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17 Attorneys for Defendants and Counterclaimants
 18 Roche Molecular Systems, Inc.; Roche Diagnostics
 19 Corporation; and Roche Diagnostics Operations, Inc.

20 UNITED STATES DISTRICT COURT
 21
 22 NORTHERN DISTRICT OF CALIFORNIA

23 THE BOARD OF THE TRUSTEES OF THE
 24 LELAND STANFORD JUNIOR UNIVERSITY,

25 Plaintiff,

26 vs.

27 ROCHE MOLECULAR SYSTEMS, INC.; ROCHE
 28 DIAGNOSTICS CORPORATION; ROCHE
 29 DIAGNOSTICS OPERATION, INC.,

30 Defendant.

31 ROCHE MOLECULAR SYSTEMS, INC.; ROCHE
 32 DIAGNOSTICS CORPORATION; ROCHE
 33 DIAGNOSTICS OPERATION, INC.,

34 Counterclaimants,

35 vs.

36 THE BOARD OF THE TRUSTEES OF THE
 37 LELAND STANFORD JUNIOR UNIVERSITY;
 38 THOMAS MERIGAN AND MARK HOLODNIY,

39 Counterclaim Defendants.

CASE NO. C-05-04158-MHP

ROCHE'S MOTION FOR
 CERTIFICATION OF
 MEMORANDUM AND ORDER RE
 CROSS MOTIONS FOR SUMMARY
 JUDGMENT PURSUANT TO 28
 U.S.C. § 1292(b) AND REQUEST
 FOR STAY OF PROCEEDINGS

Date: March 19, 2007
 Time: 3:00 PM
 Dept. 15, 18th Floor

Hon. Marilyn Hall Patel

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NOTICE OF MOTION

PLEASE TAKE NOTICE that Roche requests that the Court permit this Motion for Certification of Memorandum and Order Re: Cross-Motions Summary Judgment Pursuant to 28 U.S.C. § 1292(b) and Request for Stay of Proceedings be heard at the case management conference scheduled for Monday, March 19, 2007 at 3:00 PM, or, in the alternative, requests the Court set a briefing schedule at the conference.

MOTION

Pursuant to Civil L.R. 7-2 and Fed. R. App. P. 5(a), defendants and counterclaimants Roche Molecular Systems, Inc., Roche Diagnostics Corporation, and Roche Diagnostics Operations, Inc. (collectively, “Roche”) respectfully request that this Court amend its February 23, 2007 Memorandum & Order: Cross Motions for Summary Judgment (“SJ Order”) to certify the SJ Order for immediate appeal pursuant to 28 U.S.C. § 1292(b) and to stay proceedings pending appeal.

I. INTRODUCTION

By right, Roche cannot appeal the SJ Order until a final judgment. The Court, however, bifurcated this case to complete discovery and resolve ownership issues first. A final judgment for purposes of appellate jurisdiction will not occur until the conclusion of the second phase of this action — a long and expensive patent case. Having been denied its ownership assertions on summary judgment, Roche is now faced with having to defend and protect its life saving and FDA approved HIV kits from Stanford’s claims of patent infringement. Roche must devote resources potentially to invalidate patents that it may ultimately be found on appeal to own. The ownership, standing and license issues, however, are ripe for permissive appeal.

Section 1292(b) allows this Court to certify an order for permissive appeal if (1) it “involves a controlling question of law as to which there is a substantial ground for difference of opinion” and (2) “immediate appeal from the order may materially advance the ultimate termination of the litigation.” 28 U.S.C. § 1292(b). Both conditions are present here.

1 The SJ Order involves controlling legal questions: the SJ Order denied, as a matter of
2 law, Roche’s assertions that it owned the patents or had a license and shop rights to practice the
3 claimed inventions. The facts are undisputed: two of the Stanford researchers named as
4 inventors patented an invention that was conceived at Cetus Corporation in 1989 using Cetus’
5 PCR equipment, information and materials. Roche acquired the PCR assets of Cetus in 1991,
6 including the specific contracts that the Stanford researchers had executed in order to gain
7 access to Cetus to collaborate on the HIV/PCR project.

