Intellectual Property Appellate Board
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OA/67/2015/PT/KOL

TUESDAY, THIS THE 29TH DAY OF DECEMBER, 2020

HON'BLE SHRI JUSTICE MANMOHAN SINGH — **CHAIRMAN**
HON'BLE DR. B.P. SINGH — **TECHNICAL MEMBER (PATENTS)**

UCB PHARMA GMBH
A GERMAN COMPANY
OF, ALFRED-NOBEL-STRASSE 10
40789 MONHEIM
GERMANY..... APPELLANT

(Represented by: Ms Rupsa Gupta)

Versus

1.CONTROLLER GENERAL OF PATENTS, DESIGNS & TRADEMARKS
BOUDDHIK SAMPADA BHAVAN
NEAR ANTOP HILL POST OFFICE
S. M. ROAD, ANTOP HILL,
MUMBAI – 400 037, INDIA

2. ASSISTANT CONTROLLER OF PATENTS & DESIGNS
BOUDDHIK SAMPADA BHAWAN
CP-2, SECTOR V
SALT LAKE,
KOLKATA-700 091, INDIA ..... RESPONDENTS

(Represented by - None)

ORDER

Hon'ble Shri Justice Manmohan Singh, Chairman

Hon'ble Dr. B.P. Singh, Technical Member (Patents)

1. The present appeal is filed under Section 117A of the Indian Patents Act, 1970, against the order dated 03/08/2015, passed by the Respondent NO.2 , being the Assistant Controller of Patents & Designs (then), under Section 15 of the Indian Patents Act, refusing to grant the Appellant's Indian patent application no. 56/KOLNP/2009.
2. The learned counsel of the appellant submits as under:
    2.1 Fesoterodine is known in the art for its potency in treating urinary incontinence. However, fesoterodine exhibits substantial degradation under stress conditions, e.g., in a humid environment and at increased temperature. The inventors of the present invention have found out that by using a few particular stabilizers, such as xylitol, sorbitol, polydextrose, isomalt, and dextrose, the degradation of fesoterodine can be substantially controlled even under stress conditions. These substances are capable of inhibiting, preventing, slowing down, or reducing the hydrolyzation of fesoterodine, and thus act as stabilizers. It has been observed by the inventors of the present invention, as have been shown in Table 4 and discussed on page 48 of the specification, that whereas fesoterodine itself was found to have degraded after about 12 weeks at about 400C, 75% relative humidity (R.H.) in open vials to the extent that only about 50% of the original fesoterodine remained in undegraded form, a granulate of fesoterodine and xylitol was found to have about 93% of the original amount of fesoterodine remaining in undegraded form after about 12 weeks under the same conditions. The use of other known stabilizers like mannitol and maltitol fail to prevent the substantial degradation.
    2.2 While refusing the instant application under Section 3(d), the Respondent no. 2 made certain observations, which are based

on incorrect interpretation of the Indian patent statute and well known case laws in the related field, and also based on incorrect understanding of the present invention, as explained below in a point-wise manner:

2.2.1 The Respondent no. 2 has stated on page 3 of the 'Refusal' decision that *"The applicant has duly admitted in their submissions that the increased stability acquired by the so called combination is conferred by stabilizers like sorbitol, xylitol and polydextrose to the active compound fesoterodine. This has also been substantiated by the results given in the disclosure of the specification. It is a well-known fact in the domain of pharmaceutical science that an active pharmaceutical substance will show different stability in different solvents. It is matter of permutation/ combination to find out in which particular solvent it will be stable."*

2.2.2 The Respondent no. 2 has therefore acknowledged that the disclosure of the specification has been substantiated by results regarding increased stability of the claimed combination. However, it appears to be the contention of the Respondent no. 2 that selecting a suitable solvent is a matter of permutation/combination. It appears that the Respondent no. 2 tried to question the inventive merit of the claimed invention. The appellant submitted detailed arguments to overcome the objections against alleged lack of inventive merit of the claimed composition and Section 3(e) of the Act in the FER response, based on which this objection was waived off by the Respondent no. 2.

No such objection was raised in the Hearing Notice or discussed during the Hearing, and in fact, it was specifically submitted by the appellant in the written note of arguments pursuant to the hearing that as the objections against alleged lack of inventive step and Section 3(e) have not been maintained by the Assistant Controller, it implies that he acknowledges the inventive merit and synergistic effect of the claimed combination. Once waived, the Respondent no. 2 cannot rely upon said grounds to refuse the application without giving the appellant an opportunity of being heard, as this clearly goes against the Principles of Natural Justice.

