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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:
PROSECUTION LACHES

GENENTECH, INC.,
Defendant.

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In a separate order, the court has determined that Genentech's product, Herceptin, infringes Chiron's patent on monoclonal antibodies that bind to the HER2 human breast cancer antigen. Chiron now moves for summary judgment on Genentech's prosecution laches defense.

I. Factual Background

The patent at issue, U.S. Patent No. 6,054,561 ("561 patent"), is one of several Chiron¹ patents that date back to two

¹ Chiron's predecessor, Cetus, prosecuted and obtained a number of the patents in the '561 patent family. Chiron now owns the rights to those patents. For ease of reference, the court does not distinguish between Cetus and Chiron when referring to events in the prosecution history of the '561 patent.

1 patent applications filed in 1984 and 1985. The first patent
2 that Chiron received based on the 1984 and 1985 applications,
3 U.S. Patent No. 4,753,894 ("`894 Patent"), issued in 1988. The
4 `894 patent claims "murine monoclonal antibod[ies]" that bind to
5 human breast cancer, and has an expiration date of June 28, 2005.
6 (`894 Patent.)

7 The same year that Chiron was issued the `894 patent,
8 it filed a continuation application that ultimately issued as
9 U.S. Patent No. 5,169,774 ("`774 Patent"). The `774 patent,
10 which issued in 1992, claims "monoclonal antibod[ies]" that "bind
11 to a common monomeric 210kD protein present in cancerous breast
12 tissue." The expiration date of the `774 patent is also June 28,
13 2005. (`774 Patent.)

14 In 1994, Chiron filed another continuation application
15 which led to the issuance of U.S. Patent No. 5,629,197 ("`197
16 Patent") in 1997, which claims, among other things, monoclonal
17 antibodies "produced by a hybridoma." (`197 Patent.)

18 In 1995, Chiron filed yet another continuation
19 application, which was amended in 1999 to set forth broad claims
20 to monoclonal antibodies that bind to HER2. The Patent Office
21 accepted these amendments, and on April 25, 2000 issued the `561
22 patent to Chiron. The `561 patent is subject to a "terminal
23 disclaimer", which means that the `561 patent adopts the June 28
24 2005 expiration date of the `894 and `774 patents, thereby
25 "disclaiming" any portion of the term of the patent monopoly that
26 would have extended beyond that date. (`561 Patent; Riley Decl.
27 Ex. 22 at 1-2.) Chiron contends that the `561 patent is entitled
28 to rely on the patent applications filed in 1984 and 1985 for

1 priority.

2 While Chiron was prosecuting these various patent
3 applications, Genentech committed substantial resources to the
4 research and development of anti-breast cancer antibodies. In
5 the late 1980s, Genentech identified a murine (mouse) monoclonal
6 antibody, 4D5, that binds to HER2 and is capable of reducing
7 tumor growth and cell division. (See Riley Decl. Ex. 10.) In
8 December of 1990, Genentech submitted an application to the FDA
9 to conduct clinical trials using 4D5. (Id.) Several months
10 later, Chiron contacted Genentech, asserting that Genentech's
11 antibody infringed the '894 patent. (Id. Ex. 13, 14.) Genentech
12 declined to license Chiron's technology.

13 By 1992, Genentech had successfully "humanized" an
14 anti-HER2 antibody by combining genetic sequences modeled after
15 murine antibodies with human DNA sequences. (See id. Ex. 15.)
16 Genentech applied to the FDA and received approval to conduct
17 clinical trials of its humanized antibody. (Id.) From June of
18 1995 through January of 1996, representatives of Chiron and
19 Genentech engaged in negotiations regarding a number of patents
20 and products, including Chiron's anti-HER2 antibodies and
21 patents. (Id. Ex. 2; Celio Opp'n Decl. Ex. W.) In connection
22 with these negotiations, Genentech obtained opinion letters from
23 outside counsel concluding that the '894 and '774 patents were
24 invalid and not infringed. (Riley Decl. Ex. 13, 17, 18.)
25 Genentech did not take a license from Chiron at that time. In
26 1998, Chiron and Genentech engaged in further discussions
27 regarding the '894 and '774 patents, and the result of those
28 discussions was the same. (Id. Ex. 19; Celio Opp'n Decl. Ex. W.)

