EXHIBIT 1

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SETTLEMENT AGREEMENT

This SETTLEMENT AGREEMENT dated as of <u>May 12</u>, 1993 is made by and between Genetics Institute, Inc. ("GI") and Amgen Inc. ("Amgen"), by and through their duly authorized representatives, and is intended to be a final disposition of the controversies and disputes between GI and Amgen as more fully described below.

I. INTRODUCTION

- 1. Since at least October 1987, there have existed ongoing controversies and disputes between GI and Amgen relating to recombinant erythropoietin, including the infringement of Amgen's United States Patent No. 4,703,008 (the "'008 Patent") by GI.
- 2. These controversies and disputes have resulted in the following multiple legal proceedings:
 - Amgen Inc. v. Chugai Pharmaceutical Co., Ltd. and
 Genetics Institute, Inc., (the "Massachusetts Amgen
 Action"), Civil Action No. 87-2617-Y, commenced by
 Amgen in the United States District Court for the
 District of Massachusetts on October 27, 1987;
 - b. Genetics Institute, Inc. and Chuqai Pharmaceutical
 Co., Ltd. v. Amgen Inc., Kirin-Amgen, Inc., and
 Ortho Pharmaceutical Corp., (the "California
 Action"), Civil Action No. 87-07200-TJH (JRx),
 commenced by GI and Chuqai Pharmaceutical Co., Ltd.

AM 67 014557 CONFIDENTIAL SUBJECT TO PROTECTIVE ORDER in the United States District Court for the Central District of California on October 28, 1987;

- C. Genetics Institute, Inc. v. Amgen Inc. (the "Delaware Actions"), Civil Action Nos. 92-56, 92-57, commenced by GI on January 31, 1992, in the United States District Court for the District of Delaware, seeking, inter alia, an order setting aside a decision of the United States Patent and Trademark Office in Patent Interferences No. 102,097 and 102,334.
- 3. In addition, Ortho Pharmaceutical Corp. ("Ortho") has alleged infringement of Amgen's '008 Patent by GI in Ortho Pharmaceutical Corp. et al v. Genetics Institute, Inc. (the "Massachusetts Ortho Action"), Civil Action No. 91-12174-Y, commenced by Ortho and certain of its affiliates in the United States District Court for the District of Massachusetts on August 16, 1991.
- 4. Although each party disputes the contentions and claims asserted by the other party in the legal proceedings described in Paragraph I.2. above and GI disputes the contentions and claims made by Ortho in the Massachusetts Ortho Action, the parties have determined that continued litigation will be time consuming, protracted and expensive. In view of the foregoing, and without admitting the validity of any assertion, contention or defense

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made in said legal proceedings, who parties have agreed to settle their respective claims against one another on the terms set forth herein.

The parties intend by this SETTLEMENT AGREEMENT to fully 5. and finally settle and resolve all controversies and disputes between them which have been or could have been raised by either party against the other in the Massachusetts Amgen Action, the California Action, or the Delaware Actions, including any and all present claims either party may have against the other relating to the '008 Patent or any divisions or continuations thereof.

II. TERMS AND CONDITIONS

- GI and Amgen shall file and request the court to enter the stipulated judgment in the Massachusetts Amgen Action in the form attached as Exhibit A.
- This SETTLEMENT AGREEMENT shall be effective upon the entry of judgment in the Massachusetts Amgen Action in accordance with the form of judgment attached as Exhibit A (the "Judgment").
 - Effective upon entry of the Judgment: 3.
 - GI shall, within five business days of entry of the Judgment, pay Amgen \$13.9 million.
 - GI shall, within five business days of entry of the b. Judgment, file the stipulation for dismissal with prejudice of the Delaware Action, in the form as attached in Exhibit B.

