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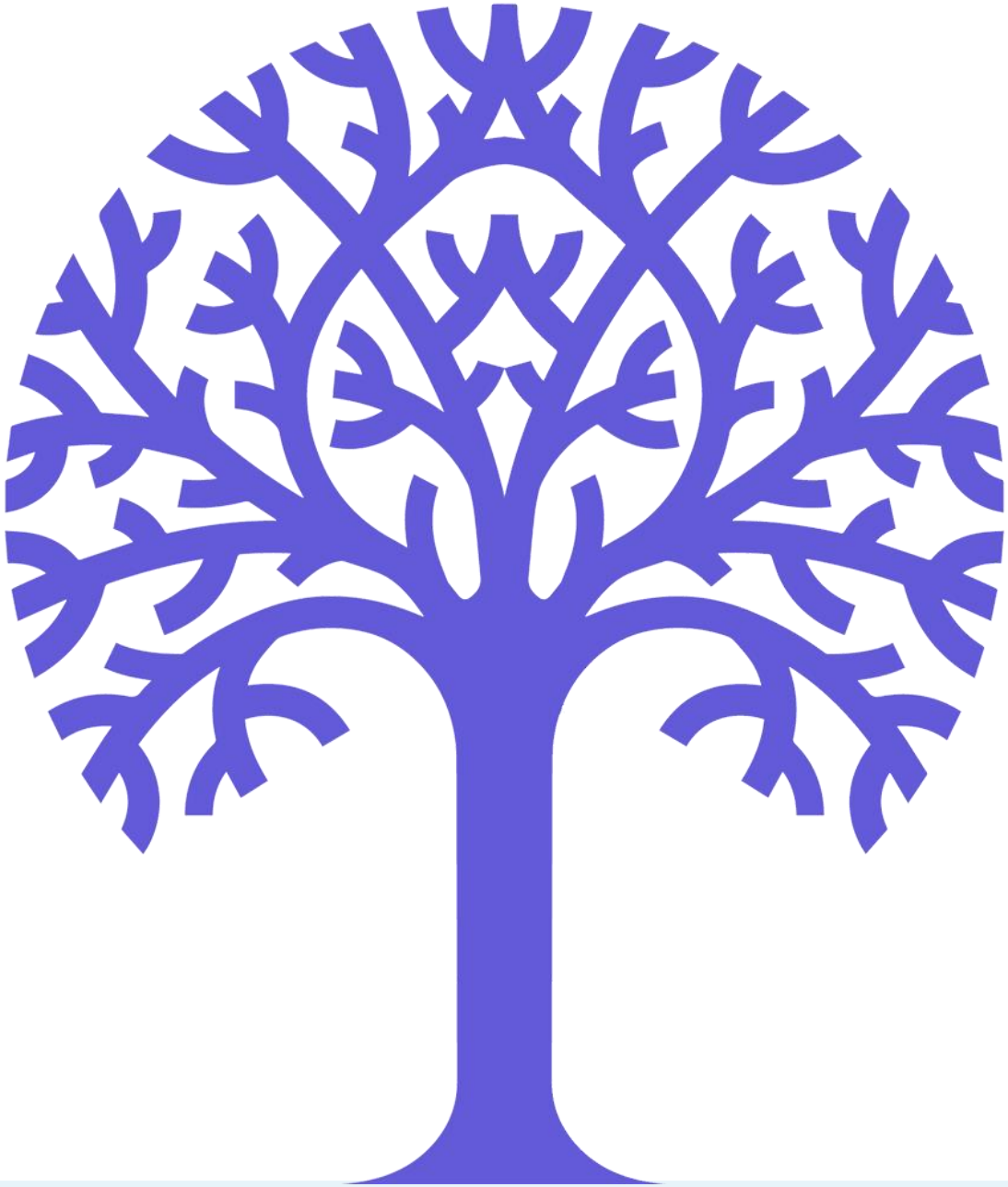
# Table of Contents





# Articles

## Reaffirming standards: Bioavailability v. Therapeutic efficacy and Coverage v. Disclosure

*By* **Dr. Malathi Lakshmikumaran, Swati Upadhyay and Swati Sangwan**

The first article in this issue of IPR Amicus elaborately discusses a recent Delhi High Court Division Bench decision which revolved around interpretation of 'enhanced efficacy' under Section 3(d) of the Patents Act, 1970. The decision focused on two pivotal issues - whether the enhanced bioavailability data could be construed as proof of enhanced 'therapeutic efficacy', and the concept of 'coverage v. disclosure' in patent applications. According to the authors, the present judgment resets the high bar for the pharmaceutical companies and reminds them of the intricacies of the provision of Section 3(d) which is exclusive to the Patents Act in India. Additionally, this ruling clarifies that the protection under Section 48 will also extend to those substances that are not specifically disclosed but are obvious to a person skilled in the art and/or can be anticipated.

# Reaffirming standards: Bioavailability v. Therapeutic efficacy and Coverage v. Disclosure

*By* Dr. Malathi Lakshmikumaran, Swati Upadhyay and Swati Sangwan

## Background:

In India, patent applications filed for new forms of known chemical entities have always faced strict scrutiny under the provisions of Section 3(d) of the Indian Patents Act, 1970 ('**Act**'). The judgement delivered by the Divisional Bench of the Delhi High Court presided by two justices, Hon'ble Justice Vibhu Bakhru and Hon'ble Justice Amit Mahajan on 24 April 2024, provided critical interpretations for some of the most disputed matters concerning the field of patenting new chemical entities (NCEs) and its forms, such as salts. The judgment which was issued in the case of *Natco Pharma* v. *Novartis Ag and Anr*.[1] reasserted the landmark decision that was made in the matter of *Novartis* v. *UoI*[2]. This case revolved around the interpretation of 'enhanced efficacy' under Section 3(d) of the Act. The Divisional Bench's decision focused on following two pivotal issues under a broader question of a credible challenge to the validity of a patent:

1. Whether the enhanced bioavailability data could be construed as proof of enhanced 'therapeutic efficacy'.
2. The concept of 'Coverage v. Disclosure' in patent applications.

