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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF CALIFORNIA

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CHIRON CORPORATION,
Plaintiff,

NO. CIV. S-00-1252 WBS GGH

v.

MEMORANDUM AND ORDER RE:
INVENTORSHIP, OBVIOUSNESS,
INEQUITABLE CONDUCT

GENENTECH, INC.,
Defendant.

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In a separate order, the court has determined that Genentech's product, Herceptin, infringes Chiron's U.S. Patent No. 6,054,561 ("561 patent"). Genentech has asserted a number of defenses and counterclaims, three of which - invalidity for failure to join a co-inventor of the patent, invalidity for obviousness, and inequitable conduct - concern the late Dr. Jorgen Fogh's contribution to the invention claimed in the '561 patent. Chiron and Genentech now bring cross motions for summary judgment on these defenses and counterclaims.

I. Factual Background

The invention claimed in the '561 patent is a genus of monoclonal antibodies that bind to a human breast cancer antigen

1 known as HER2. The '561 patent issued in April of 2000 from a
2 long line of patents and patent applications dating back to 1984
3 and 1985, when scientists at Cetus (Chiron's predecessor) first
4 discovered anti-HER2 monoclonal antibodies. The '561 patent
5 attributes these discoveries to two Cetus scientists, Dr. David
6 Ring and Dr. Arthur Frankel.

7 In the early 1980s, Drs. Ring and Frankel began a
8 program to develop monoclonal antibodies against human breast
9 cancer. Drs. Ring and Frankel obtained a number of immunogens,
10 or substances that are capable of provoking an immune response,
11 which they injected into mice to induce the production of
12 antibodies. ('561 Patent, at 15:53-65.) They then harvested the
13 spleens of the mice and isolated the spleen cells, which produce
14 antibodies. Using techniques developed by Drs. Kohler and
15 Millstein, they then combined those cells with tumor cells to
16 create hybridomas. (Id. at 16:1-18.) The hybridomas produced
17 antibodies, which Drs. Ring and Frankel ran through a series of
18 immunoassays and staining tests to determine their binding
19 properties. (Id. at 16-25.) Using these screening methods, Drs.
20 Ring and Frankel hoped to isolate monoclonal antibodies capable
21 of binding strongly and specifically to human breast cancer
22 tissue but not to normal tissue.

23 One problem the Cetus scientists encountered was
24 locating a suitable immunogen. Drs. Ring and Frankel had planned
25 from the beginning to use a broad range of immunogens, including
26 both breast cancer tissues and cell lines. (Ring Dep. at 374-
27 75.) The idea was that by using a diversity of immunogens, they
28 would develop a wider range of antibodies capable of binding to

1 breast tumors. (Id.) However, after nearly a year of testing,
2 Dr. Frankel became concerned that many of the monoclonal
3 antibodies they had generated were binding the same group of
4 antigens. (Frankel Decl. ¶ 7.) In addition, although Cetus
5 scientists had used several tissue samples and two cell lines
6 (MCF-7 and ZR-75-1) as immunogens, they had been unsuccessful in
7 producing any antibodies having the desired binding properties.
8 (Id. ¶¶ 6,7; Frankel Dep. at 50; Taylor Decl. Ex. A.)

9 "Desperate" to develop monoclonal antibodies against
10 breast cancer, Dr. Frankel consulted Dr. Jorgen Fogh in the late
11 spring or early summer of 1983 for advice on cell lines.¹
12 (Frankel Dep. at 34, 36.) Dr. Fogh maintained a collection of
13 breast cancer cell lines at the Memorial Sloan Kettering Cancer
14 Center in New York, and Dr. Frankel "felt he was the best person
15 in the world to understand them." (Id. at 35.) Dr. Frankel
16 explained the monoclonal antibody project to Dr. Fogh, as well as
17 the difficulties the Cetus scientists had encountered in
18 identifying an appropriate immunogen to use in their experiments.
19 (Id. at 34, 36.) Dr. Frankel also told Dr. Fogh that he was
20 concerned with using cell lines, which are far removed from
21 patients, as a source for identifying antigens that would be
22 related to real patient's tumors. (Id. at 36.)

23 Although Dr. Frankel understood the dogma at the time
24 to be that the MCF-7 cell line was the most appropriate cell line

25
26 ¹ Dr. Frankel initially estimated that his conversation
27 with Dr. Fogh took place in 1981 or 1982. (Frankel Dep. at 34-
28 37.) After reviewing some dated documents, however, he testified
that his meeting with Dr. Fogh took place in approximately July
of 1983 (Id. at 99, 102.) The parties do not dispute that the
meeting took place in the late spring or early summer of 1983.

1 to use as an immunogen, Dr. Fogh "insisted" that Dr. Frankel use
2 a breast cancer cell line known as SKBr-3, and provided Dr.
3 Frankel with an SKBr-3 cell line.² (Id. at 34, 36, 49.) Dr.
4 Fogh told Dr. Frankel that SKBr-3 had the characteristics Dr.
5 Frankel was looking for in an immunogen, namely that it was
6 different from the other cell lines Dr. Frankel had been using,
7 and that it had a morphology similar to cells of primary breast
8 cancer tumors. (Frankel Decl. at ¶¶ 8,9.) Other than that, Dr.
9 Frankel cannot explain why Dr. Fogh was so insistent that he use
10 SKBr-3. (Id.) Dr. Fogh died not long after their meeting. (Id.)

11 After Dr. Frankel's conversation with Dr. Fogh, the
12 Cetus scientists used SKBr-3 as an immunogen. (Id. at 103, 107-
13 108, 111.) The first fusion involving SKBr-3 yielded a much
14 higher frequency of selective antibodies, and ultimately produced
15 the first monoclonal antibodies capable of binding to the HER2
16 antigen. One of those antibodies was monoclonal antibody 454
17 C11, which is referenced in the claims of the '561 patent.
18 (Frankel Dep. at 49, 218-19; Frankel Decl. ¶ 10; '561 Patent,
19 Claim 1 ("A monoclonal antibody that binds to a human breast
20 cancer antigen that is also bound by monoclonal antibody 454 C11.
21 . . .").)

22 SKBr-3 had been available to the public since 1972, and
23 its use in cancer research had been published in trade journals
24 prior to the meeting between Drs. Frankel and Fogh. (Van Note
25 Decl. ¶12; Crotty Decl. Ex. 7-10.) It is undisputed that in
26 1983, SKBr-3 was commonly known to persons in the field. (Lanier

27
28 ² "SKBr-3" stands for Sloan-Kettering Breast Cancer Cell
Line Number 3 (Lanier Dep. at 155.)

1 Dep. at 156-58.) By the time Dr. Fogh and Dr. Frankel met,
2 scientists at Cetus had already obtained SKBr-3 for use in the
3 monoclonal antibody project,³ although SKBr-3 was initially used
4 only to test for cross-reactivity and not as an immunogen.
5 (Frankel Dep. at 48, 49, 112-114.) Dr. Frankel cannot say
6 conclusively whether he intended to immunize mice with SKBr-3
7 prior to his conversation with Dr. Fogh, but he believes it is
8 likely that he intended to do so because he "was going to go
9 through eventually as many of the cell lines as [he] could."
10 (Id. at 104, 115, 122.)

11 It is undisputed that in the course of the project, Dr.
12 Frankel contacted numerous scientists who originated or possessed
13 breast cancer cell lines to learn more about the characteristics
14 of the cell lines and to obtain additional samples for the
15 project. (Frankel Decl. ¶ 7.) Dr. Frankel states in his
16 declaration that it was not uncommon for these scientists to

17
18 ³ Genentech disputes that Cetus possessed SKBr-3 before
19 Dr. Frankel spoke with Dr. Fogh, citing Dr. Frankel's deposition
20 testimony that "what I can't tell you is are those the same cells
21 that I saw with Dr. Fogh." (Frankel Dep. at 112.) Read in
22 context, however, this statement does not create a disputed issue
23 of fact:

24 Q: "So you had SKBr-3 cells in the laboratory as of April
25 1983?

26 A: Yes; that's correct. What I can't tell you is are those
27 the same cells that I saw with Dr. Fogh. What happened a
28 lot of people believe they have earlier passage cells if
they originated a cell line or he may have told 'use the
ones you already have.' I don't remember."

(See id. at 112-113.) (emphasis added).

Rather than raising a disputed issue of fact, this uncontroverted
testimony makes clear that Cetus had obtained SKBr3 prior to Dr.
Frankel's meeting with Dr. Fogh. Dr. Frankel was simply
testifying that he could not remember whether the cells actually
used to produce the first monoclonal antibodies of the invention
came from the SKBr-3 cell line already in Cetus's possession, or
whether they came from the SKBr-3 cell line Dr. Fogh gave Dr.
Frankel at their meeting.

1 suggest that he work with their cell lines and provide him with
2 samples. (Id.) Ultimately, Cetus generated monoclonal
3 antibodies capable of binding to HER2 using at least three
4 different immunogens: the SKBr-3 cell line, the ZR-75-30 cell
5 line, and membrane extracts of a human breast cancer tissue.
6 (Crotty Decl. Ex. 12.)

7 The '561 patent does not name Dr. Fogh as a co-inventor
8 of the patented invention. However, the '561 patent and every
9 application leading up to the '561 patent states that "[h]uman
10 breast cancer cell lines were obtained from the Breast Cancer
11 Task Force, the American Type Culture Collection (ATCC), and from
12 Dr. Jorgen Fogh at Memorial Sloan Kettering. The cells were
13 maintained and passaged as recommended by the Breast Cancer Task
14 Force, the ATCC and Dr. Fogh." ('561 Patent at 15:56-61.) Both
15 Dr. Frankel and Dr. Ring have submitted declarations attesting
16 that they do not consider Dr. Fogh to be a co-inventor, and that
17 his contribution is accurately described as providing cell lines.
18 (Id.)

19 II. Discussion

20 The court must grant summary judgment to a moving party
21 "if the pleadings, depositions, answers to interrogatories, and
22 admissions on file, together with the affidavits, if any, show
23 that there is no genuine issue as to any material fact and that
24 the moving party is entitled to judgment as a matter of law."
25 Fed. R. Civ. P. 56(c). The party adverse to a motion for summary
26 judgment may not simply deny generally the pleadings of the
27 movant; the adverse party must designate "specific facts showing
28 that there is a genuine issue for trial." Fed. R. Civ. P. 56(e);

1 see Celotex Corp. v. Catrett, 477 U.S. 317 (1986). Simply put,
2 "a summary judgment motion cannot be defeated by relying solely
3 on conclusory allegations unsupported by factual data." Taylor
4 v. List, 880 F.2d 1040, 1045 (9th Cir. 1989). The non-moving
5 party must show more than a mere "metaphysical doubt" as to the
6 material facts. Matsushita Elec. Indus. Co. v. Zenith Radio, 475
7 U.S. 574, 587 (1986).

