IN THE HIGH COURT AT CALCUTTA

ORIGINAL SIDE

COMMERCIAL DIVISION

Present:

The Hon'ble Justice Krishna Rao

IPDPTA No. 117 of 2023

(OA/1/2020/PT/KOL)

UCB Pharma GMBH & Anr.

Versus

The Controller of Patents and Designs

Ms. Archana Shankar

Ms. Mini Agarwal

... For the appellant.

Mr. Nandlal Singhania

Mr. Sunil Kr. Singhania

... For the respondent.

Hearing Concluded On : 04.03.2025

Judgment on : 08.04.2025

Krishna Rao, J.:

1. This is an appeal against the order passed by the Deputy Controller of Patents and Designs dated 16th August, 2019, refused to proceed further with the application number 1574/KOLNP/2012 for grant of patent for invention, namely, *"Polyvinylpyrrolidone for the Stabilization of a Solid Dispersion of the Non-crystalline Form of Rotigotine"*. The national phase application in India was filed with 14 claims which are as follows:

> *"**1.** A method for stabilizing rotigotine, the method comprising providing a solid dispersion comprising polyvinylpyrrolidone and a non-crystalline from rotigotine, wherein the weight ratio of rotigotine to polyvinylpyrrolidone is in a range from about 9:3.5 to about 9:6.*
>
> ***2.** The method of Claim 1, wherein the weight ratio of rotigotine to polyvinylpyrrolidone in a range from about 9:3.5 to about 9:4.5.*
>
> ***3.** A solid dispersion comprising a dispersing agent and a dispersed phase, said dispersed phase comprising rotigotine and polyvinylpyrrolidone, wherein the weight ratio of rotigotine to polyvinylpyrrolidone is in a range from about 9:3.5 to about 9:6.*
>
> ***4.** The solid dispersion of Claim 3, wherein rotigotine is rotigotine free base.*
>
> ***5.** The solid dispersion of Claim 4, wherein the solubility of rotigotine in the dispersing agent is below 1 wt-%.*
>
> ***6.** The solid dispersion of Claim 3, 4 or 5 wherein the dispersing agent comprises at least one silicone pressure sensitive adhesive.*
>
> ***7.** The solid dispersion of Claim 3, 4, 5 or 6 wherein the dispersing agent comprises mixture of a first silicone pressure sensitive adhesive and a*

second silicone pressure sensitive adhesive and wherein the solid dispersion has a complex viscosity between 5 and 15 MP.

8. *The solid dispersion of Claim 3, 4, 5, 6 or 7 wherein rotigotine and polyvinylpyrrolidone are in a multitude of microreservoirs.*

9. *A pharmaceutical composition comprising a solid dispersion according to Claim 3, 4, 5, 6, 7 or 8.*

10. *A transdermal therapeutic system comprising at least one amine-compatible silicone pressure sensitive adhesive, about 0.1 to about 3.15 mg/cm^2 of rotigotine in the free base from, and polyvinylpyrrolidone, wherein the weight ratio of rotigotine to polyvinylpyrrolidone is in a range from about 9:3.5 to about 9:6.*

11. *The transdermal; therapeutic system of Claim 10, wherein rotigotine and polyvinylpyrrolidone are contained in a multitude of microreservoirs.*

12. *A transdermal therapeutic system comprising a solid dispersion of Claim 3, 4, 5, 6, 7, or 8.*

13. *The transdermal therapeutic system of Claim 12, comprising 0.1 to about 3.15 mg/cm^2 of rotigotine in the free base from and wherein the weight ratio of rotigotine to polyvinylpyrrolidone is 9:4.*

14. *A method for preparing a transdermal therapeutic system, the method comprising preparing a solid dispersion comprising a dispersing agent and a dispersed phase, said dispersed phase comprising rotigotine and polyvinylpyrrolidone, wherein the weight ratio of rotigotine to polyvinylpyrrolidone is in a range from about 9:3.5 to about 9:6."*

2. In response to First Examination Report, the appellant has revised the claims which reads as follows:

"1. *A method for stabilizing rotigotine, the method comprising providing a solid dispersion comprising a dispersing agent and a dispersed phase, said dispersing agent comprising at least one silicone pressure sensitive adhesive and said dispersed phase comprising polyvinylpyrrolidone and a non-crystalline form of rotigotine, wherein the weight ratio of rotigotine to polyvinylpyrrolidone is in a range from 9:4 to 9:6; rotigotine is rotigotine free base; and the solubility of rotigotine in the dispersing agent is below 1 w-%.*