1 When the '561 patent issued to Chiron on April 25,
2 2000, Chiron contacted Genentech and asserted that Herceptin
3 infringed its patent rights. Genentech received an opinion from
4 counsel that the '561 patent was invalid and not infringed, and
5 declined to license the patent from Chiron. (Riley Decl. Ex. 20,
6 23.)

7 II. Discussion

8 The court must grant summary judgment to a moving party
9 "if the pleadings, depositions, answers to interrogatories, and
10 admissions on file, together with the affidavits, if any, show
11 that there is no genuine issue as to any material fact and that
12 the moving party is entitled to judgment as a matter of law."
13 Fed. R. Civ. P. 56(c). The party adverse to a motion for summary
14 judgment may not simply deny generally the pleadings of the
15 movant; the adverse party must designate "specific facts showing
16 that there is a genuine issue for trial." Fed. R. Civ. P. 56(e);
17 see Celotex Corp. v. Catrett, 477 U.S. 317 (1986). Simply put,
18 "a summary judgment motion cannot be defeated by relying solely
19 on conclusory allegations unsupported by factual data." Taylor
20 v. List, 880 F.2d 1040, 1045 (9th Cir. 1989). The non-moving
21 party must show more than a mere "metaphysical doubt" as to the
22 material facts. Matsushita Elec. Indus. Co. v. Zenith Radio, 475
23 U.S. 574, 587 (1986).

24 Prosecution laches is an equitable doctrine that "may
25 be applied to bar enforcement of patent claims that issued after
26 an unreasonable and unexplained delay in prosecution even though
27 the applicant complied with pertinent statutes and rules."
28 Symbol Techs., Inc. v. Lemelson Med., 277 F.3d 1361, 1362 (Fed.

1 Cir. 2002). Until the Federal Circuit's decision in Symbol
2 Technologies, Inc. v. Lemelson Medical earlier this year, there
3 had been some confusion as to whether prosecution laches was a
4 viable defense. 277 F.3d 1261. Symbol Technologies affirmed the
5 validity of the defense, but did not articulate a test for when
6 the defense is established.

7 The court, however, is not without guidance as to what
8 must be shown before the prosecution laches doctrine will bar the
9 enforcement of an otherwise valid patent. The traditional laches
10 defense, which targets a patentee's unreasonable delay in
11 bringing a lawsuit for infringement, is well understood and
12 offers some general principles that are useful here. Traditional
13 laches requires (1) unreasonable and unexcusable delay by the
14 patentee; and (2) material prejudice to the alleged infringer
15 attributable to the delay. A.C. Aukerman v. R.L. Chaides
16 Construction Co., 960 F.2d 1020 (Fed. Cir. 1992). Pending
17 further elaboration by the Federal Circuit, the court will apply
18 this test to the facts of this case.²

19 Chiron argues that it is entitled to summary judgment
20 on Genentech's prosecution laches defense because (1) the
21 prosecution laches defense does not apply where, as here, the
22 patent is subject to a terminal disclaimer; and (2) even if it
23 does, Genentech cannot show that it was materially prejudiced as
24 a result of Chiron's delay in prosecuting the '561 patent.

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27 ² The parties are in agreement that both of these
28 elements must be established for Genentech to prevail on its
defense.

1 A. Terminal Disclaimer

2 A patent is often described as a quid pro quo between
3 the patentee and the public. Pfaff v. Wells Elecs., Inc., 525
4 U.S. 55, 63 (1998). In exchange for a limited monopoly over the
5 intellectual property in a patent, the patentee must tell the
6 public what his invention is and how to use it. When a patentee
7 delays in prosecuting his patent, he extends the monopoly over
8 his invention and deprives the public of its use. See Woodbridge
9 v. United States, 263 U.S. 50, 58-59 (1923).

10 Chiron argues that the prosecution laches defense is
11 exclusively targeted at preventing inventors from unfairly
12 extending the terms of their patent monopolies in this way.
13 According to Chiron, the defense is not implicated when an
14 inventor files a "terminal disclaimer," which limits the term of
15 a patent's monopoly so that it will expire on the date that an
16 earlier issued patent is set to expire. By definition, a
17 terminal disclaimer does not extend the term of an inventor's
18 monopoly.

19 Chiron asks the court to read the law on prosecution
20 laches too narrowly. In addition to addressing the concern over
21 patentees extending the terms of their patent monopolies, the
22 prosecution laches defense also responds to concerns that
23 inventors will file narrow claims, await intervening
24 developments, and then file broader claims to cover those
25 developments.

