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BREAKING MYTHS-

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PHARMACEUTICAL PATENTS –

INDIAN SCENARIO

Patentability of pharmaceutical inventions in India has been a topic of intense debate since 1970. In India, the patentability of pharmaceutical inventions is understood and interpreted in light of Section 2(1)(j), Section 2(1)(ja) and Section 3 [specifically, Sections 3(d), 3(e) and 3(i)] of the Patents Act, 1970 [*hereinafter referred to as the Act*]. Further, the '*Guidelines for Examination of Patent Application in the field of Pharmaceuticals*', published by the Office of the Controller General of Patents, Designs and Trademarks assist the Examiners in examination of pharmaceutical inventions.

BACKGROUND

In the 1970s, India quickly became a major supplier of cheap drugs to a number of developing and under

developed countries. During the period 1970 - 1994, the Indian pharmaceutical industry became nearly self-sufficient and one of the largest exporters of generic medicines. A large number of developing countries depended on India for the supply of cheaper generic medicines. However, since Indian patent laws did not allow patenting of pharmaceutical products at the time, innovation was discouraged.

The WTO agreement, of which India is a signatory, came into force from January 01, 1995. TRIPs (Trade Related Aspects of Intellectual Properties) agreement (Annexure 1C of the WTO agreement) under Article 27, required introduction of both product and process patenting in all fields of technology including drugs, foods, products of chemical reactions and micro-organisms. In order to become TRIPS compliant, India needed to revise its patent laws to

provide product patent protection for pharmaceuticals. While traversing the history of the development of the legislation related to pharmaceuticals, Honourable Supreme Court of India referred to a letter written by the HIV/ AIDS Director of the WHO, dated December 17, 2004, to the then Minister of Health and Family Welfare, Government of India. A part of said letter is quoted herein below:

"As India is the leader in the global supply of affordable antiretroviral drugs and other essential medicines, we hope that the Indian government will take the necessary steps to continue to account for the needs of the poorest nations that urgently need access to anti-retrovirals, without adopting unnecessary restrictions that are not required under the TRIPS Agreement and that would impede access to medicines".

Accordingly, the Indian Parliament amended section 3(d) of the Act in the year 2005 in order to strike a balance between the patent laws in India becoming TRIPS compliant vis-à-vis ensuring that such patentability does not have an adverse effect on public health and interest.

The same is reflected in the fact that as per the data provided in the Annual Reports published by the Indian Patent Office [*hereinafter referred to as the IPO*], the grant rate of pharmaceutical inventions has increased by a phenomenal 60.17% in the duration of 2012 to 2017.

SECTION 3 OF THE ACT

Section 3 of the Act stipulates, "What are not inventions" as per the Act. The main aim of the amendments of the Patents (Amendment) Act of 2005 is to prohibit ever-greening of drug patents and bring within the ambit of patentability, the patents on variants

of those chemical compounds that show significant enhancement in therapeutic efficacy.

Section 3(d) of the Act recites as follows:

“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”.

Thus, Section 3(d) of the Act stipulates that in an invention claiming an already known substance, having established medicinal activity, such substance shall be deemed to be treated as a same substance, and thus, shall fall foul of patentability, unless the invention is able to demonstrate significantly improved therapeutic efficacy with respect to that known compound.

Often misunderstood, Section 3(d) of the Act, does not in fact act as an impediment in the patentability of pharmaceutical inventions. The Supreme Court of India in a landmark judgement¹ in 2013, has emphasized on the positive construction of Section 3(d) in the patentability of pharmaceuticals as a second-tier of

¹ Novartis AG vs. Union of India (UOI) and Ors. [Civil Appeal Nos. 2706-2716 of

2013 (Arising out of SLP (C) Nos. 20539-20549 of 2009)]

qualifying standards for pharmaceutical products in order to leave the door open for true and genuine inventions, but at the same time, to check any attempt at repetitive patenting or extension of the patent term on spurious grounds.

The provision of Section 3(d) of the Act is adjudicated meticulously and with utmost care by the IPO. To enable Applicants to substantiate the therapeutic efficacy of their invention, in various matters, Controllers have permitted the Applicants to produce additional data and experimental results during the proceedings, even in cases where said data and results were not directly referenced in the specification of the application.

Section 3(e) of the Act recites as follows:

"a substance obtained by a mere admixture resulting only in the aggregation of the properties of the

components thereof or a process for producing such substance".

It is a well-accepted principle of Patent Law that mere placing side by side of old integers so that each performs its own proper function independently of any of the others is not a patentable combination, but that where the old integers when placed together has some working interrelation producing a new or improved result, then there is patentable subject matter in the idea of the working inter relations brought about by the collocation of the integers.

According to **Section 3 (i) of the Act**, any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products is not

an invention. Patent may however be obtained for surgical, therapeutic or diagnostic instrument or apparatus. Also the manufacture of prostheses or artificial limbs and taking measurements thereof on the human body are patentable.

With respect to patenting of pharmaceutical inventions in India, Section 3(d) of the Act takes the spotlight of the debate. The purpose of the above-said provision has been time and again explained by the IPO as well as the Indian Courts as to ensure that for an invention to obtain a patent for the second and subsequent use of a medicament, the therapeutic efficacy must be enhanced or at least a new reactant must be employed in its manufacture.

Landmark Cases with respect to Section 3(d) of the Act

Below is a timeline of the landmark cases decided by the IPO, Intellectual Property Appellate Board [*hereinafter referred to as IPAB*] and the Indian Courts with respect to Section 3(d) of the Act.



A landmark and vastly debated case in the development of pharmaceutical patent regime in India is the Novartis AG vs. Union of India (UOI) and Ors.², commonly referred to as the '*Glivec case*'. The judgement pronounced by the Supreme Court of India has time and again been analysed and commented upon by critics and commenders alike. The following is a brief analysis of the above-said judgement.

NOVARTIS AG VS. UNION OF INDIA (UOI) AND ORS.³

By way of a special leave petition filed before the Supreme Court of India, Novartis appealed the decision of the IPAB of rejecting the patent application⁴ "Crystal Modification of a N- Phenyl-2-Pyrimidineamine

derivative, processes for its manufacture and its use" on the ground that the subject matter claimed in the patent application was non-patentable under the provision of Section 3(d) of the Act.

Though the Supreme Court rejected the patent application and upheld the decision of the IPAB, the findings in the matter are pertinent to be noted for applicants of pharmaceutical inventions.

One imperative clarification made by the Hon'ble Court is with respect to incremental inventions. The Court clarified that the provision of Section 3(d) of the Act should not be interpreted to bar patent protection for all incremental inventions of pharmaceutical substances. The Court held that, "*We have held that*

² Civil Appeal Nos. 2706-2716 of 2013 (Arising out of SLP (C) Nos. 20539-20549 of 2009)

³ Civil Appeal Nos. 2706-2716 of 2013 (Arising out of SLP (C) Nos. 20539-20549 of 2009)

⁴ Indian Patent Application number: 1602/MAS/1998

*the subject product, the beta crystalline form of Imatinib Mesylate, does not qualify the test of Section Atomic En of the Act **but that is not to say that Section Atomic En bars patent protection for all incremental inventions of chemical and pharmaceutical substances. It will be a grave mistake to read this judgment to mean that Section Atomic En was amended with the intent to undo the fundamental change brought in the patent regime by deletion of Section 5 from the Parent Act. That is not said in this judgment.***

Further, the Hon'ble Court clearly and repeatedly clarified that the findings of the Court were based on the material/ data provided before it by the Applicant, said material/ data failing to substantiate the therapeutic efficacy of the claimed invention. It is imperative to note that the Hon'ble Court did not deny or disregard the fact that increase in bioavailability

may lead to an enhancement of therapeutic efficacy, but on the other hand, held that much like any other claim of enhancement of therapeutic efficacy, such claims must be supported by research data. Since the Applicant was unable to substantiate its claim that the beta crystalline form of Imatinib Mesylate has 30 per cent increased bioavailability as compared to Imatinib in free base form by way of any research or evidence, the Court did not find the claimed invention as disclosing enhanced therapeutic efficacy. Accordingly, the Hon'ble Court held that, "... *the position that emerges is that just increased bioavailability alone may not necessarily lead to an enhancement of therapeutic efficacy.*

Whether or not an increase in bioavailability leads to an enhancement of therapeutic efficacy in any given case must be specifically claimed and established by research data. In

*this case, there is absolutely nothing on this score apart from the adroit submissions of the counsel. **No material has been offered to indicate that the beta crystalline form of Imatinib Mesylate will produce an enhanced or superior efficacy (therapeutic) on molecular basis than what could be achieved with Imatinib free base in vivo animal model.***

*Thus, in whichever way Section Atomic En may be viewed, whether as setting up the standards of "patentability" or as an extension of the definition of "invention", it must be held that **on the basis of the materials brought before this Court**, the subject product, that is, the beta crystalline form of Imatinib Mesylate, fails the test of Section Atomic En, too, of the Act".*

Thus, to understand the above judgment as being discouraging with respect to pharmaceutical related

inventions would have a contrary result as that intended by the Hon'ble Court. Since 2013 i.e. post the Glivec judgement, the IPO as well as the Indian Courts have time and again upheld the sanctity of Section 3(d) of the Act, while at the same time maintaining the interests of innovators. The below decisions are reflective of the pro-patent and pro-innovation stand taken by the IPO and the Indian Courts alike, while deciding upon pharmaceutical related inventions.

