appeals, are instructive:

"Anticipation is a question of fact, including whether or not an element is inherent in the prior art. *See* ***In re Schreiber, 128 F.3d 1473,1477 (Fed.Cir.1997)***. Therefore, this Court reviews a finding of anticipation under the clearly erroneous standard. ***Atlas Powder Co. v. Ireco, Inc., 190 F.3d 1342,1346 (Fed.Cir.1999).*** *To anticipate, of prior art reference must place the inventive compound or composition in the possession of the public*. ***In re Brown, 51 C.C.P.A. 1254, 329 F.2d 1006,1011 (1964).*** *Thus, the prior art reference must disclose each and every feature of the claimed*

invention, either explicitly or inherently. ***Glaxo Inc. v. Novopharm Ltd., 52 F.3d 1043,1047 (Fed. Cir. 1995).***

Pointing to ***In re Petering 49 C.C..P.A. 993,301 F.2d 676 (1962)*** and ***In re Schaumann, 572 F.2d 312 (C.C.P.A.1987)***, IVAX asserts that Chakrabarti 1980a anticipated claim 1 of the '382 patent because it identified compounds from the same family of compounds (thienobenzodiazepines). Indeed, in ***Petering***, the Board of Patent Appeals affirmed the examiner's rejection of claims 1, 2, 4, 5, 7, and 10-12 of the patent applicant's application on "isoalloxazines." ***301 F. 2d*** at 677. However, *in contrast to this case, the prior art in* ***Petering*** *did more than make a broad generic disclosure. In* ***Petering****, the prior art disclosed a limited number of specific preferences from a specifically defined group of isoalloxazines. Id. As a result,* ***Petering*** *actually disclosed to one skilled in the art a limited class of only "some 20 compounds", including "6,7-dimethyl-9-(Bmonohydroxyethyl)-isoalloxazine".* ***Schaumann, 572 F.2d at 315*** (citing ***Petering, 301 F.2d at 682***).

Similarly, the prior art in ***Schaumann*** *disclosed 14 compounds, later further narrowed to 7, considering express preferences. Additionally, the structural formula of this prior art contained but a single variable.* ***572 F. 2d*** at 314. Thus, *in* ***Schaumann,*** *the prior art patent embraced a very limited number of closely related compounds and specifically described the claimed compound.* ***572 F. 2d*** *at 316. Thus, unlike this case, the prior art in both* ***Petering*** *and* ***Schaumann*** *expressly spelled out a definite and limited class of compounds that enabled a person of ordinary skill in the art to act once envisage each member of this limited class. Schaumann*, 572 F.2d at 315; *Petering* 301 F.2d at 681-82.

By contrast, the number of compounds actually disclosed by Chakrabarti 1980a numbers in the millions (including all proposed alternative substituents). Chakrabarti 1980a examine forty five specific compounds (as opposed to a genus of compounds) in the 4-Piperazinyl-10H-thieno[2,3-b][1,5]benzodiazepines family and fourteen analogous 5-piperazinyl-substituted 4H-thieno[2,3-b][1,4]benzodiazepines, which were created to compare

activity. Findings of Fact and Conclusions of Law, 364 F. Supp. 2d at 848. Indeed, Chakrabarti 1980a listed several preferred compounds and substituents, none of which resemble olanzapine:

for R–a methyl, hydroxyethyl, or hydroxypropyl;

for R1– a fluorine, chlorine, or 7, 8, difluoro [no hydrogen]: and

for R2 – a methyl, 2-ethyl, or 2-isopropyl group.

Id at 848. Five of the preferred individual compounds (9, 12, 17, 29, and 34) are more potent than clozapine (scoring a 3 CAR or higher) and having clozapine-like effect. For those five preferred compounds, the Chakrabarti 1980a authors expressed a preference for specific, complete compounds without any variation of the individual substituents on those molecules. Chakrabarti 1980a also always expressed a preference for halogen-containing compounds (fluorine or chlorine), not hydrogen. *Id.* At 832-33. Furthermore, compounds 9, 12, 17 and 29 all have fluorine at the 7-position of the benzene ring. And though Compound 34 does have hydrogen the 7-position of the benzene ring, it has a hydroxyethyl on its piperazine ring, unlike olanzapine. *Id*. In sum, *Chakrabarti 1980a* discloses nothing close to the claimed invention.

Chakrabarti 1980a does provide a general structural formula with possible substituents of "R", "R1" and "R2", but it does not define at all. Findings of Fact and Conclusions of Law, 364 F.Supp.2d at 900. No possible combination of those preferred substituents would lead to the components that make up olanzapine, because each would contain a fluorine or a chlorine. *To make olanzapine from Chakrabarti 1980a, one would have to depart from the teaching of the article and recombine the components of the specific illustrative compounds with hindsight*. Thus, Chakrabarti 1980a does not anticipate because: (1) the article prefers complete compounds, not individual substituents, (2) the article discloses no generic disclosure encompassing olanzapine or

> even stating that substituents on different compounds were interchangeable, and (3) the article does not suggest transforming unpreferred compounds 7 into a preferred compound. Thus, *Chakrabarti 1980a* did not place olanzapine in the possession of the public."
>
> (Emphasis supplied)

11.14.3 ***Apotex***[27] was a judgement of the Supreme Court of Canada, particularly dealing with the validity of selection patents. The respondent in that case ("Sanofi", in short) was the holder of a Canadian patent '875, which disclosed a genus or class of compounds useful in inhibiting platelet aggregation activity in the blood. Over 250,000 possible different compounds, useful for this purpose, were disclosed by the '875 patent. One such compound was a racemate, which is a substance containing equal amounts of two structurally different compounds, called enantiomers or optical isomers, namely the dextro-rotatory and the levo-rotatory isomer. Sanofi's subsequent patent ("the 777 patent") disclosed and claimed clopidogrel bisulphate, an anti-coagulant which inhibited platelet aggregation activity in the blood. It was an admitted position that clopidogrel bisulphate was encompassed within the scope of the claims in the '875 patent and that clopidogrel was the dextro-rotatory isomer of the racemate, which added beneficial properties over both the racemate and its levorotatory isomer. Clopidogrel bisulphate was a salt of clopidogrel, which had a better therapeutic index than the salts of the racemic mixture. The advantage of clopidogrel bisulphate or, for that matter, even clopidogrel, over the racemate and the levorotatory isomer was, therefore, admitted.

11.14.3.1 Apotex served a notice on Sanofi, alleging that the 777 patent was invalid on the ground of anticipation, obviousness and double patenting. Sanofi contended, *per contra*, that clopidogrel bisulphate was a selection patent, out of the moieties disclosed in the '875 patent.

11.14.3.2 The Court first referred to the decision in ***Farbenindustrie***[21], terming it the *locus classicus* describing selection patents**.** On this, paras 9 and 10 of the judgment read thus:

> "9. The *locus classicus* describing selection patents is the decision of Maugham J. in ***In re. I.G. Farbenindustrie A.G.'s Patents (1930), 47 R.P.C 289 (Ch. D.)***. At p. 321, he explained that in the field of chemical patents (which would of course include pharmaceutical compounds), there are often two "sharply divided classes". The first class of patents, which he called originating patents, are based on an originating invention, namely, the discovery of a new reaction or a new compound. The second class comprises patents based on a selection of compounds from those described in general terms and claimed in the originating patent. Maugham J. cautioned that the selected compounds cannot have been made before, or the selection patent "would fail for want of novelty". But if the selected compounds is "novel" and "possess[es] a special property of an unexpected character", the required "inventive" step would be satisfied (p. 321). At p. 322, Maugham J. stated that a selection patent "does not in its nature differ from any other patent".
>
> 10. While not exhaustively defining a selection patent, he set out (at pp. 322-23) three conditions that must be satisfied for a selection patent to be valid.
>
> > 1. There must be a substantial advantage to be secured or disadvantage to be avoided by the use of the selected members.

> 2. The whole of the selected members (subject to "a few exceptions here and there") possess the advantage in question.
>
> 3. The selection must be in respect of a quality of a special character peculiar to the selected group. If further research revealed a small number of unselected compounds possessing the same advantage, that would not invalidate the selection patent. However, if research showed that a large number of unselected compounds possess the same advantage, the quality of the compound claimed in the selection patent would not be of a special character."

[Though the Patents Act does not specifically refer to "selection patents", so long as (a) the invention, as selected from the Markush moiety in the genus patent, fulfils the description of "invention", (b) involves, in its fabrication of creation, an "inventive step", within the meaning of clauses (i) and (ja) of Section 2, and (c) does not suffer from any of the disabilities envisaged by Section 64 of the Patents Act, it is, *ex facie*, patentable. There is no reason, therefore, why the criteria of the patentability, *qua* selection patents, enumerated in ***Farbenindustrie***[21], should not apply in this country as well.] The Court, thereafter, went on to quote the following test, for obviousness in a patent, from ***Beloit Canada Ltd v. Valmet Oy***[30]:

> "The test for obviousness is not to ask what competent inventors did or would have done to solve the problem. Inventors are by definition inventive. The classical touchstone for obviousness is the technician skilled in the art but having no scintilla of inventiveness or imagination; a paragon of deduction and dexterity, wholly devoid of intuition; a triumph of the left hemisphere over the right. The question to be

[30] **(1986) 8 CPR (3d) 289**

> asked is *whether this mythical creature (the man in the Clapham omnibus of patent law) would, in the light of the state of the art and common general knowledge as at the claimed date of invention, have come directly and without difficulty to the solution taught by the patent*. It is a very difficult test to satisfy."

In principle, I am inclined to agree with this test, to determine whether a patent discloses a particular invention or moiety which becomes, therefore, obvious from the patent. From the teachings in the genus patent, the person skilled in the art must be in a position to arrive, without unduly straining his imaginative and creative faculties, at the specie patent, in order for the specie patent to be invalidated on the ground of obviousness. The element of "directness" must be there. The choice which the person skilled in the art would make, by way of substitutions on the Markush moiety or otherwise, must be apparent from the teachings in the genus patent, in order for the specie patent to be treated as "obvious". A "trial and error" approach would be antithetical to any suggestion of "obviousness".

11.14.3.3 ***Apotex***[27] went on to discuss, in detail, the legal situation as it prevailed in Canada. It is not necessary to embark on that discussion here; however, the following discussion on the facts of that case, in paras 70, 72 and 73 of the opinion of the Court, apply, *mutatis mutandis*, to the case on hand:

> "[70] It is well known that the pharmaceutical industry is intensely competitive. Market participants are continuously in search of new and improved medications and want to reach the market with them as soon as possible. So demand for an effective and non-toxic product to inhibit platelet aggregation might be assumed to exist. However, nothing in the '875

patent or common general knowledge provided a specific motivation for the skilled person to pursue the '777 invention. The prior patent was a genus patent, and selection might be expected. However, the prior patent did not differentiate between the efficacy and the toxicity of any of the compounds it covered. This suggests that what to select or omit was not then self-evident to the person skilled in the art.

[72] The methods to obtain the invention of the '777 patent were common general knowledge. It can be assumed that there was a motive to find a non-toxic efficacious product to inhibit platelet aggregation in the blood. However, it was not self-evident from the '875 patent or common general knowledge what the properties of the dextro-rotatory isomer of this racemate would be or what the bisulfate salt's beneficial properties would be and therefore that what was being tried ought to work. The course of conduct and the time involved throughout demonstrate that the advantage of the dextro-rotatory isomer was not quickly or easily predictable. Had the dextro-rotatory isomer been "obvious to try", it is difficult to believe that Sanofi would not have opted for it before unnecessary time and investment were spent on the racemate. I conclude that the prior art and common general knowledge of persons skilled in the art at the relevant time were not sufficient for it to be more or less self-evident to try to find the dextro-rotatory isomer.

[73] As I have earlier explained, there was a significant difference between the '875 genus patent and the '777 selection patent. The difference was not obvious. Having regard to the foregoing analysis, I conclude that the allegation of obviousness is not justified."

11.14.4 Yet another decision, from overseas, which is instructive, is the judgment of the UK Court of Appeal in ***Dr Reddy's Laboratories***[26] which again dealt with olanzapine**.** The classical explanation for why omnibus Markush claims could not be treated as obvious of individual moieties which might otherwise fall within the

generalised coverage of such claims was expressed, in the said decision, thus:

> "An old question and answer runs as a follows: "Where does a wise man hide a leaf? In a forest." It is, at least faintly, ridiculous to say that a particular leaf has been made available to you by telling you that it is in Sherwood Forest. Once identified, you can of course see it. But if not identified you know only the generality: that Sherwood Forest has millions of leaves.
>
> The contention has no logical stopping place. If there is disclosure of olanzapine here, why would one not regard an even more general disclosure as a disclosure of it. Suppose the prior art had merely been of "3-ringed organic compounds?" Such a description would encompass much much bigger numbers than the 1019 of formula I. Yet the logic of the argument would be the same – that there is a disclosure of each and every member of the class.
>
> I would add that I would regard the listing out of a great number of compounds as opposed to the use of a Markush formula in the same way. To say a particular book is identified by saying "the books in the Bodleian" is no different from saying it is identified by providing access to the catalogue of the Bodleian.
>
> Similarly it makes no sense to say that a generalised prior description discloses a specific matter falling within in (sic). The judge's example illustrates the point. A prior disclosure of "fixing means" is not a disclosure of a particular fixing means e.g. welding or riveting even though you could list out a whole number of ways of fixing things together which would include these means.
>
> Thus logic dictates rejection of the argument that a disclosure of a large class is a disclosure of each and every member of it."

These paragraphs, in the opinion of this Court, condense, in themselves, the very essence of the concepts of disclosure and

obviousness, even within the parameters of the Patents Act in this country.

11.15 ***Novartis***[17], deconstructed:

11.15.1 Intrinsically interlinked with the principle of disclosure is the judgement of the Supreme Court in ***Novartis***[17]. As this judgement constitutes the only authoritative pronouncement of the Supreme Court on pharmaceutical patents, it deserves to be examined in detail.

11.15.2 Jurg Zimmerman invented several derivatives of N-phenyl-2-pyrimidine-amine, which could inhibit certain protein kinases and could, therefore, be used to treat tumours. Zimmerman applied to the US patent office, for patenting of these derivatives one of which was Imatinib) on 28th April, 1994. The derivatives were granted US Patent No. 5521184 ("US 184", in short) on 28th May, 1996. US 184 has, in the judgement, been referred to as the "Zimmerman patent".

11.15.3 Novartis AG ("Novartis" hereinafter) applied, to the Chennai Patent Office, on 17th July, 1998, for grant of patent for the β-crystalline form of Imatinib Mesylate, which was a salt of Imatinib, claimed to have been invented by Novartis. Novartis claimed to have synthesized the β-crystalline form from the free base Imatinib in two steps; by first producing the methanesulphonic acid salt of Imatinib and, thereafter, proceeding to develop the β-crystalline form thereof.

11.15.4 In the application, Novartis claimed that the β-crystalline form of Imatinib Mesylate was superior to the α-crystalline form of Imatinib Mesylate as it had more beneficial flow properties, better thermodynamic stability and lower hygroscopicity. The patent application of Novartis did not, however, claim any superiority, of the β-crystalline form of Imatinib Mesylate, over the Imatinib freebase. Rather, it was admitted, in the patent application, that "all indicated inhibitory and pharmacological effects" of the β-crystalline form of Imatinib Mesylate were "also found with the freebase". Subsequent to amendment of the Patents Act, however, Novartis filed four affidavits of experts, in which it was claimed that the β-crystalline form of Imatinib Mesylate had "much higher bioavailability", as compared to the freebase Imatinib.

11.15.5 In its patent application, Novartis cited 18th July, 1997 as the "priority date"[31] of the patent, being the date on which Novartis

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[31] "Priority date" is defined, in Section 2(w), as having "the meaning assigned to it by Section 11. Section 11 reads thus:

> "**11. Priority date of claims of a complete specification –**
> (1) There shall be a priority date for each claim of a complete specification.
> (2) Where the complete specifications filed in pursuance of a single application accompanied by –
> (a) a provisional specification; or
> (b) a specification which is treated by virtue of a direction under sub-section (3) of section 9 has a provisional specification, and the claim is fairly based on the matter disclosed in the specification referred to in clause (a) or clause (b), the priority date of that claim shall be the date of the filing of the relevant specification.
> (3) Where the complete specifications filed or proceeded with in pursuance of two or more applications accompanied by such specifications as mentioned in sub- section (2) and the claim is fairly based on the matter disclosed –
> (a) in any of those specifications, the priority date of that claim shall be the date of filing of the application accompanied by that specification;
> (b) partly in one and partly in another, the priority date of that claim shall be the date of the filing of the application accompanied by the specification of the later date.

had applied for grant of patent of the β-crystalline form of Imatinib Mesylate in Switzerland.

11.15.6 The Assistant Controller of Patents and Designs, *vide* file order dated 25th January, 2006, rejected the application, of Novartis, for grant of patent for the β-crystalline form of Imatinib Mesylate. The reasons cited for rejecting the application were that (i) the Zimmerman Patent anticipated the invention claimed by Novartis, i.e. the β-crystalline form of imatinib Mesylate, by prior publication, (ii) the β-crystalline form of Imatinib Mesylate was obvious to a person skilled in the art, in view of the disclosure contained in the complete specifications of the Zimmerman Patent, (iii) the β-crystalline form of Imatinib Mesylate could not be patented in view of Section 3(d) of the Patents Act and (iv) Novartis had wrongly claimed the Swiss priority

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(3A)* Where the complete specification based on a previously filed application in India has been filed within twelve months of the date of the application and the claim is fairly based on the matter disclosed in the previously filed application, the priority date of that claim shall be the date of the previously filed application in which the matter was first disclosed.

(4) Where the complete specification has been filed in pursuance of a further application made by virtue of sub- section (1) of section 16 and the claim is fairly based on the matter disclosed in any of the earlier specifications, provisional or complete, as the case may be, the priority date of that claim shall be the date of the filing of that specification in which the matter was first disclosed.

(5) Where, under the foregoing provisions of this section, any claim of a complete specification would, but for the provisions of that sub-section, have two or more priority dates, the priority date of that claim shall be the earlier or earliest of those dates.

(6) In any case to which sub- sections (2), (3), (3A)*, (4) and (5) do not apply, the priority date of a claim shall, subject to the provisions of section 137, be the date of filing of the complete specification.

(7) The reference to the date of the filing of the application or of the complete specification in this section shall, in cases where there has been a post-dating under section 9 of section 17 or, as the case may be, an ante-dating under section 16, be a reference to the date as so post-dated or ante-dated.

(8) A claim in a complete specification of a patent shall not be invalid by reason only of –

(a) the publication or use of the invention so far as claimed in that claim on or after the priority date of that claim; or

(b) the grant of another patient which claims the invention so far as claimed in the first mentioned claim, in a claim of the same or a later priority date."

*Sub- section (3A) was inserted by the Patents (Amendment) Act, 2005, w.e.f. 1st January, 2005.

date as the priority date for filing of its patent application. Novartis challenged the order of the Assistant Controller by way of writ petitions filed before the High Court of Madras, which were transferred to the Intellectual Property Appellate Board (IPAB) and registered as appeals.

11.15.7 The IPAB dismissed the appeals *vide* judgement dated 26th June, 2009. Even while holding that (i) the product sought to be patented by Novartis, i.e. the β-crystalline form of Imatinib Mesylate, satisfied the tests of novelty and non-obviousness and (ii) Novartis was entitled to claim 18th July, 1997 as the priority date (for which purpose the IPAB relied on Section 133), the IPAB held that the product was, nonetheless, not patentable in view of Section 3(d) of the Patents Act which, according to the IPAB, set a "requirement of higher standard of inventive step in the law particularly for drug/pharmaceutical substances". The IPAB held, however, that Novartis was entitled to patent in respect of the process for manufacture of the β-crystalline form of Imatinib Mesylate.

11.15.8 Novartis directly approached the Supreme Court, challenging the aforesaid order of the IPAB. While criticising Novartis for having bypassed the available remedy before the High Court, the Supreme Court, in view of the importance and intricacy of the issue involved, agreed, by consent, to decide the appeal on merits. Thus came to be passed the judgement under discussion.

11.15.9 The Supreme Court observed, initially, that Section 5, which permitted patenting only of inventions for methods or process of manufacture and, therefore, prohibited grant of patent to substances intended for use, or capable of being used, as food or medicine or drug or prepared or produced by chemical processes, was deleted, w.e.f. 1st January, 2005, by the Patents (Amendment) Act, 2005 ("the 2005 Amendment Act", hereinafter). The Supreme Court proceeded, thereafter, from paras 29 to 72 of the report, to trace the entire history of the Patents Act, as well as the various amendments thereto, from time to time. Thereafter, the Supreme Court proceeded to extract clauses (ac), (j) and (ja) of Section 2[32] and delineate, in para 74, the three conditions, cumulatively required to be satisfied in order for a product to qualify as an "invention", thus:

> "Section 2(1)(j) requires a product to satisfy three conditions to qualify as an invention:
>
> (i) It must be "new", that is to say it must not have been *anticipated*;
>
> (ii) Its coming into being must involve an "*inventive step*"; and
>
> (iii) It must be "capable of industrial application", that is to say it must be capable of being made or used in an industry [Section 2(1)(ac)]."
>
> (Emphasis in original)

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[32] "**2. Definitions and interpretation –**

(1) In this Act, unless the context otherwise requires, –

*****

(ac) "capable of industrial application", in relation to any invention, means that the invention is capable of being made or used in an industry;

*****

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

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

Thus was introduced, into the concept of "invention", as defined in the Patents Act, the principle of "anticipation", as antithetical to "newness" – or, more properly, "novelty". Clearly, the Supreme Court holds that an invention which was "anticipated" cannot be regarded as "novel". Para 75 went on to paraphrase clause (ja) by holding that "the invention that creates the product must have a feature that involves technical advance as compared to the existing knowledge or having economic significance or both and this feature should be such as to make the invention not obvious to a person skilled in the art". Para 76 went on to crystallise these observations by delineating the characteristics of an "invention", for the purposes of the Patents Act, thus:

> "On a combined reading of clauses (j), (ac) and (ja) of Section 2(1), in order to qualify as "invention", a product must, therefore, satisfy the following tests:
>
> (i) It must be "new";
>
> (ii) It must be "capable of being made or used in an industry";
>
> (iii) It must come into being as a result of an invention which has a feature that:
>
> (a) entails technical advance over existing knowledge;
>
> or
>
> (b) has an economic significance;
>
> and
>
> (c) makes the invention not obvious to a person skilled in the art."

11.15.10 For being entitled to grant of a patent, however, the Supreme Court held that the product was required not only to satisfy the tests entitling it to be regarded as an "invention", but was also required to be "patentable". Section 3 of the Patents Act, it was observed, demarcated two situations in which the right to patent could be lawfully denied; firstly, where the product was not an "invention", such as in the case of clauses (b) and (e)[33] , and, secondly, where, though the product was an "invention", other considerations prohibited grant of patent, such as in the case of clause (d)[28]. The Supreme Court held, however, that it was concerned only with clause (d).