26 Woodbridge v. United States, the case referred to in
27 Symbol Technologies as the origin of the prosecution laches
28 defense, expresses these dual concerns. 263 U.S. 50. In

1 Woodbridge, the patentee filed an application for a type of rifle
2 ammunition in 1852, and then "sat down and waited until after the
3 Civil War came on in 1861 before seeking to avail himself of the
4 patent." The Court held that the patent was unenforceable
5 because the inventor's "deliberate and unlawful purpose to
6 postpone the term of the patent the inventor had always intended
7 to secure" had "deprived the public of a decade of free use of
8 the patent." Id. at 59, 55. The court was also concerned with
9 the fact that while the inventor delayed, other inventors had
10 filed applications and made advances in the art that the inventor
11 later tried to cover by applying for changes in the specification
12 and claims of the patent. Id. at 57. Accordingly, the Court
13 found that the inventor had forfeited his rights to his patent.
14 Id.

15 The next Supreme Court case to address the issue,
16 Webster Elec. v. Splitdorf Elec. Co., 264 U.S. 463 (1924), relied
17 on similar reasoning to hold a patent that issued after an eight
18 year delay unenforceable. As Chiron points out, Webster
19 emphasized that a patent should not be enforced where it would
20 result in "an undue extension of the patent monopoly against
21 private and public rights." Id. at 466. However, Webster was
22 equally concerned that the inventor in that case "simply stood by
23 and awaited developments" before seeking broad claims that he
24 could have filed with the initial patent application. Id. at
25 466. Because the broader claims of the patent were added after a
26 long delay as "an exigent afterthought, rather than a logical
27 development of the original application," the patentee lost
28 whatever rights it might otherwise have been entitled to. Id.

1 Cases following Woodbridge and Webster have picked up
2 on both rationales for the prosecution laches defense.
3 See Wirebounds Patents Co. v. Saranac Automatic Mach. Corp., 65
4 F.2d 904, 906 (6th Cir. 1933) (expressing concern both over
5 inventor's attempt to extend the terms of patent monopoly and the
6 inventor's assertion of broad claims that the inventor could have
7 asserted earlier, the sole purpose of which was to cover what had
8 been issued to others); Progressive Games, Inc. v. Amusement
9 Extra, Inc., 83 F. Supp. 2d 1180 , 1183 (D. Colo. 1999) (same).

10 The Federal Circuit may have taken a step back from the
11 second rationale for the prosecution laches defense, however. In
12 Kingsdown Med. Consultants v. Hollister, Inc., 863 F.2d 867, 874
13 (Fed. Cir. 1988), the Federal Circuit held that "there is nothing
14 improper, illegal, or inequitable in filing a patent application
15 for the purpose of obtaining a right to exclude a known
16 competitor's product from the market." Id.; see also Multiform
17 Dessicants, Inc. v. Medzam, Ltd., 133 F.3d 1473 (Fed. Cir. 1998).
18 Although Kingsdown was not a prosecution laches case, it
19 concerned another equitable defense - inequitable conduct - and
20 therefore its discussion of what is and is not equitable behavior
21 by patentees is relevant to this case.

22 However, Kingsdown did not address the question of how
23 a long period of delay affects the equities of the situation,
24 particularly where the patentee could have earlier asserted broad
25 claims that would have covered the competitor's product. Where a
26 long period of delay is involved, other inventors may work under
27 the assumption that the patentee is not going to prosecute
28 broader claims; they may develop improvements only to find that

1 they are infringers of a later-prosecuted patent. Kingsdown
2 therefore does not preclude an alleged infringer from asserting
3 these kind of circumstances as grounds for a prosecution laches
4 defense.

5 Moreover, a bright line rule that the prosecution
6 laches defense never applies when a terminal disclaimer has been
7 filed would run contrary to the principle that "with its origin
8 in equity, a determination of laches is not made upon the
9 application of mechanical rules." A.C. Aukerman, 960 F.2d at
10 1032; see also Cruz v. Melecio, 204 F.3d 14, 23 (1st Cir. 2000)
11 (holding that a court in sitting in equity should "assess the
12 totality of the circumstances and custom-tailor appropriate
13 relief"). While it certainly is appropriate to weigh the filing
14 of a terminal disclaimer as an equitable consideration, and while
15 it may weigh strongly in favor of finding the delay is
16 reasonable, there is no suggestion in the case law that the
17 filing of a terminal disclaimer necessarily and in every case
18 disposes of the defense. Moreover, the court is reluctant to
19 pronounce a bright line rule when the Federal Circuit has yet to
20 fully articulate the metes and bounds of the prosecution laches
21 defense. Therefore, the court turns to the merits of the
22 defense.