F. HOFFMANN-LA ROCHE LTD. AND ORS. VS. CIPLA LTD.

Hoffman-La Roche Ltd. [hereinafter referred to as Roche] filed a suit for infringement of Indian Patent bearing number 196774 [hereinafter referred to as IN '774] against Cipla in 2008. The suit patent protected 'A NOVEL [6, 7-BIS(2- METHOXYETHOXY) QUINAZOLIN-4-YL]- (3-

ETHYNYLPHENYL) AMINE HYDROCHLORIDE' also known as 'Erlotinib Hydrochloride' which was licensed to Roche. Roche had been manufacturing 'Erlotinib Hydrochloride' as an anti-cancer drug under the brand name 'Tarceva' across the world.

The Single judge of the Delhi High Court decided against the interests of Roche with respect to the interim relief claimed by Roche, following which Roche appealed said decision before a Divisional Bench of the Delhi High Court.

Single Judge⁵

The Single Judge primarily held the following:

i. Section 3(d) of the Act –

The Single Judge denied Cipla's contention that the requirement under Section 3(d) of the Act was unfulfilled as the 'increased efficiency'

criteria was not met forth. The Hon'ble judge followed the observations of the Controller [in the pre-grant opposition filed against Roche in the prosecution stage] with respect to the therapeutic efficacy of the patented drug and held that the invention cannot be held to be non-patentable under Section 3(d) of the Act. It is pertinent to note herein that the Controller in the above-mentioned pre-grant opposition had accepted the efficacy data submitted by Roche during the course of the pre-grant proceedings. Though the Opponent in the matter objected to acceptance of such data, the Controller rejected said objection and held the same to be sufficient for establishing enhanced therapeutic efficacy of the invention and accordingly granted the patent to Roche.

⁵ I.A. 642/2008 in CS (OS) 89/2008

ii. Balance of convenience & interim relief

While adjudicating the issue of balance of convenience, the Hon'ble Judge took note of the decisions of the Court of Appeal in the matter of Roussel Uclaf vs. G.D. Sarle⁶ and Company Ltd. and Cordis Corporation vs. Boston Scientific Corporation⁷.

The Hon'ble Judge took note that a month's dosage of Tarceva [Roche's drug] for a patient undergoing treatment for cancer was Rs.1.4 lakh whereas the equivalent cost of Erlocip [Cipla's drug] would be Rs. 46,000. The Hon'ble Judge denied the relief of interim injunction against Cipla and held that_ "*... as between the two competing public interests, that is, the public interest in granting an injunction to affirm a patent during the pendency of an infringement action, as opposed to the public*

interest in access for the people to a life saving drug, the balance has to be tilted in favor of the latter. The damage or injury that would occur to the plaintiff in such case is capable of assessment in monetary terms. However, the injury to the public which would be deprived of the defendant's product, which may lead to shortening of lives of several unknown persons, who are not parties to the suit, and which damage cannot be restituted in monetary terms, is not only uncompensatable, it is irreparable. Thus, irreparable injury would be caused if the injunction sought for is granted."

However, the single judge, being mindful to the losses that may be caused to Roche, directed Cipla to take an undertaking to pay the damages in the event of the suit being decreed and to maintain faithful accounts and file quarterly accounts

⁶ [1977] F.S.R. 25

⁷ Cordis Corporation vs. Boston Scientific Corporation

with the Court along with an annual statement of the sales figures of the impugned drug.

Thereafter, Roche appealed the decision of the Single Judge before a Divisional Bench of the High Court at Delhi.

Divisional Bench⁸

While discussing the provision of Section 3(d) of the Act, the Divisional Bench luminously noted,

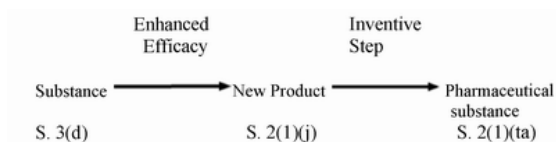
"62. ... Section 3(d) assumes that structurally similar derivatives of a known 'substance' will also be functionally similar and hence ought not to be patentable. **What is of crucial importance is that this is not a provision that merely bars certain subject matter from patentability. On the contrary, it provides that if the new form of the known substance is found despite a structural similarity to**

demonstrate a better functionality i.e. 'enhancement of the known efficacy', it would qualify for assessment under Section 2(1)(j) as if it were a new product involving an inventive step and it would thereafter be up to the applicant for the patent to demonstrate the patentability of this substance in accordance with Sections 2(1)(j) and (ja). This provision is not a patent term extension or an evergreening provision **but in fact recognizes incremental innovations in pharmaceutical patents.** The use of the words 'product' and 'substance' in Section 2(1)(j) and Section 3(d) is therefore telling, in that, the legislative intent appears clearly to demonstrate that all 'substances' may not qualify as 'products' under the Act, where the latter are only those substances that are patent-eligible. In fact, Section 2(1)(ta) provides the

⁸ RFA (OS) 92/2012 and 103/2012

bridge between Section 3 and Section 2(1)(j), in that, it defines a 'pharmaceutical substance' as 'any new entity involving one or more inventive steps'. Thus, the discovery of an entity or substance may not involve an inventive step. Insofar as there is no inventive step involved in its formation it is merely a substance even though its structural form may be hitherto unknown. A new chemical entity (NCE) that is structurally dissimilar but functionally similar to an existing chemical entity is thus merely a substance under Section 3(d). If the substance has an added layer of enhanced efficacy then it would be treated as a 'new product' and would be eligible for assessment under Section 2(1)(j) to ascertain whether its formation involved an inventive step. If the new product involved one or more inventive steps, then it would qualify as a pharmaceutical substance. Thus,

graphically represented, the same would be:--



The Hon'ble Court further held:

"We understand Section 3(d) as a positive provision that in fact recognizes incremental innovation while cautioning that the incremental steps may sometimes be so little that the resultant product is no different from the original. The inherent assumption in this is that an infringement of the resultant product would therefore be an infringement of the original i.e. the known substance and by no stretch of imagination can Section 3(d) be interpreted as constituting a defence to infringement."

Conclusively, the Divisional bench held Cipla liable for infringement of

the suit patent and consequently, liable to pay damages [to be submitted before the Joint Registrar and decided at a later date] along with costs on INR 5,00,000 [approx. USD 7200].

It is imperative to commend the High Court for intensively and concretely adjudicating issues that had been left vague by the earlier judgments. This well-reasoned judgment also does the essential job of reanalyzing the perspective and purpose of Section 3(d) of the Act.

Ajanta Pharma Limited vs. Allergan Inc., Allergan India Pvt. Ltd. and The Controller of Patents⁹

In a revocation petition filed by Ajanta Pharma Limited before the IPAB, against the granted patent of Allergan Inc. bearing patent no. 219504, the

provisions of Section 3(d) of the Act were discussed at length by both parties. The IPAB agreed with the perspective of the patent holder and clarified a distinct line between an attempt to claim derivatives of compounds vis-à-vis an invention comprising of a combination of compounds. The IPAB held as follows:

*"The section explained that a mere discovery of which is not to be considered as an invention if it is a new form of a known substance, new property of new use of known substance or a known process or the use of a known process, machine or apparatus. **But this discovery would be considered as an invention if the new form results in enhancement of known efficacy of that substance** and so on as described in the section. The explanation to the section*

⁹ ORA/21/2011/PT/KOL and MP. Nos. 60/2011, 2/2012, 59-61/2012, 72/2012, 73/2012, 127/2012, 128/2012, 134/2012,

135/2012, 12/2013 and 15/2013 in ORA/21/2011/PT/KOL

enumerates various derivatives of the known substance which shall be considered to be the same substance unless, there is significant difference in therapeutic efficacy. Therefore all forms of the known substance that are mentioned are derivatives of the known substance which could be salts, esters, ethers and so on. Combination is also mentioned here.

