PATENT COOPERATION TREATY

From the RECEIVING OFFICE

To:
KERRI POLLARD SCHRAY
C/O NOVARTIS PHARMACEUTICALS CORPORATION
IP SERVICES MAIL DATA
ONE HEALTH PLAZA 101/2
EAST HANOVER, NEW JERSEY 07936

PCT

INVITATION TO CORRECT DEFECTS IN THE INTERNATIONAL APPLICATION
(PCT Articles 3(4)(i) and 14(1) and Rule 26)

Date of mailing (day/month/year) 23 Oct 2015

REPLY DUE within TWO MONTHS from the above date of mailing

Applicant’s or agent’s file reference
56489WOPCT02

International application No.
PCT/US2015/054775

International filing date
(day/month/year) 08 Oct 2015

Applicant
NOVARTIS AG

1. [✓] The applicant is hereby invited, within the time limit indicated above, to correct in the international application as filed, the defects specified on the attached:
   - [ ] Annex A
   - [✓] Annex B1 (text matter of the international application as filed)
   - [✓] Annex C1 (drawings of the international application as filed)

2. [ ] The applicant is hereby invited, within the time limit indicated above, to correct, in the translation of the international application furnished under Rule 12.3 or 12.4, the defects specified on the attached:
   - [ ] Annex A
   - [ ] Annex B2 (text matter of the translation of the international application)
   - [ ] Annex C2 (drawings of the translation of the international application)

Additional observations (if necessary):

HOW TO CORRECT THE DEFECTS?

Except where the defect is in the request, any correction must be submitted by filing a replacement sheet embodying the correction and a letter accompanying the replacement sheet, which shall draw attention to the difference between the replaced sheet and the replacement sheet. For a defect in the request, a correction may simply be stated in a letter if it is of such a nature that the correction can be transferred clearly onto the request record copy (Rule 26.4).

ATTENTION

Failure to correct the defects will result in the international application being considered withdrawn by this receiving Office (see Rule 26.5 for further details).

A copy of this Invitation and any attachments has been sent to the International Bureau and the International Searching Authority.

Authorized officer
Rayna Lover
Telephone No. 571-272-8842

Name and mailing address of the receiving Office
Mail Stop PCT, Commissioner for Patents
P.O. Box 1450, Alexandria, VA 22313-1450
Facsimile No. 571-273-8300

Form PCT/RO/106 (16 September 2012)
ANNEX A TO FORM PCT/RO/106

The receiving Office has found the following defects in the international application as filed:

1. As to the signature of the international application (Rules 4.15, 26.2bis(a) and 90.4), the request:
   a. □ is not signed by the applicant or, if there is more than one applicant, by at least one of them*.
   b. □ is signed by what appears to be an agent/common representative, but the international application is not accompanied by a power of attorney signed by at least one of the applicants*.
   c. □ other (specify):

* The applicant’s attention is drawn to the fact that the national law applied by each designated Office may require, in connection with the processing of the international application in the national phase, that the applicant furnish the confirmation of the international application by the signature of any applicant for the designated State who has not signed the request (Rule 51bis.1(a)(vi)).

2. As to the indications concerning the applicant* who is entitled, according to Rule 19.1, to file the international application with the receiving Office, the request (Rules 4.4, 4.5 and 26.2bis(b)):
   a. □ does not properly indicate the applicant’s name (specify):
   b. □ does not indicate the applicant’s address.
   c. □ does not properly indicate the applicant’s address (specify):
   d. □ does not indicate the applicant’s nationality.
   e. □ does not indicate the applicant’s residence.

□ Further observations about indications concerning other applicants (if applicable):

* Although Rules 4.4 and 4.5 require indications concerning the applicant, or if there are several applicants, of each of them for the purposes of Article 14(1)(a)(ii), if there is more than one applicant, it shall be sufficient that the indications required under Rule 4.5(a)(ii) and (iii) be provided in respect of one of them who is entitled according to Rule 19.1 to file the international application with the receiving Office (Rule 26.2bis(b)). However, the applicant’s attention is drawn to the fact that the national law applied by each designated Office may require, in connection with the processing of the international application in the national phase, that the applicant furnish any missing indication required under Rule 4.5(a)(ii) and (iii) in respect of any applicant for the designated State (Rule 51bis.1(a)(vi)).

3. As to the language of certain elements of the international application, other than the description and claims (Rules 12.1(c) and 26.3ter(a) and (c)):
   a. □ the request is not in a language of publication accepted by this receiving Office; (the) language(s) accepted by this receiving Office is/are:
   b. □ the text matter of the drawings is not in the language in which the international application is to be published, which is:
   c. □ the abstract is not in the language in which the international application is to be published, which is:

4. The title of the invention:
   a. □ is not indicated in Box No. I of the request (Rule 4.1(a)).
   b. □ is not indicated at the top of the first sheet of the description (Rule 5.1(a)).
   c. □ as appearing in Box No. I of the request is not identical with the title heading the description (Rule 5.1(a)).