8 Roche respectfully submits that given the paucity of direct precedent for the legal
9 questions considered by the Court, there is substantial ground for difference of opinion. For
10 instance, the SJ Order interpreted the Bayh-Dole Act, 35 U.S.C. § 200, *et seq.*, automatically to
11 vest title to the patents with the United States government (to the detriment of Roche).
12 Automatic vesting with the government, however, is contrary to the plain language of the
13 statute that the government “*may* receive title” from the university but only if the university
14 fails to disclose the invention or elects not to retain title. *Id.* at §§ 202(c)(1) and (2) (emphasis
15 added). No appellate court has held that the Bayh-Dole Act automatically vests title with the
16 government. Likewise, Roche believes there is no direct precedent or decision that precludes a
17 defendant from challenging standing or raising ownership in defense of a patent action initiated
18 against it. And Roche believes there is no direct precedent or decision that voids the attempted
19 transfer of license rights granted under materials transfer agreements associated with a merger
20 or sale of a business. These determinations are matters of first impression that have far
21 reaching consequences for life science companies, especially those engaged in collaboration
22 with universities and those that have merged or acquired such companies. The SJ Order calls
23 into question many of the basic intellectual property assumptions for life science companies
24 such as Roche about the nature of the rights they believe they have acquired.

25 Stanford will not be prejudiced by a permissive appeal and stay. Unlike Roche — the
26 leading supplier of HIV kits to doctors and clinics in the United States — Stanford makes no
27 products. Instead, Stanford has sued Roche simply to generate licensing revenue. Stanford has
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1 no sales for which an immediate trial is necessary to protect market share. In addition,
2 Stanford's first patent issued in 1999, but Stanford sued in 2005. Thus, since Stanford waited
3 over five years to sue, it will not be prejudiced by waiting 6-9 months for the resolution of an
4 appeal that goes to the heart of the patent rights it seeks to enforce.

5 Resolution of these legal questions will materially advance the termination of this
6 action. The factual record relating to ownership is complete, and this Court has issued a
7 lengthy and detailed opinion setting forth the pertinent facts and deciding the controlling legal
8 questions. These are discrete and important legal issues. The Court's original bifurcation order
9 recognized the advantage of phasing this case, and Roche requests that this Court allow the
10 final resolution of the ownership issues by certifying the SJ Order for interlocutory appeal. It is
11 most efficient to appeal these questions now, instead of at the conclusion of a lengthy and
12 expensive patent case, the result of which may be the invalidation of the very patents that
13 Roche claims to own.

14 **II. PROCEDURAL HISTORY**

15 On October 14, 2005, Stanford brought this patent infringement case against Roche
16 accusing its HIV test kits of infringing two patents related to the quantification of HIV by the
17 PCR method. Docket No. 1. On November 17, 2005, Roche served its answer and
18 counterclaims, disputing that Stanford was the sole owner of the patents and had standing, as
19 well as asserting, *inter alia*, that Roche had an ownership interest in the patents and had a
20 license to practice the claimed inventions. Docket No. 15.

21 After a hearing, on March 7, 2006, this Court bifurcated ownership issues and set a
22 discovery and summary judgment schedule. Docket No. 28. The parties conducted significant
23 discovery directed to these issues, including taking thirty depositions and collectively producing
24 over 100,000 pages of documents. See Declaration of Brian C. Cannon at ¶ 3-4. In addition,
25 Stanford and Roche issued subpoenas to over 25 third parties, including former Cetus, Roche and
26 Stanford employees, obtaining documents and testimony from those persons. *Id.* at ¶ 5.

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1 On October 27, 2006, the parties filed their respective motions for summary judgment.
2 See Docket Nos. 90 and 92. On November 15, 2006, the parties filed their oppositions, as well
3 as a joint statement of undisputed facts. See Docket Nos. 107, 111 and 118.

4 On November 28, 2006, Roche filed its motion to strike based on the assertion that
5 Stanford in its opposition for the first time had raised and relied upon the Bayh-Dole Act to
6 counter Roche's claim of ownership, despite not identifying this theory in response to Roche's
7 interrogatories and not producing the relevant funding agreement between Stanford and the
8 United States government during discovery. Docket No. 120.