23 B. Unreasonable Delay

24 Chiron's '561 patent issued more than fifteen years
25 after the first parent application was filed. Chiron has not
26 proffered any reason for this delay, or argued that it was
27 unintentional. Rather, as discussed above, Chiron contends that
28 the delay is not unreasonable because the terminal disclaimer

1 does not extend the term of the patent monopoly. Although the
2 filing of the terminal disclaimer weighs heavily in favor of
3 finding that the delay was not unreasonable, there is sufficient
4 evidence in the record to support an inference in Genentech's
5 favor that the delay was unreasonable.

6 Chiron has taken the position that the '561 patent is
7 entitled to rely on the 1984 and 1985 applications for priority.
8 For this to be true, the 1984/1985 applications must support the
9 broad claims of the '561 patent. Thus, if Chiron is correct
10 about the priority date (an issue that will be resolved at
11 trial), then Chiron could have filed broad claims to monoclonal
12 antibodies as early as 1984. See Woodbridge, 263 U.S. at 57 ("In
13 this case we have a delay of nine years and a half in securing a
14 patent that might have been had at any time in that period for
15 the asking . . . This is a case of forfeiting the right to a
16 patent by designed delay.")

17 Genentech acknowledges that the 1984 and 1985
18 applications contain broad claims to "functional equivalents" of
19 murine monoclonal antibodies, and that in prosecuting the '894
20 patent, Chiron tried to obtain those claims. However, Genentech
21 points out that the '894 patent issued in 1988 with claims only
22 to "murine monoclonal antibod[ies]." ('894 Patent, emphasis
23 added.) Thus, Genentech argues that no later than the date of
24 the '894 patent, "Chiron was aware that it had not been granted
25 claims to non-murine anti-HER2 antibodies. At that point, it was
26 incumbent upon Chiron to begin seeking those claims." (Genentech
27 Opp'n at 11.)

28 The prosecution history reflects that the same year the

1 '894 patent issued, Chiron submitted another patent application
2 with claims to "monoclonal antibodies." In 1992, the '774 patent
3 issued on this application without the "murine" modifier in the
4 claims of the patent. Two years later, Chiron filed a file
5 wrapper continuation of the earlier applications. The 1994
6 application issued as the '197 patent in 1997. In 1995, Chiron
7 filed another continuation application for a patent on nucleic
8 acid molecules. After substantial back and forth with the PTO
9 Chiron filed amendments to this application in 1999, and the '561
10 patent issued the next year.

11 While Chiron appears to have repeatedly sought to
12 expand the scope of its claims throughout the prosecution history
13 of the patent, there are still unexplained periods of delay
14 between the various patent applications. Genentech argues that
15 the reason for Chiron's delay was that it was waiting for
16 Genentech or some other company to develop a lucrative product so
17 that it could craft broader claims designed specifically to cover
18 that product, and Chiron has not offered an alternative
19 explanation. Although the terminal disclaimer weighs in Chiron's
20 favor, the court must draw all reasonable inferences in
21 Genentech's favor in ruling on this motion. Therefore, the court
22 cannot say that as a matter of law, Chiron's delay was not
23 unreasonable.

24 C. Prejudice

25 Chiron argues that in any case, Genentech cannot
26 demonstrate prejudice as a matter of law. To receive the benefit
27 of a laches defense, Genentech must show not only that it was
28 prejudiced, but also that there is a nexus between Chiron's delay

1 in prosecuting the '561 patent claims and the alleged prejudice.
2 Hemstreet v. Computer Entry Sys. Corp., 979 F.2d 1290, 1294 (Fed.
3 Cir. 1992). Genentech argues that Chiron's delay in this case
4 was both presumptively and actually prejudicial.