The respondent (patent holder) had argued that this cannot be considered as a form of a known substance. The respondent is right. This invention is a combination of Brimonidine and Timolol. The applicant perhaps wants us to consider it either as a derivative of Brimonidine or as a derivative of Timolol. It is not a derivative. The combination mentioned in the Explanation can only mean a combination of two or more of the derivatives mentioned in the Explanation or combination of one or more of the derivatives with the

known substance which may result in a significant difference with regard to the efficacy. A combination of two active drugs like Brimonidine and Timolol cannot be considered derivatives of each other. This ground is rejected.”

It is significant to note that the IPAB protected Allergan’s patent from the ambit of non-patentability under Section 3(d) of the Act by going to great lengths to understand and give justice to the scope of the invention and the true intent of the patent holder with respect to the compounds claimed in the invention. The efforts undertaken by IPAB to thoroughly discuss the facts of the case and the merits of the arguments presented by both parties, is appreciable. No stone was left unturned by the Appellate Board as it conducted an in-depth discussion and thorough review of the complete specification of the patent to understand the scope of the invention.

GLOCHEM INDUSTRIES LTD. VS.
CADILA HEALTHCARE LTD.¹⁰

Glochem Industries Ltd. [*hereinafter referred to as Glochem*] filed a pre-grant opposition against the grant of the patent application filed by Cadila Healthcare Ltd. [*hereinafter referred to as Cadila/ the Applicant*], titled "*crystalline clopidogrel besylate and process for preparation thereof*". Said opposition was disposed of in January 2009 and all the grounds taken up by Glochem i.e. anticipation by prior publication, anticipation by prior claiming, anticipation by prior use, lack of inventive step, non-patentable subject matter, insufficiency of disclosure were rejected by the Controller. Particularly, the Controller intensively debated the ground under Section 3(d) of the Act taken up by the Opponent.

The Controller while adjudicating the pre-grant opposition took note of the contents of the complete specification of the application along with further data submitted by the Applicant during the course of the pleadings. The Controller held that:

"The claims 1 to 3 of the alleged invention are directed to Crystalline Clopidogrel besylate. The besylate salt of Crystalline Clopidogrel is pure, free flowing, easy to handle and chemically stable (nor hygroscopic) which can be utilized on an Industrial scale (pages 2, 3 & 5 of Complete Specification). To support this and also to meet the requirements of Section 3(d) of Patents Act, 1970 the applicants with their reply statement, have submitted the Stability study data sheet of bisulphate (Enclosure 5 & 9) and besylate (Enclosure 6); along with Stability and Comparative

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<http://ipindiaservices.gov.in/decision/413-MUM-2003-491/413MUM2003%201.pdf>

Pharmaceutical characterization Report of solvated (toluene and dioxane) and Crystalline Clopidogrel besylate (Enclosures 13 & 14).

The stability study data for the Clopidogrel bisulphate salt reveals that there is **increase in the concentration of the inactive metabolite which in the long term reduces the efficacy of bisulphate salt by reduction of therapeutic dose** (Enclosure 5). **Further in tablets of bisulphate salt there is an increase in acid impurities** (Enclosure 9). Whereas the Crystalline Clopidogrel besylate of present invention surprisingly is not detected with inactive metabolite for over six months in any of the three batches (Enclosure 6). Hence, the Crystalline Clopidogrel **Besylate of instant invention is advantageous in terms of increased shelf life of the Clopidogrel bisulphate salt.**

The stability report given in the Enclosure 13 shows that the Crystalline Clopidogrel besylate of instant invention is **more free flowing and stable even after two month period in comparison to the solvated** (toluene and dioxane) forms of Crystalline Clopidogrel besylate (cited by the opponent).

The comparative Pharmaceutical Properties data provided in Enclosure 14 shows that the solvated (toluene and dioxane) forms of Crystalline Clopidogrel besylate are more cardiotoxic compared to the Crystalline Clopidogrel besylate of present invention. The Crystalline cop besylate is non-toxic till 50 μ M concentration, whereas the toluene solvated form showed toxicity at 5 μ M and dioxane solvated form showed toxicity at 25 μ M. **Hence it shows that the Crystalline Clopidogrel besylate is better and advantageous in matters of**

toxicity in comparison to solvated forms.

In view of the advantageous effects of Crystalline Clopidogrel besylate of instant invention over the known clopidogrel bisulphate and also over the solvated forms of Clopidogrel besylate in different characterization aspects, it can be held that the Crystalline Clopidogrel besylate of present invention compound is patentable and cannot be rejected under Section 3(d) of the Patents Act, 1970".

The Controller took note of the contents of the complete specification, submissions made during the pleadings and the further evidence/ research data submitted by the Applicant, and accordingly observed that the test of patentability laid down by Section 3(d) of the Act

had been sufficiently met by the application.

In light of the same, the Controller rejected the opposition.

IND SWIFT LABORATORIES LTD.
VS. CADILA HEALTHCARE LTD.¹¹

Ind Swift Laboratories Ltd. [hereinafter referred to as Ind] also filed an opposition against the grant of the patent application filed by Cadila, titled "*crystalline clopidogrel besylate and process for preparation thereof*". Said opposition was disposed of in September 2009 and all the grounds taken up by Glochem i.e. anticipation by prior publication, anticipation by prior claiming, anticipation by prior use, lack of inventive step, non-patentable subject matter, insufficiency of disclosure were rejected by the

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<http://ipindiaservices.gov.in/decision/413-MUM-2003-491/413MUM2003%203.pdf>

Controller. Since *Ind* did not cite any new documents, the Controller reiterated the contents of the decision in the Glochem opposition with respect to Section 3(d) of the Act taken up by the Opponent and accordingly, granted the patent.

Thereafter, *Ind* filed a petition¹² for review of the order granting a patent to Cadila and submitted four new annexures to substantiate the challenge to the patentability of the subject matter claimed in the invention.

However, the Controller reiterated its decision of granting a patent to Cadila and held that “***in view of the advantageous effects of Crystalline Clopidogrel besylate of instant invention over the known clopidogrel bisulphate and also over the solvated forms of***

Clopidogrel besylate in different characterization aspects, it can be held that the Crystalline Clopidogrel besylate of present invention compound is patentable and cannot be rejected under Section 3(d) of the Patents Act, 1970”.

Thus, the Controller refused the ground taken up by the Opponent in light of the enhancement of therapeutic efficacy established by the Applicant.

**RANBAXY LABORATORIES LTD.
VS. PFIZER HEALTH AB.**¹³

In 2007, the Indian Patent Office refused the pre-grant opposition filed by Ranbaxy Laboratories Ltd. [hereinafter referred to as Ranbaxy] against the grant of a patent to Pfizer

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<http://ipindiaservices.gov.in/decision/413-MUM-2003-491/413MUM2003%205.pdf>

¹³

http://ipindiaservices.gov.in/decision/IN-PCT-2000-00084-CHE-86/inpct2000_00084_che.pdf

Health AB [*hereinafter referred to as Pfizer*] for the invention claimed in the patent application titled "A PHARMAXCEUTICAL FORMULATION".

Dealing with the arguments put forward by Ranbaxy under **Section 3(d) of the Act**, the Controller held that the therapeutic efficacy was established by the Applicant by way of reduction in the number of urge incontinence episodes per week by 71% in relation to placebo. Further, the Controller addressed the ground raised by the Opponent under **Section 3(e) of the Act** and held that the invention is patentable on account of the synergistic effect disclosed in the specification. Accordingly, the Controller granted the patent to Pfizer. Relevant excerpts from the order are reproduced hereinbelow:

"The opponent has further argued and stated that the various processes as laid in the examples provided in

the instant application for the preparation of formulation as oral and other dosage forms comprises the well known active ingredients and other well known excipients. Under Section 3(d) of the Patents Act, combination of known substances, unless they differ significantly in properties with regard to efficacy, is not patentable; and also no patent can be granted for a composition which does not exhibit any synergistic effect under Section 3(e) of the Patents Act. Since the claims are related to a composition showing neither enhancement in known efficacy nor any synergistic effect, the invention falls under Sections 3(d) &(e) of the Patents Act, the patent should not be granted.

