

6/29/2007 Varki, Ajit

6/29/2007 Varki, Ajit

EXHIBIT B

1 UNITED STATES DISTRICT COURT
 2 DISTRICT OF MASSACHUSETTS
 3
 4
 5 AMGEN INC.,)
 6 Plaintiff,)
 7 vs.) Civil Action
 8 F. HOFFMANN-LA ROCHE LTD., a Swiss) No. 05-12237 WGY
 Company, ROCHE DIAGNOSTICS GmbH,)
 9 a German Company, and HOFFMANN-LA)
 ROCHE, INC., a New Jersey)
 10 Corporation)
 11 Defendants.)

REDACTED

1 APPEARANCE:
 2
 3 For the Plaintiff:
 4 DAY CASEBEER MADRID & BATCHELDER, LLP
 BY: JONATHAN LOEB, Ph.D., ESQUIRE
 5 20300 Stevens Creek Boulevard
 Suite 400
 6 Cupertino, California 95014
 (408) 873-0110
 jloeb@daycasebeer.com

7 For the Defendants:
 8
 9 KAYE SCHOLER, LLP
 BY: CHRISTOPHER JAGOE, ESQUIRE
 10 425 Park Avenue
 New York, New York 10022
 (212) 836-8000
 cjagoe@kayescholer.com

11 Also Present:
 12
 13
 14 Michael Bullerman
 John Arel, Videographer

12
 13
 14 DEPOSITION OF AJIT VARKI, M.D.
 15 FRIDAY, JUNE 29, 2007
 16
 17
 18
 19
 20
 21
 22
 23 REPORTED BY:
 24 LINDA D. WHITE
 CSR NO. 12009
 25

21 (This Transcript contains testimony designated
 22 confidential as per Section 5(c) of the Amended
 Protective Order. Please treat the entire
 24 transcript in accordance with the protective
 25 order.)

6/29/2007 Varki, Ajit

1 UNITED STATES DISTRICT COURT
 2 DISTRICT OF MASSACHUSETTS
 3
 4
 5 AMGEN INC.,)
 6 Plaintiff,)
 7 vs.) Civil Action
 8 F. HOFFMANN-LA ROCHE LTD., a Swiss) No. 05-12237 WGY
 Company, ROCHE DIAGNOSTICS GmbH,)
 9 a German Company, and HOFFMANN-LA)
 ROCHE, INC., a New Jersey)
 10 Corporation)
 11 Defendants.)

REDACTED

12
 13
 14 DEPOSITION OF AJIT VARKI, M.D.,
 15 taken on behalf of Defendant, at
 16 333 West Harbor Drive, Suite Los
 Angeles, San Diego, California,
 17 8:03 a.m., Friday, June 29, 2007,
 before LINDA D. WHITE, Certified
 18 Shorthand Reporter Number 12009 for
 the State of California, pursuant
 19 to Notice.
 20
 21
 22
 23
 24
 25

6/29/2007 Varki, Ajit

1 BY MR. JAGOE:
 2 Q Okay. Look at your third report. You can
 3 keep that aside.
 4 Look at your third report.
 5 A 3 supplemental. Second supplemental?
 6 Q Second supplemental report.
 7 A Should I keep this here? I might get in
 8 trouble. Close it over there.
 9 Q Okay.
 10 A Okay.
 11 Q And paragraph 25 on Page 11 and 12.
 12 A 25 on Page 11 and 12. 11 and 12. Sorry.
 13 Okay.
 14 Q All right. And at the end of
 15 paragraph 25, you have six bulletpoints, right?
 16 A Right.
 17 Q And you list isoelectric points of
 18 glycoforms, sulfation, poly-lactosamine, repeat
 19 content?
 20 A Correct.
 21 Q Old glycan structure, presence of
 22 N-glycolylneuraminic acid and absence of alpha 2-6
 23 sialic acid linkages, correct?
 24 A Correct. N-glycolyl, G-L-C-O-L-Y-L.
 25 Q Would those six points summarize the

207

6/29/2007 Varki, Ajit

1 beyond the glyco -- peptide -- polypeptide itself.
 2 BY MR. JAGOE:
 3 Q Are any of the differences related to the
 4 folding of the polypeptide?
 5 A Not directly, but the -- it's well known
 6 that the glycans would -- could have a dramatic
 7 effect on the folding of the polypeptide during
 8 biosynthesis. I believe I addressed that in some
 9 other places in the reports.
 10 Q The sulfation difference, the sulfation
 11 takes place on the carbohydrate as opposed to on the
 12 amino acid residues; is that right?
 13 MR. LOEB: Objection. Vague and ambiguous.
 14 THE WITNESS: The presence of the sulfate
 15 esters, based on the data I've seen, especially the
 16 results of using the PNGase F enzyme. The data
 17 suggests. But again, sulfation is extremely
 18 difficult to study and has been very poorly studied
 19 in most of this work. It seems like it's on --
 20 attached to the sugar chains.
 21 BY MR. JAGOE:
 22 Q Okay. Now, the -- let me just ask you.
 23 So do you agree with the statement that
 24 urinary EPO and recombinant EPO are the same
 25 product?

208

6/29/2007 Varki, Ajit

1 differences between the prior art EPO that you
 2 analyzed and compounds that fall within the scope of
 3 claims of the 933 Patent?
 4 A I think those are the ones that -- yes, I
 5 think we -- I tried to summarize there what all the
 6 issues I looked at. I can't think of any other.
 7 But of course, a lot of these differences are not
 8 based on what was known in 1983. But subsequent
 9 analysis of either Miyake or Miyake-like
 10 preparations.
 11 Q All of these differences would be
 12 differences in the carbohydrate component of the
 13 erythropoietin, right?
 14 MR. LOEB: Objection. Vague and ambiguous.
 15 THE WITNESS: Carbohydrates refers to molecules
 16 that have a particular composition, a CHO
 17 composition. The sulfate, for example, would not
 18 fall in the category of carbohydrates. The
 19 N-glycolyl, I suppose, could, but it becomes a
 20 semantic issue or technical issue.
 21 All the differences -- perhaps better to
 22 put it as all the differences are related to things
 23 that are components of the glycans that are attached
 24 to the polypeptide. That is the way of summarizing
 25 all of the difference I looked at. So everything

209

6/29/2007 Varki, Ajit

1 MR. LOEB: Objection. Vague and ambiguous.
 2 THE WITNESS: Can you define "the same
 3 product"? Is it the source or is it the production
 4 method or is it --
 5 BY MR. JAGOE:
 6 Q The substances themselves are the same.
 7 MR. LOEB: Objection. Vague and ambiguous.
 8 THE WITNESS: The substance -- they're not.
 9 From everything I've seen, there is a lot of
 10 differences between them.
 11 BY MR. JAGOE:
 12 Q And are you intending to offer an opinion
 13 that urinary EPO and recombinant EPO can be
 14 distinguished?
 15 A If you define recombinant EPO as all the
 16 recombinant EPOs that have been made to date, and
 17 all the ones I've seen -- and there seems to be a
 18 lot of them that have been studied -- yes, I have
 19 not seen a single recombinant EPO prep that -- well,
 20 if you just look at the -- the way it's used in --
 21 in -- you know, looking for EPO doping in sports,
 22 it's very obvious they never have a problem telling
 23 them apart right from there.
 24 And since the differences they're looking
 25 at directly reflect differences in the glycan

210