

The Patents (Amendment) Act, 2005

And

The Patents (Amendment) Rules, 2006

In the matter of Patent Application No- 201647005434

Filed on 16/02/2016

Applicant: MERCK SHARP & DOHME CORP

Hearing attended by: Dr. Malathy Lakshmi Kumaran of L& S

Hearing Scheduled on 10/06/2021

### **DECISION**

An application for a patent bearing number 201647005434 was filed on 16/02/2016 entitled "MODULATION OF TUMOR IMMUNITY". As per the provision under Section 11-A of Patents Act, the said application was published on 31/08/2016. A request for examination under Section 11-B was filed on 16/02/2016. The said application was examined under Section 12 and 13 of Patents Act and First Examination Report containing a statement of objections was forwarded on 01/05/2019 and the applicant's agent filed response to First Examination Report on 12/11/2019. As per the provisions under Section 13 (3) of Patents Act, the said amended case after reply to Examination Report, was examined and investigated in like manner as the original specification. The applicant was offered a hearing on 10/06/2021 vide official communication dated 11/05/2021 with the following objections:

#### **Invention u/s 2(1)(j)**

1. Referring Para B of FER is maintained as the applicant's reply is not satisfactory. The D4 is regarded as being the prior art closest to the subject-matter of claim. And discloses modulation of GITR for cancer immunotherapy. Blockade of PD- 1 and its ligands along with agonistic TNFR family members is also described (introduction). GITR is presented as an additional target. Phase I clinical trial with agonistic anti GITR antibodies is described (page 220, right hand column, § last). The subject-matter of the claims therefore differs from D4 in that anti PD-1 antagonistic antibodies and GITR agonistic antibodies are used to treat cancer. The effect of the combined use is synergy in tumor cell killing. the present application, relating to the use of anti PD-1 antagonistic antibodies and GITR agonistic antibodies. The skilled person could combine anti PD-1 antagonistic antibodies and GITR agonistic antibodies he could combination and would lead to a synergistic effect. It is likely that they have same effect as the separated antibodies administered together and they are always administered simultaneously. Hence, the claim 1,2 lack inventive step u/s 2(1)(j) of Patent Act 1970.

### Non-Patentability u/s 3

Claims 1 & 2 Still attracts u/s 3(i) of the Patent act 1970 as the subject matter of claim1 relates to combination/composition of PD-1 antagonist and a GITR agonist, but the claimed subject-matter relates to application or administration of individual drugs in simultaneous, sequential or concomitant manner. In such cases, although the claims are directed to a combination/composition of PD-1 antagonist and a GITR agonist, but the claimed invention resides in the method of administration of individual drugs in the said manner and thus, it falls within the scope of section 3 (i) of the Act. This is well evident from para 18, 32, 91 and originally filed claims.

### Other Requirement(s)

1. The submissions in your letter dated 21/01/2020 and the amendments within the claims have been considered carefully.

However, the requirements of inventive step, non-patentability of First Examination Report dated 01/05/2019 have not been met.

**The agent for applicants has attended the scheduled hearing and the written submissions are filed on 12/07/2021. The written submissions provided by the applicant for addressing the objections are available in the uploaded documents of the instant case.**

**My inference from the above arguments with respect to amended claims is as follows:**

### With regard to inventive step

With regard to the inventive step, the applicant's argument has been fully considered but they are not persuasive.

The instant invention recites as follows:

A pharmaceutical combination comprising a PD-1 antagonist and a GITR agonist, wherein:

a) the PD-1 antagonist is MK-3475; and

b) the GITR agonist is an antibody or antigen-binding fragment that binds GITR comprising: CDR-L1, CDR-L2 and CDR-L3 of the variable light chain comprising the amino acid sequence set forth in SEQ ID NO: 82 wherein amino acid 31 is Q and amino acid 57 is Q; and CDR-H1, CDR-H2 and CDR-H3 of the variable heavy chain comprising the amino acid sequence set forth in SEQ ID NO: 81.

*The PD 1 antagonist is MK-3475 which is known as **Pembrolizumab** is a well-known anticancer drug. GITR agonist which was amended to define by its sequences. GITR is **glucocorticoid-induced tumor necrosis factor (TNF) receptor related gene (GITR)**, which can serve as an effective anti-tumor therapeutic drug. Both components of the instant invention are well known in antitumour therapy. A person skilled in the art can combine anti PD-1 antagonistic antibodies and GITR agonistic antibodies and can easily obtain the expected results by routine experimentation. It is likely that they have same effect*

*as the separated antibodies administrated together and always administrated simultaneously. Hence, the amended claims lack inventive step u/s 2(1)j a of Patent Act 1970.*

**With regard to Non-Patentability u/s 3(i)**

The applicant's explanation regarding 3(i) has not been found persuasive.

The subject matter of the latest amended claims still relates to combination/composition of PD-1 antagonist and a GITR agonist, but the claimed subject-matter relates to application or administration of individual drugs in simultaneous manner. In such cases, although the claims are directed to a combination/composition of PD-1 antagonist and a GITR agonist, but the claimed invention resides in the method of administration of individual drugs in the said manner and thus, it falls within the scope of section 3 (i) of the Act. The simultaneous application of the components is well evident from para 18, 32, 91 and originally filed claims. Hence the objection is retained for the latest amended claims.

Therefore I conclude that the alleged invention as claimed in the instant applicant do not meet the requirements of Sections 3(i) and 2(1)ja of the Patents Act 1970 [Amendment Act 2005]. Therefore I hereby order that the grant of patent is hereby refused under the provisions of Section 15 of the Patents Act.

22/07/2021

(Resmi C. Senan)

Assistant Controller of Patents & Designs

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