The agent for the applicant in his reply stated that the present invention is Novel, Inventive and Industrially applicable. The composition as claimed therein is not a mere admixture but it is a

synergistic composition. In support of their arguments, the applicant was referring to the Exhibit "I" referred to in the affidavit of Paul Abrams, wherein in the paper presented by Kerrebroeck et al., **it was shown that Tolterodine controlled release formulation according to the present application has significantly reduced the number of urge incontinence episodes per week by 71% in relation to Placebo. It was further stated that the description with respect to the efficacy is already provided in pages 14 & 15 of the complete specification.** Therefore it is prayed to grant the Patent right to the applicants.

Admitting the view of the applicant and also the results provided in the specification, I conclude that the amended

claims do not contradict the provisions Section 3(d) and Section 3(e) of the Patents Act and hence are allowable".

NATCO PHARMA LIMITED VS. PFIZER PRODUCTS INC.¹⁴

A Pre-grant opposition was filed by Natco Pharma Limited [hereinafter referred to as Natco] against the grant of a patent to Pfizer Products Inc. [hereinafter referred to as Pfizer] for the patent application titled "Quinazoline Derivatives Compounds and Composition Thereof". The Controller rejected the grounds taken up by Natco including but not limited to Section 3(d) of the Act and granted a patent to Pfizer.

The order of the Controller in the matter is significant as the Controller recognized and acknowledged that

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<http://ipindiaservices.gov.in/decision/537-DEL-1996-154/537del96.pdf>

data establishing therapeutic efficacy and synergistic effect of a pharmaceutical invention may not be available with the Applicant at the time of filing such application. In light of the fact that the research and development of pharmaceutical inventions is a long and gradual process, and that the purpose of examination under Section 3(d) of the Act is not to scrutinize the Applicant for the contents of the specification, but instead to evaluate the true intent and efficacy of a pharmaceutical invention, the Controller allowed the Applicant to submit further data and evidence to rebut the challenges made by the Opponent under Section 3(d) of the Act.

The Controller inspected and analysed the evidence submitted by the Applicant and on account of sufficient establishment of enhancement of therapeutic efficacy of the claimed invention by way of said data given by the Applicant, the

Controller was pleased to grant the patent. Relevant excerpt from the order of the Controller is reproduced hereinbelow:

"...The applicants submit that the providing of efficacy data at filing was not possible. However, the same has been given as and when asked by Controller. The data regarding survival rate increase has been significant as indicated in the Journal The Oncologist, Feb 5th 2007. In view of the fact that the opponents have not substantiated and elaborated this ground of objection. And further once the invention has been found inventive, the invention cannot be held non-patentable under section 3(d) of the Patents Act. Therefore, the invention cannot be held non-patentable under section 3(d) of the Patents Act, 1970".

*“.. in order to be successful on this ground **the opponent has to prove beyond doubt** that the alleged invention is either a mere discovery of any new property or new use for a known substance or it is a 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 it is a 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. **Since the opponents have proved neither clearly nor explicitly, this ground fails**”.*

– Indian Patent Office

M/S FDC LIMITED, INDIA VS.
VENUS REMEDIES LIMITED,
INDIA¹⁵

In 2009, in a matter of a pre-grant opposition filed by M/S FDC Limited, India [*hereinafter referred to as FDC*] against the grant of a patent to M/s Venus Remedies Limited [*hereinafter referred to as Venus*] for "*ANTIBIOTIC COMBINATIONS FOR PROVIDING TOTAL SOLUTION TO THE TREATMENT OF INFECTIONS*", the IPO discussed the extent of the onus on the Applicant of establishing enhancement of therapeutic efficacy and synergistic effect of the claimed invention. In the present matter, the Controller relied on the opinion of the EPO in the matter of **SUMITOMO/Yellowdyes¹⁶** wherein the Board of Appeal held that "*An invention which relates on substantial*

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<http://ipindiaservices.gov.in/decision/2510-DEL-2004-282/2510-del-2004.pdf>

¹⁶ O.J. EPO 1989, 115, (1989)

Available at: <https://www.epo.org/law-practice/case-law-appeals/pdf/t860254ep1.pdf>

and surprising improvement of a particular property need not also show advantages over the prior art with regard to other properties relevant to its, use, provided, the latter are maintained at a reasonable level so that the improvement is not completely offset by disadvantage in other respect....."

The Controller agreed with the above decision of the EPO and accordingly granted a patent to Venus. Relevant excerpt from the order of the Controller is reproduced hereinbelow:

*"Aminoglycoside cause oxidative stress when administered individually separately either alone or in combination with other antibiotic & causes toxicity, which has been reduced in the fixed dose combination of cefepime & amikacin along with the stabilizing agent L-arginine. **Therefore, the combination the individual component & its***

feature mentionally influence each other to achieve a technical advancement by way of efficacy. Therefore I feel that the combination of cefepime & amikacin enhances the synergism and qualifies the requirement of section 3(d)".

E.I. DU PONT DE NEMOURS AND COMPANY, USA VS. GHARDA CHEMICALS LIMITED, THANE

In 2010, the IPO adjudicated a pre-grant opposition filed by E.I. Du Pont De Nemours And Company, USA [hereinafter referred to as the Opponent] against the grant of a patent to Gharda Chemicals Ltd. [hereinafter referred to as the Applicant] for "A PROCESS FOR LARGE SCALE MANUFACTURE OF INDOXACARB"¹⁷. The challenge raised by the Opponent under Section 3(d) of the Act was that the invention

¹⁷ Indian Patent number 241255

claimed a mere use of a known process. The Controller rejected said ground taken up by the Opponent and held that:

*"... I have been convinced as per the discussion above that the claimed invention is novel as well as inventive over the prior art cited by the opponent. The Applicant seeks protection for an invention "Process for large scale manufacture of Indoxacarb" as contained in claims (1-3). **As the claimed process is novel and inventive it cannot be a mere use of a known process rather the said process employs a solvent mixture in the reaction scheme which is new.** Accordingly, such a ground of opposition is not validly established by the opponent".*

Accordingly, the Controller granted a patent to the Applicant.

INDIAN PHARMACEUTICAL ALLIANCE VS. CHIESI FARMACEUTICI S.P.A. OF VIA PALERMO¹⁸

In 2018, the IPO granted a patent to Chiesi Farmaceutici [hereinafter referred to as the Applicant] for "PRESSURIZED METERED DOSE INHALER COMPRISING FORMOTEROL AND BECLOMETASONE DIPROPIONATE" thereby rejecting the pre-grant opposition filed in the matter by Indian Pharmaceutical Alliance [hereinafter referred to as the Opponent]. The opposition comprised of objections under several grounds, including but not limited to the claimed invention being non-patentable subject matter under Sections 3(d) and 3(e) of the Act. It is pertinent to note that said grounds had also been taken up by the Controller in the First Examination

¹⁸

<http://ipindiaservices.gov.in/decision/779-KOLNP-2012-64903/SKS-Decision-779KOLNP2012->

[granted%20alongwith%20rejection%20of%20the%20representation%20us%2025\(1\).pdf](#)

Report [office action]. However, in light of the examples provided in the specification of the application and the submissions made by the Applicant, the Controller held all the objections to be met by the Applicant and granted the patent in the matter. Relevant excerpt from the order of the Controller is reproduced hereinbelow:

"Regarding 3(e) of the Patents Act, it is observed that the claimed inhaler comprising the formulation according to the present invention undeniably exhibits unforeseen synergistic effect as explained under Example 2, Comparative Example 3 and Comparative Example 4 of the complete specification starting from page 14, which is summarized below for your ease of reference. In the Example 2 and Comparative Examples 3 & 4 of the complete specification, the solubility of formoterol fumarate dihydrate in the presence and in the absence of each

of the ingredients of the claimed composition was estimated. It is further observed that, the presence of BDP in the mixture of HFA134a : ethanol at 2.7 % w/w significantly decreases the solubility of formoterol fumarate dihydrate suspended in the formulation, thereby hindering the occurrence of unwanted Ostwald ripening process, thus **improves stability over longer period of time**. In addition, **Example 5 of the complete specification shows that the excellent aerosol performance of the claimed inhaler, which is capable of providing upon actuation of the inhaler, a fine particle fraction (FPF) much higher than 50% for both the active ingredients that lead to improved therapeutic efficacy. This evidences that every ingredient of the inhaler has not been arbitrarily chosen, but is the useful range for having formoterol fumarate dihydrate in**

suspension and beclometasone dipropionate (BDP) in solution and exhibiting technical advancement/synergistic effect.

Therefore, the Opponent fails to establish such a ground of opposition yet again; whereas the objection raised under Non-Patentability u/s 3 of the hearing notice is also met”.