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- c. Amgen and GI shall move to dismiss with prejudice the California Action, in the form as attached in Exhibit C.
- d. GI and Amgen, for themselves and their respective predecessors, subsidiaries and parents, shall release, acquit, exonerate, and forever discharge each other and each other's respective past, present, and future subsidiaries, affiliates, parents, licensees, successors, assigns, officers, directors, and employees from all and every manner of action and actions, cause and causes of action, suits, proceedings, debts, sums of money, contracts, agreements, promises, covenants, damages, controversies, demands, judgments, decrees, claims for damages, compensation, attorney's fees, costs and expenses of suits, and any and all claims, demands, or liabilities whatsoever of every name and nature in law or equity, arising out of, as a consequence of, or resulting from the infringement in the United States of the '008 Patent, or which was or could have been asserted in the Massachusetts Amgen Action, the California Action, or the Delaware Action, saving and excepting the rights and obligations of the parties under this SETTLEMENT AGREEMENT. Nothing in this paragraph shall be

AM 67 014560 CONFIDENTIAL SUBJECT TO PROTECTIVE ORDER construed as a release of any claim Amgen may have against licensees of GI for infringement of a non-United States patent as a result of activities outside the United States.

- e. Amgen shall within five business days of entry of the Judgment discharge the attachment granted August 16, 1991 against GI's assets in the Massachusetts Amgen Action.
- 4. a. If the judgment of dismissal in the Massachusetts
 Ortho Action of December 4, 1992 ("Ortho judgment")
 remains in effect in its entirety after exhaustion
 of all rights of appeal, GI shall, within five
 business days after exhaustion of all rights of
 appeal, pay to Amgen an additional \$2 million plus
 interest at the prime rate of interest as set by
 the Bank of Boston calculated from the effective
 date of this SETTLEMENT AGREEMENT.
 - b. Alternatively, if the Ortho judgment entered in Massachusetts Ortho Action is vacated on appeal and, after remand,
 - (i) the District Court enters final judgment on the merits in favor of GI and against Ortho, dismissing the Massachusetts Ortho Action with prejudice and such final judgment is affirmed in its entirety after exhaustion of all rights of appeal, GI shall, within five business days

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following exhaustion of all rights of appeal from such final judgment, pay to Amgen the additional \$2 million plus interest at the prime rate of interest as set by the Bank of Boston calculated from the effective date of this SETTLEMENT AGREEMENT. If such final judgment is not affirmed on appeal, GI shall not have the obligation set forth in this Paragraph 4(b)(i) to pay an additional \$2 million plus interest; provided, however, such lack of affirmance on appeal shall not relieve Amgen or GI of any obligation set forth in Paragraphs II.1, II.2, and II.3 above. "Final judgment on the merits in favor of GI and against Ortho dismissing the Massachusetts Ortho Action with prejudice" as it is used in this Paragraph 4(b)(i), shall mean only a dismissal on the merits that extinguishes all of Ortho's claims against GI for damages or other relief in any action or proceeding (pending or prospective) in the United States arising from infringement of the '008 patent; such a dismissel shall not include any dismissal that allows Ortho to seek or obtain in any forum damages or other relief from GI for infringement of the '008 patent; or

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(ii) the District Court enters final judgment on the merits in favor of Ortho on its claims against GI for infringement of the '008 patent in an amount of less than \$2 million, and that judgment is affirmed after exhaustion of all rights of appeal, GI shall, within five business days following exhaustion of all rights of appeal from that judgment, pay to Amgen an additional \$2 million less the full amount of the damages awarded to Ortho (including any interest awarded Ortho) plus interest on the net amount due Amgen at the prime rate of interest as set by the Bank of Boston calculated from the effective date of this SETTLEMENT AGREEMENT; provided however that judgment shall not relieve Amgen or GI of any obligation set forth in Paragraphs II.1, II.2, and II.3 above; or

(iii) the District Court enters final judgment on the merits for Ortho on its claims against GI for infringement of the '008 patent in an amount of \$2 million or more and that judgment is affirmed after exhaustion of all rights of appeal, GI shall not have the obligations set forth in Paragraph II.4.a or Paragraph II.4.b

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or any obligation to pay any additional amount of money to Amgen; provided, however that judgment shall not relieve Amgen or GI of any obligation set forth in Paragraphs II.1, II.2, and II.3 above.