## Facts of the case:

1. **Patent IN213176 (IN'176) owned by Novartis**

   Referred to as the first patent, IN'176 covers the base compound, i.e., Eltrombopag (ELT). This patent expired on May 24, 2021.

2. **Patent IN 233161 (IN'161) owned by Novartis**

   Referred to as the suit patent, IN'161 claims a specific salt form of Eltrombopag, i.e., Eltrombopag-Olamine (ELT-O). This patent was to expire on May 21, 2023.

At the expiry of the first patent IN' 176, Natco (Appellant) launched a drug containing ELT-O under the brand name

[1] *Natco Pharma* v. *Novartis Ag and Anr*

[2] *Novartis* v. *UoI*

Trombopag. Since ELT-O was the subject matter of an active Patent, i.e., IN' 161 owned by Novartis (Respondents), the latter filed a suit seeking a decree of permanent injunction in June 2021 before the Single Bench of the Delhi High Court.

Natco in its defence alleged that IN'161 is invalid on the account of being a new form of known substance under Section 3(d) of the Act and that it is an attempt to 'evergreen' the patent on ELT by extending the monopoly beyond the expiration of IN'176. Natco also asserted that the patent ought to be revoked since ELT-O was already covered in the first patent IN'176.

Novartis in response stated that ELT-O provided enhanced solubility and bioavailability which led to enhanced therapeutic efficacy of the ELT-O when compared to the base compound, i.e., ELT. Also, ELT-O was only covered and never claimed in IN' 176.

The Single Bench allowed an interim relief that restrained Natco from dealing in any manner in ELT-O either separately or in combination with any other compound. *Primarily*, the Single Bench held that (1) ELT-O was only covered and not disclosed in IN'176 and (2) the enhanced solubility and bioavailability of ELT-O leading to therapeutic efficacy can be used to overcome the barrier of Section 3(d) of the Act.

Natco then approached the aforesaid Divisional Bench with the plea of overturning the judgement delivered by the Single Judge.

## Divisional Bench's interpretation of Section 3(d) of the Act:

The main question that the Divisional Bench had to decide on was whether the enhanced solubility and bioavailability of ELT could be construed as enhanced therapeutic efficacy or if they were only a means of overcoming/reducing the negative impact of its poor solubility, because of which it cannot be formulated into pharmaceutical dosage forms.

- ***Understanding of Section 3(d) of the Act:***

Section 3(d) of the Act bars the patenting of *'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.'*

In its Judgement, the Court first explained the reason for the inclusion of the first part of Section 3(d) of the Act along with the explanation in Patents (Amendment) Act, 2005, for which the Court referred to Supreme Court's order in *Novartis* supra and iterated that the Explanation to Section 3(d) of the Act amply sets out what are not considered as inventions. Although the legislature has excluded the incremental inventions from the Explanation substances, which differ significantly in their properties with regard to efficacy (therapeutic efficacy in pharmaceutical/chemical products), however, the statute clearly states that the aforementioned forms would be considered the same substance. The Court asserted that the rationale for excluding the specified forms of known substances was to exclude the 'evergreening' of the patents in respect of pharmaceutical/chemical substances.

➢ ***Understanding of Enhancement of Known Efficacy:***

Further, the Court focused on clarifying the term 'enhanced efficacy' within the framework of Section 3(d) of the Act. The Court specifically addressed whether data pertaining to enhanced bioavailability could satisfy the requirements of enhanced 'therapeutic efficacy'.

The Court highlighted a clear distinction between bioavailability and therapeutic efficacy:

## Bioavailability v. Therapeutic efficacy:

The Court referred to H.L. Sharma & K.K. Sharma, Principles of Pharmacology[3] in order to comprehend the term bioavailability used in the field of pharmacology. The Court observed that properties such as greater bioavailability, solubility, stability, and hygroscopicity are usual properties of the given forms of a substance.

Further, the Court referred to the Supreme Court's order in *Novartis* supra, wherein a similar question was addressed, and it was contended on behalf of certain objectors that a demonstration of increased bioavailability is not a demonstration of enhanced efficacy.

The Supreme Court in *Novartis* supra held that '*in whatever way therapeutic efficacy may be interpreted, this much is absolutely clear: that the physicochemical properties of the beta crystalline form*

[3] H.L. Shama & K.K. Sharma, Principles of Pharmacology 32-32 (Paras Medical Publisher 3d ed. 2018)

*of Imatinib Mesylate, namely, (i) more beneficial flow properties, (ii) better thermodynamic stability, and (iii) lower hygroscopicity, may be otherwise beneficial but these properties cannot even be taken into account for the purpose of the test of Section 3(d) of the Act, since these properties have nothing to do with therapeutic efficacy. …However, a determination that a drug product is bio-available is not in itself a determination of effectiveness.'*

Thus, considering the above points, the Divisional Bench in the present matter concluded that solubility is a physico-chemical property and not a property of therapeutic efficacy. Also, that bioavailability is one of the pharmacokinetic parameters and not a direct measure of therapeutic efficacy. The Court went on to stress that improved bioavailability does not equate to increased therapeutic efficacy.