Similarly, in 2018, the IPO granted a patent to **Apex Laboratories Private Limited** for “A NOVEL CREAM AND A PROCESS TO MANUFACTURE THE SAME” bearing Indian Patent number 302376. The Controller had cited Sections 3(d) and 3(e) of the Act, among other grounds, as objections in the First Examination Report [office action]. However, the Controller held that the objections had been met in light of the enhancement of therapeutic efficacy and synergistic effect of the claimed invention being established by the Applicant in its response to the Report.

A patent was granted by the IPO to **HEIDELBERG PHARMA GMBH**, a German Company, for “METHODS FOR SYNTHESIZING AMATOXIN BUILDING BLOCK AND AMATOXINS” bearing Indian Patent number 310496. The Controller had cited Section 3(d) of the Act, among other objections in the First Examination Report [office action]. However, the Controller granted the patent in light of the submissions made by the Applicant in its response to the Examination Report in merely **9 days** from the date of submission of the Reply to the Examination Report by the Applicant.

Another patent was granted by the IPO to **HEIDELBERG PHARMA GMBH** for “AMATOXIN CONJUGATES WITH IMPROVED LINKERS” bearing Indian Patent number 310961. The Controller had cited Sections 3(d), 3(e) and 3(i) of the Act, among other objections in the First Examination

Report [office action]. However, the Controller granted the patent in light of the submissions made by the Applicant in its response to the Examination Report.

A patent was granted by the IPO to **ADVERIO PHARMA GMBH**, a German Company, for "METHOD FOR PRODUCING SUBSTITUTED 5-FLUORO-1H-PYRAZOLOPYRIDINES" bearing Indian Patent number 303187. The Controller had cited Sections 3(d) and 3(i) of the Act, among other objections in the First Examination Report [office action]. However, the Controller granted the patent in light of the submissions made by the Applicant in its response to the Examination Report.

COMPULSORY LICENCE

The Indian Patents Act does not define the term compulsory licensing. However, a common interpretation of the term compulsory licensing is when a government allows someone else to produce a patented product or process without the consent of the patent owner or plans to use the patent-protected invention itself¹⁹. The grant of compulsory licence is often misconstrued to mean the relinquishment of a patent holder's rights over the patented invention. However, in reality, the patent holder continues to have rights over the patent, including a right to be paid for copies of the products made under the compulsory licence²⁰.

Chapter XVI of the Act stipulates the relevant provisions with respect to compulsory licensing in India.

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https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm

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https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm

Specifically, Sections 84 and 92 of the Act provide the imperative conditions to be fulfilled to the grant of a compulsory licence.

As per Section 84 of the Act, any person, regardless of whether he is the holder of the licence of that Patent, can make a request to the Controller for grant of compulsory licence on expiry of three years from the date of grant of patent, when any of the following three conditions is fulfilled –

1. the reasonable requirements of the public with respect to the patented invention have not been satisfied;
2. the patented invention is not available to the public at a reasonably affordable price; or
3. the patented invention is not worked in the territory of India.

Further, compulsory licences can also be issued *suo motu* by the IPO under Section 92(1) of the Act, pursuant to

a notification issued by the Central Government if there is either a '*national emergency*' or '*extreme urgency*' or in cases of '*public non-commercial use*'.

The main objective of Section 84 of the Act is to prevent the abuse of patent as a monopoly and to cut way for the commercial exploitation of an invention by an interested person. In addition to the three conditions mentioned above, Section 84(6) of the Act enunciates the key factors considered by the IPO while granting a compulsory licence, said factors including but not limited to:

- (i) the nature of the invention;
- (ii) any measures already taken by the Patentees or any Licencee to make full use of the invention;
- (iii) ability of the Applicant (requesting the compulsory licence) to work the invention to the public advantage;

- (iv) the capacity of the Applicant to undertake the risk in providing capital and working the invention, if such application for compulsory licence were granted;
- (v) time elapsed since the grant of the patent i.e. worked or not worked.
- (vi) Whether the Applicant has made efforts to obtain a license from the Patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable period ['reasonable period' construed as a period not ordinarily exceeding a period of six months]

The provisions in the Act related to compulsory licence finds its' roots in the endeavour of the Indian Parliament to strike the right balance between the interests of innovators and the wider public interest in order

to foster an environment in which creativity and innovation can flourish.

As stipulated in Section 83 of the Act, *patents are not granted merely to enable patentees to enjoy a monopoly on a patented article.* Said provision emphasizes the general consideration that *the patent right is not abused by the patentee or person deriving title or interest on patent from the patentee, and the patentee or a person deriving title or interest on patent from the patentee does not resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology,* among other considerations.

The IPO, while deciding an application for compulsory licensing, noted that, *"from its very nature, a right cannot be absolute. Whenever conferred upon a patentee, the right also carries accompanying obligations towards the public at large. These rights and*

obligations, if religiously enjoyed and discharged, will balance out each other. A slight imbalance may fetch highly undesirable results. It is this fine balance of rights and obligations that is in question in this case”.

Landmark Compulsory Licensing Cases

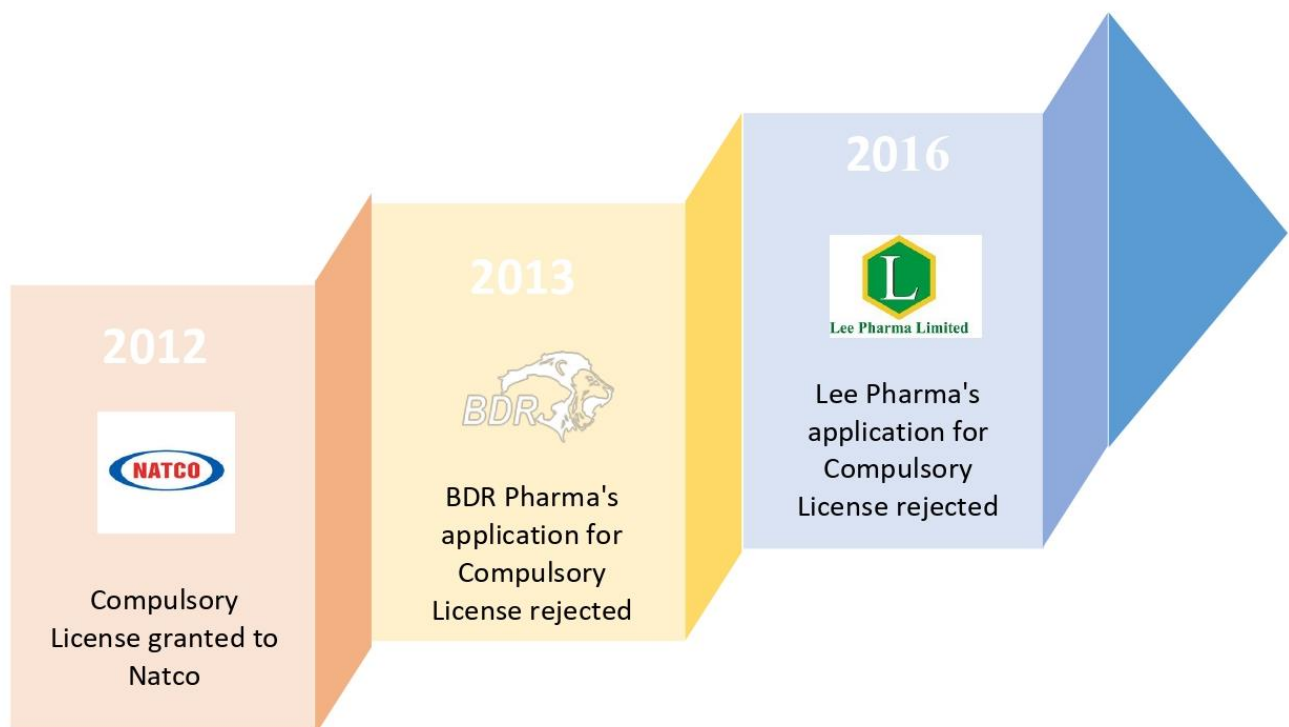
The provisions related to Compulsory licensing in India are often misconstrued as deprivative and intrusive by patent holders. The monetary investments made by patent holders for the research, development and prosecution of patented inventions, specifically pharmaceutical inventions, are a common concern. Critics are usually of the view that patent laws have been enacted to encourage innovation, technical advancement, technological progress, transfer of technology and thereby ultimately attain the common cause of development. Innovative drugs are

significantly more expensive than generic medicines on account of complex processes which are required to make the invention. It may be after thousands of trials in several permutations and combinations that a molecule reaches the market and then to the patients.

