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संदर्भ सं. / Ref. No:  
POC/Application No /201917004058

प्रेषण दिनांक / Date of Dispatch:  
05-10-2023

सेवा मे, / To

आवेदक /Applicant:  
SANOFI

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विपक्षी /Opponent:  
NA

ई-मेल पेषित /Email Sent to:  
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विषय: आवेदन संख्या 201917004058 के संदर्भ में सुनवाई नोटिस  
Sub: Hearing adjournment notice in reference of Application No. 201917004058

सुनवाई स्थल / Hearing Location: Through Video Conferencing  
सुनवाई दिनांक व समय / Hearing Date & Time: 27/10/2023 / 15:00 HRS (IST) for (30 Mins)  
नियंत्रक ईमेल /Controller's Emailld: prasadvg.ip@nic.in

आपके द्वारा प्रथम परीक्षण रिपोर्ट/ अनुवर्ती परीक्षण रिपोर्ट के उत्तर के संदर्भ में, दिनांक 27/10/2023 को 15:00 HRS (IST) for (30 Mins) बजे विडियो कॉन्फ्रेंसिंग मामले में Hearing U/S (14) सुनवाई तय की गयी है। अतः, आपको उपरोक्त दिनांक व समय पर नियंत्रक के समक्ष सुनवाई हेतु उपस्थित होना है।

With reference to your reply to the First examination Report/Subsequent Examination Report, Hearing U/S (14) is adjourned in the matter through Video Conferencing and rescheduled on 27/10/2023 at 15:00 HRS (IST) for (30 Mins) . You are therefore, required to appear before the Controller for the hearing on said date and time.

You are also advised to intimate the controller one week before appearing in hearing on scheduled date.

इस आवेदन को पेटेंट अनुदान हेतु क्रम में लाने की अंतिम तिथि से पूर्व / अंतिम तिथि के उपरांत, निम्नलिखित आपत्तियां अभी भी शेष हैं।

The following objection(s) are still outstanding before / after the expiry of last date for putting this application in order for grant of patent.

SARAVANA RAM PRASAD V G  
Deputy Controller of Patents & Designs

\*दिनांक/समय, स्थल, स्थिति व सुनवाई के बारे में अन्य विवरण के लिए: कृपया निम्नलिखित यूआरएल देखें <http://ipindiaservices.gov.in/PatentCauseList>  
Please refer to the following URL for: Date/Time, Venue, Status and other details about the Hearing  
<http://ipindiaservices.gov.in/PatentCauseList>

टिप्पणी:- विडियो कॉन्फ्रेंसिंग के माध्यम से सुनवाई के समय के संबंध में मेल अलग से भेजी जाएगी।

Note:- Separate mail will be sent regarding the time of the Hearing through Video Conference.

\* Hearing Objections are attached.

## Objections

### Claims [u/s 10(5) & 10(4) (c)]

1. The subject matter of the claims 3 and 8-14 is not a technical feature.
2. Subject matter of the claim 13 intended for use cannot be considered as an inventive feature within the meaning of section 2 (1) (j).
3. Claim 11 and 12 refers to "kit" which is not an invention u/s 2(1) (j) of The Patents Act 1970 as it lacks any functional feature. It is a mere combination of components and instructions for use with no novelty or inventive step whatsoever in the said way of placement.
4. Claims attract section 10 (5) and 10 (4) (c) as it lacks examples support in the description.

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

1. Applicant's response to FER, dated 04/05/2023 has been considered carefully; originally filed claims (1-22) are replaced with amended set of claims 1-14.

The applicant states that the alleged technical feature of the instant application lies in "prevention of stardust particles of antibody formation by placing the formulation in plastic container or raising the concentration of antibody".

The applicant's response is not persuasive and not satisfactory with respect to the objections regarding the inventive step of the amended claims. The objections have not been met and are maintained.

The presently modified claims relates to an antibody formulation comprising, an antibody, citrate buffer, polysorbate, arginine and sucrose, and a container containing the said formulation.

As already mentioned in FER, D1-D3 clearly disclosed all the components of the formulation and the antibody with 100% similarity, 100% coverage and 111 amino acid length. All the other components of the formulation were also disclosed.

The difference between the cited prior art and present application is placing the formulation in plastic container rather than glass container, and use of higher concentration of the known antibody.

The alleged solution cannot be considered as involving an inventive step, as it is technically same as the cited prior art formulation. Storage of the formulation in plastic container and use of the higher concentration of antibodies is a routine practice and doesn't involve any inventive feature.

Therefore, the subject matter of the amended claims 1-14 do not constitute an invention as per the section 2(1)(j) of The Patents Act, 1970, and the objections are sustained.

### Non-Patentability u/s 3

1. Subject matter of the claims 1-14 attracts section 3(d) of The Patents Act, 1970, in view of the cited prior art.
2. Subject matter of the claim 1-7, 13 and 14 attracts section 3(e), of The Patents Act, 1970, as it is a substance/composition obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof.