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14 UNITED STATES DISTRICT COURT
15 NORTHERN DISTRICT OF CALIFORNIA

16
17 ADVANCED CARDIOVASCULAR
SYSTEMS, INC.,

18 Plaintiff,

19 v.

20 MEDTRONIC, INC.,

21 Defendant.

Case No. C-95-3577 DLJ

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**MEDTRONIC, INC.'S NOTICE OF
MOTION AND MOTION TO MODIFY
INJUNCTION AFTER OCTOBER 29,
2008; MEMORANDUM OF POINTS AND
AUTHORITIES IN SUPPORT THEREOF**

Date: September 19, 2008
Time: 2:00 p.m.
Courtroom: 1, 4th Floor
Judge: Hon. D. Lowell Jensen
Senior Judge

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NOTICE OF MOTION AND MOTION

TO ALL PARTIES HEREIN AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that on September 19, 2008 at 2:00 p.m., or as soon thereafter as counsel may be heard in the above-captioned Court, Medtronic, Inc. (“Medtronic”) will, and hereby does, move this Court pursuant to Federal Rule of Civil Procedure 60(b) for an order modifying the injunction entered in this case on May 17, 2000 (“Falcon injunction”).

Medtronic asks the Court to exercise its broad equitable authority under Rule 60(b)(5) to order the Falcon injunction dissolved as of October 29, 2008. This motion is based upon this Notice of Motion and Motion, the Memorandum of Points and Authorities attached hereto, all other pleadings and papers on file in this action, and whatever oral argument the Court may hear.

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

Medtronic seeks relief under Federal Rule of Civil Procedure 60(b)(5) from the prospective application of an injunction entered by the Court on May 17, 2000 and scheduled to expire on October 29, 2008. The Court entered the injunction after ruling that Medtronic’s Falcon delivery system for certain medical devices infringed a single claim of U.S. Patent No. 5,451,233 (“Yock patent”), owned at that time by plaintiff Advanced Cardiovascular Systems, Inc (“ACS”). By its terms, the injunction will dissolve when the Yock patent expires on October 29, 2008, or “other legal expiration of the ‘233 patent.” Abbott Laboratories (“Abbott”), the successor-in-interest to plaintiff ACS, has now sought to extend the Yock patent, under the Hatch-Waxman Act amendments to the Patent Act, 35 U.S.C. §156, *et seq.*, thereby attempting to extend the injunction as well. *See* Declaration of Hieu H. Phan (“Phan Decl.”), ¶ 2, Ex. 1.

The medical devices at issue here are stents and angioplasty balloons, which cardiologists use to help eliminate severe arterial blockages that previously required invasive surgery. There are two relevant stent varieties: drug-eluting stents (“DES”) and bare-metal stents (“BMS”). DESs are marketed and sold commercially as a single product made up of four components: (1) a stent, which is a small, expandable metal cylinder, coated with (2) a drug that is released over a specific period of time and helps prevent further arterial plaque from collecting where the stent is

1 located. The drug is coated with a mixture of the drug and (3) a polymer. Cardiologists do not
2 perform open-heart surgery to implant DESs, but instead use (4) a delivery system that usually
3 enters the body near the groin and routes the stent, drug, and polymer through the vasculature to
4 the blockage. There are three major types of delivery systems used with DESs: rapid-exchange,
5 over-the-wire, and multi-exchange. Rapid-exchange is widely considered the best and is used in
6 approximately 80% of all procedures. The Yock patent claims a rapid-exchange delivery
7 system, and none of the other elements of a DES, or for that matter a BMS or balloon catheter
8 (which is composed of a stent and delivery system alone, with no drug or polymer).

9 Medtronic respectfully requests that the Court preclude the Yock patent from being
10 extended and to exercise its broad equitable authority under Rule 60(b)(5) to order the Falcon
11 injunction dissolved as of October 29, 2008. *See Amado v. Microsoft Corp.*, 517 F.3d 1333,
12 1360-61 (Fed. Cir. 2008). Medtronic brings this motion now because an extension of the Yock
13 patent and the Falcon injunction would adversely and irreparably harm Medtronic. Currently,
14 the FDA has approved two Medtronic products for use with a rapid-exchange delivery system:
15 (1) Endeavor DES and (2) Driver BMS.¹ Phan. Decl., ¶¶ 3-4, Exs. 2-3. Medtronic intends to
16 market commercially and sell these two products with a rapid-exchange delivery system after the
17 Yock patent expires on October 29, 2008, as Medtronic advised Abbott via letter on May 28,
18 2008. Phan Decl., ¶ 6, Ex. 5. Extension of the Yock patent and Falcon injunction would
19 jeopardize Medtronic's marketing and sale of these products.

20 There are four independent reasons why the Falcon injunction should be dissolved as of
21 October 29, 2008:

22 (1) The Hatch-Waxman Act and the patent term extension provisions of 35 U.S.C. § 156
23 provide for patent term extensions in limited circumstances, where the patented product has been
24 subject to regulatory review. The plain language of 35 U.S.C. § 156(a) requires that the Yock
25 patent must "claim[]" the "product" that was subject to review. *Hoechst-Roussel Pharm. Inc. v.*

26 _____
27 ¹ Medtronic is also in the process of obtaining FDA approval for use of rapid-exchange delivery
28 systems with its Micro-Driver (a bare metal stent system), NC Sprinter (a balloon catheter), and
Sprinter Legend (a balloon catheter) products. Phan Decl., ¶ 5, Ex. 4.

1 *Lehman*, 109 F.3d 756, 758-759 (Fed. Cir. 1997). Here, the approved product is Abbott's Xience
2 DES, which, like any other DES, is composed of a stent, a drug coating, a polymer, and a
3 delivery system. The Yock patent claims only one component of Xience DES – the delivery
4 system. Because the Yock patent does not claim the Xience DES “product,” the Yock patent is
5 ineligible for a patent term extension.

6 (2) As courts have repeatedly recognized, the purpose of the extension provided for in
7 the Hatch-Waxman Act is to compensate patent holders for the portion of a patent term during
8 which they cannot market and sell their patented invention due to the regulatory review process.
9 *See, e.g., Proveris Scientific Corp. v. Innovasystems, Inc.*, No. 2007-1428, 2008 WL 2967100, at
10 *3 (Fed. Cir. Aug. 5, 2008). But Abbott and its predecessors-in-interest to the Yock patent have
11 never been held up from commercially marketing and offering for sale their patented invention
12 because the rapid-exchange delivery system alone has never been the basis for regulatory review.
13 The Yock patent's owners have without constraint commercially exploited their rapid-exchange
14 delivery system throughout the Yock patent's life, by offering for sale at least five distinct
15 products with a rapid-exchange delivery system. In addition, the Yock patent's owners have
16 licensed the Yock patent to at least two other entities, which have sold at least nine product
17 families that incorporate the rapid-exchange delivery system. The Yock patent has also been
18 enforced against Medtronic since May, 2000, *prior to and throughout* the FDA approval process
19 on Xience.

20 (3) Even if the Yock patent were found eligible for extension, the scope of enforcement
21 of the Yock patent during its extended period must be limited to DESs identical to Xience DES.
22 Under 35 U.S.C. § 156(b)(1), the rights derived from the Yock patent during the extended period
23 should “be limited to any use approved for the product.” The Federal Circuit has held that the
24 “restoration period of the patent does not extend to all products protected by the patent but only
25 to *the product* on which the extension was based.” *Merck v. Kessler*, 80 F.3d 1543, 1547 (Fed.
26 Cir. 1996) (emphasis added). Thus, the scope of any Yock patent extension would extend only
27 to the Xience product itself, or products identical to Xience DES. Endeavor DES could never be
28 deemed a product identical to Xience DES because it employs a different stent, a different drug,

1 and a different polymer than Xience DES. Driver BMS is even further from being “identical” to
2 Xience DES, because it is of course not a DES product at all.

