

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC., APOTEX CORP., ARGENTUM PHARMACEUTICALS LLC,
ACTAVIS ELIZABETH LLC, TEVA PHARMACEUTICALS USA, INC., SUN
PHARMACEUTICAL INDUSTRIES, LTD., SUN PHARMACEUTICAL
INDUSTRIES, INC., AND SUN PHARMA GLOBAL FZE,

Petitioners,

V.

NOVARTIS AG,

Patent Owner.

Case IPR2017-00854¹

U.S. Patent No. 9,187,405

SECOND DECLARATION OF PETER J. WAIBEL, ESQ.

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P.O. Box 1450
ALEXANDRIA, VA 22313-1450

¹ Cases IPR2017-01550, IPR2017-01946, and IPR2017-01929 have been joined with this proceeding.

Apotex v. Novartis

IPR2017-00854

I, Peter J. Waibel declare as follows:

1. I am head of US Patent Litigation for Novartis Pharmaceuticals Corporation, the assignee of U.S. Patent No. 9,187,405. I previously executed a declaration in this matter on December 5, 2017. (My “First Declaration,” Ex. 2078.) This is my second declaration in this matter.

2. I submit this declaration to address Petitioners’ request for “the phase III protocol referenced in Exhibit 2065 (‘Protocol’).” (Paper 35 at 1.) Here I describe the burden, if not the impossibility, of identifying and producing the specific Protocol version Mount Sinai discussed in the emails as of March 2007.

3. I have reviewed Exhibit 2065, a March 2007 email chain between Novartis personnel and representatives of Mount Sinai hospital in New York City about Mount Sinai’s possible participation in the TRANSFORMS clinical trial for Gilenya. Dr. Lublin describes that trial in his Second Declaration. (Ex. 2025 ¶¶ 43-63.)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

9. Moreover, the interaction with Mount Sinai was over ten years ago. Only one of the Novartis employees on Exhibit 2065 is still with the company, Valentina Curovic-Perisic. (See my First Declaration, Ex. 2078 ¶ 13 (identifying employment beginning and end dates for employees identified in Exhibit 2065).) I understand from Ms. Curovic-Perisic that we cannot find the emails and attachments we would need to identify which version of the Protocol Mount Sinai had as of March 2007, [REDACTED]

[REDACTED]

10. Novartis located Exhibit 2065 only due to the happenstance that the emails of Mr. Tom Watson, another ex-employee mentioned in the emails, had been retained from late 2014 onward under a litigation document hold in another case. I understand that we have been unable to locate any emails in his retained collection that would identify which version of the Protocol Mount Sinai had as of

March 2007. Every other Novartis employee identified on Exhibit 2065 had already left the company before the 2014 litigation hold that preserved Mr. Watson's emails. (See my First Declaration, Exhibit 2078 ¶ 13 (identifying departure dates for Sylvia Burns (2010), James Prodafikas (2008), and Karen Webster (2008)).) As a result, their emails would not have been subject to that hold.

11. There is a remote chance that emails reflecting which Protocol version Mount Sinai had as of March 2007 might be in other employees' email files. However, identifying those emails would be a substantial burden, if not impossible. So far as I am aware, it would at least entail a comprehensive investigation of any remaining old records to determine who was responsible for disseminating protocol amendments to Mount Sinai. Then, if that person's emails still exist in the company, those emails would have to be collected and reviewed to determine if they reveal the last version of the protocol sent to Mount Sinai as of March 2007. Based on my experience in working with Novartis's record keeping systems, this project would likely take months with at best a remote chance of success.

12. I of course do not know if Mount Sinai's IRB would have kept confidential records related to a trial [REDACTED]. But even if they did, Novartis has no power to compel Mount Sinai to provide any of

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