8 In addition, "the inquiry involved in a ruling on a
9 motion for summary judgment . . . necessarily implicates the
10 substantive evidentiary standard of proof that would apply at the
11 trial on the merits." Anderson v. Liberty Lobby, Inc., 477 U.S.
12 242, 252 (1986). A party seeking to invalidate a patent for
13 failure to name an inventor or for obviousness bears the burden
14 of proving invalidity by clear and convincing evidence. See
15 Acromed Corp. v. Safomar Danek Group, Inc., 253 F.3d 1371, 1379
16 (Fed. Cir. 2001); Al-Site Corp. v. VSI Int'l, Inc., 174 F.3d
17 1308, 1323 (Fed. Cir. 1999). Clear and convincing proof is also
18 required before a court can find that a patent is unenforceable
19 due to the patentee's inequitable conduct. Braun, Inc. v.
20 Dynamics Corp. of America, 975 F.2d 815, 822 (Fed. Cir. 1992).
21 The court must take these standards into account in ruling on
22 this motion.

23 A. Inventorship

24 A patent must list all the inventors of the claimed
25 invention. See 35 U.S.C. § 102(f) ("A person shall be entitled to
26 a patent unless . . . he did not himself invent the subject
27 matter to be patented.") Failure to do so invalidates the patent
28

1 if the omission of an inventor is not corrected.⁴ Solomon v.
2 Kimberly-Clark Corp., 216 F.3d 1372, 1381 (Fed. Cir. 2000); Pannu
3 v. Iolab Corp., 155 F.3d 1344, 1349 (Fed. Cir. 1998).

4 Inventorship is a question of law, applied to the relevant facts.
5 See C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1352 (Fed.
6 Cir. 1998).

7 "Because 'conception is the touchstone of
8 inventorship,' each joint inventor must generally contribute to
9 the conception of the invention." Ethicon, Inc. v. U.S. Surgical
10 Corp., 135 F.3d 1456, 1460 (Fed. Cir. 1998) (citation omitted).

11 Conception is the formation in the mind of the inventor of a
12 "definite and permanent" idea of the complete and operative
13 invention. Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802
14 F.2d 1367, 1376 (Fed. Cir. 1986); Burroughs v. Wellcome Co. v.
15 Barr Labs., Inc., 40 F.3d 1223 (Fed. Cir. 1994) (conception occurs
16 when one has "a specific, settled idea, a particular solution to
17 the problem"). An idea is definite and permanent when it can be
18 reduced to practice using reasonable skill. Id. Thus, "[o]ne
19 who simply provides the inventor with well-known principles or
20 explains the state of the art without ever having a 'firm and
21 definite idea' of the claimed combination as a whole does not
22 qualify as a joint inventor." Ethicon, Inc. v. U.S. Surgical
23 Corp., 135 F.3d 1456, 1461 (Fed. Cir. 1998).

24
25 ⁴ If the error in omitting an inventor was without
26 deceptive intent, the error may be corrected under the "savings
27 provision" of 35 U.S.C. § 265. Pannu v. Iolab Corp., 155 F.3d
28 1344, 1349 (Fed. Cir. 1998). If incorrect inventorship is found,
the patentee may invoke section 265, and must be given an
opportunity to correct the disclosure of the inventor. If
inventorship is corrected, then the patent is not invalid. Id.

1 To determine whether a putative joint inventor made a
2 contribution to the conception of the invention, the court must
3 first determine what the contribution was and then determine
4 whether the contribution's role appears in the claimed invention.
5 Ethicon, 1365 F.3d at 1461. If the putative inventor "(1)
6 contribute(s) in some significant manner to the conception or
7 reduction to practice of the invention, (2) make(s) a
8 contribution to the claimed invention that is not insignificant
9 in quality, when that contribution is measured against the
10 dimension of the full invention, and (3) do(es) more than merely
11 explain to the real inventors well-known concepts and/or the
12 current state of the art," then he qualifies as a joint inventor.
13 Pannu, 155 F.3d at 1351.

14 Dr. Fogh's contribution was to suggest the use of SKBr-
15 3 as an immunogen, which led to the production of a monoclonal
16 antibody that falls within the scope of the claims of the '561
17 patent. However, Dr. Fogh's contribution itself is found nowhere
18 in the claimed subject matter of the invention. Importantly, the
19 '561 patent does not claim a method for making monoclonal
20 antibodies using the SKBr-3 cell line as an immunogen; the '561
21 patent claims monoclonal antibodies that bind to the HER2
22 antigen.⁵ Compare Ethicon, 135 F.3d at 1461 (affirming district
23 court's finding of co-inventorship where co-inventor conceived of
24

25 ⁵ Some of the claims of the '561 patent contain a
26 limitation requiring the antibodies to bind to the SKBr-3 cell
27 line. However, Dr. Fogh did not suggest testing for binding to
28 SKBr-3, and it is undisputed that the named inventors had decided
to test their monoclonal antibodies for binding to SKBr-3 by
April of 1983, prior to Dr. Frankel's meeting with Dr. Fogh.
(Frankel Decl. Ex. B.)

