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

\+ CS(COMM) 567/2024 & I.A. 33088/2024, I.A. 44310/2024, I.A. 44384/2024

F. HOFFMANN-LA ROCHE AG & ANR. .....Plaintiffs

Through: Mr. Pravin Anand, Ms. Shrawan Chopra, Ms. Prachi Agarwal, Mr. Devinder Rawat, Mr. Achyut Tewari, Mr. Aayush Maheshwari, Ms. Elisha Sinha, Ms. Krisha Baweja, Mr. N. Mahabir, and Ms. Archana Shanker, Advocates (M:8604633567)

versus

NATCO PHARMA LIMITED .....Defendant

Through: Mr. J. Sai Deepak, Sr. Adv. with Mr. Afzal B. Khan, Mr. Samik Mukherjee, Ms. Amrita Majumdar, Mr. Dominic Alvares, Mr. Avinash Kr. Sharma, and Mr. Sharad Besoya, Advocates (M: 7585965845)
Email: del.lit@majumdarip.com

CORAM:
HON'BLE MS. JUSTICE MINI PUSHKARNA

JUDGMENT

% 24.03.2025

MINI PUSHKARNA, J:

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I.A. 33088/2024

Factual Matrix:

1. The present suit has been filed alleging infringement of Patent No. IN 334397 (IN'397-Suit Patent/Species Patent). By way of the present application, the plaintiffs are seeking interim injunction for restraining the infringement of the Suit Patent, which is titled *"COMPOUNDS FOR TREATING SPINAL MUSCULAR ATROPHY"*.

2. The Suit Patent, which is a 'Species Patent' *inter alia* for the product 'Risdiplam', relates to compounds which are Survival Motor Neuron 2 ("SMN2") used in the treatment of Spinal Muscular Atrophy ("SMA"). The Suit Patent is registered in the name of plaintiff nos. 1 and 2. The bibliographic details of the Suit Patent are as below:

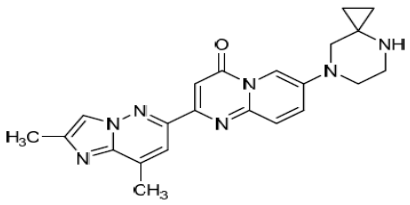
Indian Patent Number	334397
Patent Application Number	201647038542
Applicant/Patentee	Plaintiff No.1 Plain. .f No.2
Title	COMPOUNDS FOR TREATING SPINAL MUSCULAR ATROPHY
National Phase entry-filing date of Indian Application	November 11, 2016
International Application No.	PCT/EP2015/060343
International Filing Date (Date of Patent)	May 11, 2015
Date of Priority	May 15, 2014
WO Publication No.	WO2015/173181 A1
International Publication date	November 19, 2015
Publication Date (u/S 11A)	February 03, 2017
First Examination Report (FER) Issue Date	September 10, 2019
FER Response Date	January 27, 2020
Date of Grant	March 11, 2020
Publication Date (u/S 43(2))	March 13, 2020
Date of Expiry	May 11, 2035
Pre-Grant Opposition	None
Post-Grant Opposition	None
Revocation	None

3. The Suit Patent has a term of 20 years from 11th May, 2015, which expires on 11th May, 2035. There has been no pre-grant opposition, post-grant opposition or any revocation proceedings filed against the Suit Patent in India.

4. The US ("United States") Patent No. 9,969,754 ("US'754") is the

corresponding patent to the Suit Patent. US Patent No. 9,586,955 ("US'955") is the US Patent corresponding to the Patent Cooperation Treaty ("PCT") application no. PCT/US2013/025292 published as WO 2013/119916 A2 patent ("WO'916 – International Genus Patent"). An application for Patent Term Extension ("PTE") of US'955 has been filed before the United States Patent and Trademark Office ("USPTO") on 02nd October, 2020. In Australia, the request for PTE has been accepted for its corresponding Australian Genus Patent No. 2013216870 ("AU'870"). Likewise, the plaintiffs have also been granted patent in Canada, i.e., CA 2863874 ("CA'874"), which corresponds to the International Genus Patent, WO'916. The corresponding patents to the Suit Patent have been granted in about 60 countries worldwide.

5. The Suit Patent claims a compound having an International Non-Proprietary Name ("INN"), 'Risdiplam', assigned by the World Health Organization, in the year 2018. It has the molecular formula – $C_{22}H_{23}N_7O$, and has the following chemical structure:



6. Risdiplam is the Active Pharmaceutical Ingredient ("API") in the plaintiffs' commercial product, which is marketed in various countries worldwide, including, India, under the brand name, 'EVRYSDI®'. Risdiplam is an oral prescription medicine indicated for the treatment of SMA in patients two months of age or older. SMA is a rare genetic neuromuscular disorder caused by the mutation of the Survival Motor

Neuron 1 ("SMN1") gene, leading to a deficiency of SMN protein, which affects motor nerve cells, diminishing the ability to walk, sit, eat and breathe.

7. The plaintiffs came across the listing of Risdiplam on the defendant's website under the *'APIs under development'* section. Further, investigation revealed that the defendant was preparing for commercial production of Risdiplam API. Moreover, the defendant was found to have filed a patent application bearing no. 202241055182 on 26th September, 2022 under the title, *'Improved Process for the Preparation of Risdiplam and its Intermediates'* for manufacturing of Risdiplam. Thus, the present suit has been filed by the plaintiffs alleging infringement by the defendant of their rights in the Suit Patent.

8. During the hearing of the present application for interim injunction, two applications, *I.A. 44310/2024* and *I.A. 44384/2024*, were filed on behalf of the interveners, for their impleadment/intervention.

9. Though, the said interveners were not impleaded, however, for the purposes of submissions on the aspect of public interest involved, this Court has allowed the two interveners in the present case, to make their submissions before this Court. The submissions of the interveners have been considered in furtherance to the powers inured in the Court by way of Rule 25 of the Delhi High Court Intellectual Property Rights Division Rules, 2021 and in light of the judgement of the Supreme Court in the case of ***Dr. Satyanarayana Sinha Versus S. Lal and Company (P) Ltd.***[1], wherein, the Supreme Court held as follows:

> *"xxx xxx xxx*

[1] ***(1973) 2 SCC 696***

> ***10. <u>In England also the Courts have taken the view that when the application is made by a party or by a person aggrieved the Court will intervene ex debito justitiae, in justice to the applicant, and when it is made by a stranger the Court considers whether the public interest demands its intervention. In either case it is a matter which rests ultimately in the discretion of the Court</u>****: (See R.v. Thames Magistrates' Court, Exhibit p. Greenbaum). [(1957) 55 LGR 129 (Extracted in Yardley: Source Book of English Administrative Law, 1970, p. 228).]***
>
> *xxx xxx xxx"*
>
> *(Emphasis Supplied)*

<u>Submissions of the Plaintiffs</u>:

10. On behalf of the plaintiffs, the following submissions have been made:

10.1 The defendant has admitted infringement, since the defendant has admitted that it is in the process of launching Risdiplam.

10.2 The defendant's entire case is based on the WO'916, being International Genus Patent pertaining to the Suit Patent. The defendant has simply based their entire case on account of the statements made in other jurisdictions regarding the PTEs. However, none of the statements made overseas by the plaintiffs, amount to an admission of any nature that WO'916 specifically discloses Risdiplam.

10.3 The Suit Patent is an old patent filed in the year 2016 and claiming priority since the year 2014. The patent is still valid and subsisting, having been granted in the year 2020. Further, the corresponding patents to the Suit Patent that have claims directed to the specific compound Risdiplam have been granted in more than 60 countries, and the same have not been revoked/invalidated in any jurisdiction.

10.4 The fact that an INN has been granted, shows that it is a new chemical entity, as INN naming is only available for new compounds. International

Search Authority ("ISA") has held the Suit Patent to be novel and non-obvious after considering WO'916.

10.5 The defendant has simply based their entire case on account of the statements made in other jurisdictions regarding the PTE. In its arguments, the defendant did not refer to prior art document, WO'916 or the patent in question to determine patentability requirements.

10.6 The Suit Patent enjoys a strong presumption of validity, and the defendant has clearly failed in establishing any challenge to the validity of the Suit Patent. In view of the fact that the Suit Patent is *prima facie* valid, an infringement is admitted, the plaintiffs are entitled to an injunction against the defendant.

10.7 The plaintiffs have developed a new drug which is the only oral drug for SMA in the world, and expenditure in development of a new molecule as done by the plaintiffs, is highly exorbitant, whereas, companies which create generic versions, like the defendant, bear minimal costs for Research & Development ("R&D"). Therefore, a balance is necessary between the interests of the innovators and the generic medicines industry.

10.8 The plaintiffs have voluntarily provided a heavy price reduction and discounts to the Government of India for the cause of SMA patients in India.

10.9 The defendant is a habitual infringer, as there are multiple law suits filed against them in which injunctions have been granted. They have also breached undertakings and paid damages in settlements.

10.10 A Person of Ordinary Skill in the Art is an ordinary person, and not an expert, as alleged by the defendant. Tests to determine obviousness and insufficiency are all from the perspective of A Person of Ordinary Skill in the Art, and not an expert. Therefore, the defendant's understanding of A

Person of Ordinary Skill in the Art is incorrect.

10.11 There has been no evergreening in the present case. Evergreening does not apply to new compounds and it is very clear that Risdiplam is a new compound.

10.12 Risdiplam cannot be anticipated or rendered obvious on the basis of WO'916. The International Genus Patent, WO'916, does not specifically disclose Risdiplam and no one can find Risdiplam as a specific example in WO'916. A Person of Ordinary Skill in the Art, not being aware of Risdiplam without hindsight, cannot recognise that Risdiplam would be the product.

10.13 The lead candidate chosen from WO'916 was the compound RG7800, as disclosed therein. However, RG7800 was later stopped due to retinal toxicity, but it was reasonable for A Person of Ordinary Skill in the Art to select RG7800 based on WO'916. Therefore, comparing the structures of the failed compound, i.e., RG7800, with that of Risdiplam, one can easily see the difference in the same, hence demonstrating that Risdiplam was a new invention.

10.14 There was no novelty/anticipation challenge by the Indian Patent Office ("IPO") during the prosecution of the Suit Patent, despite the fact that WO'916 was looked into by the Patent Office. Moreover, WO'916 was specified in the description of the Suit Patent. Thus, both, the IPO and the ISA, as well as all of the authorities over 60 jurisdictions where the Species Patent has been granted, were specifically aware of the said document. Thus, WO'916 has been considered in multiple jurisdictions and no jurisdiction regarded the same as anticipating the Species Patent or Risdiplam.

10.15 Suit Patent is not obvious on the basis of WO'916, as alleged by the

defendant. At the priority date of the Suit Patent, A Person of Ordinary Skill in the Art, would have no basis for selecting a particular compound, as alleged by the defendant. There is no teaching for A Person of Ordinary Skill in the Art, to narrow down to the compound of formula from various Markush Structures. The defendant has miserably failed to provide reasons for A Person of Ordinary Skill in the Art to perform the various steps of selecting and modifying the compound and the multiple substituents to arrive at Risdiplam. Thus, the defendant's contentions are purely based on hindsight and on reverse engineering, i.e., after having knowledge of the structure of Risdiplam from US'955, the defendant has tried to reverse engineer to arrive and represent Risdiplam from the disclosure of WO'916.

10.16 Coverage is not the same as disclosure. Disclosure is a question of fact and must be clear and unambiguous. It cannot be implied, inferred or deemed, and is best discovered by looking at the genus patent itself. Further, for a new chemical entity, disclosure must involve identification of the compound such as by its molecular formula, molecular structure, chemical formula or International Union of Pure and Applied Chemistry ("IUPAC") name.

10.17 The International Genus Patent is not theoretical, as at the very least 835 compounds have been exemplified for the same and each one can be a subject matter of further research.

10.18 The test for infringement is not the same as the test of invalidation. The test for infringement is whether the accused product or method falls within the scope of the patent claims. For invalidity, the test is disclosure, whether the product or method is specifically disclosed by the prior art.

10.19 Risdiplam is a new chemical entity. Therefore, Section 3(d)[2] of the Patents Act, 1970 ("Patents Act") will not apply to the present case. For Section 3(d) to apply, the defendant must demonstrate that there was a known substance that had been isolated and synthesised, whose properties were known. Section 3(d) would apply only if Risdiplam was known, and the plaintiffs applied for a new salt for the same.

10.20 Reliance on plaintiffs' statements in applications for PTEs is completely misplaced and legally untenable. Statements made during prosecution of foreign applications are irrelevant, as they are in response to unique patentability requirements overseas. Whether Risdiplam is disclosed in WO'916 or not, must be arrived at by looking at the said document alone. Any subsequent statements made by any party, cannot decide or alter the scope of the patent claims or interpret the patent specification. Further, subsequent statements made by any party or the patentee cannot decide or alter the scope of the patent claims or interpret the patent specifications, especially, when the statement made was much after the priority date.

10.21 The context in which statements for grant of PTEs have been made, are completely different and cannot be termed as an admission on any account. Further, if the statements made in the other jurisdictions amounted to admission of disclosure, the novelty would be destroyed in this country

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

and in the other jurisdictions, which cannot be the intent of the plaintiffs.

10.22 It is trite law that an admission must be unequivocal and unambiguous. Further, none of the statements made by the plaintiffs in the various PTE applications ever mentioned in any manner, that the Risdiplam product was specifically disclosed in the International Genus Patent, nor A Person of Ordinary Skill in the Art would find specific disclosure of Risdiplam molecule from the International Genus Patent. Moreover, in all these jurisdictions, the Genus and the Species Patents both co-existed and if there had been anticipation, then the Species Patents would not have been granted in these countries. Therefore, the law on admissions is subservient to a verifiable fact.

10.23 It is wrong for the defendant to construe on the basis of law suit in USA against the defendant, that Risdiplam is specifically disclosed, merely owing to the coverage under the International Genus Patent.

10.24 On the aspect of Public Interest, it is to be considered that the drug in question is used for treating a life-threatening disease, which is a rare disease.

10.25 There are between 7000-8000 rare diseases and about 95% of rare diseases have no approved treatment. Therefore, there is equally an overwhelming public interest in protecting a patent for a rare disease. Further, the expenditure and time invested by the plaintiffs in R & D ought to be protected. The plaintiffs have spent billions of dollars on clinical trials, which were carried out on a global scale.

10.26 The patents have a limited life of 20 years. Therefore, if a generic manufacturer is allowed to manufacture the patented drug of the plaintiffs, then companies would be dissuaded from investing in R & D.

10.27 Plaintiffs are already giving the drug in question to the Government at heavily discounted rates. Therefore, to say that a patent creator is not entitled to protection would be destructive. The plaintiffs have spent many years on research, whereas, no development cost has been incurred by the defendant. The investment of the defendant is nothing, except in manufacturing the drug in question, if allowed by this Court.

10.28 The motive of the defendant is to only make profits by imitating the plaintiffs, which has to be seen in proportion to the investment made by the defendant, which is only for the proposed manufacture and not for R & D. On the other hand, the plaintiffs have to recoup their costs and investments on R & D and clinical trials, held globally.

10.29 In the case of *Master Arnesh Shaw Versus Union of India, W.P.(C) 5315/2020*, which was a Public Interest Litigation, the plaintiffs themselves came forward to provide the drug in question to the Government at heavily discounted rate. Further, 486 patients suffering from SMA in India, are enrolled with the plaintiffs under the Patient Assistance Program.

10.30 Allowing the defendant to manufacture would be overarching public interest, as public interest also lies in protecting the patentee. If patent rights are not protected, then the companies will not put in efforts for invention and discovery of new compounds for treatment of diseases. The defendant cannot make crime out of profitability. The larger public interest demands protection of patents, especially, in cases of drugs for rare diseases. Generic manufacturers, like the defendant, have put in no effort on clinical trials or development costs.

Submissions of the Defendant:

11. On behalf of the defendant, the following submissions have been

made:

11.1 The plaintiffs have resorted to evergreening and unlawful PTE in India, by applying for a species patent, instead of an Indian Genus Counterpart to US'955/WO'916, which would have expired in 2033. By applying for a species patent in India, the plaintiffs have secured an unlawful PTE of two years in India under the garb that Risdiplam is not specifically disclosed by the International Genus Patent, although admittedly covered by the same. Thus, the present is a case of *International Genus Versus Indian Species*.

11.2 The plaintiffs have attempted to shift the focus of the case from the question of evergreening and patent validity to the worth of the product, Risdiplam and in labelling of defendant as a 'habitual infringer'.

11.3 Interim injunction cannot be granted for the asking in suits for alleged patent infringement. The said position applies with greater rigor to suits relating to pharmaceutical patents. The Patents Act does not bestow presumptive validity on a patent, even if it has been granted pursuant to a failed pre-grant opposition, or even if it survives a post-grant opposition. As held in catena of judgments, given the absence of presumptive validity of a patent, Courts must deny grant of interim injunction if the defendant establishes a credible challenge to patent validity.

11.4 Courts have gone to the extent of holding that the issue of patent validity can be raised even in a counter claim to a suit for infringement or as a defence against infringement, without necessarily filing a counter claim. Nevertheless, the defendant has filed a counter claim, however, at the interim stage, the 'vulnerability' of the Suit Patent should be considered, and not its 'invalidity', hence, it is not necessary to even file a counter claim at

this stage.

11.5 Both, the International Genus Patent, WO'916, and Indian Species Patent, IN'397, relate to the compounds for the treatment of the same condition, namely, SMA. Therefore, WO'916 is not a random document that is being selected for assessment of the patentability/validity of the IN'397. Thus, statements made by the plaintiffs in any other jurisdiction are relevant towards the question of validity or vulnerability of Suit Patent.

11.6 The plaintiffs have misrepresented and made material suppression before the Patent Office with respect to the International Genus Patent.

11.7 On account of non-filing of the Indian Genus Patent, Risdiplam has fallen in public domain in India, notwithstanding the grant of the Species Patent.

11.8 Although patent rights are territorial in nature, the Patents Act itself recognizes the relevance of findings of Foreign Patent Offices in relation to a family of patents. Admissions made either during the prosecution of a patent application or post the grant of the patent by the applicant/patentee, are relevant in every jurisdiction in relation to the same subject matter, whether in the form of genus patent or a species patent. The Indian Suit Patent is a Species Patent of WO'916 and relates to the very same set of compounds, which are meant to address the same conditions, i.e., SMA. Consequently, all statements/admissions made by the plaintiffs/patentee, in any jurisdiction in relation to WO'916 and other Genus counterparts, are relevant for the assessment of the patentability of the Indian Species Suit Patent.

11.9 The Supreme Court and this Court in several cases relied on *'foreign admissions'* as the basis for rejection of patent applications and denial of

interim injunction.

11.10 During the pendency of the present suit, the plaintiffs have instituted a suit for infringement in US before the United States District Court against the defendant herein, alleging infringement of the US Genus Patent, US'955 and US Species Patent, US'754, in respect of Risdiplam. By filing the said suit, the plaintiffs have validated the defendant's contention that the International Genus Patent of the plaintiffs is capable of being asserted against third parties for the very same product, Risdiplam. Consequently, a genus patent which can be asserted/enforced against the third parties for infringement, can equally be used by such third parties as prior art to challenge the validity of a subsequent/species patent, which admittedly claims the same product.

11.11 The plaintiffs secured the PTE for US'955 Genus Patent through express admission that Risdiplam is a new drug whose discovery is traceable to the US Genus Patent. Thus, at the interim stage, the plaintiffs cannot take a contrary position to secure an interim injunction.