2. *The method as claimed in Claim 1, wherein the weight ratio of rotigotine to polyvinylpyrrolidone in said dispersed phase is in a range from 9:4 to 9:4.5.*

3. *The method as claimed in Claim 1 or 2, wherein the weight ratio of rotigotine to polyvinylpyrrolidone in said dispersed phase is about 9:4.*

4. *The method as claimed in any one of claims 1 to 3, wherein the molecular weight of polyvinylpyrrolidone is in the range from 1,000,000 to 1,500,000 Dalton.*

5. *A solid dispersion comprising a dispersing agent and a dispersed phase, said dispersing agent comprising at least one silicone pressure sensitive adhesive and said dispersed phase comprising rotigotine and polyvinylpyrrolidone, wherein the weight ratio of rotigotine to polyvinylpyrrolidone is in a range from 9:4 to 9:6; rotigotine is rotigotine free base ; and the solubility of rotigotine in the dispersing agent is below 1 wt-%.*

6. *The solid dispersion as claimed in Claim 5, wherein the dispersing agent comprises a mixture of adhesive and has a complex viscosity between 5 and 25 MP.*

7. *The solid dispersion as claimed in Claim in 5 or 6, wherein the molecular weight of polyvinylpyrrolidone is in the range from 1,000,000 to 1,500,000 Dalton.*

8. *A pharmaceutical composition comprising a solid dispersion as claimed in Claim 5, 6 or 7.*

9. *A transdermal therapeutic system comprising the solid dispersion as claimed in claims 5 to 7 comprising at least one amine-compatible silicone pressure sensitive adhesive, about 0.1 to about 3.15 mg/cm^2 of rotigotine in the free base form, and polyvinylpyrrolidone, wherein the weight ratio of rotigotine to polyvinylpyrrolidone is in a range from about 9:4 to about 9:6.*

10. *A transdermal therapeutic system as claimed in Claim 9, comprising 0.1 to about 3.15 mg/cm^2 of rotigotine in the free base form and wherein the weight ratio of rotigotine to polyvinylpyrrolidone is 9:4.*

11. *A transdermal therapeutic system as claimed in Claim 10, comprising 0.2 to about 1 mg/cm^2 of rotigotine in the free base form.*

12. *The transdermal therapeutic system as claimed in Claim 9, 10 or 11 having a water content of below 2 wt%.*

13. *The transdermal therapeutic system as claimed in Claim 9, 10, 11 or 12 wherein the molecular weight of polyvinylpyrrolidone is in the range from 1,000,000 to 1,500,000 Dalton.*

14. *A method for preparing a transdermal therapeutic system, the method comprising preparing a solid dispersion comprising a dispersing agent and a dispersed phase, said dispersing agent comprising at least one silicon pressure sensitive adhesive and said dispersed phase comprising rotigotine and polyvinylpyrrolidone, wherein the weight ratio of rotigotine to polyvinylpyrrolidone is in a range from about 9:4 to about 9:6."*

3. The appellant revised the claims along with written submissions and has raised only 8 claims which reads as follows:

"1. *A solid dispersion comprising a dispersing agent and a dispersed phase, said dispersing*

agent comprising at least one silicone pressure sensitive adhesive and said dispersed phase comprising rotigotine and polyvinylpyrrolidone, wherein the weight ratio of rotigotine to polyvinylpyrrolidone is in a range from 9:4 to 9:6; rotigotine is rotigotine free base ; and the solubility of rotigotine in the dispersing agent is below 1 wt-%.

2. *The solid dispersion as claimed in Claim 1, wherein the dispersing agent comprises a mixture of adhesive and has a complex viscosity between 5 and 25 MP.*

3. *The said dispersion as claimed in Claim 1 or 2 wherein the molecular weight of polyvinylpyrrolidone is in the range from 1,000,000 to 1,500,000 Dalton.*

4. *A pharmaceutical composition comprising a solid dispersion as claimed in Claim 1, 2 or 3.*

5. *A transdermal therapeutic system comprising the solid dispersion as claimed in claims 1 to 3 comprising at least one amine-compatible silicone pressure sensitive adhesive, about 0.1 to about 3.15 mg/cm^2 of rotigotine in the free base form, and polyvinylpyrrolidone, wherein the weight ratio of rotigotine to polyvinylpyrrolidone is in a range from 9:4 to 9:6.*