1 locating a blunt probe within the shaft of a surgical instrument,
2 and the patent claim required the shaft to be "longitudinally
3 accommodatable within [the] outer sleeve"). While Dr. Fogh's
4 suggestion led to the production of the first monoclonal
5 antibodies that bound to HER2, Dr. Fogh does not qualify as a
6 joint inventor simply because he contributed to reducing the
7 invention to practice. His contribution must also have been both
8 inventive and significant to what was eventually claimed. Pannu,
9 155 F.3d at 1351.

10 Measured against the dimension of the claimed invention
11 - monoclonal antibodies against HER2 - Dr. Fogh's suggestion to
12 use SKBr-3 is much less significant than Genentech suggests.
13 Genentech's contention that "[w]ithout Dr. Fogh's idea, Chiron
14 would not have used SKBr-3 in a hybridoma to produce antibodies"
15 exaggerates the evidence in the record. (Genentech Mot. Re: Non-
16 joinder of the Inventor, at 5.) Although Dr. Frankel testified
17 that he had reservations about using cell lines, he also
18 testified that he likely would have used the SKBr-3 cell line
19 eventually, because he "was going to go through . . . as many of
20 the cell lines as [he] could." Moreover, even without the
21 benefit of Dr. Fogh's advice, Cetus would have produced a
22 monoclonal antibody against HER2, because it succeeded in doing
23 so using immunogens other than SKBr-3. SKBr-3 was not critical
24 to making what was claimed. It is also undisputed that Dr. Fogh
25 did not assist Drs. Ring and Frankel in designing the experiment,
26 determining how to screen the antibodies for the desired
27 characteristics, or in doing any of the laboratory work.

28 More importantly, it is by no means clear that in

1 recommending the use of SKBr-3 as an immunogen, Dr. Fogh had a
2 "firm and definite idea" of monoclonal antibodies that would bind
3 to HER2. Ethicon, 135 F.3d at 1461. Rather than providing
4 inventive input, Dr. Fogh appears simply to have explained the
5 state of the art in cell lines and enthusiastically suggested a
6 possible material to use in the experiment. See Ethicon, 135
7 F.3d 1456.

8 The SKBr-3 cell line had been publicly available for
9 ten years at the time of Dr. Fogh's conversation with Dr.
10 Frankel, had been described in the literature and used in cancer
11 research, and had already been acquired by Cetus for use in the
12 monoclonal antibody program. One who merely supplies publicly
13 available materials to inventors and explains how those materials
14 can be used in connection with an experiment is not an inventor.
15 Hess v. Advanced Cardiovascular Sys., 106 F.3d 976 (Fed. Cir.
16 1997); see also Ethicon, 135 F.3d at 1460 ("[A]n inventor may use
17 the services, ideas, and aid of others in the process of
18 perfecting his invention without losing his rights to a
19 patent") (internal quotations and citations omitted).

20 In Hess v. Advanced Cardiovascular Sys., 106 F.3d 976
21 (Fed. Cir. 1997), for example, the invention claimed a catheter
22 for use in angioplasty that had a balloon mounted on a shaft.
23 The named inventors had some initial difficulty finding a
24 suitable material to use in making the balloon. After several
25 failed attempts, they consulted an engineer named Hess, who
26 worked for a company called Raychem. The inventors explained
27 what they were attempting to do and the problems they had
28 encountered. Hess recommended a Raychem product that he believed

1 would work, showed them how a balloon could be formed, and
2 offered other suggestions as to how to make the catheter.
3 Although the inventors followed some of Hess's suggestions and
4 used the material he gave them to make their first working
5 product, the Federal Circuit found that Hess's contribution "did
6 not constitute the conception necessary to establish co-
7 inventorship." Id. at 981.

8 . . . Mr. Hess was "doing nothing more than explaining
9 to the inventors what the then state of the art was and
10 supplying a product to them for use in their invention.
11 . . . [M]ost if not all of his discussion with them
12 were [sic] telling them what was available in the
13 marketplace by way of product, and telling them how the
14 product worked." . . . The principles Mr. Hess
15 explained to them were well known and found in
16 textbooks. Mr. Hess did no more than a skilled
17 salesman would do in explaining how his employer's
18 product could be used to meet a customer's
19 requirements. The extensive research and development
20 work that produced the catheter was done by Drs.
21 Simpson and Robert.

22 Id. at 980.

23 Similarly, in this case the named inventors consulted
24 Dr. Fogh after having little success identifying a suitable
25 material for use in their experiment, and explained to him the
26 difficulties they had encountered and the objectives of the
27 experiment. Like Hess, Dr. Fogh provided the named inventors
28 with a material that was available on the market, explained that
29 it had the characteristics they were looking for, and suggested
30 that the material would be suitable to use in a pre-existing
31 experiment. Also as in Hess, Dr. Fogh's suggestion led to the
32 first working embodiment of the invention.

33 Genentech attempts to distinguish Hess on the ground
34 that Dr. Fogh's direction to use SKBr-3 as an immunogen cannot be

1 found in any printed publication in 1983, whereas the principles
2 that Hess discussed could be found in textbooks. However, there
3 is no suggestion in Hess that any of those textbooks recommended
4 applying the principles described therein to balloon catheters.
5 Similarly, in this case, SKBr-3 had already been described and
6 characterized in the literature by 1983, but none of these
7 publications had suggested its use as an immunogen. Thus, the
8 distinction Genentech points to is really no distinction at all.

