

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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FRESENIUS KABI USA, LLC and  
FRESENIUS KABI SWISSBIOSIM GmbH,  
Petitioner,

v.

CHUGAI SEIYAKU KABUSHIKI KAISHA and  
HOFFMAN-LA ROCHE INC.,  
Patent Owner.

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IPR2021-01288 and IPR2021-01542 (Patent 8,580,264 B2)  
IPR2021-01336 (Patent 10,874,677 B2)  
IPR2022-00201 (Patent 9,750,752 B2)<sup>1</sup>

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Before ERICA A. FRANKLIN, JOHN G. NEW, and ZHENYU YANG,  
*Administrative Patent Judges.*

YANG, *Administrative Patent Judge.*

TERMINATION  
Due to Settlement After Institution of Trial  
*35 U.S.C. § 317; 37 C.F.R. § 42.74*

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<sup>1</sup> This Order addresses issues common to each captioned case. Thus, we enter the same Order in each case. The parties are not authorized to use this style caption unless directed otherwise.

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## I. INTRODUCTION

On October 4, 2022, with authorization of the Board, Petitioner, Fresenius Kabi USA, LLC and Fresenius Kabi SwissBioSim GmbH and Patent Owner, Chugai Seiyaku Kabushiki Kaisha and Hoffmann-La Roche Inc., (collectively “the Parties”) filed a joint motion to terminate in each of the above-identified proceedings due to settlement. Paper 71<sup>2</sup> (“Joint Motion”). The Parties also filed a copy of a Settlement Agreement (Ex. 1070 (“Settlement Agreement”)) governing their settlement together with a joint request (Paper 72 (“Joint Request”)) that the Settlement Agreement be treated as business confidential information and kept separate from the publicly available files of the above-captioned proceedings.

## II. DISCUSSION

In each Joint Motion, the Parties represent that they have reached an agreement to jointly seek termination of the above-identified *inter partes* review proceedings, and that the filed copy of the Settlement Agreement represents “a true and correct copy” of the settlement agreement. Joint Motion 1.

We instituted trial on IPR2021-01228 and IPR2021-01336 on February 23, 2022 (Paper 30, Paper 26), on IPR2021-01542 on March 3, 2002 (Paper 25), and on IPR2022-00201 on June 3, 2022 (Paper 23). These proceedings, however, have not yet advanced to the stage where an oral hearing has been held, nor has the Board decided the merits of the

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<sup>2</sup> For expediency, we cite to filings in IPR2021-01228 unless otherwise noted. Similar items were filed in IPR2021-01336, IPR2021-01542, and IPR2022-00201.

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proceedings. Under these circumstances, we determine that it is appropriate to terminate these proceedings. *See* 35 U.S.C. §§ 317, 327. We also determine that it is appropriate to treat each Settlement Agreement as business confidential information to be kept separate from the patent files and separate from the files of these proceedings pursuant to 37 C.F.R. § 42.74(c), and therefore grant the portion of each Joint Request to keep the Settlement Agreement separate from the file of the subject patent.

We note that in the Joint Request, the Parties additionally seek an order from the Board that, “in the event a person or entity makes a written request, as stated in 37 C.F.R. § 42.74(c)(1)-(2), for access to the settlement agreement, that any such written request be served upon Petitioners and Patent Owner on the day the written request is provided to the Board.” Joint Request 1. That request is *denied*. Under 35 U.S.C. § 317(b), settlement agreements “shall be made available only to Federal Government agencies on written request, or to any person on a showing of good cause.” The provision under 37 C.F.R. § 42.74(c) reads similarly. Here, the Parties are essentially asking us to include additional requirements to those provisions. Further, the Parties’ request would require us to issue an order for the conduct of Government agencies or individuals seeking access to the settlement agreements who are not parties to this proceeding or subject to our orders. As we find those aspects of the Parties’ request to be inappropriate, it is *denied*.

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### III. ORDER

Accordingly, it is:

ORDERED that in each of IPR2021-001288, IPR2021-01336, IPR2021-01542, and IPR2022-00201, the Joint Motion to Terminate is *granted*, and these proceedings are terminated;

FURTHER ORDERED that in each of IPR2021-001288, IPR2021-01336, IPR2021-01542, and IPR2022-00201, the Joint Request is *granted-in-part* and *denied-in-part* in the manner noted above; and

FURTHER ORDERED that in each of IPR2021-001288, IPR2021-01336, IPR2021-01542, and IPR2022-00201, the Settlement Agreement shall be kept separate from the files of the involved patents and made available only to Federal Government agencies on written request, or to any person on a showing of good cause, pursuant to 37 C.F.R. § 42.74(c).

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