2.2.3 Also, the contention of the Respondent no. 2 that 'It is matter of permutation/ combination to find out in which particular solvent it will be stable' appears to be baseless and arbitrary. The appellant has already established in the specification as also in the submissions made before the Indian Patent Office from time to time as to how the claimed invention is non-obvious and inventive. In fact, as explained above, inventive step objection was waived off by the Respondent no. 2, and hence, it is arbitrary for the respondent no. 2 to suddenly conclude in his 'refusal' decision that the presently claimed invention is based on mere permutation/combination.

2.2.4 That the selection of the specific stabilizers xylitol, sorbitol, polydextrose, isomalt, dextrose is not a

matter of mere permutation/combination, has also been established by experimental data in the specification itself. It has been surprisingly found that granulating fesoterodine with either xylitol or sorbitol provides for enhanced stability during the granulation process as compared to granulating fesoterodine with either mannitol or maltitol. When fesoterodine was granulated separately with these four sugar alcohols and tested for the amount of hydrolyzation or total degradation that occurred during granulation, it was found that granulating with xylitol or sorbitol resulted in less degradation products than granulating with mannitol or maltitol. Granulating with xylitol or sorbitol led to the formation of about 0.06% to about 0.07% of hydrolyzation products and total degradation products, while granulating with mannitol or maltitol led to the formation of about 0.42% to about 0.73% of hydrolyzation products and total degradation products. (See Table 7 of the Specification). The surprisingly superior results observed for granulation with xylitol or sorbitol were also observed when fesoterodine granulates including xylitol or sorbitol were used to prepare pharmaceutical compositions. Pharmaceutical compositions in tablet form that were prepared with granulates of fesoterodine that included xylitol or sorbitol exhibited far less hydrolyzation products and total degradation products (about 0.06% to 0.11%) than tablets prepared with fesoterodine granulates containing mannitol or

maltitol (about 1.1% to 1.7%). (See Table 8 of the Specification). The difference between sorbitol and mannitol is especially surprising since these two sugar alcohols are isomers. As discussed in pages 48 and 49 of the specification, "Table 5a shows that while fesoterodine is stabilized against degradation in open vials when mixed with xylitol or sorbitol, it decomposes more rapidly when mixed with mannitol and maltitol" and "Table 5b shows that lactose destabilizes fesoterodine, while xylitol is capable of reducing the destabilizing effect of lactose". Table 6 on page 51 of the specification shows the synergistic stabilizing effect that xylitol, sorbitol, dextrose monohydr, isomalt, and polydextrose have on fesoterodine granulate over other stabilizers mannitol, maltitol, lactose.

2.2.5 In this context, the appellant would like to refer to the several granted Indian patents such as IN 316025 (stable pharmaceutical composition of fingolimod with glycine as a stabilizer and an acceptable excipient); IN 263346 (pharmaceutical composition comprising levetiracetam and a disintegrant selected from the group consisting of polyvinylpolypyrrolidone and sodium criscarmellose); and IN 304383 (liquid formulation of long-acting erythropoietin and an albumin-free stabilizer). All the above-mentioned Indian patents have been granted for formulation/compositions comprising a known active ingredient along with a specific solvent/stabilizer/disintegrant that leads

to some superior technical effect and the grant of these Indian patents substantiate the fact that selection of a specific solvent/stabilizer/disintegrant that leads to unexpected superior technical effect does not amount to 'mere combination/permutation' to render them obvious or non-inventive. We are submitting copies of the submissions made and claims on which patents have been granted for Indian patents IN 316025 (Annexure A), IN 263346 (Annexure B), and IN 304383 (Annexure C). The respondent no. 2 appears to have failed to appreciate the present invention and the long standing technical problems associated with formulation/compositions of fesoterodine.

2.3 The Respondent no. 2 on pages 3-4 of his 'refusal' decision states that *"IPAB order no- 173 of 2013 which has been referred by the applicant actually refers to a combination wherein two active substances which act independently as pharmaceutical substances and their synergistic effect was considered on being complied treated as a combination. The submission by the applicant that in present case also, the claimed subject matter is directed to a combination of two different known substances is not acceptable."* The respondent no. 2 also relied upon the judgment of the Honb'le Supreme Court in Novartis v. Union of India while quoting the following:

