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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SANOFI-AVENTIS U.S. LLC AND
REGENERON PHARMACEUTICALS, INC.,
Petitioners

v.

GENENTECH, INC. AND CITY OF HOPE
Patent Owners

Case IPR2015-01624
Patent 6,331,415

PATENT OWNERS' PRELIMINARY RESPONSE UNDER 37 C.F.R. § 42.107

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes and Regulations

I. INTRODUCTION

In their Petition, Sanofi-Aventis U.S. LLC and Regeneron Pharmaceuticals, Inc. ("Petitioners") ask the Board to disregard the prior determinations of the Patent and Trademark Office (the "Office") that the claims of U.S. Patent No. 6,331,415 (the "Cabilly '415 patent") define a patentable invention. The grounds advanced by Petitioners, however, present arguments that were already thoroughly considered, and ultimately rejected, by the Office in prior proceedings, and ignore the substantial evidence considered by the Office in reaching that prior determination.

Petitioners contend the primary prior art references it is advancing—Bujard (Ex. 1002) and Cohen & Boyer (Ex. 1005)—describe or would have made obvious the claimed invention, which requires production of an immunoglobulin by independent expression of DNA sequences encoding the heavy and light chains in a single transformed host cell. But this prior art does not show actual production of an antibody, or doing so via a single transformed host cell as required by the claims. If anything, the prior art advanced in the Petition is ***less*** probative on the issues already considered and rejected by the Office.

Specifically, in earlier reexamination proceedings, the Office considered the question whether the mere appearance of the plural term "genes" along with the

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