THE PATENTS ACT, 1970 (AS AMENDED)
&
THE PATENTS RULES, 2003 (AS AMENDED)
SECTION 15

In The Matter of

An Application for Patent No. 201817002543

AND

In The Matter of

A Pre-grant opposition to the grant of a patent thereon under section 25(1)

AND

In The Matter of

Hearing under section 14

ABBVIE INC. **- The Applicant**
Mrs. Archana Shanker ,Anand & Anand Advocates **- Agent for the Applicant**

Vs

THE DELHI NETWORK
OF POSITIVE PEOPLE (DNP+) (PGO1) **- The Opponent I**
Priyam Lizmary Cherian **-Counsal and Agent for the Opponent**

AND

ABBVIE INC. **- The Applicant**
Mrs. Archana Shanker ,Anand & Anand Advocates **- Agent for the Applicant**

Vs

LOW COST STANDARD **- The Opponent II**
THERAPEUTICS (PGO2)
Rajeshwari H., Rajeshwari and Associates **-Agent for the Opponent**

A. FACTS OF THE APPLICATION:

a) An application for a patent bearing number 201817002543 was filed in Patent Office on 22/01/2018 entitled "SOLID PHARMACEUTICAL COMPOSITIONS FOR TREATING HCV". A request for examination under section 11-B was filed on 03/03/2009 and was assigned a Request No. R20191017136

. As per the provision under Section 11-A of Patents Act, 1970 the said application was published on 27/04/2018 .

b) The said application was examined under Section 12 and 13 of Patents Act, 1970 and First Examination Report (henceforth referred to as FER containing a statement of objection was forwarded to the applicant on 24/02/2020.

c) A reply by applicant/ agents to FER was filed on 23/11/2020.

d) A representation under section 25(1) of Patents Act, 1970 for opposing the grant of patent application no. 201817002543 was filed by **THE DELHI NETWORK OF POSITIVE PEOPLE (DNP+) (hereinafter referred as the Opponent I)** through their Advocates,Priyam Lizmary Cherian (Counsel for the Opponent) of 309, IV Floor, Prakash Mohalla, Delhi-110065 (**PGO-1**).

e) A representation under section 25(1) of Patents Act, 1970 for opposing the grant of patent application no. 201817002543 was filed by **LOW COST STANDARD THERAPEUTICS (hereinafter referred as the Opponent II)**, an associations of person registered under the SOCIETIES REGISTRATION ACT, XXI OF 1860 represented by RAJESHWARI H., Advocates and IP Attorneys of S-357, FIRST FLOOR NEAR HDFC BANK PANCHSEEL PARK, NEW DELHI-110017 (**PGO-2**).

f) A notice under rule 55(3) of the Patents Rules was issued to the applicant's agent, Mrs. Archana Shanker ,Anand & Anand Advocates on 14/11/2025 , informing the applicant that a representation u/s 25(1) has been filed. The applicant was intimated that, if they are interested in contesting said representation, they may file the reply statement and evidence within two months from the date of the said notice.

g) Applicant/agents for the applicant didnot filed reply statement/evidence with respect to representation filed by Ms. Priyam Lizmary Cherian and Ms.RAJESHWARI H. **.**

h) A hearing notice was issued with reference to reply of applicant to the First examination Report/Subsequent Examination Report filed on 23/11/2020 and a hearing was fixed in the matter on 04/05/2026 for PGO-1,PGO-2 and hearing u/s 14 .

B. <u>Claims on record:</u>

<u>Following claims were filed by the applicant on 23.11.2020 -</u>

1. A solid oral pharmaceutical dosage formulation comprising:
a first composition comprising:
50% to 80% by weight of one or more pharmaceutically acceptable polymers, and 100 mg Compound 1 , wherein the weight percentage of the one or more pharmaceutically acceptable polymers is relative to the total weight of the first composition; and
a second composition comprising:

50% to 80% by weight of one or more pharmaceutically acceptable polymers, and 40 mg Compound 2 , wherein the weight percentage of the one or more pharmaceutically acceptable polymers is relative to the total weight of the second composition;

wherein the formulation is a tablet comprising a first layer and a second layer, the first layer comprising the first composition and the second layer comprising the second composition; and

wherein administration of three of the tablets to a population of healthy, non-fasted adult humans results in a mean Cmax value between about 333 ng/mL and about 1113 ng/mL for Compound 1.

2. The solid oral pharmaceutical dosage formulation as claimed in claim 1, wherein the first composition comprises a first amorphous solid dispersion comprising Compound 1.

