Amgen Inc. v. F. Hoffmann-La Roche Ltd, et al.
Case No. 05-CV-12237WGY

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Roche's Request for Production No. 19:
All Documents and Electronic Data Concerning any communications with Lawrence Souza and/or his researchers or assistants, that Concern the subject matter disclosed or claimed in Amgen's EPO Patents, or to the design, development and manufacture of pegylated erythropoietin or pegylated G-CSF.

Amgen's Response to Roche's Request for Production No. 19:
In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: Amgen objects to this Request to the extent that it seeks production of documents and electronic data concerning "the design, development and manufacture of . . . pegylated G-CSF" on the grounds that it is overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiver of these Specific Objections and General Objections set forth above which are incorporated herein by reference, Amgen responds as follows: Amgen will produce relevant, responsive, non-privileged documents regarding erythropoietin.

Roche's Request for Production No. 20:
All Documents and Electronic Data Concerning any communications with Joan C. Egrie and/or her researchers or assistants, that Concern the subject matter disclosed or claimed in Amgen's EPO Patents, or to the design development and manufacture of any erythropoiesis stimulating agent other than human erythropoietin, or to the design, development and manufacture of any Pegylated Compound.

Amgen's Response to Roche's Request for Production No. 20:
In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: Amgen objects to this Request to the extent that it seeks production of documents and electronic data concerning "the design development and manufacture of any erythropoiesis stimulating agent" or "any Pegylated Compound" other than erythropoietin, on the grounds that it is overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiver of these Specific Objections and General Objections set forth above which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents.

Roche's Request for Production No. 24:
All Documents and Electronic Data Concerning any submissions to or communications with the United States Food and Drug Administration (FDA) by or on behalf of Amgen, with respect to any ESA, Including epoetin alfa, marketed and sold under the brand names Epogen®, Procrit®, Eprex®, and Erypo®, and darbepoetin alfa, marketed and sold under the brand name Aranesp®.

Amgen's Response to Roche's Request for Production No. 24
In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: To the extent that this Request seeks production of documents and electronic

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data concerning "any submissions to or communications with the . . . FDA . . . with respect to any ESA" other than "epoetin alfa, marketed and sold under the brand names Epogen®, Procrit®, Eprex®, and Erypo®," it is irrelevant, overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence. To the extent that this Request also seeks production of "all" documents and electronic data concerning "any submissions to or communications with" the FDA with respect to epoetin alfa, it is overly broad and unduly burdensome. Amgen does not understand how the requested scope of documents is relevant to any claim or defense in this action; but, Amgen is willing to negotiate with Defendants to the extent Defendants believe otherwise in an effort to identify what, if any, subset of documents is relevant to this action.

Subject to and without waiver of these Specific Objections and General Objections set forth above which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents.

Roche's Request for Production No. 25:
All Documents and Electronic Data Concerning any submissions to or communications with any government agency or department which regulates drugs or biologics outside the United States by or on behalf of Amgen, with respect to any ESA, Including epoetin alfa, marketed and sold under the brand names Epogen®, Procrit®, Eprex®, and Erypo®, and darbepoetin alfa, marketed and sold under the brand name Aranesp®.

Amgen's Response to Roche's Request for Production No. 25:
In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: To the extent that this Request seeks production of documents and electronic data concerning "any submissions to or communications with any government agency or department which regulates drugs or biologics outside the United States . . . with respect to any ESA" other than "epoetin alfa, marketed and sold under the brand names Epogen®, Procrit®, Eprex®, and Erypo®," it is irrelevant, overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence. To the extent that this Request also seeks production of "all" documents and electronic data concerning "any submissions to or communications with any government agency or department which regulates drugs or biologics outside of the United States" with respect to "epoetin alfa," it is overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence. Amgen does not understand how the requested scope of documents is relevant to any claim or defense in this action; but, Amgen is willing to negotiate with Defendants to the extent Defendants believe otherwise in an effort to identify what, if any, subset of documents is relevant to this action.

Subject to and without waiver of these Specific Objections and General Objections set forth above which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents.

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Roche's Request for Production No. 31:
All Documents and Electronic Data Concerning any pending United States or foreign Patent Application relating to any ESA and/or any Pegylated Compounds or related methods.

Amgen's Response to Roche's Request for Production No. 31:
In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: To the extent that this Request seeks production of documents and electronic data concerning "any ESA" and/or "any Pegylated Compounds" other than erythropoietin, it is overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiver of these Specific Objections and General Objections set forth above which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents.

Roche's Request for Production No. 33:
All Documents and Electronic Data Concerning the preparation and publication of any articles not listed in Request for Production No. 32 that refer or relate to any ESA, any Pegylated Compounds, pegylation or any related methods, Including all drafts, underlying data and lab notebooks, and all Communications referring or relating thereto.

Amgen's Response to Roche's Request for Production No. 33:
In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: To the extent that this Request seeks production of documents unrelated to erythropoietin, Defendants' accused product, the patents-in-suit, or any claim or defense in this action, it is overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence.