3 (4) Irrespective of the Yock patent’s eligibility for patent term extension, or the scope of
4 such an extension, prospective application of the injunction beyond October 29, 2008 would be
5 inequitable. Abbott has received the full benefit of the Yock patent since issuance. Physicians
6 strongly prefer stents with rapid-exchange delivery systems. Federal regulators have found DES
7 products, in particular, confer enormous public benefit. Phan Decl., ¶ 7, Ex. 6 (FTC Analysis of
8 Agreement Containing Consent Order to Aid Public Comment, *In the Matter of Boston Scientific*
9 *Corp. and Guidant Corp. File No. 061 -0046* at 2). PTE applications can take two or more years
10 to resolve and interim applications are generally subject to only a facial pro forma review. Phan
11 Decl., ¶ 8, Ex. 7; Declaration of Professor R. Carl Moy (“Moy Decl.”) ¶¶ 9, 11. During this
12 period, permitting Medtronic to market and sell Endeavor RX (let alone the completely-distinct
13 bare-metal stents and balloon catheters) would increase competition in the U.S. market and
14 provide more choices for physicians who utilize life-saving stent products.

15 II. BACKGROUND

16 A. **Treating physicians prefer rapid-exchange delivery systems incorporated into** 17 **stents.**

18 A DES is a medical device typically consisting of a thin, metallic stent coated with an
19 antiproliferative drug and a polymer, mounted on a delivery system. Phan Decl., ¶ 7, Ex. 6 (FTC
20 Analysis of Agreement Containing Consent Order to Aid Public Comment, *In the Matter of*
21 *Boston Scientific Corp. and Guidant Corp. File No. 061 -0046* at 2). Interventional cardiologists
22 use DESs to treat coronary-artery disease, a condition caused by the build-up of plaque deposits
23 within one or more coronary arteries, leading to reduced blood flow and, if untreated, death. *Id.*
24 DESs work by opening up and scaffolding the clogged artery or arteries and eluting a drug,
25 which helps prevent the renarrowing of the artery, called restenosis. *Id.* DESs are the most
26 effective minimally-invasive method for treating coronary artery disease, and other products and
27 procedures are not economic substitutes for DESs. *Id.* DESs are sold as a unitary product in a
28 single package, with the drug and polymer loaded onto the stent, which is itself mounted on a

1 delivery system used to maneuver the stent through the patient's body to the blocked area of the
2 coronary artery. *Id.*

3 Of the three types of delivery systems, the most common are over-the-wire and rapid-
4 exchange. *Id.* Rapid-exchange delivery systems are strongly preferred by physicians in the
5 United States and account for roughly 80% of the market. Declaration of Brian Donlon
6 ("Donlon Decl."), ¶ 4. Abbott owns the patent rights to the rapid-exchange delivery system and
7 has provided licenses to Boston Scientific Corporation ("BSC") and Johnson & Johnson ("J&J").
8 Phan Decl., ¶ 9, Ex. 8 & ¶ 7, Ex. 6 at 5.

9 **B. The Falcon catheter litigation and injunction.²**

10 The Yock patent was issued to Paul G. Yock on September 19, 1995, and is set to expire
11 on October 29, 2008. The Yock patent is an apparatus patent that addresses rapid-exchange
12 delivery systems for performing coronary angioplasty. Yock originally licensed his patent to
13 ACS, a unit of Guidant Corporation ("Guidant").

14 On October 10, 1995, ACS filed a complaint against Medtronic, alleging that
15 Medtronic's Falcon catheter delivery system infringed, *inter alia*, claim 3 of the Yock patent. In
16 brief, claim 3, like the other Yock patent claims, covers specific features of a rapid-exchange
17 delivery system, and not the features of the accompanying stent, drug, or polymer. Phan Decl.,
18 ¶ 10, Ex. 9. Medtronic had begun marketing and selling the Falcon catheter prior to the issuance
19 of the Yock patent, and stopped selling it early in 1999.

20 On August 25, 1999, the Court granted ACS summary judgment, holding that the Yock
21 patent was valid and enforceable, and that Medtronic's Falcon catheter infringed claim 3 of the
22 patent. *Advanced Cardiovascular Sys., Inc. v. Medtronic, Inc.*, 81 F. Supp. 2d 978 (N.D. Cal.
23 1999). After a jury trial on damages, the Court entered judgment on May 17, 2000 and enjoined
24 Medtronic from the manufacture, use, offer for sale, or sale within the United States of the

25 _____
26 ² For a complete factual and procedural background, Medtronic refers the Court to its summary-
27 judgment order of August 25, 1999, *Advanced Cardiovascular Sys., Inc. v. Medtronic, Inc.*, 81 F.
28 Supp. 2d 978 (N.D. Cal. 1999), and final judgment of May 17, 2000, *Advanced Cardiovascular
Sys., Inc. v. Medtronic, Inc.*, No. C-95-3577 (N.D. Cal. May 17, 2000) (judgment). (Phan Decl.,
¶ 11, Ex. 10).

1 Falcon catheter and “any colorable variation” that infringes claim 3 of the Yock patent. Phan
2 Decl., ¶ 11, Ex. 10 at 2. The injunction was to operate until October 29, 2008, “or other legal
3 expiration of the [Yock] patent.” *Id.*

4 Abbott acquired Guidant’s vascular business, which included the Yock patent, in April
5 2006, because the Federal Trade Commission (“FTC”) required Guidant to divest the business
6 following its merger with BSC. Phan Decl., ¶ 7, Ex. 6 (FTC Analysis of Agreement Containing
7 Consent Order to Aid Public Comment, *In the Matter of Boston Scientific Corp. and Guidant*
8 *Corp. File No. 061 -0046* at pp. 4-5). The FTC concluded that the Guidant/BSC merger would
9 cause significant competitive harm in the market for DESs by eliminating Guidant as the only
10 potential competitor to BSC and J&J with the ability to offer a DES with a rapid-exchange
11 delivery-system component. *Id.* at 2-3. The FTC emphasized that physicians strongly prefer
12 rapid-exchange delivery systems, which continue to increase in popularity, and concluded that
13 “[u]nless remedial action is taken,” the merger “would deprive customers of the benefits of a
14 third fully competitive entrant in the U.S. DES market” with access to the rapid-exchange
15 delivery system. *Id.* at 3. That reduced competition would “decrease[] the number of potential
16 DES suppliers with access to the RX delivery system from three to two until at least late 2008,
17 when Guidant’s key patents relating to the RX delivery system begin to expire.” *Id.*

18 **C. The development and approval of Abbott’s Xience V and Medtronic’s Endeavor**
19 **coronary-stent-system rapid-exchange products.**

20 **1. Abbott’s Xience V coronary-stent system.**

21 Abbott’s Xience V coronary-stent system has undergone a regulatory review period
22 before the FDA, beginning on May 4, 2005, and concluding on July 2, 2008.³ Phan Decl., ¶ 2,
23 Ex. 1 at 11 & ¶ 13, Ex. 11. The FDA reviewed the Xience system as a medical device under 21
24 U.S.C. § 515. Previously, the Xience system received regulatory approval from the European
25 Commission in October 2006. Abbott has supplied a private-label version of the Xience system
26 to Boston Scientific for sale outside of the United States, called the Promus Everolimus-Eluting
27 Coronary Stent System, as part of a distribution agreement entered between the companies in

28 ³ Pursuant to 35 U.S.C. § 156(g)(3)(B), a “regulatory review period” begins on the effective date

1 2006. The Promus/Xience system has been sold in 64 countries other than the United States
2 since 2006, and is now sold in the United States.