11.15.11 Apropos Section 3(d), the Supreme Court rejected the contention, advanced before it, that the provision had been introduced *ex majore cautela*. Section 3(d), it was held, underscored the distinction between the concepts of invention and patentability, and was amended, by the 2005 Amendment Act, especially to deal with chemical substances, and more particularly with pharmaceutical products. As amended, it was observed that Section 3(d) set up a second tier of qualifying standards for chemical

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[33] "**3. What are not inventions –**
The following are not inventions within the meaning of this Act, –
*****
(b) an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality, or which causes serious prejudice to human, animal or plant life or health or the environment;
*****
(e) a substance obtained by a mere admixture resulting only in the application of the properties of the components thereof or a process for producing such substance;"

substances/pharmaceutical products, which would, while enabling patenting of true and genuine inventions, "check any attempt at repetitive patenting or extension of the patent term on spurious grounds" (in para 87 of the report). *The importance of section 3(d), in a case where a plea of repetitive patenting, or extension of a patent beyond its expiry, was set up by the defendant cannot, therefore, be gainsaid.* Para 88 of the report went on to observe that, read in conjunction, clauses (j) and (ja) of Section 2(1), and Section 3(d), "set different standards for qualifying as "invention" things belonging to different classes, and for medicinal and other chemical substances, the Act sets the invention threshold further higher, by virtue of the amendments made in Section 3(d) in the year 2005".

11.15.12 Plainly, the sequitur of this observation would be that, in the case of pharmaceutical substances, the product, in order to be "patentable", would not only have to qualify as an "invention", and as the result of an "inventive step", but would also have to satisfy the rigour of Section 3(d). Of course, this would be relevant only where, on facts, Section 3(d) would apply, i.e. where there was an earlier "known substance", and the product/process being sought to be patented was either

(i) a new form of the known substance, *in which case the product was required to possess "enhanced efficacy", as compared to the "known efficacy" of the "known substance"*, or

(ii) a "mere discovery of any new property or a new use" for the known substance, or "the mere use of a known process, machine or apparatus", *in which case the known process had to either*

(a) result in a new product or

(b) employ at least one new reactant, or

(iii) a salt, ester, ether, polymorph, metabolite, pure form, particle size, isomers, mixtures of isomers, complex, combination or other derivative of the known substance, *which, then, would be considered to be the same substance, and in which case the product would have to differ, significantly, in efficacy.*

11.15.13 The precise claim of Novartis was, thereafter, thus set out by the Supreme Court in its judgement:

(i) Example 21 of the Zimmerman Patent specifically claimed Imatinib.

(ii) Novartis contended that formulation of the following two inventions were involved in the production of the β-crystalline form of Imatinib Mesylate, from the freebase Imatinib:

(a) The first invention, in the process of conversion of Imatinib to the β-crystalline form of Imatinib Mesylate, was Imatinib Mesylate itself. For this, Example 21 had

to be selected out of the 37 examples specified in the Zimmerman Patent and methanesulphonic acid had to be chosen, to produce Imatinib Mesylate. It was contended, by Novartis, that neither of these steps was either "taught" or suggested, by Example 21 of the Zimmerman Patent, to a person skilled in the art. In producing Imatinib Mesylate from Imatinib, therefore, it was contended that technical advance was involved, as compared to the existing knowledge, and the new substance had come into being.

(b) The second invention was the invention which Novartis desired to patent, namely the β-crystalline form of Imatinib Mesylate. The necessity of this invention, contended Novartis, was to ensure that Imatinib Mesylate was suitable for administration in solid oral dosage form. The process parameters, resulting in the creation of the β-crystalline form of Imatinib Mesylate, were also required to be defined. Novartis pointed out that the Zimmerman Patent made no reference to polymorphism or to any crystalline structure. The crystalline form of Imatinib Mesylate was, therefore, it was contended, a distinct, and further, invention, beyond Imatinib Mesylate itself. While thus synthesising the β-crystalline form of Imatinib Mesylate, suitability of administration to human beings was also required to be ensured. Comparing the

characteristics of the β-crystalline form of Imatinib Mesylate with the freebase Imatinib, Novartis submitted that the Zimmerman Patent described, at best, (i) how to prepare the freebase Imatinib and (ii) the anti-tumour properties of the freebase Imatinib. Both the steps involved in proceeding from the freebase Imatinib to the β-crystalline form of Imatinib Mesylate, therefore, it was submitted, resulted in distinct inventions.

11.15.14 Examination of the correctness of these contentions, noted the Supreme Court, would involve detailed analysis of the Zimmerman Patent and the developments that took place thereafter, especially with respect to Novartis. These developments were set out thus (in paras 93 to 93.11 of the report):

(i) The application for grant of the Zimmerman Patent was filed, by M/s Ciba Geigy, in the US, on 28th April, 1994. (An earlier application filed on 2nd April, 1993 was abandoned.) The invention declared by the application related to N-phenyl-2-pyrimidine-amine derivatives which, in the application, were parenthesized as "Formula I", as well as their compounds, their process of preparation and therapeutic uses. The application specifically stated that the compounds in Formula I included their respective salts, by expressly stipulating that "any reference to the free compounds should be understood as including the corresponding salts, where appropriate and

expedient". It was further declared that the compounds of Formula I had valuable pharmacological properties and could be used as, *inter alia*, anti-tumour drugs, by "(inhibiting) the tyrosine kinase activity of the receptor for the epidermal growth factor". By this mechanism, the application declared that the compounds of Formula I were able to prevent metastizing of tumours, and to achieve regression thereof. Example 21 in the application admittedly related to Imatinib, with the chemical formula N - {5 - [4 - [(4 - methyl - piperazinomethyl) - benzoylamido] - 2 -methylphenyl} - 4 - (3 - pyridyl) - 2 - pyrimidine amine. It was further provided, under S. No. 23 towards the end of the application, thus:

> "The compounds according to claim 1 of the formula I, said compound being N-{5-[4-[(4-methyl-piperazinomethyl)-benzoylamido]-2-methylphenyl}-4 (3-pyridyl)-2- pyrimidine amine *or a pharmaceutically acceptable salt thereof*."
>
> (Emphasis provided in the judgement)

(ii) The Zimmerman Patent (US 184) was granted on 28th May, 1996.

(iii) Prior to launching of a new drug, laws in the US require the intending manufacturer to file a New Drug Application (NDA), initially at an investigative stage. On 9th April, 1998, Novartis filed the investigational NDA for Gleevec, the name under which it was proposing to manufacture and market Imatinib Mesylate, with the Food and Drug Administration

(FDA), US. The original NDA, for Imatinib Mesylate, for treatment of patients with chronic myeloid leukaemia, was filed by Novartis with the FDA, on 27th February, 2001. US laws also required declaration of the patent information, relating to the new drug, while filing the NDA. *Novartis, in the patent information furnished in connection with the NDA for Imatinib Mesylate, declared Imatinib Mesylate as the active ingredient and, further, declared that the active ingredient, the drug product (composition/formulation) and method of use were covered by the Zimmerman Patent (US 184).*

(iv) Approval for Gleevec (Imatinib Mesylate), in the form of 50 mg and 100 mg capsules, was granted, by the FDA, *vide* letter dated 10th May, 2001. Following this, Novartis launched Gleevec, commercially, in the market. This was much before any application was filed, by it, for patenting the β-crystalline form of Imatinib Mesylate. The description of the drug, on the package insert of Gleevec capsules, as marketed by Novartis, declared as under:

> "GLEEVEC™ capsules contain Imatinib Mesylate equivalent to 100 mg of Imatinib freebase. Imatinib Mesylate is designed chemically as 4 - [(4 - Methyl - 1 - piperazinyl) methyl] - N - [4 - methyl - 3 - [[4 - (3 - pyridinyl) - 2 - pyrimidinyl] amino] - phenyl] benzamide methanesulfonate …"

(v) On 3rd July, 2001, Novartis applied for a patent term extension for the Zimmerman Patent (US 184), for extending

the term of the Zimmerman Patent for the time taken in the regulatory review for Gleevec. This, observes the Supreme Court (in para 101 of the report), "leaves no room for doubt that Imatinib Mesylate, marketed under the name Gleevec, was submitted for grant approval as covered by the Zimmerman Patent". This was underscored by the fact that, even in the patent application, Novartis declared that the sole active ingredient in Gleevec was Imatinib Mesylate. In so far as the manner in which Imatinib Mesylate was claimed in the Zimmerman Patent, the patent term extension application declared thus:

> "Statement showing how the claims of the patent for which extension is sought cover the approved product:
>
> The operative claims in question are Claims 1-5, 10-13 and 21-23. Each of Claims 1-5, 10-13 and 23 claim a compound or compounds which include the approved product, Imatinib Mesylate. Claim 21 claims of composition containing a compound or compounds which include the approved product, Imatinib Mesylate. Claim 22 claims a method for treating tumours in warm-blooded animals with a compound or compounds which include the approved product, Imatinib Mesylate."

The application was accepted and the term of the Zimmerman Patent (US 184), otherwise due to expire on 28th May, 2013, was extended for 586 days.

(vi) Novartis had applied, in the US, for grant of patent for the β-crystalline form of Imatinib Mesylate. The examiner

rejected the application, against which Novartis appealed to the Board of Patent Appeals and Interferences ("the Board of Patent Appeals", in short). The Board of Patent Appeals reversed the decision of the examiner. It was held, by the Board of Patent Appeals, that, though the Zimmerman Patent did teach any person skilled in the art how to use Imatinib, a compound of Formula I, or a pharmaceutically acceptable salt thereof, in a pharmaceutical composition for treating tumours, the teaching in the Zimmerman Patent did not go further, and did not extend to the β-crystalline form of Imatinib Mesylate, which represented a "manipulative step" in the method of treating tumours in patients.

11.15.15 In view of the above, the Supreme Court held (in para 105 of the report) that the Zimmerman Patent did teach how to make Imatinib Mesylate from Imatinib, and the use of Imatinib Mesylate in pharmacological compositions for treating tumours, though the Board of Patent Appeals opined that the β-crystalline form of Imatinib Mesylate might not have been covered by the Zimmerman Patent. These findings, held the Supreme Court, were binding on Novartis, and could not be revisited. After referring to certain publications on the issue, the submission, of Novartis, that Imatinib Mesylate was a new invention, *vis-à-vis* Imatinib, involving technical advance over existing knowledge was, unequivocally rejected by the Supreme Court, in paras 111 and 113 of the report. Paras 105, 111 and 113 of the report in ***Novartis***[17] read thus:

"**105.** From the above discussion it would be clear that the drug Gleevec directly emanates from the Zimmermann Patent and comes to the market for commercial sale. Since the grant of the Zimmermann Patent, the appellant has maintained that Gleevec (that is, Imatinib Mesylate) is part of the Zimmermann Patent. It obtained drug approval for Gleevec on that basis. It claimed extension of the term of the Zimmermann Patent for the period of regulatory review for Gleevec, and it successfully stopped NATCO Pharma Ltd. from marketing its drug in UK on the basis of the Zimmermann Patent. Not only the appellant but the US Board of Patent Appeals, in its judgment granting patent for β-crystalline form of Imatinib Mesylate, proceeded on the basis that though the beta-crystalline form might not have been covered by the Zimmermann Patent, the Zimmermann Patent had the teaching for the making of Imatinib Mesylate from Imatinib, and for its use in a pharmacological composition for treating tumours or in a method of treating warm-blooded animals suffering from a tumoral disease. This finding was recorded by the US Board of Patent Appeals, in the case of the appellant itself, on the very same issue that is now under consideration. The appellant is, therefore, fully bound by the finding and cannot be heard to take any contrary plea.

*****

111. In the face of the materials referred to above, we are completely unable to see how Imatinib Mesylate can be said to be a new product, having come into being through an "invention" that has a feature that involves technical advance over the existing knowledge and that would make the invention not obvious to a person skilled in the art. Imatinib Mesylate is all there in the Zimmermann Patent. It is a known substance from the Zimmermann Patent.

*****

113. We thus find no force in the submission that the development of Imatinib Mesylate from Imatinib is outside the Zimmermann Patent and constitutes an invention as understood in the law of patent in India."

11.15.16 Paras 114 and 116 of the report went on to record certain submissions, advanced by learned Senior Counsel for Novartis, which are of considerable significance insofar as the controversy in issue before me is concerned and which, in fact, constitutes the fulcrum of the debate which the decision in ***Novartis*** attracts, in case after case. To the extent relevant, paras 114 and 116 of the report may, therefore, be reproduced as under:

> "114. Mr Andhyarujina and Mr Gopal Subramanium, learned Senior Advocates appearing for the appellant, strenuously argued that the patent information furnished by the appellant before the US FDA, or its patent term extension application, or the legal notice given at its behest to NATCO Pharma Ltd. should not be construed to mean that Imatinib Mesylate was anticipated in the Zimmermann Patent. Mr Andhyarujina submitted that the Zimmermann Patent did not disclose Imatinib Mesylate. That the Zimmermann Patent did not describe any working method for converting Imatinib to Imatinib Mesylate. It only stated that a salt may be formed by acid without disclosing any method, but simply calling the method to be "*per se*". The Zimmermann Patent mentioned multiple choices of compounds including Imatinib free base but not any salt of any compound, much less Imatinib Mesylate. Mr Andhyarujina further submitted that it is well settled that the disclosure of an invention must be in a manner clear enough and complete enough for the invention to be performed by a person skilled in the art (*Terrell on Law of Patents*, 16th Edn., p. 51, Para 3.2/7). The learned counsel further submitted that there was a difference between that which is *covered* and that which is *disclosed*. Imatinib Mesylate is *covered* by the Zimmermann Patent but not *disclosed* therein.
>
> *****
>
> 116. Mr Subramanium further submitted that the scope of *coverage* is distinct from the scope of *disclosure* in a patent. Imatinib Mesylate could be said to be not new and known from the Zimmermann Patent only in case there was a complete *disclosure* of the method of its preparation in the

Zimmermann Patent. The learned counsel strongly contended that *coverage* under a patent of the Markush kind cannot lead to any presumption of *disclosure*, much less any *enabling disclosure* of all the compounds within the genus. The learned counsel further contended that *coverage* that is granted in respect of a patent is not always coextensive with what is *disclosed* in that patent. In certain circumstances, where it is a pioneering invention (as in the case of the Zimmermann invention), the patent may be entitled to larger *coverage* than what is specifically *disclosed* in it. The learned counsel argued that *coverage* cannot be used to presume an *enabling disclosure* of the β-crystalline form of Imatinib Mesylate in the Zimmermann Patent. *Disclosure* in a specification can never be presumed, and that is a question of the clear teaching contained in the specification. The teaching of a patent lies in the *disclosure/specification* that supports the claim. The *disclosure* describes the invention. The claim defines through language the various ways the invention could be used i.e. possible but not actualised products. This is the scope of protection granted under the patent. For the purpose of *prior art*, it is the *disclosure* in the *specification* supporting the claim and not the written description or the claims themselves, that must be assessed. The claim can never be the teaching. He further contended that it would be wrong to say that the appellant's claims for β-crystalline form of Imatinib Mesylate is a case of double or repeat patenting, that is, the same invention is being sought to be patented twice. The claim for patent for β-crystalline form of Imatinib Mesylate relates to a second and different invention. Though the invention in the first part (Imatinib) may be necessary to arrive at the invention in the second part, the final product does not come into existence without inventions. The principle is that if a product is covered, it means that it infringes a patent. Whether the patent infringed disclosed every aspect of the product in its specification is a separate inquiry."

(Italics in original, underscoring supplied)

This submission is noted, yet again – thereby emphasizing its importance to the entire dispute – in para 125, in which the Supreme Court again records the submission, of Mr Andhyarujina and Mr

Subramanium, on behalf of Novartis, "that the *coverage* or the claim and the *disclosure* or the teaching, had different parameters in a patent, and that the former may have extended boundary within which *disclosure* or teaching may be confined to a narrow extent" (with the italics provided by the Supreme Court itself, in the judgement).

11.15.17 Novartis, therefore, sought to distinguish, in its submissions before the Supreme Court, between "coverage" and "disclosure", in a patent specification. Even while admitting, in so many words, that Imatinib Mesylate was *covered* by the Zimmerman Patent, Novartis nevertheless asserted that Imatinib Mesylate was not *disclosed* by the Zimmerman Patent. Disclosure, it was sought to be submitted, was required to be "in a manner clear enough and complete enough for the invention to be performed by a person skilled in the art". Complete disclosure would also require disclosure of the method of preparation of the compound, i.e. the disclosure had to be "enabling" in character. It was contended that the Zimmerman Patent, while mentioning multiple choices of compounds, including the Imatinib free base (and, therefore, being in the nature of a "Markush" patent), did not refer to any salt of any compound, much less Imatinib Mesylate. Nor was the method for arriving at the salt, from the Markush moiety, disclosed. Though, therefore, Imatinib was necessary to arrive at Imatinib Mesylate, the process was "inventive" in nature. The idea was sought to be expressed, otherwise, by distinguishing between the "boundary" of the Zimmerman Patent and the "enablement" or "disclosure" therein. Though the boundary of the

Zimmerman Patent extended up to Imatinib Mesylate, Novartis contended that the Zimmerman Patent did not, nevertheless, disclose Imatinib Mesylate, in an enabling fashion.

11.15.18 Dealing with the submissions, the Supreme Court held, in para 118 and 119 of its decision, thus:

> "**118.** The submissions of Mr Andhyarujina and Mr Subramanium are based on making a distinction between the *coverage* or claim in a patent and the *disclosure* made therein. The submissions on behalf of the appellant can be summed up by saying that the boundary laid out by the claim for *coverage* is permissible to be much wider than the *disclosure/enablement/teaching* in a patent.
>
> **119.** The dichotomy that is sought to be drawn between *coverage* or claim on the one hand and *disclosure* or *enablement* or *teaching* in a patent on the other hand, seems to strike at the very root of the rationale of the law of patent. Under the scheme of patent, a monopoly is granted to a private individual in exchange of the invention being made public so that, at the end of the patent term, the invention may belong to the people at large who may be benefited by it. To say that the *coverage* in a patent might go much beyond the *disclosure* thus seem to negate the fundamental rule underlying the grant of patents."
>
> (Italics in original; underscoring supplied)

11.15.19 Considerable reliance was placed, by learned Senior Counsel for Novartis in the Supreme Court, on the decision of the United States Court of Customs and Patent Appeals in ***In re. Hogan***[34], to support the contention "that the Zimmerman Patent is a patent covering a genus with certain known species, and many other species

[34] **559 F 2d 595 (CCPA 1977)**

that were unknown at that time, but which are equally covered by the patent, even though there is no enabling disclosure in the patent in respect thereof". It is not necessary to refer to ***Hogan***[34] in any great detail, as (in para 133 of the report), the Supreme Court held the said decision not to be applicable to the facts of the case before it. Having noted the above reliance, by learned Senior Counsel for Novartis on ***Hogan***[34], the Supreme Court reiterated its finding that "Imatinib Mesylate is a known substance from the Zimmerman Patent". As such, the Supreme Court found ***Hogan***[34], which dealt with the issue of whether species which were unknown at the time of the original patent, could be covered thereby, in the absence of an enabling disclosure, not to be relevant to the facts before it. Having so noted, the Supreme Court went on to hold, in para-134 of the report, thus:

> "However, before leaving ***Hogan*** and proceeding further, we would like to say that in this country the law of patent, after the introduction of product patent for all kinds of substances in the patent regime, is in its infancy. We certainly do not wish the law of patent in this country to develop on lines where there may be a vast gap between the *coverage* and the *disclosure* under the patent; where the scope of the patent is determined not on the intrinsic worth of the invention but by the artful drafting of its *claims* by skilful lawyers, and where patents are traded as a commodity not for production and marketing of the patented products but to search for someone who may be sued for infringement of the patent."
>
> (Emphasis supplied)

11.15.20 The Supreme Court, therefore (in para-135 of the report) held, in terms, that Imatinib Mesylate did not qualify the test of "invention", as contained in clauses (j) and (ja) of Section 2(1) of the Patents Act.

11.15.21 Having so held, the Supreme Court went on to examine whether the β-crystalline form of Imatinib Mesylate was patentable, as contended by Novartis. This issue, the Supreme Court observed, directly brought into play Section 3(d) of the Patents Act. Novartis, through learned Senior Counsel, advanced, at this stage, yet another ground to contest the applicability of Section 3(d). It was submitted that Section 3(d) applied only to new forms of a known substance having a known efficacy. Stress was laid on the expression "known", to submit that it could not be equated with "conceivable". "Known", it was submitted, indicated that the substance, as well as its efficacy, had to be proven and well-established, empirically and beyond doubt. Novartis submitted that neither Imatinib nor Imatinib Mesylate had any known efficacy, so that the requirement of establishing that the β-crystalline form of Imatinib Mesylate had enhanced efficacy over Imatinib or Imatinib Mesylate, could not arise at all. The Supreme Court rejected (in para 137 of the report) the interpretation suggested, by Novartis, of the expression "known", as contained in Section 3(d), *vis-à-vis* the concept of "efficacy". Citing, for the purpose, the precedent in ***Monsanto Co. v. Coromandal Indag Products (P) Ltd***[35] (which interpreted the expression "publicly known", as employed in Section 64(1)(e) and (f) of the Patents Act), the Supreme Court observed that, apart from the finding, already returned by it, that Imatinib Mesylate was a known substance from the Zimmerman patent, the NDA submitted by Novartis to the US FDA clearly stated

[35] **(1986) 1 SCC 642**

that Imatinib Mesylate had undergone extensive preclinical, technical and clinical research, along with the details thereof. The efficacy of Imatinib, therefore, it was held, was equally known and evident from the Zimmerman Patent. Per sequitur, it was held that the β-crystalline form of Imatinib Mesylate was, clearly, a new form of a known substance, i.e. Imatinib Mesylate, with known efficacy.

11.15.22 The fallout, observed the Supreme Court, was that, in order for it to be patentable, the β-crystalline form of Imatinib Mesylate had necessarily to satisfy the tests contained in the substantive Section 3(d) as well as the Explanation thereto.

11.15.23 The Supreme Court advanced the following reasons, for rejecting the plea of Novartis that the β-crystalline form of Imatinib Mesylate had enhanced efficacy, *vis-à-vis* Imatinib, or even *vis-à-vis* Imatinib Mesylate *per se*:

> (i) The patent application filed by Novartis specifically acknowledged that "all the indicated inhibitory and pharmacological effects" of the β-crystalline form of Imatinib Mesylate "are also found with the free base … or other cells thereof". There could, therefore, be no question of the β-crystalline form of Imatinib Mesylate having any enhanced efficacy over the known substance (Imatinib/Imatinib Mesylate), of which it was a new form.