Roche's Request for Production No. 34:
All Documents and Electronic Data Concerning any ESA, any Pegylated Compounds, pegylation or any related methods maintained by Graham Molineux, Olaf Kinstler and/or Stephen Elliot and/or their researchers or assistants.

Amgen's Response to Roche's Request for Production No. 34:
In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: To the extent that this Request seeks production of documents and electronic data concerning "any ESA, any Pegylated Compounds, pegylation or any related methods" not directed to erythropoietin, it is overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiver of these Specific Objections and General Objections set forth above which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents regarding erythropoietin. Amgen is willing to negotiate with Defendants regarding narrowing this Request to a reasonable scope of documents relevant to a claim or defense in this action.

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Roche's Request for Production No. 35:
All Documents and Electronic Data Concerning any ESA, any Pegylated Compounds, pegylation or any related methods currently or previously maintained by the following people:

1. Thomas Boone
2. David N. Brems
3. Robert Briddell
4. William J. Callahan
5. Byeong S. Chang
6. Art Cohen
7. Randolph B. DePrince
8. Stephen P. Eisenberg
9. Gary S. Elliott
10. Christine E. Farrar
11. Frederick A. Fletcher
12. MaryAnn Foote
13. Nancy E. Gabriel
14. Sheila Gardner
15. Colin V. Gegg
16. V. Goldshteyn
17. Alan D. Habberfield
18. James B. Hamburger
19. Cynthia Hartley
20. R. Wayne Hendren
21. Jerry M. Housman
22. Anna Y. Ip
23. Kathleen E. Jensen-Pippo
24. Brent S. Kendrick
25. Brent Kern
26. Bruce A. Kerwin
27. Patrick Kerzic
28. Elliot Korach
29. Andrew A. Kosky
30. David Ladd
31. Scott L. Lauren
32. Tiansheng Li
33. B. C. Liang
34. Pamela Lockbaum
35. Alexis M. K. Lueras
36. Patricia McElroy
37. Eugene S. Medlock
38. Mary Ann Miller-Messana
39. Russell T. Migita
40. George Morstyn

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41. Linda O. Narhi
42. Ralph W. Niven
43. Amiee G. Paige
44. Rahul S. Rajan
45. Lloyd Ralph
46. J. Renwick
47. Gisela Schwab
48. Linda Shaner
49. Christopher Sloey
50. Greg Stoney
51. Weston Sutherland
52. Lisa D. Trebasky
53. T. Tressel
54. Michael Treuheit
55. Tom Ulich
56. Tim Walker
57. K. Lane Whitcomb
58. J. Wilson
59. D. Winters
60. Qiao Yan
61. Heather Yeghnazar
62. John D. Young
63. V. Zani
64. Yu Zhang

Amgen's Response to Roche's Request for Production No. 35:
In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: To the extent that this Request seeks production of documents and electronic data concerning "any ESA, any Pegylated Compounds, pegylation or any related methods" not limited to erythropoietin, Defendants' accused product, the patents-in-suit, or any claim or defense in this action, it is overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiver of these Specific Objections and General Objections set forth above which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents regarding erythropoietin.

Roche's Request for Production No. 105:
All Documents and Electronic Data, Including laboratory notebooks, raw data, reports, memoranda, meeting minute notes, research proposals and requests for proposals and correspondence Concerning the interaction between any Pegylated Compound and the EPO receptor, e.g., the in vitro or in vivo erythropoietin receptor binding activity of any Pegylated Compound, the in vitro or in vivo affinity of any Pegylated Compound for the EPO receptor, and /or the internalization by cells of any ESA that has been chemically modified by pegylation,

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including, but not limited to, studies of Kd, Smax, or Bmax, on and off binding rates, and/or structure-activity studies, modeling and analysis, and all documents that compare or contrast any such characteristic of any ESA that has been chemically modified by pegylation, to a characteristic of any ESA, including but not limited to epoetin alfa, epoetin beta, RECORMON®, NEORECORMON®, EPOGEN®, EPREX®, PROCRIT®, or ARANESP®.

Amgen's Response to Roche's Request for Production No. 105:
In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: To the extent that this Request seeks production of documents and electronic data concerning "any Pegylated Compound," "any ESA that has been chemically modified by pegylation," or products other than erythropoietin, it is overly broad, vague and ambiguous, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiver of these Specific Objections and General Objections set forth above, which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents regarding erythropoietin.

Roche's Request for Production No. 106:
All Documents and Electronic Data, Including laboratory notebooks, raw data, reports, memoranda, meeting minute notes, research proposals and requests for proposals and correspondence Concerning any difference in the nature, magnitude, and/or duration of any response by an animal (including but not limited to humans) to the administration of any ESA that has been chemically modified by pegylation, compared to the administration of any ESA, including but not limited to epoetin alfa, epoetin beta, RECORMON®, NEORECORMON®, EPOGEN®, EPREX®, PROCRIT®, or ARANESP®.

Amgen's Response to Roche's Request for Production No. 106:
In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: To the extent that this Request seeks production of documents and electronic data concerning "any ESA that has been chemically modified by pegylation," or products other than erythropoietin, it is overly broad, vague and ambiguous, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiver of these Specific Objections and General Objections set forth above, which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents regarding erythropoietin.