3 Abbott has applied for a patent term extension under 35 U.S.C. § 156 based on the period
4 Xience DES was subject to FDA review. Phan. Decl., ¶ 2, Ex. 1. As described in Abbott’s PTE
5 application, the “product” for purposes of 35 U.S.C. § 156 is Xience DES, a medical device
6 composed of four separate components: (1) a metal, balloon-expandable stent; (2) a drug; (3) a
7 polymer coating; and (4) a delivery system. *Id.*, ¶ 2, Ex. 1 at 2; Declaration of Dr. Josiah N.
8 Wilcox (“Wilcox Decl.”), ¶3. As sold, the metal stent coated with the drug and polymer is
9 mounted on a particular balloon-catheter delivery system and packaged and sold to physicians
10 for use in treating patients with coronary-artery disease. Thus, in order for a doctor to select a
11 particular delivery system for each product, the system must be purchased as assembled with that
12 particular delivery system. Wilcox Decl., ¶4. The Xience system is approved for use and sold
13 with either of two delivery systems: over the wire or rapid-exchange.⁴ Phan Decl., ¶ 2, Ex. 1 at
14 2 The Yock patent covers Abbott’s rapid-exchange delivery system, among others.

15 Xience DES’s primary components—the stent and drug—have been previously offered
16 commercially for sale. Xience’s stent component is a cobalt chromium alloy stent that has been
17 previously approved for use without a drug, and was sold as Abbott’s Multilink Vision bare-
18 metal stent. Wilcox Decl., ¶10. Xience’s drug component is a drug, known as “Everolimus,”
19 developed by Novartis Pharmaceutical Corporation and previously sold by Novartis since 2004
20 under the trade name “Certican[®]” as an injectable drug for use in preventing heart and kidney
21 transplant rejection. Abbott obtains the Everolimus drug component for the Xience system from
22 Novartis. *Id.*, ¶11. The drug component is applied to the stent while mixed with a polymer
23 component, where the polymer acts as a time-release that releases the drug into the patient’s
24 tissue over a period of 120 days. Wilcox Decl., ¶¶ 12-13.

25
26 of the investigational device exemption (“IDE”).

27 ⁴ “RX” was originally a trade name used to describe the rapid-exchange delivery system that the
28 Yock patent claims. RX is, however, not the only such trade name used to describe a rapid-
exchange delivery system that the Yock patent claims—other such trade names include
“Monorail” and “Single Operator Exchange (SOE).” Phan Decl., ¶ 14.

1 On July 25, 2008, Abbott filed an application with the PTO under 35 U.S.C. § 156(d)(1)
2 for an extension of the Yock patent based on the FDA's approval of Xience. As of the date of
3 this filing, the PTO website did not reflect that Abbott had applied for an interim term extension
4 of the Yock patent under 35 U.S.C. § 156(e)(2). It is very likely, however, that Abbott will apply
5 for an interim extension as a full PTE application can take two or more years to resolve and the
6 Yock patent will be expiring soon. See Phan Decl., ¶ 8, Ex. 7. Abbott's application for an
7 extension of the Yock patent improperly seeks to continue to extend the Falcon injunction
8 beyond its natural term, and thereby continue to enjoin Medtronic from making, using, offering
9 for sale, or selling stents with rapid-exchange delivery systems in the United States, and to
10 prevent Medtronic from further penetrating the DES market in the United States.

11 **2. Medtronic's Endeavor stent system**

12 Medtronic's Endeavor® Drug-eluting Stent System has undergone its own independent
13 FDA regulatory review and was approved for sale in the United States on February 1, 2008.
14 Wilcox Decl., ¶¶ 16-18. Like Abbott's Xience stent system, Endeavor has four components: (1)
15 a metal, balloon expandable stent (previously sold as Medtronic's Driver stent); (2) a drug
16 component, known as zotarolimus (which Medtronic obtains from Abbott); (3) a polymer
17 coating (which Medtronic obtains from Abbott); and (4) a delivery system. *Id.*, ¶¶ 3 & 19-23.
18 Both the stent (Driver) and the drug (zotarolimus) used in Endeavor differ from those used in
19 Xience. Medtronic's polymer coating also is a different material, and serves a different purpose,
20 than the polymer coating used with Xience. Medtronic's Endeavor stent releases all of the
21 zotarolimus drug into the patient's tissue in less than fourteen days after implantation. *Id.*, ¶ 22.

22 The Endeavor stent system was reviewed and approved for use by the FDA with three
23 different delivery systems: over-the-wire, rapid-exchange, and multi-exchange. *Id.*, ¶ 23. Once
24 the Endeavor system can be sold with the rapid-exchange delivery system, Medtronic's DES
25 sales and relative market share will increase. Donlon Decl., ¶ 6.

26 **D. The Hatch-Waxman Act.**

27 The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-
28 417, 98 Stat. 1585 (1984) (commonly known as the Hatch-Waxman Act) provides for a limited

1 extension of the term of a patent for a drug or medical device for which marketing and sales were
2 held up during the patent term by the process of obtaining FDA approval. *See Merck*, 80 F.3d at
3 1546. The patent term restoration portion of the legislation was codified in 35 U.S.C. § 156,
4 which reads in pertinent part:

5 (a) The term of a patent which **claims a product**, a method of using a product, or
6 a method of manufacturing a product shall be extended in accordance with this
7 section from the original expiration date of the patent, which shall include any
8 patent term adjustment granted under section 154(b), if--

9 (1) the term of the patent has not expired before an application is submitted under
10 subsection (d)(1) for its extension;

11 (2) the term of the patent has never been extended under subsection (e)(1) of this
12 section;

13 (3) an application for extension is submitted by the owner of record of the patent
14 or its agent and in accordance with the requirements of paragraphs (1) through (4)
15 of subsection (d);

16 (4) **the product has been subject to a regulatory review period before its
17 commercial marketing or use;**

18 (5)(A) except as provided in subparagraphs (B) or (c), **the permission for the
19 commercial marketing or use of the product after such regulatory review⁵
20 period is the first permitted commercial marketing or use of the product**
21 under the provision of law under which such regulatory review period occurred.

22

23 The product referred to in paragraphs (4) and (5) is hereinafter in this section
24 referred to as the "approved product".

25 (b) Except as provided in subsection (d)(5)(F), the rights derived from any patent
26 the term of which is extended under this section shall during the period during
27 which the term of the patent is extended--

28 (1) **in the case of a patent which claims a product, be limited to any use
approved for the product—**

(A) before the expiration of the term of the patent--

(i) under the provision of law under which the applicable regulatory review

⁵ Under 35 U.S.C. § 156(g)(3)(B), a "regulatory review period" for a medical device includes only "premarket approval" ("PMA") under section 515 of the Federal Food, Drug, and Cosmetic Act ("FFDCA"). *See also In re Nitinol Medical Technologies, Inc.*, 17 U.S.P.Q.2D (BNA) 1492, 1493 (Comm'r Patents 1990) ("Congress clearly intended that the medical device be approved for marketing under a regulatory review having a testing phase and an approval phase under section 515 of the FFDCA to be eligible for patent term extension."). The FDA review associated with a PMA supplement does not qualify as a "regulatory review period" under § 156. *See* 35 U.S.C. § 156(g)(3)(B).