(ii) Though there was some degree of ambivalence on this aspect, the application for grant of patent, filed by Novartis, conveyed the impression that the β-crystalline form of Imatinib Mesylate was derived directly from the Imatinib free base. Apropos the claimed "enhanced efficacy" of the β-crystalline form of Imatinib Mesylate, *vis-à-vis* the free base Imatinib, two affidavits, by Paul William Manley and Giorgio Pietro Massimini, were filed by Novartis. Relevant passages, from the said affidavits, were reproduced by the Supreme Court in paras 147 and 148 of the report, which read thus:

"**147.** Manley, in Para 8 of his affidavit, stated:

> "The *physical properties* of the free base and Imatinib Mesylate differ in that the free base is only very slightly soluble in water (0.001 g/100 ml) while Imatinib Mesylate is very soluble in water (β-crystalline form: 130 g/100 ml). Other physical characteristics of the subject compound are described at pp. 2-3 of the specification. The attendant advantages because of these properties are also simultaneously described therein. These characteristics and hence the attendant properties/advantages are not shared by the free base. Furthermore, the β form significantly differs from the alpha form:
>
> *Physical attributes*:
>
> (a) The beta crystal form has substantially more beneficial flow properties and thus results in better processability than the alpha crystal form.
>
> (b) The beta crystal form of the methanesulfonic acid addition salt is the thermodynamically more stable form at room

temperature. Greater stability is thus to be expected.

(c) The beta crystal form is less hygroscopic than the alpha crystal form of the methanesulfonic acid addition salt of a compound of Formula I.

(d) The lower hygroscopicity is a further advantage for processing and storing the acid addition salt in the beta crystal form."

(Emphasis supplied)

148. Massimini, in Para 9 of his affidavit stated:

"A study conducted on rats provided statistical evidence for a difference in the relative bioavailability of the free base and Imatinib Mesylate in the beta crystalline form. In such study, a mean AUC (0-48h) value of 264.000 h*ng/mL was found for the free base compared with a mean AUC (0-48h) value of 344000 h*ng/mL for Imatinib Mesylate having the β-crystal form. In other words, an about 30% improvement in bioavailability was observed for the β-crystalline form of Imatinib Mesylate compared to the free base. The test results are attached herewith as Annexure 'A'."

(iii) These affidavits compared the β-crystalline form of Imatinib Mesylate with the free base Imatinib. That, however, was insufficient, as the declaration, in the application for grant of patent filed by Novartis, as well as in the affidavits, that the β-crystalline form of Imatinib Mesylate was derived from Imatinib in free base form, was based on the premise that the Zimmerman Patent extended only to free base Imatinib and did

not cover Imatinib Mesylate. This had already been found to be incorrect, in the judgement. That apart, before the Supreme Court, Novartis contended that two stages were involved in processing from the free base Imatinib to the β-crystalline form of Imatinib Mesylate, in which the substance immediately preceding the β-crystalline form of Imatinib Mesylate was the non-crystalline Imatinib Mesylate. Novartis had, therefore, necessarily to establish enhanced efficacy of the β-crystalline form of Imatinib Mesylate over the non-crystalline Imatinib Mesylate. No material, whatsoever had, however, been filed by Novartis on this aspect.

(iv) Insofar as the higher solubility, attributed to the β-crystalline form of Imatinib Mesylate in the affidavits filed by Novartis, was concerned, that might, quite possibly, had been a property of Imatinib Mesylate itself, as it was a well-known fact that salts were more soluble than compounds in free base form. If solubility were to be excluded, the "additional" properties possessed by the β-crystalline form of Imatinib Mesylate, were (i) more beneficial flow properties, (ii) better thermodynamic stability and (iii) lower hygroscopicity.

(v) These additional properties, however, did not amount to enhanced efficacy of the β-crystalline form of Imatinib Mesylate, even *vis-à-vis* the free base Imatinib. Noting the fact that Novartis has already acknowledged the possession, by the

free base Imatinib, of all the pharmacological effects of the β-crystalline form of Imatinib Mesylate, the Supreme Court went on to deal with an additional submission, advanced by Novartis, to the effect that the free base Imatinib had little or no solubility. This, contended Novartis, rendered the free base Imatinib incapable of administration as a drug to human beings, as it would "sit in the stomach like a brick and would pass out with no therapeutic effect". The methanesulfonic acid addition salt of Imatinib made the therapeutic ingredient of the compound, which was Imatinib, much more highly soluble and, consequently, suitable for administration as a drug to human beings. These properties, contended Novartis, were enhanced in the β-crystalline form which, therefore, was even more suitable for administration as a drug than Imatinib Mesylate. Novartis contended that this amounted to "enhanced efficacy".

(vi) Dealing with this contention, the Supreme Court, in paras 157 and 158 of the report, explained, in detail, what "efficacy", in the context of Section 3(d) of the Patents Act, meant. These paras read as under:

> "**157.** What is "efficacy"? "Efficacy" means "the ability to produce a desired or intended result" [*The New Oxford Dictionary of English*, Edn. 1998.]. Hence, the test of efficacy in the context of Section 3(*d*) would be different, depending upon the result the product under consideration is desired or intended to produce. In other words, the test of efficacy would depend upon the function, utility or the purpose of the product under consideration. Therefore, in the case of a medicine that claims to cure a disease, the test of

efficacy can only be "therapeutic efficacy". The question then arises, what would be the parameter of therapeutic efficacy and what are the advantages and benefits that may be taken into account for determining the enhancement of therapeutic efficacy? With regard to the genesis of Section 3(d), and more particularly the circumstances in which Section 3(d) was amended to make it even more constrictive than before, we have no doubt that the "therapeutic efficacy" of a medicine must be judged strictly and narrowly. Our inference that the test of enhanced efficacy in case of chemical substances, especially medicine, should receive a narrow and strict interpretation is based not only on external factors but there is sufficient internal evidence that leads to the same view. It may be noted that the text added to Section 3(d) by the 2005 Amendment lays down the condition of "enhancement of the known efficacy". Further, the Explanation requires the derivative to "differ significantly in properties *with regard to efficacy*". What is evident, therefore, is that not all advantageous or beneficial properties are relevant, but only such properties that directly relate to efficacy, which in case of medicine, as seen above, is its therapeutic efficacy.

158. While dealing with the Explanation it must also be kept in mind that each of the different forms mentioned in the Explanation have some properties inherent to that form e.g. solubility to a salt and hygroscopicity to a polymorph. These forms, unless they differ significantly in property with regard to efficacy, are expressly excluded from the definition of "invention". Hence, the mere change of form with properties inherent to that form would not qualify as "enhancement of efficacy" of a known substance. In other words, the Explanation is meant to indicate what is not to be considered as therapeutic efficacy."

(Italics in original; underscoring supplied)

"Efficacy", when applied to a pharmaceutical product in the context of Section 3(d) of the Patents Act has, therefore, necessarily to be "therapeutic efficacy". The product must, therefore, demonstrate "enhanced therapeutic efficacy", if it is one to which Section 3(d) is otherwise attracted. "Therapeutic efficacy" cannot, additionally, relates to properties already possessed by the "known substance", as was made apparent by the Explanation to Section 3(d).

(vii) Viewed thus, more beneficial flow properties, better thermodynamic stability and lower hygroscopicity could not be regarded as enhancing the "therapeutic efficacy" of the β-crystalline form of Imatinib Mesylate, over the free base Imatinib or over the non-crystalline Imatinib Mesylate.

(viii) Novartis, however, also pleaded that the β-crystalline form of Imatinib Mesylate possessed "30% increased bioavailability", as compared to the free base Imatinib. In this context, the Supreme Court relied on an article titled "Appropriateness of Bioavailability and Bioequivalency as Pre-Market Clearance Considerations" by Jane Moffitt[36], which opined that "a determination that the drug product is bioavailable is not in itself a determination of effectiveness". Even otherwise, the Supreme Court observed that mere increased bioavailability would not necessarily lead to

[36] **34 Food Drug Cosm LJ 640 (1979)**

> enhancement of therapeutic efficacy and that if, in a particular case, it did, that was required to be claimed and established, by the patent applicant, by research data. No material, to that effect, it was noted, was forthcoming before the Supreme Court "to indicate that the β-crystalline form of Imatinib Mesylate will produce an enhanced or superior efficacy (therapeutic) on molecular basis than what could be achieved with Imatinib free base *in vivo* animal model".

Thus, held the Supreme Court, the β-crystalline form of Imatinib Mesylate had failed the Section 3(d) test.

11.15.24 Even while so holding, the Supreme Court went on to clarify, *ex abundanti cautela*, in paras 168 and 169 of the report, that Section 3(d), and the requirement of establishing enhanced therapeutic efficacy, applied only where the product, for which patent protection was sought, was a new form of a known substance with known efficacy. In all other cases, what applied was Section 2(1)(j) (which defined "invention") which, in the case of chemicals and pharmaceuticals, did not necessarily require the product of the applicant to be something altogether new, unfamiliar, strange or not existing before. It could also "mean something "different from a recent previous" or "one regarded as better than what went before" or "in addition to another or others of the same kind" "[37].

[37] Taken from The New Oxford Dictionary of English, Edn. 1998 in para 169 of the report

11.15.25 As a concluding observation, the Supreme Court took note of the fact that Imatinib Mesylate, in its non-crystalline form, had been marketed since 2001 as Gleevec and that, consequent to grant of exclusive marketing rights on 10th November, 2003, Novartis was marketing Gleevec in India as well. The package, wherein Gleevec was sold, described the drug as "Imatinib Mesylate Tablets 100 mg", and further declared that "each film-coated tablet contains 100 mg Imatinib (as Mesylate)". There was no reference, on the package, to the β-crystalline form of Imatinib Mesylate. What was being sold by Novartis, therefore, it was observed, was not the β-crystalline form of Imatinib Mesylate, but Imatinib Mesylate *per se*. This additional fact portrayed the case of Novartis, in the opinion of the Supreme Court, "in rather poor light", and revealed that the patent claim of Novartis, for the β-crystalline form of Imatinib Mesylate, was only an attempt to obtain a patent for Imatinib Mesylate which, otherwise, was not permissible in India.

11.16 Before proceeding to assess the effect, if any, on the present dispute, of ***Novartis***[17], it is necessary to deal with the contention, of Mr. Sai Deepak, that, in paras 23 to 27 of the plaint and in paras 14 to 15 of the replication, the plaintiff has admitted coverage of CTPR by Claim 22 in IN'978. Paras 23 to 27 of the plaint and Paras 14 and 15 of the replication read as under:

> Paras 23 to 27 of the plaint
>
> "23. In the interest of full disclosure, the Plaintiffs wish to state that apart from the suit patents, the Plaintiffs are also the proprietors of a number of other patents, including product,

process and composition patents, protecting insecticidal anthranilamides including CTPR. An exemplary list of such patents granted in India include: IN 204978, IN213177, IN205622, IN215218, IN298645, IN261551, IN284017, IN252356 and IN261276.

24. It would be pertinent to mention that the Plaintiffs' patent IN 204978 (IN '978) mentioned in paragraph 23 is a granted and subsisting genus patent *covering a vast number of compounds of a class of anthranilamides. The compounds of Formula 1 of the suit patent are a novel and inventive selection from the disclosure of IN '978. CHLORANTRANILIPROLE (CTPR) is not specifically disclosed in the genus patent IN '978, although it is within the scope of the numerous compounds included in the Markush Formula disclosed and claimed in the patent.* A person skilled in the art would not have recognized CTPR from the genus patent.

25. In fact during the prosecution of the application corresponding to the suit~~,~~ patent IN 201307 in the US, a Declaration was filed at the United States Patent and Trademarks Office (USPTO) comparing compounds disclosed in the suit patent with the closest, specifically disclosed compounds in IN '978. A copy of the said declaration is annexed with the list of documents filed with the present plaint.

26. The said Declaration mentions tests conducted with the compounds of the selection invention (i.e. suit patent IN '307) and a comparison with the closest compounds disclosed in IN '978. In the tests, all the new compounds of the suit patent (IN '307) showed unexpected and unpredictable superior insecticidal activity compared with the closest compounds disclosed in IN '978. CTPR is not specifically disclosed in IN '978. A person skilled in the art would not arrive at CTPR from Formula 1 of IN '978 without human intervention and ingenuity on account of extensive, thorough and undue experimentation or hindsight knowledge. Nonetheless, *CTPR is in the class of anthranilamides within the scope of the numerous compounds included in the Markush Formula disclosed and claimed in the IN '978 patent*.

27. The Plaintiff reserves its right under Order II Rule 2, CPC to include any additional patents (as mentioned above) as part of the present suit subject to discovery of the complete activities of the Defendant herein."

(Emphasis supplied)

Paras 14 and 15 of replication

"14. The suit patent specifically discloses and claims CTPR by way of a chemical structure and/or specific chemical name. One of the main defenses taken by the Defendant herein is that CTPR is disclosed and claimed by a previous India patent IN '978 and that therefore IN '307 is an invalidly granted patent. This contention of the Defendant is false and misleading since to qualify as a disclosure in a prior publication, the invention, *i.e.* the compound CTPR in this case, has to be specifically and particularly disclosed in the prior art either by way of a chemical structure, or a specific Chemical/IUPAC name.

15. The Plaintiffs also submit the following:

i. The compounds of formula I of IN'307 are a novel and inventive selection from the disclosure of IN'978. All of the compounds of the suit patent (IN'307) contain a 3-substituted-2-pyridyl ring and two substituents (R1 and R2) on the phenyl ring. After tedious and painstaking research, it was found that this combination of groups leads to compounds with unexpected superior insecticidal activity compared to other insecticidal anthranilamides disclosed in IN'978.

ii. In fact during the prosecution of the patent application corresponding to the suit patent IN 201307 in the US, a Declaration was filed at the United States Patent and Trademarks Office (USPTO) comparing compounds disclosed in the said patent application with the closest, specifically disclosed compounds in the US equivalent of IN'978. The said Declaration mentions tests conducted with the compounds of the selection invention (i.e. the patent application

> corresponding to suit patent IN'307) and a comparison with the closest compounds disclosed in the US equivalent of IN'978. In the tests, all the new compounds of the suit patent (IN'307) showed unexpected and unpredictable superior insecticidal activity compared with the closest compounds disclosed in IN'978.
>
> iii. Further, the Indian Patents Office has granted the suit patent after a thorough examination and after being duly satisfied regarding the novelty and inventiveness and patentability of the invention disclosed in IN'307 over IN'978. Moreover, there had been no pre-grant opposition or post grant opposition or a revocation proceeding filed against the suit patent till the filing of the present suit."

11.17 Paras 23 to 27 of the plaint and paras 14 and 15 of the replication, as extracted hereinabove, do not reveal any admission, on the part of the plaintiff, that CTPR is covered by Claim 22 in IN'978. What the plaintiff has contended is that CTPR is "within the scope" of the class of anthranilamides covered by the Markush formula disclosed in Claim 22 in IN'978. There is, therefore, no admission, by the plaintiff, either of coverage, or of disclosure, of CTPR in Claim 22 of IN'978.

11.18 The "coverage versus disclosure" conundrum, in the light of ***Novartis***[17]

11.18.1 Considerable debate was generated, at the Bar, on the exact scope of import of paras 119 and 134 of ***Novartis***[17], specifically with respect to the following three observations/findings, to be found therein:

(i) "The dichotomy that is sought to be drawn between *coverage* or claim on the one hand and *disclosure* or *enablement* or *teaching* in a patent on the other hand, seems to strike at the very root of the rationale of the law of patent." (in para 119)

(ii) "To say that the *coverage* in a patent might go much beyond the *disclosure* thus seems to negate the fundamental rule underlying the grant of patents." (in para 119)

(iii) "We certainly do not wish the law of patent in this country to develop on lines where there may be a vast gap between the *coverage* and the *disclosure* under the patent…" (in para 134)

11.18.2 The immediate query that these observations of the Supreme Court generate is – Has the Supreme Court held that "coverage" and "disclosure" are the same, or that "coverage" implies "disclosure"

11.18.3 Mr. Sethi did not leave any stone unturned in his effort to repel the submission, of Mr. Sai Deepak, that the Supreme Court, in ***Novartis***[17] held that "coverage" of the patent was the same as "disclosure", and that the existence of either one predicated, as a necessary corollary, the existence of the other. Pointing out that the dispute in ***Novartis***[17] did not even relate to any infringement claim,

Mr. Sethi also sought to distinguish the decision on other parameters, already noted hereinbefore. In order to examine the correctness of Mr. Sethi's submissions, it would be required, in the first instance, to understand what exactly the Supreme Court held, on the aspect of coverage *vis-à-vis* disclosure in the patent and, in the second, to assess whether the applicability, of the law enunciated by the Supreme Court in this regard, was compromised in view of the factual distinctions highlighted by Mr. Sethi.

11.18.4 It is true, as held by the Supreme Court itself, that propositions enunciated by courts, in judicial decisions, are not to be likened to Euclid's theorems[38]. It is equally true that, ordinarily, the enunciation of the law by the Supreme Court is to be appreciated in the light of the factual and contextual backdrop in which the enunciation took place.[39] Equally true is it, however, that, where the Supreme Court enunciates or expounds the law in general or omnibus terms, clearly intended to be applicable even beyond the peripheries of the controversy before it, Courts, hierarchically below the Supreme Court, would be well advised not to limit, or their own accord, such declaration of the law, to the facts which were before the Supreme Court. Any such effort, in my view, would be an affront not only to Article 141, but also to Article 144 of the Constitution of India, which requires all authorities to act in aid of the Supreme Court.

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[38] **Chintels India Ltd v. Bhayana Builders Pvt Ltd, AIR 2021 SC 1014**

[39] **State of Rajasthan v. Jainudeen Shekh and Ors., AIR 2015 SC 3469; Uttaranchal Road Transport Corpn. And Ors. v. Mansaram Nainwal, AIR 2006 SC 2840**

11.18.5 Paras 118, 119 and 134 of the decision in ***Novartis***[17] have, in my view, to be understood in the light of paras 114 and 116, which set out the submissions advanced, before the Supreme Court, by learned Senior Counsel Mr. Subramanium and Mr. Andhiyarujina. Though the submissions of learned Senior Counsel were, as they necessarily had to be, advanced in the light of the factual controversy before the Supreme Court, the propositions advanced were general in nature, and the findings of the Supreme Court, as contained in paras 118, 119 and 134 also, in my opinion, equally omnibus. What was contended, by learned Senior Counsel, as recorded in paras 114 and 116 of the report, was that "the scope of coverage is distinct from the scope of disclosure in a patent". This argument stands reiterated, in the same para (para 116) – "that coverage that is granted in respect of a patent is not always co-extensive with what is disclosed in the patent". In the light of the Zimmerman invention, learned Senior Counsel contended that "the patent may be entitled to larger coverage than what is specifically disclosed in it". The teaching in the patent, it was contended, lay "in the disclosure/specification that supports the claim", which "describes the invention". Dealing with these submissions, the Supreme Court held, in para 119 of the report, that "the dichotomy… sought to be drawn between coverage or claim on the one hand and disclosure or enablement or teaching *in a patent* on the other hand, (seemed) to strike at the very root of the rationale of the law of patent". The words "in *a* patent", as used by the Supreme Court, indicated of the intent of the Supreme Court to be expounding the law in general terms, and not limited to the Zimmerman patent, or

the suit patent before it. In fact, a bare reading of para 118 of the report in ***Novartis***[17] makes it clear that the Supreme Court has expressed its view with respect to patents in general. The opening sentence of para 119 of the report is a proposition couched in absolute terms and, in my respectful opinion, it would be folly, on the part of this Court, to restrict those observations to the facts of ***Novartis***[17]. According to the Supreme Court (and at the cost of repetition), any dichotomy, sought to be drawn between coverage or claim, and disclosure or enablement or teaching, in a patent, struck at the very root of the rationale of patent law. Obviously, the Supreme Court has disapproved, in no uncertain terms, of any dichotomy being sought to be drawn between coverage and disclosure.

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

Novartis[17], the word "dichotomy" with "distinction" or "difference". That, I am afraid, I cannot do. Apparently, in fact, the Supreme Court has, in disapproving the existence of any "wide gap" between coverage and disclosure, clarified that it merely disapproved of any dichotomy between these concepts, and was not seeking to hold that the concepts were identical.

11.18.7 Indeed, the judgement of the Supreme Court, read thus, would be in entire accord with the covenants of the Patents Act, which make repeated reference, in more than one provision, to "disclosure"[40]. Clearly, the framers of the Patents Act did not envisage the "claim" or "coverage" of the claim, to be identical to "disclosure". Nor, for that matter, has the Supreme Court so held. What was being sought to be contended, before the Supreme Court, by learned Senior Counsel was that, though the specific claim in the Zimmerman patent covered Imatinib with its pharmaceutically acceptable salts, and though Imatinib Mesylate was a pharmaceutically acceptable salt of Imatinib and, therefore, covered by the Zimmerman Patent, it was, nevertheless, not disclosed by it. Such an argument, if accepted, would amount to holding that there was *complete dichotomy* between "coverage" and "disclosure", with no connection between the two. It would amount to holding that, while examining what was disclosed in a patent, the authority, or the Court concerned, was to remain oblivious to the coverage of the patent. Such a dichotomy, which would result in a "wide gap"

[40] Refer, for instance, to Section 10(4), 11(2), (3), (3A) and (4), 16, 33(2), 54(1), 59(1), 64(1)(h), (i), (m) and (p), among others.

between coverage and disclosure was, in terms, disapproved by the Supreme Court. If, however, there was clear coverage of a product in the claim (as was found to exist in the Zimmerman Patent, qua Imatinib Mesylate), it would be difficult for the patent holder to assert, before the Court, that, despite such coverage, the claim did not disclose the product. That, in my view, is what ***Novartis***[17] holds. It does not pronounce that coverage and disclosure are identical or synonymous terms, in patent law. The submission, by Mr. Sai Deepak, to that effect cannot, therefore, be accepted.

11.18.8 Proceeding from this premise, the Supreme Court went on to hold that, as Imatinib, with its pharmaceutically acceptable salts, stood claimed in the Zimmerman patent, and as Imatinib Mesylate was a pharmaceutically acceptable salt of Imatinib, it was also claimed in the Zimmerman Patent. It was not open, therefore, to the appellants before the Supreme Court to contend that, though Imatinib Mesylate was claimed/covered by the Zimmerman Patent, it was not disclosed thereby. This would amount to creating a complete divide – or dichotomy – between coverage, or claim, and disclosure which, according to the Supreme Court, was not permissible. In other words, something which is specifically claimed or covered by the specific claim cannot be disowned by asserting that it was not disclosed.

11.18.9 To that extent, the interpretation, of ***Novartis***[17], as advanced by Mr Sai Deepak, commends itself to acceptance.

11.18.10 Where, however, ***Novartis***[17] fails to come to the aid of the defendant in the present case, is the point of distinction where, unlike the circumstances which obtained before the Supreme Court, there is, in the present case, no claim, no coverage and no disclosure, by the plaintiff, of CTPR in the genus patent, i.e. Claim 22 of IN'978, as I have already opined hereinabove. No question of any dichotomy between claim and disclosure, therefore, arises in the present case.

11.19 ***Novartis***[17] cannot, therefore, assist the case of the defendant.

