# UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

AMGEN INC.,	)
Plaintiff,	) ) Civil Action No.: 05-12237 WGY
v.	) CIVII ACUOII No 05-12237 WG I
F. HOFFMANN-LA ROCHE	)
LTD., a Swiss Company, ROCHE	)
DIAGNOSTICS GmbH, a German	)
Company and HOFFMANN-LA ROCHE	)
INC., a New Jersey Corporation,	, )
	)
Defendants.	)

# AMGEN INC.'S BENCH MEMORANDUM REGARDING AUTHENTICATION OF JANUARY 16, 1984 LETTER

At trial on September 7, 2007, Roche objected to the admission of Amgen Trial Exhibit BAH,<sup>1</sup> a Telex from Chugai Pharmaceutical Co., Ltd. to Genetics Institute, Inc. dated January 11, 1984, challenging its authenticity. Roche argued that the document "came from Amgen," and not from Genetics Institute ("GI"), thereby questioning whether under Fed. R. Evid. 901(8) the document was found in a place where, if authentic, it would likely be.<sup>2</sup>

Amgen also seeks to introduce Trial Exhibit FJX.<sup>3</sup> Because Amgen Trial Exhibit FJX also originated from GI's production of documents in the *Amgen v. Chugai* case, was authentic at

<sup>&</sup>lt;sup>1</sup> Exh. 1 (Amgen Trial Exhibit BAH).

<sup>&</sup>lt;sup>2</sup> See 9/7/07 Tr. Transcript at 416:19-22. "Ms. Ben-Ami: The fact it's an ancient document doesn't prove the truth of any of this, and there's no authentication of this document. This document was – this came from Amgen. This didn't come from --".

<sup>&</sup>lt;sup>3</sup> Exh. 6 (Amgen Trial Exhibit FJX). Numbered exhibits refer to the Declaration of Aaron R. Hand in Support of Amgen's Bench Memoranda Regarding Authentication of Jan. 11, 1984 Telex and Jan. 16, 1984 Letter.

the time it was produced, and has been maintained by Amgen in its files since its production and use in the earlier case, there is sufficient evidence to support the finding that Trial Exhibit FJX is what it purports to be.

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Authentication of evidence is a condition precedent for admission in accordance with Fed. R. Evid. 901. "Only a 'reasonable likelihood' that proffered evidence is what it purports to be need be shown to authenticate it." Fed. R. Evid. 901(b) provides various illustrations of methods through which a party may demonstrate that "the matter in question is what its proponent claims." Because, as discussed below, Trial Exhibit FJX, a January 16, 1984 letter<sup>5</sup> from M. Yang (Genetics Institute) to R. Sadahiro (Chugai), is authentic under the Fed. R. Evid. 901(a), (b)(1), (b)(4), and (b)(8), it should be admissible evidence under the ancient document hearsay exception pursuant to Fed. R. Evid. 803(16).

## Fed. R. Evid. 901(b)(8): Ancient documents or data compilation.<sup>6</sup>

Amgen Trial Exhibit FJX, a 1/16/84 letter ("1/16/84 Letter") from M. Yang (Genetics Institute) to R. Sadahiro (Chugai) is properly authenticated as an ancient document under Rule 901(b)(8). Trial Exhibit FJX was produced to Amgen in a litigation between Amgen Inc. and defendants Chugai and Genetics Institute.<sup>7</sup> The handwritten notes present on the face of Trial Exhibit FJX indicate that it is an "unexpurgated document" bearing document number 017806-10. A search of Amgen's counsel's files located the original expurgated version of the 1/16/84

<sup>&</sup>lt;sup>4</sup> United States v. Perez-Montanez, 202 F.3d 434, 440 (1st Cir. 2000), cert. denied, 531 U.S. 886 (2000). See also United States v. Alicea-Cardoza, 132 F.3d 1, 4 (1st Cir. 1997); United States v. Holmquist, 36 F.3d 154, 168 (1st Cir. 1994).

<sup>&</sup>lt;sup>5</sup> Exh. 1 (Amgen Trial Exhibit BAH).

<sup>&</sup>lt;sup>6</sup> "Evidence that a document or data compilation, in any form, (A) is in such condition as to create no suspicion concerning its authenticity, (B) was in a place where it, if authentic, would likely be, and (C) has been in existence 20 years or more at the time it is offered."