1 occurred, or

2 (ii) under the provision of law under which any regulatory review described in
3 paragraph (1), (4), or (5) of subsection (g) occurred, and

4 (B) on or after the expiration of the regulatory review period upon which the
5 extension of the patent was based.

6 35 U.S.C. § 156(a)(1)-(b)(1) (emphasis added). While the Hatch-Waxman Act was enacted (and
7 drafted) with pharmaceutical products in mind, the benefits of patent term extension also apply
8 to medical devices. See 35 U.S.C. § 156(f)(1)(B); *Eli Lilly & Co. v. Medtronic, Inc.*, 872 F.2d
9 402, 405 (Fed. Cir. 1989).

10 The Hatch-Waxman Act was designed “to respond to two unintended distortions” of the
11 patent term produced by the requirement that certain products must receive premarket regulatory
12 approval. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669 (1990). *First*, it eliminated a
13 pre-1984 requirement that a company seeking to market a generic version of a patented drug had
14 to conduct its own testing program, which requirement had artificially lengthened the monopoly
15 afforded by the patent while the generic underwent regulatory approval post-expiration. *Id.* at
16 670; see also *Merck*, 80 F.3d at 1547. *Second*, the Act extends the patent term for the approved
17 product for the period during which, because of FDA regulatory review, the patent holder could
18 derive no benefit from the patent. *Eli Lilly*, 496 U.S. at 669-670. This corrects the “distortion”
19 that results because patent holders, as a practical matter, cannot “reap any financial rewards
20 during the early years of the term . . . if the discovery relates to a product that cannot be
21 marketed without substantial testing and regulatory approval [such that] the ‘clock’ on his patent
22 term will be running even though he is not yet able to derive any profit from the invention.” *Id.*

23 A patentee who files an application under Section 156 for patent term extension can also
24 receive an interim extension pending final determination, under subsection 156(e)(2):

25 If the term of a patent for which an application has been submitted under
26 subsection (d)(1) would expire before a certificate of extension is issued or denied
27 under paragraph (1) respecting the application, the Director *shall extend*, until
28 such determination is made, the term of the patent for periods of up to one year if
he determines that the patent is eligible for extension.

Such interim extensions are routinely allowed because the PTO determines the eligibility of a
patent for interim extension based on the representations made by the applicant on the face of the

1 application. Moy Decl., ¶¶ 9, 11. In other words, the PTO conducts a pro forma, facial review
2 of the application. *Id.* If the PTO later determines that a patent is not eligible for extension, any
3 interim extensions previously granted are void *ab initio*. *Id.*, ¶ 8.

4 The conclusion that the PTO determines that a patent is “eligible for extension” on the
5 basis of a pro forma, facial review is supported by the letter the PTO sent to the FDA only five
6 days after Abbott filed for patent term extension of Yock. Phan Decl., ¶ 15, Ex. 12. In the letter,
7 the PTO admits that it “has *not* made a determination of whether the [Yock] patent ... claims a
8 product which has been subject to the Federal Food, Drug and Cosmetic Act.” *Id.* (emphasis
9 added). Yet, at the same time, the PTO concludes that its “review of the application to date
10 indicates that the subject patent would be eligible for extension of the patent term under 35
11 U.S.C. § 156.” *Id.*

12 III. ARGUMENT

13 A. Federal Rule of Civil Procedure 60(b) affords great discretion to the Court in 14 modifying or terminating its final judgments.

15 “The power of a court of equity to modify a decree of injunctive relief is long-
16 established, broad, and flexible.” *New York State Ass’n for Retarded Children, Inc. v. Carey*,
17 706 F.2d 956, 967 (2d Cir. 1983); *see also Amado*, 517 F.3d at 1358-59. Rule 60(b) codifies and
18 makes explicit this traditional principle that courts are vested with continuing equitable authority
19 to modify or vacate their final judgments. *See Bellevue Manor Assocs. v. United States.*, 165
20 F.3d 1249, 1252 (9th Cir. 1999). Rule 60(b) provides that “[o]n motion and upon such terms as
21 are just, the court may relieve a party . . . from a final judgment, order, or proceeding . . . [if] it is
22 no longer equitable that the judgment should have prospective application.” Fed. R. Civ. P.
23 60(b)(5). “Due to the equitable nature of injunctive relief, district courts have wide discretion to
24 determine under what circumstances the grant of injunctive relief is appropriate, and under what
25 circumstances the modification or dissolution of that injunctive relief is warranted.” *Amado*, 517
26 F.3d at 1360-1361 (internal citation omitted). The standard is “flexible” and the Ninth Circuit
27 has directed courts to “take all the circumstances into account in determining whether to modify
28 or vacate a prior injunction or consent decree.” *Bellevue Manor Assocs.*, 165 F.3d at 1256.

1 **B. The Yock patent is ineligible for extension under 35 U.S.C. § 156(a) because the**
2 **patent does not claim the product that was the subject of regulatory review.**

3 The Yock patent will expire by its natural term on October 29, 2008, and Medtronic will
4 be free to practice claim 3 of the patent (*i.e.*, sell its products in the United States with the rapid-
5 exchange delivery system) unless Abbott is allowed to unfairly extend the Court's injunction by
6 extending the Yock patent's term, whether by a final patent term extension or by an interim
7 patent term extension that may later be void *ab initio*. Abbott has applied for a patent term
8 extension under 35 U.S.C. § 156 based on the period its Xience DES was subject to FDA review.

9 Certain requirements must be met for a patent's term to be extended under the Hatch-
10 Waxman Act. Foremost among them, the patent must *claim a product* that was subject to
11 regulatory review:

- 12 (a) The term of a patent *which claims a product*, a method of using a product, or a
13 method of manufacturing a product shall be extended in accordance with this section
14 from the original expiration date of the patent, which shall include any patent term
15 adjustment granted under section 154(b). . .

16 35 U.S.C. § 156(a) (emphasis added). The Yock patent is ineligible for term extension under
17 Section 156(a) because it does not *claim* the approved product, Xience, but merely one of two
18 alternative delivery-system components approved for use with Xience.

19 In *Hoechst*, 109 F.3d at 758-759, the Federal Circuit squarely addressed what the term
20 "claims" means in the context of 35 U.S.C. § 156(a), and held that a patent must claim the
21 product subject to FDA approval to be eligible for term extension. The plaintiff in *Hoechst* had
22 argued that a patent is eligible for extension if the predicate FDA-approved product merely
23 infringes a claim of the patent. The Federal Circuit disagreed. After reviewing the statutory
24 language of § 156(a) and the legislative history of the Hatch-Waxman Act, the Court explained
25 that the plain meaning of "claims" is not the same as "infringement" and concluded:

26 [G]iven the distinction between a 'claim' and its infringement, had Congress
27 intended the usage urged by Hoechst, it could have drafted section 156(a) to make
28 that intention more clear than appears from the language actually chosen. For
29 example, Congress could have drafted section 156(a) to recite: "The term of a
30 patent which claims a product, a method of using a product, or a method of
31 manufacturing a product *which claim is infringed by an FDA-approved product,*
32 *use of an FDA-approved product, or manufacture of an FDA-approved product*
33 *shall be extended...*"

1 *Hoechst*, 109 F.3d at 760 (bold emphasis added). The Court emphasized that “[s]uch a statute
2 would clearly indicate that the patent need not claim the FDA-approved product or a method of
3 using an FDA-approved product; rather, it need only claim a product or method of using that
4 product, so long as that claim is infringed by the FDA-approved product or its use. Instead,
5 Congress chose to require that the patent, itself, **claim** the FDA-approved product or its use.” *Id.*
6 at 760-761 (citations omitted and emphasis added). Accordingly, the Court held that in the
7 context of § 156, “claims” means that a patent must claim the entire product subject to regulatory
8 review—just as an inventor “claims” his or her inventions—to be eligible for extension.⁶ *Id.* at
9 758-60. In other words, a product that merely infringes a claim of the patent cannot qualify;
10 rather, the patent *must claim* the product that was subject to regulatory review.