6. *The transdermal therapeutic system as claimed in Claim 5, comprising 0.2 to about 1 mg/cm^2 of rotigotine in the free base form.*

7. *The transdermal therapeutic system as claimed in Claim 5 or 6 having a water content of below 2 wt%.*

8. *A method for preparing a transdermal therapeutic system as claimed in Claims 5 to 7."*

4. The respondent no.1 refused to grant patent on the following grounds:

"8. *Respondent submits about what are known in the art. First, rotigotine the active ingredient and its use in TDS is known in the art. Mixture of rotigotine and PVP is also disclosed in*

cited document. It is also known that PVP may be used as crystallization in inhibitor. As respondent discussed that ratio of rotigotine and PVP can be adjusted by skilled person. Cited document also discloses that PVP can be used as crystallization inhibitor. As per the appellant, finding of particular ratio of rotigotine and PVP is very important for stability of rotigotine and prevent crystallization of rotigotine. But as per respondent finding out a particular ratio of rotigotine and PVP is a routine experimentation, because all the components and their use are already known from cited prior art documents. Furthermore use of PVP as crystallization prevent is also disclosed in cited document ***D4****."*

5. In the hearing notice, three documents were cited i.e. D1: WO 03/092677, D2: EP 1669063 and D3: WO2009006787A1 but at the time of hearing, the respondent has raised two additional citations i.e. D4:EP2177217 and D5:US2005/0079206. Documents D3 and D4 are the same documents of same family but the respondent comes to the different analysis. The respondent rejected the Claims 4 to 7 under Section 2(1)(j) of the Patens Act, 1970 but in the hearing notice, no such objection was raised for the claims 4 to 7. The objection raised in the hearing notice are as follows:

*"**1.** After going through claim 1 it is not clear for which protection has been sought, for product or for method. In claim 1 there is no method step, rather this claim discloses features of solid dispersion. So claim 1 is not allowable u/s 10(4) of the Act. Claim 5 is redundant wrt claim 1 and so not allowable.*

***2.** Claims 9-14 are transdermal therapeutic system and method for preparation of transdermal therapeutic system. However, the claims 1-8 are defining method for stabilizing rotigotine and composition comprising rotigotine. Hence, these claims 9-14 are beyond the scope of claim 1-9."*

6. The commercial transdermal therapeutic system Neupro® was approved in 2006/2007 comprising the active ingredients rotigotine. Rotigotine is an active drug compound used for the treatment of patient suffering from Parkinson's Disease, depression, Restless-legs syndrome etc. In the year 2008, there was an emergence of Form II crystal as a result of which Neupro® had to be withdrawn from the market in the US and was only permitted in European Patent provided the transdermal patch is maintained through cold chain. Neupro® patch is appellants earlier TTS and has a ratio of 9:2 of Rotigotine : PVP.

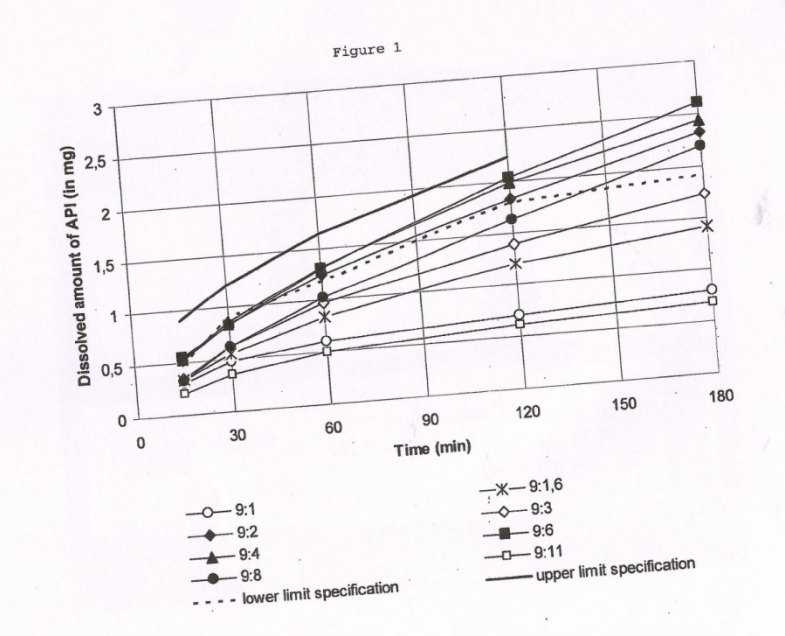
7. There was long term stability problems were associated with rotigotine. If rotigotine crystals that are formed in the self-adhesive matrix during long term storage, crystal growth can lead to reduce release rates of rotigotine with the risk eventually falling below the specified values. There was a need to develop a TTS that displays an appropriate drug release profile combined with adequate stability and should be stable at room temperature.