3. The solid oral pharmaceutical dosage formulation as claimed in claim 1, wherein the second composition comprises a second amorphous solid dispersion comprising Compound 2.

4. The solid oral pharmaceutical dosage formulation as claimed in claim 2, wherein the first amorphous solid dispersion comprises the one or more pharmaceutically acceptable polymers.

5. The solid oral pharmaceutical dosage formulation as claimed in claim 2, wherein the first amorphous solid dispersion further comprises one or more pharmaceutically acceptable surfactants.

6. The solid oral pharmaceutical dosage formulation as claimed in claim 4, wherein the first amorphous solid dispersion further comprises one or more pharmaceutically acceptable surfactants.

7. The solid oral pharmaceutical dosage formulation as claimed in claim 3, wherein the second amorphous solid dispersion comprises the one or more pharmaceutically acceptable polymers.

8. The solid oral pharmaceutical dosage formulation as claimed in claim 3, wherein the second amorphous solid dispersion further comprises one or more pharmaceutically acceptable surfactants.

9. The solid oral pharmaceutical dosage formulation as claimed in claim 7, wherein the second amorphous solid dispersion further comprises one or more pharmaceutically acceptable surfactants.

10. The solid oral pharmaceutical dosage formulation as claimed in claim 6, wherein the one or more pharmaceutically acceptable polymers comprise copovidone, and the one or more pharmaceutically acceptable surfactants comprise Vitamin E TPGS.

11. The solid oral pharmaceutical dosage formulation as claimed in claim 9, wherein the one or more pharmaceutically acceptable polymers comprise copovidone, and the one or more pharmaceutically acceptable surfactant comprises Vitamin E TPGS.

12. The solid oral pharmaceutical dosage formulation as claimed in claim 11, wherein the one or more pharmaceutically acceptable surfactants further comprise propylene glycol monocaprylate.

13. The solid oral pharmaceutical dosage formulation as claimed in claim 1, wherein the first composition comprises a first amorphous solid dispersion comprising Compound 1, one or more pharmaceutically acceptable polymers and one or more pharmaceutically acceptable surfactants; and

the second composition comprises a second amorphous solid dispersion comprising Compound 2, one or more pharmaceutically acceptable polymers and one or more pharmaceutically acceptable surfactants.

14. The solid oral pharmaceutical dosage formulation as claimed in claim 13, wherein the one or more pharmaceutically acceptable polymers comprise copovidone, and the one or more pharmaceutically acceptable surfactants comprises Vitamin E TPGS.

15. The solid oral pharmaceutical dosage formulation as claimed in claim 3, wherein the first amorphous solid dispersion comprises Compound 1, one or more pharmaceutically acceptable polymers comprising copovidone, and one or more pharmaceutically acceptable surfactants comprises Vitamin E TPGS; and the second amorphous solid dispersion comprises Compound 2, one or more pharmaceutically acceptable polymers comprising copovidone, and one or more pharmaceutically acceptable surfactants comprising Vitamin E TPGS and Propylene glycol monocaprylate.

16. The solid oral pharmaceutical dosage formulation as claimed in claim 1, wherein the first amorphous solid dispersion comprises 10% to 40% by weight of Compound 1, and the second amorphous solid dispersion comprises 5% to 20% by weight of Compound 2.

17. The solid oral pharmaceutical dosage formulation as claimed in claim 1, wherein the first amorphous solid dispersion comprises 15% to 30% by weight of Compound 1, and the second amorphous solid dispersion comprises 5% to 15% by weight of Compound 2.

18. The solid oral pharmaceutical dosage formulation as claimed in claim 13, wherein the first amorphous solid dispersion comprises 15% to 30% by weight of Compound 1, and the second amorphous solid dispersion comprises 5% to 15% by weight of Compound 2.

19. The solid oral pharmaceutical dosage formulation as claimed in claim 15, wherein the first amorphous solid dispersion comprises 15% to 30% by weight of Compound 1, and the second amorphous solid dispersion comprises 5% to 15% by weight of Compound 2.

20. The solid oral pharmaceutical dosage formulation as claimed in claim 1, wherein the first layer further comprises a disintegrant.

21. The solid oral pharmaceutical dosage formulation as claimed in claim 20, wherein the disintegrant comprises Croscarmellose sodium.

22. The solid oral pharmaceutical dosage formulation as claimed in claim 1, wherein the first layer and the second layer further comprise a lubricant.

