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December 21, 2018

THE CONTROLLER OF PATENTS
THE PATENT OFFICE
DELHI

KIND ATTENTION
ASST. CONTROLLER: DR. SUNITA RANI
EXTENDED FINAL DATE: DECEMBER 27, 2018

Dear Sirs,

Re: ALLERGAN, INC.
Indian Patent Application No. **4045/DELNP/2014**
Filing Date: May 20, 2014

With regard to the First Examination Report dated March 27, 2018, we submit the under-mentioned documents and present the following reply:

TECHNICAL

With respect to the technical objections raised by the learned Controller, the Applicant humbly submits the following:

I. LACK OF INVENTIVE STEP

The Applicant humbly submits that the claims of the subject are inventive over the teachings of the following cited prior art documents D1 and D2:

D1: WO2005072701

D2: US20100305046A1

In this regard, the Applicant humbly submits the following:

Document D1 and D2 does not disclose cyclosporin A form 2. The Applicant submits that the surprising technical effect resulting from the aforesaid distinguishing feature is

provided at page 19, lines 11-12 of the specification, which clearly indicates that the Form 2 is surprisingly more chemically and physically stable than other forms of cyclosporin A.

Further, the Applicant emphasizes that the present invention discloses formulations of cyclosporine A and biocompatible suspending agent which are exceptionally stable to heat sterilization and have excellent long-term stability. The Applicant submits that none of the cited prior art documents provide any motivation to a person skilled in the art to anticipate the results of the instant invention.

Further, the Applicant submits Cyclosporin A Form 2 (claimed in the formulations of the present application) is new and non-obvious. In support of this position, the Applicants submit herewith as Exhibit 1, a Declaration of Prem S. Mohanty (hereinafter, "Mohanty Declaration"), Senior Professional at Allergan, Inc. Mr. Mohanty has over 6 years of experience in the pharmaceutical industry, submitted in the corresponding US Application (Annexure 1).

As described by Mr. Mohanty, Cyclosporin A Form 2 exhibits several unexpected properties not shown in prior art forms of Cyclosporin A. Specifically, as described in paragraphs 4-6 of the Mohanty Declaration, Cyclosporin A Form 2 exhibits at least (1) unique crystal parameters, (2) unique *d*-spacing of major peaks observed under x-ray diffraction, and (3) unique thermal behavior compared to the other forms of Cyclosporin A.

The Applicants submits that, at least in view of the Mohanty Declaration, since Cyclosporin A Form 2 is not disclosed or rendered obvious by the cited prior arts, the pending claims, which all recite Cyclosporin A Form 2, are not anticipated nor rendered obvious by the cited arts.

Attention of the learned Controller is also drawn to the grant of a patent of the counterpart applications in US, EP and AU, which have been allowed after undergoing a stringent examination of the requirement of novelty and inventive step, which further affirms the novelty and inventive step of the claimed invention.

In view of the above, learned Controller is requested to kindly reconsider and waive the objection in this regard.

2. (i) Non- Patentability under Section 3(e):

The Applicant submits that the Controller has acknowledged the novelty of the claimed composition, therefore, the claimed composition cannot be considered as a mere admixture of known components. Further, the Applicant emphasizes that the present invention discloses formulations of cyclosporin A and biocompatible suspending agent which are exceptionally stable to heat sterilization and have excellent long-term stability.

The Applicant wishes to invite the attention of the Controller towards table 4 and 5 provided in the specification which clearly indicates that slurries of cyclosporin A Form 2 are both physically and chemically stable. In view of the above, learned Controller is requested to kindly reconsider and waive the objection in this regard.

(ii) Non-Patentability under Section 3(i):

It is submitted that the claims are duly amended to overcome the said objection. In view of the above submission, learned Controller is requested to kindly reconsider and waive the objection in this regard.

(4) Clarity and conciseness:

The word "about" is deleted from the claim 2. In view of the above submission, learned Controller is requested to kindly reconsider and waive the objection in this regard.

(5) Definitiveness

a) The Applicant submits that the claims have been suitably amended to overcome the objection raised. Claim 1 has been suitably amended to incorporate the ratio-percentages. In view of the above submission, learned Controller is requested to kindly reconsider and waive the objection in this regard.

b) The Applicant submits that claims 3 and 4 define all the essential parameters required to a person skilled in the art to arrive at the claimed invention. Further, the Applicant emphasizes that a similar claim set has been allowed in the corresponding EP Application.

In view of the above submission, learned Controller is requested to kindly reconsider and waive the objection in this regard.

Other requirements (Part I, Paragraph 4 of the FER)

a) The Applicant submits that claims 3 and 4 recite the processes of making a formulation of cyclosporin A and are not redundant in view of each other. Further, we will submit that a similar claim set has been allowed in the corresponding EP Application.

b) The Applicant submits that the claims have been suitably amended by replacing the term "Carbopol Ultrez 10NF" with "cross-linked polyacrylic acid polymer" and term "Piuronic F127" with "poloxamer" which is well supported by page 7, lines 29-31 of the specification.

In view of the above submission, learned Controller is requested to kindly reconsider and waive the objection in this regard.

FORMAL REQUIREMENTS:

Statement and undertaking (Form 3 details)/Section 8(1) details:

The Applicant herewith submits a petition to overcome the objection raised.

Other Deficiencies:

- a) The Applicant herewith submits the revised Form 1 in prescribed format.
- b) **Section 8(2) details:** The Applicant herewith submits the prosecution history of the corresponding foreign applications to comply with the statutory requirement under Section 8(2) of the Act.
- c) The updated details of the corresponding foreign applications will be submitted in due course.
- d) The Applicant herewith submits marked up and clean copy of amended set of claims in accordance with the provisions of Indian Patent Act.
- e) We have the honour to submit the revised Form 18.

Format of Specification:

1. The Applicant humbly submits that the claims have been amended to commence with 'We claim' in accordance with the Indian Practice.
2. The Applicant has the honour to submit revised abstract in the prescribed format.

Translation of Pr. Document (Certified copy etc.):

The Applicant humbly submits that the PCT application as filed in India in English language. The Applicant herewith submits the verification certificate to overcome the objection raised.

Format of Drawings: The Applicant humbly submits the formal drawings in prescribed format.

The remaining official requirements have also been complied with.

Grant of this application within the final period expiring on **December 27, 2018** is respectfully requested. Before taking any adverse decision on this case, the Controller is respectfully requested to give an opportunity to the applicants to be officially heard in this matter.

Yours faithfully,



[DEBASHISH BANERJEE]

IN/PA-1291

OF REMFRY & SAGAR

ATTORNEY FOR THE APPLICANT

Enclosures:

Revised Form 1;

Amended claims;

Marked copy of claims;

Verification certificate;

Petition under rule 137 to condone the irregularity;

Section 8(2) details;

A copy of Form 18;

Annexure 1;

Formal drawings; and

Abstract.