8. It is found that the object of the present invention is to provide a TTS that displays crucial pharmaceutical aspect of a TTS such as drug release profile distribution of the drug within the patch, drug solubility in the matrix, drug or patch stability, adhesiveness of the patch to the skin, smooth and complete removability of the patch from the skin.

9. Figure-1 shows the influence of varying rotigotine to polyvinylpyrrolidone weight ratios on the release of rotigotine from a

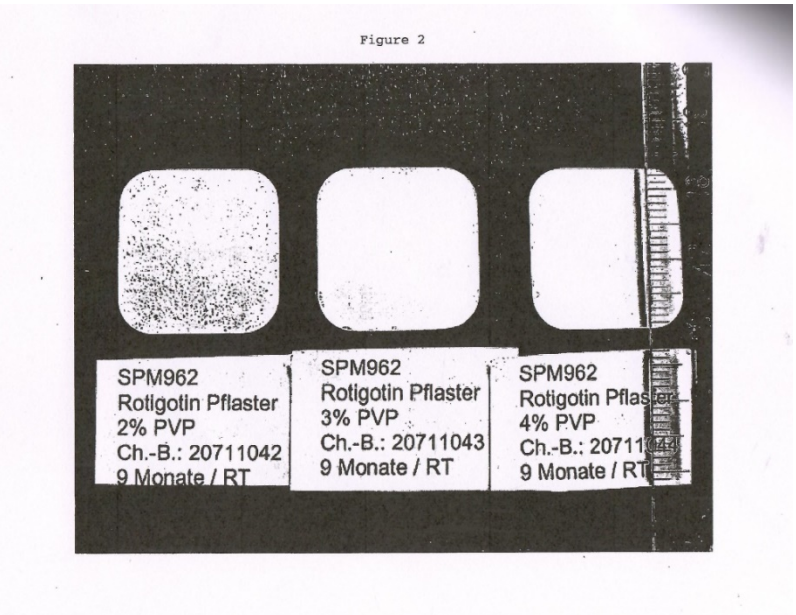
TTS. API = active pharmaceutical ingredient (rotigotine): PVP = polyvinylpyrrolidone. “Specification” is related to the product specification of the existing Neupro® Rotigotine patch.

Figure 1



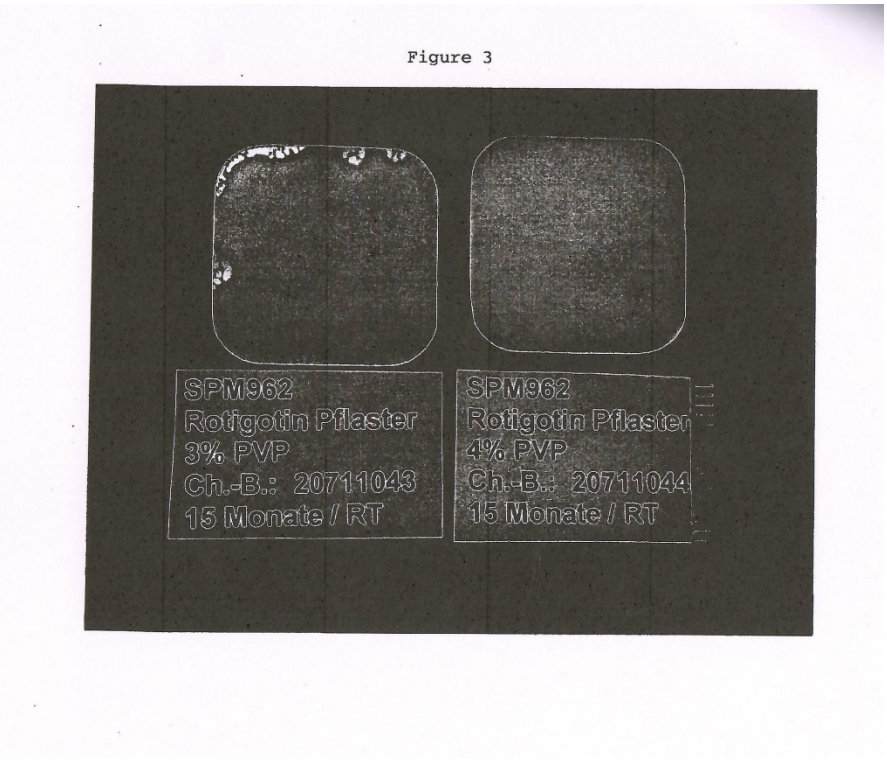
10. Figure -2 shows that the physical stability of rotigotine patches containing different amounts of PVP (rotigotine:PVP weight ratio of 9:2, 9:3 and 9:4) after 9 months at room temperature.