23. The solid oral pharmaceutical dosage formulation as claimed in claim 22, wherein the lubricant comprises sodium stearyl fumarate.

24. A solid oral pharmaceutical dosage formulation comprising:

a first composition comprising:

50% to 80% by weight of one or more pharmaceutically acceptable polymers, and 100 mg Compound 1 , wherein the weight percentage of the one or more pharmaceutically acceptable polymers is relative to the total weight of the first composition; and

a second composition comprising: 50% to 80% by weight of one or more pharmaceutically acceptable polymers, and 40 mg Compound 2 ,

wherein the weight percentage of the one or more pharmaceutically acceptable polymers is relative to the total weight of the second composition;

wherein the formulation is a tablet comprising a first layer and a second layer, the first layer comprising the first composition and the second layer comprising the second composition; and

wherein administration of three of the tablets to a population of healthy, non-fasted adult humans results in a mean AUC value between about 1099 ng·h/mL and about 3680 ng/mL for Compound 1.

25. A solid oral pharmaceutical dosage formulation comprising: a first composition comprising: 50% to 80% by weight of one or more pharmaceutically acceptable polymers, and 100 mg Compound 1 , wherein the weight percentage of the one or more pharmaceutically acceptable polymers is relative to the total weight of the first composition; and

a second composition comprising:

50% to 80% by weight of one or more pharmaceutically acceptable polymers, and 40 mg Compound 2 , wherein the weight percentage of the one or more pharmaceutically acceptable polymers is relative to the total weight of the second composition;

wherein the formulation is a tablet comprising a first layer and a second layer, the first layer comprising the first composition and the second layer comprising the second composition;

and wherein administration of three of the tablets to a population of healthy, fasted adult humans results in a mean Cmax value between about 85 ng/mL and about 684 ng/mL for Compound 1.

26. A solid oral pharmaceutical dosage formulation comprising: a first composition comprising:

50% to 80% by weight of one or more pharmaceutically acceptable polymers, and 100 mg Compound 1 , wherein the weight percentage of the one or more pharmaceutically acceptable polymers is relative to the total weight of the first composition; and

a second composition comprising:

50% to 80% by weight of one or more pharmaceutically acceptable polymers, and 40 mg Compound 2 , wherein the weight percentage of the one or more pharmaceutically acceptable polymers is relative to the total weight of the second composition;

wherein the formulation is a tablet comprising a first layer and a second layer, the first layer comprising the first composition and the second layer comprising the second composition; and

wherein administration of three of the tablets to a population of healthy, fasted adult humans results in a mean AUC value between about 429 ng·h/mL and about 2431 ng/mL for Compound 1.

27. A solid oral pharmaceutical dosage formulation that is bioequivalent to a solid oral tablet pharmaceutical dosage formulation comprising

a. 500 mg of Compound 1 20% extrusion granulation, comprising:

i. 20% (100 mg) Compound 1 ,

ii. 69% copovidone,

iii. 10% vitamin E TPGS, and

iv. 1% colloidal silicon dioxide;

b. 400 mg of Compound 2 10% extrusion granulation, comprising i. 10% (40 mg) Compound 2 ,

ii. 79% copovidone,

iii. 8% vitamin E TPGS,

iv. 2% propylene glycol monocaprylate, and

v. 1% colloidal silicone dioxide;

c. 26.3 mg croscarmellose sodium;

d. 4.7 mg colloidal silicon dioxide;

e. 4.7 mg sodium stearyl fumarate; and

f. 28.1 mg HPMC coating.

C. Pre-Grant Opposition under Section 25(1) of the Patents Act-

a. Grounds of opposition relied upon by the opponent I:

Section 25(1)(e)-lack of inventive step

Section 25(1)(f) -not an invention and non -patentable

Section 25(1)(g)-Insufficiency

Section 25(1)(h) – Fails to disclose section 8 details

b. Grounds of opposition relied upon by the opponent II:

Section 25(1) (b)- Lack of novelty

Section 25(1) (e)-Lack of inventive step

Section 25 (1)(f) -Invention is not patentable under section 3(d), 3(e) and 3 (i)

Section 25(1)(g)- Insufficiency

Section 25(1)(h)- Fails to disclose section 8 details

D. Objections communicated in hearing notice are as follows –

Clarity and Conciseness

1. Claims are vague and broad in respect of terms such as pharmaceutically acceptable polymers, one or more pharmaceutically acceptable surfactants , pharmaceutical dosage formulation .