9 On December 7, 2006, this Court held a hearing on the parties cross motions for
10 summary judgment. See Docket No. 133. On February 23, 2007, this Court issued its SJ
11 Order. See Docket No. 139. The SJ Order denied Roche's challenge to Stanford's standing to
12 assert the patents, and denied Roche's assertion of ownership of the patents, as well as its
13 assertion of license and shop rights to practice the claimed inventions. *Id.* The SJ Order
14 granted Stanford's motion for summary judgment on these issues. *Id.*

15 As the SJ Order is not otherwise appealable, Roche hereby respectfully requests the
16 Court certify the SJ Order for immediate appeal pursuant to 28 U.S.C. § 1292(b), which will
17 enable Roche to address the important questions of law regarding ownership of these HIV
18 patents without having to defend against these patents in the course of an expensive patent
19 infringement action.

20 **III. ARGUMENT**

21 Federal Rule of Appellate Procedure 5(a)(3) provides that the district court may amend
22 its order, either on its own or in response to a party's motion, to include a statement that the
23 necessary conditions for permissive appeal are met. Fed. R. App. P. 5(a)(3). Section 1292 sets
24 forth the conditions for permissive appeal, providing that a Court can certify an otherwise
25 unappealable order for immediate appeal if the order: (1) "involves a controlling question of
26 law as to which there is a substantial ground for difference of opinion" and (2) "immediate
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1 appeal from the order may materially advance the ultimate termination of the litigation.” 28
2 U.S.C. § 1292(b). This Court’s February 23, 2007 SJ Order meets both of these conditions.

3 **A. The Factual Record Is Complete On The Issues Sought To Be Appealed**

4 As a threshold matter, the parties conducted extensive discovery on ownership issues
5 and submitted a joint statement of undisputed facts. The Court drew upon this record to set
6 forth pertinent facts relating to the existence and interpretation of the contracts, as well as the
7 development of the HIV PCR assay that is the subject of the patents. The Court ruled:

- 8 • “It is undisputed that Stanford developed the PCR assay disclosed in its patents
9 after working with Cetus Corporation (“Cetus”), which later sold its PCR assets
10 and business to Roche.” SJ Order at p. 2.
- 11 • “[Stanford researcher and named inventor] Holodniy spent approximately nine
12 months working at Cetus, receiving technical information from Cetus scientists
13 and proprietary physical materials from Cetus.” *Id.* at p. 5.
- 14 • “By fall 1989, an assay for quantitating HIV RNA using PCR was developed at
15 Cetus that was comprised of five steps.” *Id.* at p. 6.
- 16 • “Holodniy has testified that he had never performed any of the five steps
17 comprising the assay prior to working at Cetus.” *Id.* at p. 6.
- 18 • “While the record demonstrates that the patented invention was not complete
19 until after Holodniy left Cetus, the invention was clearly conceived at the latest
20 when Holodniy had developed the PCR assay.” *Id.* at p. 19
- 21 • “The specific method of using the assay to monitor HIV treatment was therefore
22 clear in the minds of Holodniy and the other Stanford researchers scientists when
23 the assay was completed at Cetus.” *Id.* at p. 19
- 24 • “The record unambiguously reflects that the PCR assay and the ensuing patented
25 invention were developed ‘as a consequence of’ Holodniy’s access to Cetus’
26 facilities and information.” *Id.* at p. 23.

1 Thus, the Court found that the conception of the patented invention at Cetus “was
2 sufficient to trigger the assignment provision” of the Visitors Confidentiality Agreement that
3 Holodniy executed as part of his collaboration with Cetus. *Id.* at pp. 19-20. In addition, the
4 collaboration at Cetus also triggered the license provisions of a second contract — the Materials
5 Transfer Agreement executed by Stanford in its collaboration with Cetus. *Id.* at p. 24 (“The
6 contract granted Cetus, by default, a free non-exclusive license.”) The Court ruled, however,
7 that controlling issues of law prevented enforcement of these two contracts, either to provide
8 ownership or license to Roche or to deprive Stanford of standing to enforce the patents.