<sup>&</sup>lt;sup>7</sup> Amgen, Inc. v. Chugai Pharm. Co., No. 87-2617-Y, 13 U.S.P.O.2d 1737 (D. Mass. 1989).

Letter bearing original GI production numbers 017806-10.8 The handwritten document number on the face of Amgen Trial Exhibit FJX, therefore, corresponds to the GI production number affixed to the original expurgated document. Further, contemporaneous communications between Amgen's counsel and GI's counsel from the time of its production demonstrates that GI produced to Amgen documents bearing production numbers 000001 – 018175, including the 1/16/84 Letter at production numbers 017806-10, from its files. In a reply letter, GI's counsel also confirmed that GI produced documents to Amgen, including a document bearing GI production numbers 017806-10 produced from the files of custodian Edward Fritsch. 10 Additionally, Amgen's counsel has regularly kept and maintained these prior litigation documents in the ordinary course of business.<sup>11</sup>

Nothing about the condition of the 1/16/84 Letter creates any suspicion regarding its authenticity. Instead, the facts and circumstances support the conclusion that Trial Exhibit FJX offered for admission by Amgen is authentic. During the Amgen v. Chugai litigation, Genetics Institute produced relevant and responsive documents to Amgen. Because many of those documents—including the 1/16/84 Letter—were relevant in subsequent proceedings involving Dr. Lin's patents, Amgen was required to produce them in those subsequent proceedings. Over the years, Amgen has regularly kept and maintained these prior litigation documents in the ordinary course of business.<sup>12</sup>

<sup>&</sup>lt;sup>8</sup> Exh. A, Redacted version of the 1/16/07 letter from M. Yang (Genetics Institute) to R. Sadahiro (Chugai) bearing original GI production numbers 017806-10. Lettered exhibits refer to the Declaration of Kevin M. Flowers Regarding Genetics Institute Documents.

Exh. 8, 8/3/88 Letter from Schnurr to Moroz.

<sup>&</sup>lt;sup>10</sup> Exh. B, 8/9/88 Letter from Fedowich to Schnurr.

<sup>&</sup>lt;sup>11</sup> See Declaration of Kevin M. Flowers Regarding Genetics Institute Documents.

<sup>&</sup>lt;sup>12</sup> Declaration of Cherie St. Jean in Supp. of Amgen's Bench Mem. Regarding the Authentication of Jan. 11, 1984 Telex and Jan. 16, 1984 Letter.

Because the 1/16/84 Letter was originally produced to Amgen by Genetics Institute and preserved by Amgen and its counsel as part of its prior litigation files, one would expect to find the authentic 1/16/84 Letter in Amgen's archive of documents relevant to Dr. Lin's patents. On its face, Trial Exhibit FJX has been in existence 20 years or more. Therefore, the document is admissible in accordance with Rule 901(b)(8).

### Fed. R. Evid. 901(b)(1): Testimony of witness with knowledge.<sup>13</sup>

The 1/16/84 letter ("1/16/84 Letter") from M. Yang (Genetics Institute) to R. Sadahiro (Chugai) is also properly authenticated by the trial testimony of a witness with knowledge of the document pursuant to Fed. R. Evid. 901(b)(1).

In trial testimony from Amgen Inc. v. Chugai Pharmaceutical Co., <sup>14</sup> Gabriel Schmergel, the President and CEO of Genetics Institute testified under oath that he was familiar with the 1/16/84 Letter from Mr. Yang to Mr. Sadahiro:

O: I will show you, Mr. Schmergel, Plainitff's Exhibit 320, which is a letter dated January 16, 1984, from Mr. Yang to Mr. Sadahiro at Chugai, with a copy designated to you. Are you familiar with that letter, Mr. Schmergel? A. Yes. 15

This is not surprising because the last page of the 1/16/84 Letter indicates that a copy was sent to Mr. Schmergel. After acknowledging his familiarity with the document, Mr. Schmergel answered several questions regarding the subject matter, content, and timing of the 1/16/84 Letter. The following passages exemplify Mr. Schmergel's familiarity with the 1/16/84 Letter and support the likeness of Amgen Trial Exhibit FJX and the document introduced to Mr. Schmergel:

<sup>&</sup>lt;sup>13</sup> "Testimony that a matter is what it is claimed to be."

<sup>&</sup>lt;sup>14</sup> Exh. 5, Amgen, Inc. v. Chugai Pharm. Co., No. 87-2617-Y, 10/18/89 Trial Tr. Vol. 36.