## Divisional Bench's interpretation on the concept of 'Coverage v. Disclosure' in patent applications:

To understand the concept of Coverage v. Disclosure, the Divisional Bench again relied on the Supreme Court's order in *Novartis (Supra)* and held that ***there is no dichotomy between coverage and disclosure.***

The Court held that the protection in respect of the said claim would extend to substances disclosed as well as to those that are not specifically disclosed but are ***obvious to a person skilled in art and/or can be anticipated.***

The Court further held that 'The *gap between coverage and disclosure would thus, necessarily have to be confined to only those substances which are otherwise anticipated or obvious to a person skilled in the art. It cannot extend to other substances or products that are neither disclosed nor are obvious to or anticipated by a person skilled in the art.'*

## Conclusion

This ruling following the judicial precedent from the Honorable Supreme Court's stance in the matter of *Novartis* reiterated that increased bioavailability is not a direct measure of enhanced efficacy. This indicates that for a new form of known substance, one must demonstrate enhanced therapeutic efficacy over the known substance, which cannot be solely based on the bioavailability data of the new form. The Divisional Bench further relied on the orders in the matters of *Merck Sharp & Dohme Corporation & Anr.* v. *Glenmark*

*Pharmaceuticals Ltd*[4]. and *Astrazeneca Ab & Anr.* v. *Intas Pharmaceuticals Ltd. Intas*[5] for this ruling.

The present judgment resets the high bar for the pharmaceutical companies and reminds them of the intricacies of the provision of Section 3(d) of the Act which is exclusive to the Patents Act in India. Additionally, this ruling clarifies that the protection under Section 48 of the Act will also extend to those substances that are not specifically disclosed but are obvious to a person skilled in art and/or can be anticipated.

**[The authors are Executive Director, Senior Associate and Senior Patent Analyst, respectively, in IPR practice at Lakshmikumaran & Sridharan Attorneys]**

[4] Merck Sharp & Dohme Corporation & Anr. vs Glenmark Pharmaceuticals Ltd

[5] Astrazeneca Ab & Anr. vs Intas Pharmaceuticals Ltd. Intas

# Articles

## Exploring the uncertainties surrounding Section 15 and Section 21(1) of the Patents Act

*By* **Ankit Anand and Pulkit Doger**

The second article in this issue of the newsletter examines a recent Bombay High Court decision wherein the Court had analysed the Order issued by the Controller under Section 21(1) of the Patents Act [deemed abandonment], and as to whether the order was correctly issued under Section 21(1). As per the High Court, the patent application is to be deemed abandoned if the Applicant fails to comply with all the requirements imposed on him under the Act, though the quality of those responses is a separate consideration. Further, observing that the Controller in this case issued a hearing notice informing the Applicant that the patent application was deemed to be abandoned, the authors highlight that the Applicants may seek an opportunity to be heard even in cases where no response to the FER was submitted at all. According to them, the Applicant can hence seek to re-initiate prosecution of patent applications which are already deemed abandoned under Section 21(1).

# Exploring the uncertainties surrounding Section 15 and Section 21(1) of the Patents Act

*By* Ankit Anand and Pulkit Doger

This article discusses the judgment[6] passed by the Hon'ble High Court of Bombay on a petition filed by Sonalkumar Sureshrao Salunkhe and Kunal Sureshrao Salunkhe ('**Petitioner(s)**') against an impugned order passed by the Assistant Controller of Patents and Designs ('**Respondent**') on 16 September 2021, refusing the grant of the Petitioner(s)' patent application under Section 21(1)[7] of the Patents Act, 1970. The petition was an appeal under the provisions of Section 117A[8] of the Patents Act, 1970 ('**Patents Act**') challenging the order passed by the Respondent.

In said order, the Respondent refused to proceed with the grant of the patent application due to non-compliance with all the objections raised in the First Examination Report (FER) in

[6] Judgement dated 6 May 2024 in Commercial Miscellaneous Petition No. 8 of 2022

[7] Section 21(1): Time for putting application in order for grant:
An application for a patent shall be deemed to have been abandoned unless, within such period as may be prescribed, the applicant has complied with all the requirements imposed on him by or under this Act, whether in connection with the complete specification or otherwise in relation to the application from the date on which the first statement of objections to the application or complete specification or other documents related thereto is forwarded to the applicant by the Controller.
*Explanation.*—Where the application for a patent or any specification or, in the case of a convention application or an application filed under the Patent Cooperation Treaty designating India any document filed as part of the application has been returned to the applicant by the Controller in the course of the proceedings, the applicant shall not be deemed to have complied with such requirements unless and until he has re-filed it or the applicant proves to the satisfaction of the Controller that for the reasons beyond his control such document could not be re-filed.

[8] Section 117A: Appeals to Appellate Board:
(1) Save as otherwise expressly provided in sub-section (2), no appeal shall lie from any decision, order or direction made or issued under this Act by the Central Government, or from any act or order of the Controller for the purpose of giving effect to any such decision, order or direction.
(2) An appeal shall lie to the Appellate Board from any decision, order or direction of the Controller or Central Government under section 15, section 16, section 17, section 18, section 19,section 20, sub-section (4) of section 25, section 28, section 51, section 54, section 57, section 60, section 61, section 63, section 66, sub-section (3) of section 69, section 78, sub-sections (1) to (5) of section 84, section 85, section 88, section 91, section 92 and section 94.
(3) Every appeal under this section shall be in the prescribed form and shall be verified in such manner as may be prescribed and shall be accompanied by a copy of the decision, order or direction appealed against and by such fees as may be prescribed.
(4) Every appeal shall be made within three months from the date of the decision, order or direction, as the case may be, of the Controller or the Central Government or within such further time as the Appellate Board may, in accordance with the rules made by it allow.

due time, as per the provisions of Section 21(1) of the Patents Act read with Rule 24-B(5)[9] of the Patents Rules. The Respondent argued that since the order was passed under Section 21(1) of the Patents Act, the present petition was not maintainable, as per the provisions of Section 117A of the Patents Act.

On the other hand, in said petition, the Petitioner(s) argued that all the requirements under the FER were responded to in due time, as per the provisions of Section 21(1) of the Patents Act read with Rule 24-B(5) of the Patents Rules. The Petitioner(s) further argued that since all the requirements under the FER were complied with, the Petitioner(s) did not have any intention to abandon the patent application. Accordingly, based on the grounds taken in said petition, the Petitioner(s) argued that the Respondent had erred in passing the order under Section 21(1) of the Patents Act which should have ordinarily and correctly been passed under Section 15[10] of the Patents Act, since the Respondent did not find the response to the FER satisfactory. Therefore, the order is appealable under Section 117A of the Patents Act.