9 **B. Controlling Questions Of Law Exist With Respect To The Patent Assignment**

10 Because the factual record is complete, the Court ruled as a matter of law to deny
11 Roche’s challenge to Stanford’s standing and to deny Roche’s claim to own the patents. With
12 respect to Roche’s assertion of ownership pursuant to Holodniy’s assignment of his interest in
13 the patents to Cetus, the Court ruled that Roche’s positions are “properly viewed as
14 counterclaims subject to the applicable statute of limitations.” SJ Order at p. 13.

15 With respect to applying a time bar to Roche’s assertion of ownership, Roche
16 respectfully submits that there is a substantial ground for difference of opinion because Roche
17 is aware of no California authority (from which the statute of limitations is applied) that bars a
18 defendant from raising an assertion of patent ownership in response to the commencement of an
19 action against it. The federal authority cited in the SJ Order concerned a *plaintiff* (City of St.
20 Paul) that commenced a declaratory judgment action and, in response to compulsory
21 counterclaims, raised affirmative defenses that would have been time barred had they been
22 included in the complaint. *City of St. Paul v. Evans*, 344 F.3d 1029 (9th Cir. 2003). The
23 plaintiff City of St. Paul was time barred. Because Roche is not the plaintiff, and did not
24 commence this action, Roche submits there is substantial ground for difference of opinion as to
25 whether its assertions should be time barred, considering California law that “a defense may be
26 raised at any time, even if the matter alleged would be barred by a statute of limitations if
27 asserted as the basis for affirmative relief.” *Styne v. Stevens*, 26 Cal. 4th 42, 51 (Cal. 2001).

1 In addition, to Roche's assertions being time barred, the Court ruled that Stanford
2 researcher Holodniy could not assign patent rights to Cetus because under the Bayh-Dole Act
3 "Holodniy's interest would have vested immediately in the United States, and Stanford would
4 have acquired that interest by satisfying certain requirements." SJ Order at p. 21 ("[U]nder the
5 Bayh-Dole Act, title vests automatically in the government, not the inventor.").

6 Roche respectfully submits that there is a substantial ground for difference of opinion
7 with respect to the Court's interpretation of the Bayh-Dole Act. The Act provides that "to
8 promote collaboration between commercial concerns and nonprofit organizations, including
9 universities" (35 U.S.C. § 200), the "funding agreement" between the university and the
10 government must include certain provisions "to effectuate" certain patent rights. *Id.* at §
11 202(c). Those contractual based rights include that the university "disclose" inventions made
12 under funding to the government within "a reasonable time" and that the "Federal Government
13 *may* receive title to any subject invention not disclosed to it within such time." *Id.* at §
14 202(c)(1). Furthermore, the Act provides that the "funding agreement" shall contain provisions
15 to effectuate that the Federal Government "may receive title" if the university does not elect to
16 retain it. *Id.* at § 202(c)(2). The plain language of the Bayh-Dole Act does not include any
17 "automatic vesting" of title provision with the government upon conception of an invention.
18 Instead, the "funding agreement" must effectuate that the government "may" receive title under
19 certain conditions. There is no appellate case interpreting the Bayh-Dole Act to provide
20 automatic vesting of title with the government.

21 Stanford cited in its papers, and the court relied upon, *FilmTec Corp. v. Hydranautics*,
22 982 F.2d 1546, 1548 (Fed. Cir. 1992). SJ Order at 21. That case did not concern the Bayh
23 Dole Act. *FilmTec* concerned the predecessor statute to the Bayh-Dole Act under which the
24 title did automatically vest with the government. Congress enacted the Bayh-Dole Act in 1980,
25 however, precisely to address the problem of title passing automatically to the government
26 being a disincentive for industry collaboration with universities. *See* S. Rep. No. 96-480 (1979)
27 at pp. 21-22. As an editorial in the leading U.S. journal *Science* put it at the 25-year
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1 anniversary of the Bayh-Dole Act: “This legislation has had a profound impact on science in
2 the United States To review: Under B-D, the U.S. government renounced intellectual
3 property claims on research supported by federal funds in universities or other non-government
4 institutions.” Donald Kennedy, Editor in Chief, 307 *Science* 1375 (March 4, 2005).