"...With regard to the genesis of section 3(d), and more particularly the circumstances in which section 3(d) was amended to make it more constrictive than before, we have no doubt that the 'therapeutic efficacy' of a medicine must be

judged strictly and narrowly. ...From this it is seen that only those properties that are directly related to efficacy are relevant for S. 3(d) and not all advantageous or beneficial properties. More importantly, considering the genesis of S. 3(d) the words 'therapeutic efficacy' must receive a narrow and strict interpretation. The net cannot be widened to bring in other non therapeutic advantages". The Respondent no. 2 has concluded that *"In the present case applicant has not provided sufficient evidence through submission and experimental evidence to demonstrate that the claimed so-called composition demonstrate significantly improved therapeutic efficacy when compared to the prior art. The so-called pharmaceutical composition claimed in the instant application has only one active ingredient (fesoterodine/ fesoterodine hydrogen fumarate), which is not novel in the domain of prior art. The efficacy shown therein does not show any superior therapeutic efficacy. Accordingly, it fails to pass the test of section 3(d) of the Patents Act (as amended)."*

2.4 The appellant wishes to traverse the respondent number 2's refusal under Section 3(d) of the Act based on two points –

2.4.1 the subject matter claimed for the present invention ought not to be deemed to fall within the mischief of Section 3(d) of the Act as it does not pertain to a 'new form of a known substance', rather, at best Section 3(e) could have been invoked as the claimed subject matter relates to combination of know substances; and

2.4.2 As Section 3(d) is not applicable, hence superior therapeutic efficacy is not required to be established, rather, unexpected synergistic efficacy

was required to be shown to satisfy the test of Section 3(e) of the Act, which was already established in Tables 4-8 of the original specification, and the synergistic effect was also acknowledged by the Respondent no. 2 in his hearing notice as well as in the refusal decision.

2.5 In fact, the appellant itself referred to IPAB Order Number 173 of 2013 (Ajanta Pharma Ltd v Allergan Inc) during the Hearing with the Asst. Controller (Respondent No. 2) and in the written note of arguments filed pursuant to Hearing. In this regard the IPAB held that *"The respondent is right. This invention is a combination of Brimonidine and Timolol. The combination mentioned in the Explanation [of Section 3(d)] 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."* Thus, if compound X is known and an inventor comes up with a polymorph Form A and polymorph Form B of compound X, then the term "combination" used in the 'Explanation' part of Section 3(d) will mean either the combination of Form A and Form B or a combination of compound X with either Form A or Form B, and such "combination" will have to show "superior therapeutic efficacy" over the known compound X. The term "combination" used in the context of Section 3(d) cannot be applied to a combination of two or more known substances. For combination of known substances, the Indian Patents Act specifically has the provision of Section

3(e), under which unexpected synergistic effect needs to be established.

2.6 In the refusal decision, the Respondent no. 2 has relied on the judgement of the Honb'le Supreme Court of India in the matter of Novartis AG vs. Union of India. However, it seems that the Respondent no. 2 has not considered the portion where the history and genesis of incorporation of provisions under Section 3(d) have been discussed. In the said judgement of the Honb'le Supreme Court of India, it has been stated that the best way to understand a law is to know the reason for it. In Utkal Contractors and Joinery Pvt. Ltd. and others vs. State of Orissa and others [(1987) 3 SCC 279], Justice Chinappa Reddy said: *"...A statute is best understood if we know the reason for it. The reason for a statute is the safest guide to its interpretation. The words of a statute take their colour from the reason for it."*

2.7 Also, in Reserve Bank of India v. Peerless General Finance and Investment Co. Ltd. and others [(1987) 1 SCC 424] Justice Reddy said: *"Interpretation must depend on the text and the context. ...Neither can be ignored. Both are important..A statute is best interpreted when we know why it was enacted.....If a statute is looked at, in the context of its enactment, with the glasses of the statute-maker, provided by such context, its scheme, the sections, clauses, phrases and words may take colour and appear different than when the statute is looked at without the glasses provided by the context...No part of a statute and no word of a statute can be construed in isolation...It is by looking at the definition as a whole in the setting of the entire Act and by reference to what preceded the enactment and the reasons for it that the Court*

construed the expression 'Prize Chit' in Srinivasa and we find no reason to depart from the Court's construction."

2.8 The said Novartis judgment also goes on to present a detailed account of how and why the provisions of Section 3(d) were introduced in the Patents Act - Section 3(d) was introduced for preventing evergreening of compounds, especially pharmaceutical compounds, by innovator companies, by way of claiming new forms of such compounds. For example, if an innovator company has invented a novel pharmaceutical compound X and has obtained a patent therefor in India, the company will be prevented from ever-greening the said compound by merely claiming an ester, a polymorph, a salt, an isomer or other derivatives thereof in a separate patent application, thereby intending to extend the patent term on the original compound X due to the provisions of Section 3(d). Under Section 3(d), if the innovator company wishes to obtain a separate patent on a salt or polymorph or ester or isomer or any other derivative of the original compound X, then it will have to establish that the said derivative differs significantly from the original compound X in terms of its efficacy, especially its therapeutic efficacy. In India, Section 3(d) was introduced, wherein it is specifically stated that *"mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance..."* is not patentable and it has been specifically stated by way of the 'Explanation' provided with Section 3(d) that *"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". Hence, clearly, Section 3(d) is applicable to such derivatives (salt, ester, polymorph, isomer etc.) of known compounds. Section 3(d) cannot be applied to a composition that comprises a combination of a known active ingredient and a known stabilizer, as is the case for the instant application. However, the respondent no. 2 appears to have completely erred in appreciating the intent, the context, and correct interpretation of Section 3(d) of the Act and has merely reproduced certain portions of the said landmark judgement of the Hon'ble Supreme Court without understanding the context under which Section 3(d) has been introduced in the Indian patent statute. For this reason alone, the decision of Respondent no. 2 may be set aside and overturned by the IPAB.