11.12 In case of Grouped Claim/Markush Claim, the Patents Act requires only fair disclosure and not express or specific disclosure. By requiring only fair and not specific disclosure, the Act permits a few examples to be presented in the disclosure on an illustrated basis, without necessarily limiting the scope of claims only to such examples. Markush Claim, which is based on a common inventive step, need not be supported by examples which relate to every embodiment within that claim. Therefore, a Markush Claim and the disclosure of the patent are co-extensive, and the scope of Markush Claim is not limited by or to the specific examples contained in the patent specifications, thereby, allowing benefit of the provision to both the

patentee and third parties, such as the defendant.

11.13 The issue of *Coverage Versus Disclosure*, has been settled by the Supreme Court in the case of ***Novartis AG Versus Union of India and Others***[3], which is also covered by several decisions of this Court. Thus, there is no distinction between coverage or claim in the Species Patent and disclosure in the International Genus Patent.

11.14 Even in foreign jurisdictions, the law is that if the prior art discloses a species falling within the claimed genus, then, the species patent cannot be granted. Thus, by plaintiffs' admissions towards the coverage of WO'916/US'955 extending to Risdiplam and claiming infringement of the US Genus Patent, the plaintiffs have put themselves in a position of the Species Patent being susceptible to invalidity.

11.15 A species/selection patent can be granted despite the grant of a genus patent, only if it is demonstrated that the species patent has significant technical advancement and enhanced therapeutic efficacy over the genus patent. The species patent must disclose substantial advantage over the genus patent/prior art in the specification. However, the Suit Patent fails to disclose any such advantage over the International Genus Patent.

11.16 All the substituent specifically mentioned in Claim 1 of the Suit Patent, are disclosed in the International Genus Patent. Any modifications or substitutions which result in the same chemical and physical properties, and are necessary to arrive at the compounds claimed in the Suit Patent from the compounds disclosed in the International Genus Patent, are routine and predictable by a person skilled in the art, being disclosed in prior art itself. This could include modification to functional groups, side chains or other

structural elements, which are commonly employed in medicinal chemistry.

11.17 Even though it has been admitted by the plaintiffs that the International Genus Patent discloses Risdiplam, the complete specification of Suit Patent fails to present any comparative data showing technical advancement or enhancement of therapeutic efficacy over the International Genus Patent.

11.18 Risdiplam cannot enjoy any protection in a later filed Species Patent, whose novelty is destroyed by the plaintiffs' own prior published genus patent family.

11.19 The plaintiffs are not adequately working the patent in India. The plaintiffs are not manufacturing Risdiplam in India, and only importing the same in India, whereas, the defendant will be manufacturing the drug in India.

11.20 The intent of the plaintiffs is to monetize the said invention, and in such cases if the plaintiffs succeed, monetary damages are adequate compensation, and interim injunction should not be granted in such cases. The drug is not accessible or affordable to regular patients and the plaintiffs have failed to make the drug accessible and affordable.

11.21 When a big gap exists in the price of the plaintiffs' drugs and the defendant's drugs, balance of convenience will be in favour of the defendant, subject to the defendant establishing a credible challenge to the validity of the patent. The defendant intends to make the product available at a price that is nearly 80-90% lesser than the plaintiffs' price.

Submissions of Intervener in Application, I.A. 44310/2024:

12. On behalf of the intervener, Ms. Purva Mittal, in application being

[3] ***(2013) 6 SCC 1***

I.A. 44310/2024, it has been submitted as follows:

12.1 The intervener, Ms. Purva Mittal, is a patient diagnosed with the rare genetic disease of SMA, in which muscles throughout the body are weakened because nerve cells in the spinal cord and brainstem do not work properly.

12.2 The intervener is undergoing treatment at LNJP Hospital, New Delhi. She has been recommended Risdiplam, but is unable to start treatment with the drug, as the price thereof, is exorbitant and completely unaffordable. The average/approximate cost for one year's treatment is around Rs. 1,48,00,000/- (One Crore Forty-Eight Lacs) per year, which is highly unaffordable.

12.3 The spirit of considering public interest while granting injunction, is reflected in the jurisprudence that has developed in India, as well as in other countries. Furthermore, in cases of life saving drugs, public interest is a critical factor.

12.4 SMA is a debilitating disease and there is no cure for the same. The plaintiffs claim to run a Patient Assistance Program, which is meant to assist patients and provide drugs at an affordable price. However, from a study done by the plaintiffs on its Patient Assistance Program, Risdiplam was made available to only 75 patients in India in 2023. If any person, such as the defendant, is able to manufacture the drug and make it available at an affordable price, in such a case, public interest would have to outweigh the need for grant of injunction.

12.5 Since injunction is an equitable remedy and public interest is an important factor in the grant of injunction, this Court should consider this aspect in the overall scheme before granting any injunction.

Submissions of Intervener in Application, I.A. 44384/2024:

13. On behalf of the intervener, Ms. Seba P.A., in application being, *I.A. 44384/2024*, it has been submitted as follows:

13.1 The applicant is living with the rare, life threatening progressive neuromuscular genetic disease, SMA. She is vitally interested in increasing access to treatment for SMA, including, the drug Risdiplam, for herself and for thousands of others in the country diagnosed with the rare disease, which is not easily accessibly on account of the patent monopoly that allows the plaintiffs to have dominant position and charge an exorbitant price for the drug, Risdiplam.

13.2 The applicant had approached the High Court of Kerala, wherein, by an order dated 23rd February, 2024 in *W.P. (C) No. 43275 of 2023*, the Court directed that the medicine be procured for the applicant from the one time amount of Rs. 50 Lacs available under the National Rare Disease Policy. Consequently, the Kerala Government had procured 18 bottles, which the applicant has received. She will receive another 6 bottles in the next three months, which will exhaust the said threshold limit of Rs. 50 Lacs. Thereafter, without affordable access, the applicant would be left without treatment.

13.3 In a patent suit, public interest in terms of availability and accessibility of the drug, is a relevant factor to grant or to refuse the injunction.

13.4 The price under Roche's Patient Support Program in India, is also unaffordable. Patients pay Rs. 12.5 Lacs for 2 bottles and get 3 bottles free. Thus, patients get 5 bottles for Rs. 12.5 Lacs, and for a patient weighing 20 Kilograms ("Kgs") or more, needing 30 bottles a year, will still pay over Rs.

30 Lacs.

13.5 The high cost of the drug Risdiplam, the only approved drug in India, is leading to challenges in making it available and accessible to all patients diagnosed or undiagnosed with SMA in India.

13.6 The Government of India has launched National Policy for Rare Diseases, 2021, for the treatment of patients with rare diseases, whereby, the rare diseases have been categorized. Provision for financial support of upto Rs. 50 Lacs for patients suffering from rare disease has been introduced. However, considering the high cost of patented medicines such as Risdiplam, the said provisions of the Government will be inadequate unless generic competition for lowering prices by local manufacturing is introduced.

13.7 The Court ought to balance the public interest, and the constitutionally protected right to health of patients and balance them against the exorbitant price of the drug.

Analysis and Findings:

14. I have heard learned counsels for the parties and have perused the record.

I. *Finding on the Aspect of Prima Facie Case:*

15. In the present suit, the defendant has challenged the validity of the Suit Patent primarily on the following grounds:

a. **Section 64(1)(e)**[4] – The invention so far as claimed in any claim of

[4] ***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 157[* * *] 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,—*

(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

the Suit Patent is not new, having regard to what was published in India or elsewhere before the priority date in any of the documents referred to in Section 13[5] of the Patents Act.

b. **Section 64(1)(f)[6]** – The invention claimed in Suit Patent 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.

c. **Section 64(1)(d)[7]** – The subject of any claim of the Suit Patent is not

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claim or to what was published in India or elsewhere in any of the documents referred to in Section 13;

[5] ***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.

(2) The examiner shall, in addition, make such 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 sub-section (1) before the date of filing of the applicant's complete specification.*

(3) Where a complete specification is amended under the provisions of this Act before 69[the grant of a patent], the amended specification shall be examined and investigated in like manner as the original specification.

(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.

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

(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;

[7] ***64. Revocation of patents.****—(1) Subject to the provisions contained in this Act, a patent, whether granted before or after the commencement of this Act, may, [be revoked on a petition of any person interested or of the Central Government [* * *] or on a counter-claim in a suit for*

an invention.

d. **Section 64(1)(j)**[8] – The patent was obtained on a false suggestion or representation.

e. **Section 64(1)(m)**[9] – Non-compliance of requirements under Section 8[10] of the Patents Act.

16. It is to be noted that the defendant has primarily argued on the aspect of invalidity of the Suit Patent on various grounds, as mentioned above, and the aspect regarding non-infringement of the Suit Patent has not been

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infringement of the patent by the High Court] on any of the following grounds, that is to say,—

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

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

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

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

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

[10] ***8. Information and undertaking regarding foreign applications.—*** *(1) Where an applicant for a patent under this Act is prosecuting either alone or jointly with any other person an application for a patent in any country outside India in respect of the same or substantially the same invention, or where to his knowledge such an application is being prosecuted by some person through whom he claims or by some person deriving title from him, he shall file along with his application [or subsequently [within the prescribed period as the Controller may allow—*

(a) a statement setting out detailed particulars of such application; and

(b) an undertaking that, up to the date of [grant of patent] in India he would keep the Controller informed in writing, from time to time, of [detailed particulars as required under] clause (a) in respect of every other application relating to the same or substantially the same invention, if any, filed in any country outside India subsequently to the filing of the statement referred to in the aforesaid clause, within the prescribed time.

(2) At any time after an application for patent is filed in India and till the grant of a patent or refusal to grant of a patent made thereon, the Controller may also require the applicant to furnish details, as may be prescribed, relating to the processing of the application in a country outside India, and in that event the applicant shall furnish to the Controller information available to him within such period as may be prescribed.

pressed at the time of arguments.

17. Thus, each ground raised by the defendant is being considered separately, herein below.

A. *Anticipation by Prior Publication – Section 64(1)(e) of the Patents Act:*

18. According to Sections 2(1)(*l*)[11] and 13(2) of the Patents Act, India follows a principle of absolute novelty with strict novelty requirements. As per the definition of *'new invention'*, stipulated in Section 2(1)(*l*) of Patents Act, only those inventions or technology which are not 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, can be considered as a new invention. This is to say that there are no other prior published documents claiming a priority date earlier than the date on which an application for the invention in question is filed, on the basis of which, an invention can be anticipated. Accordingly, only an invention that has not already become a part of the public domain, affecting the novelty of the invention in question, can be considered as a new invention. Thus, as per the law of the land, anticipatory publications extend to those published anywhere in the world. It is relevant to note here that in the present case, the anticipatory documents cited by the defendant, i.e., the International Genus Patent, WO'916 and its corresponding US Patent, US'955, are patent applications published internationally, without claiming any patent protection in India, having a priority date earlier than the Suit

[11] ***2. Definitions and interpretation.—****(1) In this Act, unless the context otherwise requires,—*

(l) "new invention" means 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;

Patent.

19. In India, the test or approach for determining anticipation has evolved and has been consolidated by a Coordinate Bench of this Court in a recent decision, ***LAVA International Limited Versus Telefonaktiebolaget LM Ericsson***[12]. The test for determining anticipation, *(which is one of the material factors while dealing with the issue of novelty),* as drawn in the said judgement, is as under:

(i) Understanding of the Claims of the Invention,

(ii) Identifying Relevant Prior Art,

(iii) Analysing the Prior Art,

(iv) Determination of Explicit and Implicit Disclosures,

(v) Assessment of material differences while considering the entire scope of the claims,

(vi) Verifying Novelty in light of Comprehensive Scope and Specific Combination of Claimed Elements,

(vii) Documentation of the Analysis and Novelty Determination.

20. Thus, keeping in view the aforesaid approach, this Court has proceeded to analyse as to whether any credible challenge has been raised by the defendant towards vulnerability of the Suit Patent.

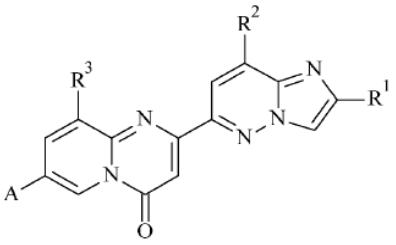
21. The present suit alleges infringement of IN'397, a Species Patent (Suit Patent). The Suit Patent relates to a compound of formula (I) and methods for their preparation, which are potentially useful in treating or preventing SMA. The plaintiffs assert their rights on the compound 'Risdiplam', which according to the plaintiffs, is *'covered and claimed in the Suit Patent'*.

22. The chemical name of Risdiplam is, *7-(4,7-diazaspiro [2.5] octane-7-yl)-2-(2,8dimethylimidazo[1,2-b] pyridazin-6-yl)-4H-pyrido[1,2-a] pyrimidin-4-one*, which has the molecular formula – $C_{22}H_{23}N_7O$.

23. At this juncture, to understand the scope of the claims, a reference is made to the granted claims of the complete specification. Claim 1 of the Suit Patent, that discloses the compound of formula (I), which is the basic structure of the species claimed in the Suit Patent, is reproduced as under:

We Claim

1. A compound of formula (I)



(I)

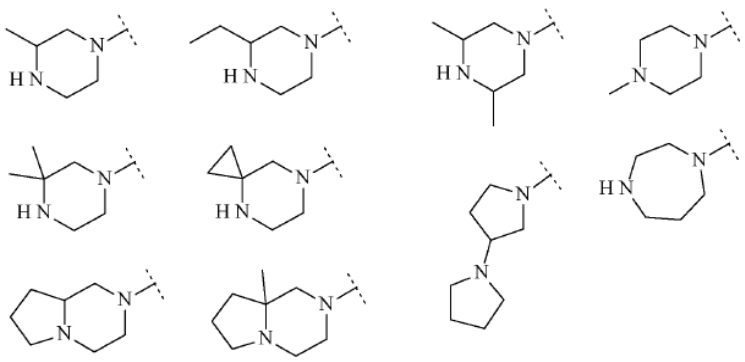
wherein

R^1 is C_{1-7}-alkyl;

R^2 is hydrogen or C_{1-7}-alkyl;

R^3 is hydrogen or C_{1-7}-alkyl;

A is selected from the group of:



and pharmaceutically acceptable salts thereof.

24. Thus, upon examination of the above, as per the Markush Structure in Claim 1 of the Suit Patent, the following is manifest:

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[12] ***2024 SCC OnLine Del 2497***

24.1 '$R^{1'}$ could be alkyl groups that contain between one and seven carbon atoms (C_{1-7}).

24.2 '$R^{2'}$ could be Hydrogen or alkyl group with $C_{1-7.}$

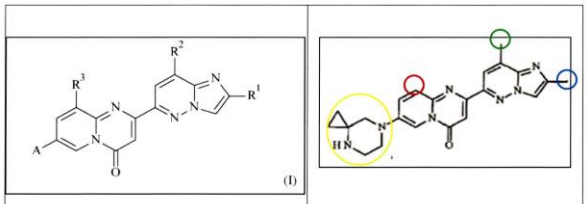
24.3 '$R^{3'}$ could be Hydrogen or alkyl group with $C_{1-7.}$

24.4 'A' could be a heterocyclic compound containing Nitrogen.

25. From the Markush Claim 1 of the Suit Patent and the substitutions proposed in the dependent claims, the derivation of Risdiplam, as per the plaint, is reproduced here under for clarity:

"xxx xxx xxx

23. Risdiplam can be derived from the Markush claim 1 as follows:



(I)

Markush structure in Claim 1

- R^1 is methyl CH_3 (Claim 1 and 2) in blue
- R^2 is methyl CH_3 (Claim 1 and Claim 3) in green
- R^3 is Hydrogen H (Claim 1 and Claim 4) in red

Structure of Risdiplam

- A is  (Claim 5) in yellow

xxx xxx xxx"

26. From the claims asserted by the plaintiffs in the Suit Patent and the illustrations given therein, especially, Example *Compound 20*, it is the categorical case of the plaintiffs that the compound Risdiplam is explicitly disclosed and covered in the Suit Patent.

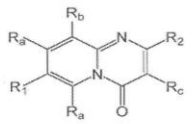
27. It is relevant to note that the plaintiffs have a Species Patent, i.e., US'754, in US, corresponding to the Suit Patent. Further, it is to be noted that prior to the aforesaid US Species Patent, US'754, the plaintiffs have

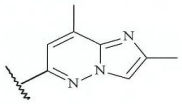
also obtained a Genus Patent, i.e., US'955, in US, which corresponds to the International Genus Patent, WO'916. This International Genus Patent of the plaintiffs published internationally as WO'916, has been cited as prior art by the defendant. The defendant has challenged the validity of the Suit Patent, which is a species patent, *inter alia* on the basis of anticipation of Risdiplam compound by prior publication in the International Genus Patent.

28. Therefore, the moot question is whether Risdiplam is explicitly or implicitly disclosed in the International Genus Patent, which has been cited as prior publication/prior art, by the defendant.