11 Although *Hoechst* addressed patent term extension for a drug product and not a medical
12 device, the Federal Circuit’s analysis does not distinguish between the two. The Court focused
13 on how the term “claims” was used in § 156 and determined that the plain language of the statute
14 and its legislative history supported the conclusion that “claims” is to be given its ordinary
15 meaning in the patent law. Thus, *Hoechst*’s holding that “claims” in § 156(a) does not mean
16 “infringed by” equally applies to a case concerning drugs or medical devices and is applicable to
17 the case at bar.⁷ Indeed, the only Federal Circuit case to apply § 156 to a medical device
18 supports the view that a patent must “claim” (not merely be infringed by) an FDA-approved
19 product to be eligible for term extension. *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*
20 involved a patentee who had licensed its defibrillator patent to two other companies that sold
21 their own separately approved defibrillators. 381 F.3d 1371, 1384 (Fed. Cir. 2004). The patent
22 holder later developed its own defibrillator, sought its own FDA approval, and later applied for a
23 patent term extension based on the regulatory review period for its own product. *Id.* The Court

24 _____
25 ⁶ The Court further held that “the term ‘claims’ has been used in patent legislation since the
26 Patent Act of 1836 to define the invention that an applicant believes is patentable;” that is, the
27 claims “define[] the patent owner’s property rights.” *Hoechst*, 109 F.3d at 758.

28 ⁷ Indeed, a later district-court decision, *Mylan Pharmaceuticals v. Thompson*, reviewed the
29 *Hoechst* court’s analysis of the statutory language and legislative history of Section 156 and
30 concluded that “the Federal Circuit’s interpretation of the word ‘claims’ in Section 156—an
31 interpretation based entirely on plain meaning—is **compelling authority**.” 139 F. Supp. 2d 1, 21
(D.D.C. 2001) (emphasis added).

1 affirmed the patent term extension, a decision consistent with *Hoechst* because the *Cardiac*
2 *Pacemakers* patent in fact claims the entire approved defibrillator “product.” See Phan Decl.,
3 ¶ 16, Ex. 13.

4 **1. Two separate federal administrative authorities affirm that the Yock**
5 **patent’s term cannot be extended based on Xience.**

6 The Manual of Patent Examining Procedure (MPEP) supports the *Hoechst* holding.⁸
7 MPEP § 2751, which governs the eligibility requirements for patent term extension, explains that
8 “[a]s required by 35 U.S.C. 156(a), patents eligible for extension of patent term are those which:
9 (A) *claim* a ‘product’ as defined in 35 U.S.C. 156(f)(1).” MPEP, 8th Ed., 6th Rev., § 2751
10 (September 2007) (emphasis added). MPEP § 2751 further clarifies that “[t]he term ‘claims a
11 product’ is not synonymous with ‘infringed by a product,’” citing *Hoechst*. The MPEP thus
12 makes plain that it is not sufficient for purposes of a patent term extension for an FDA-approved
13 product merely to infringe a patent; the patent must *claim* the product.

14 Title 37 of the Code of Federal Regulations (“CFR”), which codifies the rules and
15 regulations of the PTO, also supports the meaning of “claims a product” as used in 35 U.S.C. §
16 156(a). Multiple sections of Title 37 of the CFR track § 156(a)’s statutory language and require
17 that a patent “claim” (not merely be infringed by) an FDA-approved product to be eligible for
18 term extension. See, e.g., 37 C.F.R. § 1.710(a) (“A patent is eligible for extension of patent term
19 if the patent *claims* a product ... and meets all other conditions and requirements of this
20 subpart.”) (emphasis added); 37 C.F.R. § 1.740(9)(a) (requiring “[a] statement that the patent
21 claims the approved product, or a method of using or manufacturing the approved product”).

22 **2. The FDA’s regulatory-review procedure also demonstrates that the Yock**
23 **patent cannot be extended based on Xience.**

24 The FDA review of Xience was not based upon the rapid-exchange delivery system
25 described in the Yock patent. Rather, the review was based upon the stent and the drug coating,
26 neither of which the Yock patent addresses.

27 ⁸ The MPEP is a manual for patent agents and patent examiners published by the PTO that
28 describes all of the laws and regulations that must be followed in the examination of U.S. patent
applications. See <http://www.uspto.gov/web/offices/pac/mpep/documents/foreword.htm>.

1 The FDA is charged with determining whether a product should be approved for
2 commercial marketing and use, and the FDA must approve a product before it can become the
3 basis for a patent term-extension application. Under the FDA's rules, a "combination product"⁹
4 like Xience is reviewed based on the product's "primary mode of action" (*i.e.*, "the single mode
5 of action that provides the most important therapeutic action of the combination product").¹⁰ 21
6 C.F.R. §§ 3.4(a) & 3.2(m). Specifically, for a medical device to serve as the basis for a patent
7 term-extension, the device must have received FDA "premarket approval"¹¹ – *i.e.*, a "regulatory
8 review period" under § 156 (see footnote 5).

9 The FDA has determined that for a DES system such as Xience, the "primary mode of
10 action" is the stent because it provides the most therapeutic effect, while the drug plays a
11 secondary role. *See* Phan Decl, ¶ 17, Ex. 14 ("FDA has determined ... that the uncoated stent
12 functions to physically maintain vessel lumen patency, while the drug component [plays] a
13 secondary role in preventing restenosis, augmenting the safety and/or effectiveness of the
14 uncoated stent"). The FDA does not consider a DES's delivery system a "mode of action" at all,
15 because the delivery system does not achieve either the therapeutic effects of maintaining vessel-
16 lumen patency or preventing restenosis. Because the delivery system is not a "mode of action"
17 of a DES, it *cannot* be the basis for the FDA's regulatory review, and a patent covering such a
18 component does not 'claim' the product that underwent such regulatory review under 35 U.S.C.
19 §§ 156(a) and (a)(4).¹²

20
21 ⁹ A "combination product" is a product comprised of two or more regulated components, *i.e.*,
22 biological products, devices, and drugs. *See* 21 C.F.R. § 3.2(e)(1).

23 ¹⁰ A "mode of action" is "the means by which a product achieves an intended therapeutic effect
24 or action." 21 C.F.R. § 3.2(k).

25 ¹¹ Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate
26 the safety and effectiveness of medical devices such as DESs. It is "the most stringent type of
27 device marketing application required by FDA." <http://www.fda.gov/cdrh/devadvice/pma/>. "An
28 approved PMA is, in effect, a private license granting the applicant (or owner) permission to
market the device." *Id.* A PMA supplement seeks approval for a change or modification to a
previously-approved PMA. *See* 21 C.F.R. § 814.3.