11.20 The defendant, in its written statement, asserts, in para 93, that the patents IN'978 (the genus patent in the present case), US patent 5998424 (US'424), US Patent 6020357 (US'357), PCT International Publication WO 01/70671 (WO'671), European Patent 0946508 (EP'508), US Patent 4214090 (US'090) and PCT International Application WO 96/16954 (WO'954) "expressly disclosed and/or provide sufficient teaching and guidance in respect of Chlorantraniliprole and are therefore relevant prior art vis-à-vis IN'307". It is further asserted, in para 101, thus: "... Claim 1 of IN'307 discloses and claims Chlorantraniliprole. *The corresponding claim/coverage for Chlorantraniliprole in IN'978 is expressly present in Claim 22 as granted*".

11.21 It has already been noticed, hereinabove, that the Markush formula claimed in Claim 1 of IN'307 was not, in fact, claimed in Claim 22 of IN'978. Insofar as disclosure is concerned, too, I have

already opined that the manner in which the defendant has arrived at CTPR, or the Markush structure claimed in Claim 1 of IN'307, from Claim 22 of IN'978, in paras 101-102, and 103, of the written statement, respectively, indicate that the defendant has cherry picked select substitutions from the mass of substitutions suggested in Claim 22 of IN'978, applying, in the process, hindsight knowledge. There is nothing, in the written statement, to indicate the basis for the selections made by the defendant, for substitution on the Markush moiety claimed in Claim 22 of IN'978. The defendant does not aver, or plead, that the teachings in IN'978 contained any such material as would propel a person skilled in the art to synthesise, from the Markush formula in Claim 22, the compound having the Markush formula in Claim 1 of IN'307. No reference is made to any such specific or specialised properties of CTPR, to arrive at which requisite teaching is contained in IN'978. *Prima facie*, therefore, the present case is one of classic hindsight substitution of radicals on a Markush moiety, and cannot be said to make out a case of obviousness, of Claim 1 in IN'307 or of CTPR, in Claim 22 of IN'978 or any other teaching contained in IN'978, as granted.

11.22 Mr. Sai Deepak has also contended that, in "multiple patent applications and patents", the plaintiff has asserted that CTPR was first claimed and disclosed in US 6747047, which was the equivalent of IN'978. Additionally, he has submitted that other patentees in the same field have, in patent applications filed by them, stated that US'047 claimed and disclosed CTPR. He has also sought to

highlight, in this context, the fact that some of the admissions contained in the applications relating to these patents were by George Philip Lahm, who was one of the inventors of the suit patent and of IN'978.

11.23 Mr. Sethi has contended, in rebuttal, that statements made in documents relating to other patents cannot be relied upon or treated as evidence, by the defendants, to make out a case of vulnerability of the suit patent in the present case, as their validity has not been tested in these proceedings. I entirely agree with this submission. While it is true that the degree of proof, which the defendant is required to attain, is only that of a credible challenge, and the challenge need only to disclose vulnerability of the suit patent, rather than a clear cut case for revocation, the challenge has, nevertheless, to be credible. Reliance on documents filed by other patentees in applications relating to other patents, or even on documents filed by the plaintiff itself while applying for other patents, cannot be relied upon, *prima facie*, to plead the existence of a credible challenge to the validity of the suit patent. These are unrelated documents, pertaining to unrelated patent applications. Mr. Sethi is correct in pointing out that the validity of the statements have not been tested in the present proceedings and that, therefore, at a *prima facie* stage, this Court cannot hold one way or another, relying on such material. Needless to say, this would not inhibit the defendant from relying on such material during the course of trial in the present case.

11.24 Mr. Sethi has relied, for this purpose, on the order, dated 8th December, 2015 in ***F. Hoffmann-La Roche***[22] and, on a reading of the said decision, the reliance is found to be apt. In para 61 of the order, the Division Bench of this Court has held it to be "a cardinal principle of claim construction that the claim must be interpreted on its own language and if it is clear then resort cannot be had to subsequent statements or documents either to enlarge the scope or to narrow the same". In so holding, the Division Bench relied on the earlier Division Bench ruling in ***Merck Sharp & Dohme Corpn v. Glenmark Pharmaceuticals***[41], in which, too, it was held that "claim construction to determine the coverage in the suit patent is to be determined objectively on its own terms with regard to the words used by the inventor and the context of the invention in terms of knowledge existing in the industry". Equally, reliance was placed on ***Glaverbel SA v British Coal Corpn***[42], which disapproves construction of a plain "with an eye on prior material, in order to avoid its effect".

11.25 The sequitur would be that when, as in the present case, the Court has examined Claim 22 of IN'978, *vis-à-vis* the suit patent, and found the submission, of the defendant, that the suit patent was disclosed in, taught by, or obvious from Claim 22 of IN'978, to be *prima facie* unacceptable, no occasion would arise for the Court to forage through declarations or assertions made by other patentees, or even by the plaintiff, while applying for other patents. The text of the claims, and of the declarations contained in the complete

[41] 2015 (63) PPC 257; FAO (OS) No. 190/2013
[42] 1995 RPC 255 (United Kingdom)

specifications of the genus patent and specie patent, which are before the Court, has necessarily to prevail.

11.26 It cannot be said, therefore, that the defendant has been able to establish, *prima facie*, that CTPR was either claimed, or disclosed, in Claim 22 in IN'978, or that Claim 1 of IN'307, or CTPR itself, was obvious from Claim 22 in IN'978.

12. Vulnerability of the suit patent IN'307 on the ground of anticipation by prior claiming, under Section 13(1)(b) read with Section 64(1)(a) of the Patents Act

12.1 Mr. Sai Deepak urges that the claims in IN'307 are invalid on the ground of anticipation by prior claiming, for which statutory recognition is to be found in Section 13(1)(b)[43] read with Section 64(1)(a)[44] of the Patents Act. In fact, the reliance on Section 13(1)(b) is largely superfluous, as the ingredients of the said provision stands

[43] "**13. Search for anticipation by previous publication and by prior claim. –**
(1) The examiner to whom an application for a patent is referred under section 12 shall make investigation for the purpose of ascertaining whether the invention so far as claimed in any claim of the complete specification –
(a) has been anticipated by publication before the date of filing of the applicant's complete specification in any specification filed in pursuance of an application for a patent made in India and dated on or after the 1st day of January, 1912;
(b) is claimed in any claim of any other complete specification published on or after the date of filing of the applicant's complete specification, being a specification filed in pursuance of an application for a patent made in India and dated before or claiming the priority date earlier than that date.

[44] "**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 by the Appellate Board or on a counterclaim 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;"

reiterated in Section 64(1)(a) which, insofar as the liability to revocation of a patent is concerned, is self contained.

12.2 Mr. Sai Deepak submits that, on the satisfaction of three conditions, a suit patent would stand invalidated under Section 13(1)(b)/Section 64(1)(a). These three conditions, to be found in either of these provisions, are that (i) the claim in the suit patent is claimed in any claim of any other complete specification, (ii) such complete specification must have been filed in pursuance of an application for a patent in India and (iii) the priority date claimed in such complete specification must be earlier in point of time to the priority date of the suit patent. If these three conditions are fulfilled, Mr. Sai Deepak submits that Section 13(1)(b)/Section 64(1)(a) renders the date of publication of the suit patent irrelevant. As such, the fact that IN'978 was published after the priority date of IN'307, submits Mr. Sai Deepak, makes no difference to the applicability of Section 13(1)(b).

12.3 Aropos the first requirement of Section 13(1)(b), which is the claiming, of the suit patent (IN'307) in any claim of any other complete specification, Mr. Sai Deepak relies on paras 23 to 27 of the plaint to contend that the plaintiff has acknowledged and admitted the coverage of CTPR within IN'978 i.e. the genus patent. These paras already stand reproduced in para 11.16 *supra.* Mr. Sai Deepak's contention is that, having thus admitted the coverage of CTPR under IN'978 (which assertion the defendants deny), the only basis for the

assertion, by the plaintiff, regarding validity of IN'307, is that CTPR is not disclosed in IN'978. This, according to him, is an irrelevant consideration, as disclosure forms no part of Section 13(1)(b). In other words, Mr. Sai Deepak would contend, irrespective of whether the claim in the suit patent is, or is not, disclosed in the earlier genus patent, the claim in the suit patent would nonetheless be vulnerable to revocation on the ground of anticipation by prior claiming, if it satisfies the three conditions of Section 13(1)(b).

12.4 Apropos the second condition, Mr. Sai Deepak relies on the bibliographic details of IN'978 and IN'307, as provided in the plaint, which indicate that IN'307 claimed priority dates (based on the date of filing of the corresponding US patents) of 13th August, 2001 (*vis-à-vis* US 60/311,919), 21st September, 2001 (*vis-à-vis* US 60/324,128) and 2nd April, 2002 (*vis-à-vis* US 60/396,661), whereas IN'978 claimed the priority dates 22nd March, 2000 (*vis-à-vis* US 60/191,242), 27th July, 2000 (*vis-à-vis* US 60/220,232), 11th December, 2000 (*vis-à-vis* US 60/254,635) and 17th January, 2001 (*vis-à-vis* US 60/262,015). As the earliest priority date of IN'307 is later than the latest priority date of IN'978. Mr. Sai Deepak submits that the second condition of Section 13(1)(b), with respect to "priority of priority dates" also stands satisfied.

12.5 The third condition in Section 13(1)(b), Mr. Sai Deepak points out, obviously stands satisfied as both IN'978 and IN'307 are Indian patents.

12.6 Having thus attempted to demonstrate that the three conditions of Section 13(1)(b)/ Section 64(1)(a), which render IN'307 vulnerable to revocation on the ground of anticipation by prior claiming stand satisfied, Mr. Sai Deepak submits that no statutory exception or defence is available in such a case. Whether, or not, the claim of the suit patent has been disclosed in the genus patent, submits Mr. Sai Deepak, is entirely irrelevant and foreign to Section 13(1)(b). It is not open, in other words, according to Mr. Sai Deepak, for the plaintiff to escape the rigour of Section 13(1)(b) by contending that CTPR was not disclosed in IN'978.

12.7 In para 20 of the written submissions filed by the defendant, it is additionally asserted thus:

> "Critically, it is not important for the scope of the prior claim of the prior patent and the impugned claim of the impugned patent to be identical. If it is established that the subject-matter claimed in the impugned patent falls within the scope of/is covered by the prior claim of the prior patent, then the claim of the impugned patent is invalid to that extent."

As such, Mr. Sai Deepak submits that, as "Claim 22 of IN'978 encompasses within its scope the entire principal claim, Claim 1 of the impugned patent IN'307", the entire Claim 1 of IN'307 is rendered vulnerable to revocation.

12.8 In this context, Mr. Sai Deepak has placed reliance on the judgment dated 2nd December, 1966 of the UK Patents Appeal

Tribunal in ***In Re: Merck & Co. (MACEK's) Patent***[45], rendered in the context of Section 14(1)(c) of the United Kingdom Patents Act, 1949 (the "UK Patents Act") which, according to Mr. Sai Deepak, is *in pari materia* with Section 13(1)(b) of the Patents Act. Specific reliance has been placed on the following passages from the said decision:

> *"The 1949 Act introduced this phrase "the invention so far as claimed in any claim" not only in section 14 (1)(c) but elsewhere in the Act and in particular in section 14(1)(b) (prior publication), section 14(1)(d) (prior user) and section 14(1)(e) (obviousness).* The acceptance of the principle of multiple priorities required some such introduction, so that it cannot be assumed that Parliament in phrasing the alteration as it did was intending to do more than to adjust the Act to accord with this principle, It would be a matter of surprise if, in purporting to do this, the legislature had made a fundamental alteration in the principles by which the validity of claimed monopolies has hitherto been determined. So far as concerns prior publication and prior user, if a claim to a manner of manufacture includes one embodiment of it which is not new, that claim has always been regarded as invalid whatever novel and ingenious embodiments the claim also covers (see ***Molins v. Industrial Machinery Co. Ltd. (1938) 55 R.P.C. 31***). So too with obviousness ***(Woodrow v. Long Humphreys & Co. (1934) 51 R.P.C. 25***); and unless and until the patentee has been able, by suitable amendment, to exclude from the claim the invalid portion of the monopoly, the taint of invalidity attaches to it in its fulness and deprives it of monopoly effect.
>
> *There would appear to be no ground for construing the phrase "the invention so far as claimed in any claim" in different senses in the sub-divisions of section 14(1), so that, if the cited prior claim on its fair construction can be seen to grant as a manner of manufacture that which the later claim on its fair construction would re-monopolise, the objection of prior claiming is established, and this despite the inclusion in*

[45] **[1967]6 RPC 157**

> *the later claim of variants of the manner of manufacture to which no objection can properly be raised. The later circumstance will of course be of concern in the determination of the relief to be accorded if and when the plea is established, but it cannot shield a vulnerable embodiment of the invention claimed from attack on the ground of pre-claiming any more effectively than it can from the other objections available at the opposition stage."*
>
> (Emphasis provided by the defendant in the written submissions)

(I may note, here, that para 26 of the written submissions filed by the defendant also refers to another extract, purportedly from the decision in ***In Re: Merck & Co***[45], but that the said extract does not appear to form part of the judgment, and only figures in the head note.)

12.9 Applying this decision, it is contended by Mr. Sai Deepak that, even if Claim 1 in IN'307 included variants which were outside the scope of Claim 22 in IN'978, to the extent the claim in Claim 1 of IN'307 fell within the scope of Claim 22 of IN'978 – which would include the claim for patenting of CTPR – Claim 1 in IN'307 is rendered vulnerable, at least *prima facie*. In this context, he goes on to submit that though, ordinarily, any examination of the applicability of Section 13(1)(b) would require complete construction of the claims in the suit patent and the genus patent, that exercise is obviated in the present case, in view of the admission, by the plaintiff, of the coverage of CTPR within Claim 22 of IN'978.

12.10 Responding to the arguments of Mr. Sai Deepak, Mr. Sethi submits that Section 13(1)(b) applies only where, on comparison of

claims, the claim in the specie patent is found to be identical to that in the genus patent. It is not enough, submits Mr. Sethi, that the claim in the specie patent is comprehended in the claim in the genus patent; it must be specifically claimed therein. He relies, for this purpose, on the ruling of the US Courts of Customs and Patent Appeals in ***In re. Vogel***[46] and of the UK Supreme Court in ***In re. Daikin Kogyo Ltd***[47] which, he submits, also explains ***In Re: Merck & Co***[45], on which Mr. Sai Deepak relied. Mr. Sethi points out that approximately 4000 compounds have been exemplified in IN'978, none of which is CTPR. Apropos the Form 27s filed for IN'978, Mr. Sethi points out that they reflected IN'978 as "worked" only after the plaintiff's CTPR products CORAGEN and FERTERRA had been manufactured and tested. This was because CTPR was encompassed within the scope of IN'978, but was not claimed or disclosed therein. To emphasise this distinction, Mr. Sethi relies on the judgement of a coordinate bench of this Court in ***Astrazeneca AB v. Emcure Pharmaceuticals***[48]. He submits that there is a distinction between that which is "encompassed" in a claim and that which is claimed or covered thereby. He submits that, if the interpretation sought to be advanced by Mr. Sai Deepak were to be accepted, it would seriously compromise advancement in pharmaceuticals, as, on the principle that all entities which may come within the broad coverage of a claimed Markush moiety cannot be patented, the incentive to invent superior pharmaceutical products would be lost. This is a factor which, submits Mr. Sethi, has been

[46] **422 F. 2d. 438**
[47] **(1974) RPC 18**
[48] **2020 (81) PPC 588**

noted by this Court in its judgement in ***F. Hoffman la Roche***[8]. He submits that the insecticidal activity of CTPR was superior to that of the compounds envisaged in IN'978. He also submits that the Patents Act permits coverage of one product by more than one patent, in Sections 3(d), 19, 88(3), 91 and 141. Thus, submits Mr Sethi, the objection of Mr Sai Deepak, predicated on Section 64(1)(a)/13(1)(b) of the Patents Act, is without substance.

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

12.12 Having said that, it is, of course, always open to the defendant, as an alternative plea, that Claim 22 of IN'978 was itself invalid. As I have already held here in before, however, no challenge to the validity of Claim 22 of IN'978 having ever been raised by the defendant, least of all in these proceedings, I am not willing to enter into that aspect. I proceed, therefore, on the premise that Claim 22 of IN'978 was a valid claim, validly granted.

12.13 CTPR is the "invention… claimed in Claim 1 of the complete specification" in IN'307, i.e. the suit patent. The "valid claim of earlier priority date" in the prior patent, for the purposes of Section 64(1)(a), as alleged by Mr. Sai Deepak, is Claim 22 of IN'978. Section 64(1)(a) would, therefore, render the suit patent vulnerable if CTPR is, *prima facie*, claimed in Claim 22 of IN'978.

12.14 I have already held, hereinabove, that CTPR is *not* claimed, or even disclosed, in Claim 22 of IN'978. Claim 22 of IN'978 claims a Markush moiety. It is possible to travel from said Markush moiety to Claim 1 in IN'307, or to CTPR, only by cherry picking select radicals out of the innumerable choices provided in the complete specifications accompanying Claim 22 of IN'978, for substitution on said Markush moiety. Save and except for demonstrating how, by substituting such select radicals, it is possible to move from the Markush moiety in Claim 22 of IN'978 to Claim 1 of IN'307, or to CTPR, the defendant has, in its written statement, not indicated any teaching or guidance, available in the complete specifications of

IN'278, as would guide a person skilled in the art to pick the select radicals and substitute them on the Markush moiety in Claim 22 of IN'978, so as to "lead" him to CTPR. Neither CTPR, nor the Markush formula claimed in Claim 1 of IN'307, is obvious from the disclosure provided in Claim 22 of IN'978.

12.15 The defendant appears to be aware of this legal position, as is apparent from the assertion, in para 21 of the written submissions filed by the defendant that "Claim 22 of IN'978 encompasses within its scope the entire principal claim, Claim 1 of the impugned patent IN'307, thereby rendering the entirety of the principal claim of IN 307 vulnerable to revocation"[49]. The correctness of this argument of the defendant appears to be somewhat doubtful and, in fact, also appears to be contrary to the contention, of Mr. Sai Deepak, that the words used in Section 13(1)(b) have to be strictly construed. While advancing this contention, the defendant has introduced two new concepts, which find no place in Section 13(1)(b), viz. the concepts of "scope" and "coverage". Section 13(1)(b) clearly applies where a claim in the suit patent "is *claimed* in any claim of any other complete specification". It does not make any reference either to the scope of the claim or the coverage of the claim. What is required therefore, *prima facie*, is comparison of the claims, not whether the claim in the suit patent is covered by or within the scope of the claim in the genus patent. This position is also conceded by the defendant, in its written submissions, by accepting that, ordinarily, a challenge of anticipation

[49] Refer para 12.8 *supra*

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

12.16 The defendant has made a strained effort to justify invocation of Section 13(1)(b)/64(1)(a) by contending that, even if Claim 1 in IN'307 includes variants which were outside the scope of Claim 22 in IN'978, the former claim was, nonetheless, rendered *prima facie* vulnerable to the extent it fell within the scope of Claim 22 of IN'978, i.e. to the extent it claimed CTPR. Neither Section 13(1)(b), nor Section 64(1)(a), in my considered opinion, lends itself to such an interpretation. All that these provisions require the Court – or authority before whom the challenge to the validity is raised – to do is to assess whether the invention, insofar

12.17 as it has been claimed in the suit patent, was, or was not, claimed in the prior patent. CTPR, directly or indirectly, is not

claimed in Claim 22 of IN'978. The highest that the defendant can assert, at least at this juncture, is that CTPR, as an arthropodicidal anthranilamide, falls within the broader Markush coverage of Claim 22 of IN'978. In the discussion here in before, I have already opined that the sequitur of any such *coverage* cannot be that CTPR has been *claimed* in Claim 22 of IN'978.

12.18 What Mr. Sai Deepak seeks to contend is, essentially, this: "Let us assume CTPR was not disclosed in IN'978. No matter, as disclosure is irrelevant for the purposes of Section 13(1)(b). The plaintiff has acknowledged that CTPR comes within the coverage of Claim 22 of IN'978. That is sufficient to make out, at least on a *prima facie* basis, a case of vulnerability of the suit patent, under Section 13(1)(b)/64(1)(a)." There is, in my view, a subtle fallacy in this argument. The Patents Act does not define "coverage". Indeed, coverage, as a concept, is not even envisaged by the Patents Act. In patent law, there are coverages and coverages. Where the substitutions to be effected on the claimed moiety are limited and easily discernible to a person skilled in the art, the resultant products may be obvious from the genus patent, and any separate species patent issued in respect of such products may become vulnerable to revocation. Where, however, the genus claim is in the form of a Markush formula, with multifarious suggested substitutions, they, unless the complete specifications of the genus patent instruct, or teach, the person skilled in the art to effect the requisite substitutions in order to arrive at the specie patent, the specie patent cannot be

treated as vulnerable to revocation. The question is, ultimately, one of degree. No cast iron formula is possible, and it would be for the Court to examine, from the genus patent and specie patent, as to whether the latter is obvious from the former. Mere coverage, therefore, does not, in every case, result in obviousness. In the present case, even if the Markush moiety claimed in Claim 1 of IN'307, or CTPR itself, falls within the overall coverage of the Markush structure claimed in Claim 22 of IN'978 that, by itself, cannot result in any claiming, in Claim 22 of IN'978, of CTPR, or of the Markush structure claimed in Claim 1 of IN'307.

12.19 ***In Re: Merck & Company***[45] is, in my view, clearly distinguishable. Merck, in that case, applied for a patent, which was opposed on the ground of anticipation by prior claiming. The invention, for which Merck sought to patent, was "a composition having enhanced bactericidal activity comprising novobiocin in combination with at least one other antibiotic selected from the following, namely, penicillin, tetracycline, oxytetracycline, chlortetracycline, streptomycin, chloramphenicol, bacitracin, neomycin, spiramycin, streptothricin and grisein". Thus, the claim was comprehensive in nature, permitting alternative additions to novobiocin, in the form of one or more of the named antibiotics. The Patents Appeal Tribunal ("the Tribunal"), before which the case came up, observed that the prior claim, in that case, read "A therapeutic composition, comprising novobiocin and a tetracycline". Merck's claim also included, expressly, novobiocin with tetracycline,

oxytetracycline and chlortetracycline as suggested additives. Elucidating the principle of anticipation by prior claiming, correctly, as whether "the cited prior claim on its fair construction can be seen to grant as a manner of manufacture that which the latter claim on its fair construction would re-monopolise", the Tribunal held that Merck's patent stood claimed, prior in point of time, by the prior patent. The prior patent, it was noted, clearly claimed novobiocin and tetracycline combinations, to which Merck's claim extended.

12.20 This case, in fact, presents a classical example of an instance in which the prior genus patent, though worded in general terms, may still invalidate a subsequent specie patent, where the latter is, to a person skilled in the art, obvious from the former. In the case before the Tribunal, in fact, the degree of skill required to be possessed by the "person skilled in the art" was also minimal, as, in effect, both genus and species patents claimed novobiocin in combination with a tetracycline. There is obviously no similarity, whatsoever, between the facts in ***In Re: Merck & Co.***[45] and the present. ***In Re: Merck & Co***[45] did not even deal with a Markush claim.