5 1. Presumption of Laches

6 In a traditional laches case, a presumption of laches
7 will arise where the patentee delays bringing a lawsuit for six
8 years or more after the date the patentee knew or should have
9 known of the alleged infringing activity. A.C. Aukerman, 960
10 F.2d at 1038. Once the presumption arises, the patentee may
11 offer proof directed toward rebutting the laches factors. Id. at
12 1037. "Such evidence may be directed to showing either that the
13 patentee's delay was reasonable or that the defendant suffered no
14 prejudice or both. By raising a genuine issue respecting either
15 factual element of a laches defense, the presumption of laches is
16 overcome." Id. (citations omitted) (emphasis added).

17 Even if this presumption applies in a prosecution
18 laches defense, and even if the delay in question here exceeded
19 six years,³ Chiron has submitted evidence to rebut the
20 presumption. As discussed above, the filing of a terminal
21 disclaimer raises a "genuine issue" respecting the reasonableness
22 of Chiron's delay. Because a patentee may overcome the
23 presumption by raising a genuine issue on one of the laches
24 factors, no presumption of laches applies here.

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27 ³ Chiron contends that the presumption does not apply in
28 the context of prosecution laches, and that the period of delay
was a mere five months. The court does not address the merits of
these contentions.

1 2. Actual Prejudice

2 A plaintiff's delay may result in both evidentiary and
3 economic prejudice to the defendant. Genentech does not allege
4 that it suffered evidentiary prejudice as a result of Chiron's
5 delay, but contends that it suffered economic prejudice.

6 Economic prejudice may arise where the defendant will suffer the
7 loss of monetary investments or incur damages which likely would
8 have been prevented had it not been for the plaintiff's delay.

9 Auckerman, 960 F.2d at 1033. The change in the defendant's

10 economic position "must be because of and as a result of the
11 delay, not simply a business decision to capitalize on a market
12 opportunity." Gasser Chair Co. v. Infanti Chair Mfg. Corp., 60

13 F.3d 770, 774 (Fed. Cir. 1995). Damages attributable to a
14 finding of liability do not constitute economic prejudice,
15 because then economic prejudice would arise in every suit.

16 Auckerman, 960 F.2d at 1033. However, "this does not mean that a
17 patentee may intentionally lie silently in wait watching damages
18 escalate, particularly where an infringer, if he had had notice,
19 could have switched to a non-infringing product." Id. (citations
20 omitted).

21 Genentech alleges that had Chiron prosecuted the patent
22 earlier (1) it would not have been "trapped" into an "exorbitant
23 royalty rate" by Chiron; and (2) Genentech could have designed
24 around the patent and therefore avoided infringement.⁴

26 ⁴ Chiron asserts that "Genentech confessed that it would
27 not have done anything differently had the '561 patent claims
28 issued earlier." (Chiron Mot. For S.J. Re: Laches in
Prosecution, at 12.) However, the two pieces of evidence on
which Chiron relies do not support this assertion. First, Chiron

1 a. Royalties

2 Genentech's argument that Chiron delayed prosecution of
3 the '561 patent in order to "trap" Genentech into a high royalty
4 rate is based on testimony by Chiron's damages experts that in
5 general, the later in drug development a licensing deal is
6 struck, the higher the royalty rate will be. (Edwards Report ¶
7 19; Leitzinger Report ¶ 18; Leitzinger Dep. at 81-82.) Genentech
8 contends that by waiting until Herceptin was in a late stage of
9 product development to prosecute the '561 patent, Chiron was able
10 to demand a higher royalty rate in licensing negotiations with
11 Genentech once the patent issued. The purported prejudice to
12 Genentech, therefore, appears to be that had Chiron obtained the
13 '561 patent earlier, Genentech could have taken a license on the
14 patent at a low royalty rate and avoided both the cost of
15 litigation and the possibility of a high damage award.

16 Chiron argues that court ordered royalty payments and
17 litigation costs are damages that are "attributable to a finding
18 of liability," and therefore cannot as a matter of law support a
19 finding of economic prejudice. See Auckerman, 960 F.2d at 1033.
20 However, the Federal Circuit has emphasized that "a patentee may

21 _____
22 relies on Genentech's answer to Chiron's interrogatory asking
23 what Genentech would have done differently "had Genentech not
24 believed that Chiron abandoned its infringement allegations."
25 (Riley Decl. Ex. 27, at 6) (emphasis added). Genentech's response
26 that it would not have done anything differently does not answer
27 the question of what Genentech would have done had Chiron
28 prosecuted the '561 patent earlier. Second, Chiron relies on the
deposition testimony of Steve Julesgaard, Genentech's General
Counsel. However, in the portions of Mr. Julesgaard's deposition
that Chiron cites, Mr. Julesgaard was explaining what Genentech's
thought process was after the '561 patent issued, not what
Genentech would have done had the '561 patent issued earlier.
(See Julesgaard Dep. at 32.)