5. As to the abstract (Rules 8 and 26.1):
   □ the international application does not contain an abstract.

Form PCT/RO/106 (Annex A) (16 September 2012)
This receiving Office has found that, with regard to the presentation of the text matter of the international application as filed, the physical requirements are not complied with to the extent that compliance therewith is necessary for:

1. __☐__ reasonably uniform international publication (Rules 11 and 26.3(a)(i)) (defects to be specified):

   a. __☐__ the sheets do not admit of direct reproduction
   b. __☐__ the element does not commence on a new sheet
   c. __☐__ sheets are not free from creases, cracks, folds
   d. __☐__ sheets are not used in the upright position
   e. __☐__ one side of the sheets is not left unused
   f. __☐__ the paper of the sheets is not flexible/strong/white/smooth/non-shiny/durable
   g. __☐__ the sheets are not connected as prescribed (Rule 11.4(b))
   h. __☐__ sheets are not A4 size (29.7cm x 21cm)
   i. __☐__ the minimum margins on the sheets are not as prescribed
   (top: 2 cm; left side: 2.5 cm; right side: 2 cm; bottom: 2 cm)
   j. __☐__ the file reference number indicated on the sheets does not appear in the
   left-hand corner of the pages, within 1.5 cm of the top of the sheets
   k. __☐__ the file reference number exceeds the maximum of 12 characters
   l. __☐__ the sheets of the description, claims and abstract are not numbered
   in consecutive Arabic numerals
   m. __☐__ the sheet numbers are not centered at the top or bottom of the sheets
   n. __☐__ the sheet numbers are in the margin (see i. above for the size of the margins)
   o. __☐__ the text matter is not typed or printed
   p. __☐__ the typing on the sheets is not 1½-spaced
   q. __☐__ the characters in the text matter on the sheets are less than 0.28 cm high
   in capital letters
   r. __☐__ the text matter on the sheets is not in dark, indelible color
   s. __☐__ the element contains drawings
   t. __☐__ the sheets contain alterations/overwritings/interlineations/too many erasures
   u. __☐__ the sheets contain photocopy marks

2. __☐__ satisfactory reproduction (Rules 11 and 26.3(b)(i))

Further observations (if necessary):
This receiving Office has found that, with regard to the presentation of the drawings of the international application as filed, the physical requirements are not complied with to the extent that compliance therewith is necessary for:

1. [X] reasonably uniform international publication (Rules 11 and 26.3(a)(i)) (defects to be specified):

   Sheets containing drawings:
   a. [ ] the sheets do not admit of direct reproduction
   b. [ ] the sheets are not free from creases, cracks, folds
   c. [ ] one side of the sheets is not left unused
   d. [ ] the paper of the sheets is not flexible/strong/white/smooth/non-shiny/durable
   e. [ ] the drawings do not commence on a new sheet
   f. [ ] the sheets are not connected as prescribed (Rule 11.4(b))
   g. [ ] the sheets are not A4 size (29.7cm x 21cm)
   h. [ ] the minimum margins on the sheets are not as prescribed
      (top: 2.5cm; left side: 2.5cm; right side: 1.5cm; bottom: 1cm)
   i. [ ] the file reference number indicated on the sheets does not appear in the left-hand corner of the sheets, within 1.cm
      of the top of the sheets
   j. [ ] the file reference number exceeds the maximum of 12 characters
   k. [ ] the sheets are not free from frames around unusable or used surfaces
   l. [X] the sheets are not numbered in consecutive Arabic numerals (e.g. 1/3, 2/3, 3/3)
   m. [ ] the sheet numbers are not centered at the top or bottom of the sheets
   n. [ ] the sheet numbers are in the margin (see h. above for the size of the margins)
   o. [ ] the sheets contain alterations/overwritings/interlinings/too many erasures
   p. [ ] the sheets contain photocopy marks

Drawings (Rule 11.13):
   a. [ ] do not admit of direct reproduction
   b. [ ] contain unnecessary text matter
   c. [ ] contain words so placed as to prevent translation without interference with lines thereof
   d. [ ] are not executed in durable black color; the lines are not uniformly thick and well-defined
   e. [ ] contain cross-sections not properly hatched
   f. [ ] would not be properly distinguishable in reduced reproduction
   g. [ ] contain scales not represented graphically
   h. [ ] contain numbers, letters and reference lines lacking simplicity and clarity
   i. [ ] contain lines drafted without the aid of drafting instruments
   j. [ ] contain disproportionate elements of a figure not necessary for clarity
   k. [ ] contain numbers and letters of height less than 0.32 cm
   l. [ ] contain letters not conforming to the Latin, and where customary, Greek alphabets
   m. [ ] contain figures on two or more sheets which form a single complete figure but which are not able to be assembled
      without concealing parts thereof
   n. [ ] contain figures which are not properly arranged and clearly separated
   o. [ ] contain different figures not numbered in consecutive Arabic numerals
   p. [ ] contain different figures not numbered independently of the numbering of the sheets
   q. [ ] are not restricted to reference signs mentioned in the description
   r. [ ] do not contain reference signs that are mentioned in the description
   s. [ ] contain the same feature denoted by different reference signs
   t. [ ] are not arranged in an upright position, clearly separated from one another
   u. [ ] are not presented sideways with the top of the figures at the left side of the sheets

2. [ ] satisfactory reproduction (Rules 11 and 26.3(b)(i))

Further observations (if necessary):