9 Genentech also argues that this case is different from
10 Hess because in Hess, the inventors had fully conceived of the
11 invention before receiving input from Hess, while in this case,
12 Drs. Ring and Frankel had only a general research plan until they
13 spoke with Dr. Fogh. It is true that a general research plan is
14 not firm or definite enough to qualify as a "conception" of the
15 invention. Burroughs Wellcome, 40 F.3d at 1228 ("An idea is
16 definite and permanent when the inventor has a specific, settled
17 idea, not just a general goal or research plan he hopes to
18 pursue.") However, even if Drs. Ring and Frankel had not fully
19 conceived of their invention before speaking with Dr. Fogh, it
20 does not necessarily follow that Dr. Fogh conceived of the
21 invention.

22 Genentech argues that Dr. Fogh conceived of the
23 invention because he supplied Drs. Ring and Frankel with an
24 operative mode for making their invention and the necessary
25 insight to make it work. See Ora v. Youssefyeh, 849 F.2d 581
26 (Fed. Cir. 1988) ("Conception requires (1) the idea of the
27 structure of the chemical compound, and (2) possession of an
28 operative method of making it.") The evidence that Dr. Fogh had

1 and offered this kind of "insight," however, is insubstantial.
2 As discussed above, Dr. Fogh supplied the inventors with a
3 material they likely planned to use and already had. Dr. Fogh
4 never explained his reasons for suggesting SKBr-3, and there is
5 no evidence that Dr. Fogh had any experience in immunology or in
6 making monoclonal antibodies. It is therefore unlikely that when
7 Dr. Fogh suggested the use of SKBr-3 as an immunogen, he had
8 solved in his own mind the problem of how to make monoclonal
9 antibodies against human breast cancer.

10 Genentech also argues that Dr. Fogh's contribution was
11 inventive because Dr. Frankel was initially reluctant to use cell
12 lines, and understood the dogma at the time to be that MCF-7 was
13 the most appropriate cell line to use. However, the record
14 reflects that Dr. Frankel had already tried using MCF-7 to no
15 avail, and that it had occurred to him before speaking with Dr.
16 Fogh that cell lines other than MCF-7 might be appropriate - that
17 is why he sought Dr. Fogh's advice in the first place. The fact
18 that Dr. Fogh was extremely knowledgeable (the "best in the
19 world") in the art of cell lines, and that Dr. Frankel sought Dr.
20 Fogh's advice because of his expertise does not make Dr. Fogh an
21 inventor. The Supreme Court has long recognized that

22 no invention can possibly be made, consisting of a
23 combination of different elements . . . without a
24 thorough knowledge of the properties of each of them,
25 and the mode in which they operate on each other. And
26 it can make no difference, in this respect, whether
[the inventor] derives his information from books, or
from conversation with men skilled in the science. If
it were otherwise, no patent, in which a combination of
different elements is used, could ever be obtained.

27 O'Reilly v. Morse, 56 U.S. 62 (1853). As Chiron aptly puts it,
28 Dr. Frankel's questions for Dr. Fogh "were not blind inquiries,

1 but informed questions by a skilled scientist to which Dr. Fogh,
2 among others, responded. There is no evidence, whatsoever that
3 Dr. Fogh - or any of the other scientists contacted by Dr.
4 Frankel - made an inventive contribution when they provided
5 information on cell lines in response to Dr. Frankel's
6 questions." (Chiron Opp'n at 7.)

7 It simply assumes too much to infer from Dr. Fogh's
8 "insistence" to use SKBr-3 as an immunogen that he conceived of
9 monoclonal antibodies capable of binding in an immunologically
10 significant manner to human breast cancer. Dr. Fogh is no longer
11 alive, and the record appears to be as complete as it will get.
12 There is not enough evidence, let alone clear and convincing
13 evidence, to support a finding that the '561 patent is invalid
14 for failing to mention Dr. Fogh as an inventor. Chiron is
15 therefore entitled to summary judgment on this issue.
16 See Anderson, 477 U.S. at 249-40 (If the defendant bears a clear
17 and convincing burden of proof at trial and presents evidence on
18 summary judgment that "is merely colorable, or is not
19 significantly probative, summary judgment may be granted.")

20 B. Obviousness

21 Genentech contends that the conclusion that Dr. Fogh is
22 not a co-inventor leads inevitably to the conclusion that the
23 monoclonal antibodies claimed in the '561 patent are obvious in
24 light of the prior art.

25 A patent is invalid "if the differences between the
26 subject matter sought to be patented and the prior art are such
27 that the subject matter as a whole would have been obvious at the
28 time the invention was made to a person having ordinary skill in

1 the art" 35 U.S.C. § 103. The determination of
2 obviousness is a question of law based on underlying factual
3 considerations, including (1) the scope and content of the prior
4 art; (2) the differences between the prior art and the claims at
5 issue; (3) the level of ordinary skill in the art; and (4) any
6 "secondary considerations," such as whether the inventor was
7 responding to long felt but unsolved needs, the failures of
8 others, and the commercial success of the invention. Graham v.
9 John Deere Co., 383 U.S. 1, 17 (1966). The court must also take
10 care not to enter the "tempting but forbidden zone of hindsight"
11 in analyzing whether an invention would have been obvious. In re
12 Dembiczak, 175 F.3d 994 (Fed. Cir. 1999).