- c. Alternatively, if GI at any time after the effective date of this Settlement Agreement enters into a settlement with Ortho of the Massachusetts Ortho Action, GI shall, within five business days of settlement with Ortho, pay to Amgen an additional \$2 million plus interest at the prime rate of interest as determined by the Bank of Boston calculated from the effective date of this SETTLEMENT AGREEMENT.
- Upon GI's performance of the obligations set forth in Paragraph II.3 and II.4 above, Amgen shall request that the Clerk of the United States District Court record the judgment against GI in the Massachusetts Amgen Action satisfied.
- The amounts paid to Amgen by GI pursuant to this б. SETTLEMENT AGREEMENT are paid in full satisfaction of all claims of Amgen to damages arising from GI's infringement of the '008 Patent in the Massachusetts Amgen Action. No portion of the amount paid is compensation for any asserted claim for multiple damages based on bad faith or similar conduct.

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- Amgen covenants not to sue GI or its licensees anywhere in the world for any claim or cause of action related to or arising from the manufacture of recombinant erythropoletin by GI prior to September 4, 1991, or from the use, sale, or other disposition of such recombinant erythropoietin manufactured by GI and sold to Boehringer Mannheim GmbH prior to September 4, 1991.
- GI warrants and represents that after October 27, 1987, GI did not ship or deliver to Boehringer Mannheim GmbH or Chugai Pharmaceutical Co., Ltd. any genetically engineered host cell that is used for the production of recombinant erythropoietin and that GI is not aware of any indirect shipment or transfer of such genetically engineered host cells to either Boehringer Mannheim GmbH or Chugai Pharmaceutical after October 27, 1987.
- GI warrants and represents that prior to September 4, 1991, it manufactured and sold to Boehringer Mannheim GmbH no more than 190 grams of recombinant erythropoietin that were accepted by Boehringer Mannheim GmbH for use in humans.
- 10. Entry into and consummation of the SETTLEMENT AGREEMENT shall not be construed as an admission of liability or culpability on the part of any party hereto, nor shall the mutual releases contained above in Paragraph II.3.d. be construed to support the validity of any claim or contention made by or threatened against either party hereto.
- 11. The terms and conditions of this SETTLEMENT AGREEMENT, and the contents of the negotiations and discussions resulting in this SETTLEMENT AGREEMENT shall be maintained as confidential by

AM 67 014565 CONFIDENTIAL SUBJECT TO PROTECTIVE ORDER the parties and their agents and representatives and shall not be disclosed except (a) in confidence to the parties' exclusive licensees, (b) in confidence and under a protective order during any judicial or arbitral dispute, or (c) to the extent required by federal or state law or otherwise agreed to in writing by counsel for the parties.

- 12. Each of the parties represents and warrants that it is the sole and lawful owner of all right, title and interest in and to every claim of GI and Amgen that it purports to settle or release by terms of this SETTLEMENT AGREEMENT and that it has not heretofore assigned or transferred, or purported to assign or transfer, any such claim.
- 13. This SETTLEMENT AGREEMENT shall inure to the benefit of and shall be binding upon the successors and assigns of the parties.
- 14. This SETTLEMENT AGREEMENT and its attachments hereto constitute a single, integrated written contract expressing the entire agreement of the parties and shall not be modified or supplemented except by a writing signed by each of them. No covenants, agreements, representations or warranties of any kind whatsoever have been made by any party, except as specifically set forth in this Agreement. All prior discussions, written communications, and negotiations have been and are merged and integrated into and are superseded by this Agreement.

10.

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15. This SETTLEMENT AGREEMENT shall be construed in accordance with, and be governed by, the laws of the Commonwealth of Massachusetts.

IN WITNESS WHEREOF, the parties being fully authorized and empowered to bind the parties to the SETTLEMENT AGREEMENT, have authorized and executed this SETTLEMENT AGREEMENT on the date set forth opposite their respective signatures.

GENETICS INSTITUTE, INC.

Dated: 5-13-93

AMGEN INC.

Dated: 5-17-93

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EXHIBIT A

UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

AMGEN INC.,

v.