A closer examination of Section 21(1) and Section 15 of the Act reveals potential confusion in the applicability of the two provisions. The provision under Section 21(1) requires the Applicant to comply with the objections raised by the Controller in the first statement of objections within the prescribed period of time, failing which the patent application is deemed to have been abandoned. The assumption that is made is that the non-compliance with Section 21(1) is indicative of the Applicant's disinterest in pursuing the patent application. On the other hand, the provisions under Section 15 dictate that if the Controller is satisfied that the patent application is in conformance with the requirements of the Act

[9] Rule 24-(B)(5) and (6): Examination of application:
(5) The time for putting an application in order for grant under section 21 shall be six months from the date on which the first statement of objections is issued to the applicant to comply with the requirements.
(6) The time for putting an application in order for grant under section 21 as prescribed under sub-rule (5) may be further extended for a period of three months on a request in Form 4 for extension of time along with prescribed fee, made to the Controller before expiry of the period specified under sub-rule (5).

[10] Section 15: Power of Controller to refuse or require amended applications, etc., in certain case:
Where the Controller is satisfied that the application or any specification or any other document filed in pursuance thereof does not comply with the requirements of this Act or of any rules made thereunder, the Controller may refuse the application or may require the application, specification or the other documents, as the case may be, to be amended to his satisfaction before he proceeds with the application and refuse the application on failure to do so.

then the Controller can proceed to grant the patent application. Otherwise, the Controller can refuse the patent application, after providing a chance to the Applicant to amend the patent application as per the requirements of the Act. If the Applicant addresses only some of the Controller's objections while leaving others unaddressed, this constitutes insufficient compliance. Therefore, the question is whether to treat this insufficient compliance as non-compliance to the cited objections and analyze this matter in the context of Section 21(1) or treat this insufficient compliance as unsatisfactory response by the Applicant and analyze such unsatisfactory response in the context of Section 15. Further, as per the provisions of Section 117A of the Act, the Applicant can appeal against a refusal order passed under Section 15 in the Hon'ble High Court, however, the Applicant cannot appeal against the refusal order passed under Section 21(1) in the Hon'ble High Court.

The Hon'ble High Court, after considering the facts of the case, decided that the Petitioner(s), while responding to the FER, dealt with only one of the objections in the FER and did not deal with the other objections and, therefore, did not comply with the requirements under Section 21(1) of the Patents Act. Therefore, the order of the Respondent was indeed an order under Section 21(1) of the Patents Act and not under Section 15 of the Patents Act which made the petition non-maintainable under Section 117A of the Patents Act. In view of the above, the petition was dismissed. This article analyzes the assessment of the Hon'ble High Court of the order issued by the Controller under Section 21(1) of the Patents Act and whether the order was correctly issued under Section 21(1).

## Facts of the case

The Petitioner(s) filed an ordinary patent application, i.e., an application first filed directly at the Indian patent office, on 17th January 2015, titled A SYSTEM FOR PREPARING SEED BED AND/OR FURROWS bearing application number 174/MUM/2015. The FER for the patent application was issued to the Petitioner(s) on 24 June 2019 and a response to the FER (RTFER) was filed by the Petitioner(s) on 24 December 2019. In the FER, the Controller raised objections under Section 2(1)(ja) (Inventive Step) and other objections under the headings Sufficiency of Disclosure, Definitiveness, Others Requirements, and Formal Requirements, few of which necessitated either cogent argumentation or appropriate amendments to the claims. However, in the RTFER, the Petitioner(s) responded to

only the objection related to Inventive Step arguing that the cited documents were not relevant and claims 1-7 were novel and inventive. It is of note that no technical analysis of either the claimed subject matter or of the cited prior art references was provided. Instead, a statement dismissing the references as irrelevant was made by the Applicant while submitting the RTFER. Further, in the RTFER, the Petitioner(s) has also requested the Controller for a hearing under Section 14[11] so as to discuss and explain the features of the present invention. For the outstanding objections, the Petitioner(s) responded by simply saying that the Petitioner(s) would comply with the other objections in due course. After filing the RTFER, the Petitioner(s) filed a Form-30 on 15 September 2020 as a follow up after filing the RTFER in which, the Petitioner(s) informed the Controller that the RTFER had been filed and further instructions from the Controller were being awaited. The Petitioner(s), in said Form-30, again requested the Controller to issue a hearing notice in case any formal or technical requirements were to be met.

On 3 August 2021, the Respondent issued a hearing notice to the Petitioner(s) where the Respondent raised an objection that in the RTFER the Petitioner(s) merely argued that the claimed invention is novel and inventive and did not comply with other objections raised in the FER. Accordingly, the Respondent objected that the RTFER could not be taken on record due to non-compliance with the objections raised in the FER, as per Section 21(1) of the Patents Act read with Rule 24-B(5) of the Patents Rules.

The hearing was held on 20 August 2021, and, during the hearing, the Petitioner(s) challenged the contention of the Respondent. In response to the objections raised in the hearing notice the Petitioner(s) argued that the applicant has every right to file any document(s) at any stage during the course of proceedings before the disposal or grant of the application. The Petitioner(s) further argued that any document filed at the IPO

[11] Section 14: Consideration of the report of examiner by Controller:
Where, in respect of an application for a patent, the report of the examiner received by the Controller is adverse to the applicant or requires any amendment of the application, the specification or other documents to ensure compliance with the provisions of this Act or of the rules made thereunder, the Controller, before proceeding to dispose of the application in accordance with the provisions hereinafter appearing, shall communicate as expeditiously as possible the gist of the objections to the applicant and shall, if so required by the applicant within the prescribed period, give him an opportunity of being heard.

during the course of the proceedings of the patent application has to be taken on record and processed accordingly. The Petitioner(s) further submitted that the Form-30 dated 15 September 2020 was also filed to the IPO after the filing of the RTFER to establish that the Petitioner(s) interests in keeping the patent application alive. The Petitioner(s) cited an opinion of a former Controller General of Patents, Designs and Trademarks regarding Section 21(1) of the Patents Act, who had once opined that no patent application can be deemed to have been abandoned under Section 21(1) if the Applicant has shown interest and addressed any objection in the FER, for instance, even merely complied with Section 8 requirement by submitting a Form 3. In other words, the Petitioner(s) had contended that even if a single piece of paper has been filed after issuance of FER, the patent application cannot be processed and abandoned under Section 21. In such a case, the patent application is required to be processed under Section 15 of the Patents Act along with supporting rules.