1 [not] intentionally lie silently in wait watching damages
2 escalate," which is essentially the substance of Genentech's
3 allegation of prejudice. See id.; Baker Mfg. Co. v. Whitewater
4 Mfg. Co., 430 F.2d 1008, 1014 (7th Cir. 1970) (finding laches
5 where patentee decided to remain silent until litigation would be
6 worthwhile before suing). Therefore, the authority cited by
7 Chiron does not preclude Genentech's royalty argument as a matter
8 of law.

9 Nor is Genentech's argument without factual support.
10 Sean Johnston, Genentech's Vice President of Intellectual
11 Property who was involved in several of the licensing
12 negotiations with Chiron, states in his declaration that "[h]ad
13 Chiron filed and prosecuted in the United States Patent Office
14 claims directed to non-murine monoclonal antibodies earlier than
15 it did, or had Chiron discussed such claims with Genentech,
16 Genentech might have acted differently." (Johnston Decl. ¶ 4.)
17 Robert Garnick, Genentech's Senior Vice President of Regulatory
18 Affairs, also attests that "Genentech might have taken a
19 different approach in its discussions with Chiron regarding anti-
20 HER2 antibodies."⁵ (Garnick Decl. ¶ 3.) These declarations,
21

22 ⁵ Chiron moves to strike the declarations of Mr. Johnston
23 and Mr. Garnick on the grounds that they are speculative and
24 lacking in personal knowledge and are therefore inadmissible.
25 However, Mr. Johnston was personally engaged in licensing
26 negotiations with Chiron, and therefore is in a position to opine
27 as to what Chiron might have done differently in those
28 negotiations. Mr. Garnick attests that he has personal knowledge
of Genentech's approaches to product development, including the
considerations that Genentech gives to the intellectual property
rights of others. Therefore, his observations about what
Genentech might have done differently are also purportedly based
on his own personal knowledge and experience. The court
therefore will not strike these declarations from the record.

1 coupled with the testimony of Chiron's experts regarding the
2 economics of licensing agreements, are sufficient to create a
3 disputed issue as to whether Genentech would have changed its
4 economic position vis-a-vis Chiron had Chiron filed the '561
5 patent earlier.

6 Chiron argues that because Genentech refused to license
7 Chiron's patents, any increase in royalty rate is Genentech's own
8 fault, and therefore cannot be attributed to Chiron's delay.
9 However, Genentech did not have the option to consider the
10 significance of the '561 patent when it declined to license
11 Chiron's technology, because the '561 patent did not exist at a
12 time when royalty rates would have been low. Genentech cannot
13 have assumed the risk of not licensing a patent that did not
14 exist.

15 Chiron also argues that Genentech would probably not
16 have taken a license on the '561 patent had it issued earlier,
17 because Genentech obtained an opinion letter of counsel stating
18 that the '561 patent was invalid and not infringed, and Genentech
19 had not taken a license on the '894 and '774 after obtaining
20 similar opinion letters. While this evidence certainly supports
21 Chiron's position, the appropriate time for the court to weigh
22 this and other evidence is after a trial on the merits, not on
23 summary judgment.

24 b. Designing Around the Patent

25 Genentech has also submitted evidence that it might
26 have attempted to design around the patent. According to Mr.
27 Garnick, Genentech may have considered designing a different
28 breast cancer drug altogether. (Garnick Decl. ¶ 3). Mr. Garnick