Plaintiff

Judge William G. Young

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CHUGAI PHARMACEUTICAL CO., LTD. and GENETICS INSTITUTE, INC.,

Defendants

Civil Action No. 87-2617-Y

JUDGMENT

WHEREAS, on October 27, 1987, AMGEN, INC. ("Amgen") commenced this lawsuit alleging that CHUGAI PHARMACEUTICAL CO. ("Chugai") and GENETICS INSTITUTE, INC. ("GI") had infringed Amgen's United States Patent No. 4,703,008 ("the '008 Patent"); and

WHEREAS, infringement of the '008 Patent by GI has been found but damages resulting from that infringement are yet to be determined; and

WHEREAS, Amgen and GI have informed the Court that they have entered into a Settlement Agreement subject to entry of this stipulated judgment.

NOW, THEREFORE, IT IS HEREBY ORDERED, ADJUDGED AND DECREED:

This Court has jurisdiction over the subject matter of this action and over each of the parties hereto.

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- 2. The '008 Patent was duly and legally issued, is valid and enforceable in law and equity, and has been infringed by GI.
 GI has been and by this judgment continues to be enjoined from any further infringement thereof.
- 3. Based upon the stipulation and representation of GI and Amgen as reflected in their Settlement Agreement, judgment shall enter against GI for damages arising from GI's infringement of the '008 Patent in the amount set forth in that agreement.
- 4. The counterclaims of GI and Chugai are dismissed on the merits with prejudice.
- 5. Each party herein shall bear its own attorneys' fees and costs.
- 6. This Court shall retain jurisdiction over the parties and over the subject matter of the action for the purposes of insuring compliance with this Judgment.

SO.	ORDERED	THIS	D.	AY (OF	, 1993

United States District Judge

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STIPULATED TO:

GENETICS INSTITUTE, INC.

By: William F. Lee BBO \$291960 Hale and Dorr 60 State Street Boston, MA 02109 (617) 742-9100

AMGEN INC.

D. Dennis Allegretti BBO #545511 Allegretti & Witcoff, Ltd. 75 State Street Boston, MA 02109 (617) 345-9100

CHUGAI PHARMACEUTICAL CO., LTD.

ву: Kurt E. Richter Morgan & Finnegan 345 Park Avenue New York, NY 10154 (212) 758-4800

> AM 67 014570 CONFIDENTIAL SUBJECT TO PROTECTIVE ORDER

EXELBIT B

UNITED STATES DISTRICT COURT DISTRICT OF DELAWARE

GENETICS INSTITUTE, INC.,

Plaintiff,

ν.

AMGEN INC.

Defendant.

CIVIL ACTION NOS. 92-56 and 92-57

STIPULATION OF DISMISSAL

The parties hereto, by and through their respective counsel, stipulate and agree that all claims and counterclaims in the above-referenced matter shall be, and hereby are, dismissed with prejudice and without costs, each party to bear its own costs.

The parties expressly waive all rights of appeal.

GENETICS INSTITUTE, INC.

Dated: J-13-98

AMGEN INC.

Dated:

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EXHIBIT C

UNITED STATES DISTRICT COURT CENTRAL DISTRICT OF CALIFORNIA

GENETICS INSTITUTE, INC. and CHUGAI PHARMACEUTICAL CO., LTD.,

Plaintiffs,

v.

AMGEN INC., KIRIN-AMGEN INC. and ORTHO PHARMACEUTICAL CORP.,

Defendants.

CIVIL ACTION NO. 87-07200-TJH (JRx)

JOINT MOTION TO DISMISS

Genetics Institute, Inc. ("GI"), Chugai Pharmaceutical Co., Ltd. ("Chugai"), Amgen Inc. ("Amgen"), and Kirin-Amgen Inc. ("Kirin-Amgen") hereby move jointly that the Court dismiss all claims and counterclaims in the above-referenced action with prejudice and without costs.

In support of their joint motion, GI, Chugai, Amgen, and Kirin-Amgen state the following:

- The above-named parties have entered into a Settlement Agreement stipulating that this action be dismissed with prejudice and without costs.
- Simultaneously with the submission of this joint motion, GI is moving to dismiss Ortho Pharmaceutical Corp.'s counterclaims.



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GENETICS INSTITUTE, INC.

Dated: 5.15-93

CHUGAI PHARMACEUTICAL CO., LTD.

Dated:

By:____

Title:____

AMGEN INC.

Dated: [72-0

KIRIN-AMGEN INC.

Dated: May 12, 1943

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