The Respondent went on to refuse the patent application on the basis of Section 21(1) of the Patents Act, read with Rule 24-B(5), (6), while dismissing the contentions raised by the Petitioner(s). Therefore, the patent application was deemed to have been abandoned. Aggrieved by the order of the Respondent, the Petitioner approached the Bombay High Court by way of the petition.

In response to the petition filed with the Hon'ble High Court by the Petitioner(s), the Respondent had raised a preliminary objection that the present petition was not maintainable owing to the fact that the provisions of Section 117A of the Patents Act did not provide for an appeal against an order passed under Section 21(1) of the Patents Act. In response to this preliminary objection, the Petitioner(s) submitted that, in the present case, in the RTFER, the Petitioner(s) had responded to all the requirements raised in the FER. The Petitioner(s) further drew the Court's attention to a letter dated 15 September 2020 issued by the Petitioner(s) as a follow-up to the reply dated 24 December 2019 in which the Petitioner had informed the Controller that the RTFER had been filed and further inputs from the Controller were awaited. The Petitioner(s) contended that since the requirements in the FER were complied with, the patent application could not be deemed to have been abandoned as per Section 21(1) of the Patents Act. The Petitioner(s) further submitted that, if the Respondent found that the Application ought to have been

rejected owing to the unsatisfactory response of the Petitioner(s), then the order rejecting the application would be tantamount to an order passed under Section 15 of the Patents Act, which is appealable under Section 117A. The Petitioner(s), thus, submitted that the present petition was maintainable. In support of the submissions, the Petitioner(s) relied upon the judgements of the Delhi Hon'ble High Court in *Merck Serono S.A.* v. *Union of India*, *Telefonaktiebolaget LM Ericsson (PUBL)* v. *Union of India (UOI) and Ors.* and *Ferid Allani* v. *Union of India (UOI) and Ors.* Based on the cited judgments the Petitioner(s) argued that responding to the objections raised as a result of examination of the patent application and whether the objections had been satisfactorily responded to were two different matters. Thus, as per the provisions of Section 21(1) the patent application is deemed to have been abandoned if the Applicant had failed to comply with all the objections. On the other hand, according to the provisions of Section 15 the patent application is refused if the Applicant had failed to *satisfactorily* comply with all the objections.

## Discussion and decision

The Hon'ble High Court pointed out that the FER issued to the Petitioner(s) made detailed observations on the requirements under the Patents Act in respect of (i) Inventive Step (ii) Sufficiency of Disclosure (iii) Definitiveness and (iv) other requirements. The reply dated 24 December 2019 of the Petitioner(s), however, did not comply with all the requirements. An examination of the reply to the FER revealed that, apart from some remarks on the inventive step requirement, the Petitioner(s) did not address any other requirements of the FER. In this factual scenario, it would have to be considered whether Section 21(1) is applicable and whether, accordingly, an order rejecting the application is passed under Section 21(1) or under Section 15. The Hon'ble High Court highlighted the fact that not only did the Petitioner(s) not respond to the majority of the objections raised in the FER, in the given situation, the Petitioner(s) also did not seek an extension of time for complying with the requirements of the FER which was available to them. In such circumstances, after considering the written submissions of the Petitioner(s) and after issuing a hearing, the impugned order was correct in holding that the patent application was deemed to have been abandoned in that it has failed to comply with the requirements of Section 21(1).

In passing its order, the Hon'ble High Court referred to the judgments of the Delhi High Court in *Telefonaktiebolaget LM Ericsson (PUBL)* v. *Union of India (UOI)*, *Ferid Allani* v. *Union of India (UOI)* and *Merck Serono S.A.* v. *Union of India (UOI).* Based on these judgments, the Hon'ble High Court emphasized two distinct points: first, the Applicant must respond to all objections raised in the FER; second, the quality of those responses is a separate consideration. The patent application would be deemed to have been abandoned when the Applicant fails to comply with all the requirements imposed on him under this Act. However, if the Applicant has replied to the objections but the reply is found to be unsatisfactory by the Controller, even after a further opportunity if any is given, then the Controller must proceed to take a decision under Section 15, after complying with Section 14 of the Act. After considering the arguments presented by both the Respondent and the Petitioner(s) the Hon'ble High Court held that the Petitioner(s) complied with only one of the objections and did not comply with the rest of the objections raised in the FER. As a result of the non-compliance, the impugned order held that the patent application shall be deemed to have been abandoned and that no further technical examination was required as the Applicant had failed to discharge its due responsibility. In view of these facts, the Hon'ble High Court concluded that the impugned order is an Order under Section 21(1) of the Patents Act and not under Section 15 of the Patents Act. Given this, Section 117A of the Patents Act would not apply and the petition was dismissed.