12.21 In view thereof, no *prima facie* case of invalidity, or even vulnerability, of Claim 1 of IN'307, or of CTPR, on the ground of anticipation by prior claiming, under Section 64(1)(a), can be said to have been made out.

13. Alleged invalidity of suit patent on the ground of anticipation by prior publication and lack of novelty – Section 64(1)(e)

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

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

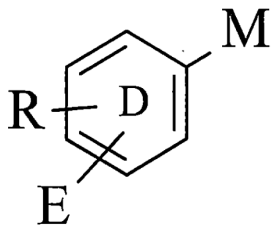
> date of filing of the applicant's complete specification."

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

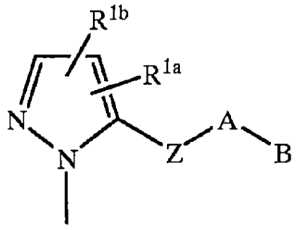
13.2 Mr. Sai Deepak alleges that CTPR was disclosed and published in the US'424, US'357 and EP'508 patents, all of which were granted and published before the earliest priority date of IN'978. He submits that CTPR was within the coverage of the Markush structure as claimed in US'424, US'357 and EP'580, albeit in the context of pharmaceuticals. For this reason, he submits that the suit patent is also vulnerable as lacking any inventive step. Paras 112 to 131 of the written statement filed by the defendant, which contain the relevant assertions in this regard, may be reproduced thus:

> "**UNITED STATES PATENT 5998424 (HEREINAFTER US'424)**
>
> 112. US Patent 5998424 (US'424) was filed on 18.06.1998 and has an earliest priority date of 19.06.1997. It was granted on 07.12.1999 and has expired on 18.06.2018. therefore, US'424 is relevant and material prior art. US'424 is titled "Inhibitors of Factor XA with neutral P1 Specificity Group" and was filed by Du Pont Pharmaceuticals Company which is a sister concern of Du Pont the original owner of IN'307. While US'424 claims to relate to compounds for use in medical treatment, the disclosure of this patent expressly covers and encompasses Chlorantraniliprole as set out below.

113. US'424 in its Abstract, Columns 3 and 4, written description and in its claims describes a set of compounds covered by the following general structure:



114. It is submitted that this structure leads to and is Chlorantraniliprole thereby also encompassing its intermediates when the following substitutions which are all set out in the description in Columns 3 and 4 and also in Claim 1 of US'424 are made:
- ring D is phenyl or pyridyl:
- E is Cl;
- R is H;
- M is selected from the group:



where Z is $(CH_2)_r$ $C(O)NR^3(CH_2)_r$; where R^{1a} and R^{1b} are independently absent or --(CH_2)r __ $R^{1'}$; $R^{1'}$ is Br;
- R^2, at each occurrence, is H;
- R^{2a}, at each occurrence, is C_{1-6} alkyl
- R^3, at each occurrence, is H;
- A is selected from: C_{3-10} carbocyclic group substituted with 0- 2 R^4, and
- B is X-Y, where X is --C(O)-and Y is $(CH_2)_r$ NR^2 R^{2a},
- r is 0.

115. It is submitted that all of the above substitutions outlined above are expressly provided for and encompassed and disclosed and claimed in US'424. It is submitted that for the reasons aforesaid, US'424 clearly and unambiguously discloses Chlorantraniliprole thereby rendering IN'307 liable

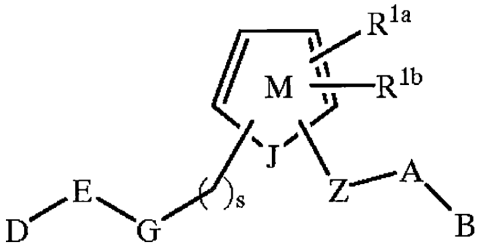
to be revoked on the ground of anticipation by prior publication.

US PATENT 6020357 (HEREINAFTER US'357)

116. US Patent 6020357 (US'357) was filed on 22.12.1997 and has an earliest priority date of 23.12.1996. It was granted on 01.02.2000 and has expired on 22.12.2017.

117. US'357 is titled "Nitrogen containing Inhibitors of Factor XA' and was also filed by Du Pont Pharmaceuticals Company which is a sister concern of the original owner of IN'307. While US'357 claims to relate to compounds for use in medical treatment, the disclosure therein expressly covers Chlorantraniliprole and encompasses its intermediates as set out below.

118. US'357 in its Abstract, Columns 3 to 11, written description and in its claims describes a set of compounds covered by the general structure:

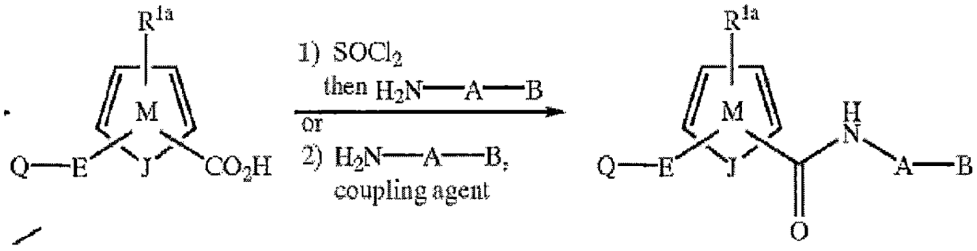


119. It is submitted that this structure leads to and is Chlorantraniliprole thereby also encompassing its intermediates when the following substitutions which are all set out in the description in Columns 3 to 10 and in the claims US'357 are made:
- ring M contains, in addition to J, 0-3 N atoms, provided that if M contains 2 N atoms then R^{1b} is not present;
- J is N;
- alternatively, D--E--G together represent pyridyl substituted with 1 R;
- R is selected from H, halogen, $(CH_2)_t$ OR^3, C_{1-4} alkyl, OCF_3, and CF_3;
- Z is $(CH_2)_r$ $C(O)NR^3(CH_2)_r$;
- R^{1a} and R^{1b} are independently absent or are --(CH_2)r—$R^{1'}$;

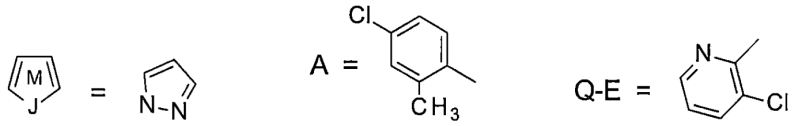
- $R^{1'}$ is halo,
- R^2, at each occurrence is H;
- R^{2a}, at each occurrence is C_{1-6} alkyl,
- R^3, at each occurrence is H;
- A is C_{3-10} carbocyclic residue substituted with 0-2 R^4;
- B is X-Y where X is --C(O)-- and Y is $(CH_2)_r NR^2 R^{2a}$,
- R^4, at each occurrence, is selected from halo, C_{1-4} alkyl;
- r, at each occurrence is 0;
- s, at each occurrence is 0.

120. It is submitted that in addition to the above disclosure, US'357 also teaches a method of preparation of Chlorantraniliprole as set out below:

General reaction (Ref: Scheme-07; Page No: 18)

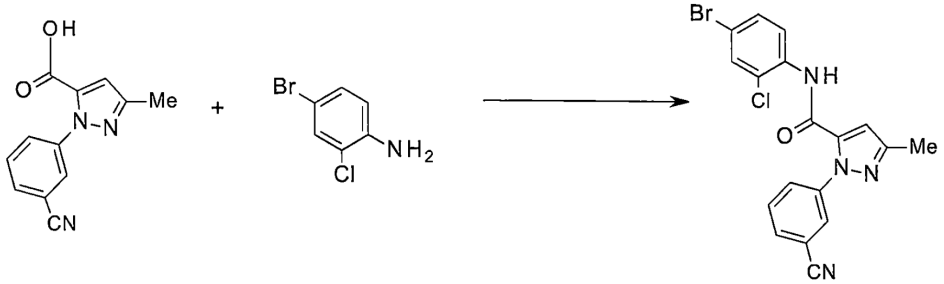


wherein



R^{1a} = Br ; B = -$CONHCH_3$

Further in Example 66, US'357 discloses the following reaction scheme, which leads to the preparation of Chlorantraniliprole.



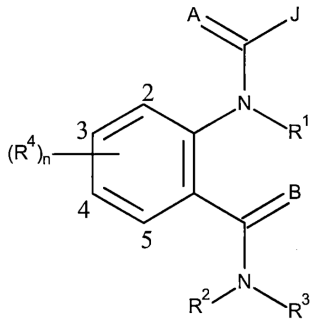
121. It is submitted that all of the above substitutions outlined above are expressly provided for and encompassed

and disclosed and claimed in US'357. It is submitted that for the reasons aforesaid, US'357 clearly and unambiguously discloses Chlorantraniliprole thereby rendering IN'307 liable to be revoked on the ground of anticipation by prior publication.

PCT INTERNATIONAL PUBLICATION WO0l/70671 (WO'671)

122. WO 01/70671 (WO'671) was filed on 20.03.2001 much before IN'307 or IN'332 and claims an effective priority date of 22.03.2000. This application was also filed by Du Pont and is titled Insecticidal Anthranilamides. It was published on 23.09.2001 and therefore is relevant and material prior disclosure which has fallen in the public domain.

123. WO'671 through its abstract and written description provides a compound of the general formula as given below:



Formula-I

124. WO'671 also states that in the above general formula certain specific substitutions can be made. A bare reading of the substitutions and selection from those listed in WO'671 as given below leads inextricably to Chlorantraniliprole and its intermediates.

- A and B are O;
- each J is independently a 5-or 6-membered heteroaromatic ring wherein each ring is optionally substituted with 1 to 4 R^7;
- n is 1 to 4;
- R^1 is H;
- R^2 is H;
- R^3 is C_1-C_6 alkyl

- each R^4 is independently C_1-C_6 alkyl or halogen;
- each R^7 is independently halogen.

125. It is submitted that the above clearly discloses, and encompasses Chlorantraniliprole and its intermediates. It is further submitted that WO'671 in the description provided on internal pages 37 to 42 as well as in Table 9 on page 75 again clearly discloses not only the same method as IN'332, but also the same intermediate formation. Page 163 of WO'671 discloses the same use of the compounds encompassed in WO'671 i.e. Chlorantraniliprole for the prevention of Lepidoptera, Coleoptera, Hemiptera and Homoptera as well as Thysanoptera.

126. Thus, it is amply clear that WO'671 provides the necessary teaching and guidance to a person of ordinary skill to manufacture and use Chlorantraniliprole for the same purposes as IN'307 and IN'332.

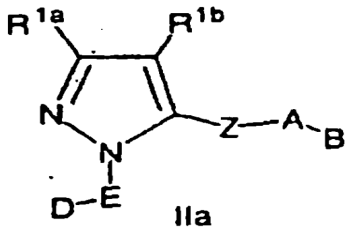
127. It is submitted that all of the above substitutions outlined above are expressly provided for and encompassed and disclosed and claimed in WO'671. It is submitted that WO'671 is a relevant document in as much as it relates to the same field and originates from the same source. It is submitted that for the reasons aforesaid, WO'671 clearly and unambiguously discloses Chlorantraniliprole thereby rendering IN'307 liable to be revoked on the ground of anticipation by prior publication.

EUROPEAN PATENT 0946508 (EP'508)

128. It is respectfully submitted that EP'508 was filed on 23.l5.l997 and has an earliest priority date of 23.12.1996, and therefore constitutes relevant and material prior art for IN'307.

129. It is respectfully submitted that EP'508 claims and discloses a Markush structure in Claim 1 which encompasses Chlorantraniliprole as follows:

Claim 1: A compound of formula IIa



IIa

or a stereoisomer or pharmaceutically acceptable salt thereof, wherein;

D is selected from CN, $C(=NR^8)NR^7R^9$, $NHC(=NR^8)NR^7R^9$, $NR^8CH(=NR^7)$, $C(O)NR^7R^8$, and $(CR^8R^9)_tNR^7R^8$, provided that

D is substituted meta or para on E;

E is selected from phenyl, pyridyl, pyrimidyl, pyrazinyl, pyridazinyl, and piperidinyl substituted with 1 R;

alternatively, **D-E- together represent pyridyl substituted with 1R**;

R is selected from H, halogen, $(CH_2)_tOR^3$, C_{1-4} alkyl, OCF_3, and CF_3;

Z is selected from a C(O), $CH_2C(O)$, $C(O)CH_2$, NHC(O), **C(O)NH**, $C(O)N(CH_3)$, $CH_2S(O)_2$, $S(O)_2(CH_2)$, SO^2NH, and $NHSO_2$,

provided that Z does not fonn a N-N, N-O, or N-S bond with group A;

R^{1a} and R^{1b} are independently absent or selected from **$-(CH_2)_r-R^{1'}$**, $NCH_2R^{1"}$, $OCH_2R^{1"}$, $SCH_2R^{1"}$, $N(CH_2)_2(CH_2)_tR^{1'}$, $O(CH_2)_2(CH_2)_tR^{1'}$, and $S(CH_2)_2(CH_2)_tR^{1'}$, or combined to fonn a 5-8 membered saturated, partially saturated or unsaturated ring substituted with 0-2 R^4 and which contains from 0-2 heteroatoms selected from the group consisting of N, O, and S;

$R^{1'}$ is selected from H, C_{1-3} alkyl, **halo**, $(CF_2)_rCF_3$, OR^2, NR^2R^{2a}, $C(O)R^{2c}$, $OC(O)R^2$, $(CF_2)_rCO_2R^{2c}$, $S(O)_pR^{2b}$, $NR^2(CH_2)_rOR^2$, $NR^2C(O)R^{2b}$, $NR^2C(O)NHR^{2b}$, $NR^2C(O)_2R^{2a}$, $OC(O)NR^{2b}$, $C(O)NR^2R^{2a}$, $SO_2NR^2R^{2a}$, $NR^2SO_2R^{2b}$, C_{3-6} carbocyclic residue substituted with 0-2 R^4, and 5-10 membered heterocyclic system containing from 1-4 heteroatoms selected from the group consisting of N, O, and S substituted with 0-2 R^4;

$R^{1"}$ is selected from H, $C(O)R^{2b}$, $C(O)NR^2R^{2a}$, $S(O)R^{2b}$, $S(O)_2R^{2b}$, and $SO_2NR^2R^{2a}$;

R^2, at each occurrence, is selected from H, CF_3, C_{1-6} alkyl, benzyl, C_{3-6} carbocyclic residue substituted with 0-2 R^{4b}, and 5-6 membered heterocyclic system containing from 1-4 heteroatoms selected from the group consisting of N, O, and S substituted with 0-2R^{4b};

R^{2a}, at each occurrence, is selected from H, CF_3, **C_{1-6} alkyl**, benzyl, C_{3-6} carbocyclic residue substituted with 0-2 R^{4b}, and 5-6 membered heterocyclic system containing from 1-4 heteroatoms selected from the group consisting of N, O, and S substituted with 0-2 R^{4b};

R^{2b}, at each occurrence, is selected from CF_3, C_{1-4} alkoxy, C_{1-6} alkyl, benzyl, C_{3-6} carbocyclic residue substituted with 0-2 R^{4b}, and 5-6 membered heterocyclic system containing from 1-4 heteroatoms selected from the group consisting of N, O, and S substituted with 0-2 R^{4b};

R^{2c}, at each occurrence, is selected from CF_3, OH, C_{1-4} alkoxy, C_{1-6} alkyl, benzyl, C_{3-6} carbocyclic residue substituted with 0-2 R^{4b}, and 5-6 membered heterocyclic system containing from 1-4 heteroatoms selected from the group consisting of N, O, and S substituted with 0-2 R^{4b};

alternatively, R^2 and R^{2a} combine to form a 5 or 6 membered saturated, partially saturated or unsaturated ring substituted with 0-2 R^{4b} which contains from 0-1 additional heteroatoms selected from the group consisting of N, O, and S;

R^3, at each occurrence, is selected from H, C_{1-4} alkyl, and phenyl;

R^{3a}, at each occurrence, is selected from H, C_{1-4} alkyl, and phenyl;

A is selected from one of the following **carbocyclic** and heterocyclic systems which are substituted with **0-2 R^4**; phenyl, piperidinyl, piperazinyl, pyridyl, pyrimidyl, furanyl, morpholinyl, thiophenyl, pyrrolyl, pyrrolidinyl, oxazolyl, isoxazolyl, thiazolyl, isothiazolyl, pyrazolyl, imidazolyl, oxadiazolyl, thiadiazolyl, triazolyl, 1,2,3 -oxadiazolyl, 1,2,4-oxadiazolyl, 1,2,5-oxadiazolyl, 1,3,4-oxadiazolyl, 1,2,3 -thiadiazolyl, 1,2,4-thiadiazolyl, 1,2,5- thiadiazolyl, 1,3 ,4-thiadiazolyl, 1,2,3 -triazolyl, 1,2,4-triazolyl,
1,2,5-triazolyl, and 1,3,4-triazolyl;

B is selected from: Y, **X-Y**, NR^2R^{2a}, $C(=NR^2)NR^2R^{2a}$, and $NR^2C(=NR^2)NR^2R^{2a}$;

X is selected from C_{1-4} alkylene, **-C(O)-**, -C(=NR)-, $-CR^2(NR^2R^{2a})-$, $-C(O)CR^2R^{2a}-$, $-CR^2R^{2a}C(O)$, $-C(O)NR^2-$, -

$NR^2C(O)$-, -$C(O)NR^2CR^2R^{2a}$-, $NR^2C(O)CR^2R^{2a}$-,-$CR^2R^{2a}C(O)NR^2$-, -$CR^2R^{2a}NR^2C(O)$-, -$NR^2C(O)NR^2$-, -NR^2-, -$NR^2CR^2R^{2a}$- , - $CR^2R^{2a}NR^2$- , O , -CR^2R^{2a} O-, and -OCR^2R^{2a}-;

Y is NR^2R^{2a}, provided that X-Y do not form a N-N or O-N bond; alternatively, Y is selected from one of the following carbocyclic and heterocyclic systems which are substituted with 0-2 R^{4a}; cylcopropyl, cyclopentyl, cyclohexyl, phenyl, piperidinyl, piperazinyl, pyridyl, pyrimidyl, furanyl, morpholinyl, thiophenyl, pyrrolyl, pyrrolidinyl, oxazolyl, isoxazolyl, isoxazolinyl, thiazolyl, isothiazolyl, pyrazolyl, imidazolyl, oxadiazolyl, thiadiazolyl, triazolyl, 1,2,3-oxadiazolyl, 1,2,4-oxadiazolyl, 1,2,5- oxadiazolyl, 1,3 ,4-oxadiazolyl, 1,2,3-thiadiazolyl, 1,2,4- thiadiazolyl, 1,2,5-thiadiazolyl, 1,3,4-thiadiazolyl, 1,2,3-triazolyl, 1,2,4-triazolyl, 1,2,5-triazolyl, 1,3,4-triazolyl, benzofuranyl, benzothiofuranyl, indolyl, benzimidazolyl, benzoxazolyl, benzthiazolyl, indazolyl, benzisoxazolyl, benzisothiazolyl, and isoindazolyl;

R4, at each occurrence, is selected from =0, (CH2)rOR2, **halo,**

C_{l-4} alkyl, -CN, NO_2, $(CH_2)_rNR^2R^{2a}$, $(CH_2)_rC(O)R^{2b}$, $NR^2C(O)R^{2b}$, $C(O)NR^2R^{2a}$, $NR^2C(O)NR^2R^{2a}$, $CH(=NR^2)$ NR^2R^{2a}, $NHC(=NR^2)NR^2R^{2a}$, $SO_2NR^2R^{2a}$, $NR^2SO_2NR^2R^{2a}$, NR^2SO_2-C_{l_4}alkyl, $NR^2SO_2R^5$, $S(O)_pR^5$, $(CF_2)_rCF_3$, $NCH_2R^{1''}$, $OCH_2R^{1''}$, $SCH_2R^{1''}$, $N(CH_2)_2(CH_2)_tR^{1'}$, $O(CH_2)_2(CH_2)_tR^{1'}$, and $S(CH_2)_2(CH_2)_tR^{1'}$,

alternatively, one R^4 is a 5-6 membered aromatic heterocycle containing from 1-4 heteroatoms selected from the group consisting of N, O, and S;

R^{4a}, at each occurrence, is selected from =O, $(CH_2)_rOR^2$, halo, C_{l-4} alkyl, -CN, NO_2, $(CH_2)_rNR^2R^{2a}$, $(CH_2)_rC(O)R^{2b}$, $NR^2C(O)R^{2b}$, $C(O)NR^2R^{2a}$, $NR^2C(O)NR^2R^{2a}$, $CH(=NR^2)NR^2R^{2a}$, $NHC(=NR^2)NR^2R^{2a}$, $SO_2NR^2R^{2a}$, $NR^2SO_2NR^2R^{2a}$, NR^2SO_2-C_{1-4}alkyl, $NR^2SO_2R^5$, $S(O)_pR^5$, and $(CF_2)_rCF_3$; alternatively, one R^{4a} is a 5-6 membered aromatic heterocycle containing from 1-4 heteroatoms selected from the group consisting of N, O, and S substituted with 0-1 R^5;

R^{4b}, at each occurrence, is selected from =O, $(CH_2)_rOR^3$, halo, C_{1-4} alkyl, -CN, NO_2, $(CH_2)_rNR^3R^{3a}$, $(CH_2)_rC(O)R^3$, $NR^3C(O)R^{3a}$, $C(O)NR^3R^{3a}$, $NR_3C(O)NR^3R^{3a}$, $CH(=NR^3)NR3R^{3a}$, $NH^3C(=NR^3)NR^3R^{3a}$, $SO_2NR^3R^{3a}$,

$NR^3SO_2NR^3R^{3a}$, NR^3SO_2-C_{1-4}alkyl, $NR^3SO_2CF_3$, NR^3SO_2-phenyl, $S(O)_pCF_3$, $S(O)_p$-C_{1-4} alkyl, $S(O)_p$-phenyl, and $(CF_2)_rCF_3$;

R^5, at each occurrence, is selected from CF_3, C_{1-6} alkyl, phenyl substituted with 0-2 R^6, and benzyl substituted with 0-2 R^6;

R^6, at each occurrence, is selected from H, OH, $(CH_2)_rOR^2$, halo, C_{1-4} alkyl, CN, NO_2, $(CH_2)_rNR^2R^{2a}$, $(CH_2)_rC(O)R^{2b}$, $NR_2C(O)R^{2b}$, $NR_2C(O)NR^2R^{2a}$, $CH(=NH)NH_2$, $NHC(=NH)NH_2$, $SO_2NR^2R^{2a}$, $NR^2SO_2NR^2R^{2a}$, and $NR^2SO_2C_{1-4}$ alkyl;

R^7, at each occurrence, is selected from H, OH, C_{1-6}alkyl, C_{1-6} alkylcarbonyl, C_{1-6} alkoxy, C_{1-4} alkoxycarbonyl, (CH_2)n-phenyl, C_{6-10} aryloxy, C_{6-10} aryloxycarbonyl, C_{6-10} arylmethylcarbonyl, C_{1-4} alkylcarbonyloxy, C_{1-4} alkoxycarbonyl, C_{6-10} arylcarbonyloxy, C_{1-4}alkoxycarbonyl, C_{1-6} alkylaminocarbonyl, phenylaminocarbonyl, and phenyl C_{1-4} alkoxycarbonyl;

R^8, at each occurrence, is selected from H, C_{1-6} alkyl and (CH_2)n-phenyl;

alternatively, R^7 and R^8 combine to form a 5 or 6 membered saturated, ring which contains from 0-1 additional heteroatoms selected from the group consisting of N, O, and S;

R^9, at each occurrence, is selected from H, C_{1-6} alkyl and (CH_2)n-phenyl;

n, at each occurrence, is selected from 0, 1,2, and 3;

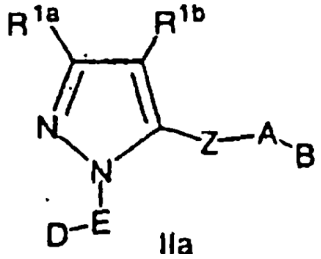
p, at each occurrence, is selected from 0, 1, and 2;

r, at each occurrence, is selected from 0, 1,2, and 3;

t, at each occurrence, is selected from 0 and 1;

provided that D-E- and -Z-A-B are not both benzamidines.