Invention u/s 2(1)(ja)

1. Reply to FER dated 24.02.2020 was filed within the stipulated time period on 23.11.2020 (with extension) along with other necessary documents. However, after considering the amendments the objections regarding inventive step still stand due to the following reasons:-

D1: WO2014152514A1

D2: US20140080868A1

D3: C-W Lin et al; STEADYSTATE PHARMACOKINETICS AND SAFETYOF COADMINISTRATION OF PANGENOTYPIC, DIRECTACTING PROTEASE INHIBITOR, ABT493 WITH PAN-GENOTYPIC NS5A INHIBITOR, ABT-530, IN HEALTHYADULT SUBJECTS; Journal of Hepatlogy 2015

D4: US6087386A (11/07/2000) [cited fresh]

D1 discloses compound 1 and compound 2 as claimed by the alleged invention [0022]-[0023].It also discloses the coadministration of compounds 1 and 2. It further discloses that the two compounds may be co-formulated in a single dosage form. It further discloses that the compounds are preferably formulated as amorphous solid dispersion in a matrix comprising a pharmaceutically acceptable polymer and a pharmaceutically acceptable surfactant [0062].

D2 discloses compound 2 of the alleged invention. It further discloses pharmaceutically acceptable polymer ascopovidone [0032]. It moreover discloses pharmaceutically acceptable surfactant as vitamin E TPGS.

D3 discloses composition containing 100 mg of compound 1 (hereinABT-493) and 40 mg of compound 2 (hereinABT530) [Table 1].

D4 discloses that multiple activities may be provided in a dosage form as a bilayer tablet. Thus, it is obvious for the person skilled in the art to provide compound I and compound II as a bilayer tablet with reasonable expectation of success.

Thus, it is obvious for a person skilled in the art to combine the knowledge of D1- D4 i.e. a person skilled in the art can use the knowledge of excipients from D2 and use those excipients to prepare the composition using compounds of D1 and as D3 discloses the amount of compounds 1 and 2 in the composition it is obvious for a person skilled in the art to reach the composition of the alleged invention.

Thus, based on the above topics the subject matter of claims 1-27 lacks in inventive step in view of D1-D3 u/s 2(1)(ja) of The Patents Act, 1970.

Non-Patentability u/s 3

1. Claim(s)1-27 fall(s) within the scope of such clause (i) of section 3 of Patents Act 1970 as amended by Patents (A) Act 2005 in respect of term solid dosage form and as stated in examples and as described in description.

2. Claims 1-27 fall u/s 3(d) of the Patents (Amended) Act, 2005 as the said claims defines new use and new form of the known compound (as cited by the prior art documents). In the absence of experimental data, it is not clear that the solid oral pharmaceutical dosage formulation provide an enhancement of the known efficacy i.e., demonstrate a greater technical effect and/or differ significantly in properties w.r.t the known compound.

Decision -

The agent for the applicant didnot filed the reply statement/evidence with respect to representation filed by Ms. Priyam Lizmary Cherian and Ms.Rajeshwari H. .Hearing has been offered u/s 25(1) in the instant patent application to opponents I ,opponents II and u/s 14 of the Patent Act1970 on 4 May 2026 .

Opponent I informed to office that “Since the applicant has abandoned the application, the Opponent will not attend the scheduled hearing on 4th May 2026.Agents for the opponent will not be attending the hearing under Section 25(1) scheduled on 4th May 2026”.

Opponent II informed to office that “Due to unavailability of the Arguing Counsel, the Agent for the Opponent will not be able to attend the hearing as scheduled. We therefore, request an accommodation and pray that the hearing may be adjourned”.

The agent for the applicant informed that “ the Applicant wishes to abandon the application. In view of above, the Agent for the Applicant will not be attending all three hearings scheduled for 4 May 2026 at

the Patent Office on the said date. We request the Learned Controller to kindly take the said letter along with Form 30 on record."

Thus, the objections raised in hearing notice dated 06/04/2026 have not been met by the applicant within the time as prescribed under section 21(1) of the Patent Act 1970. Therefore, in view of above fact the instant application has been refused to grant of patent in accordance with Section 15 of The Patents Act, 1970 (as amended).

In view of the above mentioned decision on the instant application ,the pre-grant opposition filed u/s 25(1) and corresponding rule 55 of The Patents Rules, 2003 (as amended) which is in r/o this application automatically stands disposed off with the disposal of this application.

Dated 07th May 2026 **- Sd/ -**

Reena Singh

Deputy Controller of Patents & Designs