2.9 The appellant also pointed out to the Respondent no. 2 that the presently claimed composition is a combination of known substances – namely, fesoterodine as the active ingredient and xylitol / sorbitol / polydextrose as the stabiliser. Thus, the claimed combination cannot come within the purview of Section 3(d) of the Act, which bars from patentability new form of a known substance. The presently claimed invention is not a new form of a known substance but is rather, a combination of known substances. The claimed combination, at best, may be objected under Section 3(e) of the Act which bars mere combination of known substances that does not result in any unexpected synergistic effect. In fact, in the FER issued by Learned Dy. Controller of Patents & Designs, Dr. Dilip Kr. Chakraborty, in respect of the instant application, the objection under Section 3(d) was never raised, while an objection under Section 3(e) was raised. The issue of Section

3(d) was raised by the Respondent No. 2 in the Hearing Notice for the first time.

2.10 According to Section 3(e) of the Act, “A substance obtained by mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance” is not a patentable subject-matter. This provision of the Act specifically relates to compositions that are obtained by mere admixture of known substances which results only in the aggregation of the properties of the ingredients/components thereof. However, as the Respondent no. 2 has not maintained the objection under Section 3(e) in the Hearing Notice, and has gone on to acknowledge in his 'refusal' decision that “the applicant has duly admitted in their submissions that the increased stability acquired by the so called combination is conferred by stabilizers like sorbitol, xylitol and polydextrose to the active compound fesoterodine. This has also been substantiated by the results given in the disclosure of the specification.” Therefore, appellant has successfully overcome the non-patentability issues pertaining to Section 3(e) of the Act.

2.11 The appellant relied upon IPAB Order Number 173 of 2013 (Ajanta Pharma Ltd v Allergan Inc) (composition directed to combination of Brimonidine and Timolol) to establish the argument that combination of known substances cannot be objected under Section 3(d), but may be objected under Section 3(e) of the Act. While commenting on the above decision of IPAB in the 'refusal' decision, the Respondent no. 2 stated that the IPAB order number 173 of 2013 refers to a combination of two active substances which act independently as pharmaceutical substances and their synergistic effect was considered on being treated as

combination and that the submission by the appellant/applicant that in the present case also, the claimed subject matter is directed to a combination of two different known substances is not acceptable. The Respondent no. 2 again appears to have failed to appreciate the reason of citing the above IPAB order number 173 of 2013 and also failed to understand the logic applied by IPAB in arriving at the decision that Section 3(d) was not applicable in that case. It is not the issue of having one or two active ingredients in the composition/combination, the important consideration in this regard is that when the composition is a combination of known substances, then Section 3(d) is not applicable – this is irrespective of the fact that the composition comprises a combination of more than one active ingredients or that the composition comprises combination of one active ingredient along with other known excipients that render the composition some synergistic effect.

2.12 In this context, the appellant would once again like to refer to the previously-mentioned several granted Indian patents such as IN 316025 (stable pharmaceutical composition of fingolimod with glycine as a stabilizer and an acceptable excipient); IN 263346 (pharmaceutical composition comprising levetiracetam and a disintegrant selected from the group consisting of polyvinylpolypyrrolidone and sodium criscarmellose); and IN 304383 (liquid formulation of long-acting erythropoietin and an albumin-free stabilizer). In all of the above cases, Section 3(e) was argued and overcome based on the superior synergistic technical effect achieved in terms of improved stability or improved dissolution profile. In case of a composition falling within the ambit of Section 3(e), it is

required to establish the superior and unexpected synergistic effect, which may be in terms of stability, dissolution, bioavailability, solubility, impurity load etc. It is not required to establish superior therapeutic efficacy. Superior therapeutic efficacy is required to be established in cases of Section 3(d) which are basically directed to new salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers of a known compound, which is not the case in the present application.