<sup>&</sup>lt;sup>15</sup> *Id.* at 22.

Q: I call your attention to the first paragraph of the letter. Mr. Yang states in the second sentence: We came to the conclusion that although we missed the chance to be the first one to clone EPO, we will continue to pursue this project aggressively, for the following two major reasons: And there follows two headings. One is the patent situation and the other on page 2, Item 2, is development of commercial product. My question to you, Mr. Schmergel, is,

Did you reach an agreement with Chugai that any patent procured by Amgen enforceable patent against the EPO project work would be vigorously resisted?

A: No.<sup>16</sup>

Q: In January of 1984 the first paragraph of Dr. Fritsch's answers states that: To clone EPO, Amgen used new sequence information obtained from tryptic fragments of EPO from Dr. Goldwasser. Now, January of 1984 is well prior to the arrangement with Dr. Miyake and the procurement of purified material from him, is it not?

A: For GI, you mean?

Q: Yes, for GI

A: Yes. 17

Mr. Schmergel's acknowledgment and familiarity with the 1/16/84 Letter evidences the subject matter, content, and timing of the communication between Genetics Institute and Chugai. Plainly, his testimony evidences the existence and authenticity of the 1/16/84 Letter from M. Yang (Genetics Institute) to R. Sadahiro (Chugai).

## Fed. R. Evid. 901(b)(4): Distinctive characteristics and the like.<sup>18</sup>

The 1/16/84 letter ("1/16/84 Letter") from M. Yang (Genetics Institute) to R. Sadahiro (Chugai) that Amgen seeks to introduce bears distinctive characteristics, contents and substance that, combined with the circumstances set forth above, serve as an independent basis for its authentication under Fed. R. Evid. 901(b)(4). The 1/16/84 Letter bears distinct markings from entry as an exhibit in prior proceedings, including Plaintiff's Exhibit 320, 19 as mentioned above,

<sup>&</sup>lt;sup>16</sup> *Id.* at 22-23 (emphasis supplied).

<sup>&</sup>lt;sup>17</sup> *Id.* at 24 (emphasis supplied).

<sup>&</sup>lt;sup>18</sup> "Appearance, contents, substance, internal patterns, or other distinctive characteristics, taken in conjunction with circumstances."

<sup>&</sup>lt;sup>19</sup> Exh. 7 (Amgen Trial Exhibit GVK).

and Plaintiff's Exhibit 683.<sup>20</sup> Additionally, Amgen, Chugai and Genetics Institute jointly stipulated that certain exhibits, identified by exhibit number, were admitted during the prior trial, including Plaintiff's Exhibits 320 and 683—two copies of the 1/16/84 Letter.<sup>21</sup> The joint stipulation was filed with the District Court, as indicated by the Court Clerk's stamp on the face of the document.<sup>22</sup>

Authentication of Amgen Trial Exhibit FJX is further substantiated by comparing it with the redacted version of the 1/16/07 letter from M. Yang (Genetics Institute) to R. Sadahiro (Chugai) bearing original GI production numbers 017806-10. Unmistakably, the distinctive edits and marginalia present on the redacted version are also present on Amgen Trial Exhibit FJX. Rule 901(b)(4), therefore, provides a proper basis for the authentication of the 1/16/84 letter from M. Yang (Genetics Institute) to R. Sadahiro (Chugai).

For the foregoing reasons, Amgen has provided sufficient evidence to satisfy the requirement of authentication for the 1/16/84 letter from M. Yang (Genetics Institute) to R. Sadahiro (Chugai) as a condition precedent to its admissibility pursuant to Rules 901 and 803(13). Amgen respectfully requests that the Court allow Amgen to introduce Amgen Trial Exhibit FJX into evidence.

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<sup>&</sup>lt;sup>20</sup> Exh. 6 (Amgen Trial Exhibit FJX).

<sup>&</sup>lt;sup>21</sup> See Exhs. 6, 7. (Amgen Trial Exhibit FJX and GVK).

<sup>&</sup>lt;sup>22</sup> Exh. 4, Amgen, Chugai, and Genetics Institute Stipulation Concerning Admitted Exhibits.

Respectfully Submitted,

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September 12, 2007

### **CERTIFICATE OF SERVICE**

I hereby certify that this document, filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing and paper copies will be sent to those indicated as non-registered participants on the above date.

\_\_\_\_\_\_\_/s/ Patricia R. Rich
Patricia R. Rich