The concerns of patent holders in this regard, specifically pharmaceutical companies, have not fallen on deaf ears. On various occasions, the IPO and the Indian Courts have acknowledged and appreciated the investments in terms of time, money and efforts made by pharmaceutical companies for the development of pharmaceutical inventions. Both, the patent office and the Courts have aligned their practice in matters of compulsory licensing, taking a pro-patent stand by interpreting the relevant provisions with a view to protect and uphold the rights of the Patentee. A stern and severe test has been observed for the Applicants

filing for compulsory licences. The same is evident from the fact that in the duration of 2012 – 2017, merely 3 applications requesting a compulsory licence have been filed with the IPO, out of which only one of said applications has been granted. It is also pertinent to note that in the case where a compulsory licence was in fact granted, all three conditions stipulated in Section 84 were satisfied and the same is attributed by experts to be a vital reason behind the expeditious passage of the judgement.

Below is a timeline of the cases decided by the IPO with respect to Compulsory Licensing.



NATCO PHARMA LTD. vs BAYER
CORPORATION²¹
– COMPULSORY LICENCE
GRANTED

Natco Pharma Ltd. [*hereinafter referred to as Natco/ the Applicant*] filed an application for a compulsory licence for 'Nexavar', bearing patent number 215758, before the IPO under Section 84 of the Act. In a judgment delivered on March 9, 2012, the Controller granted the licence to Natco, against which Bayer filed an appeal before the IPAB.

IPO²²

Natco being a leading manufacturer and distributor of various drugs in India approached Bayer [*hereinafter referred to as the Patentee*] requesting a voluntary licence to manufacture and sell the drug,

however, the same did not materialize. The price for sale of the drug proposed by the Applicant was of a fraction [approx. 3%] of the price that the Patentee was selling the drug for at the time of making the Application. The Controller held that all the three grounds mentioned under Section 84 of the Act were met, i.e. the reasonable requirements of the public with respect to Bayer's drug were unsatisfied, it was not available to the public at a reasonably affordable price, and the patented invention was not being worked in the territory of India.

IPAB²³

In the interim, Bayer sought a stay on the Controller's decision, however, the same was denied by the IPAB. The IPAB upheld the Controller's decision to grant a compulsory licence to

²¹ C.L.A. No.1 of 2011

²²

<http://ipindiaservices.gov.in/decision/IN-PCT-2001-00799-MUM->

39950/INPCT200100799MUM-215758-compulsory_License_12032012.pdf

²³ OA/35/2012/PT/MUM

Natco. The below is a brief discussion of the technical and substantial issues adjudicated by the IPAB.

Technical issues –

- *Audi alteram partem*

The IPAB while adjudicating the Patentee's argument with respect to the IPO's failure to issue a notice before arriving at a prima facie determination under Section 87 of the Act. The IPAB clarified that the principles of *audi alteram partem* would only come into play after determination by the Controller on his prima facie satisfaction that the case needed to be heard, and thus the Patentee's objection in this regard was rejected.

- *The Applicant's attempt at obtaining a voluntary licence*

Another issue adjudicated by the IPAB was with respect to the Patentee's contention regarding the failure of the Applicant to make

reasonable efforts to negotiate the terms of a potential licence. For reference, it is to be noted that the Applicant had sent a letter to the Patentee seeking a voluntary licence. The Patentee's objection to said letter was that the Applicant failed to mention any terms and conditions that he was willing to accept. The Patentee had further given the Applicant 14 days to respond to the Patentee's response to the above-mentioned letter, which the Applicant had failed to avail. The IPAB held that the Applicant's efforts were reasonable and there was no obligation on the Applicant to make any further attempts.

It is pertinent to mention that the IPAB's decision on the issue has its pros and cons. Critics state that the decision sets a low bar of obligation for the Applicants of compulsory licence and the same has a significant impact on the nature of communication that could be

construed as an 'attempt'. Further, critics state that it would allow Applicants to successfully employ the threat of a potential compulsory licence as a bargaining chip for obtaining a voluntary licence on favourable terms. However, the flip side of the decision is that Patentees will be encouraged to engage in negotiations with voluntary licence seekers rather than summarily rejecting such requests without seriously considering the same.

Substantive issues –

- CIPLA's role in the dispute

The Patentee had filed infringement proceedings²⁴ against CIPLA in 2010 for selling a generic version of the patented drug [Nexavar] for the price of INR 30,000. In light of the same, the Applicant contended that the Patentee must not be permitted to include the sales of CIPLA in the total

sales of the subject drug in India as the Patentee was responsible for satisfying the reasonable requirements of the public with respect to the subject drug, as provided under Section 84(1)(a) of the Act.

With respect to the above objection, the Patentee submitted that since CIPLA was selling the same drug, purchase of CIPLA's drug by consumers would consequently affect/ reduce the requirement of the consumers to buy the Patentee's drug. The Patentee pointed out that on account of the significantly lower pricing of CIPLA, the Patentee's market was notably affected and the same would consequently result in the inability of the Patentee to satisfy the provisions of Section 84 (1) (a) of the Act. Thus, the Patentee submitted that its interests would be prejudiced on account of the actions of CIPLA.

²⁴ C.S. No. 523 of 2010

The IPAB concluded that the requirement had to be met by the Patentee alone and that it could not rely on CIPLA's sales especially since it was contesting CIPLA's market presence in a separate litigation. Further, the IPAB noted that the objective of granting a patent is to increase public access to the patented product. Consequently, the *quid pro quo* for patent protection is the Patentee's obligation to make the patented product available to the public at affordable prices. The IPAB opined that since the Patentee alone was getting the benefit of the patent, the burden of ensuring reasonable access also had to be met solely by the beneficiary i.e., the Patentee and/or his Licencee(s). Therefore, it held that CIPLA's presence was irrelevant for the purpose of determining the extent of the Patentee's compliance with the law.

The adjudication of this issue has been criticised on the grounds that

CIPLA's sale of the patented drug in violation of the Patentee's exclusive rights with respect to said drug would have had a noticeable impact on the Patentee's sale on account of the severely low prices allocated by CIPLA. However, it is pertinent to note that the decision on this issue is sound in law as CIPLA was not a party to the matter before the IPAB. Further, the IPAB considered the issue in view of the public's interest. It opined that the sole consideration in granting compulsory licences was whether the patented product was available to the public at a price that was reasonably affordable for them. Bayer argued that it had instituted an effective Patient Assistance Program subsequent to the filing of the application which should be taken into account. However, this was overruled by the IPAB on the ground the same would not count for the purposes of satisfying the requirements of Section 84 of the Act. **However, it is**

pertinent to note that the IPAB emphasized that there was no absolute bar on considering occurrences subsequent to the application. Thus, if said programme of the Patentee had met the reasonable requirements of the public, it could have been considered. Since that was not the case, the IPAB held that it would not count.

An important take away from this observation of the IPAB is the overall outlook taken by the IPAB while adjudicating such matters. Even without stipulating it in such terms, the emphasis on the public perspective is heartening. It illustrates yet again that the focal point of Indian pharmaceutical patent law seems to be on ensuring affordable access to the largest numbers and that the judiciary's primary consideration is that of public interest. The IPAB has sent out a clear message that it will not allow drug

companies to wriggle out of compulsory licences without actually working their patent to the advantage of the public. Indian patents are based on a *quid pro quo* and the IPAB seems unwilling to compromise on this aspect.

- Working of the drug

The Patentee submitted that it was not feasible to manufacture the drug in India and thus, the Patentee's only option was to import. However, the IPAB refused to accept the Patentee's plea in this regard. Differing slightly from the opinion of the Controller, the IPAB held that the word 'worked' could have a flexible meaning based on the specific facts. However, it pointed out that any contentions regarding the non-feasibility of local 'working' had to be proven, not merely stated. In the instant case, they agreed with the Controller that Bayer had failed to demonstrate why it could not 'work' the drug locally.

- Royalty Rate

The IPAB increased the royalty rate fixed by the Controller payable by the Applicant to the Patentee in respect of the licence to 7% from 6%. While acknowledging the United Nations Development Programme's specific recommendation that the rate of royalty be set at 4% and adjusted upwards as much as 2% for products of particular therapeutic value, the IPAB also took note of the disparate profit margins of the Patentee (roughly 14%) and distributors of Nexavar (about 30%). **Therefore, the IPAB increased the royalty rate to 7% so as to allow the Patentee to derive a reasonable advantage from its patent.**

Since the grant of a compulsory licence in favor of Natco Pharma Ltd. to manufacture Bayer's patented cancer drug, Nexavar, the provisions related to compulsory licence in India have been debated intensely.