2.13 The Respondent No. 2 has clearly erred in refusing the application on the grounds of Section 3(d), as the presently claimed invention ought not to be deemed to come within the purview of Section 3(d) of the Act, as it is not directed to a new form of a known substance. Respondent No. 2 has failed to appreciate the objective and scope of the claimed subject matter that relates to a composition comprising fesoterodine, or a pharmaceutically acceptable salt or solvate thereof, and a pharmaceutically acceptable stabilizer, wherein said stabilizer is selected from the group consisting of xylitol, sorbitol, polydextrose, isomalt, dextrose and combinations thereof and has wrongly invoked Section 3(d) alleging that the claimed subject matter is directed to a new form of a known substance. The Respondent No. 2 though has acknowledged the novelty and inventive merit of the claimed subject matter and has also acknowledged the increase in stability of the pharmaceutically active compound fesoterodine by addition of specific stabilizers has incorrectly asked for superior therapeutic efficacy of the composition.

3. The operating portion of the order of the respondent is as under:

3.1 ANALYSIS :

The applicant has duly admitted in their submissions that the increased stability acquired by the so called combination is conferred by stabilizers like sorbitol, xylitol and polysdextrose to the active compound fesoterodine. This has also been substantiated by the results given in the disclosure of the specification. It is a well-known fact in the domain of pharmaceutical science that an active pharmaceutical substance will show different stability in different solvents. It is matter of permutation/ combination to find out in which particular solvent it will be stable. Notwithstanding to the above fact the active pharmaceutical substance fesoterodine is not novel and a well-known compound in the domain of prior art. Fesoterodine is a prodrug. It is broken down into its active metabolite, 5-hydroxymethyl tolterodine, by plasma esterases. The IPAB order no- 173 of 2013 which has been referred by the applicant actually refers to a combination wherein two active substances which act independently as pharmaceutical substances and their synergistic effect was considered on being complied treated as a combination. The IPAB clearly stated –

> *"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 4 drugs like*

Brimonidine and Timolol cannot be considered derivatives of each other".

3.2 The submission by the applicant -that in present case also, the claimed subject matter is directed to a combination of two different known substances is not acceptable.

3.3 Further 4 documents were cited in the prior art. Applicants submission with respect to the cited prior art documents were mainly as follows –

3.3.1 D1(WO03/099268)- D1 does not discriminate between lactose mannitol and microcrystalline cellulose, on one hand , and sorbitol , on the other hand. Hence this reference does not provide any teaching from which skilled person could conclude that sorbitol is superior over other excipients with respect to the stabilizing action on festerodine.

3.3.2 D2 (WO01/35957)- It relates to stable salts of 3,3-diphenylpropylamine derivatives. The most preferred embodiment being fesoterodine hydrogen fumarate. But D2 fails to provide any information with respect to the stable pharmaceutical formulations and is silent to sugar alcohols such as xylitol, sorbitol etc.

3.3.3 D4(EP0957073)- It basically relates to fesoterodine and its salts. D4 does not give any examples of stabilizers and fails to mention sugar alcohols, such as sorbitol, xylitol etc. Hence there is no teaching which could incite the skilled person to favour sorbitol and/or xylitol over other excipients. Applicant also cited the following excerpt from opinion of the ISA –

" the claims appear to involve an inventive step in the light of the prior art available. The closest prior art D2 proposes for preventing degradation of fesoterodine conversion of the same into salt form. It has been shown with the application on file that combination with xylitol, sorbitol, polydestrose , isomalt or dextrose improves fesoterodine stability, whereas other sugar alcolhols , such as mannitol or maltitol fail to do so. The objective technical problem to be solved in the light of D2 was to provide an alternative for stabilising fesoterodine. None of the prior art documents available points to sorbitol or xylitol for solving the above technical problem. From D3 it was known that sorbitol and xylitol like other sugar (alcohols) can be used as stabilizers in lyophilized pharmaceutical compositions of specific phospholipase inhibitor."

3.4 *In the present case applicant has not provided sufficient evidence through submission and experimental evidence to demonstrate that the claimed so-called composition demonstrate significantly improved therapeutic efficacy when compared to the prior art.*

3.5 *Honb'le Madras High Court in the decision of Novartis Ag. v. Union of India (2007 4 MLJ 1153) said-*

"…Efficacy means 'the ability to produce a desired or intended result'. Hence, the test of efficacy in the context of section 3(d) would be different, depending upon the result the product under consideration is desired or intended to produce. In other words, the test of efficacy would depend on the function, utility or the purpose of the product under consideration. Therefore, in

the case of medicine that claims to cure a disease, the test of efficacy can only be 'therapeutic efficacy'".