13 Genentech contends that if Dr. Fogh is a not co-
14 inventor, the invention claimed in the '561 patent must be
15 obvious in light of (1) a 1975 textbook published by Dr. Fogh
16 describing the characteristics of a number of cell lines
17 including SKBr-3; (2) the method developed by Drs. Kohler and
18 Millstein for producing hybridomas, which was also published in
19 1975; and (3) a 1982 publication by Michael D. Waterfield, et al.
20 and a 1985 patent for an invention by Dr. Schlom, U.S. Patent
21 4,612,282, which describe screening procedures, and how to screen
22 for hybridoma-derived monoclonal antibodies that are reactive
23 with human breast cancer cells.⁶ Specifically, Genentech argues

24
25 ⁶ In its interrogatory responses, Genentech stated that
26 its obviousness defense was also based on a combination of (1)
27 Padhy (2) Kohler and Millstein and (3) Schlom or Waterfield.
28 Chiron motion for summary judgment argues that the patent is not
obvious in light of these references. Genentech does not oppose
Chiron's motion to the extent it relates to the non-obviousness
of combining Padhy with Kohler and Millstein and Schlom or

1 that if Dr. Fogh's suggestion to use SKBr-3 to produce an anti-
2 breast cancer antibody was not unique enough to warrant
3 inventorship, then using SKBr-3 as an immunogen to make
4 hybridomas and screening the resulting hybridomas for reactivity
5 with breast cancer must be considered obvious.

6 Where, as here, the claimed invention is challenged on
7 the grounds that it is obvious in view of a combination of prior
8 art references, "a proper analysis under § 103 requires, inter
9 alia, a consideration of two factors: (1) whether the prior art
10 would have suggested to those of ordinary skill in the art that
11 they should make the claimed [product]; and (2) whether the prior
12 art would also have revealed that in so making or carrying out,
13 those of ordinary skill would have a reasonable expectation of
14 success." In re Vaeck, 947 F.2d 488 (Fed. Cir. 1988). It is
15 insufficient that one skilled in the art might find it "obvious
16 to try" combining the prior references. In re Geiger, 818 F.2d
17 686, 688 (Fed. Cir. 1987).

18 Chiron argues that at most it would have been "obvious
19 to try" to use SKBr-3 as an immunogen in light of the references
20 cited above. "An 'obvious-to-try' situation exists when a
21 general disclosure may pique the scientist's curiosity, such that
22 further investigation might be done as a result of the
23 disclosure, but the disclosure itself does not contain a
24 sufficient teaching of how to obtain the desired result, or that
25 the claimed result would be obtained if certain directions were
26 followed." In re Eli Lilly & Co., 902 F.2d 943, 945 (Fed. Cir.

27 _____
28 Waterfield.

1 1990).

2 It is undisputed that none of the cited references
3 contain an express suggestion that one or all of them should be
4 used in combination with the other.⁷ Moreover, nothing would have
5 suggested to a person of ordinary skill in the art at the time
6 that SKBr-3 would be superior to use as an immunogen in making
7 monoclonal antibodies against human breast cancer. The testimony
8 of Genentech's expert, Dr. Unkeless, is helpful in elucidating
9 this point. At his deposition, Dr. Unkeless explained that the
10 probability of making antibodies is proportional to the
11 expression of an antigen on the surface of a tumor cell.
12 (Unkeless Dep. at 131.) The more a cell line expresses an
13 antigen, the more likely it is that one skilled in the art can
14 use that cell line to make monoclonal antibodies. (Id.)

15
16 ⁷ Although Dr. Fogh verbally suggested that Dr. Frankel
17 use SKBr-3 as an immunogen, his spoken communication does not
18 qualify as "prior art" for purposes of the obviousness analysis.
19 "Unpublished documents or private discussions not of common
20 knowledge do not constitute 'prior art' within the meaning of
21 section 103(a)." Layne-New York Co. v. Allied Asphalt Co., 363
22 F. Supp. 299, 305 (W.D. Penn. 1973); Massachusetts Institute of
23 Technology v. AB Fortia, 774 F.2d 1104, 1109 (Fed. Cir.
24 1985) (holding that for purposes of analyzing obviousness, the
25 alleged prior art must be a printed publication, i.e.
26 "disseminated or otherwise made available to the extent that
27 persons interested and of ordinary skill in the subject matter or
28 art, exercising reasonable diligence can locate it. . . ."). The
only "evidence" that Genentech cites for the proposition that
SKBr-3's use as an immunogen was suggested in the literature is a
Chiron's brief regarding the question of inventorship. Genentech
cites to attorney argument, not to any facts or publications.
The court also notes that in concluding that Dr. Fogh was not a
co-inventor, the court did not rely on Chiron's representation
that SKBr-3's use as an immunogen had been suggested in 1983.
The reference cited for that proposition appears to have been a
European patent application published on December 9, 1984, which
states that "to a lesser extent" SKBr-3 can be used as an
immunogen to generate monoclonal antibodies. (Crotty Decl. Ex.
19.)

1 Importantly, Dr. Unkeless also testified that in the time period
2 between 1983 and 1985, "there was no knowledge of which cell line
3 over-expressed what." (Id.) Later, it was discovered that SKBr-
4 3 over-expresses HER2. However, based on what was known in the
5 art at the time of the invention, there would not have been a
6 "reasonable expectation of success" in creating anti-breast
7 cancer antibodies using SKBr-3 as opposed to some other
8 immunogen. In re O'Farrell, 853 F.2d 894, 903-904 (Fed. Cir.
9 1988). SKBr-3 was simply one of many possible immunogens that
10 the inventors experimented with in their attempts to create a
11 monoclonal antibody against human breast cancer.