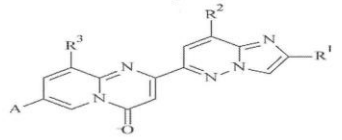
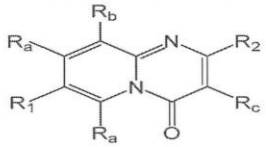
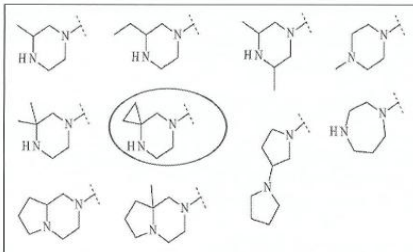
29. In this regard, it would be apposite to refer to the submissions made in the written statement filed on behalf of the defendant, with respect to the compound of formula (I) being disclosed in the International Genus Patent, wherein, it has been stated as follows:

> *"xxx xxx xxx*
>
> *34. The subject matter of the Suit Patent relates to a compound of formula (I), and methods for their preparation. It is submitted that* ***WO '916 Patent (D1)*** *discloses in para [00959] a compound of Formula-(IIa1);*

[00959] An embodiment of the use of the compound of Formula (IIa) is the use of the compound of Formula (IIa1):  (IIa1)
R_1 is heterocyclyl, wherein, heterocyclyl is optionally substituted with one, two or three R_3 substituents and optionally, with one additional R_4 substituent or,

wherein, heterocyclyl is optionally, substituted with one, two or three or four R_3 substituents;	
R_2 is heteroaryl wherein, heteroaryl is optionally substituted with one, two or three **R_6** substituents and optionally, with one additional R_7 substituent;	
Reference: Page No: 37 and 38, paragraph [00215] of WO '916 (D1). **R_2 is** heteroaryl selected from thienyl, IH-pyrazolyl, IH-imidazolyl, 1,3-thiazolyl, 1,2,4-oxadiazolyl, 1,3,4-oxadiazolyl, pyridinyl, pyrimidinyl, lH-indolyl, 2H-indolyl, lH-indazolyl, 2H-indazolyl, indolizinyl, benzofuranyl, benzothienyl, 1H-benzimidazolyl, 1,3-benzothiazolyl, 1,3-benzoxazolyl, 9H-purinyl, furo [3,2-b]pyridinyl, furo [3,2-c]pyridinyl, furo [2,3 -c]pyridinyl, thieno[3,2-c]pyridinyl, thieno[2,3-d] pyrimidinyl, 1H-pyrrolo[2,3-¾]pyridinyl, 1H-pyrrolo[2,3-c]pyridinyl, pyrrolo[1,2-a]pyrimidinyl, pyrrolo[l,2-a]pyrazinyl, pyrrolo[1,2-b]pyridazinyl, pyrazolo[1,5-a]pyridinyl, pyrazolo[1,5-a]pyrazinyl, imidazo[1,2-a]pyridinyl, imidazo[1,2-a]pyrimidiny 1, imidazo [1,2-c]pyrimidinyl, **imidazo[1,2-b]pyridazinyl**, imidazo[1,2-a]pyrazinyl, imidazo[2, 1 -b] [1 ,3]thiazolyl,	
imidazo[2,l-£][l,3,4]thiadiazolyl, [l,3]oxazolo[4,5-£]pyridinyl or quinoxalinyl; wherein, each instance of heteroaryl is optionally substituted with R_6 and R_7 substituents.	
R_6 is, in each instance, independently selected from halogen, hydroxy, cyano, nitro, **C_{1-8}alkyl**, C_{2-8}alkenyl, halo-C_{1-8}alkyl, hydroxy-C_{1-8}alkyl, C_{1-8}alkoxy, halo-C_{1-8}alkoxy, C_{1-8}alkoxy-C_{1-8}alkyl, amino, C_{1-8}alkyl-amino, (C_{1-8}alkyl)$_2$-amino or C_{1-8}alkyl-thio;	C_{1-8} alkyl
R_a is, in each instance, independently selected from **hydrogen**, halogen or C_{1-8}alkyl	Hydrogen
R_b is **hydrogen**	Hydrogen
R_c is hydrogen, halogen or C_{1-8}alkyl	Hydrogen

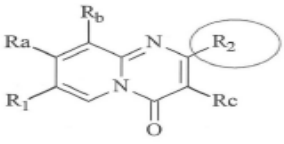
35. The comparison of the compound claimed in the Suit Patent and disclosed in WO '916 Patent is provided below:

IN334397	WO '916 Patent
Claim 1: A compound of formula (I)  (I) wherein R^1 is C_{1-7}-alkyl; R^2 is hydrogen or C_{1-7}-alkyl; R^3 is hydrogen or C_{1-7}-alkyl; A is	 (IIa1) R_1 is Heterocyclyl R_1 is heterocyclyl wherein, heterocyclyl is optionally substituted with one, two or three R_3
	substituents. [The definition covered] R_2 is Heteroaryl Wherein, heteroaryl is optionally substituted with one, two or three **R_6** substituents; R_6 is C_{1-8} alkyl [The definition covered] **Reference: Page No: 37 and 38, paragraph [00215] of WO '916.** **R_2 is** heteroaryl selected from **imidazo[1,2-b]pyridazinyl**; wherein, each instance of heteroaryl is optionally substituted with R_6 and R_7 substituents. R_a is hydrogen; R_b is hydrogen; R_c is hydrogen.

xxx xxx xxx"

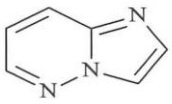
45. …….

g. WO '916 at Page No: 37 and 38, paragraph [00215] discloses Markush structure (IIa1)



(IIa1)

*Wherein **R_2 is heteroaryl selected from imidazo[1,2- b]pyridazinyl**; wherein, each instance of heteroaryl is optionally substituted with R_6 and R_7 substituents.*



Imidazo[1,2-b]pyridazinyl

In view of the above, the core structure having an imidazo[1,2-b]pyridazine-2-yl-pyrido [1,2-a] pyrimidine of formula (I) is also clearly disclosed in WO '916 (prior art).

xxx xxx xxx"

30. Thus, it is the case of the defendant that the core structure of the compound of formula (I) in the Suit Patent is disclosed in the International Genus Patent under the compound of formula (IIa1). As per the defendant, the compounds of formula, as claimed in Claim 1 of the Suit Patent, IN'397, i.e., Risdiplam, is disclosed in the International Genus Patent, from the teachings as contained in the complete specification of the International Genus Patent.

31. On the aspect of disclosure, this Court notes the stand of the plaintiffs, as given in its rejoinder to the reply of the defendant to the interim application, wherein, it has been stated as follows:

"xxx xxx xxx

126. .....

***The genus patent claims a genus of compounds to which Risdiplam belongs, but does not specifically claim Risdiplam, nor does the specification of the genus patent specifically disclose Risdiplam**. …….*

xxx xxx xxx"

(Emphasis Supplied)

32. Reading of the aforesaid clearly shows that it is the categorical stand of the plaintiffs that the International Genus Patent does not specifically disclose Risdiplam, while the International Genus Patent claims a genus of compounds to which the Risdiplam belongs. Thus, it is an admitted position that the International Genus Patent and the Species Patent relate to the very

same product, namely, Risdiplam. In this background, the question arises as to the gap between the coverage and disclosure.

33. On this aspect, it would be fruitful to refer to the judgment of the Supreme Court in the case of ***Novartis AG Versus Union of India and Others***[13], wherein, the Supreme Court, has held as follows:

> *"xxx xxx xxx*
>
> ***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****.*
>
> *xxx xxx xxx*
>
> ***124.*** *Chisum on Patents: A Treatise on the Law of Patentability, Validity, and Infringement (Vol. 3-6-2007) in chapter "Adequate Disclosure" notes:*
>
> > *"§ 7.03. — The enablement requirement*
> >
> > ***Since 1790, the patent laws have required that the inventor set forth in a patent specification sufficient information to enable a person skilled in the relevant art to make and use the invention****.*
> >
> > *The 'invention' that must be enabled is that defined by the particular claim or claims of the patent or patent application. This is consistent with the general principle of patent law that the claim defines the invention for purposes of both patentability and infringement."*
>
> *xxx xxx xxx*
>
> ***134.*** *However, before leaving Hogan [Hogan, In re, 559 F 2d 595 (CCPA 1977)] 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***

[13] ***(2013) 6 SCC 1***

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.*

xxx xxx xxx"

(Emphasis Supplied)

34. It is established law that disclosure can be either explicit or implicit/inherent in nature. The concept of implicit/inherent disclosure is now a widely settled principle, both in India and internationally. Reference may be made to judgment of this Court in the case of ***Bayer Healthcare LLC Versus NATCO Pharma Limited***[14], wherein, it has been considered as follows:

> *"xxx xxx xxx*
>
> *63. In the Manual of Patent Office Practice and Procedure, published by the office of the Controller General of Patents Design and Trademarks, it is stated that a generic disclosure in the prior art may not necessarily take away the novelty in a specific disclosure. The onus of proving that the 'applied for' patent is not anticipated by prior art is on the applicant. In its 'Guidelines For Examination of Patent Applications in the Field of Pharmaceuticals', it is stated as under:*
>
> > *"1. Often broad (generic) patent claims are drafted covering a family of a large number (sometimes thousands or millions) of possible compounds. The so-called 'Markush claims' refer to a chemical structure with plurality of functionally equivalent chemical groups in one or more parts of the Compound. The Markush claims are drafted to obtain a wide scope of protection encompassing a large number of compounds whose properties might not have-been tested, but only theoretically inferred from the equivalence with other compounds within the claim. Quite often the Markush claims generate confusion regarding the novelty, non-obviousness and industrial applicability of a group of*

[14] ***2023 SCC OnLine Del 3921***

compounds covered within the sald Markush formula. Also, the Markush claims may invoke the question of sufficiency and plurality of distinct group of inventions surrounding such claims."

64. It further states that in case of Markush formulae, it is to be checked from the prior art whether compounds disclosed specifically in the prior are of such structure so that they can unambiguously take away the novelty of the compound(s) in the subsequent patent. If the compounds of prior art disclosed specifically do not take away the novelty of the compounds in question, then the generic disclosure in the prior art may still be cited for the purpose of inventive step.

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

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

necessary that inherent anticipation requires that a person of ordinary skill in the art at the time would have recognized the inherent disclosure. But it is necessary that the result is a necessary consequence of what was deliberately intended in the invention"."

xxx xxx xxx"

(Emphasis Supplied)

35. Similarly in ***Schering Corporation Versus Geneva Pharmaceuticals, INC. & Others***[15], United States Court of Appeals, Federal Circuit, has dealt the same principle in detail. The relevant extract from the judgement is reproduced here below:

"xxx xxx xxx

[5] This court recognizes that this may be a case of first impression, because the prior art supplies no express description of any part of the claimed subject matter. The prior art '233 patent does not disclose any compound that is identifiable as DCL. In this court's prior inherency cases, a single prior art reference generally contained an incomplete description of the anticipatory subject matter, i.e., a partial description missing certain aspects. Inherency ****1379*** *supplied the missing aspect of the description. Upon proof that the missing description is inherent in the prior art, that single prior art reference placed the claimed subject matter in the public domain. This case does not present the issue of a missing feature of the claimed invention. Rather, the new structure in this case, DCL, is not described by the prior '233 patent.*

Patent law nonetheless establishes that a prior art reference which expressly or inherently contains each and every limitation of the claimed subject matter anticipates and invalidates. *See, e.g., EMI Group N. Am., Inc., v. Cypress Semiconductor Corp., 268 F.3d 1342, 1350 (Fed.Cir.2001) ("A prior art reference anticipates a patent claim if the reference discloses, either expressly or inherently, all of the limitations of the claim."); Verdegaal Bros., Inc. v. Union Oil Co. of Cal., 814 F.2d 628, 631 (Fed.Cir.1987) ("A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.").* ***In these prior cases, however, inherency was only necessary to supply a single missing limitation that was not expressly disclosed in the prior art. This case, as explained before,***

[15] ***339 F.3d 1373 (2003)***

asks this court to find anticipation when the entire structure of the claimed subject matter is inherent in the prior art.

Because inherency places subject matter in the public domain as well as an express disclosure, the inherent disclosure of the entire claimed subject matter anticipates as well as inherent disclosure of a single feature of the claimed subject matter. The extent of the inherent disclosure does not limit its anticipatory effect. In general, a limitation or the entire invention is inherent and in the public domain if it is the "natural result flowing from" the explicit disclosure of the prior art. *See Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 970 (Fed.Cir.2001); see also In re Kratz, 592 F.2d 1169, 1174 (CCPA 1979) (suggesting inherent anticipation of a compound even though the compound's existence was not known).*

In reaching this conclusion, this court is aware of In re Seaborg, 51 C.C.P.A. 1109, 328 F.2d 996 (CCPA 1964). In that case, this court's predecessor considered claims drawn to an isotope of americium made by nuclear reaction in light of a prior art patent disclosing a similar nuclear reaction process but with no disclosure of the claimed isotope. The court reversed a United States Patent and Trademark Office rejection of the claims for lack of novelty. This court's predecessor found that the prior art process did not anticipate the claims because the process would have produced at most one billionth of a gram of the isotope in forty tons of radioactive material, i.e., the isotope would have been undetectable. Id. at 998–99 ("[T]he claimed product, if it was produced in the Fermi process, was produced in such minuscule amounts and under such conditions that its presence was undetectable."). In this case, DCL forms in readily detectable amounts as shown by the extensive record evidence of testing done on humans to verify the formation of DCL upon ingestion of loratadine.

[6]. ***This court sees no reason to modify the general rule for inherent anticipation in a case where inherency supplies the entire anticipatory subject matter. The patent law principle "that which would literally infringe if later in time anticipates if earlier," Bristol–Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1378 (Fed.Cir.2001), bolsters this conclusion.***

*Similarly, "if granting patent protection on the disputed claim would allow the patentee to exclude the public from practicing the prior art, then that claim is anticipated." Atlas Powder, 190 F.3d at 1346. "****The *1380 public remains free to make, use, or sell prior art compositions or processes, regardless of whether or not they understand their complete makeup or the underlying scientific principles which allow them to operate. The doctrine of anticipation by inherency, among other doctrines, enforces that basic principle."***

Id. at 1348. ***Thus, inherency operates to anticipate entire inventions as well as single limitations within an invention.***

Turning to this case, the use of loratadine would infringe claims 1 and 3 of the '716 patent covering the metabolite DCL. This court has recognized that a person may infringe a claim to a metabolite if the person ingests a compound that metabolizes to form the metabolite. See Hoechst–Roussel Pharms., Inc. v. Lehman, 109 F.3d 756, 759 (Fed.Cir.1997) ("[T]he right to exclude may arise from the fact that when administered, [the accused product] metabolizes into another product ... which Hoechst has claimed."); see also Zenith Labs., Inc. v. Bristol–Myers Squibb Co., 19 F.3d 1418, 1421– 22 (Fed.Cir.1994) (stating that a compound claim could cover a compound formed upon ingestion). An identical metabolite must then anticipate if earlier in time than the claimed compound.

The record shows that the metabolite of the prior art loratadine is the same compound as the claimed invention. Claims 1 and 3 are compound claims in which individual compounds are claimed in the alternative in Markush format. DCL is within the scope of claims 1 and 3. Because the prior art metabolite inherently disclosed DCL, claims 1 and 3 are anticipated and invalid. In other words, the record shows that a patient ingesting loratadine would necessarily metabolize that compound to DCL. That later act would thus infringe claims 1 and 3. Thus, a prior art reference showing administration of loratadine to a patient anticipates claims 1 and 3.

C.

This court next examines whether Schering's secret tests of loratadine before the critical date placed DCL in the public domain. Before the critical date, Schering only tested loratadine in secret. Thus, according to Schering, "DCL was not publicly used, or described in any printed publication, until after February 15, 1983, the critical date for the '716 patent under 35 U.S.C. § 102(b)." Schering thus argues that DCL did not "exist" in the public domain such that DCL could be prior art against the '716 patent.

[7] ***Anticipation does not require the actual creation or reduction to practice of the prior art subject matter; anticipation requires only an enabling disclosure.*** *In re Donohue, 766 F.2d 531, 533 (Fed.Cir.1985). Thus, actual administration of loratadine to patients before the critical date of the '716 patent is irrelevant. The '233 patent suffices as an anticipatory prior art reference if it discloses in an enabling manner the administration of loratadine to patients.*

[8] Thus, this court examines whether the '233 patent contains an enabling disclosure of DCL. ***A reference may enable one of skill in the art to make and use a compound even if the author or inventor did not actually make or reduce to practice that subject matter.***

Bristol–Myers, 246 F.3d at 1379; see also In re Donohue, 766 F.2d at 533 (sustaining an anticipation rejection over a reference disclosing a compound and other references disclosing sufficient information to make that compound). ***Indeed, information arising after the critical date may show that the claimed subject matter, as disclosed in a prior art reference, "was in the public's possession."*** *Bristol– Myers, 246 F.3d at 1379 (citing In re Donohue, 766 F.2d at 534).*

.....

xxx xxx xxx"

(Emphasis Supplied)

36. Accordingly, it is evident that as per law of the land, disclosure can be implicit/ inherent, and there is no stringent rule that it ought to be explicit in nature. Thus, if from the prior art, it can be inferred that there is disclosure, though implicit/ inherent, that would be a valid ground for challenging the validity of a patent.

37. It is also pertinent to mention here that the plaintiffs have filed a suit for infringement against the defendant herein, in US, alleging infringement by the defendant of the US Genus Patent, US'955, on the ground that the defendant is planning to launch Risdiplam, which infringes the said Genus Patent. Thus, by plaintiffs' own showing, Risdiplam is disclosed in the US Genus Patent, US'955 *(Corresponding Patent to the International Genus Patent, WO'916)* and the right of the plaintiffs in the said Genus Patent is capable of being enforced with respect to claims of infringement towards the compound Risdiplam. The plaintiffs on account of this fact, cannot as per convenience, agitate their claims in different jurisdictions for different patents of the same family, and thereafter assert non-disclosure of Risdiplam in the International Genus Patent, when it comes to the Suit Patent.

38. In this regard, reference may be made to the judgment of this Court in the case of ***Astrazeneca AB and Others Versus P. Kumar and Another***[16],

[16] ***2019 SCC OnLine Del 9555***

wherein, it has been held as follows:

> *"xxx xxx xxx*
>
> ***72.*** *As noted above, the facts here show that the plaintiffs have been showing working of IN 229 through TICAGRELOR to the Controller of Patents while filing Form 27.* ***The plaintiffs have filed proceedings for breach of IN 229 when the drug in question was TICAGRELOR in USA. These are important facts which have a material bearing on the issue as to whether TICAGRELOR is disclosed in IN 229 and is known and anticipated****. The plaintiffs were obliged to have revealed the full facts in the plaint. This is especially so, keeping in view the fact that Micro Labs Ltd. had already filed an application for revocation of the suit patents before IPAB in 2015 where various grounds were urged including the fact that the suit patents are disclosed and covered in IN 229. The said petition clearly states that the compounds as disclosed in IN 907 and IN 984 are known and anticipated in light of IN 229 and could have been developed by a person skilled in the art. There is clear omission of the plaintiff to mention these materials and important facts in the plaint.*
>
> ***73.*** *The above facts, in my opinion, show that the claim of the plaintiff that TICAGRELOR is not disclosed in IN 229 and is not anticipated is subject to a strong challenge by the defendant.* ***This is so on account of the admissions which prima facie the plaintiff have not been able to explain properly****. This is also shown on account of the conduct of the plaintiff as noted above.*
>
> *xxx xxx xxx"*
>
> *(Emphasis Supplied)*

39. Likewise, the Division Bench of this Court in the case of ***Astrazeneca AB and Another Versus Intas Pharmaceutical Ltd.***[17], has held that when a party has pleaded infringement of its genus patent, while claiming a species patent, at the stage of consideration of interim application, the same has to be treated as an admission that the invention in question was known while obtaining the genus patent. Thus, it has been held as follows:

> *"xxx xxx xxx*
>
> ***21.*** ***In our opinion, with respect to one invention, there can be only one patent. The appellants/plaintiffs herein however, while claiming one invention only i.e. DAPA, are claiming two patents with respect thereto,***

[17] ***2021 SCC OnLine Del 3746***

with infringement of both, by the respondent(s)/defendant(s). The same alone, in our view, strikes at the very root of the claim of the appellants/plaintiffs and disentitles the appellants/plaintiffs from any interim relief*.*

xxx xxx xxx"

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

xxx xxx xxx

39. *Rather, according to the arguments of the counsel for the appellants/plaintiffs, IN 147 was with respect to mere discovery of a scientific principle or formulation of an abstract theory or was a mere presentation of information and qua which under Sections 3(c) and 3(n) respectively, no patent could be granted. However, not only was the patent obtained but also infringement thereof claimed in the suits from which these appeals arise, admitting DAPA to be the new product subject matter of IN 147. If IN 147 did not disclose DAPA and specifications thereof did not describe DAPA or the best method of industrially manufacturing DAPA, there could be no infringement of IN 147 from the action of the respondent(s)/defendant(s) making and selling medicines/drugs with DAPA as ingredient thereof. The provisions afore noticed of the Patents Act, in our view, do not permit a patent to be granted with respect to the important stage in the inventive process and at which stage there is no product capable of industrial application, even if having technical advancement as compared to the existing knowledge.* ***The appellants/plaintiffs on the other hand, as aforesaid, not only claimed patent IN 147 at the "breakthrough" stage, when according to them DAPA was not even known but even after obtaining patent IN 625 with respect to DAPA, by suing the respondent(s)/defendant(s) have pleaded infringement of IN 147 also. At least at this stage the same has to be treated as an admission of DAPA being known while obtaining IN 147****.*

xxx xxx xxx

46. ***In our opinion, a single formulation as DAPA, is incapable of protection under two separate patents having separate validity period. The appellants/plaintiffs, in their pleadings, are not found to have pleaded the difference, save for pleading that DAPA was discovered by further research. From the field of the invention subject matter of the***

two patents being verbatim same, at this stage, it also appears that there is no enhancement of the known efficacy, within the meaning of Section 3(d) of the Act, between the product subject matter of IN 147 and the product subject matter of IN 625.

