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संदर्भ सं. / Ref. No:
POD/Application No /201847020374

प्रेषण दिनांक / Date of Dispatch:
12/01/2024

सेवा में, / To

आवेदक /Applicant:
IONIS PHARMACEUTICALS, INC.

Registered Address For Service :Saibal Ghosh, Anand and Anand Advocates B-41, Nizamuddin East New Delhi – 110013, India Phone No: 0091-11-24355076,. Email: email@anandandanand.com,patent@depenning.com

विपक्षी /Opponent:
NA

ई-मेल पेषित /Email Sent to:
email@anandandanand.com,patent@depenning.com

विषय: आवेदन संख्या 201847020374 के संदर्भ में सुनवाई नोटिस
Sub: Hearing Notice in Reference of Application No. 201847020374

सुनवाई स्थल / Hearing Location: Through Video Conferencing
सुनवाई दिनांक व समय / Hearing Date & Time: 22/02/2024 / 11:00 HRS (IST) for (1h)
नियंत्रक ईमेल /Controller's Email: akash.ip@nic.in

आपके द्वारा प्रथम परीक्षण रिपोर्ट/ अनुवर्ती परीक्षण रिपोर्ट के उतर के संदर्भ में, दिनांक 22/02/2024 को 11:00 HRS (IST) for (1h) 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, a Hearing U/S (14) hearing has been scheduled in the matter through Video Conferencing on 22/02/2024 at 11:00 HRS (IST) for (1h) . You are therefore, required to appear before the Controller for the hearing on said date and time.

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.

Akash Kumar
Assistant 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

Formal Requirement(s)

1. Fees for 2 newly added claims (Rs 3,200) has to be paid.

Invention u/s 2(1)(ja)

1. The submissions in your letter dated 14/03/2023 have been considered carefully. However, following objections have been raised.

Newly added claims 3-4 are not allowable u/s 59 of the Patents Act, 1970. As no amendment of an application for a patent or a complete specification or any document relating thereto shall be made except by way of disclaimer, correction or explanation, and in not in way of addition.

Para 1 of FER is maintained as the applicant's reply is not satisfactory. The applicant in his correspondence argues that D1 teaches that ISIS 681257 was subcutaneously administered to 8-week-old female mice at 0.3, 1, 3, or 10mg/kg, but fails to provide any teaching or suggestion regarding an amount suitable for humans is not satisfactory. As, para [0175 and 0201-0202] of D1 talks about that administered of a said compound is not limited to mice, but it also includes humans.

Applicant's arguing that in examples 1 and 2 of the present application, a ≥ 30 -fold improvement in potency in humans was observed for oligomeric compound ISIS 681257 in sterile saline solution is not satisfactory. As, the said examples does not clearly defined the said improvement in the specification.

Hence, by routine experimentation, the typical dose for humans can be arrived by a person skilled in the art in view of the cited documents.

Hence there is no technical advancement over the cited documents and the inventive feature of the current invention is obvious to a person skilled in the art in view of the cited documents D1 to D2. Therefore, amended claims 1-2 and 5-13 do not involve inventive steps as required u/s 2[1(j)(a)] of the Patents Act, 1970.

Non-Patentability u/s 3

1. Para 2 of FER is maintained, As, the amended claims 1-2 and 5-13 are not patentable under section 3(e) as the composition claimed is just an admixture of various ingredients without any demonstrated synergistic effect.

Sufficiency of Disclosure u/s 10 (4)

1. Para 3(l) of FER is maintained as the applicant's reply is not satisfactory for the amended claims 1-2 and 5-13 pertaining to a pharmaceutical composition are not enabled in the specification via working example. Hence, these claims do not meet the requirement of 10(4) (b) of the Patents Act, 1970.