## Conclusion:

The order of the Hon'ble High Court has brought the interpretation of Section 21(1) of the Patents Act under the microscope. As per the order, in response to the FER issued for the patent application the Petitioner(s) did not comply with all the objections raised in the FER and, instead, only complied with one of the objections while committing to comply with the outstanding objections in due course. However, the Petitioner(s) never did comply with the rest of the objections. In view of this, the Controller issued a hearing notice informing the Applicant that the patent application was deemed to be abandoned under Section 21(1). Issuance of a hearing notice for a patent application which was deemed abandoned begs the question of whether a hearing was required to be afforded to the Applicant if the patent application was deemed abandoned. This chain of events seemingly leads to a fresh interpretation of Section 21(1) taken by the Patent Office and corroborated by the

Hon'ble High Court that even if the requirement of Section 21(1) is not met, owing to which the application is *deemed* to have been abandoned, the Applicant is still afforded an opportunity to be heard for an otherwise abandoned application. In other words, the deemed fiction created by Section 21(1) is brought subject to a hearing opportunity in which the Applicant is allowed to make a case for an application which should have ceased to be active as soon as the compliance with Section 21(1) was not done.

As a result of this interpretation of Section 21(1) the Applicants may seek an opportunity to be heard even in cases where no response to the FER was submitted at all and, by way of this, the Applicants may seek to re-initiate prosecution of patent applications which are already deemed abandoned under Section 21(1). Therefore, the current order of the Hon'ble High Court of Bombay is likely to effectively trigger a debate on the interpretation of Section 21(1).

**[The authors are Senior Associate and Partner, respectively, in IPR practice at Lakshmikumaran & Sridharan Attorneys]**

# Ratio Decidendi

- Patent for a product is not deniable for lack of inventive step when a patent for the process involved in manufacturing the said product was earlier granted to the applicant – Madras High Court
- Patentability of a lamp made from cow ingredients and certain leaves – Madras High Court upholds denial under Section 3(p) relating to 'traditional knowledge'
- Patentability of computer programme – Madras High Court clarifies Section 3(k) while allowing grant of a patent
- Patent for a salt formulation for dry food products – Madras High Court overrules rejection under Section 3(e) as 'admixture'
- Patentability – Filtrate material acting merely as a medium for facilitating doping is not a 'reactant' under Section 3(d) – Higher cost than prior art is not material for 'industrial capability' under Section 2(1)(ac) – Madras High Court
- Patentability – Bioavailability per se does not establish therapeutic efficacy under Section 3(d) – Madras High Court

## Patent for a product is not deniable for lack of inventive step when a patent for the process involved in manufacturing the said product was earlier granted to the applicant

The Madras High Court has upheld the contention of the patent applicant that the reason for rejecting the application as lacking inventive step is not sustainable when the patent for the process involved in manufacturing the product was earlier granted to the applicant. The product for which the patent was claimed was a tablet which dissolved in the mouth without requiring water and thus making swallowing easier and thus safe for use by children as well as elderly people.

According to the High Court, the Patent Office was estopped from even examining 'lack of inventive steps' in the first place and conclude that the invention claimed was well known to a person skilled in the art. It was of the view that merely because the appellant had successfully obtained a patent for the process, the application for patent for the product cannot be refused.

The Court in this regard though observed that an owner of a patent for a process cannot claim monopoly rights over the product of the process and such patent holder also cannot stop a person from claiming a different process which may result in even the same product, it noted that in this case, after having granted a patent for the process to manufacture the tablet, the Controller had non-suited the applicant, citing the process involved alone, in coming to the conclusion that there was no inventive step and that there was no teaching away from the prior arts.

The findings of the Patent Office regarding lack of inventive steps were thus set aside by the Court while it also observed that the Controller had also not discussed and deliberated on the reasons given by the appellant regarding the prior arts that were put against the appellant.

[*Kyorin Pharmaceutical Co. Limited* v. *Assistant Controller* – Judgement dated 5 July 2024 in (T) CMA (PT) No. 9 of 2023, Madras High Court]

## Patentability of a lamp made from cow ingredients and certain leaves – Madras High Court upholds denial under Section 3(p) relating to 'traditional knowledge'

The Madras High Court has upheld the rejection of product and process patent claims for a lamp made from six ingredients

originating from cow (dung, urine, ghee, butter, milk and curd) and a mixture of leaves selected from the neem tree, lemon tree and peepal tree.

Upholding rejection under Section 3(p) of the Patents Act, 1970, the Court observed that cow dung, cow urine, cow ghee and other cow products along with leaves of the neem tree, lemon tree and peepal tree are animal and plant products that have been used traditionally in India. It in this regard also observed that even assuming that urine, milk and curd from the cow were not known to be used as fuel, since one of the known properties of other ingredients (cow dung cake, cow ghee and cow butter) is their use as fuel, the claimed invention would fall within Section 3(p). The Court for this purpose also noted that the traditional knowledge of use of neem and lemon leaves as insect repellents and for fragrance.

Observing that Section 3(p) provides protection of traditional knowledge by excluding inventions which are 'in effect' traditional knowledge from patent eligibility, the High Court was of the view that the term 'in effect' ensures that there is no circumvention of the prohibition by concealing the usage of traditionally known components or their properties in a claimed invention.

Joint Parliamentary Committee Report on the Patents (Second Amendment) Bill, 1999, Patents (Amendment) Act, 2002, and definition of 'traditional knowledge' by the World Intellectual Property Organisation (WIPO) and by the United Nations Educational Scientific and Cultural Organisation (UNESCO), were considered by the Court for this purpose.

The claimed invention was also held as obvious to a person skilled in the art on the basis of the cited prior arts and common general knowledge.

[*The Zero Brand Zone Pvt. Ltd.* v. *Controller of Patents & Designs* – Judgement dated 5 July 2024 in (T) CMA (PT) No.146 of 2023, Madras High Court]

## Patentability of computer programme – Madras High Court clarifies Section 3(k) while allowing grant of a patent

The Madras High Court has set aside the Order of the Assistant Controller of Patents rejecting the patent for 'Associating Command Services with Multiple Active Components'. The Patent Office had rejected the patent alleging exclusion under Section 3(k) of the Patents Act, 1970 as constituting computer programme *per se* and not involving any inventive hardware. The finding of the Patent office that the invention lacked

inventive step under Section 2(1)(ja) in view of certain prior arts, was also set aside by the High Court here.

The claimed invention processed commands to multiple unrelated applications by associating the command surface to more than one component registered to receive commands from the command surface. This enabled the outflow of commands to unrelated applications from a single command surface removing the necessity of multiple command surfaces. According to the Court, this technical contribution made the claimed invention efficacious over conventional systems which required the presence of multiple command surfaces on the web page for processing unrelated applications.

The High Court in this regard observed that the claimed commanding system was more than a set of instructions in code or any other language and was not limited in impact to a particular application or data set, i.e. it was application/data set agnostic. The Court noted that the programme possessed a 'technical effect' that enhanced the system's functionality by processing multiple unrelated applications using the same command surface.

The Court for this purpose also took note of the Joint Parliamentary Committee Report in respect of the Patents (Second Amendment) Bill, 1999, which recommended the inclusion of the expression '*per se*', and was of the view that there is sufficient basis in text and legislative history to conclude that Parliament's intention was not to exclude all computer related inventions (CRI) from patent eligibility.

Also, relying upon precedents from the United Kingdom and the European Union, the Court noted that that the JPC Report equated the qualifier '*per se*' with 'as such' and that the latter expression finds place both in the UK Patents Act and the European Patents Convention. It was thus held that even when the claimed invention relates to a computer related invention, if it results in a technical effect that improves the system's functioning and efficacy (effect on hardware) or provides a technical solution to a technical problem and is, therefore, not limited in its impact to a particular application or data set, it will surmount the exclusion under Section 3(k).

It may be noted that while setting aside the Assistant Controller's Order, the High Court also concluded that the definition of computer programme as given in the Copyright Act is applicable in the context of the Patents Act, including for appreciating what 'computer programme *per se*' means. The Court was also of the view that a computer related invention used in a business method would not fall within the 'business

method' exclusion under Section 3(k), as the monopoly claim is being sought for the CRI and not for the business method.

Lastly, the Court elaborately discussed few cited prior arts and distinguished them. It was hence of the view that the invention passes the inventive step test under Section 2(1)(ja) of the Patents Act, 1970. It was noted that the commanding system resulted in a shared command surface that accommodated the functioning of various unrelated applications, a technical advancement which would not be obvious to the person skilled in the art (PSITA).

***The applicant-appellant was represented by Lakshmikumaran & Sridharan Attorneys in this case.*** [*Microsoft Technology Licensing LLC* v. *Assistant Controller of Patents* – Judgement dated 3 July 2024 in (T) CMA (PT) No.49 of 2023, Madras High Court]

## Patent for a salt formulation for dry food products – Madras High Court overrules rejection under Section 3(e) as 'admixture'

The Madras High Court has allowed grant of a patent claim relating to dry food products containing table salt formulations with an object to give the same salt perception, i.e. retaining the salty flavour and at the same time, do away with the harmful effects of high sodium levels in salt.

The applicant had stated that the desired result was achieved by not mere an admixture of two inorganic salts but by adopting a process of producing building blocks in a flame spray process and by feeding the resulting salt containing off gas from the reactor, i.e. the aerosol directly onto a dry food product.

The Court in this regard observed that formation of aggregates from the primary particles by heating or compaction or exposure to diluted steam or a combination thereof is something that had not been used earlier. The High Court also distinguished the various prior arts while it observed that the prior arts taught away from the claimed invention.

Overruling the Patent Office's rejection under Section 3(e) of the Patents Act, 1970, the High Court was of the view that the Controller misdirected himself in concluding that the formulation was only a combination of two types of salts with varied degree of primary particle sizes with the said particles exhibiting their own properties.

[*Frito-Lay Trading Company-GMBH* v. *Assistant Controller of Patents and Designs* – Judgement dated 5 July 2024 in (T) CMA (PT) No.202 of 2023, Madras High Court]

## Patentability – Filtrate material acting merely as a medium for facilitating doping is not a 'reactant' under Section 3(d) – Higher cost than prior art is not material for 'industrial capability' under Section 2(1)(ac)

The Madras High Court has upheld the rejection of the patent for 'Method of doping Potassium into Ammonium Perchlorate'. In the claimed invention, Ammonium Perchlorate was dissolved in water and filtered using a stainless-steel sieve or cotton or filter paper, wherein recrystallization of Ammonium Perchlorate caused Potassium to be doped in Ammonium Perchlorate during the filtering process.

The Court upheld the objections of the Patent Office under Section 3(d) while it observed that an invention which makes mere use of a known process that does not result in a new product or does not employ a new reactant is excluded from patentability as per Section 3(d) of the Patents Act, 1970. It noted that the invention employed dissolution, filtration, heating, drying and reheating, which all processes were known, and that the resultant product in the invention was not new, being a mere variant of the one in a prior art. The Court was also of the view that the filtrate material cannot be considered as a reactant, as was a mere medium that facilitated doping.

On the question of industrial capability, the Court, however, overruled the decision of the Patent Office. The High Court observed that the 'capable of industrial applicability' under Section 2(1)(ac) does not require that the claimed invention should be capable of industrial use at a lower cost than prior art. According to the Court, the Patent Office's contention that changing the filtrate material during the filtration process is expensive, is not a relevant consideration for ascertaining the claimed invention's industrial applicability.

[*IIT Madras* v. *Controller of Patents & Designs* – Judgement dated 11 June 2024 in (T) CMA (PT) No.52 of 2023, Madras High Court]

## Patentability – Bioavailability *per se* does not establish 'therapeutic efficacy' under Section 3(d)

Setting aside the decision of the Patent Office rejecting a patent under Section 3(d) of the Patents Act, 1970, the Madras High Court has remanded the matter back to examine whether the enhanced bioavailability of the hemisulphate salt of a base compound is significant and whether it has the effect of enhancing therapeutic efficacy, *albeit* not by way of enhanced intrinsic pharmacological activity per unit of API.