Figure 2



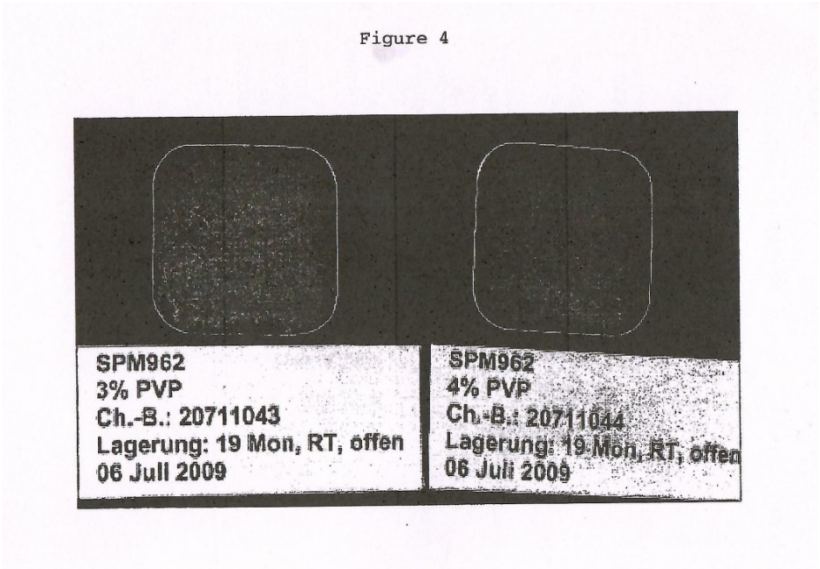
11. Figure -3 shows the physical stability of rotigotine patches containing different amount of PVP (rotigotine:PVP weight ratio of 9:3 and 9:4) after 15 months at room temperature.

Figure 3



12. Figure - 4 shows the physical stability of rotigotine patches containing different amounts of PVP (rotigotine:PVP weight ratio of 9:3 and 9:4) after 19 months at room temperature.

Figure 4



13. Table -3 Results from storage stability testing of sample nos. 1-9 at 25 degree Celsius/60%RH (+=crystal,-= no crystals).

Sample No.	1	2	3	4	5	6	7	8	9
Rotigotine:PVP [weight ratio]	9:1	9:1.6	9:2	9:3	9:4	9:6	9:8	9:11	9:4
0 weeks	+	+	-	-	-	-	-	-	-
1 week	+	+	+	+	-	-	-	-	-
4 weeks	+	+	+	+	-	-	-	-	-
8 weeks	+	+	+	+	-	-	-	-	-

14. Taking also the above discussed data from release testing into account, optimum result could be achieved with rotigotine to polyvinylpyrrolidone weight ratios between 9:4 and 9:6. Higher ratios failed to sufficiently prevent rotigotine from crystallization and made the system prone to crystal growth or were even unprocessable. Lower ratios led to insufficient drug release by reducing the amount of rotigotine, which is released from the patch, below those values specified for the marketed Neupro® patch.

15. Test for inventive steps as provided under Section 2(1)(ja) which reads as follows:

> *"**2. Definitions and interpretation.— (1)** In this Act, unless the context otherwise requires,- **(ja)** "inventive step" means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art."*

16. In the case of ***Avery Dennison Corporation Vs. Controller of Patents and Designs*** reported in ***2022/DHC/004697,*** the Delhi High Court decided as follows:

