

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION**

ELI LILLY AND COMPANY, and
IMCLONE SYSTEMS LLC

Plaintiffs,

v.

GENENTECH, INC., and CITY OF
HOPE,
Defendants.

Case No. 2:13-cv-07248-MRP-JEM

**ORDER DENYING PLAINTIFFS'
MOTION FOR SUMMARY
JUDGMENT ON
DOUBLE PATENTING**

1 **I. Introduction**

2 Plaintiffs Eli Lilly and Company and Imclone Systems LLC (collectively, “Eli
3 Lilly”) have filed for summary judgment on the invalidity of U.S. Patent Nos.
4 6,331,415 (“Cabilly II”) and 7,923,221 (“Cabilly III”) against defendants
5 Genentech, Inc. and City of Hope (collectively, “Genentech”). The basis of this
6 motion is that Cabilly II and Cabilly III are invalid for double patenting. For the
7 reasons set forth in this order, the Court denies Eli Lilly’s motion.

8 **II. Background**

9 The subject matter of Cabilly II and III has been described in past orders of
10 this Court. *See, e.g., Eli Lilly & Co. v. Genentech*, No. 2:13-cv-07248-MRP-JEM
11 (C.D. Cal. Apr. 18, 2014); *Medimmune, Inc. v. Genentech, Inc.*, No. 2:03-cv-
12 02567-MRP-CT, 2007 WL 5760839 (C.D. Cal. Aug. 16, 2007). Cabilly II and III
13 are directed to methods, host cells, and vectors for making genetically engineered
14 immunoglobulins. Immunoglobulins are proteins normally produced by cells of
15 the immune system in response to an infection. Antibodies¹ have a Y-shape that
16 comprises two heavy chains and two light chains. Antibodies can bind to antigens
17 like bacteria and viruses and destroy them.

18 Cabilly II and III claim methods for producing antibodies by inserting DNA
19 that codes for heavy and light chains into a host cell through the use of one or two
20 vectors. The host cells then produce antibodies. Claim 33 of Cabilly II is
21 representative of that patent and recites:

22 A process for producing an immunoglobulin molecule or an immunologically
23 functional immunoglobulin fragment comprising at least the variable domains
24 of the immunoglobulin heavy and light chains, in a single host cell, comprising:
25 independently expressing a first DNA sequence encoding at least the
26 variable domain of the immunoglobulin heavy chain and a second DNA

27 ¹ The parties have disputed the claim constructions of the terms “immunoglobulin” and
28 “antibody.” The Court has taken no position on the constructions of these terms. For the
purposes of this section, “antibody” means an immunoreactive immunoglobulin molecule.

1 sequence encoding at least the variable region of the immunoglobulin light
2 chain so that said immunoglobulin heavy and light chains are produced as
3 separate molecules in said single host cell transformed with said first and
4 second DNA sequences.

5 Claim 20 of Cabilly III is representative of that patent. Claim 20 depends from
6 claim 15. Together, they recite:

7 15. A method for making an antibody or antibody fragment capable of
8 specifically binding a desired antigen, wherein the antibody or antibody
9 fragment comprises (a) an antibody heavy chain or fragment thereof comprising
10 a human constant region sequence and a variable region comprising non human
11 mammalian variable region sequences and (b) an antibody light chain or
12 fragment thereof comprising a human constant region sequence and a variable
13 region comprising non human mammalian variable region sequences, the
14 method comprising coexpressing the heavy chain or fragment thereof and light
15 chain or fragment thereof in a recombinant host cell.

16 20. The method of claim 15 which results in the production of an antibody.
17 Significant to this motion, Cabilly II and III claim a process called “coexpression,”
18 in which DNA that codes for both heavy and light chains may be inserted into a
19 single host cell, so that the host cell may express both chains at the same time.
20 Cabilly II and III include vector claims and host cell claims related to this process.