The High Court in this regard examined the Supreme Court decision in *Novartis AG* v. *Union of India* and noted that a claim for enhanced therapeutic efficacy cannot be accepted merely on the basis of an assertion of enhanced bioavailability. According to the High Court, the Supreme Court had held that bioavailability is essential for therapeutic efficacy but bioavailability *per se* does not establish therapeutic efficacy in respect of a new form of a known substance.

Explaining the Supreme Court decision, the High Court stated that the *Novartis* decision should be understood as requiring that a patent application based on enhanced bioavailability should establish through data that administration of a specific quantity of the claimed new form of a known substance by a particular mode has greater therapeutic efficacy in view of the greater bioavailability thereof *vis-a-vis* administration of an equal quantity of the base compound by the same mode.

The High Court was also of the view that the applicant could also show that greater bioavailability enables administration of lower doses thereby lowering toxicity or other adverse effects, which would impair therapeutic efficacy. Further, according to the Court, enhanced therapeutic efficacy as regards a claim based on bioavailability, cannot be tested on enhanced intrinsic pharmacological activity per unit of API.

The High Court for this purpose deliberated on the definition of 'bioavailability' in medical literature, which refers to the extent and rate at which the API in a formulation reaches the intended site of action in the body. It was noted that bioavailability is a pharmacokinetic parameter, with mode of administration, distribution, metabolism and clearance/excretion as factors impacting the same.

[*Bristol Myers Squibb Company* v. *Deputy Controller of Patents* – Judgement dated 10 July 2024 in CMA (PT) No.2 of 2023, Madras High Court]


# News Nuggets

- Patents – Delhi HC sets aside abandonment, finding lack of diligence by Patent Agent – CGPDTM directed to have Code of Conduct by December 2024 to regulate Patent and Trademark Agents
- Patents – Finding of lack of inventive step without discussing prior arts is wrong
- Copyright infringement – AI music generators sued by group of US music labels
- Geographical Indication (GI) tag for Indian Basmati rice rejected by New Zealand
- Copyright infringement in news feed – ANI sues PTI for alleged copying of a video

## Patents – Delhi HC sets aside abandonment, finding lack of diligence by Patent Agent – CGPDTM directed to have Code of Conduct by December 2024 to regulate Patent and Trademark Agents

The Delhi High Court has set aside the abandonment of the patent application, finding fault in the working of the Patent Agent in not communicating the issuance of the First Examination Report (FER) to the patent applicant (petitioner here) and not informing that a reply to the FER is to be filed. The Court in this regard noted that prosecution of patents is a technical matter, which requires detailed discussion with clients as also inventors. Observing that Patent Agents are the only persons who can prosecute patents before the patent office, the Court held that they have enormous responsibility on their shoulders to ensure that valuable innovations are properly protected as per the procedures prescribed in law.

Also, according to the Court, the mere fact that the FER would be uploaded on the website may not be sufficient to hold that the applicant-petitioner had notice of the FER. The High Court in this regard was of the view that the availability of access to the IP office website cannot be a ground which can be taken, since most inventors and clients may not have the resources to access the IP office website and the technical expertise to understand the same.

Further, as per the High Court, considering the expanse of the duties and functions of Patent Agents, any carelessness, professional negligence or misconduct, unless accidental or inadvertent, deserves to be dealt with in a stringent manner. Considering the applicable conduct for Advocates and Chartered Accountants as also the rules being followed by some international IP offices, the Court was of the view that there is an imminent need for a proper system/ framework to be established for regulating the conduct of Patent Agents and Trademark Agents. The High Court in *Saurav Chaudhary* v. *Union of India* [Judgement dated 4 July 2024] hence directed the Controller General of Patents, Designs & Trade Marks (CGPDTM) to prepare and notify the Code of Conduct to regulate Patent and Trademark Agents within a period of 6 months, latest by 31 December 2024.

## Patents – Finding of lack of inventive step without discussing prior arts is wrong

The Madras High Court has remanded for fresh consideration the matter wherein a patent application was rejected by the Indian Patent Office after finding lack of inventive step. The Court in this regard observed that the conclusion that the

technical features of the claims were foreseeable by a person skilled in the art, was not arrived at by the Controller by way of supplying any justifiable reasons. The High Court in *Green Cross Holdings Corporation* v. *Controller of Patents and Designs* [Judgement dated 28 June 2024] also noted that the Patent Office had not discussed the prior arts with specific reference to the method claimed to be invented by the appellant - method of preparation of Plasma-derived Hepatitis B Human Immunoglobulin Agent.

## Copyright infringement – AI music generators sued by group of US music labels

A group of US music labels including Universal Music Group, Warner Music Group, and Sony Music Group has, as per reports, filed lawsuits in US Federal Court alleging copyright infringement by two of the most prominent AI music generators. According to the news dated 24 June 2024, as available here in www.wired.com, the record labels allege that the leading AI music generators trained on their artists' work without permission. The news report also asserts that the music labels have stated that they were independently able to prompt the AI music generators into producing outputs that 'matched' copyrighted work from various artists.

## Geographical Indication (GI) tag for Indian Basmati rice rejected by New Zealand

New Zealand has rejected a GI tag for Indian Basmati rice by stating that the specific fragrant rice is also grown outside India and those growers also have legitimate right to use the term 'Basmati'. As per news report dated 4 July 2024 available here, India's Agricultural and Processed Food Products Export Development Authority (APEDA) had argued for exclusive rights based on the historical association of 'Basmati' with its agriculture and culinary traditions. It may be noted that as per the news item in www.pressreader.com, earlier Australia also had in January 2023 rejected India's application seeking geographical indication tag for its Basmati rice.

## Copyright infringement in news feed – ANI sues PTI for alleged copying of a video

The Asian News International (ANI) has sued the Press Trust of India (PTI) for alleged copying of few specific videos of passengers suffering in a flight on the runway for nearly an hour. As per news reports dated 5 July 2024 by Bar & Bench, as available here, the ANI has sought damages of INR 2 crore and has also demanded a permanent injunction restraining PTI from copying its original work.

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