¹² This conclusion is further supported by the fact that a company whose stent product received
original PMA without a certain delivery system, *e.g.* RX, may later add that delivery system to
the product by filing merely a PMA supplement and is not required to go through the filing of a
new original PMA. *See* Phan Decl. ¶ 4, Ex. 3, ¶ 5, Ex. 4 & ¶ 21, Ex. 17. Such was the case for
ACS's Simpson-Robert Coronary Dilatation Catheter, Phan Decl. ¶ 21, Ex. 17 (PMA supplement

1 The PTO has denied patent term extension applications in similar cases where the patent
2 only claimed the polymer component in a drug product and not the active ingredient that
3 provided the “mode of action” of the drug.¹³ In one such case, the applicant OraPharma sought
4 extension of its patent based on the FDA’s approval of the drug product Arestin, which was
5 composed of PGLA microspheres and minocycline HCl. Phan Decl., ¶ 18, Ex. 15 (OraPharma
6 PTE denial). OraPharma’s patent claimed “microparticles” and the antibiotic “minocycline.”
7 The PTO determined that minocycline HCl was the active ingredient of Arestin, not the PGLA
8 microspheres (which were just a polymer combined with the active ingredient minocycline HCl)
9 because “PGLA is not understood to furnish a pharmacological activity or other direct effect in
10 [the] body of humans or animals” (*i.e.*, the PGLA microspheres were not the “mode of action”
11 since they had no therapeutic effect). *Id.* The microspheres therefore could not be the active
12 ingredient/mode of action that was the basis for the FDA’s review of Arestin. Similarly, the RX
13 delivery system is not a “mode of action” and was not the basis for the FDA’s review of

14
15 to add the RX delivery system), and Medtronic’s Driver Stent System, Phan Decl. ¶ 4, Ex. 3
16 (PMA supplement to add the MX2 delivery system). Medtronic has also filed PMA supplements
17 to obtain FDA approval for the use of rapid-exchange delivery systems in its Micro-Driver, NC
18 Sprinter and Sprinter Legend products. Phan Decl., ¶ 5, Ex. 4. The FDA review associated with
19 a PMA supplement does NOT qualify as a “regulatory review period” under § 156. *See* 35
20 U.S.C. § 156(g)(3)(B) (“The regulatory review period for a medical device is . . . the date an
21 application was *initially submitted* with respect to the device under section 515”) (emphasis
22 added). Accordingly, if the addition of a delivery system is subject to only a PMA supplement,
23 then FDA review of that delivery system is insufficient to support a patent term extension,
24 because the review does not qualify as a “regulatory review period” under § 156.

25
26
27
28 ¹³ The PTO apparently adopted a different position with respect to medical devices in a February
20, 2008 letter to Congressman Howard L. Berman that addressed how the agency interprets the
patent term extension provisions of the Hatch-Waxman Act. Phan Decl., ¶ 19, Ex. 16. In that
letter, Jefferson D. Taylor, Director of the Office of Governmental Affairs of the PTO, wrote that
the PTO “liberally construes the statutory provision requiring that a patent claim a product” to
mean that a patent claiming a component part of a medical device is eligible for an extension. *Id.*
The PTO’s “liberal” construction of § 156(a) is wrong and should be rejected because it ignores
flatly contradictory authority, including the Federal Circuit’s opinion in *Hoechst*, the USPTO’s
own rules as contained in the MPEP and codified in Title 37 of the CFR, and the FDA’s rules
governing its review of “combination products.” As Mr. Taylor concedes in the letter, “[b]ased
on a strict statutory interpretation of section 156, one may conclude that a patent claiming a
component part of a medical device would not be eligible for extension because the patent did
not claim the product.” *Id.* The PTO’s belief that this was not the intent of the Hatch-Waxman
Act is supported by no authority or reasoning. Moreover, the PTO’s letter indicates that it
believes any problems raised by permitting patents claiming only a component of a medical
device to be extended are remedied by the fact that “any rights during the extended period **are
limited to the product subject to regulatory review.**” *Id.* (emphasis added); *see infra*, at III.D.

1 Xience.¹⁴

2 **C. Extending the Yock patent would contradict the purpose behind the Hatch-**
3 **Waxman Act.**

4 The Hatch-Waxman Act is intended to compensate patent holders for the portion of a
5 patent term during which they cannot market and sell their patented invention due to required
6 regulatory review. *Eli Lilly & Co.*, 496 U.S. at 669-670; *see also Merck*, 80 F.3d at 1547; *Fisons*
7 *v. Quigg*, 8 U.S.P.Q. 2d 1491, 1497 (D.D.C. 1988). In other words, it is intended to return to the
8 patentees a portion of the patent term lost while their patented inventions were under regulatory
9 review. Abbott and its predecessors-in-interest have never been held up from marketing or
10 selling their patented invention, and the Yock patent has not lost a single day of coverage or
11 enforcement.

12 Abbott cannot have it both ways—if the RX delivery-system component of Xience is a
13 sufficient basis for a patent term extension under § 156(a), Abbott’s application must fail under
14 the first-commercial-marketing-or-use provision of § 156(a)(5)(A). This provision requires that
15 the product on which a patent term extension is sought not have been previously marketed or
16 used commercially:

17 the permission for the commercial marketing or use of the product after such
18 regulatory review period is the first permitted commercial marketing or use of the
19 product under the provision of law under which regulatory review period
20 occurred.

21 35 U.S.C. § 156(a)(5)(A). But the RX delivery system has been commercially marketed and
22 used during the entire life of the Yock patent, which of course includes the *entire period* that
23 Xience DES underwent regulatory review, from May 4, 2005 to July 2, 2008. Phan Decl., ¶ 2;
24 Ex. 1 at 11. Extending the Yock patent based on the RX delivery system would thus turn the
25 Hatch-Waxman Act on its head and extend a government-sanctioned monopoly over a product
26 that Abbott and the previous owners of the Yock patent have marketed commercially *even before*

27 ¹⁴ The PTO in the end denied OraPharma’s application for patent term extension because the
28 active ingredient minocycline had previously been approved for commercial marketing and use
of whether a patent must claim the product on which the term extension is sought.

1 *the patent issued.*¹⁵ Abbott and its predecessors-in-interest have collectively sought and received
 2 pre-market approval, a PMA supplement, or both from the FDA to market products that use the
 3 Yock patent's rapid-exchange delivery system **105 times** for **four** different product families over
 4 the last **18 years**:

Product Family	Applicant for first PMA with RX	Date of first PMA with RX	# of PMAs with RX	Phan Decl.,
Simpson-Robert Coronary Balloon Dilatation Catheter	ACS	4/20/1990	65	¶ 21, Ex. 17
ACS Multi-Link Coronary Stent System	Guidant	11/05/1998	33	¶ 22, Ex. 18
FX Minirail RX Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter	Abbott	6/11/2003	2	¶ 23, Ex. 19
Multi-Link RX/OTW Vision Coronary Stent Systems	Abbott	7/16/2003	5	¶ 24, Ex. 20

16 It is safe to assume that Abbott will continue to use the Yock patent's rapid-exchange
 17 delivery system with its current products and those under development. And why not? As
 18 Abbott's predecessor-in-interest ACS acknowledged in another patent filing, the rapid-exchange
 19 delivery system engineered "the biggest reversal of sales in medical device history." *Id.*, ¶ 12 &
 20 ¶ 25, Ex. 21.

21 One of the benefits that the patent monopoly confers on the inventor is the right to license
 22 the patented technology during the patent's term, as a reward for having disclosed the invention.
 23 Abbott has not missed this opportunity—in addition to its own commercial marketing of the
 24 Yock rapid-exchange delivery system, Abbott and its predecessors have also *licensed* the Yock
 25

26 ¹⁵ The Federal Circuit recently stated in *Proveris* that the Hatch-Waxman was intended to
 27 provide patent term extensions for those patentees whose "market entry was delayed pending
 28 regulatory review [because] the early years of the patent term were spent obtaining premarket
 approval for the patented invention rather than generating profits." *Proveris*, 2008 WL 2967100,
 at *3.