47. *To hold, that an inventor, merely on the basis of his work, research, discovery and prior art, but which has not yielded any product capable of commercial exploitation, is entitled, by obtaining patent thereof, to restrain others from researching in the same field, would in our view, not be conducive to research and development and would also be violative of the fundamental duties of the citizens of this country, enshrined in Article 51A of the Constitution of India, to develop the scientific temper and a spirit of inquiry. The same will enable busy bodies to, by walking only part of the mile, prevent others also from completing the mile.*

xxx xxx xxx"

(Emphasis Supplied)

40. Another important factor that bears consideration by this Court is the fact that at least four lead inventors are common to the International Genus Patent and the Suit Patent, which is the Indian Species Patent. Reference may be made to the details of the inventors of the Suit Patent and the International Genus Patent, which is reproduced, herein under:

	International Genus Patent – WO'916	***Suit Patent – IN'397***
Inventors	***Ratni Hasane; Green Luke;*** ***Naryshkin Nikolai;*** ***Weetall Maria L;*** *Qi Hongyan;* *Choi Soongyu;* *Dakka Amal;* *Karp Gary Mitchell;* *Narasimhan Jana;* *Turpoff Anthony A;* *Welch Ellen;* *Woll Matthew G;* *Yang Tianle;* *Zhang Nanjing;* *Zhang Xiaoyan;* *Zhao Xin;* *Pinard Emmanuel*	***Ratni, Hasane; Green, Luke;*** ***Naryshkin, Nikolai A;*** ***Weetall, Maria L.***

41. In this regard, the Division Bench in the case of ***Astrazeneca AB Versus Intas Pharmaceutical Limited (DB)***[18], has held as follows:

> *"xxx xxx xxx*
>
> ***29. It cannot be lost sight of, that the inventor of both, IN 147 and IN 625 and/or of US equivalents thereof was/is the same. The said inventor, as compared to a third person, was best placed to know the inventive step i.e. technical advancement in the invention subject matter of IN 625, over that of the earlier invention subject matter of IN 147. However, in the description of field of invention of IN 625, neither any technical advancement or difference in efficacy of the new products subject matter thereof over the product subject matter of IN 147 is mentioned nor any economic significance of the new invention claimed. Once the inventor himself, while writing and seeking the patent, has not mentioned so, the subsequent claims of the assignee of the patent, in this regard, at least at the stage of judging prima facie case, cannot be accepted and have to be necessarily put to trial.***
>
> ***30. The tests of "obvious to a person skilled in the art" and "anticipation by publication" and "use before the date of filing of patent application with complete specification", in the context of an earlier patent and its specifications, in our view, have to be different, when the inventor of both is the same. The counsel for the appellants/plaintiffs has argued, that owing to delays in obtaining approvals of Drug Regulators in different jurisdictions, for marketing of a new drug/medicine, after obtaining patent with respect thereto, results in the inventor/patentee being not able to enjoy the exclusivity granted under the Patent Laws to the inventor/patentee, for the full term of the patent. However merely because there are such delays, would not be a reason for the Court to give to the patent a longer life than provided in the statute.*** *The cure therefore is with the Legislature and not with the Courts, by allowing more than one patent with respect to the same invention. The said argument of the counsel for the appellants/plaintiffs has however made us suspicious, that the appellants/plaintiffs, though invented DAPA at the time of seeking IN 147 and/or US equivalent thereof, though 'covered' it therein (to prevent others from inventing it) but intentionally did not disclose it, to subsequently claim patent with respect thereto, and in the interregnum obtain approvals of the Drug Regulators.* ***When the inventor is the same, the tests aforesaid, in our opinion, cannot be in the context of***

[18] ***2021 SCC OnLine Del 3746***

"person ordinarily skilled in the art" but have to be of the "person in the know". The enquiry, in such a situation, has to be guided by, whether the inventor, while writing first patent, knew of the invention claimed in the subsequent patent*.*

31. The Patents Act, though protects the rights and interests of inventors, but for a limited period, whereafter the monopoly of the patentee ceases and comes to an end and the invention with respect to which patent was granted, falls in public domain i.e. open for all to practice and reap benefit of. *A patent, vide Section 48 of the Act, confers a right on the patentee of a product patent, as DAPA is, to, during the life of the patent, prevent others from making, using, offering for sale, selling or importing, the new product with respect whereto patent is granted. The life of a patent is limited, whereafter, notwithstanding the new product having been invented by the patentee, patentee no longer has exclusive right to make, use or offer for sale the same and anyone else interested can also make, use or offer for sale the said new product invented by the patentee, without any interference from the patentee. If patents with respect to the same invention can be granted more than once, successively in time, the same will negate the legislative intent of limiting the life of the patent and enable the patentee to prevent others from making, using or offering for sale, the new product invented by the patentee, till the time patentee successively keeps on obtaining patent therefore.*

xxx xxx xxx"

(Emphasis Supplied)

42. It is pertinent to note that the Supreme Court, *vide* order dated 19th July, 2022, refused to interfere in the aforesaid judgment of this Court, in ***Special Leave to Appeal (c) Nos. 15650-15658/2021***, ***Astrazeneca AB & Anr. Versus Intas Pharmaceutical Limited***.

43. Accordingly, in cases where all or some of the inventors are common, the test while considering *'anticipation by publication'*, would be from point of view of *'person in the know'*, and not in the context of *'person ordinarily skilled in the art'*. As noted above, all the four inventors of the Suit Patent, are also the inventors of the International Genus Patent, besides the other inventors of the International Genus Patent. Therefore, this aspect becomes

pertinent for the purposes of considering an application, wherein an interim relief is sought.

a. *Statements Made in Foreign Jurisdictions:*

44. Another important point highlighted during the course of arguments is with regard to the various statements made on behalf of the plaintiffs in foreign jurisdictions, wherein, the plaintiffs have made categorical admissions that the International Genus Patent not only covers the product, Evrysdi, i.e., Risdiplam, but is also generically disclosed in the Genus Patent. Thus, it becomes manifest that on the one hand the plaintiffs have argued that despite coverage of Risdiplam by International Genus Patent, the product was first discovered and specifically disclosed only in the Species Patent, and on the other hand, the plaintiffs have secured PTEs for Genus Patents in almost every major jurisdiction, such as US and Australia, on the strength of express statements that Evrysdi, i.e., Risdiplam, is the specific commercial product whose discovery and regulatory approval is directly traceable to the respective Genus Patents. The factual admissions made by the plaintiffs in relation to the PTE applications for Genus Patent in US and Australia, reveal the position taken by the patentee itself that the discovery and development of Risdiplam, was traceable to the US Genus Patent, US'955, and consequently the International Genus Patent, i.e., WO'916.

45. Reference in this regard may be made to the PTE application dated 02nd October, 2020, made by the plaintiffs for the US Genus Patent, i.e., US'955, wherein, it has been stated as follows:

> *"xxx xxx xxx*

Docket No.: 14639-20516.30

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of: Hongyan Qi *et al.*

Patent No.: 9,586,955

Issued: March 7, 2017

Application No: 14/377,531

For: COMPOUNDS FOR TREATING SPINAL MUSCULAR ATROPHY – Application for § 156 Patent Term Extension

Attorney Docket No: 14639-20516.30

Assignees: PTC Therapeutics Inc.; Hoffmann-La Roche Inc.

Unit: Office of Patent Legal Administration

Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PATENT TERM EXTENSION APPLICATION UNDER 35 U.S.C. § 156

Dear Commissioner:

Applicant, Genentech, Inc., as an agent of patent owners PTC Therapeutics Inc. and Hoffmann-La Roche Inc. hereby submits this application for extension of the term of United States Letters Patent No. 9,586,955 ("the '955 patent") under 35 U.S.C. § 156 by providing the following information in accordance with the requirements specified in 37 C.F.R. § 1.740.[1]

[1] This submission is made via a USPTO patent electronic filing system in accordance with the Notice by Director Andrei Iancu dated May 29, 2020 entitled "Relief Available to Patentees in View of the COVID-19 Outbreak for Submission of Initial Patent Term Extension Applications Filed Pursuance to 35 U.S.C. 156", by which the USPTO has permitted the filing of initial patent term extension applications pursuant to 35 U.S.C. 156 via the USPTO patent electronic filing

A statement executed by an authorized representative of PTC Therapeutics Inc. attesting that Genentech, Inc. is authorized to act as an agent of PTC Therapeutics Inc. for extension of the term of the '955 patent under 35 U.S.C. § 156 is included as Attachment A.[2] A statement executed by an authorized representative of Hoffmann-La Roche Inc. attesting that Genentech, Inc. is authorized to act as an agent of Hoffmann-La Roche Inc. for extension of the term of the '955 patent under 35 U.S.C. § 156 is included as Attachment B.[3]

Applicant, on behalf of the patent owners PTC Therapeutics Inc. and Hoffmann-La Roche Inc., represents that PTC Therapeutics Inc. and Hoffmann-La Roche Inc. are the assignees of the entire interest in and to the '955 patent granted to Hongyan Qi, Soongyu Choi, Amal Dakka, Gary Mitchell Karp, Jana Narasimhan, Nikolai Naryshkin, Anthony A. Turpoff, Marla L. Weetall, Ellen Welch, Matthew G. Woll, Tianle Yang, Nanjing Zhang, Xiaoyan Zhang, Xin Zhao, Luke Green, Emmanuel Pinard, and Hasane Ratni by virtue of assignments from such inventors to PTC Therapeutics Inc. and F. Hoffmann-La Roche AG as evidenced by assignments at reel frame 035052/0249 and 035052/0611 and subsequent transfer from F. Hoffmann-La Roche AG to Hoffman-La Roche Inc., copies of which are provided in Attachment C.

1. Identification of the Approved Product [§ 1.740(a)(1)]

The name of the approved product is Evrysdi™. The chemical name of the active ingredient of Evrysdi is 7-(4,7-diazaspiro[2.5]octan-7-yl)-2-(2,8 dimethylimidazo[1,2-b]pyridazin-6-yl)pyrido-4H-[1,2-a]pyrimidin-4-one, which has a molecular formula of $C_{22}H_{23}N_7O$ and a molecular weight of 401.46 g/mol. Section 11 of Product Label, provided as Attachment D. The active ingredient of Evrysdi is also known as risdiplam or RO7034067. Attachment G.

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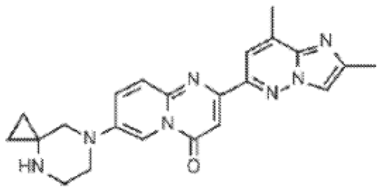
systems until further notice. No further notice withdrawing the May 29, 2020 Notice has been made. This submission, dated October 2, 2020, is therefore entitled to the relief set forth in the May 29, 2020 Notice and is submitted in conformity therewith.

[2] Attachment A also provides the practitioners associated with customer number 25226 Power of Attorney-in-Fact to file and prosecute this application for patent term extension. Attachment A also includes a Statement under 3.73(c).

[3] Attachment B also provides the practitioners associated with customer number 25226 Power of Attorney-in-Fact to file and prosecute this application for patent term extension. Attachment B also includes a Statement under 3.73(c).

Application for Patent Term Extension
Patent No.: 9,586,955 Docket No.: 14639-20516.30

The chemical structure of the active ingredient of Evrysdi is:



Section 11 of the Product Label, provided as Attachment D.

2. Federal Statute Governing Regulatory Approval of the Approved Product [§ 1.740(a)(2)]

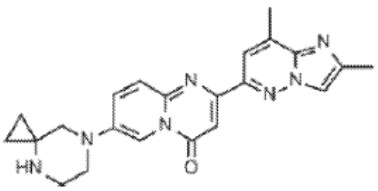
The approved product was subject to regulatory review under, *inter alia*, §§ 505(i) and (b) of the Federal Food, Drug and Cosmetic Act codified at 21 U.S.C. §§ 355(i) and (b).

3. Date of Approval for Commercial Marketing [§ 1.740(a)(3)]

Evrysdi was approved for commercial marketing or use under § 505(b) of the Federal Food, Drug and Cosmetic Act on August 7, 2020. Attachment I.

4. Identification of Active Ingredient and Certifications Related to Commercial Marketing of Approved Product [§ 1.740(a)(4)]

(a) The chemical name of the active ingredient of Evrysdi is 7-(4,7-diazaspiro[2.5]octan-7-yl)-2-(2,8 dimethylimidazo[1,2-b]pyridazin-6-yl)pyrido-4H-[1,2-a]pyrimidin-4-one, which has a molecular formula of $C_{22}H_{23}N_7O$ and a molecular weight of 401.46 g/mol. Section 11 of Product Label, provided as Attachment D. The chemical structure of the active ingredient of Evrysdi is:



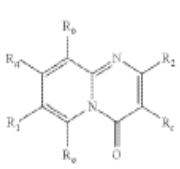
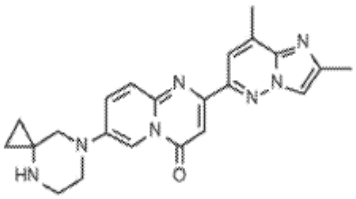
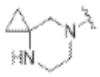
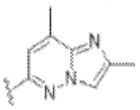
(b) Applicant certifies that the active ingredient of Evrysdi had not been approved for commercial marketing or use under the Federal Food, Drug and Cosmetic Act, the Public Health Service Act or the Virus-Serum-Toxin Act prior to the approval

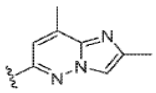
sf-4332736

xxx xxx xxx"

9. …….

The table below demonstrates how claim l of the '955 patent reads on the active ingredient of Evrysdi, which is depicted in the right hand column of the table. For convenience, the individual moieties of the active ingredient of Evrysdi as covered by claim 1 of the '955 patent are individually depicted in the table below, together with a brief explanation describing how such moieties are covered by claim 1.

Claim 1	Active Ingredient of Evrysdi
A compound of Formula (IIa1):  (IIa1) or a form thereof, wherein:	
R_1 is heterocyclyl; wherein, heterocyclyl is optionally substituted with one, two or three R_3 substituents and optionally, with one additional R_4 substituent; or, wherein, heterocyclyl is optionally substituted with one, two, three or four R_3 substituents;	R_1 is heterocyclyl; 
R_2 is heteroaryl; wherein, heteroaryl is optionally substituted with one, two or three R_6 substituents and optionally, with one additional R_7 substituent;	R_2 is heteroaryl substituted with two R_6 substituents; 
R_a is, in each instance, independently selected from hydrogen, halogen or C_{1-8}alkyl;	R_a is hydrogen;
R_b is hydrogen, halogen, C_{1-8}alkyl or C_{1-8}alkoxy;	R_b is hydrogen;
R_c is hydrogen, halogen or C_{1-8}alkyl;	R_c is hydrogen;
R_3 is, in each instance, independently selected from cyano, halogen, hydroxy, oxo, C_{1-8}alkyl, halo-C_{1-8}alkyl, C_{1-8}alkyl-carbonyl, C_{1-8}alkoxy, halo-C_{1-8}alkoxy, C_{1-8}alkoxy-C_{1-8}alkyl, C_{1-8}alkoxy-carbonyl, amino, C_{1-8}alkyl-amino, $(C_{1-8}alkyl)_2$-amino, amino-C_{1-8}alkyl, C_{1-8}alkyl-amino-C_{1-8}alkyl, $(C_{1-8}alkyl)_2$-amino-C_{1-8}alkyl, amino-C_{1-8}alkyl-amino, C_{1-8}alkyl-amino-C_{1-8}alkyl-amino, $(C_{1-8}alkyl$-amino-$C_{1-8}alkyl)_2$-amino, $(C_{1-8}alkyl)_2$-amino-C_{1-8}alkyl-amino, $[(C_{1-8}alkyl)_2$-amino-$C_{1-8}alkyl]_2$-amino, (C_{1-	N/A

8alkyl-amino-C1-8alkyl)(C1-8alkyl)amino, [(C1-8alkyl)2-amino-C1-8alkyl](C1-8alkyl)amino, C1-8alkoxy-C1-8alkyl-amino, (C1-8alkoxy-C1-8alkyl)2-amino, (C1-8alkoxy-C1-8alkyl)(C1-8alkyl)amino, C1-8alkyl-carbonyl-amino, C1-8alkoxy-carbonyl-amino, hydroxy-C1-8alkyl, hydroxy-C1-8alkoxy-C1-8alkyl, hydroxy-C1-8alkyl-amino, (hydroxy-C1-8alkyl)2-amino or (hydroxy-C1-8alkyl)(C1-8alkyl)amino;	
R4 is C3-14cycloalkyl, C3-14cycloalkyl-C1-8alkyl, C3-14cycloalkyl-amino, aryl-C1-8alkyl, aryl-C1-8alkoxy-carbonyl, aryl-sulfonyloxy-C1-8 alkyl, heterocyclyl or heterocyclyl-C1-8alkyl; wherein, each instance of C3-14cycloalkyl, aryl and heterocyclyl is optionally substituted with one, two or three R5 substituents;	N/A
R5 is, in each instance, independently selected from halogen, hydroxy, cyano, nitro, C1-8alkyl, halo-C1-8alkyl, C1-8alkoxy, halo-C1-8alkoxy, amino, C1-8alkyl-amino, (C1-8alkyl)2-amino or C1-8alkyl-thio;	N/A
R6 is, in each instance, independently selected from halogen, hydroxy, cyano, nitro, C1-8alkyl, C2-8alkenyl, halo-C1-8alkyl, hydroxy-C1-8alkyl, C1-8alkoxy, halo-C1-8alkoxy, C1-8alkoxy-C1-8alkyl, amino, C1-8alkyl-amino, (C1-8alkyl)2-amino or C1-8alkyl-thio; and,	R2 is heteroaryl substituted with two R6 substituents, wherein both R6 substituents are C1-8alkyl; 
R7 is C3-14cycloalkyl, C3-14cycloalkyl-oxy, aryl, heterocyclyl or heteroaryl.	N/A

Therefore, claim 1 reads on the approved product.

xxx xxx xxx"

(Emphasis Supplied)

46. Perusal of the aforesaid shows that the plaintiffs have themselves expressly admitted and demonstrated that the active ingredient of 'Evrysdi', i.e., Risdiplam, is covered and claimed by Claim 1 of US'955, which is equivalent or the counterpart of the International Genus Patent, WO'916. Another aspect which is important in this regard is that on the date of filing of the PTE for the US Genus Patent citing Risdiplam, the US Species Patent, US'754 stood granted as on 15th May, 2018. Despite the same, the plaintiffs filed an application for PTE for the US Genus Patent, citing Risdiplam.

47. Similarly, in the US FDA Orange Book Listing for Risdiplam, the product Risdiplam is categorically claimed for US Genus Patent, US'955, which is equivalent to the International Genus Patent, WO'916. The relevant

portion of the Orange Book is reproduced as under:

Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/)

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Home (index.cfm?resetfields=1) | Back to Product Details

Additional Information about Patents

- Patent information is published on or after the submission date as defined in 21 CFR 314.53(d)(5).
- Patent listings published prior to August 18, 2003, only identify method-of-use claims. The listed patents may include drug substance and/or drug product claims that are not indicated in the listing.
- As of December 5, 2016, an NDA holder submitting information on a patent that claims both the drug substance and the drug product (and is eligible for listing on either basis) is required only to specify that it claims either the drug substance or the drug product. Orange Book users should not rely on an Orange Book patent listing, regardless of when first published, to determine the range of patent claims that may be asserted by an NDA holder or patent owner.