130. It is respectfully submitted that in Formula IIa of EP'508, the following substitutions as outlined in Claim 1 is Chlorantraniliprole:



IIa

D-E- together represent pyridyl substituted with 1 R;
R is halogen;
Zis C(O)NH;
R^{1a} and R^{1b} are independently absent or selected from -$(CH_2)_r$-$R^{l'}$,;
$R^{l'}$ is halo;
R^2, at each occurrence, is H;
R^{2a}, at each occurrence, is C_{1-6} alkyl;
A is carbocyclic systems which are substituted with 0-2 R^4;
B is X-Y;
X is -C(O)-;
Y is NR^2R^{2a};
R^4 , at each occurrence, is selected from halo, C_{1-4} alkyl, r, at each occurrence, is selected from 0.

131. It is submitted that all of the above substitutions outlined above are expressly provided for and encompassed and disclosed and claimed in EP'508. It is submitted that for the reasons aforesaid, EP'508 clearly and unambiguously discloses Chlorantraniliprole thereby rendering IN'307 liable to be revoked on the ground of anticipation by prior publication."

13.3 Responding to the submission, Mr. Sethi contends, in the first instance, that there cannot be any anticipation by a Markush claim. For this proposition, he relies on the decision of the Federal Court of Australia in ***Eli Lilly & Co. Ltd v. Apotex Pty Ltd***[50] . Besides, he submits, disclosure of the subject matter of the suit patent, in the alleged prior patent, is mandatory for an allegation of anticipation by prior publication. He submits that CTPR cannot be derived by a person skilled in the art, from the disclosure in any of the alleged prior patents on which Mr. Sai Deepak relies, except by cherry picking on

[50] **(2013) FCA 214**

hindsight analysis. As such, he submits that CTPR is not disclosed in any of these patents, namely US'424, US'357 and EP'508. EP'508, in fact, he submits is the European equivalent of US'357 and has been separately cited by the defendant only to make it appear that there has been anticipation by a multitude of prior patents. US'424 and US'357, submits Mr. Sethi, are in the nature of Markush claims enveloping millions of compounds. It cannot be said that, in these patents, CTPR was published. Apart from ***Eli Lilly***[19], Mr. Sethi relies on ***Dr Reddy's Laboratories***[26].

13.4 On the allegation, of Mr. Sai Deepak, that, in the production of CTPR, there is no "inventive step" involved, Mr. Sethi submits that no person, skilled in the art, was in the position to produce CTPR from any of the alleged prior art documents on which Mr. Sai Deepak places reliance. Nor, he points out, has any material been produced by the defendant to support such a submission. He highlights the fact that, till the suit patent, CTPR was never invented by anyone after publication of IN'978. CTPR, in fact, he submits, was a selection patent, out of the Markush structure claimed in Claim 22 of IN'978. Relying on ***Farbenindustrie***[21], Mr. Sethi submits that such selection patents, so as to obtain additional or advantageous results, are valid. He relies, additionally, on ***Merck Sharp & Dohme Corpn***[41], ***Takeda Chemical Industries v. Alphapharm***[51] and the judgment of a coordinate Single Bench of this Court in ***Bristol Myers Squibb***

[51] **492 F. 3d. 1350**

Holdings Ireland Ltd v. B.D.R. Pharmaceuticals International Pvt Ltd[52] .

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

[52] **2020 SCC OnLine Del 1700**

invention", which envisages absence of novelty either on account of anticipation by publication, or on account of use. We are not, in the present case, concerned with loss of novelty on account of prior use of the invention in the suit patent, i.e. CTPR, no such case having been pleaded by the defendant. The defendant pleads loss of novelty on the ground of anticipation by prior publication.

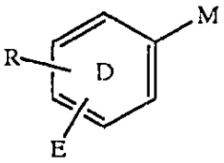
13.6 Section 64(1)(e) is, on a plain reading, somewhat peculiarly – and significantly – worded. The words "before the priority date of the claim" succeeds the first part of the clause, i.e. the words "what was publicly known or publicly used in India". No such caveat as to time follows the latter part of Section 64(1)(e), which deals with publication in India or elsewhere in any of the documents referred to in Section 13. Three circumstances are, therefore, contemplated, in Section 64(1)(e) as divesting the invention in the suit patent of novelty, viz. (i) public knowledge in India before the priority date of the claim in the suit patent, (ii) public usage in India before the priority date of the claim in the suit patent and (iii) publication in India or elsewhere in any of the documents referred to in Section 13. Section 64(1)(e) does not, therefore, envisage publication of the invention in India or elsewhere in any of the documents referred to in Section 13 *prior to the priority date of the claim in the suit patent*. The reference, by Mr. Sethi, to the priority date of the suit patent, does not, therefore, appear to be appropriate, in view of the manner in which Section 64(1)(e) has been crafted by the legislature.

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

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

13.9 Publication involves making known to the public the patent application. Every application is required to disclose the invention for which it relates. Sub-section (4) of Section 10 of the Patents Act[4] (already reproduced above) specifically requires disclosure, in the complete specification of the patent, not only of the invention, its operation or use and the method by which it is to be performed, but also its claims defining the scope of the invention for which protection is claimed. In order, therefore, for the defendant to be able to successfully allege that CTPR was published in US'424 and US'357 (being the US equivalent of EP'508), the defendant would have to establish that CTPR was disclosed in these patents.

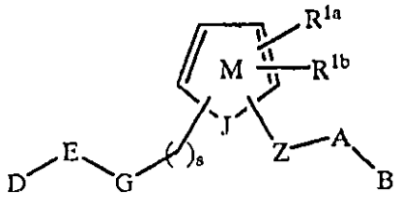
13.10 IN'307 claims "Arthropodicidal Anthranilamides". The opening paragraphs of the Complete Specifications of IN'307, which sets out the background of the invention, specifically state that the invention "relates to certain Anthranilamides, their *N*-oxides, agriculturally suitable salts and compositions, and methods of their use for control of the invertebrate pests such as arthropods in both agronomic and non-agronomic environments". US'424 is titled "Inhibitors of Factor XA with a Neutral P1 Specificity Group". The opening Abstract in the Complete Specification states that the application "describes inhibitors of factor Xa with a neutral P1 specificity group of formula I:



or pharmaceutically acceptable salt forms thereof, wherein R and E may be groups such as methoxy and halo". The Field of the Invention is described thus:

> "This invention relates generally to novel inhibitors of factor Xa with a neutral P1 specificity group, *pharmaceutical compositions containing the same, and methods of using the same as anticoagulant agents for treatment and prevention of thromboembolic disorders*."
>
> (Emphasis supplied)

Similarly, US'357 is titled "Nitrogen Containing Heteroaromatics as Factor XA Inhibitors". The Abstract, towards the commencement of the complete specifications, reads thus:

> "The present application describes nitrogen-containing heteroaromatics and derivatives thereof of formula I:
>
> 
>
>
> or pharmaceutically acceptable salt or prodrug forms thereof, wherein J is N or NH and D may be C(=NH)NH_2, which are useful as inhibitors of factor Xa."

The Field of the Invention is described thus:

> "This invention relates generally to nitrogen-containing heteroaromatics which are inhibitors of trypsin -like serine protease enzymes, especially factor Xa, *pharmaceutical*

compositions containing the same, and methods of using the same as anticoagulant agents for treatment and prevention of thromboembolic disorders."

(Emphasis supplied)

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

13.11 I also find, in this context, *prima facie* substance in the contention of Mr. Sethi that, in asserting that Claim 1 of US'424 and US'357 leads the person skilled in the art to CTPR, the defendant has, as in the case of Claim 22 of IN'978, cherry picked selected substituents from the substituents suggested in the complete specifications relating to the said claims. This is apparent from paras 114 and 119 of the written statement, which already stand reproduced *(supra)*.

13.12 Para 120 of the written statement further contends that, in Example 66 of US'357, the reaction scheme, leading to the preparation of CTPR, is disclosed. Unfortunately, while raising all these contentions, predicated on US'424 and US'357, the defendant

has not chosen to place the complete specifications relating to the said patent on record. At a *prima facie* stage, this fact by itself would be sufficient to reject these contentions as making out a case of vulnerability of the suit patent. The plaintiff has, however, filed the said complete specifications of US'424 and US'357, as granted. I am unable to find, in Example 66 in US'357, anything to substantiate the averment, in that regard, contained in para 120 of the written statement. I may note, here, that no oral arguments, explaining this assertion in the written statement, were advanced at the Bar; nor do the written submissions of the defendant enlighten on this aspect. Nevertheless, for the sake of clarity, Example 66 in US 357 is reproduced thus:

"EXAMPLE 66

1-(3-amidinophenyl)-5-[(2'-aminosulfonyl)-3-chloro-[1,1']-biphen -4-yl)aminocarbonyl]-3-methylpyrazole

Part A: 1-(3-cyanophenyl)-3-methyl-pyrazol-5-yl carboxylic acid and 4-bromo-2-chloroaniline were coupled via standard conditions (67%). ^{1}HNMR($CDCl_3$)δ: 8.27 (d, j=8.79Hz, 1H), 8.17 (s, lH), 7.82 (t, j=1.80 Hz, 1H), 7.75 (m,2H)7.59 (m, 2H), 7.42 (dd,j=8.78, 2.2 Hz, lH), 6.72 (s, lH),2.41 (s, 3H) ppm.

Part B: The bromo compound from part A (0.4 g, 0.96 mmol), 2-t-butylsulfonamide phenylboronic acid (0.32 g, 1.2 mmol), 2M sodium carbonate (1 mL), and 1:1 toluene/ethanol were combined and degassed with nitrogen. Tetrakibiphen-striphenyphosphine palladium(0) (1 mg) was added and the reaction refluxed for 18h. The reaction was filtered, concentrated and extracted with ethyl acetate and dried($MgSO_4$). Purification by flash chromatography on silica gel using 1:1 hexanes/ethyl acetate as eluent afforded 0.43 g (81%).^{1}HNMR($CDCl_3$)δ: 8.45 (d, j=8.42 Hz, 1H), 8.32 (s, 1H), 8.18;(dd,j=1.47, 7.69 Hz, 1H), 7.85 (d,j=1.83 Hz, 1H),

7.79 (d. j-8.05. Hz, 1H), 7.72 (d, j-7.69 Hz, 1H), 7.61 (m, 4H), 7. 39 (dd, j=2.20, 8.79 Hz, 1H), 7.28 (m, 1H), 6.76 (s, 1H), 3.67 (s, 1H), 2.43 (s, 3H), 1.07(s, 9H) ppm., MS (ESI) m/z 548.3 $(M+H)^+$, 570.3 $(M+Na)^+$

Part C: The nitrile from part B was subjected to the standard Pinner conditions to afford the amidine (43%). ^{1}HNMR (DMSO-d_6)δ: 10.36 (s, 1H), 9.43 (s, l.5H), 9.09 (s, 1.5H), 8.05 (dd, j=6.96, 2.20 Hz, 1H), 7.96 (s, lH), 7.82 (d, j=7.32 Hz, 2H), 7.71 (m, 1H), 7.65 (m, 2H), 7.57 (d, j-6.59 Hz,1H), 7.54 (s, 1H), 7.46 (s, 2H), 7.39 (m, 2H), 7.06 (s, 1H), 2.35 (s, 3H) ppm, HRMS 509.116263 (calcd), 509.117360 (observed); Analysis calcd for $C_{24}H_{21}ClN_6O_3S_1$ (TFA) (H_2O) C:48.72, H:3.77, N:13.l1, found C:48.56, H:3.53, N:12.75."

How Example 66, as extracted, can be said to teach the manner or mode of preparation of CTPR, *prima facie* defeats comprehension.

13.13 Equally, the submission of Mr. Sai Deepak that the suit patent is vulnerable for lack of any inventive step, also, *prima facie*, fails to impress. Bar a bald averment, no material substantiating this contention is forthcoming from the written statement or from the written submissions filed by the defendant. Mr. Sethi is correct in his submission that, had the invention of CTPR by the plaintiff lacked any inventive step, there is no explanation as to why, till CTPR was synthesised by the plaintiff, no other manufacturer, including the defendant, managed to do so despite, as the defendant would seek to contend, so many prior art documents being in existence.

13.14 At the cost of repetition, it merits emphasis that, in order to make out a case of teaching, by a Markush claim in a prior art

document, of the suit patent, the defendant would have to establish not only that the substitutions, on the Markush moiety, the effecting of which would be necessary to arrive at the suit patent are clearly disclosed in the prior art, but also, additionally, that the prior art contains the requisite teaching which would motivate the person skilled in the art to carry out the said substitutions. Ordinarily, this would require guidance, in the prior art document, regarding the additional advantages which would result, if the substitutions in question were made on the Markush moiety claimed therein. In the present case, *prima facie*, neither of these twin requirements stands satisfied despite the manifold grounds of challenge raised by the defendant, assiduously canvassed, on its behalf, by Mr. Sai Deepak.

14. Re. Section 53(4)

14.1 Mr. Sai Deepak also presses, into service, Section 53(4) of the Patents Act, which reads as under:

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

As, in his submission, CTPR stands covered by Claim 22 in IN'978, Mr. Sai Deepak submits that, on expiry of the term of IN'978 on 20th March, 2021, the protection available to CTPR from exploitation would cease and CTPR would become available in the public domain. This, he submits, cannot be avoided by recourse to IN'307, in view of

Section 13(1)(b) read with Section 64(1)(a).

14.2 The submission does not survive for consideration, in view of the finding, hereinabove, that CTPR is, in fact, neither claimed nor disclosed in Claim 22 of IN'978.

14.3 That apart, a bare reading of Section 53(4) reveals that it is claim-specific and invention-specific. Section 53(4) applies, therefore, individually and independently, to IN'978 and the suit patent (IN'307). Irrespective, therefore, on the expiry of IN'978, the protective umbrella of Section 53(4) would continue to remain available to IN'307, being a granted patent, till such time IN'307 is invalidated by a competent forum. Expressed otherwise, Section 53(4) cannot authorise exploitation of the invention covered by the specie patent by third parties even before the expiry of the specie patent, on the presumptive assertion that the specie patent is invalid, whether on the ground of anticipation by prior claiming, anticipation, by prior publication, or any other ground.

14.4 I cannot, therefore, agree with Mr. Sai Deepak, even as regards the applicability of Section 53(4) of the Patents Act.

15. Re. Section 3(d) read with Section 64(1)(d)

15.1 Though this submission of Mr. Sai Deepak, too, does not survive for consideration in view of the findings already returned by me, it may, nevertheless, be briefly noticed. Section 64(1)(d)

provides, as one of the grounds for revocation of a granted patent, the ground "that the subject of any claim of the complete specification is not an invention within the meaning of this Act". Mr. Sai Deepak's submission is that CTPR is not an "invention" within the meaning of the Patents Act. Juxtaposed with this, Mr. Sai Deepak invokes Section 3(d) to contend that, in the absence of any data demonstrating added efficacy of CTPR over which the invention is claimed in IN'978, the suit patent is also invalid under Section 3(d).

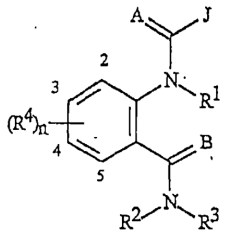
15.2 The submissions are interconnected, and effectively stand decided by the findings hereinbefore. The basis for this contention is elucidated, in para 48 of the written submissions of the defendant, in which it is contended that "the complete specifications of the genus patent IN'978 and the suit Species Patent IN'307 are identical in all material respects with no additional data on efficacy which renders the patent vulnerable to revocation under Section 64(1)(d) in view of Section 3(d) of the Act". Reference has been invited, by the defendant, in this context, to page 399, *vis-à-vis* page 76 of the defendant's documents. These are the opening pages of the suit patent (IN'307) and the genus patent (IN'978) respectively. The suit patent is titled "Arthropodicidal Anthranilamides", whereas the genus patent is titled "Insecticidal Anthranilamides". The textual "identity" of the complete specifications of these two patents, as emphasised in para 48 of the written submissions of the defendant, however, is limited to the initial recital containing the "Background of the Invention". The "Summary of the Invention", which follows the "Background", as

well as all that follows thereafter, are totally different in the two patents. For ready reference, the "Summary of the Invention" in IN'978 and IN'307 are reproduced thus:

Summary of the invention in IN'978:

"SUMMARY OF THE INVENTION

This invention pertains to a method for controlling arthropods comprising contacting the arthropods or their environment with an artbropodicidally effective amount of a compound of Formula 1, its *N*-oxide or agriculturally suitable salts



wherein
A and B are independently O or S;

each J is independently a phenyl or naphthyl group substituted with 1 to 2 R^5 and optionally substituted with 1 to 3 R^6;

or each J is independently a 5- or 6-membered heteroaromatic ring or an aromatic 8-,9- or 10-membered fused heterobicyclic ring system wherein each ring or ring system is optionaly; substituted with 1 to 4 R^7;

n is 1 to 4;

R^1 is H; or C_1-C_6 alkyl, C_2-C_6 alkenyl, C_2-C_6 alkynyl or C_3-C_6 cycloalkyl each optionally substituted with one or more substituents selected from the group consisting of halogen, CN, NO_2, hydroxy, C_1-C_4 alkoxy, C_1-C_4 alkyltbio, C_1-C_4 aIkylsulfinyl, C_1-C_4 alkylsulfonyl, C_2-C_4 alkoxycarbonyl. C_1-

C_4 alkylamino, C_2-C_8 dialkylamino and C_3-C_6 cyclmilkylamino; or

R^1 is C_2-C_6 alkylcarbonyl, C_2-C_6 alkoxycarbonyl, C_2-C_6 alkylaroinocarbonyl, C_3-C_8 dialkylaminocarbonyl or C(=A)J;

R^2 is H, C_1-C_6 alkyl, C_2-C_6 alkenyl, C_2-C_6 alkynyl, C_3-C_6 cycloalkyl, C_1-C_4 alkoxy, C_1-C_4 alkylamino, C_2-C_8 dialkylamino, C_3-C_6 cycloalkylamino, C_2-C_6 alkoxycarbonyl or C_2-C_6 alkylcarbonyl;

R^3 is H; G; C_1-C_6 alkyl, C_2-C_6 alkenyl, C_2-C_6 alkynyl, C_3-C_6 cycloalkyl, each optionally substituted with one or more substituents selected from the group consisting of halogen, G, CN, NO_2, hydroxy, C_1-C_4 alkoxy, C_1-C_4 haloalkoxy, C_1-C_4 alkylthio, C_1-C_4 alkylsulfinyl, C_1-C_4 alkylsulfonyl, C_2-C_6 alkoxycarbonyl, C_2-C_6 alkylcarbonyl, C_3-C_6 trialkylsilyl, or a phenyl, phenoxy or 5- or 6-membered heteroaromatic ring, each ring optionally substituted with one to three substituents independently selected from the group consisting of C_1-C_4 alkyl, C_2-C_4 aIkenyl, C_2-C_4 alkynyl, C_3-C_6 cycloalkyl, C_1-C_4 haloalkyl, C_2-C_4 haloalkenyl, C_2-C_4 haloalkynyl, C_3-C_6 halocycloalkyl, halogen, CN, NO_2, C_1-C_4 alkoxy, C_1-C_4 haloalkoxy, C_1-C_4 alkyltbio, C_1-C_4 alkylsulfinyl, C_1-C_4 alkylsulfonyl, C_1-C_4 alkylamino, C_2-C_8 cllalkylamino, C_3-C_6 cycloalkylamino, C_3-C_6 (alkyl)cycloalkylamino, C_2-C_4 alkylcarbonyl, C_2-C_6 alkoxycarbonyl, C_2-C_6 alkylaminocarbonyl, C_3-C_8 dialkylaminocarbonyl or C_3-C_6 trialkylsilyl; C_1-C_4 alkoxy; C_1-C_4 alkylamino; C_2-C_8 dialkylamino; C_3-C_6 cycloalkylamino; C_2-C_6 alkoxycarbonyl or C_2-C_6 alkylcarbonyl; or

R^2 and R^3 can be taken together with the nitrogen to which they are attached to form a ring containing 2 to 6 atoms of carbon and optionally one additional atom of nitrogen, sulfur or oxygen, said ring may be optionally substituted with 1 to 4 substituents selected from the group consisting of C_1-C_2 alky, halogen, CN, NO_2 and C_1-C_2 alkoxy;

G is a 5- or 6-membered nonaromatic carbocyclic or heterocyclic ring, optionally including one or two ring members selected from the group consisting of C(=O), SO or