> *"**10.** In order to decide this issue, some of the fundamental principles for determining the existence of an inventive step and the lack of obviousness need to be emphasised.*
>
> ***11.** For determining inventive step or lack thereof, various approaches and tests have emerged over the years from decisions of courts/authorities as also from examination guidelines of patent offices from different jurisdictions. The same include:*
>
> ***i. Obvious to try approach:***
>
> - *This approach involves an analysis of whether in view of the teachings/solutions proposed in the prior art, it was obvious to try and arrive at the subject invention.*
>
> ***ii. Problem/solution approach:***
>
> - *This approach considers whether in the light of the closest prior art and the objective technical problem, the solution claimed in the invention would be obvious to the skilled person. If the skilled person can decipher the solution being claimed, then the subject matter is held to be obvious.*
> - *This test has been discussed by the Division Bench in **F. Hoffmann-La Roche Ltd. and Ors. v. Cipla Ltd., 2016(65) PTC 1 (Del)**.*
>
> ***iii. Could-Would Approach***
>
> - *In this approach the question that is raised is whether there is any teaching in the prior art as a whole that would and not simply could have prompted a skilled person, with the knowledge of the objective technical problem, to either modify or adapt the closest prior art to arrive at the subject matter of the claims.*

iv. <u>Teaching Suggestion Motivation (TSM test)</u>

- *This test originated in the USA as per which, if by the Teaching, Suggestion or Motivation from the prior art, an ordinary skilled person can modify the prior art reference or combine prior art references to arrive at the claimed invention, then the subject matter being claimed is obvious.*

- *However, the application of this test ought not to be done in a narrow manner as held by the US Supreme Court in the case of* ***KSR International v. Teleflex, 550 U.S. 398 (2007)****."*

17. The documents D1 and D2 do not provide any kind of suggestion to an artisan to the solution offered by the present invention as any cited documents, particularly D1 or D2 as not concerned with the problem of producing a stable transdermal therapeutic system, which prevents the crystallization of newly described Form II of rotigotine as the said form was only described some years after D1 and D2 for the 1st time in WO2009/068520 that has a priority date of November 2007. The comparative data provided in the specification which clearly shows that the claimed ratio of rotigotine to PVP gives the best result compared to others ratios including the ratio of D1, D3 or D4.

18. In the impugned order, the Deputy Controller of Patents and Designs has admitted that two new documents cited at the time of hearing and the said documents are US2005/0079206 and EP2177217. The respondent has relied the said two documents and held that :

"Now I would like to discuss the other cited documents which were raised at time of hearing.

Cited document EP2177217 (D4) teaches composition containing Rotigotine and the use thereof in the manufacture of a Rotigotine – containing transdermal patch. Wherein said composition is based on a matrix mixture system formed from a combination of an acrylic pressure-sensitive with a silicone pressure-sensitive adhesive, and polyvinylpyrrolidone which are present in a particular weight ratio. The Rotigotine-containing transdermal patch of the present invention has a multi-layer complex structure comprising a backing layer, a drug-containing matrix layer comprising the active ingredient Rotigotine and a covering layer on the drug-containing matrix layer, may further optionally comprise auxiliaries commonly used in transdermal drug delivery systems, such as permeation enhancers and antioxidants. This document also discloses that a matrix mixture system comprising a combination of an acrylic pressure-sensitive adhesive with a silicone pressure-sensitive adhesive in a certain ratio improves the solubility and skin permeability of the drug significantly, and the addition of a small amount of polyvinylpyrrolidone further improves the drug load and penetration level without affecting the mechanical properties of the patch.

The other cited document (US2005/0079206) also teaches about improved transdermal delivery system for rotigotine. It is disclosed that drug release properties of a TDS having a silicone-type adhesive matrix containing rotigotine can be significantly enhanced by

(1) minimizing the amount of rotigotine which is present in the protonated form (salt form);

(2) incorporating rotigotine in a multitude of microreservoirs within the self-adhesive matrix consisting of a solid or semi-solid semi-permeable polymer.

This document also discloses that rotigotine exists in various isomeric forms and any single isomer or a mixture of different isomers may be used in the TDS according to the invention. Hence, the S- or R-enantiomer or the racemate or any other enantiomer mixture of rotigotine may be used. In

such matrix type TDS the drug is dispersed in a polymer layer. The TDS of the matrix type in their simplest version comprise a one-phase (monolayer) matrix. They consist of a backing layer, a self-adhesive matrix containing the active agent and a protective foil or sheet, which is removed before use. This document also discloses about a mixture of silicone adhesives comprises a blend of high tack silicone pressure sensitive adhesive comprising polysiloxane with a resin and a medium tack silicone type pressure sensitive adhesive comprising polysiloxane with a resin. The device of this document also contains a backing layer which is inert. This patch also contains protective foil.