Patent and Exclusivity for: N213535

Product 001
RISDIPLAM (EVRYSDI) FOR SOLUTION 0.75MG/ML

Patent Data

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
001	9586955	02/08/2033	DS	DP			09/03/2020
001	9969754	05/11/2035	DS	DP	U-1943		09/03/2020
001	11534444	10/04/2038			U-1943		01/25/2023
001	11827646	01/25/2036			U-1943		12/14/2023

Exclusivity Data

Product No	Exclusivity Code	Exclusivity Expiration
001	NPP	05/27/2025

Product No	Exclusivity Code	Exclusivity Expiration
001	NCE	08/07/2025
001	M-270	10/03/2026
001	ODE-334	08/07/2027
001	ODE-400	05/27/2029

View a list of all patent use codes (results_patent.cfm)
View a list of all exclusivity codes (results_exclusivity.cfm)

48. In this regard, reference may also be made to letter dated 9th February, 2023 written on behalf of the USPTO, to the Food and Drug Administration

("FDA"), wherein, the application of the plaintiffs was considered eligible for PTE and it was categorically observed that the product by the tradename Evrysdi, i.e., Risdiplam, is covered under the claims of US'955 Patent, which is equivalent of WO'916, the International Genus Patent. The letter dated 09th February, 2023, is reproduced as under:

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22314-1450
www.uspto.gov

Food and Drug Administration
CDER, Office of Regulatory Policy
10903 New Hampshire Avenue
Bldg. 51, Room 6250
Silver Spring, MD 20993-0002

February 9, 2023

Attention: Beverly Friedman

We transmitted a copy of an application for patent term extension (PTE) of U.S. Patent No. 9,586,955 (the '955 patent) to your office by our letter dated December 29, 2021. The application was filed on October 2, 2020, under 35 U.S.C. 156. Claims of '955 patent cover the product known by the tradename Evrysdi® (risdiplam), which, as your office informed us by letter dated September 13, 2022, has been subject to a regulatory review period (RRP) before its commercial marketing or use, as required under 35 U.S.C. 156(a)(4).

Subject to final review, the '955 patent is considered to be eligible for PTE. Thus, a determination by your office of the applicable RRP is necessary. Accordingly, notice is provided pursuant to 35 U.S.C. 156(d)(2)(A).

Inquiries regarding this communication should be directed to Andrea Grossman at 571-270-3314 or andrea.grossman@uspto.gov.

/Ali Salimi/
Ali Salimi
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner for Patents

cc: Shannon Reaney
Morrison & Foerster LLP
755 Page Mill Rd.
Palo Alto, CA 94304

RE: Evrysdi® (risdiplam)
Docket No. FDA-2022-E-2090

49. Likewise, the plaintiffs have taken the position before the Australian Patent Office that Risdiplam was in *'substance generically disclosed'* in the Australian Genus Patent AU'870. The statement made by the plaintiffs in their PTE application before the Australian Patent Office, is reproduced as

under:

"xxx xxx xxx

SUBMITTED ONLINE

Commissioner of Patents P O Box 200 Woden ACT 2606	**SPRUSON & FERGUSON** Sydney NSW Speed Dial 509 (CCN 3710000177)

10 November, 2021

Our Ref: 29576AU1X:EBB
Telephone Contact: Elizabeth Barrett

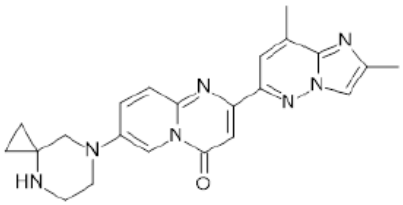
Dear Commissioner

Australian Patent No. 2013216870
PTC Therapeutics, Inc.
F. Hoffmann-La Roche AG
Patent Term Extension (EVRYSDI)

Please find enclosed an application for an extension of term in respect of the above-referenced patent.

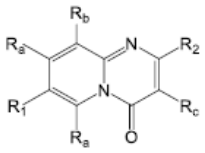
The extension of term is based on the pharmaceutical substance risdiplam which is identified in the complete specification of Australian patent no. 2013216870.

Risdiplam has the chemical name 7-(4,7-diazaspiro[2.5]octan-7-yl)-2-(2,8-dimethylimidazo[1,2-b]pyridazin-6-yl)pyrido[1,2-a]pyrimidin-4-one, and the structural formula:



(I)

Risdiplam, as it occurs in the goods registered on the ARTG, is generically disclosed in the complete specification as a compound of formula (IIa1)



(IIa1)

where R_a is, in each instance, hydrogen;
R_b is hydrogen,
R_c is hydrogen,
R_1 is heterocyclyl,
R_2 is heteroaryl, namely imidazo[1,2-b]pyridazinyl, substituted with two R_6 substituents,
R_6 is, in each instance, C_{1-8}alkyl, namely methyl.

Risdiplam is in substance generically disclosed in the patent specification at page 67, paragraph [00430] and page 73, paragraph [00464]. Risdiplam in substance falls within the scope of any one of claims 1, 7, 9, 10 and 12.

The application for inclusion of the goods in the ARTG was made with the consent of the patentees.

The date of first inclusion in the ARTG for a good containing a pharmaceutical substance that is in substance generically disclosed in the specification and in substance falls within the scope of a claim of the specification is **2 June 2021**.

In support of this application we enclose the following documents:

- Official form - Request for an Extension of Term;
- Print out of the ARTG public summary (dated 10 November 2021);
- ARTG certificate showing the date of inclusion of the goods on the ARTG; and
- Official extension of term fee.

We look forward to receiving official notification of the grant of the extension of term.

In the meantime, please do not hesitate to contact the undersigned with any comments or questions you may have concerning this application.

Yours faithfully
SPRUSON & FERGUSON

EBarrett

Elizabeth Barrett
Registered Patent Attorney

Fee: P910 - Extension of Patent Term - $2000

xxx xxx xxx"

P/00/052b

Australia

Patents Act 1990

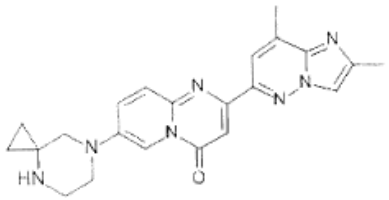
Application for an Extension of Term of a Standard Patent

We, F. Hoffmann-La Roche AG of Grenzacherstrasse 124, 4070 Basel, Switzerland and PTC Therapeutics, Inc. of 100 Corporate Court Middlesex Business Center, South Plainfield New Jersey 07080, United States of America the Patentees of Patent No. 2013216870 request an extension of the term of the patent.

1. Goods containing, or consisting of, the pharmaceutical substance risdiplam are currently included in the Australian Register of Therapeutic Goods (ARTG).

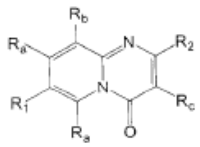
2. The pharmaceutical substance is in substance generically disclosed in the patent specification at least because:

Risdiplam has the chemical name 7-(4,7-diazaspiro[2.5]octan-7-yl)-2-(2,8-dimethylimidazo[1,2-b]pyridazin-6-yl)pyrido[1,2-a]pyrimidin-4-one, and the structural formula:



(I)

Risdiplam, as it occurs in the goods registered on the ARTG, is generically disclosed in the complete specification as a compound of formula (IIa1)



(IIa1)

where R_a is, in each instance, hydrogen;
R_b is hydrogen,
R_c is hydrogen,
R_1 is heterocyclyl,

R_2 is heteroaryl, namely imidazo[1,2-b]pyridazinyl, substituted with two R_s substituents,

0006d(28583204_1):KZA

This data, for application number 2013216870, is current as of 2024-11-10 23:00 AEDT

R_6 is, in each instance, $C_{1\text{-}8}$alkyl, namely methyl.

Risdiplam is in substance generically disclosed in the patent specification at page 67, paragraph [00430] and page 73, paragraph [00464].

3. The pharmaceutical substance in substance falls within the scope of the claims at least because:

Risdiplam in substance falls within the scope of any one of claims 1, 7, 9, 10 and 12.

4. The goods containing, or consisting of, the pharmaceutical substance that are included in the ARTG are:

EVRYSDI risdiplam 0.75 mg/mL powder for oral solution bottle

5. The application for inclusion of the goods in the ARTG was made with the consent of the patentees.

6. To the best of the patentee's knowledge, the ***first regulatory approval date*** (as defined by Section 70 for the goods containing, or consisting of, the pharmaceutical substance, is:

2 June 2021

7. To the best of the patentee's knowledge, the earliest ***first regulatory approval date*** (for the purpose of Section 77) in relation to goods containing, or consisting of, any pharmaceutical substance that is, in substance, generically disclosed in the specification and falls within the scope of the claims is:

2 June 2021

8. A copy of a print out of the Public Summary from the ARTG is attached showing that the goods are currently included in the ARTG.

9. A certificate issued to the sponsor of the goods under the ***Therapeutic Goods Act 1989***, showing the date of commencement of the first inclusion in the ARTG of goods that contain, or consist of, the substance is attached.

10. There are no relevant proceedings in relation to this patent.

Our address for service is:

Spruson & Ferguson
Patent and Trade Mark Attorneys
Level 24 Tower 2 Darling Park
201 Sussex Street
Sydney, New South Wales, Australia [Code **SF**]
(CCN 3710000177)

Dated 10 November 2021

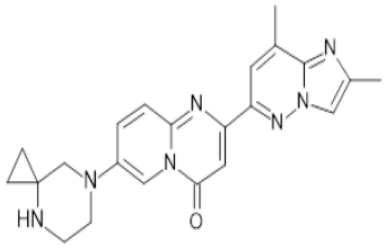
E Barrett

Registered Patent Attorney

IRN:29576AU1X

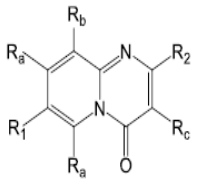
INSTR CODE:[055541]

Risdiplam has the chemical name 7-(4,7-diazaspiro[2.5]octan-7-yl)-2-(2,8-dimethylimidazo[1,2-b]pyridazin-6-yl)pyrido[1,2-a]pyrimidin-4-one, and the structural formula:



(I)

Risdiplam, as it occurs in the goods registered on the ARTG, is generically disclosed in the complete specification as a compound of formula (IIa1)



(IIa1)

where R_a is, in each instance, hydrogen;
R_b is hydrogen,
R_c is hydrogen,
R_1 is heterocyclyl,
R_2 is heteroaryl, namely imidazo[1,2-b]pyridazinyl, substituted with two R_6 substituents,
R_6 is, in each instance, C_{1-6}alkyl, namely methyl.

Risdiplam is in substance generically disclosed in the patent specification at page 67, paragraph [00430] and page 73, paragraph [00464]. Risdiplam in substance falls within the scope of any one of claims 1, 7, 9, 10 and 12.

xxx xxx xxx"

50. Similarly, in Canada also, the plaintiffs filed a request (Form IV), to include in the patent register maintained by the Ministry of Health, the Canadian Genus Patent, CA'874 which is corresponding to WO'916 (International Genus Patent), in connection with Risdiplam. The voluntary statement made by the plaintiffs in Canada with respect to its patent rights over Risdiplam in the Canadian Genus Patent, which is corresponding to the WO'916, i.e., the International Genus Patent, is reproduced as under:

Health Canada Santé Canada

185

FORM IV PATENT LIST
PATENTED MEDICINES (NOTICE OF COMPLIANCE) REGULATIONS
COMPLETE ONE FORM PER PATENT PER SUBMISSION

* denotes a mandatory field
\+ denotes a field with validation error or missing data

PART 1: PATENT FILING INFORMATION

Please select from the Patent List Filing Option below, and then enter the required information.

Patent List Filing Option *: Newly issued patent for listing against previously filed submission

Submission Number *: 2 4 2 3 7 3

Related Submission *: New Drug Submission (NDS)

Newly issued patent must be submitted within 30 days of grant in accordance with subsection 4(6).

PART 2: MEDICINAL INGREDIENT(S)

risdiplam

Brand Name: Evrysdi

Human/Veterinary *: Human

Strength per Unit *: 0.75 mg/ml (after reconstitution)

Dosage Form *: Powder For Solution

Route(s) of Administration *: Oral

DIN: 02514931

Uses(s) of Medicinal Ingredient(s) *: EVRYSDI (risdiplam) is indicated for the treatment of spinal muscular atrophy (SMA).

PART 3: PATENT INFORMATION

Patent Number*	Code*	Canadian Filing Date of Patent Application (YYYY-MM-DD)*	Date Granted (YYYY-MM-DD)*	Expiration Date (YYYY-MM-DD)*
2863874	☐ A ☐ B ☒ C	2013-02-08	2021-02-16	2033-02-08

PART 4: SERVICE IN CANADA

NAME & ADDRESS (FOR SERVICE IN CANADA)

Canada

FORM IV: PATENT LIST
Date Finalized: 2021-02-19 VERSION 2.11 FINAL DRAFT Access date: 2021-02-19

Health Canada Santé Canada

186

Company Name *: Gowling WLG (Canada) LLP Attn: James Buchan

Street/Suite *: 1 First Canadian Place, 100 King St W, Suite 1600

City - Town *	Country*	Province *	Postal Code *
Toronto	Canada	Ontario	M5X 1G5

PART 5: MANUFACTURER INFORMATION AND CERTIFICATION

Company Name *: Hoffmann-La Roche Limited

Street/Suite/PO Box *: 7070 Mississauga Road

City/Town *	Country *	Province/State *	Postal/ZIP Code *
Mississauga	Canada	Ontario	L5N 5M8

MANUFACTURER CONTACT

Salutation *	Given Name *	Initial	Surname *	Title *
Ms.	Victoria		Heppell	Director, Intellectual Property

Telephone No. *	Ext.	Fax No. *	Email
(416) 902-7541		905-542-5689	victoria.heppell@roche.com

CERTIFICATION

In accordance with paragraph 4(4)(f), I certify that the information included in this Patent List is accurate and that the patent on the list meets the eligibility requirements of subsection 4(2) or 4(3) of the Patented Medicines (Notice of Compliance) Regulations.

Salutation *	Given Name *	Surname *	Position Title *
Ms.	Victoria	Heppell	Director, Intellectual Property

○ Digital ID ◉ Image Signature

Signature:

Date (YYYY-MM-DD): 2021-02-19

51. It is to be noted that the plaintiffs have contested the issue as regards the statements made by them in foreign jurisdictions by stating that such statements have been made purely in the context of the law in those jurisdictions. It is also the case of the plaintiffs that the alleged admissions are made after the priority date of the Suit Patent, and hence not relevant for adjudication on the issue of anticipation by prior publication. Further, it is to be noted that the plaintiffs submitted in their rejoinder that the requirement of *'in substance'* disclosure for PTE in Australia is different from the disclosure requirement. In this regard, the plaintiff has relied on ***Pfizer Versus Commissioner of Patents***[19]. The relevant extract from the said judgement is reproduced here below:

> *"75. There is, in my view, much to be said for the proposition that "in substance disclosure" imports a "real and reasonably clear disclosure". If there is a difference, to my mind the requirement for "in substance" disclosure is a lesser requirement than for a "real and reasonably clear disclosure" or description. Section 70(2)(a) does not require express disclosure. If it did, there would be no need for the words "in substance." It seems to me that the additional words cannot import a higher test than "real and reasonably clear disclosure."*

52. However, it is to be noted that for the purposes of establishing a *prima facie* view and for considering the issue regarding credible challenge being raised by the defendant while considering the application for grant of interim injunction, the various statements made by the plaintiffs in foreign jurisdiction are material and relevant. The Supreme Court in the case of ***Novartis AG Versus Union of India and Others*** [20] factored the stand taken by the patentee in US in respect of the *'International genus patent'* by relying on the PTE filed in US for the genus patent, in determining the

[19] ***[2005] FCA 137***
[20] ***(2013) 6 SCC 1***

validity of the *'species patent'*. The relevant extract from the said judgment, is reproduced as under:

> *"xxx xxx xxx*
>
> *101. After the grant of drug approval for Gleevec, on 3-7-2001,* ***the appellant made a patent term extension application for the Zimmermann Patent (US Patent No. 5,521,184) under 35 U.S.C. § 156(g)(1)(B), for extending the term of the patent for the time taken in the regulatory review for Gleevec. This application leaves no room for doubt that Imatinib Mesylate, marketed under the name Gleevec, was submitted for drug approval as covered by the Zimmermann Patent.*** *In Column 4 of the application, it was stated that the sole active ingredient in Gleevec is Imatinib Mesylate. Further, it was stated that Imatinib, or any salt thereof, including Imatinib Mesylate, had not previously been approved for commercial marketing under the Federal Food, Drug and Cosmetic Act prior to the approval of NDA # 21-235. In Column 9 of the application, it was stated as under:*
>
> > *"(9)* ***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 a composition containing a compound or compounds which include the approved product, Imatinib Mesylate. Claim 22 claims a method of treating tumors in warm-blooded animals with a compound or compounds which include the approved product, Imatinib Mesylate."*
> >
> > *(emphasis supplied)*
>
> *102.* ***The application was accepted and the term of the patent, which was due to expire on 28-5-2013, was extended for the period of 586 days.***
>
> *xxx xxx xxx*
>
> *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 beta 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 compositions 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****.*

xxx xxx xxx"

(Emphasis Supplied)

53. It has consistently been held that at the stage of consideration of an application praying for an interim order, the challenge posed by the defendant to the validity of a plaintiffs' patent need not be such, so as to demonstrate conclusively, the invalidity thereof. It would be sufficient if the defendant is able to make out the case of the suit patent being vulnerable to revocation under the Patents Act. Thus, this Court in the case of ***Bayer Healthcare LLC Versus NATCO Pharma Limited***[21], has held as follows:

"xxx xxx xxx

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

"xxx xxx xxx

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

xxxxx

35.4*. This is acutely true when seen in the context of enforcement of patents concerning drugs.* ***The Court has to be***

[21] ***2023 SCC OnLine Del 3921***

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

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

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

31. *The Patents Act, though protects the rights and interests of inventors, but for a limited period, whereafter the monopoly of the patentee ceases and comes to an end and the invention with respect to which patent was granted, falls in public domain i.e. open all to practice and reap benefit of. A patent, vide Section 48 of the Act, confers a right on the patentee of a product patent, as DAPA is, to, during the life of the patent, prevent others from making, using, offering for sale, selling or importing, the new product with respect whereto patent is granted. The life of a patent is limited, whereafter, notwithstanding the new product having been invented by the patentee, patentee no longer has exclusive right to make, use or offer for sale the same and anyone else interested can also make, use or offer for sale the said new product invented by the patentee, without any interference from the patentee. If patents with respect to the same invention can be granted more than once, successively in time, the same will negate the legislative intent of limiting the life of the patent and enable the patentee to prevent others from making, using or offering for sale, the new product invented by the patentee, till the time patentee successively keeps on obtaining patent therefore.*

xxxxx

34. *The words 'Markush', 'Genus', 'Species', do not find mention in the Patents Act. We thus proceeded to examine, whether in the Indian statutory regime, what the counsel for the*

appellants/plaintiffs has argued, is permissible i.e. of a patent being first granted of "a core structure" and/or of a formula, only "generally describing the molecules, rather than detailing each and every molecule covered by the formula" and thereafter a second patent being granted detailing each and every molecule. The counsel for the appellants/plaintiffs referred to Section 10(5) in this regard.

xxxxxx

***39**. Rather, according to the arguments of the counsel for the appellants/plaintiffs, IN 147 was with respect to mere discovery of a scientific principle or formulation of an abstract theory or was a mere presentation of information and qua which under Sections 3(c) and 3(n) respectively, no patent could be granted. However, not only was the patent obtained but also infringement thereof claimed in the suits from which these appeals arise, admitting DAPA to be the new product subject matter of IN 147. **If IN 147 did not disclose DAPA and specifications thereof did not describe DAPA or the best method of industrially manufacturing DAPA, there could be no infringement of IN 147 from action of the respondent(s)/defendant(s) making and selling medicines/drugs with DAPA as ingredient thereof. The provisions afore noticed of the Patents Act, in our view, do not permit a patent to be granted with respect to the important stage in the inventive process and at which stage there is no product capable of industrial application, even if having technical advancement as compared to the existing knowledge. The appellants/plaintiffs on the other hand, as aforesaid, not only claimed patent IN 147 at the "breakthrough" stage, when according to them DAPA was not even known but even after obtaining patent IN 625 with respect to DAPA, by suing the respondent(s)/defendant(s) have pleaded infringement of IN 147 also. At least at this stage the same has to be treated as an admission of DAPA being known while obtaining IN 147**.*

xxxxx

47**. **To hold, that an inventor, merely on the basis of his work, research, discovery and prior art, but which has not yielded any product capable of commercial exploitation, is entitled, by obtaining patent thereof, to restrain others from researching in the same field, would in our view, not be conducive to research and development and would also be violative of the fundamental duties of the citizens of this country, enshrined in Article 51A of the Constitution of India, to develop the scientific temper and a spirit of inquiry. The

same will enable busy bodies to, by walking only part of the mile, prevent others also from completing the mile.*"*

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

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

32. ***Undoubtedly, multiple patents can be filed for different aspects of a particular product, if the tests for novelty, inventive steps and industrial applicability are satisfied and the inventions are patentable. However, serial patenting in order to 'Evergreen' a particular monopoly, is not permissible****.*

33. This would also clearly constitute an abuse of the patenting system and curb legitimate manufacture and sale of such products in India, especially if most of the patents/inventions are not being worked. The effort to extend the monopoly beyond the permissible period of 20 years in this manner is contrary to law as held by the Supreme Court in Novartis AG v. Union of India, (2013) 6 SCC 1 : AIR 2013 SC 1311"

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

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

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

xxx xxx xxx"

(Emphasis Supplied)

54. In the aforesaid judgement of ***Bayer Healthcare LLC Versus NATCO Pharma Limited***[22], while taking note of the statements made by the patentee in foreign jurisdiction, the Court held that from the said material, the defendants therein have *prima facie* raised a credible defence and challenge to the Suit Patent.