3.6 *Honb'le Supreme Court in the judgment of Novartis v. Union of India said :*

"…With regard to the genesis of section 3(d), and more particularly the circumstances in which section 3(d) was amended to make it more constrictive than before, we have no doubt that the 'therapeutic efficacy' of a medicine must be judged strictly and narrowly. …From this it is seen that only those properties that are directly related to efficacy are relevant for S. 3(d) and not all advantageous or beneficial properties. More importantly, considering the genesis of S. 3(d) the words 'therapeutic efficacy' must receive a narrow and strict interpretation. The net cannot be widened to bring in other non therapeutic advantages" (emphasis added).

3.7 *In the instant case as discussed above the improved properties of the claimed invention provide advantages over the prior art in terms of stability of known compounds, but these advantages did not result in greater therapeutic efficacy.*

3.8 *Fesoterodine is used to treat overactive bladder (a condition in which the bladder muscles contract uncontrollably and cause frequent urination, urgent need to urinate, and inability to control urination). Fesoterodine is in a class of medications called antimuscarinics. It works by relaxing the bladder muscles to prevent urgent, frequent, or uncontrolled urination. The fumarate salt of fesoterodine is sold under the brand name of Toviaz.*

3.9 *The so-called pharmaceutical composition claimed in the instant application has only one active ingredient*

(fesoterodine/ fesoterodine hydrogen fumarate), which is not novel in the domain of prior art. The efficacy shown therein does not show any superior therapeutic efficacy.

3.10 Accordingly it fails to pass the test of section 3(d) of the Patents Act (as amended).

3.11 On the above foregoing discussion , considering all facts and submissions made by the agent on behalf of the applicant hence I hereby refuse to proceed with this instant application for grant of Patent.

4. It is evident that the respondent has refused the instant patent application only on the sole ground of non-patentability under section 3(d) of the Patents Act, 1970.

5. Hon'ble Supreme Court in Novartis case[1] examined the development of section 3(d) of the Patent Act, 1970 as follows:

"94....We once again examine here what was the amendment introduced in section 3(d) by the amending Act of 2005. Immediately before its amendment in 2005, section 3(d) was, in the Patents (Amendment) Ordinance, 2004 (Ordinance No. 7 of 2004), as under:—

"Section 3. What are not inventions.– The following are not inventions within the meaning of this Act,—

(d) the mere discovery of any new property or mere 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."

95. After the amendment with effect from Jan 1, 2005, section 3(d) stands as under: -

[1] Novartis AG vs Union Of India & Ors Available at https://indiankanoon.org/doc/165776436/

"Section 3. What are not inventions.– The following are not inventions within the meaning of this Act,—

(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

Explanation.—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy."

*96. As may be seen, the amendment (i) adds the words "**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"** at the beginning of the provision; **(ii) deletes the word "mere" before "new use";** and (iii) **adds an explanation at the end of the clause**. [Emphasis added]*

6. Further on the issue of interpretation Hon'ble Apex Court held that:

6.1 *"27. The best way to understand a law is to know the reason for it. In Utkal Contractors and Joinery Pvt. Ltd. and others v. State of Orissa and others[7], Justice Chinnappa Reddy, speaking for the Court, said:*

"9. … A statute is best understood if we know the reason for it. The reason for a statute is the safest guide to its interpretation. The words of a statute take their colour from

the reason for it. How do we discover the reason for a statute? There are external and internal aids.…"

6.2 *"28. Again in Reserve Bank of India v. Peerless General Finance and Investment Co. Ltd. and others[8] Justice Reddy said:*

"33. Interpretation must depend on the text and the context. They are the bases of interpretation. One may well say if the text is the texture, context is what gives the colour. Neither can be ignored. Both are important. That interpretation is best which makes the textual interpretation match the contextual. A statute is best interpreted when we know why it was enacted.…"

7. As is evident from the amendments of the Patents Act that the new words "*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"* was added for the first time through Patents (Amendment) Act, 2005 and since no definition was provided as to what could or couldn't be treated to be within the purview of "known substance"; an explanation was added which enumerated all the possible forms, combinations and even other derivatives as well, to be treated as the same substance *unless they differ significantly in properties with regard to efficacy.*

8. On the issue of "efficacy" Hon'ble High Court of Madras[2] and Hon'ble Supreme Court in the same case[3] has settled it to be 'therapeutical efficacy'. This is settled law of the land today.