1 patent for at least the last eight years to two different companies. *Id.*, ¶ 9, Ex. 8 & ¶ 7, Ex. 6 at 5.
2 The licensees, major medical-device manufacturers J&J/Cordis Corporation (“Cordis”) and BSC
3 have exploited their licenses commercially by seeking 83 PMA approvals and supplements for
4 **nine** different product lines using the Yock patent’s rapid-exchange delivery system, marketed
5 under the trade names “RX,” “Monorail,” or “SOE.” *See* Phan Decl., ¶ 26.

6 Many of the Abbott, ACS, Guidant, J&J/Cordis, Boston Scientific, and SciMed stents
7 that have used the Yock patent’s rapid-exchange delivery system have competed and continue to
8 compete directly with Medtronic products. Donlon Decl., ¶ 3. Further, for nearly eight years
9 Abbott has enjoyed the benefits of the injunction that was issued in this case against Medtronic.
10 Abbott has thus reaped uninterrupted the benefits from its own and its licensees’ having
11 practiced and continuing to practice the Yock patent’s rapid-exchange delivery system. One
12 could hardly expect to find a patent owner less deserving of the benefits the Hatch-Waxman Act
13 was intended to provide.¹⁶

14 **D. Even if the Yock patent were eligible for extension, the extension must be limited to**
15 **Abbott’s Xience product.**

16 In addition to restricting the circumstances under which a patent term may be extended,
17 the Hatch-Waxman Act also restricts the *scope* of a granted extension. The “rights derived”
18 from a patent extended under the Hatch-Waxman Act are, “in the case of a patent which *claims a*
19 *product*, [] limited to any use *approved for the product.*” 35 U.S.C. § 156(b)(1) (emphasis
20 added).

21 Few decisions interpret the language of Section 156(b)(1), and the one Federal Circuit
22 case that explicitly does affirms that the scope of any extension “does not extend to all products

23 ¹⁶ As with its incorrect reading of § 156(a), the PTO similarly errs in interpreting § 156(a)(5)(A)
24 to provide that a patent that covers a component of a previously-marketed-and-approved medical
25 device may qualify for extension, so long as the medical device on which the extension is based
26 is different. *See* Phan Decl., ¶ 19, Ex. 16 (Taylor letter). The PTO recognizes that this is a
27 question in which it lacks competence, because “[t]he determination of whether a product
28 complies with § 156(a)(5)(A) is within the purview of the . . . FDA,” and that “the PTO is not the
best source to answer the question presented.” *Id.* at 2. The USPTO’s view misreads *Cardiac
Pacemakers*, which did not address the issue of whether a patent, such as Yock, that claims only
a component product with no “mode of action” is eligible for term extension under *either* Section
156(a) (“claims a product”) *or* Section 156(a)(5)(A) (first permitted commercial marketing or
use).

1 protected by the patent but only to *the product* on which the extension was based.” *Merck* , 80
2 F.3d at 1547 (emphasis added).¹⁷ The PTO’s rules support the holding in *Merck*:

3 The rights derived from extension of the patent term are *limited to the approved*
4 *product* (as defined in 35 U.S.C. 156(a)(4) and (a)(5)). See 35 U.S.C. 156(b).
5 Accordingly, *if the patent claims other products in addition to the approved*
product, the exclusive patent rights to the additional products expire with the
original expiration of the patent.

6 MPEP, 8th Ed., 6th Rev., § 2750 (September 2007) (emphasis added).

7 Limiting the extension’s scope to *the product* on which the extension is based accords
8 with the purpose of the Hatch-Waxman Act, which is to make a patentee whole, not to reward
9 disproportionately a patentee by extending the patent claiming the approved product to *all*
10 products the patent once covered. The Hatch-Waxman Act was designed to provide a restoration
11 period to a patent for time lost due to delays caused by mandatory FDA review. Thus, the time
12 restored to the patent is roughly equivalent to the amount of time lost in performing FDA-
13 mandated clinical trials and waiting for the FDA to complete the application review process. See
14 35 U.S.C. § 156(g)(3)(B). The patentee is made whole by allowing the patentee the exclusive
15 right to make, use, offer for sale, and sell *the product* subject to regulatory approval, and the time
16 restored roughly is equal to the exclusivity period the original patent would have provided. This
17 restores to the patentee the most fundamental of the “rights derived” from a patent – the right to
18 exclude others from making, using, selling, or offering to sell an embodying product, and
19 enforcing that right via civil litigation. See 35 U.S.C. §§ 271 & 281.

20 Thus, it makes sense that the restored patent term provides for exclusivity only as to the
21 *approved product*. To permit the patentee greater rights would reward the patentee simply for
22 seeking regulatory review. The patent claiming the product under regulatory review remains
23 *fully enforceable* against *all other products* the patent covers during the regulatory review
24 process. A patentee never loses *any* patent rights as to those products. The sole “harm” the
25 patentee suffers during the regulatory process is the lost patent exclusivity with respect to the

26 _____
27 ¹⁷ In *Pfizer, Inc. v. Reddy’s Labs., Ltd.*, 359 F.3d 1361 (Fed. Cir. 2004), the Federal Circuit also
28 applied Subsection 156(b)(1), but based its opinion on a plain reading of “product” under
Subsection 156(f), and did not examine Subsection 156(b)(1).

1 FDA-approved product only. Thus the scope of any legitimate extension is less than the full
 2 scope of the original patent – it is extended as to the approved product only. Even if Yock
 3 claimed Xience (which it does not) and was eligible for extension, the scope of the extension
 4 would be limited to the product which underwent regulatory review. Thus, the scope of any
 5 patent term extension would be limited to the Xience product, which has a distinct drug, design,
 6 and polymer.

7 The inappropriateness of extending the patent term beyond the single approved product is
 8 manifest here. Abbott’s predecessor-in-interest obtained an injunction against Medtronic based
 9 on the Yock patent – an injunction that has remained in effect throughout the entire period that
 10 Xience DES underwent FDA approval (a period during which Abbott continued to market, sell
 11 and license other products utilizing the rapid-exchange delivery system). Abbott has been denied
 12 none of the “rights derived” from the Yock patent beyond simply not being able to market and
 13 sell the Xience *product* during the FDA approval period. Not only was Abbott able to exploit
 14 commercially its RX delivery system throughout the Xience review period, it received the full
 15 exclusivity rights conferred by the Yock patent. Accordingly, it is consistent with the statutory
 16 language and purpose that any rights Abbott derives from a patent term extension should be
 17 limited to the approved uses for *the* product on which the extension was based.

18 Endeavor RX is not identical to “the product” on which the Yock patent would be
 19 extended, Xience DES. As explained in Section C above, drug-eluting stents are composed of
 20 four constituents: (1) the stent; (2) the drug applied to the stent that prevents arterial blockage;
 21 (3) the polymer that binds the drug to the stent; and (4) the delivery system. Wilcox Decl., ¶ 3.
 22 The only shared element between Endeavor RX and Xience DES is the rapid-exchange delivery
 23 system—they differ on all other counts:

Xience DES product	Endeavor RX product
Multi-Link “Vision” stent	“Driver” stent
Everolimus drug	Zotarolimus drug
Two-part polymer: PBMA	Phophorylcholine polymer (14-day

1 2	primer & PVDF-HFP copolymer (120 day drug-release time).	or less drug-release time)
3	Rapid-exchange delivery system	Rapid-exchange delivery system.