While analyzing applications for compulsory licence, the Indian Patent Office ensures that the relevant provisions are not misemployed to diminish the rights of the Patentee and that the basic jurisprudence governing the subject of compulsory licence lies in striving to achieve a balance in the conflicting interest of the Patentee's exclusive rights and making the invention available at an affordable price to third parties in case of need.

BDR PHARMACEUTICALS
INTERNATIONAL PVT. LTD. vs.
BRISTOL MYERS SQUIBB
COMPANY²⁵
- APPLICATION FOR
COMPULSORY LICENCE REJECTED

In 2013, BDR Pharmaceuticals International Pvt. Ltd. [*hereinafter referred to as the Applicant*] filed an application for a compulsory licence under Section 84 of the Act, for Indian patent no. 203937 titled 'A COMPOUND 2-AMINO-THIAZOLE-5-CARBOXAMIDE'.

In May, 2013, the Controller issued a notice to the Applicant informing that no *prima facie* case was made out upon consideration of the application. Thereafter the Applicant requested to be heard in the matter and the same was allowed by the Controller. In a detailed order dated October 29, 2013, the Controller rejected the

application for compulsory licence. A brief discussion of the order and the significant observations of the Controller are as follows -

Person interested -

Based on the submissions made by the Applicant, the IPO noted that it was *prima facie* borne out that the Applicant was a person interested and had the capacity to undertake the risk in providing the capital and working the invention, if the application for a compulsory licence were to be granted, as the Applicant had his own manufacturing and marketing infrastructure.

Applicant's efforts to obtain a voluntary licence -

The Controller considered the communication between both parties, specifically, one letter dated February 2, 2012 vide which the Applicant requested a voluntary licence from

²⁵ C.L.A. No. 1 of 2013

the Patentee for said patented drug and one letter dated March 13, 2012 vide which the Patentee responded to the Applicant's letter and requested further information including but not limited to the details that demonstrate the ability of the Applicant to consistently supply high volumes of the patented drug in the market, any factors that may jeopardize Patentee's market position, quality related facts, etc. The Controller noted that the Applicant took the Patentee's response as '*clearly indicative of the rejection of the application for voluntary licence*' and thus, the Applicant did not pursue the matter and made no further efforts to arrive at an amicable settlement with the Patentee. It is imperative to note that the Controller in the order specifically clarified that '*a specific rejection letter of the offer made by the applicant to the patentee*' was not required to establish that sufficient

efforts have been made by the Applicant to obtain a voluntary licence. In fact, the Controller reiterated the contents of the notice (May, 2013) and stated that **the lack of *prima facie* case was based on the fact (not limited to) that "more than four and a half months remained unutilized out of the 'reasonable period' prescribed by the legislature for the purpose of mutual confabulations but the Applicant chose not to take any action during this precious time period which was available to the Applicant"**. The Applicant among other submissions in this regard, stated that the Patentee's request for further information was clearly indicative of unfair exploitation of the provision of Section 84(6)(iv) of the Act and that the Patentee would have misused such information in the (ongoing) infringement litigation filed by the Patentee against the Applicant.

Further, the Applicant submitted that such request for further information was a tactic to indefinitely delay the application for compulsory licence for want of specific denial from the Patentee. Specifically addressing this misplaced contention, the Controller clarified that the above-said provisions clarified beyond doubt that a Patentee cannot indefinitely prevent an Applicant for voluntary licence for making an application for a compulsory licence, and in fact, such delay can at most be for a period of six months from making an application for compulsory licence.

With respect to the queries raised by the Patentee in the response letter (March 2012), the Controller held the same to be reasonable. Further, the Controller specifically noted that the Applicant had not specifically highlighted any query that would jeopardize the Applicant before the IPO or the Court. Thus, the Controller refused to accept

the 'mere argument' submitted by the Applicant without any justification or reasoning. Further, in light of the communication undertaken by the Applicant with the Patentee after filing the application for compulsory licence (in furtherance of the earlier communication for voluntary licence to which the Applicant did not respond), the Controller noted such communication as clearly indicative of the Applicant's realization of the mistake and an attempt to justify the early inaction and consequently, the same being an afterthought.

It is imperative to note that the Controller specifically and concretely emphasized the duty cast upon an applicant for a compulsory licence to 'make efforts to obtain a licence from the Patentee on reasonable terms and conditions' was absolute, inflexible and without any exceptions. The Controller held the **conduct of the Applicant** in sending

a letter to the Patentee (dated February 2, 2012) for a voluntary licence and thereafter not responding to the Patentee's reply (dated 13th March 2012) **cannot** be termed as "efforts" and therefore would not satisfy the duty imposed on the Applicant under the provision of Section 84(6) of the Act.

Concluding the above discussion, the Controller momentarily held that "while a patentee may try to prolong the process of mutual deliberations by raising unnecessary queries, he was also entitled to satisfy himself regarding the credentials and capability of the applicant for a voluntary licence as well as the terms and conditions. The decision to grant a voluntary licence, particularly on a subject-matter covered by a patent, is an important decision for a patentee. While, it is possible that some of the queries raised by the patentee may not be strictly reasonable, it is natural that the

patentee may seek additional information from the requesting party to satisfy himself about the credentials and capability of the said party."

The above clarification comes as a saving grace to Patentees who have put considerable time, efforts and monetary investments into researching, developing and patenting their invention and the same acts as a much required acknowledgement of their rights with respect to granting or refusing licences.

Further, the Controller held that even if the Applicant was under an impression that the Patentee was engaging in delaying tactics, the act of not replying at all to the Patentee's reply (March 2012) is unexplainable as it goes against the golden thread apparently visible in Section 84(6)(iv) of the Act. **The Applicant ought to have appreciated that the**

provisions relating to compulsory licence are to be invoked as the last resort i.e. if the mutual deliberations do not lead to a result within six months, in accordance with the scheme of the law.

Thus, the Controller laid a strict test for the duty imposed by way of the above-mentioned provision, on the Applicant to undertake 'efforts' to obtain a voluntary licence from the Patentee and the same was not to be treated or interpreted as a mere formality.

In light of the above, the Controller held that the Applicant did not make efforts to obtain a licence from the Patentee on reasonable terms and conditions.

Matters subsequent to the making of application –

After receiving the IPO's notice dated May 04, 2013, the Applicant

responded to the Patentee's reply (March 2012) on May 10, 2013 i.e. after a noticeable delay of about 14 months. The Applicant thereafter filed a petition under Rule 137 of the Patents Rules, 2003, requesting the Controller to take on record the communication between the Applicant and the Patentee subsequent to the filing of the application for compulsory licence. The Applicant substantiated the above request by submitting that the provision of Section 84(6) of the Act which stipulated that the Controller "... shall not be required to take into account matters subsequent to the making of the application", was only applicable with respect to the Patentee.

The Controller discussed at length the relevant portion of Section 84(6) of the Act and held that contrary to the Applicant's assertion, the relevant provision was also applicable to the Applicant and not only the Patentee.

In light of the same, the Controller held that considering such subsequent communication would amount to granting an undue advantage to an Applicant seeking a compulsory licence, empowering him to file an application for compulsory licence and simultaneously enter into negotiations with the patentee. In such a case, the applicant would always have an undue advantage and the patentee will always be prejudiced, which is against the underlying intent behind the said clause.

Conclusively, the Controller did not go into the merits of the Applicant's submissions under Section 84(1) of the Act and held that the "*deliberate intent on part of the Applicant to refrain from entering into any kind of dialogue with the Patentee for the purpose of securing the grant of a voluntary licence, and the exercise of*

a deliberate choice to only invoke the provisions relating to compulsory licences without taking the requisite steps laid down by the law, cannot be classified as an "irregularity in procedure/timeline", which can be waived or condoned or declared to be not applicable."

LEE PHARMA vs. ASTRAZENECA

AB²⁶

– APPLICATION FOR COMPULSORY LICENCE REJECTED

In 2015, Lee Pharma, a Hyderabad based Indian pharmaceutical company, filed an application for compulsory licence under Section 84(1) of the Act, for the patent covering AstraZeneca's diabetes management drug 'Saxagliptin' [bearing Indian patent number 206543]. Said patent, titled "A cyclopropyl-fused pyrrolidine-based compound", was granted to Bristol-

²⁶ C.L.A. No. 1 OF 2015

Myers Squibb Company (BMS) and was assigned to AstraZeneca AB.