1 also suggests that Genentech could have manufactured Herceptin
2 abroad, added more antibodies to Herceptin to make it a non-
3 homogeneous preparation of antibodies, and then imported it back
4 to the United States for sale. (Id. ¶ 4.) By manufacturing
5 Herceptin abroad, Genentech could have avoided the Patent Act's
6 prohibition against making a patented invention in the United
7 States. See 35 U.S.C. § 271 (a) ("[W]hoever without authority
8 makes, uses, offers to sell, or sells any patented invention,
9 within the United States, or imports into the United States any
10 patented invention during the term of the patent therefor,
11 infringes the patent"). Because the '561 patent defines a
12 monoclonal antibody as "an antibody composition having a
13 homogeneous antibody population," (See '561 Patent at 8:40-42),
14 Genentech contends that it could have simply added more
15 antibodies into the pure product manufactured abroad to make it
16 non-homogeneous. Thus, according to Genentech, by the time the
17 adulterated preparation was imported and sold in the United
18 States, it would not have read onto the '561 patent, and
19 therefore would not have run afoul of the Patent Act's
20 prohibition against the importation, use, or sale of a patented
21 invention in the United States. See 35 U.S.C. § 271(a).

22 Chiron argues that the latter alternative does not get
23 around the patent, because infringement is not avoided by the
24 addition of extra elements that do not eliminate an inherent
25 feature of the patent's claims. Northern Telecom, Inc. v.
26 Datapoint Corp., 908 F.3d 931, 945 (Fed. Cir. 1990); Suntinger,
27 Inc. v. Scientific Research Funding Group, 189 F.3d 1327 (Fed.
28 Cir. 1999). Even if Chiron were correct that adding more

1 antibodies to Herceptin would not have made the relevant
2 population of antibodies heterogenous, Genentech is entitled to
3 the benefit of every reasonable inference, which includes an
4 inference that it could have and would have developed a different
5 product entirely. Therefore, summary judgment in Chiron's favor
6 is not appropriate.

7 Chiron protests that Genentech should be precluded from
8 asserting prejudice on the basis of lost opportunities to design
9 around the patent or to take a license at a lower rate. Chiron's
10 argument is based on representations made by Genentech's counsel
11 during a March 11, 2002 hearing on Genentech's motion for leave
12 to amend its answer to add a prosecution laches defense. At that
13 hearing, the court expressed concern that Chiron would not have
14 adequate time to conduct discovery into the prejudice suffered by
15 Genentech, given the late stage of the litigation at which the
16 motion was brought. (See Mar. 11 Tr. at 41, 45-46.) Counsel for
17 Genentech assured the court that the only prejudice Genentech
18 suffered was that it spent millions of dollars developing
19 Herceptin, and that much of the discovery into this injury had
20 already been conducted in the case. (Id.) Relying in part upon
21 Genentech's representations, the court granted Genentech leave to
22 add a prosecution laches defense to its answer.

23 Genentech's current allegations of prejudice are not
24 wholly inconsistent with the representations made at the hearing
25 on the motion for leave to amend. However, the court has serious
26 concerns about the additional prejudice to Chiron that may result
27 if the court allows Genentech to litigate issues at trial that
28 the court did not anticipate at the time the original decision

1 was made to grant leave to amend. Therefore, the court will
2 determine the laches question in a separate hearing after the
3 jury trial, after Chiron has had an opportunity to conduct
4 further discovery. The court's previous Order of April 12, 2002,
5 will therefore be amended to permit Chiron to conduct open-ended
6 discovery on laches until the time of the separate hearing on the
7 issue.⁶

8 IT IS THEREFORE ORDERED that:

9 (1) Chiron's motion for summary judgment on Genentech's
10 defense of prosecution laches be, and the same hereby
11 is, DENIED;

12 (2) The court will hear Genentech's prosecution laches
13 defense in a separate hearing that will take place
14 after the jury trial, if the prosecution laches defense
15 is not moot at that time;

16 (3) Chiron may conduct open-ended discovery on
17 prosecution laches until the time of the separate
18 hearing on the defense.

19 DATED: June 24, 2002

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21

WILLIAM B. SHUBB
UNITED STATES DISTRICT JUDGE

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23 ⁶ Chiron has requested that in the event its summary
24 judgment motion is denied, the court issue an order pursuant to
25 Federal Rule of Civil Procedure 56(d) specifying facts that are
26 established for trial. The court does not find it practicable in
27 this case "to ascertain what material facts exist without
28 substantial controversy and what material facts are actually and
in good faith controverted" such that the court can issue a Rule
56(d) order. Fed. R. Civ. Proc. 56(d). Moreover, the court in
its discretion does not choose to narrow issues or establish
facts where doing so does not eliminate a claim or defense. In
the court's experience, such piecemeal resolution of the case
makes trial more difficult and complex as opposed to streamlined.