55. Similarly, commenting on the issue of coverage and disclosure and statements made by the plaintiffs after the priority date of the suit patent, this Court in the case of ***Boehringer Ingelheim Pharma GMBH & Co. KG Versus Vee Excel Drugs and Pharmaceuticals Private Ltd. and Others***[23], has held as follows:

"xxx xxx xxx

90. In the present case also, the plaintiffs are trying to make a distinction between the words, "claimed", "covered", "encompassed" and "disclosed". The words "covered" and "encompassed" essentially mean the same thing and the plaintiffs are only relying on semantics to make an artificial distinction, which

[22] ***2023 SCC OnLine Del 3921***
[23] ***2023 SCC OnLine Del 1889***

does not exist. When the product is specifically "covered" in the claims of a patent, whether specific disclosure with regard to the same has been made or not is immaterial. In fact, if the submissions of the plaintiffs that Linagliptin has not been disclosed in the suit patent is to be accepted, it would result in violation of the requirement of Section 10(4) of the Patents Act that every complete specification of a patent must satisfy.

xxx xxx xxx

100. It has been vehemently contended on behalf of the plaintiffs that no reliance can be placed on any post grant admissions made by the plaintiffs after the priority date of the suit patent. However, in the judgments of the Supreme Court in Novartis (supra) as well as the judgment of the Division Bench in Astra Zeneca (supra), the Court has placed reliance on admissions made by the plaintiffs in the pleadings that were filed much after the grant of the suit patent. Therefore, there is no merit in the submission of the plaintiffs that reliance cannot be placed on any admissions made by the plaintiffs after the priority date or after the grant of the suit patent.

xxx xxx xxx"

(Emphasis Supplied)

56. Likewise, in the case of ***Astrazeneca AB and Others Versus P. Kumar and Another***[24], it has been held that the plaintiffs have *prima facie* failed to explain the admissions/conduct in foreign jurisdiction, thus, the admissions/conduct can be considered for the purpose of an injunction application. The relevant portion of the said judgment, is reproduced as under:

"xxx xxx xxx

67. *Hence, the Supreme Court negated the argument that is sought to be made by learned counsel for the plaintiff that coverage in a patent might go much beyond disclosure. The plea of the plaintiff that genus patent has worked through TICAGRELOR though TICAGRELOR is not disclosed in IN 229 cannot prima facie, at this stage, be accepted.* ***For the purpose of the present injunction application, it can be said that the plaintiff have prima facie failed to explain the admissions/conduct as contained in Form 27 filed as***

[24] ***2019 SCC OnLine Del 9555***

noted above and the litigation commenced in USA against Mylan INC.

68. *What is further surprising is that the plaint is strikingly silent about the said aspect of the patent IN 229 especially keeping in view the own admissions of the plaintiff whereby they have claimed that IN 229 is worked through TICAGRELOR.*

69. *The date of grant of IN 229 is 24.06.2010. The date of grant of IN 907 is 11.09.2007.*

70. *The plaintiff states in the plaint that the drug regulatory approval for the drug TICAGRELOR came in May 2011 and the same was commercially launched in India in October, 2012 under the trademark BRILINTA. It is the case of the plaintiffs in their submissions that it is only the act of isolation of TICAGRELOR through the species patent i.e. IN 907 that the plaintiffs have been able to state that the genus patent is being worked or commercialized through Brilinta. Hence, the stand is that prior to isolation of TICAGRELOR through species patent, there was no commercial working of IN 229. Surprisingly, no such averment has been made in the plaint by the plaintiffs. The only averment in the plaint about the patent IN 229 is that the same is a genus patent covering vast number of compounds and TICAGRELOR is not specifically disclosed in the genus patent though it is technically within the generic scope of numerous compounds including in Formula-I of the said application. It is further stated that a person skilled in the art could not have recognized TICAGRELOR from the genus patent. That is the sum and substance of the averment made by the plaintiffs in the plaint regarding the patent IN 229 and it's connect with TICAGRELOR. None of the above facts/explanations were pleaded or stated in the plaint. There is no averment in the plaint to claim that IN 229 (genus patent) was worked through TICAGRELOR though not disclosed in the said patent as is now sought to be pleaded in course of arguments. There is no averment in the plaint that IN 229 does not pertain to a commercialized patent.*

71. *The Division Bench of this court in F. Hoffmann-LA Roche Ltd. v. Cipla Ltd. (supra) had on the question of disclosure as in the facts of that case noted as follows:—*

"40. This Court holds that in an application seeking ad interim injunction in a suit for infringement of patent, it would be incumbent on the plaintiffs to make a full disclosure of the complete specification of the product whose patent is claimed to have been infringed. The plaintiffs will also have to disclose to Court the x-ray

diffraction data of the product, particularly if it is a pharmaceutical drug. ***The plaintiffs have to make an unequivocal disclosure that the patent they hold covers the drug in question; whether there are any other pending applications seeking the grant of patent in respect of any derivatives or forms of the product for which they already hold a patent and the effect of such applications on the suit patent.*** *Short of the above details, the Court being approached for the grant of an ad interim relief will be unable to form a view on whether the plaintiff has made out a prima facie case. Otherwise it would be a case of suppression of material facts that would have a bearing on the question."*

72. *As noted above, the facts here show that the plaintiffs have been showing working of IN 229 through TICAGRELOR to the Controller of Patents while filing Form 27. The plaintiffs have filed proceedings for breach of IN 229 when the drug in question was TICAGRELOR in USA. These are important facts which have a material bearing on the issue as to whether TICAGRELOR is disclosed in IN 229 and is known and anticipated. The plaintiffs were obliged to have revealed the full facts in the plaint. This is especially so, keeping in view the fact that Micro Labs Ltd. had already filed an application for revocation of the suit patents before IPAB in 2015 where various grounds were urged including the fact that the suit patents are disclosed and covered in IN 229. The said petition clearly states that the compounds as disclosed in IN 907 and IN 984 are known and anticipated in light of IN 229 and could have been developed by a person skilled in the art. There is clear omission of the plaintiff to mention these materials and important facts in the plaint.*

73. *The above facts, in my opinion, show that the claim of the plaintiff that TICAGRELOR is not disclosed in IN 229 and is not anticipated is subject to a strong challenge by the defendant.* ***This is so on account of the admissions which prima facie the plaintiff have not been able to explain properly. This is also shown on account of the conduct of the plaintiff as noted above.***

xxx xxx xxx"

(Emphasis Supplied)

57. The judgment in the case of ***F. Hoffman-LA Roche Ltd. & Anr. Versus Cipla Ltd.***[25], as relied upon by the plaintiffs, is clearly distinguishable. The said judgment was a post-trial judgment, wherein, the

Division Bench held that the statements made during prosecution of foreign applications are irrelevant and are made in unrelated applications. However, in the present case, this Court is dealing with an application for interim injunction, wherein, the Court only has to formulate a *prima facie* opinion while considering the facts related to establishing a credible challenge by the defendant to the Species Patent of the plaintiffs.

58. Accordingly, it is held that the defendant has raised a *prima facie* credible challenge to the validity of the Suit Patent with regard to the issue of anticipation by prior publication.

B. *Issue of Obviousness – Section 64 (1)(f) of the Patents Act:*

59. The defendant has also challenged the validity of the Suit Patent, which is a Species Patent, under Section 64(1)(f) of the Patents Act, on the ground of obviousness, i.e., the defendant has alleged that the compound in question, i.e., Risdiplam, is obvious to a person skilled in the art/ person in the know, on account of the International Genus Patent, WO'916.

60. As noted in the preceding paragraphs, in the case of ***Astrazeneca AB and Another Versus Intas Pharmaceutical Limited (DB)***[26], the Division Bench of this Court, has held categorically that when the inventor is the same, the tests of *'obvious to person skilled in the art'*, cannot be in the context of *'person ordinarily skilled in the art'*, but has to be seen in the context of a *'person in the know'*. It has already been noted by this Court that at least four inventors in the International Genus Patent, which has been cited as prior art by the defendant, are common in the Suit Patent, which is a Species Patent. Therefore, following the *dicta* of the Division Bench in the

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[25] ***2015 SCC OnLine Del 13619***
[26] ***2021 SCC OnLine Del 3746***

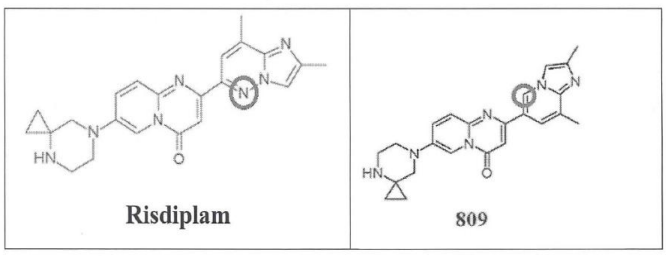
aforesaid case, the test of obviousness in the present case would be seen in the context of a *'person in the know'*.

61. Accordingly, the question before this Court is to decide whether the compound in question, i.e., Risdiplam, is obvious to a person skilled in the art/ person in the know, from the cited prior art, i.e., International Genus Patent, WO'916.

62. This Court notes that the defendant has relied upon *Compound 809* in the complete specification of the International Genus Patent, WO'916 and the chemical name of *Compound 809* of the International Genus Patent, as given in the complete specification of the International Genus Patent, is reproduced as under:

16	**809**	7-(4,7-diazaspiro[2.5]oct-7-yl)-2-(2,8-dimethylimidazo[1,2-a]pyridin-6-yl)-4H-pyrido[1,2-a]pyrimidin-4-one	ND	401.4

63. At this stage it would be pertinent to note the comparison between Risdiplam, as claimed in the Suit Patent and *Compound 809*, as given in the complete specification of the International Genus Patent, which is reproduced as under:

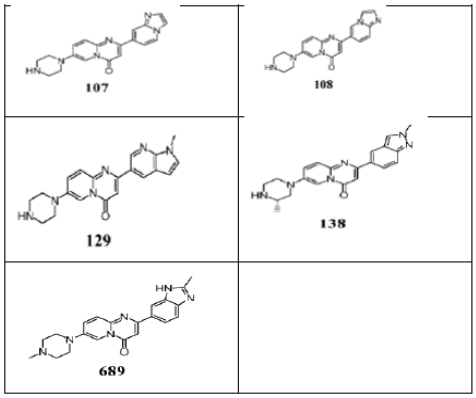


64. As highlighted during the course of arguments, the primary distinction between the *Compound 809* in the International Genus Patent and Risdiplam in the Suit Patent, is the presence of Nitrogen (N) in Risdiplam, whereas, the compound of the International Genus Patent features a Carbon-Hydrogen

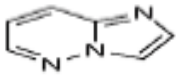
("CH") group at the even position.

65. It is noted that in the International Genus Patent, 835 compounds have been disclosed, of which, Pyrimidine is a constituent in almost all the compounds, including, *Compound 809*. Further, it is seen that Pyridine is also a constituent in most of the compounds. As per the scientific definition, Pyridine has just one Nitrogen atom, whereas, Pyrimidine, has two Nitrogen atoms. As such, it is clear that the common component in most of the compounds, as disclosed in the International Genus Patent, is with respect to the Nitrogen atom, which could be either Pyridine or Pyrimidine.

66. At this stage, it would be fruitful to refer to the reply of the defendant to the interim injunction application, i.e., *IA 33088/2024*, wherein, it has been stated in categorical terms that the International Genus Patent discloses different chemical structures with Nitrogen placed at different positions. Relevant portion of the reply, is extracted as follows:

> *"xxx xxx xxx*
>
> *52. WO '916 further provides that various fused-ring heterocycles with nitrogen placed at different positions in the same ring could be used. The compounds are reproduced below:*
>
> 
>
>
> *53. Therefore, it is submitted that using the same kind of ring varying the number of nitrogen atom and position is obvious for a person skilled in the art.*

54. Further, Imidazo[1,2-b]pyridazinyl is one of the substituents for R2 specifically disclosed in WO '916 (Page No: 37 and 38, paragraph [00215] of D1).



xxx xxx xxx"

67. Therefore, on account of myriads of occurrences of the 'Nitrogen' atom in the various compounds, it is *prima facie* established that it would have been obvious to a person skilled in the Art/person in the know that Nitrogen is a dominant component of most of the compounds as disclosed in the International Genus Patent. Therefore, such person skilled in the Art/ person in the know would have easily been motivated to use the Nitrogen atom instead of the Carbon atom, while looking at *Compound 809* in the International Genus Patent. The defendant has *prima facie* established that the compounds claimed in the Suit Patent represent routine optimization of compounds disclosed in the prior art. Further, this Court notes the submission of the defendant that, it is common practice in the field of pharmaceuticals to make iterative modifications to chemical structures in order to improve properties such as potency, selectivity or metabolic stability.

68. There is another aspect that needs to be considered. As noted above, the difference between the two compounds, i.e., Risdiplam and *Compound 809* of WO'916, is the replacement of the CH group by Nitrogen (N). It is to be noted that in Chemistry, the table under the '*Grimm's Hyride Displacement Law'*, clearly places Nitrogen (N) and CH in the same group. According to Grimm, each vertical column of the table represents a group of isosteres. Isosterism has been defined as compounds or groups of atoms

having the same number of electrons. Bioisosteres have been defined as atoms or molecules that fit the broadest definition for isosteres and have the same type of biological activity. The Table 2 of '*Grimm's Hyride Displacement Law*', representing a group of isosteres, is reproduced as under:

Table 2. Grimm's Hydride Displacement Law

C	N	O	F	Ne	Na
	CH	NH	OH	FH	–
		CH_2	NH_2	OH_2	FH_2^+
			CH_3	NH_3	OH_3^+
				CH_4	NH_4^+

69. Thus, it is evident that Nitrogen (N) and CH groups are often considered Bioisosteres. Therefore, substitution of a CH group with a Nitrogen (N) atom which are Bioisosteres, would be obvious to a person skilled in the Art of medicinal chemistry, or to *'a person in the know'*, in the facts and circumstances of the present case. Given the aforesaid fact, it would be obvious for a person skilled in the art of medicinal chemistry/person in the know, to consider/explore replacing or substituting the CH group with a Nitrogen atom, in order to explore its effects on the compound's biological activity and furthermore, on account of the considerable occurrences of Nitrogen atom in the compounds exemplified from the International Genus Patent.

70. Moreover, it is to be noted that the comparative data showing the values of compounds, reflected as Effective Concentration of a drug for measuring the dosage of a drug for achieving the desired biological response, i.e., $EC_{1.5x}$, shown by the plaintiffs for proving technical advancement or therapeutic efficacy, has been heavily contested by the defendant. Hence, the analysis of this data requires further examination and expert testimony, which can only be addressed during the trial.

71. Therefore, this Court is of the *prima facie* view that the Suit Patent is vulnerable on the grounds of obviousness on account of compounds, as disclosed in the Genus Patents.

C. *Challenge qua Non Patentability – Section 64(1)(d) of the Patents Act:*

72. Another defence of invalidity raised by the defendant is that the subject of the Suit Patent, is not an invention within the meaning of Section 64(1)(d) of the Patents Act. However, this aspect has not been widely argued by the defendant. Thus, no *prima facie* finding on this aspect can be given at this stage.

D. *Issue of Misrepresentation – Section 64(1)(j) of the Patents Act:*

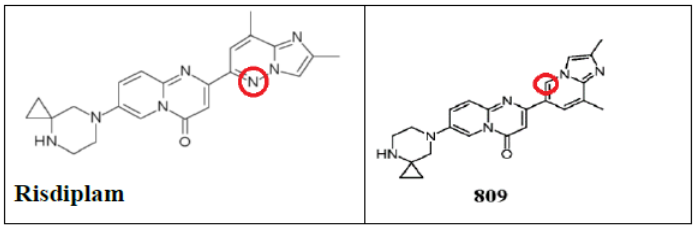
73. Another challenge raised by the defendant is with regard to misrepresentation before the Patent Office and challenge to the Patent under Section 64(1)(j) of the Patents Act on the ground that the patent was obtained on a false suggestion or misrepresentation. This Court notes the submissions made by the defendant in this regard in its reply to the interim application, wherein, it has been stated as under:

> *"xxx xxx xxx*
>
> *80. The Defendant states that the subject patent was obtained on a false suggestion or representation by Plaintiffs/ Patentees. The contentions of the Defendant mainly revolve around the specification, the claims and finally the submissions made by Plaintiffs at the time of filing the response to First Examination Report.*
>
> *81. It is pertinent to point out that in the First Examination Report of the Suit patent dated September 10, 2019, the Patent Office raised a specific objection under Section 3(d), namely-*

(2).NON PATENTABILITY:
(I) Claim(s) (1-56) are statutorily non-patentable under the provision of clause (d, e, i) of Section 3 for the following reasons:
The subject matter of claims falls under section 3 of the Patent Act, 1970 and are not inventions under the said section/clause:
a) Claim 1-44 falls within the scope of such clause (d) of section 3 of the Patents Act, 1970-The compound as defined in the claims is non-patentable. In view of the compound as mentioned in the prior art (see above), the compound of the instant invention would be considered as "same substance" as per the clause/Act.
b) Claims 45-49 fall within the scope of such clause (d) of section 3 of the Patents Act, 1970-The process as defined in the claims is not novel or inventive. In view of the process as mentioned in the prior art (see above), the process of the instant invention would be considered as "known process" as per the clause/Act.