Lee Pharma [*hereinafter referred to as the Applicant*] attempted to establish that their negotiations for a voluntary licence with AstraZeneca [*hereinafter referred to as the Assignee*] were not rewarding as they did not receive any response from the latter within a reasonable period. The grounds alleged by Lee Pharma were that:

- The Patentee has failed to meet the reasonable requirements of the public,
- The patented invention is not available to the public at a reasonably affordable price, and
- The patented invention is not worked in India.

Person interested -

Based on the submissions made by the Applicant, the IPO noted that it

was *prima facie* borne out that the Lee Pharma was a person interested and had the capacity to undertake the risk in providing the capital and working the invention, if the application for a compulsory licence were to be granted.

Applicant's efforts to obtain a voluntary licence -

Further, with respect to the Applicant's efforts to procure a licence, the Controller took note of the communication between the Applicant and the Assignee and observed that over a year had passed in the process of the Applicant's attempt to obtain a licence and thus held that the Applicant has made efforts to obtain a licence from the Assignee on mutually agreeable terms.

The IPO took a pro-patent stand and laid down strict tests for the Applicant with respect to all allegations including but not limited to the

alleged reasonable requirement of the public and unreasonable pricing of said drug. The IPO noted that the Applicant failed to demonstrate and establish concretely its allegations and thus, rejected all grounds raised by the Applicant and refused the application for Compulsory licence.

A brief discussion of the IPO's observation and order in the matter follows.

Section 84(1)(a) of the Act –

While considering the Applicant's assertion under Section 84(1)(a) of the Act, the Controller placed reliance on the Hon'ble Bombay High Court's decision in the matter of Bayer Corporation vs. Union of India & Ors.²⁷, and noted the ruling of the Hon'ble Court that the reasonable requirement of the public has to be considered by the authorities in the context of number of patients

requiring the patented drug. The Controller observed that in the present application, the Applicant has not shown what is the reasonable requirement of the public with respect to the patented drug in India in the context of number of Type-II DM patients requiring the patented drug.

Further, the Controller observed that the Applicant also failed to demonstrate the comparative requirement of the patented drug vis-à-vis other drugs which were also Dipeptidyl Peptidase-4 [DPP-4] inhibitors, which are required for the treatment of Type-II DM and are available in the Indian market so that the reasonable requirements of the public in respect of the patented drug could be arrived. Furthermore, the Controller observed and noted the failure of the Applicant to submit any authentic data/ statistics on the patent drug's prescription by the

²⁷ Writ Petition no. 1323 of 2013

doctors in India over the other DPP-4 inhibitors. In fact, the Controller noted that the patented drug was listed as an Essential Medicine in the Essential Medicines List of the Govt. of NCT of Delhi for the treatment of Type-II DM.

The Controller noted that the calculations submitted by the Applicant to assert that the reasonable requirement of the public were not met by the Assignee, were mere assumptions and conjecture and did not arise out of authentic data/ statistics and thus, such assumptions were not sufficient and could not form the basis to prove the Applicant's assertion.

Additionally, while discussing the veracity and admissibility of the data submitted by the Applicant in the above regard, the Controller noted that evaluation should be done only for the patented invention on the

basis of the statutory provisions of the Act and in view of the precedents, and on no other grounds. Such evaluation should not include any third party or any other product or patent.

Accordingly, the Controller held that a *prima facie* case has not been made out by the Applicant to the effect that the reasonable requirements of the public with respect to the patented invention were not satisfied and thus, no case was made out in terms of Section 84(1)(a) of the Act.

Section 84(1)(b) of the Act –

In Bayer Corporation vs. Union of India & Ors.²⁸, the Hon'ble Bombay High Court held "*We are of the view that the Act itself does not bestow any powers of investigations with regard to the reasonably affordable price and therefore, the authorities do not have the where withal/personnel to carry*

²⁸ Writ Petition no. 1323 of 2013

out the above exercise. Thus, the same has to be arrived at on the basis of the evidence led by the parties before it of their respective prices...".

The Controller took note of the facts as stated/ assumed by the Applicant and observed that prices of the DPP-4 inhibitors in the Indian market are at par with the price of the patented drug of the Assignee, with the only exception of one such drug having a price slightly lower than that of the patented drug. The Controller clarified in his order that the observation relating to the prices was made on the basis of the per day requirements of the medicines presented in the Applicant's submissions.

It is important to note that the Controller in his order specifically pointed out that the Applicant in their application for grant of compulsory licence had proposed its own selling price in a range [in the range of INR

27 – 32 per tablet] similar to that of the price of the patented drug being sold by the Assignee. Though the Applicant submitted a revised selling price [in the range of INR 11 – 16 per tablet] and the same was considered by the Controller, it was also noted that the Applicant was unable to provide any details whatsoever when asked by the Controller that 'how many poor people in India were prescribed the patented drug but couldn't buy it because of the affordability issue'.

Based on the data provided by the Applicant, the Controller observed that it was difficult for him to infer that the patented drug was the only option for patients in India and was not made available to the general public at a reasonably affordable price.

It is imperative to note herein that it is sufficiently clarified by the Controller via his order that the

burden of proof for substantiating the assertions under Section 84(1)(b) of the Act and submitting concrete, clear and authentic evidence were on the Applicant in order to enable the Controller to determine the question of the availability and affordability of the patented drug. In the absence thereof, the Controller held that the Applicant had failed to *prima facie* show that the patented invention was not available to the public at a reasonably affordable price, and thus, no case was made out in terms of Section 84(1)(b) of the Act.

Section 84(1)(c) of the Act –

The Applicant submitted that despite the lapse of a long period of about 8 years from the date of the grant, the Assignee has not taken adequate steps to manufacture the patented drug and make full use of the invention in India to an adequate extent that is reasonably practicable.

Further, the Applicant submitted that the working of the patented product in the country is hindered by the importation from abroad.

To this regard, the Controller once again placed reliance on the judgement of the Hon'ble Bombay High Court in Bayer Corporation vs. Union of India & Ors.²⁹, and noted that it is clearly borne out of the above-said judgement that, to manufacture in India is not a necessary pre-condition in all cases to establish patent's working in India. However, it is pertinent to note that the Controller took notice of the requirement imposed on the patent holder to establish the reasons which make it impossible/ prohibitive to manufacture the patented drug in India, particularly when the patent holder has manufacturing facilities within India.

²⁹ Writ Petition no. 1323 of 2013

The Controller focused and allocated the burden on the Applicant to clearly establish/ fix the exact quantitative requirement of the patented drug in terms of number of patients requiring it or whether it is in shortage by way of authentic data, report, evidence or comparative study. In light of the Applicant's failure to do so, the Controller held that it is difficult to conclude whether manufacturing in India is necessary or not.

Another important aspect of the Controller's judgement in this regard is the inter-relationship identified and explained by the Controller between the three sub-sections/ grounds under Section 84(1) of the Act. The Controller held that, *"although each ground under Section 84(1) is independently provided in the Act, the Applicant's failure to prima facie make out any of the other two grounds has a consequential implication on this ground of manufacturing in India because whether the patented*

invention is required to be worked in the territory of India would be decided on the basis of its reasonable requirements at affordable price in India". The Controller thus held that the other two grounds had not been proved by the Applicant. Further, no evidence had been produced by the Applicant that led to pointing any shortage of the patented drug in India because of its importation only. Furthermore, the Controller held that the total volume requirement vis-à-vis quantity imported and availability at reasonable price shall only justify the manufacturing as a necessary pre-condition for patent being worked in India.

Accordingly, the Controller held that the Applicant had failed to establish that the patented invention is not worked in the territory of India and thus, no case was made out with respect to Section 84(1)(c) of the Act.

Since the Applicant was unable to concretely establish any of the grounds raised under Section 84(1) of the Act, the application for compulsory licence filed by Lee Pharma was denied by the IPO.

The IPO in its immaculate orders in matters of application for compulsory licences, has repeatedly and beyond any doubt clarified that an application under Section 84 of the Act is a last resort and must not be taken undue advantage of, by Applicants.

The IPO has consistently considered the conduct of the Applicant as relevant and has upheld the rights of the Patentees in matters where the Applicant's efforts for obtaining a voluntary license have fallen short.

The above orders come as a sense of relief for Patentees and a caution notice for Applicants failing to fulfill their obligations under the relevant provisions of the Act.

accelerated speed. Understanding the need for patentability of pharmaceuticals in India, the IPO is aligning its practice with the rest of the world and adopting a pro-patent attitude. Genuine and true pharmaceutical inventions are being welcomed in India to enable and ensure protection of the efforts and investments of the pharmaceutical industry.

It is evident from the above decisions of the IPO and the Indian Courts that the scenario of pharmaceutical patents in India is evolving at an

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