So from above said discussion following points are amply clear:

Rotigotine and its use is already known. Cited documents also disclose about transdermal therapeutic system, which contain rotigotine polyvinylpyrrolidone in particular amount. Cited document also disclose about and matrix system which contain silicone adhesive as matrix. Furthermore, use of polyvinylpyrrolidone as crystallization inhibitor is also known from cited documents. Ratio between rotigotine and PVP also disclosed in prior art documents."

19. In the case of ***Guangdong Oppo Mobile Telecommunications Corp., Ltd. Vs. The Controller of Patents and Designs*** reported in ***MANU/WB/ 1263/2023,*** the Coordinate Bench of this Court held that:

*"**14.** On the question of issuance of the Second Examination Report, section 13(3) of the Act makes it apparent that upon amendment of the claims, the amendment application ought to be examined in a manner similar to the original application. When a complete specification is amended, such amended specification should be re-examined and a Report issued in the manner stipulated under section 12 of the Act. In passing the impugned order, there has been a violation of the statutory provisions in issuing the hearing notice citing additional objections and relying on the same in without*

granting an opportunity to the appellant to amend its claim and without issuance of a Second Examination Report."

20. In the case of ***Man Truck Bus Se Vs. Assistant Controller of Patents and Designs*** reported in ***2024 SCC OnLine Del 874*** wherein the Delhi High Court held that:

> ***"24.*** *A perusal of the impugned order bears out that the paragraphs with respect to documents D1-D4 have simply been repeated and copied. Aside from that document D5 was not made part of the notice of hearing and came up during the hearing itself to which the appellant placed a protest (but without prejudice responded to the same in written submissions). The Controller did advert to prior art document D5 in the following manner:*
>
> > *"The D5 solves these problems associated with prior art honeycomb catalysts/filters so that catalytic conversion is approximately uniform for all flow regions of the honeycomb catalyst/filter (see col. 2 Ins. 50-59) by providing a honeycomb catalyst/filter wherein there is a first group of channels having a higher flow resistance and a second group of channels having a lower flow resistance (see col. 2 Ins.60-67). In particular, note that figures 3 and 6 in the D5 illustrate the honeycomb wherein certain cross-facial regions of the honeycomb catalyst/filter have relatively smaller openings and the other cross-facial regions of the honeycomb have relatively larger openings, so that this D5 honeycomb can also be said to have different flow regions wherein each flow region is configured to allow particles of essentially different sizes or masses to be separated out in the different regions (which is required by the Applicants' independent claims)."*

21. In the case of ***Otsuka Pharmaceutical Co. Ltd. Vs. Controller of Patents*** reported in ***2022 SCC OnLine Del 4982,*** the Delhi High Court held that:

> ***"10.*** *Perusal of the hearing notice reflects that objection to the grant of patent was predicated on lack of inventive step, citing prior art documents D1 and D4. There is no mention of D2 and D3 as rightly pointed by learned counsel for the Appellant. Relevant part of the hearing notice is extracted hereunder:—*
>
> > *"The reply submission by the applicant is not persuasive as D4 discloses a pharmaceutical composition comprising : (i) at least onecarbostyril derivatives (i.e. i.e. aripiprazole) in combination with (ii) at least one serotoninreuptake inhibitor, and (iii) a pharmaceutically acceptable carrier (p. 6, line 6-11). It also discloses that the serotonin reuptake inhibitor can be fluoxetine, citalopram, fluvoxamine, paroxetine, sertraline and escitalopram, and salts thereof (p.7, line 22-26). D4 also discloses a method for treating major depressive disorder by administering to a patient with major depressive disorder said composition (p.12, line 19-25). D1 discloses a heterocyclic compound of formula (I) or salts thereof, which the preferable compound (I) is 7-[4-(4-benzo[b]thiophen-4-yl-piperazin-1-yl) butoxy]-1 H-quinolin-2-one (p.12, line 10-14 : see Compound (1)). D1 discloses that the above compound of formula (I) can be provided in a pharmaceutical composition as an active ingredient mixed with a pharmaceutically acceptable carrier for the treatment or prevention of central nervous system disorders, i.e. major depression (p. 13, line 16-23; & p. 14, line 4). A person skilled in the art would have been motivated to combine the teachings of D1 with D4 to produce a new composition for use in the very same treatment of major depressive disorder, and it is prima facie obvious to combine two compositions each of which is taught by the prior art to be*

useful for the same purpose, in order to form a third composition to be used for the very same purpose. Hence the subject matter of claims 1-8 lacks inventive step u/s 2(1)(ja) of the Patents Act, 1970 in view of the prior art D1 and D4."