21 Cabilly II and III were preceded by U.S. Patent No. 4,816,567 (“Cabilly I”). In
22 contrast to the later patents, Cabilly I does not claim the coexpression of heavy and
23 light chains in the same host cell. Instead, Cabilly I merely claims the expression
24 of either a chimeric heavy chain or light chain in a host cell. Eli Lilly primarily
25 relies on claim 2 of Cabilly I, which depends from claim 1. Claim 1 recites:

26 A method comprising

27 (a) preparing a DNA sequence encoding a chimeric immunoglobulin heavy
28 or light chain having specificity for a particular known antigen wherein a

1 constant region is homologous to the corresponding constant region of an
2 antibody of a first mammalian species and a variable region thereof is
3 homologous to the variable region of an antibody derived from a second,
4 different mammalian species;

5 (b) inserting the sequence into a replicable expression vector operably linked
6 to a suitable promoter compatible with a host cell;

7 (c) transforming the host cell with the vector of (b);

8 (d) culturing the host cell; and

9 (e) recovering the chimeric heavy or light chain from the host cell culture.

10 Claim 2 recites the “method of claim 1 wherein the first mammalian species is
11 human.” Cabilly I also claims host cells and vectors related to the process of claim
12 1. For all relevant claims, the crucial difference between the claims of Cabilly I
13 and the claims of Cabilly II and III is that Cabilly II and III recite the coexpression
14 of heavy and light chains while Cabilly I recites the expression of a heavy or light
15 chain.

16 III. Standard for Summary Judgment

17 The Court shall grant summary judgment if there is no genuine dispute as to
18 any material fact, as supported by facts on the record that would be admissible in
19 evidence, and if the moving party is entitled to judgment as a matter of law. Fed.
20 R. Civ. P. 56; *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *Anderson v.*
21 *Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986). In order to grant summary
22 judgment, the Court must identify material facts by reference to the governing
23 substantive law, while disregarding irrelevant or unnecessary factual disputes.
24 *Anderson*, 477 U.S. at 248. If there is any genuine dispute about a material fact
25 such that a reasonable jury could return a verdict for the nonmoving party,
26 summary judgment cannot be granted. *Id.* The Court must view facts and draw
27 reasonable inferences in favor of the nonmoving party. *Scott v. Harris*, 550 U.S.
28 372, 378 (2007). If the party moving for summary judgment does not bear the

1 burden of proof as to a particular material fact, the moving party need only give
2 notice of the absence of a genuine issue of material fact so that the nonmoving
3 party may come forward with all of its evidence. *See Celotex*, 477 U.S. at 325.

4 **IV. Law of Double Patenting**

5 The doctrine of double patenting originates in the text of § 101 of the Patent
6 Act, which states that anyone “may obtain a patent” for an invention. Courts have
7 read this text to prohibit an inventor from obtaining multiple patents for the same
8 invention. *See Sun Pharm. Indus., Ltd. v. Eli Lilly & Co.*, 611 F.3d 1381, 1384
9 (Fed. Cir. 2010). Courts refer to § 101’s prohibition as statutory double patenting.
10 *Id.* Courts have created another doctrine to pair with statutory double patenting.
11 This doctrine is known as obviousness-type double patenting (“ODP”)—the type
12 of double patenting alleged in this case. ODP forbids an inventor’s second, later-
13 expiring patent on an invention when a person of ordinary skill would not view the
14 second patent as containing a patentably distinct invention from the inventor’s first
15 patent.² *Id.* ODP must be proven by clear and convincing evidence. *Procter &*
16 *Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 999 (Fed. Cir. 2009).

17 ODP rests on the policy reflected by § 101. A patent represents a bargain with
18 the federal government. The government will give an inventor the right to exclude
19 others from making his invention for a limited term, and in exchange, the inventor
20 discloses the invention and dedicates it to the public after the patent term expires.
21 Without an ODP restriction, an inventor could extend indefinitely the right to
22 exclude by filing subsequent patents on obvious modifications of the invention,
23 effectively nullifying the public’s right to practice the invention after the first
24 patent expires. *See Abbvie Inc. v. Mathilda & Terence Kennedy Inst. of*
25 *Rheumatology Trust*, 764 F.3d 1366, 1372–73 (Fed. Cir. 2014).

26 _____
27 ² A patentee may overcome an ODP problem by filing a terminal disclaimer, which shortens a
28 second patent’s term so that it expires at the same time as an earlier-expiring patent. *In re*
Goodman, 11 F.3d 1046, 1052 (Fed. Cir. 1993). In this case, the patentee did not file a terminal
disclaimer of Cabilly II or Cabilly III over Cabilly I.

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.