

Filed on behalf of Patent Owners Genentech, Inc. and City of Hope by:

David L. Cavanaugh  
Reg. No. 36,476  
Heather M. Petruzzi  
Reg. No. 71,270  
Robert J. Gunther, Jr.  
*Pro Hac Vice* Application Pending  
Wilmer Cutler Pickering  
Hale and Dorr LLP  
1875 Pennsylvania Ave., NW  
Washington, DC 20006

Adam R. Brausa  
Reg. No. 60,287  
Daralyn J. Durie  
*Pro Hac Vice* Application Pending  
Durie Tangri LLP  
217 Leidesdorff Street  
San Francisco, CA 94111

UNITED STATES PATENT AND TRADEMARK OFFICE

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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

v.

GENENTECH, INC. AND CITY OF HOPE  
Patent Owners

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Case IPR2015-01624  
Patent 6,331,415

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**PATENT OWNERS' PRELIMINARY RESPONSE UNDER**

**37 C.F.R. § 42.107**

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## 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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