5 Roche respectfully submits that the Court’s interpretation of the Bayh-Dole Act has far-
6 reaching consequences, especially in the life sciences field, for companies that have, or are
7 considering, collaborations with university researchers. The SJ Order creates precedent that
8 calls into question the basic presumptions of ownership that the Bayh-Dole Act was designed to
9 make clear. This urgent matter should be addressed in the Court of Appeals.

10 With respect to standing, Roche respectfully submits that there is a substantial ground
11 for difference of opinion as to whether standing must be coupled to ownership. SJ Order at 13-
12 14. Standing is a jurisdictional question for which Stanford bears the burden. *Rite-Hite Corp.*
13 *v. Kelley Co.*, 56 F.3d 1538 1551 (Fed. Cir. 1995) (en banc) (1990); *Sicom Sys., Ltd. v. Agilent*
14 *Tech., Inc.*, 427 F.3d 971 (Fed. Cir. 2005); *MyMail, Ltd. v. America Online, Inc.*, slip op. at 5
15 (Fed. Cir. February 20, 2007). Thus, whether or not Roche can assert rights as an owner should
16 be considered a separate question from whether Stanford lacks standing because a named
17 inventor assigned his rights to a third party (Cetus or otherwise).

18 C. Controlling Issues Of law Exist With Respect To Cetus’ License

19 The Court ruled as a matter of law that Cetus’ free and non-exclusive license could not
20 be transferred to Roche when Roche purchased the PCR business and assets of Cetus. The
21 Court ruled that the “assignability of patent licenses is governed by federal law” and cited *In re*
22 *CFLC, Inc.*, 89 F.3d 673, 679 (9th Cir. 1996), for the proposition that a nonexclusive patent
23 license cannot be assigned without the patent owner’s permission. SJ Order at p. 26. Roche
24 respectfully submits that *In re CFLC* is a bankruptcy case concerning disposition of the assets
25 in bankruptcy and not directly pertinent to the issues involved in this action, and that there
26 could be substantial grounds for difference of opinion as to whether interpretation of the
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1 Materials Transfer Agreement requires Stanford's consent for the default license granted under
2 the agreement to be transferred to an purchaser of Cetus' business.

3 **D. Controlling Issues Of Law Exist With Respect To Shop Rights**

4 The Court ruled as a matter of law that the shop rights doctrine was inapplicable
5 because a contract (albeit void under the SJ Order) existed that governed the rights in question.
6 SJ Order at p. 27-28. Roche respectfully submits that there is a substantial ground for
7 difference of opinion on this question. *United States v. Dubilier*, 289 U.S. 178, 187-88 (1933)
8 does not address the application of a contract to shop rights, and also does not address the issue
9 of a void contract as it applies to shop rights. *Dubilier* concerned the applicability of
10 intellectual property principles ("settled as respects private employment") with respect to
11 employees of the federal government. *Id.* Roche respectfully submits that the interplay
12 between contracts and shop rights is not well settled and that authority exists for a substantial
13 difference of opinion with respect to the Court's holding. Cf. *Gate-Way, Inc. v. Hillgren*, 82
14 F.Supp. 546, 554-555 (S.D. Cal. 1949) (finding that an oral agreement to license a patent was
15 barred under the California statute of frauds; but that the license agreement, albeit void, did not
16 prevent the application of shop rights).

17 **E. Immediate Appeal From The SJ Order Will Materially Advance The Ultimate**
18 **Termination Of The Litigation**

19 The issues raised in the SJ Order may be dispositive of this litigation. If Stanford does
20 not have standing or if Roche has ownership or license rights, then Stanford cannot proceed
21 with this action. The Court's original bifurcation order recognized this issue. Indeed, appeal of
22 the ownership decision will prevent the potentially unnecessary re-opening of depositions,
23 including those of third parties.

24 **IV. CONCLUSION**

25 Roche respectfully requests the Court enter the proposed order to amend the SJ Order to
26 allow Roche to seek permissive appeal of the SJ Order, and that the Court stay this action
27 pending resolution of the appeal.

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DATED: March 12, 2007

Respectfully submitted,

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