UNITED STATES PATENT AND TRADEMARK OFFICE

_____

BEFORE THE PATENT TRIAL AND APPEAL BOARD

_____

REGENERON PHARMACEUTICALS, INC.,
Petitioner

v.

NOVARTIS PHARMA AG,
NOVARTIS TECHNOLOGY LLC,
NOVARTIS PHARMACEUTICALS CORPORATION,
Patent Owners

_____

Case IPR2021-00816
Patent 9,220,631

_____

PATENT OWNERS' CONTINGENT MOTION TO AMEND UNDER 37 C.F.R. § 42.121

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

I. INTRODUCTION

Patent Owner[1] files this contingent Motion to Amend pursuant to 35 U.S.C. § 316(d)(3) and 37 C.F.R. § 42.121, and requests preliminary guidance pursuant to the Motion to Amend Pilot Program, 84 Fed. Reg. 9497; 86 Fed. Reg. 51656.

Patent Owner maintains its position that the '631 patent claims are not unpatentable under any of the instituted grounds. In the event that the Board accepts Petitioner's obviousness arguments and concludes otherwise, Patent Owner contingently moves to amend the original claims with corresponding proposed substitute claims. The substitute claims further distinguish the prior art of record in this proceeding by proposing two amendments to original independent claim 1: (1) reducing the upper level of silicone oil that is present in the syringe barrel to an amount of about 25 µg, and (2) additionally requiring that the terminally sterilized syringe have a shelf-life of at least twelve months after terminal sterilization. The substitute claims meet the requirements of 35 U.S.C. § 316(d)(3) insofar as they narrow the claims, have express support in the disclosures of the '631 patent application as originally filed, and address an issue of patentability raised by the Board in the Institution Decision.

None of the prior art cited by Petitioner renders the substitute claims unpatentable. None of the references teach the lowered amount of silicone oil in

[1] Novartis Pharma AG, Novartis Technology LLC, Novartis Pharmaceuticals Corp.

the syringe barrel. Nor do any of the references support a reasonable expectation that such low amounts of silicone oil, even if suggested, could provide the recited break loose force and other properties for a pre-filled, terminally sterilized, intravitreal syringe comprising a VEGF therapeutic, let alone provide them over the course of a shelf-life of at least twelve months following terminal sterilization. Finally, Patent Owner is not aware of any prior art or teaching that a person of ordinary skill in the art (POSA) would combine with Petitioner's prior art, Sigg, Lam or Boulange (or any other art of record), to render the proposed substitute claims obvious.

II. STATEMENT OF RELIEF REQUESTED

To the extent the Board finds any original claim unpatentable in this proceeding, Patent Owner respectfully requests that the Board grant this contingent motion to amend with respect to each corresponding substitute claim below for which the original claim was found unpatentable. The Board should not consider this motion for any original claim that it determines is patentable.

III. THE REQUIREMENTS OF 35 U.S.C. § 316(d)(3) and 37 C.F.R. § 42.121 ARE MET

To satisfy 35 U.S.C. § 316(d) and 37 C.F.R. § 42.121, this Motion to Amend must (1) not present substitute claims that enlarge the scope of the claims of the challenged patent or introduce new subject matter; (2) propose a reasonable number of substitute claims; and (3) respond to a ground of unpatentability

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.