12 This case presents a classic situation in which it is
13 obvious to "try each of numerous possible choices until one
14 possibly arrived at a successful result, where the prior art gave
15 either no indication of which parameters were critical or no
16 direction as to which of many possible choices is likely to be
17 successful." Id. As the Federal Circuit has held, this does not
18 render a patent "obvious" within the meaning of section 103. Id.
19 This conclusion is reinforced by Dr. Unkeless's deposition
20 testimony that it would not have been obvious in 1983 to combine
21 the Fogh text with Kohler and Milstein, and Schlom and
22 Waterfield. (Unkeless Dep. at 130-131.)

23 There is nothing inconsistent in finding that it would
24 have been obvious to try using SKBr-3 as an immunogen and finding
25 that Dr. Fogh's suggestion to use SKBr-3 as an immunogen was not
26 inventive. As discussed above, Dr. Fogh does not qualify as an
27 inventor in part because he suggested what was obvious to try.

28 Finally, Genentech's motion does not address which of

1 the claims in the '561 patent are obvious in light of the
2 asserted prior art references. For example, some of the claims
3 of the '561 patent require strong staining on one or less or
4 three or less non-breast cancer cells and tissues. Genentech has
5 failed to present any evidence that it would have been obvious to
6 combine the cited references to make a monoclonal antibody that
7 meets these limitation. "[A] party challenging the validity of a
8 claim, absent a pretrial agreement or stipulation, must submit
9 evidence supporting a conclusion of invalidity for each claim the
10 challenger seeks to destroy." Ortho Pharm. Corp. v. Smith, 959
11 F.2d 936, 942 (Fed. Cir. 1992) (quoting Shelcore, Inc. v. Durham
12 Indus, 745 F.2d 621, 625 (Fed. Cir. 1984)) (emphasis added); 35
13 U.S.C. § 282 ("Each claim of a patent (whether independent,
14 dependent, or multiple dependent form) shall be presumed valid
15 independently of the validity of other claims"). Therefore,
16 Chiron is entitled to summary judgment on Genentech's defense
17 that the patent is obvious in light of Fogh, Kohler and
18 Millstein, and Schlom and Waterfield.

19 C. Inequitable Conduct

20 Genentech contends that Chiron engaged in inequitable
21 conduct by mischaracterizing and marginalizing Dr. Fogh's
22 contribution when prosecuting the '561 patent. Genentech also
23 faults the lawyers who handled the patent prosecution for not
24 taking further steps to investigate the nature of Dr. Fogh's
25 contribution to the invention.⁸

26
27 ⁸ In its First Amended Answer and Responses to
28 Interrogatories, Chiron alleged a number of other inequitable
conduct theories. Chiron moved for summary judgment on all of

1 A patent is unenforceable if, in acquiring the patent,
2 a patent applicant or his or her representative engaged in
3 "inequitable conduct" before the Patent and Trademark Office
4 ("PTO"). Inequitable conduct occurs when a patent applicant (1)
5 affirmatively misrepresents a material fact, fails to disclose
6 material information, or submits false material information to
7 the PTO, and (2) does so with an intent to deceive the PTO.
8 Baxter Int'l, Inc. v. McGaw, Inc., 149 F.3d 1321, 1327 (Fed. Cir.
9 1998).

10 Determination of inequitable conduct requires a two
11 step analysis. Id. First, the district court must determine
12 whether the withheld reference meets the threshold level of
13 materiality, and whether the evidence shows a threshold level of
14 intent to mislead the PTO. Id. Second, the district court is
15 required to weigh materiality and intent. Id. "The more
16 material the omission, the less evidence of intent will be
17 required in order to find that inequitable conduct has occurred."
18 Id. "In light of all the circumstances, the court must then
19 determine whether the applicant's conduct is so culpable that the
20 patent should be held unenforceable." Id.; Kingsdown Med.
21 Consultants, Ltd v. Hollister, Inc., 863 F.3d 867, 876 (Fed. Cir.
22 1988). Inequitable conduct is a matter for the court to decide
23 in the exercise of its equitable discretion. Kingsdown, 863 F.3d
24 at 876; General Elec. Music Corp. v. Samick Music Corp., 19 F.3d

25 _____
26 them. Genentech filed a non-opposition to Chiron's motion with
27 respect to all of these other theories, and stated that it was
28 withdrawing them from the case. Genentech's sole basis for its
inequitable conduct defense, therefore, is its allegation that
Chiron intentionally misrepresented the full scope of Dr. Fogh's
contribution.

1 1405, 1408 (Fed. Cir. 1994); Paragon Podiatry Lab., Inc. v. KLM
2 Labs., 984 F.2d 1182, 1190 (Fed. Cir. 1993).