9. Therefore, as per settled law if a new form of known substance is discovered and that new form do not have enhanced efficacy (read therapeutical efficacy) with that of the known substance; such new

[2] Novartis Ag vs Union Of India available at https://indiankanoon.org/doc/266062/

[3] Supra 1

form is not held to be patentable. This is clear from Hon'ble Supreme Court judgment[4]

> *"189. ……. 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.*
>
> *"190. Thus, in whichever way section 3(d) 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 3(d), too, of the Act."*

10. Hon'ble Supreme Court in the Novartis case[5] held further as :

> *"191. We have held that the subject product, the beta crystalline form of Imatinib Mesylate, does not qualify the test of Section 3(d) of the Act but that is not to say that Section 3(d) 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 3(d) 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.*
>
> *"192. Section 2(1)(j) defines "invention" to mean, "a new product or …", but the new product in chemicals and especially pharmaceuticals may not necessarily mean something altogether new or completely unfamiliar or strange or not existing before. It may mean something "different from a*

[4] Supra 1

[5] Supra 1

recent previous" or "one regarded as better than what went before" or "in addition to another or others of the same kind"[53]. However, in case of chemicals and especially pharmaceuticals if the product for which patent protection is claimed is a new form of a known substance with known efficacy, then the subject product must pass, in addition to clauses (j) and (ja) of section 2(1), the test of enhanced efficacy as provided in section 3(d) read with its explanation."

11. Looking at the teachings of section 3(d) mathematically, if substance X is known one and its new forms X' or X" is discovered; these new forms i.e. X' or X" or their combinations such as (X'+X") will not be held patentable, unless they show enhancement in the efficacy read (therapeutical efficacy) over the known substance i.e X.

12. Here, the issue in the instant case is different. The inventor herein has arrived at a composition of two substances though known, but the combination of these two, as claimed by the appellant and as held by the respondent is new and inventive. So to say, the inventive composition is made out of a substance 'A' i.e. fesoterodine and substance 'B' i.e. pharmaceutically acceptable stabilizer. There could be a debate as to whether this admixture satisfies the test of patentability as per the teachings of the section 3(e) quoted below:

(e) 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;[6]

but certainly not on the applicability of section 3(d) of the Patents Act, 1970.

13. Once we say so, we refute the submission of the learned counsel of the appellant who says that the objection of section 3(d) was not

[6] Available at http://ipindia.nic.in/writereaddata/Portal/ev/sections/ps3.html

raised at the time of First Examination Report. As we could see there is an objection on 3(d); however it is without any specifics. The FER issued on 09/10/2013 carried at para 10 &11 identical objections on section 3(d):

10. Claims fall u/s 3(d) of the Act.
11. Claims fall u/s 3(d) of the Act.

The response to that FER filed on 18/07/2018 carried the follwing submissions in that regard:

(2), (5) & (9) - (11) The surprising beneficial effect of the present application is demonstrated by way of the examples (Tables 4-8). **It is clearly apparent from these Tables that xylitol and sorbitol have a stabilizing effect on fesoterodine hydrogen fumarate which is significantly**

superior to the one of mannitol, lactose and microcrystalline cellulose. E.g., Table 5a shows that while fesoterodine is stabilized against degradation in open vials when mixed with xylitol or sorbitol, **it decomposes more rapidly when mixed with mannitol and maltitol**. Table 5b shows that **lactose destabilizes fesoterodine, while xylitol is capable of reducing the destabilizing effect of lactose**. The unexpected and exceptional stability of fesoterodine formulations according to the invention is not a mere aggregation of the properties of the components in the mixture, *i.e.* of fesoterodine and xylitol and/or sorbitol.

Additionally, the applicant would like to submit copies of two affidavits (enclosed as **Annexure B and C**) which were submitted at the USPTO to establish the inventive step. **These affidavits summarize the experimental data provided in the present application which supports the exceptional and unexpected effect of xylitol and sorbitol.**

14. Hence mentioning that the objection on 3(d) was first time taken by the respondent during hearing in not correct.
15. Further, we see that the respondent herein, appears to have confused himself. He holds after comparing the submission of the applicant on the prior arts cited, that *In the present case applicant has not provided sufficient evidence through submission and experimental evidence to demonstrate that* ***the claimed so-called composition demonstrate significantly improved therapeutic efficacy when compared to the prior art. [Emphasis added]***
16. By no teaching of the law or from the judicial pronouncements, the applicant is required to show the enhanced efficacy with regard to

the prior art(s). The efficacy (therapeutical) has to be exhibited if some new form of any known substance has been discovered and the applicant seeks patent for such "new form". Of course such 'new form' will not be patentable unless enhanced efficacy (therapeutical) is proven over the parent known substance.