*82. Confronted with the objection aforesaid, from the Patent Office, the Plaintiff chose to respond to the First Examination Report, stating that "**It is submitted that the claims as amended and currently on file are compounds that are structurally remote over those known in the art (D1-D5) and hence cannot be considered as new form of known substance nor derivatives**. Accordingly, Section 3(d) does not apply."*

83. The Defendant states that the compounds claimed in impugned patent is the new form of the known compound 809 disclosed in WO '916 Patent which does not result in the enhancement of known efficacy and thus not patentable under section 3 (d). Complete specification of the Suit Patent does not provide any comparative data to demonstrate enhancement in the therapeutic efficacy with respect to the compounds disclosed in WO '916 and specifically with the compound 809 'exemplified' in WO '916. WO'916 is cited in the First examination report (D1 of the present revocation petition), although compound 809 was not mentioned in the First Examination Report, and which is closest compound 'exemplified' in WO'916 to Risdiplam, and is part of prior art.



84. The fact that the Plaintiffs/ Patentees made such misleading statements in spite of being aware about compound 809 of WO '916 Patent which is the Patentees' own document, indicates that the Suit Patent was obtained by a false suggestion.

*85. **The Plaintiffs made a further false representation that the citation such as D1 (WO '916 Patent), does not even remotely disclose the compounds of claim 1 or other claims of the Suit patent, when in fact,***

the Plaintiff all along specifically knew that WO '916 'exemplified' the compound 809.

xxx xxx xxx"

(Emphasis Supplied)

74. Reading of the aforesaid shows that in the First Examination Report of the Suit Patent dated 10th September, 2019, the Patent Office raised a specific objection under Section 3(d), referring to the International Genus Patent, WO'916. The plaintiffs responded to the First Examination Report by stating that the claims, as amended and currently on file, were compounds that were structurally remote over those known in the art. This is in stark contrast to the admissions and PTEs in foreign jurisdictions. However, whether the same constitutes misrepresentation, is subject matter of trial and no finding in that regard, can be given at this stage.

E. ***Ground with regard to non-compliance of requirements – Section 8 of the Patents Act:***

75. The defendant has raised the issue of non-compliance of Section 8 of the Patents Act. In this regard, it is the contention of the defendant that the plaintiffs ought to have made necessary declaration in Form-3 filed for the Suit Patent. The plaintiffs deliberately chose not to do the same, and instead portrayed as though WO'916 was for a different invention.

76. However, whether or not there has been any non-compliance of Section 8 of the Patents Act, is a finding that can be given only after appreciating the evidence on record, post the trial. No finding can be given on this issue at this stage. In this regard, it would be fruitful to refer to the judgment of the learned Single Judge in the case of ***Koninklijke Phillips Electronics N.V. Versus Maj. (Retd.) Sukesh Behl and Anr.***[27], wherein,

[27] ***2013 SCC OnLine Del 4444***

while dealing with the issue of non-compliance of Section 8 of the Patents Act with regard to the aspect of non-disclosure of information pertaining to foreign applications, it was categorically held that no definitive opinion in this regard can be given before trial, without examining the evidence. Whether any material information was withheld by the plaintiff, can be determined only on the basis of evidence after conclusion of the trial. Thus, it was held as follows:

> *"xxx xxx xxx*
>
> *14.* ***It requires to be noted that while the Plaintiff does not deny that a part of the information concerning the pending foreign applications was inadvertently not disclosed, there is no admission as to the withholding of that information being deliberate or that there was wilful suppression of such information. That surely would be a matter for evidence. Further, the question whether the non-disclosure of the above information contained on the reverse of the first page in the first instance before the COP was material to the grant of the patent raises a triable issue. It is not possible at the present stage for the Court to form a definitive opinion on the above aspects. If at the end of the trial the Court, after examining the evidence, agrees with the Defendants that the information that was withheld was material to the grant of the patent itself, it might proceed to revoke the patent. Alternatively, it might disagree with the Defendant and decline to revoke the patent. In other words, that determination would have to await the conclusion of the trial.***
>
> *xxx xxx xxx"*
>
> *(Emphasis Supplied)*

77. The aforesaid judgment of the learned Single Judge was upheld by the learned Division Bench in the case of ***Maj. (Retd.) Sukesh Behl & Anr. Versus Koninklijke Phillips Electronics***[28], in the following manner:

> *"xxx xxx xxx*
>
> *49. Under the circumstances, as rightly held by the learned Single Judge revocation is not automatic under Section 64(1)(m), but it is always open to the Court to examine the question whether the omission to furnish the information was deliberate or intentional. The revocation would follow only if the Court is of the view that the omission to furnish the information*

[28] ***2014 SCC OnLine Del 2313***

was deliberate. Therefore, it cannot be held that there is any unequivocal admission by the plaintiff and consequently, it is not a matter for granting a decree even before the evidence is let in by the parties as provided under Order XII Rule 6 of CPC.

xxx xxx xxx"

F. *No presumption of validity of a Patent:*

78. In the judgment of ***F. Hoffman-LA Roche Ltd. & Anr. Versus Cipla Ltd.***[29], the Division Bench has held in categorical terms that unlike the Trade Marks Act, 1999, there is no presumption of validity of a patent under the Patents Act, as the scheme of the Patents Act contemplates multiple challenges to the validity of a patent. Thus, it has been held as follows:

"xxx xxx xxx

51. It is contended on behalf of the defendant that under the Patents Act, 1970, as contrasted with the Trade Marks 1999, there is no presumption of validity of a patent. This is evident from reading of Section 13(4) as well as Sections 64 and 107 of the Act. ***It is possible to raise multiple challenges to validity of patent at various stages. It could be at the pre-grant and post-grant stages before the Controller of Patents. Thereafter before the Appellate Board or in a suit for infringement the defendant could question the validity of a patent on the grounds set out in Section 64. The patent in the instant case was, therefore, vulnerable to challenge notwithstanding it surviving the challenge at the pre-grant stage. The object behind this was to ensure that known inventions are not granted patents and that the patent is used for the public benefit****.*

52. The above submissions have been considered. It must be clarified that this Court has held already that the Plaintiffs have failed to make out a prima facie case. The above submissions of the plaintiffs are therefore being dealt with assuming, as the learned Single Judge did, that the Plaintiffs have made out a prima facie case. ***Given the scheme of Patents Act it appears to this Court that it does contemplate multiple challenges to the validity of a patent. Unlike Section 31 of the Trade Marks Act which raises a prima facie presumption of validity, Section 13(4) of the Patents Act 1970 specifically states that the investigations under Section 12 "shall not be deemed in any way to warrant the validity of any patent." Section 48 of the Act also is in the form of a negative right preventing third parties, not having the consent of the patent holder, from making, selling or importing the said product or using the patented***

[29] ***2009 SCC OnLine Del 1074***

process for using or offering for sell the product obtained directly by such process. It is also made subject to the other provisions of the Act. This is very different from the scheme of the Trade Marks Act as contained in Section 28 thereof. Section 3(d) itself raises several barriers to the grant of a patent particularly in the context of pharmaceutical products. It proceeds on the footing inventions are essentially for public benefit and that non-inventions should not pass off as inventions. The purpose of the legal regime in the area is to ensure that the inventions should benefit the public at large. The mere registration of the patent does not guarantee its resistance to subsequent challenges. *The challenge can be in the form of a counter claim in a suit on the grounds set out in Section 64. Under Sections 92 and 92A the Central Government can step at any time by invoking the provision for compulsory licencing by way of notification.* ***Therefore, the fact that there is a mechanism to control the monopoly of a patent holder (Section 84 and Section 92) and to control prices (by means of the drug price control order) will not protect an invalid grant of patent****.*

xxx xxx xxx"

(Emphasis Supplied)

79. In the present case, the plaintiffs heavily relied upon the fact that there was neither any pre-grant opposition, nor any post-grant opposition against the Suit Patent. However, the aforesaid fact does not in any manner establish or guarantee the validity of the Suit Patent. As per the prevalent law in the country, validity of patents cannot be presumed. Thus, the Supreme Court in the case of ***Bishwanath Prasad Radhey Shyam Versus Hindustan Metal Industries***[30], has held as follows:

"xxx xxx xxx

32. ***It is noteworthy that the grant and sealing of the patent, or the decision rendered by the Controller in the case of opposition, does not guarantee the validity of the patent, which can be challenged before the High Court on various grounds in revocation or infringement proceedings. It is pertinent to note that this position viz. the validity of a patent is not guaranteed by the grant, is now expressly provided in Section 13(4) of the Patents Act. 1970. In the light of this principle, Mr Mehta's argument that there is a presumption in favour of the validity of the patent, cannot be accepted****.*

xxx xxx xxx"

[30] ***(1979) 2 SCC 511***

(Emphasis Supplied)

G. *Criteria at the time of considering an application for interim injunction and Prima Facie Case:*

80. At the time of considering an application for interim injunction, this Court is required to only see whether a credible challenge has been laid by the defendant, that is to say, that the challenge by the defendant is a genuine one and not vexatious. It would be sufficient if the defendant is able to put forth a substantial question of invalidity, and need not prove actual invalidity at the interim stage. The defendant has to make out a *prima facie* case that the Suit Patent is vulnerable to revocation under the Patents Act. In the present case, this Court is of a considered view that the defendant has raised a credible challenge by raising various grounds pertaining to invalidity of the Suit Patent.

81. Thus, a Division Bench of this Court in the case of ***F. Hoffman La-Roche Ltd. & Anr. Versus Cipla Ltd.*** [31], has held as follows:

> *"xxx xxx xx*
>
> *53. The plea of the plaintiff that since there is a multi-layered, multi-level examination of the opposition to the grant of patent it should accorded the highest weightage, is not entirely correct. The contention that there is a heavy burden on the defendant to discharge since it has to establish that it has a stronger prima facie case of the plaintiff is contra indicated of the decisions in the context of Section 13(4). Reference may be made to the decisions in Biswanath Prasad Radhey Shyam v. Hindustan Metal Industries, AIR 1982 SC 1444 : PTC (Suppl)(1) 731 (SC), Standipack Pvt. Ltd. v. Oswal Trading Co. Ltd., AIR 2000 Del 23 : 1999 PTC (19) 479 (Del), Bilcare Ltd. v. Amartara Pvt. Ltd., 2007 (34) PTC 419 (Del), Surendra Lal Mahendra v. Jain Glazers, (1979) 11 SCC 511. In Beecham Group Ltd. v. Bristol Laboratories Pty Ltd., (1967-1968) 118 CLR 618 and Australian Broadcasting Corporation v. O'Neill, (2006) 229 ALR 457 it was held that the defendant alleging invalidity bears the onus of establishing that there is "a serious question" to be tried on that issue. In Hexal Australai Pty Ltd. v. Roche Therapeutics Inc., 66 IPR 325 it was held that where the validity of a patent is raised in interlocutory*

[31] ***2009 SCC OnLine Del 1074***

proceedings, "the onus lies on the party asserting invalidity to show that want of validity is a triable question." In Abbot Laboratories v. Andrx Pharmaceuticals Inc. (decision dated 22nd June 2006 of the U.S. Court of Appeals for the Federal Circuit 05-1433) the Court of Appeals followed its earlier ruling in Helifix Ltd. v. Blok-Lok Ltd. 208 F.3d 1339 where it was held (at 1359): ***"In resisting a preliminary injunction, however, one need not make out a case of actual invalidity. Vulnerability is the issue at the preliminary injunction stage, while validity is the issue at trial. The showing of a substantial question as to invalidity thus requires less proof than the clear and convincing showing necessary to establish invalidity itself.****" (emphasis supplied) In Erico Int'll Corprn v. Vutec Corprn (U.S. Court of Appeals for the Federal Circuit, 2007-1168)* ***it was held that the "defendant must put forth a substantial question of invalidity to show that the claims at issue are vulnerable."***

xxx xxx xxx"

(Emphasis Supplied)

82. Accordingly, this Court is of the view that the defendant has *prima facie* raised a credible challenge as to the validity of the Suit Patent and that plaintiffs have been unable to make out a *prima facie* case for grant of an interim injunction.

II. *Aspect of Balance of Convenience:*

83. Another aspect which is material to be considered by this Court at the interim stage is the balance of convenience. This Court notes that the plaintiffs do not manufacture their drugs in India, but import their drugs into India. On the other hand, the defendant intends to manufacture the drug in India and make the product available at a price that is nearly 80-90% lesser than the plaintiffs' price. These factors are crucial in assessing the balance of convenience.

84. Another material aspect which is crucial at this stage is that the plaintiffs had shared in a sealed cover with this Court, the pricing of Evrysdi, i.e., Risdiplam in India, and the proposed effective price as part of Patient Assistance Program to National Rare Diseases Committee. In this

regard, it is to be noted that the Patient Assistance Program is limited to a very miniscule number of patients, compared to the number of patients who are actually suffering from SMA in India. At this stage, it would be apposite to refer to the submissions made on behalf of the intervener, Ms. Purva Mittal in *I.A. 44310/2024*, wherein, with regard to the Patient Assistance Program, it has been stated as follows:

> *"xxx xxx xxx*
>
> *11. In the facts of the present case, it is an admitted fact that SMA is a debilitating the case and there is no cure for the same. There are enough articles to demonstrate that the product is not available at an reasonably affordable price in India.* ***The Plaintiff claims to run a Patient Assistance Program (PAP Program), which is meant to assist patients and provide the drug at an affordable price. However, as per the article Global Risdiplam Compassionate Use Program for Patients with Type 1 or 2 Spinal Muscular Atrophy by Rakesh Kantaria, et. Al published in Clinical Therapeutics, 2024, which is a study done by Roche on its PAP Program, Risdiplam was made available to 75 patients in India in 2023****. Ref. Fig. 2 of the Paper.*
>
> *xxx xxx xxx"*
>
> *(Emphasis Supplied)*

85. In its website, i.e., https://www.rocheindia.com/solutions/focus-areas/rare-diseases with regard to the number of children that may be afflicted by SMA, 'Roche' has stated as follows:

> *"xxx xxx xxx*
>
> *Spinal Muscular Atrophy (SMA) is a rare genetic neuromuscular condition, affecting approximately one in 10,000 live births globally and one in 7744 live births in India and is the leading genetic cause of infant mortality. SMA is caused by the mutation of the survival motor neuron 1 (SMN1) gene, leading to a deficiency of SMN protein which is critical for muscle function. This protein is found throughout the body and is essential to the function of nerves that control muscles and movement. Without it, nerve cells cannot function correctly, leading to muscle weakness over time.*
>
> *xxx xxx xxx"*

86. Further, in the case of ***Master Arnesh Shaw Versus Union of India***

and Another[32], this Court has noted the submission regarding the number of patients suffering from SMA and the availability of drug for the same, in the following manner:

> *"xxx xxx xxx*
>
> *262. Mr Anand Grover, learned Senior Counsel, appears for the cure SMA Foundation in WP (C) No. 11610 of 2017, which is stated to represent over* ***1800 SMA patients****. Mr Grover's primary submission concerns the pricing of the drugs currently used for the treatment of SMA in India.* ***According to him, the main drug is marketed by M/s Roche in India and was approved by the US FDA in August 2020 for SMA patients between 2 months and 60 years, covering all types of SMA.*** *The drug was also approved by the DCGI in October 2020 and was commercially launched in July 2021.* ***He submits that under the Patient Support Program, Roche makes the drug available at Rs 72 lakhs annually for the first two years and Rs 56 lakhs annually for the third year. However, the same medicine is available at much lower costs in countries such as China and Pakistan.*** *He, thus contends that the Union of India has a responsibility to negotiate better prices with the Company to ensure that a larger number of patients can access these medicinal products at an affordable price. He further submits that the reason these products are not available at more affordable prices is due to the fact that they are patented products.*
>
> *xxx xxx xxx"*
>
> *(Emphasis Supplied)*

87. It is also to be noted that Division Bench of Kerala High Court in the case of ***Union of India and Others Versus Seba P.A. and Others***[33], directed the Central Government to provide medicine to the respondent therein, who was the petitioner before the Single Judge, for treatment of SMA, for which the only approved drug in India is Risdiplam, which is sold under the product name Evrysdi. The Union of India approached the Supreme Court against the said order and the Supreme Court in the case of ***Union of India and Others Versus Seba P.A. and Others***, ***Special Leave to Appeal (c)***

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[32] ***2024 SCC OnLine Del 7114***
[33] ***2025 SCC OnLine Ker 814***

4684/2025, *vide* order dated 24th February, 2025, has directed as follows:

> *"xxx xxx xxx*
>
> ***Respondent No. 1, Seba P.A., shall also try and arrange for financial aid from other sources for her treatment. It will also be open to respondent No. 1, Seba P.A., as well as the Union of India to get in touch with the companies that manufacture the subject drug(s) so as to enable economical treatment of the patients suffering from the disease in question, that is, Spinal Muscular Atrophy. Further, it will be open to respondent No. 1, Seba P.A., to send a copy of this order to the companies which are manufacturing the subject drug(s), with a request to supply the drug(s) at concessional rates****.*
>
> *xxx xxx xxx"*
>
> *(Emphasis Supplied)*

88. It may also be noted that as regards the requirement of the quantity of Risdiplam required for a patient suffering from SMA, the intervener, Ms. Seba P.A., in *I.A. 44384/2024*, has stated as follows:

> *"xxx xxx xxx*
>
> *3. .....*
> ***Currently, the said medicine costs around Rupees Six Lakhs per bottle. For a patient weighing more than 20 kg, a bottle will last only for 12 days and over the course of the year he/she will require approximately 30 bottles per year, amounting to Rs. 1 Crore 80 Lakh a year****.*
>
> *xxx xxx xxx"*
>
> *(Emphasis Supplied)*

89. Likewise, with regard to requirement of Risdiplam for a patient suffering from SMA, the intervener, Ms. Purva Mittal, in *I.A. 44310/2024*, has stated as follows:

> *"xxx xxx xxx*
>
> *4.* ***It is submitted that for a patient suffering from SMA, 36 bottles of Risdiplam is prescribed in a year (2 bottles per month for a patient of above 20 kgs.). Currently, the cost for a bottle of Risdiplam is Rs. 6.2 lacs. Therefore, any patient of SMA in order to avail the treatment of Risdiplam must incur an approximate cost of 1,48,00,000 (One crore Forty Eight lacs) per year, which is highly unaffordable****.*
>
> *xxx xxx xxx"*
>
> *(Emphasis Supplied)*

90. Reading of the aforesaid clearly brings to the fore the predicament of the persons suffering from SMA and their inability to purchase the only approved drug in India for SMA, i.e., Risdiplam, on account of its exorbitant cost. Thus, it is evident that the *'Patient Assistance Program'* of the plaintiffs, clearly does not resolve the issue of accessibility of the drug in question to the patients of SMA. Even if the plaintiffs provide the drug in question at their proposed price, as indicated to this Court in a sealed cover, even then, the same would not be a viable proposition in economic terms for the patients who are suffering from SMA. Furthermore, the said proposal would only affect the patients enrolled in the Patient Assistance Program, leaving a broad space, for the patients who are not enrolled in the said program. Further, the same would be of limited consequence, on account of the pecuniary constraint under the National Policy for Rare Diseases. In contrast, the proposal of the defendant, would bring to effect price reduction to the drug in its entirety, which would for reasons that are apparent, be applicable to all patients suffering from SMA. Therefore, this Court is not satisfied that on account of the proposed price, as given by the plaintiffs for providing the drug in question to National Rare Diseases Committee, as part of Patient Assistance Program, there is any leverage for grant of injunction in their favour.

91. It is to be noted that during the course of arguments, the plaintiffs have heavily relied upon the judgment in the case of ***Master Arnesh Shaw Versus Union of India and Another***[34], and in particular, have relied upon the following paragraphs from the said judgment.