Roche's Request for Production No. 107:
All Documents and Electronic Data, Including laboratory notebooks, raw data, reports, memoranda, meeting minute notes, research proposals and requests for proposals and correspondence Concerning the properties of any ESA that has been chemically modified by pegylation, with respect to pharmacokinetics, pharmacodynamics, clearance, receptor binding

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activity, safety, maintenance of hemoglobin levels, antigenicity, and/or immunogenicity, including all documents that compare or contrast such properties of any ESA that has been chemically modified by pegylation, to any ESA, including but not limited to epoetin alfa, epoetin beta, RECORMON®, NEORECORMON®, EPOGEN®, EPREX®, PROCRIT®, or ARANESP®.

Amgen's Response to Roche's Request for Production No. 107:
In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: To the extent that this Request seeks production of documents and electronic data concerning "any ESA that has been chemically modified by pegylation," or products other than erythropoietin, it is overly broad, vague and ambiguous, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiver of these Specific Objections and General Objections set forth above, which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents regarding erythropoietin.

Roche's Request for Production No. 108:
All Documents and Electronic Data, Including laboratory notebooks, raw data, reports, memoranda, meeting minute notes, research proposals and requests for proposals and correspondence Concerning any comparison of any ESA that has been chemically modified by pegylation, to any ESA, including but not limited to epoetin alfa, epoetin beta, RECORMON®, NEORECORMON®, EPOGEN®, EPREX®, PROCRIT®, or ARANESP®.

Amgen's Response to Roche's Request for Production No. 108:
In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: To the extent that this Request seeks production of documents and electronic data concerning "any ESA that has been chemically modified by pegylation" and "any ESA," it is overly broad, vague and ambiguous, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiver of these Specific Objections and General Objections set forth above, which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents.

Roche's Request for Production No. 109:
All Documents and Electronic Data, Including laboratory notebooks, raw data, reports, memoranda, meeting minute notes, research proposals and requests for proposals and correspondence Concerning any difference between any ESA that has been chemically modified by pegylation, and any ESA, including but not limited to epoetin alfa, epoetin beta, RECORMON®, NEORECORMON®, EPOGEN®, EPREX®, PROCRIT®, or ARANESP®.

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Amgen's Response to Roche's Request for Production No. 109:
In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: To the extent that this Request seeks production of documents and electronic data concerning "any ESA that has been chemically modified by pegylation" and "any ESA," it is overly broad, vague and ambiguous, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiver of these Specific Objections and General Objections set forth above, which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents.

Roche's Request for Production No. 110:
All Documents and Electronic Data, Including laboratory notebooks, raw data, reports, memoranda, meeting minute notes, research proposals and requests for proposals and correspondence Concerning every comparative study or analysis of the mechanism of action, the pharmacodynamic and/or pharmacokinetic properties of an ESA that has been chemically modified by pegylation, upon administration to humans relative to those of any ESA, including but not limited to epoetin alfa, epoetin beta, RECORMON®, NEORECORMON®, EPOGEN®, EPREX®, PROCRIT® and/or ARANESP® upon administration to humans, including a description of any data, tests, and/or experiments regarding such comparisons.

Amgen's Response to Roche's Request for Production No. 110:
In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: To the extent that this Request seeks production of documents and electronic data concerning "an ESA that has been chemically modified by pegylation" and "any ESA," it is overly broad, vague and ambiguous, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiver of these Specific Objections and General Objections set forth above, which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents.

Roche's Request for Production No. 111:
All Documents and Electronic Data, Including laboratory notebooks, raw data, reports, memoranda, meeting minute notes, research proposals and requests for proposals and correspondence Concerning any ESA that has been chemically modified by pegylation, used in any clinical trial to date, the protocol(s) for each such clinical trial, the principal investigators involved in each such clinical trial, and summaries of the results of each such clinical trial.

Amgen's Response to Roche's Request for Production No. 111:
In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: To the extent that this Request seeks production of documents and electronic data concerning "any ESA that has been chemically modified by pegylation" or products other than erythropoietin, it is overly broad, vague and ambiguous, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence.

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Subject to and without waiver of these Specific Objections and General Objections set forth above, which are incorporated herein by reference, Amgen responds as follows: Amgen has produced and will produce relevant, responsive, non-privileged documents.

Roche's Request for Production No. 112:
All Documents and Electronic Data, Including laboratory notebooks, raw data, reports, memoranda, meeting minute notes, research proposals and requests for proposals and correspondence Concerning the timing, nature of, and reasons for any amendments to any protocol for any clinical trial in which any ESA that has been chemically modified by pegylation, has been administered to a human being.

Amgen's Response to Roche's Request for Production No. 112:
In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this request: To the extent that this Request seeks production of documents and electronic data concerning "any ESA that has been chemically modified by pegylation" or products other than erythropoietin, it is overly broad, vague and ambiguous, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence.

Subject to and without waiver of these Specific Objections and General Objections set forth above, which are incorporated herein by reference, Amgen responds as follows: Amgen will produce relevant, responsive, non-privileged documents.

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