4 Two products that share only one of four features are not identical, even under the most
5 charitable interpretation of § 156(b)(1). Thus, even if the term of the Yock patent were to be
6 extended, its scope would not include the Endeavor DES, and most certainly would not include
7 Medtronic's Driver BMS, nor its other, non-DES products for which PMA supplement approvals
8 for use with a rapid-exchange delivery system are pending.

9 **E. Prospective application of the injunction beyond the October 29, 2008 would be**
10 **inequitable.**

11 Even if the Court determines that the Yock patent is eligible for extension *and* that
12 Abbott's enforcement rights cover Endeavor, equity calls for the Court not to extend the
13 injunction beyond October 29, 2008.

14 District courts possess broad equitable authority to modify injunctions. *See Amado*, 517
15 F.3d at 1358. "The power of a court of equity to modify a decree of injunctive relief is long-
16 established, broad, and flexible." *New York State Ass'n for Retarded Children, Inc.*, 706 F.2d at
17 967. Federal Rule of Civil Procedure 60(b) codifies and makes explicit this traditional principle
18 that courts are vested with continuing equitable authority to modify or vacate their final
19 judgments. *See Bellevue Manor Assocs.*, 165 F.3d at 1252. Rule 60(b)(5) provides that "[o]n
20 motion and upon such terms as are just, the court may relieve a party . . . from a final judgment,
21 order, or proceeding . . . [if] it is no longer equitable that the judgment should have prospective
22 application." Fed. R. Civ. P. 60(b)(5).

23 Here, prospective application of the injunction beyond the natural termination of the
24 Yock patent would be inequitable for several reasons. *First*, Abbott would suffer no irreparable
25 harm or undue hardship if the injunction were to expire with the natural expiration of the Yock
26 patent.¹⁸ The only injury that Abbott might suffer from the entry of Medtronic's competing

27
28 ¹⁸ Courts have recognized that in exercising their equitable authority under Rule 60(b)(5),
application of the traditional factors relevant to injunctive relief, including irreparable harm and
balancing hardships, is appropriate. *See Amado*, 517 F.3d at 1360-1361. In *Amado*, the Federal

1 Endeavor rapid-exchange product on the market would be potential lost sales that could be
2 compensated with monetary damages. Abbott is neither a new nor small company seeking to
3 protect its principal product, for whom lost market share could constitute irreparable injury. *See,*
4 *e.g., Tivo, Inc. v. EchoStar*, 446 F. Supp. 2d 664, 668 (E.D. Tex. 2006) (court found irreparable
5 injury where plaintiff was relatively new company with only one primary product in a nascent
6 market such that loss of market share and customer base could cause severe injury); *Praxair, Inc.*
7 *v. ATMI, Inc.*, 479 F. Supp. 2d 440, 443-444 (D. Del. 2007) (court denied injunction where both
8 plaintiff and defendant were large companies with revenues in the hundreds of millions of dollars
9 annually, and where plaintiff failed to present sufficient evidence that money damages
10 inadequate). Abbott itself has stated publicly to its shareholders in a recent Annual Report filed
11 with the Securities and Exchange Commission that it does not believe that the expiration of the
12 Yock patent in 2008 would be “material” to the company. *See* Phan Decl., ¶ 36, Ex. 31 at 32.

13 *Second*, if the injunction were extended beyond the Yock patent’s term, Medtronic would
14 lose a critical opportunity to capture sales from which it has been kept for the past eight years
15 under threat of contempt. Medtronic has refrained from sales of a rapid-exchange delivery
16 system in compliance with the injunction’s terms, and has also spent significant time and money
17 conducting clinical trials and seeking FDA approval for its Endeavor DES. If the injunction
18 were extended, the returns from Medtronic’s investment would be diminished and Medtronic
19 would continue to be excluded from capturing lucrative DES-product sales using the physician-
20 preferred rapid-exchange delivery system.¹⁹

21 *Third*, Abbott could conceivably be given years lead time for its competing Xience DES
22 product with a rapid-exchange delivery system. The injury that Medtronic would suffer during
23 this period would be enormous and irreparable as the market for DESs is fast-moving, rendering
24 products like Endeavor quickly obsolete. This hardship would be particularly harsh given the

25 Circuit held that the “district court was well within its discretion” when it dissolved an injunction
26 after finding an absence of irreparable harm and that the public interest would be disserved by
27 prospectively applying the injunction. *Id.*

28 ¹⁹ For example, in Western Europe, where Medtronic is able to sell DES products utilizing the
rapid-exchange delivery system, Medtronic has 20% of the market share, worth approximately \$
175 million in annual sales. Donlon Decl., ¶ 5.

1 PTO's rule that an interim patent extension under Section 156(e)(2) is void *ab initio* where it is
2 subsequently determined that the patent is not eligible for extension. MPEP, 8th Ed., 6th Rev., §
3 2755.01 (September 2007). The PTO appears to rely on voiding interim patent term extensions
4 *ab initio*.²⁰ Moy Decl., ¶ 11. The risk inherent in this "no harm, no foul" practice is exemplified
5 by the case of Arkion Life Sciences, Inc. Phan Decl. ¶ 8, Ex. 7.²¹ The PTO granted Arkion three
6 consecutive § 156(e)(2) interim extensions. *See id.* However, the PTO ultimately rejected
7 Arkion's application for patent term extension and voided all three § 156(e)(2) interim
8 extensions *ab initio*. *Id.*, at 1; *See also In re Reckitt & Colman Products Ltd.*, 2 U.S.P.Q.2d 1450
9 (Comm'r Patents 1987) (voiding applicant's § 156(e)(2) interim extension *ab initio*). If this
10 Court were to extend the Yock injunction based on an interim extension, and the PTO ultimately
11 determines that the Yock patent is ineligible for extension voiding it *ab initio*, then Medtronic's
12 Endeavor DES with a rapid-exchange delivery system would be wrongfully kept off the market.
13 Such a result would irreparably harm Medtronic as well as disadvantage the public, whose
14 choices of DES's used with a rapid-exchange delivery system would be limited. The process of
15 deciding whether a patent is eligible for a final patent term extension can take two to three years
16 or more, as two agencies, the PTO and FDA, are involved in making the final determination on
17 the extension. Phan Decl., ¶ 8, Ex. 7. In the meantime, the applicant may be awarded interim
18 extensions in one year increments until a final determination is made. *See* 37 C.F.R. § 1.740.
19 Such a result could keep Medtronic off the market for years before a final determination on
20 Abbott's patent term extension is made, in effect furnishing Abbott a de facto patent term
21 extension.²²

23 ²⁰ During Professor Moy's conversation with Mary Till (the PTO employee who oversees the
24 processing of patent term extensions), she indicated that the PTO relies on the principle that
interim extensions may later be voided *ab initio* when granting such extensions. Moy Decl.,
¶ 11.

25 ²¹ Similarly, Ms. Till encouraged Arkion Life Sciences to apply for an interim extension, even
26 though the PTO had already issued a Final Determination denying its patent term extension.
Phan Decl., ¶ 37, Ex. 32 at 2. However, the Federal Circuit later held that the PTO has *no*
27 *statutory authority* to issue a § 156(e)(2) interim extension after it has already denied an
application for extension. *Somerset Pharms., Inc. v. Dudas*, 500 F.3d 1344, 1346 (Fed. Cir.
28 2007).

²² Interim extensions may be granted up to the maximum period of extension for which the