3 1. Materiality

4 Information is material when "it is not cumulative to
5 information already of record or being made of record in the
6 application, and (1) [i]t establishes, by itself or in
7 combination with other information, a prima facie case of
8 unpatentability of a claim; or (2) [i]t refutes, or is
9 inconsistent with, a position the applicant takes in: (i)
10 [o]pposing an argument of unpatentability relied on by the
11 Office, or (ii) [a]sserting an argument of patentability." 37
12 C.F.R. § 1.56.⁹

13 Failure to name a co-inventor invalidates a patent, and
14 therefore "information about inventorship is material under 37
15 C.F.R. § 1.56." Perceptive Biosystems, Inc. v. Pharmacia
16 Biotech, Inc., 225 F.3d 1315 (Fed. Cir. 2000). The fact that the
17 court has found that Dr. Fogh is not a joint inventor of the
18 patent is not dispositive of Genentech's inequitable conduct
19 defense. Falsehoods and omissions "calculated to 'obfuscate the
20 threshold issue of inventorship'" are sufficient to support an
21 inequitable conduct defense. Id. at 1321. "[T]he issue is not
22 inventorship per se, but misinformation about inventorship." Id.
23 at 1322.

24
25 ⁹ The rule in force when Chiron was prosecuting the
26 parent applications of the '561 patent was somewhat different,
27 requiring "a substantial likelihood that a reasonable examiner
28 would consider it important in deciding whether to allow the
application to issue as a patent." Baxter Int'l, Inc. v. McGaw,
Inc., 149 F.3d 1321, 1327 (Fed. Cir. 1998). As applied to the
facts of this case, the old rule does not dictate a different
outcome.

1 The '561 patent and every parent application discloses
2 that Dr. Fogh provided cell lines to the named inventors.
3 Genentech argues that this statement is misleading because it
4 implies that Dr. Fogh's role was limited to supplying cell lines,
5 when in reality his contribution was to suggest using SKBr-3 as
6 an immunogen. The court finds nothing misleading in the
7 disclosure in the '561 patent.

8 2. Intent

9 Even if the '561 patent could be construed as
10 misleading, there is no evidence in the record that anyone
11 involved in prosecuting the '561 patent believed Dr. Fogh to be
12 an inventor of the patent and intentionally obscured his
13 contribution because of that belief. It is undisputed that Dr.
14 Frankel was the only person who was aware of his conversation
15 with Dr. Fogh while the patent was being prosecuted. Dr. Frankel
16 attests in his declaration that he did not consider Dr. Fogh's
17 contribution to be significant enough to qualify him as an
18 inventor. Given the enormous volume of research the named
19 inventors conducted, the time they spent developing their
20 research plan and carrying it out apart from Dr. Frankel's one-
21 time meeting with Dr. Fogh, and the fact that Dr. Fogh's
22 suggestion to use SKBr-3 as a cell line was one among many
23 suggestions the inventors received from other scientists, there
24 is nothing suspicious about Dr. Frankel's statement that he did
25 not believe Dr. Fogh to be a co-inventor.

26 Genentech has also suggested that the attorneys
27 involved in prosecuting the patent acted with deceptive intent
28 because they failed to investigate Dr. Fogh's contribution. This

1 suggestion does not withstand scrutiny. It is undisputed that
2 Dr. Frankel's discussion with Dr. Fogh was first brought to the
3 attention of these attorneys sometime after September 22, 2001.
4 The '561 patent, however, had issued in April of 2000. These
5 attorneys cannot have intended to deceive the PTO while
6 prosecuting the patent if they were not aware of the relevant
7 facts until after the patent had issued. Moreover, the Manual of
8 Patent Examination and Procedure provides that the duty to
9 disclose information ends when a patent is granted on an
10 application. Manual of Patent Examination and Procedure §
11 2001.4.

12 Genentech nevertheless insinuates that Chiron minimized
13 Dr. Fogh's contribution in order to maintain total control over
14 the rights to the '561 patent, and keep Dr. Fogh and Sloan
15 Kettering from gaining a share of the royalties Chiron hoped to
16 recover from Genentech through litigation. However, Chiron's
17 disclosure about the scope of Dr. Fogh's contribution has
18 remained unchanged since the first application was filed in 1984,
19 long before Genentech had developed Herceptin and before any
20 litigation against Genentech was contemplated by Chiron.
21 Moreover, the court finds it difficult to believe that Dr.
22 Frankel, a scientist having no legal training of which the court
23 is aware, and the only person who knew about Dr. Fogh's
24 contribution while the patent was being prosecuted, was concerned
25 with Chiron's litigation strategy. Genentech's argument is not
26 supported by any evidence and amounts to nothing more than
27 speculation. See Nova Biomedical Corp. v. Mallinckrodt Sensor
28 Sys., Inc., 997 F. Supp. 187, 191-92 (D. Mass. 1998) (finding that

1 suspicious circumstances were insufficient to support an
2 inequitable conduct defense where defendant had presented only
3 speculation and conjecture regarding patentee's knowledge and
4 intent). Therefore, Chiron is entitled to summary judgment on
5 Genentech's inequitable conduct defense.

6 IT IS THEREFORE ORDERED that:

7 (1) Summary judgment on the defense of inventorship be, and
8 the same hereby is, GRANTED to Chiron and DENIED to
9 Genentech;

10 (2) Summary judgment on the defense of obviousness be, and
11 the same hereby is, GRANTED to Chiron and DENIED to
12 Genentech;

13 (3) Summary judgment on the defense of inequitable conduct
14 be, and the same hereby is, GRANTED to Chiron.

15 DATED: June 24, 2002

16
17

WILLIAM B. SHUBB
UNITED STATES DISTRICT JUDGE