S(O)2 and optionally substituted with 1 to 4 substituents selected from the group consisting of C_1-C_2 alkyl, halogen, CN, NO_2 and C_1-C_2 alkoxy;

each R^4 is independently H, C_1-C_6 alkyl, C_2-C_6 alkenyl, C_2-C_6 alkynyl, C_3-C_6 cycloalkyl, C_1-C_6 haloalkyl, C_2-C_6 haloalkenyl, C_2-C_6 haloalkynyl, C_3-C_6 halocycloalkyl, halogen, CN, NO_2, hydroxy, C_1-C_4 alkoxy, C_1-C_4 haloalkoxy, C_1-C_4 alkylthio, C_1-C_4 alkylsulfinyl, C_1-C_4 alkylsulfonyl, C_1-C_4 haloalkylthio, C_1-C_4 haloalkylsulfinyl, C_1-C_4 haloalkylsulfonyl, C_1-C_4 alkylamino, C_2-C_8 dialkylamino, C_3-C_6 cycloalkylamino, or C_3-C_6 trialkylsilyl; or

each R4 is independently phenyl, benzyl or phenoxy; each optionally substituted with C_1-C_4 alkyl, C_2-C_4 alkenyl, C_2-C_4 alkynyl, C_3-C_6 cycloalkyl, C_1-C_4 haloalkyl, C_2-C_4 haloalkenyl, C_2-C_4 haloalkynyl, C_3-C_6 halocycloalkyl, halogen, CN, NO_2, C_1-C_4 alkoxy, C_1-C_4 halo alkoxy, C_1-C_4 alkylthio, C_1-C_4 alkylsulfinyl, C_1-C_4 alkylsulfonyl, C_1-C_4 alkylamino, C_2-C_8 dialkylamino, C_3-C_6 cycloalkylamino, C_3-C_6 (alkyl)cycloalkylamino, C_2-C_4 alkylcarbonyl, C_2-C_6 alkoxycarbonyl, C_2-C_6 alkylaminocarbonyl, C_3-C_8 dialkylaminocarbonyl or C_3-C_6 trialkylsilyl;

each R^5 is independently C_1-C_6 alkyl, C_2-C_6 alkenyl, C_2-C_6 alkynyl, C_3-C_6 cycloalkyl, C_1-C_6 haloalkyl, C_2-C_6 haloalkenyl, C_2-C_6 haloalkynyl, C_3-C_6 halocycloalkyl, halogen, CN, CO_2H; $CONH_2$, NO_2, hydroxy, C_1-C_6 alkoxy, C_1-C_6 haloalkoxy, C_1-C_6 alkylthio, C_1-C_6 alkylsulfinyl, C_1-C_6 alkylsulfonyl, C_1-C_6 haloalkylthio, C_1-C_6 haloalkylsulfinyl, C_1-C_6 haloalkylsulfonyl, C_1-C_6 alkylamino, C_2-C_{12} dialkylamino, or C_3-C_6 cycloalkylamino, C_2-C_6 alkylcarbonyl, C_2-C_6 alkoxycarbonyl, C_2-C_6 alkylaminocarbonyl, C_3-C_8 dialkylaminocarbonyl, C_3-C_6 triAlkylsilyl; or

$(R^5)_2$ when attached to adjacent carbon atoms can be taken together as -OCF_2O-, -CF_2CF_2O-, or -OCF_2CF_2O-;

each R^6 is independently H, halogen, C_1-C_6 alkyl, C_2-C_6 alkenyl, C_2-C_6 alkynyl, C_3-C_6 cycloalkyl, C_1-C_4 alkoxy or C_2-C_4 alkoxycarbonyl; or

each R^6 is independently a phenyl, benzyl, phenoxy, 5- or 6-membered heteroaromatic ring or an aromatic 8-, 9- or 10-membered fused heterobicyclic ring system, each ring optionally substituted with one to three substitutes independently selected from the group consisting of C_1-C_4 alkyl, C_2-C_4 alkenyl, C_2-C_4 alkynyl, C_3-C_6 cycloalkyl, C_1-C_4 haloalkyl, C_2-C_4 haloalkenyl, C_2-C_4 haloalkynyl, C_3-C_6 halocycloalkyl, halogen, CN, NO_2, C_1-C_4 alkoxy, C_1-C_4 haloalkoxy, C_1-C_4 alkyltbio, C_1-C_4 alkylsulfinyl, C_1-C_4 alkylsulfonyl, C_1-C_4 alkylamino, C_2-C_8 dialkylamino, C_3-C_6 cycloalkylamino, C_3-C_6 (alkyl)cycloalkylamino, C_2-C_4 alkylcarbonyl, C_2-C_6 alkoxycarbonyl, C_2-C_6 alkylaminocarbonyl, C_3-C_8 dialkylaminocarbonyl or C_3-C_6 trialkylsilyl;

each R^7 is independently H, C_1-C_6 alkyl, C_2-C_6 alkenyl, C_2-C_6 alkynyl, C_3-C_6 cycloalkyl, C_1-C_6 haloalkyl, C_2-C_6 haloalkenyl, C_2-C_6 haloalkynyl, C_3-C_6 halocycloalkyl, halogen, CN, CO_2H, $CONH_2$, NO_2, hydroxy, C_1-C_4 alkoxy, C_1-C_4 haloalkoxy, C_1-C_4 alkylthio, C_1-C_4 alkylsulfinyl, C_1-C_4 alkylsulfonyl, C_1-C_4 haloalkylthio, C_1-C_4 haloalkylsulfinyl, C_1-C_4 haloalkylsulfonyl, C_1-C_4 alkylamino, C_2-C_8 dialkylamino, C_3-C_6 cycloalkylamino, C_2-C_6 alkylcarbonyl, C_2-C_6 alkoxycarbonyl, C_2-C_6 alkylaminocarbonyl, C_3-C_8 dialkylaminocarbonyl, C_3-C_6 trialkylsilyl;

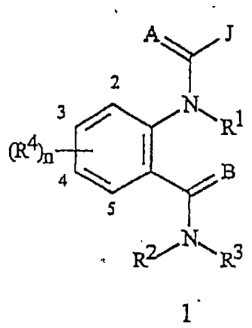
each R^7 is independently a phenyl, benzyl, benzoyl, phenoxy, 5- or 6-membered heteroaromatic ring or an aromatic 8-,9- or 10-membered fused heterobicyclic ring system, each ring optionally substituted with one to three substituents independently selected from the group consisting of C_1-C_4 alkyl, C_2-C_4 alkenyl, C_2-C_4 alkynyl, C_3-C_6 cycloalkyl, C_1-C_4 haloalkyl, C_2-C_4 haloalkenyl, C_2-C_4 haloalkynyl, C_3-C_6 halocycloalkyl, halogen, CN, NO_2, C_1-C_4 alkoxy, C_1-C_4 haloalkoxy, C_1-C_4 alkylthio, C_1-C_4 alkylsulfinyl, C_1-C_4 alkylsulfonyl, C_1-C_4 alkylamino, C_2-C_8 dialkylamino, C_3-C_6 cycloalkylamino, C_3-C_6 (alkyl)cycloalkylamino, C_2-C_4 alkylcarbonyl, C_2-C_6 alkoxycarbonyl, C_2-C_6 alkylaminocaroqnyl, C_3-C_8 dialkylaminocarbonyl or C_3-C_6 trialkylsilyl;

provided that

(1) when A and B are both O, R^2 is H or C_1-C_3 alkyl, R^3 is H or C_1-C_3 alkyl and R^4 is H, halogen, C_1-C_6 alkyl, phenyl, hydroxy or C_1-C_6 alkoxy, then one R^5 is other than halogen, C_1-C_6 alkyl, hydroxy or C_1-C_6 alkoxy; or

(2) J is other than an optionally substituted 1,2,3-thiadiazole.

This invention also pertains to compounds of Formula 1, their *N*-oxides and agriculturally suitable salts



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wherein
A and B are independently O or S;
each J is independently a phenyl or naphthyl group substituted with 1 to 2 R^5 and optionally substituted with 1 to 3 R^6;
or each J is independently a 5- or 6-membered heteroaromatic ring or an aromatic 8-, 9- or l0-membered fused heterobicyclic ring system wherein each ring or ring system is optionally substituted with 1 to 4 R^7;

n is 1 to 4;

R^1 is H; or C_1-C_6 alkyl, C_2-C_6 alkenyl, C_2-C_6 alkynyl or C_3-C_6 cycloalkyl each optionally substituted with one or more substituents selected from the group consisting of halogen, CN, NO_2, hydroxy, C_1-C_4 alkoxy, C_1-C_4 alkylthio, C_1-C_4 alkylsulfinyl, C_1-C_4 alkylsulfonyl, C_2-C_4 alkoxycarbonyl, C_1-C_4 alkylamino, C_2-C_8 dialkylamino and C_3-C_6 cycloalkylamino; or

R^1 is C_2-C_6 alkylcarbonyl, C_2-C_6 alkoxycarbonyl, C_2-C_6 alkylaminocarbonyl, C_3-C_8 dialkylaminocarbonyl or C(=A)J;

R^2 is H, C_1-C_6 alkyl, C_2-C_6 alkenyl, C_2-C_6 alkynyl, C_3-C_6 cycloalkyl, C_1-C_4 alkoxy, C_1-C_4 alkylamino, C_2-C_8 dialkylamino, C_3-C_6 cycloalkylamino, C_2-C_6 alkoxycarbonyl or C_2-C_6 alkylcarbonyl;

R^3 is H; C_1-C_6 alkyl, C_2 -C_6 alkenyl, C_2 -C_6 alkynyl, C_3 -C_6 cycloalkyl, each optionally substituted with one or more substituents selected from the group consisting of halogen, CN, NO_2, hydroxy, C_1-C_4 alkoxy, C_1-C_4 haloalkoxy, C_1-C_4 alkylthio, C_1-C_4 alkylsulfinyl, C_1-C_4 alkylsulfonyl, C_2-C_6 alkoxyocarbonyl, C_2-C_6 alkylcarbonyl, C_3-C_6 trialkylsilyl, or a phenoxy ring optionally substituted with one to three substituents independently selected from the group consisting of C_1-C_4 alkyl, C_2-C_4 alkenyl, C_2-C_4 alkynyl C_3-C_6 cycloalkyl, C_1-C_4 haloalkyl, C_2-C_4 haloalkenyl C_2-C_4 haloalkynyl, C_3-C_6 halocycloalkyl, halogen, CN, NO_2, C_1-C_4 alkoxy, C_1-C_4 haloalkoxy, C_1-C_4 alkylthio, C_1-C_4 alkylsulfinyl, C_1-C_4 alkylsulfonyl, C_1-C_4 alkylamino, C_2-C_8 dialkylamino, C_3-C_6 cycloalkylamino, C_3-C_6 (alkyl)cycloalkylamino, C_2-C_4 alkylcarbonyl, C_2-C_6 alkoxycarbonyl, C_2-C_6 alkylaminocarbonyl, C_3-C_8 dialkylaminocarbonyl or C_3-C_6 trialkylsilyl; C_1-C_4 aIkoxy; C_1-C_4 alkylamino.; C_2-C_8 dialkylamino; C_3-C_6 cycloalkylamino; C_2-C_6 alkoxycarbonyl or C_2-C_6 alkylcarbonyl; or

R^2 and R^3 can be taken together with the nitrogen to which they are attached to form a ring containing 2 to 6 atoms of carbon and optionally one additional atom of nitrogen, sulfur or oxygen, said ring may be optionally substituted with 1 to 4 substituents selected from the group consisting of C_1-C_2 alkyl, halogen, CN, NO_2 and C_1-C_2 alkoxy;

each R^4 is independently H, C_1-C_6 alkyl, C_2-C_6 alkenyl, C_2-C_6 alkynyl, C_3-C_6 cycloalkyl, C_1-C_4 haloalkyl, C_2-C_6 haloalkenyl, C_2-C_6 haloalkynyl, C_3-C_6 halocycloalkyl, halogen, CN, NO_2, hydroxy, C_1-C_4 alkoxy, C_1-C_4 haloalkoxy, C_1-C_4 alkylthio, C_1-C_4 alkylsulfinyl, C_1-C_4 alkylsulfonyl, C_1-C_4 haloalkylthio, C_1-C_4 haloalkylsulfinyl, C_1-C_4 haloalkylsulfonyl, C_1-C_4 alkylamino, C_2-C_8 dialkylamino, C_3-C_6 cycloalkylamino, C_3-C_6 trialalkylsilyl; or

each R^4 is independently phenyl, benzyl or phenoxy, each optionally substituted with C_1-C_4 alkyl, C_2-C_4 alkenyl, C_2-C_4 alkynyl, C_3-C_6 cycloalkyl, C_1-C_4 haloalkyl, C_2-C_4 haloalkenyl, C_2-C_4 haloalkynyl, C_3-C_6 halocycloalkyl, halogen, CN, NO_2, C_1-C_4 alkoxy, C_1-C_4 haloalkoxy, C_1-C_4 alkylthio, C_1-C_4 alkylsulfinyl, C_1-C_4 alkylsulfonyl, C_1-C_4 alkylamino, C_2-C_8 dialkylamino, C_3-C_6 cycloalkylamino, C_3-C_6 (alkyl)cycloalkylamino, C_2-C_4 alkylcarbonyl, C_2-C_6 alkoxycarbonyI, C_2-C_6 alkylaminocarbonyl, C_3-C_8 dialkylaminocarbonyl or C_3-C_6 trialkylsilyl;

each R^5 is independently C_1-C_6 haloalkyl, C_2-C_6 haloalkenyl, C_2-C_6 haloalkynyl, C_3-C_6 halocycloalkyl, C_1-C_4 haloalkoxy, C_1-C_4 alkylthio, C_1-C_4 alkylsulfinyl, C_1-C_4 alkylsulfonyl, C_1-C_4 haloalkylthio, C_1-C_4 haloalkylsulfinyl, C_1-C_4 haloalkylsulfonyl, CN, NO_2, C_1-C_4 alkoxycarbonyl, C_1-C_4 alkylamino, C_2-C_8 dialkylamino, C_3-C_6 cycloalkylamino, C_2-C_6 alkylcarbonyl, C_2-C_6 alkoxycarbonyl, C_2-C_6 alkylaminocarbonyl, or C_3-C_8 dialkylamInocarbonyl; or

$(R^5)_2$ attached to adjacent carbon atoms can be taken together as -OCF_2O-, -CF_2CF_2O-, or -O CF_2CF_2O-;

each R^6 is independently H, halogen, C_1-C_6 alkyl, C_2-C_6 alkenyl, C_2-C_6 alknyl, C_3-C_6 cycloalkyl, C_1-C_4 alkoxy or C_2-C_4 alkoxycarbonyl; or

each R^6 is independently a phenyl, benzyl, phenoxy, 5- or 6-membered heteroaromatic ring or an aromatic 8-,9- or 10-membered fused heterobicyclic ring system, each ring optionally substituted with one to three substituents independently selected from the group consisting of C_1-C_4 alkyl, C_2-C_4 alkenyl, C_2-C_4 alkynyl, C_3-C_6 cycloalkyl, C_1-C_4 haloalkyl, C_2-C_4 haloalkenyl, C_2-C_4 haloalkynyl,..... haloalkoxy, C_1-C_4 alkylthio, C_1-C_4 alkylsulfinyl, C_1-C_4 alkylsulfonyl, C_1-C_4 alkylamino, C_2-C_8 dialkylamino, C_3-C_6 cycloalkylamino, C_3-C_6 (alkyl)cycloalkylamino, C_2-C_4 alkylcarbonyl, C_2-C_6 alkoxycarbonyl, C_2-C_6 alkylaminocarbonyl, C_3-C_8 dialkylaminocarbonyl or C_3-C_6 trialkylsilyl;

each R7 is, independently H, C_1-C_6 alkyl, C_2-C_6 alkenyl, C_2-C_6 alkynyl, C_3-C_6 cycloalkyl, C_1-C_6 haloalkyl, C_2-C_6 haloalkenyl, C_2-C_6 haloalkynyl, C_3-C_6 halocycloalkyl, halogen, CN, CO_2H, $CONH_2$, NO_2, hydroxy, C_1-C_4 alkoxy, C_1-C_4 haloalkoxy, C_1-C_4 alkylthio, C_1-C_4 alkylsulfinyl, C_1-C_4 alkylsulfonyl, C_1-C_4 haloalkyltbio, C_1-C_4 haloalkylsulfinyl, C_1-C_4 haloalkylsulfonyl, C_1-C_4 alkylamino, C_2-C_8 dialkylamino, C_3-C_6 cycloalkylamino, C_2-C_6 alkylcarbonyl, C_2-C_6 alkoxycarbonyl, C_2-C_6 alkylaminocarbonyl, C_3-C_8 dialkylaminocarbonyl, C_3-C_6 trialkylsilyl; or

each R^7 is independently a phenyl,.benzyl, benzoyl, phenoxy or 5- or 6-membered heteroaromatic ring 8-, 9- or 10-membered fused heterobicyclic ring system, each ring optionally substituted with one to three substituents independently selected from the group consisting of C_1-C_4 alkyl, C_2-C_4 alkenyl, C_2-C_4 alkynyl, C_3-C_6 cycloalkyl, C_1-C_4 haloallcyl, C_2-C_4 haloalkenyl, C_2-C_4 haloalkynyl, C_3-C_6 halocycloalkyl, halogen, CN, NO_2, C_1-C_4 alkoxy, C_1-C_4 haloalkoxy, C_1-C_4 alkylthio, C_1-C_4 alkylsulfinyl, C_1-C_4 alkylsulfonyl, C_1-C_4 alkylamino, C_2-C_8 dialkylamino, C_3-C_6 cycloalkylamino, C_3-C_6 (alkyl)cycloalkylamino, C_2-C_4 alkylcarbonyl, C_2-C_6 alkoxycarbonyl, C_2-C_6 alkylaminocarbonyl, C_3-C_8dialkylaminocarbonyl or C_3-C_6 trialkylsilyl;

provided that

(i) at least one R^4 and at least one R^7 are other than H;

(ii) J is other than an optionally substituted 1,2,3-thiadiazole;

(iii) when J is an optionally substituted pyridine and R^2 is H, R^3 is other than H or CH_3;

(iv) when J is an optionally substituted pyridine, then R^7 cannot be $CONH_2$, C_2-C_6 alkylaminocarbonyl or C_3-C_8 dialkylaminocarbonyl;

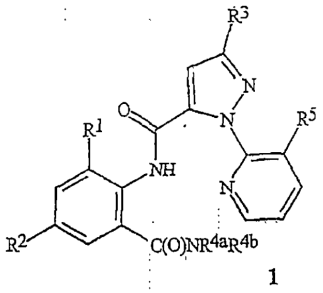
(v) when J is an optionally substituted pyrazole, tetrazole or pyrimidine, then R^2 and R^3 cannot both be hydrogen.

This invention also pertains to arthropodicidal compositions comprising an arthropodicidally effective amount of a compound of Formula 1 and at least one additional component selected from the group consisting of surfactants, solid diluents and liquid diluents."

Summary of the invention in IN'307

"SUMMARY OF THE INVENTION

This invention pertains to a compound of Formula 1, its *N*-oxide or an agriculturally suitable salt of the compound



1

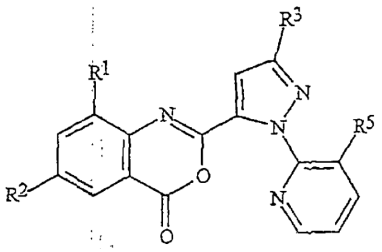
wherein
R^1 is CH_3, F, Cl orBr;
R^2 is F, CI, Br, I or CF_3;
R^3 is CF_3, Cl, Br or OCH_2CF_3;
R^{4a} is C_1-C_4 alkyl;
R^{4b} is H or CH_3; and,
R^5 is CI or Br.

This invention also pertains to a composition for controlling an invertebrate pest comprising a biologically effective amount of a compound of Formula 1 and at least one additional component selected from the group consisting of surfactants, solid diluents and liquid diluents. This invention also pertains to a composition comprising a biologically effective amount of a compound of Formula 1 and an effective amount of at least one additional biologically active compound or agent.

This invention also pertains to a method for controlling an invertebrate pest comprising contacting the invertebrate pest

or its environment with a biologically effective amount of a compound of Formula 1 (e.g., as a composition described herein). This invention also relates to such method wherein the invertebrate pest or its environment is contacted with a biologically effective amount of a compound of Formula 1 or a composition comprising a compound of Formula 1 and a biologically effective amount of at least one additional compound or agent for controlling invertebrate pests.

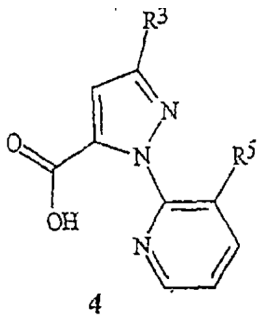
This invention further relates to a benzoxazinone compound of Formula 2



wherein
R^1 is CH_3, F, Cl or Br;
R^2 is F, CI, Br, I or CF_3;
R^3 is CF_3, Cl, Br or OCH_2CF_3; and
R^5 is Cl or Br;

which is useful as a synthetic intermediate for preparing a compound of Formula l.

This invention also relates to a pyrazolecarboxylic acid compound of Formula 4



4

wherein

R^3 is CF_3, CI, Br or OCH_2CF_3; and
R^5 is Cl or Br;

> which is useful as a synthetic intermediate, for preparing a compound of Formula 1."

The contention, in para 48 of the written submissions of the defendant, that "there is no difference whatsoever in any aspect of the disclosure" is, therefore, erroneous and is accordingly rejected.

15.3 Para 48 of the written submissions of the defendant further asserts that "there is no reason stated either in IN'307 for selecting a particular molecule from the Markush disclosed in IN'978, nor is any additional efficacy either hinted or suggested or disclosed". This contention, too, does not appear to be correct, *prima facie*. Mr. Sethi has pointed out that as many as 13 tests have been explained, in the "Biological Examples of the Invention", in the complete specifications of IN'307, which explained the superior insecticidal activity of CTPR. These superior insecticidal qualities of CTPR also stand borne out in the affidavit of the inventor George Lahm, as filed before the US Patents and Trademarks Office along with the declaration filed for registration of the US'836 patent, the equivalent of the IN'307 patent. It is averred, in the said affidavit, thus:

> "I am familiar with the subject matter of the present application and the subject matter of U.S. Patent 6,747,047 of which I am also a named inventor. Both the present application and U.S. Patent 6.747,047 encompass within their subject matter certain insecticidal anthranilamides. U.S. Patent 6,747,047 discloses a broad scope wherein, for example, J (the ring moiety directly attached to carbonyl) is defined as optionally substituted phenyl, naphthyl or, a 5-10 membered heteroaromatic mono- or bicyclic ring system. The

present invention is drawn to a narrow scope of pyrazole-*N*-2-pyridinyl analogs, that is, J is limited to pyrazole substituted with a 2-pyridinyl ring. Further, U.S. Patent 6,747,047 allows for broad substitution (up to four broadly defined substituents) on the central anthranilamide phenyl ring and primarily teaches compounds with monosubstitution on this phenyl ring; although, the teachings are not limited to monosubstitution. U.S. Patent 6,747,047 does not teach any examples of the present invention, that is, wherein J is *N*-(2-pyridinyl)-substituted pyrazole with disubstitution on the anthranilamide phenyl ring. Furthermore, in the present invention, disubstitution on the aruthranilamide phenyl ring is required and the positions are specifically defined.

Insecticidal activity data from tests conducted by DuPont was extracted from DuPont's biological testing database for compounds of the present invention and compounds of U.S. Patent 6,747,047 that differ by only one substituent. This data is presented in the attached Appendix. The tables in the attached Appendix show the activity of compounds of the present invention and compares this activity with activity of compounds of U.S. Patent 6,747,047, which compounds differ in only one substituent, as can be determined by examining the structure above the table and column headings describing the relevant compounds. Compounds of the present invention are designated by their Compound number as found in lNDEX TABLE A at paragraph [0248] on pages 32-33 of the present specification, as published, i.e. US 2004/0198984 A1. Compounds of U.S. Patent 6,747,047 are designated by their Compound number as found in the INDEX of TABLE D in columns 163-167 of U.S. Patent 6,747,047 or are identified by column number and their respective position in TABLE 9 of U.S. Patent 6,747,047.