> *"xxx xxx xxx*

[34] ***2024 SCC OnLine Del 7114***

3. It is the case of the petitioners that the medicines and therapies for all these rare diseases are exorbitantly expensive, and directions ought to be issued to the respondents i.e. the Union of India and its Ministry of Health and Family Welfare, All India Institute of Medical Science (hereinafter "AIIMS"), as well as the GNCTD, to provide continuous and uninterrupted treatment to the petitioners, free of cost.

xxx xxx xxx

*168. **On the said date, Mr Pravin Anand, learned counsel for Roche, informed the court that Roche manufactures "Evrysdi-Risdiplam", which is the only approved treatment for SMA in India. Roche has made significant efforts to make the drug available for patients, both through compassionate programs and commercially of the 168 patients receiving Roche's treatment for SMA, 56 are treated for free under the company's compassionate use program (CUP). Another 53 patients are covered under various Government policies. The remaining 59 patients are purchasing the drug under roche's patient access program, where for every two bottles purchased, three are provided free of cost.***

xxx xxx xxx

*332. **Insofar as SMA is concerned, negotiations have taken place between NRDC and M/s Roche Pharma, which has given a price and has now been accepted by the NRDC as captured in the document dated 14-6-2024 signed by Dr B.S. Charan, ADG, Member Secretary. The procurement/approvals may now be commenced.***

xxx xxx xxx

348. The NRDC, which was constituted vide order dated 15-5-2023, shall continue to function for a further period of 5 years. The constitution of the NRDC is as follows:

S. No.	Name of the member	Capacity
1.	Director General - Indian Council for Medical Research	Chairperson
2.	Dr Nikhil Tandon, Professor - AIIMS	Member
3.	Secretary - Ministry of Health and Family Welfare or one of his nominee.	Member
4.	Drug Controller General of India	Member
5.	Dr Madhulika Kabra, Professor-AIIMS	Member

349. The mandate of the said Committee would be as under:

(i) monitor and provide guidance on strategies for implementation of R&D policy in the country;
(ii) continue identification and recognition of rare diseases;
(iii) finalisation and implementation of uniform guidelines for objective inclusion, exclusion and exit criteria for treatment of patients with rare diseases;

(iv) to support MoHFW in creating a central uniform and robust system for procurement of drugs for rare diseases across COEs;
(v) ensure that procurement of drugs for treatment of rare diseases is done at a reasonable and affordable price;
(vi) to negotiate prices for bulk purchase for other rare diseases drugs with companies, as majority of these drugs are manufactured by a single Company and are proprietary in nature. These negotiated prices may be provided to the Rare Disease Cell, MoHFW, for doing the needful;
(vii) monitor and promote development of indigenous rare disease drugs in India by engaging and supporting various stake holders;
(viii) in addition to the above mandate, the NRDC shall be the overall authority for:

(a) Receiving the proposals from the CoEs in respect of patients who need to be administer therapies/treatments.
(b) Reviewing and assessing the recommendations made by CoEs and, thereafter, approving the treatments/therapy.
(c) The procurement of the medicines would commence immediately after the NRDC has approved a particular patient for treatment.

(ix) Conduct periodic reviews of the Rare Diseases Policy and make recommendations to update or refine the policy based on emerging research, treatments, and challenges faced by patients and healthcare providers.

B. Directions to Union of India

.....

B-4. The NDRF shall be administered by the National Rare Diseases' Cell consisting of one or more Nodal Officers in the MoHFW, who shall release the funds for treatment of patients under the National Policy for Rare Diseases', 2021, as directed by the NRDC. The fund would not lapse or revert due to under utilisation. Monthly reports of utilisation of the fund and the number of patients receiving treatment shall be submitted to the NRDC.

B-5. The upper limit of Rs 50 lakhs under NRDP, 2021 for the treatment of rare diseases shall be flexible in case of rare diseases in Group 3 category such as DMD, SMA, Gaucher, etc. as per the recommendation of NRDC. No ceiling shall be imposed qua funding of individual CoEs.

.....

C. Directions to the pharmaceutical companies, including Roche, Sarepta and other such companies.

C-1. Companies shall ensure the adequate availability of therapies and medicines in India for rare diseases, whether through manufacturing or imports. A proper distribution network, established by these companies, shall be in place to ensure continuous supplies. Procedures and timelines must be fixed to guarantee adequate and sufficient provision of these

medicines and therapies.

xxx xxx xxx"

92. At this stage, it is to be noted that the reliance by the plaintiffs on the aforesaid judgment is totally misplaced, for the reason that by order dated 09th December, 2024, in *Special Leave to Appeal (c) No. 28777/2024*, ***Union of India Versus Arnesh Shaw***[35], Supreme Court has stayed the operation of the said judgment, in the following manner:

> *"xxx xxx xxx*
>
> *Our attention is drawn to Annexure P-12 and it is stated that an identical issue is pending before this Court in W.P.(C) No.1012/2023, titled "Ratnesh Kumar Jigyasu & Ors. vs. Union of India & Ors.".*
>
> *The present petition under Article 136 of the Constitution of India has thus been filed before this Court, instead of approaching a Division Bench of the High Court. SLP(C) No. 28777/2024 Issue notice and tag with W.P.(C) No. 1012/2023. Notice will be served by all modes, including dasti.*
>
> *In the meanwhile, the petitioner, Union of India, will comply with the terms and conditions of the notification/Office Memorandum File No.: W-11037/40/2022-Grants (RD) dated 19.05.2022 issued by the Rare Diseases Cell, Ministry of Health and Family Welfare, Government of India.*
>
> *There will be stay of operation of the impugned judgment, subject to the petitioner, Union of India, complying with the aforesaid notification and also issuing directions for payment on a case to case basis, whenever it is required.*
>
> *xxx xxx xxx"*

93. Further, it is to be noted that though, reading of the aforesaid DB judgment in the case of ***Master Arnesh Shaw (supra)*** points out that National Rare Diseases Committee has already accepted the negotiated price of the drug in question from the plaintiffs, however, the fact remains that despite the aforesaid measures, the impact on the availability of the drug in

[35] ***MANU/SCOR/143702/2024***

question for general public, considering the economic scenario, cannot be accepted on the face of it at the present stage of consideration of an application for interim injunction. Such facts and statistics would have to be established by the plaintiffs during the course of trial, and its effect and impact, cannot be countenanced at this stage, in order to grant injunction in favour of the plaintiffs.

94. In this regard, reference may be made to the official statement of the Ministry of Health and Family Welfare, Government of India, with regard to National Policy for Rare Diseases, posted on the official website of Government of India, having the URL: https://pib.gov.in/PressReleaseIframePage.aspx?PRID=2043516. The relevant extract of the official statement from the said website, is reproduced as under:

"Details of National Policy for Rare Diseases

63 Rare Diseases are included under National Policy for Rare Diseases on recommendation of Central Technical Committee for Rare Diseases

Financial support of up to Rs. 50 lakhs per patient is provided for treatment at notified Centres of Excellence for Rare Diseases

A total number of 1,118 patients have benefited under National Policy for Rare Diseases

XXX XXX XXX

(b) ***For the following disorders for which the cost of treatment is very high and either long term follow up literature is awaited or has been done on small number of patients***

1. Cystic Fibrosis (Potentiators)

2. Duchenne Muscular Dystrophy (Antesensce oligoneucletides, PTC)

3. Spinal Muscular Atrophy (Antisense oligonucleotides both intravenous & oral & gene therapy)

4. Wolman Disease

5. Hypophosphatasia

6. Neuronal ceroid lipofuschinosis

xxx xxx xxx"

95. Reading of the aforesaid shows that 63 diseases have been included

under the National Policy for Rare Diseases. A total number of only 1,118 patients suffering from rare diseases, in all the 63 categories, have benefitted under the said policy. Further, financial support of upto Rs. 50,00,000/- per patient, is provided for treatment of such rare diseases.

96. However, considering the requirement of the drug in question by a patient suffering from SMA, in terms of the discussion hereinabove, it is evident that the National Policy for Rare Diseases, has its limitations, on account of which, the effective need of the patients suffering from rare diseases, including, SMA, is not fully addressed. The costs involved for the drug in question, as per the requirement of the patients for treatment of SMA, are much larger, as compared to the aid provided under the aforesaid National Policy for Rare Diseases.

97. The stand of the Government of India with regard to the financial burden on it for supplying drugs to persons for rare diseases, as encapsulated in the judgment of the High Court of Kerala, in the case of ***Union of India and Others Versus Seba P.A. and Others***[36], is reproduced as under:

> *"xxx xxx xxx*
>
> *4. The learned ASGI has relied upon the order passed by the Hon'ble Supreme Court in W.P.(C) No. 1012/2023 which was filed under Article 22 of the Constitution of India, on behalf of 251 persons who were suffering from rare diseases. The learned ASGI submits that this writ petition has been admitted and notice has been issued, however, there is no interim order.* ***He also submits that the learned Single Judge of Delhi High Court in W.P.(C) No. 5315/2020 and others in case of Master Arnesh Shaw v. Union of India, after elaborate discussion, has issued several directions including removal of cap of Rs. 50 lakhs for the treatment of rare diseases declaring it to be flexible one. The learned ASGI submits that this decision of the learned Single Judge of Delhi High Court was challenged by the Union of India directly before the Hon'ble Supreme Court by filing a Special Leave Petition (SLP) No. 28777/2024. On 9 December 2024, the Hon'ble Supreme Court has***

[36] ***2025 SCC OnLine Ker 814***

passed an order issuing notice and staying operation of the impugned judgment.

5. The order passed by the Hon'ble Supreme Court reads thus:

Our attention is drawn to Annexure P-12 and it is stated that an identical issue is pending before this Court in W.P.(C) No. 1012/2023, titled "Ratnesh Kumar Jigyasu v. Union of India"

The present petition under Article 136 of the Constitution of India has thus been filed before this Court, instead of approaching a Division Bench of the High Court.

Issue notice and tag with W.P.(C) No. 1012/2023.

Notice will be served by all modes, including dasti.

In the meanwhile, the petitioner, Union of India, will comply with the terms and conditions of the notification/Office Memorandum File No.: W-11037/40/2022-Grants (RD) dated 19.05.2022 issued by the Rare Diseases Cell, Ministry of Health and Family Welfare, Government of India.

There will be stay of operation of the impugned judgment, subject to the petitioner, Union of India, complying with the aforesaid notification and also issuing directions for payment on a case to case basis, wherever it is required.

Based on the order of the Hon'ble Supreme Court, the learned ASGI contends that the order passed by the learned Single Judge which is prior to the order passed by the Hon'ble Supreme Court on 9 December 2024, needs to be stayed. He also submits that there are thousands of applications of identically situated patients all over the country and if direction such as the one issued in the impugned order is made applicable to all other patients, it will place a substantial financial burden on the Union of India running into almost Rs. 32 thousand crores.

xxx xxx xxx"

(Emphasis Supplied)

98. Reading of the aforesaid order clearly shows that the Government of India itself has expressed concern about the financial burden in respect of providing economic/financial aid for supply of the drugs for rare diseases to the patients suffering from such rare diseases.

99. Further, as noted above, the Supreme Court in its order dated 24th February, 2025 in the case ***Union of India and Others Versus Seba P.A.***

and Others[37], has given directions to the Government to get in touch with the companies which manufacture the drug for the disease in question, i.e., SMA, so as to enable economical treatment of the patients suffering from the said diseases. Thus, it is apparent that it cannot be stated that balance of convenience for grant of injunction, lies in favour of the plaintiffs.

100. Accordingly, the issue of balance of convenience is decided against the plaintiffs, and in favour of the defendant.

III. *Aspect of Irreparable Damage/Prejudice:*

101. The plaintiffs are currently importing the drug in India, on account of which, the cost of the drug is highly exorbitant. Clearly, the plaintiffs' intention is to monetize the drug. Therefore, the plaintiffs can clearly be compensated in damages, if they were to succeed at the end of trial. Thus, in this regard, this Court in the case of ***Astrazeneca AB and Another Versus Intas Pharmaceuticals Limited***[38], has held as follows:

> *"xxx xxx xxx*
>
> ***134. This is acutely true when seen in the context of enforcement of patents concerning drugs. The Court has to be vigilant towards attempts of the patentee that aims at evergreening an invention which does not inter alia involve an inventive step i.e. technical advance or economic significance. Therefore, depriving the defendants, at this stage, from manufacturing and selling their drugs, when, during the validity period of the genus patent i.e. IN 147 they largely held themselves in check would, in my opinion, not be appropriate, especially, when they have set up a credible challenge to the suit patents.***
>
> ***135. What persuades me to decline injunction, in addition to what I have stated above, is also the fact that in this case damages if proved at trial, appear to be compensable****. The defendants have averred that the plaintiffs have, possibly, licensed their rights under the suit patents to two entities i.e. Sun and Abbott. The packaging of the products of the drug sold through these entities is indicative of this aspect. The*

[37] ***Special Leave to Appeal (c) 4684/2025***
[38] ***2020 SCC OnLine Del 2765***

plaintiffs, however, for reasons best known to them have not placed on record the agreements arrived at with these entities in support of their plea. Therefore, it has to be inferred that the said entities are licensees.

136. Besides this, the plaintiffs also aver that they are importing their drug into the country. Therefore, the plaintiffs seek to monetize their invention. Thus, at the end of the trial, if they were to succeed, they could be granted damages, if proved, under the law. Thus, as long as a mechanism can be put in place for securing the recovery of damages by the plaintiffs, it would, at this stage balance the interest of the parties*. [See: Dynamic Manufacturing, Inc. v. David A. Craze, and Miller Industries, Inc., 1998 WL 241201]*

xxx xxx xxx"

(Emphasis Supplied)

102. Holding that the plaintiffs can be appropriately compensated by way of damages if the case of the plaintiffs is proved after trial and public interest would also demand that injunction be refused if there is a huge disparity between the price offered by the plaintiffs and the defendant, this Court in the case of ***Bayer Healthcare LLC Versus NATCO Pharma Limited***[39], has held as follows:

"xxx xxx xxx

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

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

[39] ***2023 SCC OnLine Del 3921***

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

xxx xxx xxx"

(Emphasis Supplied)

103. Accordingly, it is held that no prejudice shall be caused to the plaintiffs, as the plaintiffs can be compensated by damages, as discussed hereinabove.

IV. ***Public Interest:***

104. In the book titled as *'Prathiba M. Singh on Patent Law'*, in Chapter 13, it has been clearly elucidated that at the interim stage, the impact of an injunction, if granted, on the public would also be considered by the Court. In the said book, it has been discussed as under:

"xxx xxx xxx

Public Interest

13-031 ***At the interim stage, the impact of an injunction if granted on the public would also be considered by the Court. In addition to the three conditions for grant of injunctions, a fourth factor, i.e., public interest, has also been applied in few patent cases. The US Supreme Court in Ebay v. MercExchange[50] termed public interest as the fourth factor which would merit consideration in grant of injunctions in patent cases, owing to the repercussions that such injunctions could have on the consuming public. More recently, the UK Court of Appeal in Neurim Pharmaceuticals Ltd v. Generics UK Limited[51] recognised public interest as a factor and denied an injunction***.

13-032 ***In the Indian context, one of the few earliest cases which took public interest into consideration was in the context of***

> ***EMRs granted to the drug Imatinib. In three decisions involving the said drug EMR, different High Courts refused interim injunction on the ground of public interest. In one case,[52] despite the patentee giving an undertaking to supply specified amounts of patented drug free to low-income earning patients and agreeing to meet the amount that falls short of insurance policies of patients or reimbursement schemes under which the patients are covered, and also undertaking to supply of patented drug according to the requirements of the hospitals, the Court refused interim injunction****.*
>
> *xxx xxx xxx"*
>
> *(Emphasis Supplied)*

105. Thus, it is clear that the spirit of considering public interest while granting injunction is reflected in the jurisprudence that has developed in the country in this regard. Considering the public interest to be paramount, Division Bench of this Court in the case of ***F. Hoffman-LA Roche Ltd. & Anr. Versus Cipla Ltd.***[40], has held as follows:

> *"xxx xxx xxx*
>
> ***80. Turning to the case on hand, there is no doubt that the product in question is a drug for cancer treatment at the terminal stages. It is the second line treatment after the first line of treatment by way of chemotherapy had proved unsuccessful. It is expected to be directed of a particular form of non-small cell lung cancer. This drug is not readily available in India. The plaintiffs do not yet manufacture it in India. They import and sell the drug. Even if the price per tablet is taken to be Rs. 3200 as claimed by the plaintiffs it is a drug which is expensive. It is clearly beyond the reach of many patients suffering from this dreaded form of cancer****.*
>
> ***81. This Court is inclined to concur with the learned single Judge that in a country like India where question of general public access to life saving drugs assumes great significance, the adverse impact on such access which the grant of injunction in a case like the instant one is likely to have, would have to be accounted for. Erlocip is the Indian equivalent produced by the defendant in India as a generic drug manufacturer. It is priced at Rs. 1600 per tablet. Even if this does not make it inexpensive, the question of greater availability of such drug in the market assumes significance.***

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83. *The judgments relied upon by the plaintiffs underscore the approach of determining these questions on a case by case basis. Whether indeed the public interest in the availability of the drug to the public at large is outweighed by the need to encourage research in the invention, would obviously differ from ease to case and depend on a host of factors. This Court finds no ground to differ with the reasoning or the conclusions arrived at by the learned Single Judge on this aspect after an analysis of all the relevant factors.*

xxx xxx xxx"

(Emphasis Supplied)

106. This Court also takes note of the submissions made on behalf of the interveners, wherein, it has been brought forth that SMA is a debilitating disease and there is no cure for the same. The approved drug, i.e., Risdiplam, which is marketed under the name Evrysdi, is not available at reasonably affordable prices in India. Thus, if a party is able to manufacture the drug and make it available at an affordable price, in such a case, the public interest would have to outweigh the need for grant of injunction.

107. In relation to pharmaceuticals, which not just borders on the public good, but brings about the foremost good of the public, i.e. health, is not something that should be dealt with lightly. A drug which is the only one available for treatment in India, for a rare disease, its availability to the public at large at very economical and competitive prices, is a material factor which a Court will consider at the time of dealing with an application for interim injunction. Besides, the plaintiffs can be compensated by way of damages. However, there exists no right for the public to lessen or compensate itself.

Conclusion and Directions:

108. Accordingly, in view of the detailed discussion above, it is held that

the defendant, i.e., NATCO Pharma Limited, has *prima facie* raised a credible challenge to the validity of the Suit Patent. Thus, this Court is not inclined to grant any injunction in favour of the plaintiffs and against the defendant. Besides, the plaintiffs can be compensated in damages, as held in the preceding paragraphs. Further, balance of convenience is also against the plaintiffs and is in favour of the defendant.

109. Nonetheless, it is clarified that in case the plaintiffs ultimately succeed in the trial, the defendant shall be liable to pay damages to the plaintiffs. For this purpose, the defendant shall file its list of assets, encumbered and unencumbered, along with its market value, before this Court within a period of four weeks.

110. It is further directed that the defendant shall maintain complete accounts of the manufacture, sale and supply of the products. The defendant shall file statements of accounts before this Court on quarterly basis, duly supported by affidavit. The defendant shall also file the annual statements of sales of their products, duly authenticated by its auditor.

111. The present application is accordingly dismissed, in view of the aforesaid detailed discussion.

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112. List before the Joint Registrar (Judicial) on 21st April, 2025.

(MINI PUSHKARNA)
JUDGE

24th MARCH, 2025
KR/AU/AK/C