19. *The impugned order thus suffers from several infirmities, including procedural. The order is a non-speaking and unreasoned order; takes into account prior arts D2 and D3, while finally adjudicating on the patent application albeit they did not form a part of the objections referred to in the Hearing Notice and that too without giving an opportunity to the Appellant to respond to them. Vital issues and documents relied upon by the Appellant have not been considered, including applicability of Section 3(d) of the Act, seriously contested by the Appellant."*

22. In the case of ***Perkinelmer Health Sciences Inc and Ors. Vs. Controller of Patents*** reported in ***2023 SCC OnLine Del 8590*** wherein the Delhi high Court held that :

"7. *The hearing notice dated 12th February, 2018 makes no mention of objection under Section 3(f). Appellant ought to have been made aware of all grounds of objection before the hearing and afforded sufficient opportunity to contest the same at the time of hearing. It was incumbent upon Respondent to have raised this objection in the notice of hearing itself. Albeit the Appellant had submitted written submissions subsequent to the hearing and not given any response qua Section 3(f) of the Act, that does not absolve the Respondent of its obligations under the Circular to communicate objections prior to the hearing and provide reasonable opportunity to the applicant/Appellant. Objection under Section 3(f) of the Act has ex-facie been raised for the first time at hearing stage as is apparent from afore-extracted portion of the impugned order. There is thus merit in the submission of Mr. Banerjee that Respondent has violated the principles of natural justice."*

23. The unreported judgment in case of ***Protean Electric Ltd. Vs. The Controller of Patents and Designs*** in ***AID No. 15 of 2022*** dated ***06th April, 2023***, the Coordinate Bench of this Court held that:

> ***"10.*** *The primary grievance of the appellant is that the Controller of Patents proceeded to re-examine the application of the appellant despite the appellant having made all necessary amendments to the application in view of the objections raised by the Controller of Patents. The appellant also assails the raising of fresh citations being D2 and D3 in the hearing notice against the amended application.*
>
> ***11.*** *Significantly, clause 9.04 of the Manual of Patent Office Practice and Procedure, provides that when an applicant re-files the documents post amendment, the application must be examined in a fresh manner by the Examiner and a Report with his observation must be forwarded to the Controller of Patents upon further examination of such application. If thereafter an application is found to comply with all the requirements of the Act and Rules, the Controller is expected to grant the patent.*
>
> ***13.*** *I also find that the examination request was filed on 20 September, 2014. The First Examination Report was issued on 7 January, 2019. Despite affidavits, the respondent Controller has taken approximately 8 years to complete the entire process of examination. This is unacceptable and renders nugatory the sprit and object of the Act. There is also blatant violation of the statutory timelines provided under Rule 24 B of the Patent Rules 2003 for examination which has caused inordinate delay in the entire examination process. Moreover, the process of examination and subsequent steps leading to disposal of the application have been given a go-bye. The application had been re-examined and further examination reports were not issued to the appellant. The two new prior art documents cited in the hearing notice are in violation of the mandate of section 13(3) of the Act and alters the entire character of the examination."*

24. Documents D5:US2005/0079206 (US 8246979) and D4:EP2177217 were cited by the respondent for the first time during the hearing. The appellant was not aware of the objection of the respondent with regard to the said two documents and the appellant was also not aware of the teachings of the said documents according to which the respondent considered the invention to lack inventive steps in view of the said documents.

25. When the notice for hearing is sent, the appellant should clearly know the objections and the prior art that the Controller will be relying on during the hearing. The patent office while dealing with the grant of patent, exercises quasi-judicial power and quasi-judicial authority is not an adversary of the patent applicant. Any objection to the prior art must be known to the applicant before the date of hearing.

26. Accordingly, the impugned order dated 16th August, 2019 passed by the Deputy Controller of Patents and Designs is set aside and the matter is remanded back to the respondent for fresh consideration. The respondent other than the officer who passed the impugned order shall hear the parties after permitting the appellant to place on record their replies/response to the documents being D4:EP2177217 and D5:US2005/0079206.

27. It is made clear that the Controller or any competent officer other than the officer who passed the impugned order shall decide the matter on merits, in accordance with law without being influenced by any

observations made by this Court in this order or in the impugned order dated 16th August, 2019. The decision shall be taken as expeditiously as possible, not later than six months from the date of receipt of the copy of this Order.

28. IPDPTA No. 117 of 2023 is **disposed of**.

(Krishna Rao, J.)