I consider the data in the Appendix to be particularly pertinent to a comparison of the control activity of compounds of the present application with compounds of U.S. Patent 6,747,047; and I conclude that the data in the Appendix conflrms that compounds of the present application provide superior (and unexpected) insecticidal activity over compounds in U.S. Patent 6,747,047."

The primacy required to be accorded to the evidence of the inventor of the patented invention stands underscored in para 47 of ***Bishwanath Prasad Radhey Shyam***[10], thus:

> "The learned trial Judge then noted that Purshottam, who was stated to be the inventor, and, as such, was the best person to describe the invention, did not appear in the witness-box, though, as admitted by Sotam Singh (D.W.3), Purshottam had attended on some dates of hearing. Sotam Singh tried to explain Purshottam's disappearance from the Court without appearing in the witness-box, by saying that he had gone away due to illness. The learned Judge found this explanation unsatisfactory and rejected it — and in our opinion rightly — with the remark that recording of evidence lasted for several days and it was not difficult to secure Purshottam's attendance. Apart from being the best informed person about the matter in issue, Purshottam was not a stranger. He was a partner of the patentee firm and a brother of Sotam Singh (D.W.3). He was the best informed person who might have answered the charge of lack of novelty levelled by the opponent side, by explaining what was the novelty of the alleged invention and how and after what research, if any, he made this alleged 'discovery'. Being a partner of the respondent firm, and personally knowing all the circumstances of the case, it was his duty as well as of the respondent-firm, to examine him as a witness so that the story of the particular invention being a new manufacture or improvement involving novelty, could, in all its aspects, be subjected to cross examination. By keeping Purshottam away from the witness-box, the respondent-firm, therefore, took the heavy risk of the trial court accepting the charge of lack of novelty made by the appellant herein."

The plea of want of additional efficacy of CTPR, over the subject matter of IN'978, therefore, is also *prima facie* devoid of merit.

15.4 The suit patent cannot, therefore, *prima facie* be regarded as vulnerable to invalidation under Section 64(1)(d) read with Section 3(d) of the Patents Act.

Resultantly

16. As a result, the defendant has not been able to make out any *prima facie* case for treating the suit patent IN'307 as vulnerable to revocation or to invalidation.

B. Re. IN'332

17. IN'332 is the process patent, associated with IN'307. The title of IN'332 is "A Process for Preparing a Compound of Formula 1", where Formula 1 is the Markush moiety claimed in Claim 1 of IN'307. IN'332 contains 22 Claims. Claim 1 discloses the process for preparing CTPR by reacting benzoxazinone (of Formula 2) with a C1-C4 alkyl amine or dimethyl amine. Claims 2 to 22 disclose the process steps for arriving at the reactants to be used in Claim 1. As such, IN'332 is restricted, entirely, to the process for manufacture of CTPR. This position is not disputed by Mr. Sai Deepak.

18. Mr. Sai Deepak submits that (i) the plaint does not set out how IN'332 is being infringed by the defendants, (ii) as IN'307 is vulnerable, no protection can be extended to IN'332 either and (iii)

research activity is, in any event, protected by Sections 47[53] and 107A[54] of the Patents Act.

19. None of these contentions, unfortunately, impress.

20. It cannot be said that the plaintiff has not asserted IN'332 in the plaint. Para-21 of the plaint reads thus:

> "Indian Patent No. 213332 is a valid and subsisting patent and has a term of 20 years from 13th August, 2002 in India (i.e. till 13th August, 2022). The aforesaid patent was neither a post in a pre-grant opposition nor in a post-grant opposition by any member of the public or interested party in India. By virtue of grant of the suit patent 213332, the Plaintiffs have the exclusive right to prevent any 3rd party from the act of making, using, offering for sale, selling, exporting or

---

[53] **"47. Grant of patents to be subject to certain conditions –**
The grant of a patent under this Act shall be subject to the condition that –
(1) any machine, apparatus or other article in respect of which the patent is granted or any article made by using a process in respect of which the patent is granted, may be imported or made by or on behalf of the government for the purpose merely of its own use;
(2) any process in respect of which the patent is granted may be used by or on behalf of the government for the purpose merely of its own use;
(3) any machine, apparatus or other article in respect of which the patent is granted or any article made by the use of the process in respect of which the patent is granted, may be made or used, and any process in respect of which the patent is granted may be used, by any person, for the purpose merely of experiment or research including the imparting of instructions to pupils; and
(4) in the case of a patent in respect of any medicine or drug, the medicine or drug may be imported by the Government for the purpose merely of its own use or for distribution in any dispensary, hospital or other medical institution maintained by or on behalf of the Government or any other dispensary, hospital or medical institution which the Central Government may, having regard to the public service that such dispensary, hospital or medical institution renders, specify in this behalf by notification in the Official Gazette."

[54] "**107A. Certain acts not to be considered as infringement –**
For the purposes of this Act, –
(a) any act of making, constructing, using, selling or importing the patented invention, solely for use as reasonably relating to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product;
(b) importation of patented products by any person from a person who is duly authorised under the law to produce and sell or distribute the product,
shall not be considered as an infringement of patent rights."

> importing the subject matter of the suit patent up to 13th August, 2022. It would be pertinent to note that counterparts of this patent had been granted in more than 40 countries and in none of these jurisdictions have the said patents been revoked or invalidated."

Similarly, in para 35 of the plaint, the plaintiff has specifically alleged that the imminent commercial launch, by the defendant, of its CTPR product "would result in infringement of the suit patents IN 201307 and IN 213332". Allegations, similar to these, are also contained in paras 45 and 46 of the plaint, of which the latter concludes with the assertion that "it is … reasonable to presume that the Defendant is either using or intends to use a process for manufacture of their CTPR product which infringes the suit patent IN'332." The submission of Mr. Sai Deepak that the plaintiff does not assert IN'332, or allege possible infringement thereof is, therefore, not correct.

21. On merits, Mr. Sai Deepak submits, in the first instance, that, IN'307 being vulnerable, IN'332 is not entitled to protection. This submission, obviously, cannot sustain, in view of the findings, hereinbefore returned by me, that IN'307 is not vulnerable to revocation, and that no *prima facie* case of such vulnerability has been made out by the defendant. Secondly, Mr. Sai Deepak relies on Sections 47 and 107A. At a bare reading, these provisions do not apply, and the reliance thereon is merely a reliance of desperation, for the simple reason that protection is granted, by these provisions, only for use of the patented process "for the purpose merely of experiment or research". The plaintiff has sought protection of IN'332 to the

extent it is used in the manufacture of CTPR, and it is not the defendant's case that it is merely engaged in experiment or research.

22. Once I have held that Claim 1 in IN'307/CTPR is entitled to protection, the challenge to its validity being *prima facie* devoid of merit, IN'332 also becomes, inexorably, also entitled to protection, being a process for manufacture of CTPR.

23. It has been sought to be contended, by the defendants, that the process being used by them to manufacture their CTPR product is not the process which is patented in IN'332. Mr. Sethi, however, asserts that it is not open to the defendants to adopt this stance, as an application for discovery of the process used by the defendants to manufacture their CTPR product has been filed by the plaintiff and notice has been issued thereon but, despite more than a year having lapsed thereafter, the defendants have chosen not to respond to the application. As such, he submits, the Court would be entitled to presume that the process being adopted by the defendants is the process which stands patented in favour of the plaintiff in IN'332.

24. To my mind, this controversy is really tangential to the issue of interim injunction. The plaintiff has only sought protection against infringement of IN'332. In case, the defendants are not using the process patented in favour of the plaintiff in IN'332, they would, naturally, be unaffected by the injunction sought by the plaintiff, *insofar as protection of the process for manufacture of CTPR, claimed*

in IN'332, is concerned. If, on the other hand, the defendants are using the process claimed in IN'332, this order would apply to them.

Conclusion

25. As a result, the plaintiff is held entitled to protection from infringement in respect of both the suit patents IN'307 and IN'332.

26. Pending disposal of the present suit, therefore, the defendant is restrained from

(i) manufacturing, using, selling, distributing, advertising, exporting, offering for sale or in any other manner, directly or indirectly, dealing in any product which infringes the subject matter of IN 201307, including the product Chlorantraniliprole, claimed that disclosed therein, and

(ii) using, directly or indirectly, any of the process as claimed in IN 213332, for the manufacture of Chlorantraniliprole, or the claimed subject matter of IN 201307.

27. IA 15352/2019 stands allowed in the aforesaid terms.

IA 2084/2021 in CS (Comm) 69/2021 [*F.M.C. Corpn & Anr. v. Best Crop Science LLP & Anr.*]

28. I may note, at the very outset, that the order, dated 11th February, 2021 passed in this application, records thus:

> "Mr. J. Sai Deepak, learned counsel for the defendant, submits that the suit patent in the present case is the same as that which forms the subject matter of controversy in CS (Comm) 611/2019, the submissions on the application under Order XXXIX Rules 1 and 2 of the CPC would be substantially identical in both the cases. *He undertakes on behalf of his client, to abide by the order passed on to be passed in IA 15352/2019 in CS (Comm) 611/2019*, in which arguments have been heard in part, and learned counsel for the plaintiff is presently in rejoinder. That matter is listed for hearing on 15th February, 2021."
>
> (Emphasis supplied)

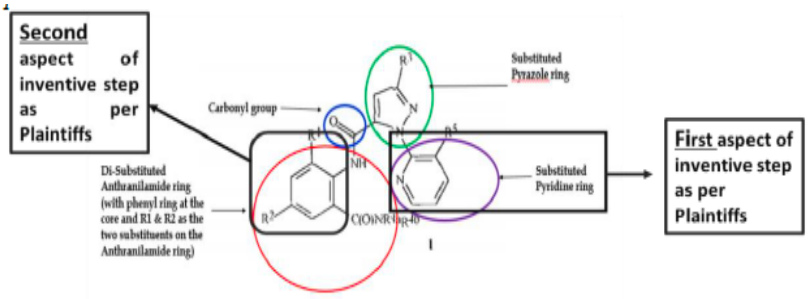
In view of the statement, made by learned Counsel for the defendant in this suit/application, it is obviously not permissible for the defendant to sail in a boat different from that in which the defendants in CS (Comm) 611/2019 cast oar. Nonetheless, the defendant in the present case has advanced detailed arguments, initially through Mr. Sai Deepak and, later, through Mr. Gopal Subramanium, learned Senior Counsel, assisted by Mr. Saikrishna Rajagopal, learned Counsel. Separate written submissions have also been filed by the defendant in the present application. For ease of reference, the defendant in this case would be denoted, thereafter, as "BCS".

29. BCS has, in its written submission (to which Mr. Subramanium specifically alludes), provided a "chart", "to show coverage and prior claiming of IN'307 patent (species patent) in claim 22 of IN'978 patent", which constitutes Annexure 1 to this judgement.

30. A bare glance at said chart demonstrates, as has already been noticed hereinabove, that BCS has "cherry picked" substituents, out of the substitutions envisaged in the disclosure in Claim 22 of IN'978, for A, B, J, R^1, R^2, R^3, R^{4a}, R^{4b} and R^5. Even within the "J" substituent, BCS has cherry-picked a "suitable" substituent for R^7. No justification for selecting the substituents in question is forthcoming in the submissions advanced by BCS, except the intent of "reaching" CTPR. Thus viewed, CTPR cannot be regarded as "obvious" from, or "taught by" IN'978.

31. BCS has also sought to discredit the affidavit of Mr. Lahm. The plaintiff relied on the said affidavit both for the submission that proceeding from IN'978 to Claim 1 in IN'307 involved "inventive steps" as well as for the submission that CTPR possessed additional efficacy, over the compounds claimed in IN'978. The written submissions of BCS, even while acknowledging the contents of the affidavit of Mr. Lahm regarding the inventive steps involved in synthesising CTPR from the Markush moiety forming subject matter of Claim 22 in IN'978, contains no submissions on the basis of which the assertions of the affidavit of Mr Lahm could be discredited. In this regard, the written submission of BCS merely *states* thus:

> "Plaint and declaration of Plaintiff's expert Mr. George Lahm claims that novelty an inventive step resides in the following part of the Markush structure of Formula 1 of claim 1 of IN'307 patent:
> "



Having thus noted the observations of Mr. Lahm regarding the inventive steps involved in arriving at Claim 1 of IN'307, BCS does not furnish any reason or justification for rejecting the affidavit of Mr. Lahm on this aspect. The reservations, expressed by BCS to the affidavit of Mr. Lahm, are restricted to the issue of additional efficacy of CTPR over the subject matter of IN'978. Presumably, therefore, BCS acknowledges the existence of inventive steps, in proceeding from Claim 22 in IN'978 to Claim 1 in IN'307. Even otherwise, I have, by comparing the two claims, found, on facts, that such inventive steps do, *prima facie*, exist.

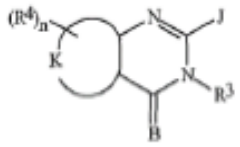
32. When this application was heard in part, BCS sought to introduce an affidavit of Mr Ajit Singh Gujral, who, in turn, sought to discredit the declaration of Mr. Lahm. I have already noted, hereinabove, that the evidence of the inventor of the invention has been accorded additional credibility, even by the Supreme Court. Any further examination of the comparative declarations of Mr. Lahm and affidavit of Mr. Gujral has, necessarily, to await trial. At this stage, in the face of the declaration of Mr. Lahm, I am unwilling to treat the

affidavit of Mr. Gujral, filed belatedly and in the midst of hearing, as rendering the suit patent vulnerable.

33. The written submission of BCS further contends that "Plaintiffs' alleged inventive step ... wherein chemical structure has N – (2 – pyridinyl)-substituted pyrazole which disubstitution on the anthranilamide phenyl ring is also claimed on disclosed in compounds of Plaintiffs' own earlier document WO'978 and in particular, WO'115." This, it is stated, stands explained in paras 58 to 75 of the reply, filed by BCS, to IA 2084/2021. Presumably, by this averment, BCS is seeking to assert vulnerability, of Claim 1 in IN'307 on the ground of "anticipation by prior publication".

34. I have already noted, earlier in this order, that "anticipation by prior publication" can be alleged only where the claim of the specie patent is expressly published in the alleged genus patent. BCS has alleged "disclosure" of CTPR in WO'115. The parameters of the concept of "disclosure" have already been examined and explained hereinabove. Within the said parameters, I am unable to convince myself that the averments contained in paras 58 to 75 of the reply filed by BCS to the present application, indicate disclosure of CTPR, or of Claim 1 in IN'307, in WO'115.

35. What is claimed, in WO'115, and which, according to BCS, "discloses compounds of Formula I", is the following:



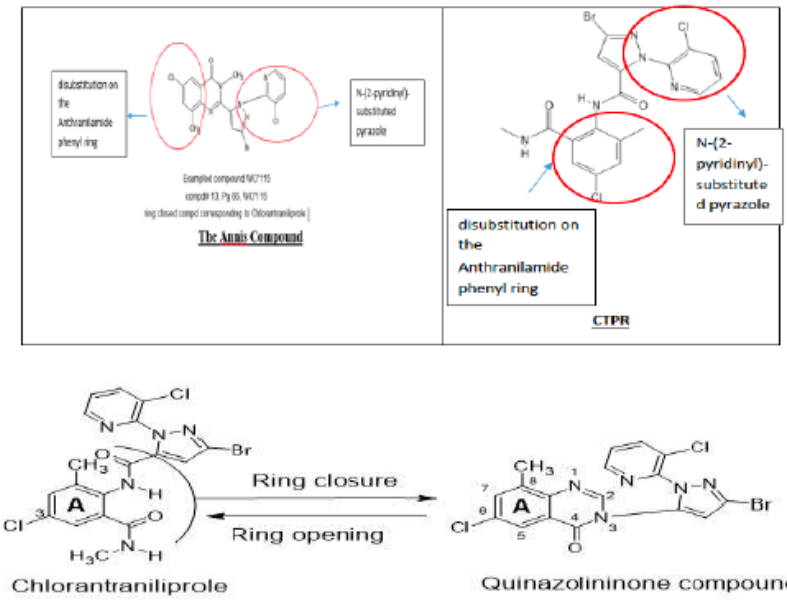
Formula – I

36. BCS asserts, in its reply to the present application, that "Cyclicized version of CTPR is derived from Markush structure of claim 1 of WO'115 *when the following substitutions are made*". Thereafter, the reply proceeds to cherry-pick substituents, out of the suggested substituents in Claim 1 of WO'115. Even after such cherry-picking, BCS arrives, not at CTPR, but, allegedly, at "a derivative of Chlorantraniliprole/CTPR in which the ring closure has been done in the other direction". Thereafter, the reply proceeds to set out, in detail, "the generic strategy of ring closure", resulting in synthesis of an "open ring compound". It is not the contention of the BCS, in the reply, that this "open ring compound" is CTPR. Reliance has also been placed, in the reply, to the declaration, in WO'115 that "by the procedures described herein together with methods known in the art, the following compounds of Tables 1 to 33 can be prepared". Proceeding therefrom, the reply asserts that "Example 2 in Pages 41-43 of WO'115 discloses the preparation of *one of the structurally closest molecules, i.e., 6 – chloro – 2 – [- 1 – (3 – chloro – 2 – pyridinyll) - 3 – (trifluoromethyl) – 1H – pyroazol – 5 – yl] – 3,S – dimethyl – 4 (3H) – quinazoline*".

37. All these submissions, even seen in conjunction, do not make out a case of disclosure of CTPR in WO'115. This, in fact, has been acknowledged, albeit by a side wind, in para 71 of the reply, of BCS, to the present application, which reads thus:

> "Thus, in view of the above, WO'115/US'614 invariably and unequivocally anticipates Chlorantraniliprole *as well as its precursor – the Benzoxazinone key intermediate*, claimed in IN'307 patent."

38. It is not necessary, at this interlocutory stage, to analyse, further, the involved process by which, by effecting select substitutions on the claims in WO'115, BCS asserts that it has arrived at "key intermediates" for CTPR. One may just reproduce, in this regard, the diagrammatic representation of the manner in which such "disclosure" is alleged, by BCS, to have taken place in WO'115, as contained in the written submissions filed by BCS, thus:



39. Thus, even on a comprehensive reading of the said assertions in the pleadings of BCS, it is not possible to hold that CTPR was disclosed in WO'115, or that its validity has been rendered vulnerable as a result thereof.

40. Other submissions, advanced by BCS, have already been dealt with hereinabove. BCS has sought to contend that denial of injunction to the plaintiff would not result in irreparable loss to it, as it could be compensated in damages and that public interest is in favour of denial of injunction, especially during the COVID-19 pandemic. These are, obviously, merely "residuary" submissions. Without citing judicial authorities in this regard, it is well settled that, in intellectual property infringement cases, especially in patent infringement claims and, most specifically, where the infringement case of a pharmaceutical/agrochemical patent, public interest dictates injuncting perpetuation of an invention which is, *prima facie*, infringing in nature. Damages, it is well settled, are no panacea in such a case.

41. BCS does not dispute the fact that it seeks to exploit the claim in IN'307. As with the defendant in CS (Comm) 611/2019, BCS, too, seeks to assail the validity of IN'307 as a ground to justify such exploitation. For the reasons cited hereinabove, no *prima facie* case can be said to exist, in the said challenge. The inexorable sequitur is that the proposed exploitation deserves to be injuncted.

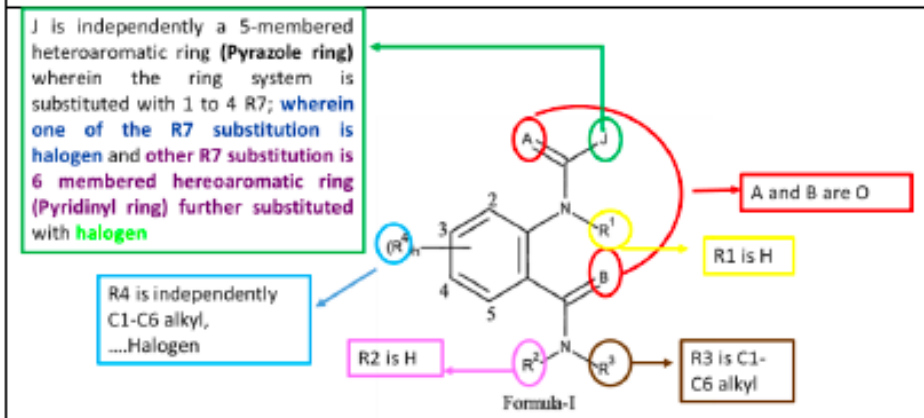
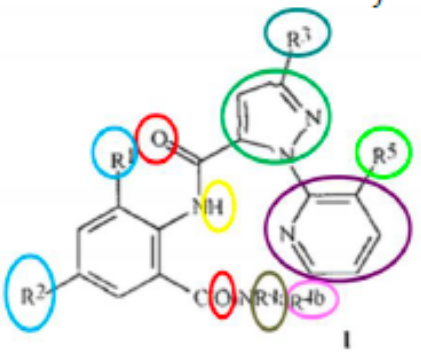
42. For this reason, IA 2084/2021 also succeeds and is allowed, in terms of the directions issued, hereinabove, in IA 15352/2019 in CS (Comm) 611/2019 which apply, *mutatis mutandis*, to the present application as well.

43. As the Court is presently functioning on a virtual mode, and it is not possible to furnish a physical copy of this judgement to the parties, the judgement would take effect from the time of its uploading on the website of this Court or from the time it is emailed to learned Counsel for the parties, whichever is earlier. The Registry is directed to email a copy of this judgement to learned Counsel for the parties as expeditiously as possible.

C. HARI SHANKAR, J

July 7, 2021

ANNEXURE - I

IN 204978 (Genus patent) *(See pg. 3221 of Defendants docs dt. 04.04.2021)*	**IN 201307 (species patent)** *(See pg. 3013 of Defendants docs dt. 04.04.2021)*	**IN 201307 (species patent)** **Chemical structure of CTPR/Chlorantraniliprole** *(See pg. 3002 of Defendants docs dt. 04.04.2021)*
J is independently a 5-membered heteroaromatic ring **(Pyrazole ring)** wherein the ring system is substituted with 1 to 4 R7; **wherein one of the R7 substitution is halogen** and **other R7 substitution is 6 membered hereoaromatic ring (Pyridinyl ring) further substituted** with **halogen**  Formula-I	*A compound selected from Formula I or an N-oxide thereof:*  I *wherein* R^1 *is* CH_3, *F, Cl or Br;* R^2 *is F,* Cl, *Br, I or* CF_3; $R3$ *is* CF_3, *Cl,* Br *or* OCH_2CF_3; R^{4a} *is* C_1-C_4 *alkyl;* R_{4b} *is* H *or* CH_3; *and* R^5 *is* Cl *or Br*