17. **Combination/Compositions**

The provisions with regard to compositions claiming combinations are discussed as follows in the Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals[7]

> *"7.7 Combination/ Composition Claims*
>
> *Quite often, the claims of combination of pharmaceutical products escape the question of novelty and are dealt under the inventive step or relevant clauses of Section 3 of the Act. However, sometimes it may happen that the combination has already fallen in the public domain and hence, should be dealt under novelty also.*
>
> *7.8 Illustrative Examples for determination of novelty for combination/ composition claims:*
>
> *Example 1: Claimed invention relates to a composition for enhancing corneal healing said composition comprising vitamin A and a sterile buffer administered to the eye. Prior art discloses the use of the eye-drops to rewet contact lenses, wherein said eyedrops comprising Vitamin A , the sterile buffer and other excipients.*
>
> *Analysis: The claim lacks novelty, as being anticipated by the said prior art, which discloses all the features of claimed composition useful for enhancing corneal*

[7] Available at http://www.ipindia.nic.in/writereaddata/Portal/IPOGuidelinesManuals/1_37_1_3-guidelines-for-examination-of-patent-applications-pharmaceutical.pdf

healing. Thus, the claimed subject matter lacks novelty."

18. Further, discussing about the combination mentioned in section 3(d) the Guidelines mentions:

"10.10 The term "combination" as appearing in Section 3(d) has been explained by IPAB as "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"

19. The above quoted paragraph of the guidelines is based on one of the order of this Board in Ajantha Pharma Limited Vs Allergan Inc. and Others[8]. The foot note carries the citations.

20. The paragraph mentioned in footnote, however needs be corrected in the Guidelines as it mentioned paragraph 84 whereas it should be paragraph 83.

21. We quote the relevant paragraph 83 of the said order of this Board for better clarity:

83. According to the respondent this combination is not "a new form of a known substance" and can by no stretch of the imagination be considered as encompassing a comparison of dosing regimens where two actives are administered serially one TID and the other BID. Therefore assuming without admitting 3(d) applies, the comparison can be done only with monotherapy of the two drugs. According to the respondent, the clinical trial 12T and 13T shows numerically better and statistically significant IOP lowering compared to Brimonidine Monotherapy. ***Moreover, the fixed combination of the invention shows an improved safety profile.*** *Therefore*

[8] ORA/21/2011/PT/KOL of Order no. 173 of 2013

according to the respondent, the section 3(d) describes one category of substance or process which is not an invention, but it is a "mere discovery". 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 enumerates various derivatives of the known substance which shall be considered to be the same substance unless, there is significantly different in therapeutic efficacy. Therefore all the 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 had argued that this cannot be considered as a form of a known substance. The respondent is right. This is 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 be 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.[Emphasis added]*

22. It is pertinent to mention here that the novelty has been tested and found to satisfy the test of section 2(1)(j) of the Patent Act, 1970 and there is no objection on novelty discussed in the order of the respondent. Further the combinations of the instant invention of fesoterodine and pharmaceutically acceptable stabilizer in a specific given ratio cannot be termed as the combinations of the new forms or derivatives of the known substance.

23. Now an analysis of the order of the respondent:

22.1 The respondent mentions in his order that *it is a well-known fact in the domain of pharmaceutical science that an active pharmaceutical substance will show different stability in different solvents. It is matter of permutation/ combination to find out in which particular solvent it will be stable.*

22.2 Such statement, without any reasoning and backed by objective findings, particularly so, when there is no objection on "novelty" and "inventive step"; shows his insincere approach towards patent law. For any invention to be obvious and/or result of any *permutations /combinations,* should have been objectively countered; not through stray comments.

24. We, are, therefore inclined to accept the submission of the appellant that the claimed composition is a combination of known substances – namely, fesoterodine as the active ingredient and xylitol / sorbitol / polydextrose as the stabiliser. Thus, the claimed combination cannot come within the purview of Section 3(d) of the Act, which bars from patentability new form of a known substance. The presently claimed invention is not a new form of a known substance but is rather, a combination of known substances.

25. The respondent findings on applicability of section 3(d) in this case is totally negated as the claimed composition neither relates to a

new form of known substance nor any of the derivatives thereof. The composition of the present invention relate to combination of two ingredients. The claimed composition is held to be novel and inventive as there is no such objection. Since the invention do not attract the provisions of section 3(d) as well, there is no other objection left, which bars the patentability of the subject invention.

26. We, therefore, set aside the impugned order dated 03/08/2015 issued by the respondent, and direct the respondents to grant patent to the appellant on the existing set of claims within 3 weeks from the issuance of this order.

27. Keeping in view the above facts and circumstances, the instant appeal is allowed. No cost.

-Sd/- **-Sd/-**

(Dr. B.P. Singh)
Technical Member (Patents)

(Justice Manmohan Singh)
Chairman