IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

TEVA PHARMACEUTICALS USA, INC., Plaintiff-Appellant, v. KATHLEEN SEBELIUS, in her Official Capacity as Secretary of Health and Human Services, et al., Defendants-Appellees.	No. 09-5281 (consolidated with No. 09-5308)

APPELLEES' OPPOSITION TO APPELLANT'S EMERGENCY MOTION TO ISSUE MANDATE FORTHWITH

Pursuant to Fed. R. App. P. 27(a)(3), Cir. R. 27, and the Court's March 9, 2010, order, appellees Kathleen Sebelius, Secretary of Health and Human Services, et al. ("the government"), hereby oppose the emergency motion of appellant Teva Pharmaceuticals USA, Inc. ("Teva"), which seeks immediate issuance of the mandate. As explained herein, the government has just learned of a significant fact that has a direct bearing on this litigation: according to publicly available information from the Patent and Trademark Office ("PTO"), the Merck '075 patent here at issue expired in *March 2009*. Because of that fact and other substantial reasons, expedited issuance of the mandate would be plainly inappropriate. The Court should therefore deny Teva's motion.

BACKGROUND

The complexity of this matter warrants a brief recitation of the background and most pertinent aspects of this case.

Pending before the Food and Drug Administration ("FDA") are Teva's Abbreviated New Drug Applications ("ANDAs"), which seek approval to market generic versions of brand-name drugs marketed by Merck and used to treat hypertension. Teva asserts that, because its ANDAs were the first to contain a "paragraph IV certification" directed at Merck's patent No. 5,608,075 ("the '075 patent"), it is entitled to a 180-day period of marketing exclusivity for its generic products under the Federal Food, Drug, and Cosmetic Act ("FDCA"). See 21 U.S.C. § 355(j)(5)(B)(iv). The 180-day exclusivity period, however, can be forfeited if any one of six events, specified in the statute, occurs. See *id*. § 355(j)(5)(D)(i), (ii). One such event (termed a "Failure to market" in the statute) may occur when the patent that is the subject of a paragraph IV certification is withdrawn, or "delisted." See *id*. § 355(j)(5)(D)(i)(I)(bb)(CC). Another "forfeiture event" is the expiration of the patents "as to which the [ANDA] applicant submitted a certification qualifying it for the 180-day exclusivity period." *Id*. § 355(j)(5)(D)(i)(VI).

Although Merck has delisted the '075 patent – the only patent qualifying Teva for exclusivity – Teva contends that, under its interpretation of the statute, it is

nonetheless entitled to 180 days of marketing exclusivity upon approval of its pending ANDAs. Believing that, upon approval of its ANDAs, FDA would determine that Teva forfeited exclusivity because of the '075 patent's delisting, Teva brought this pre-enforcement action in June 2009, seeking declaratory and injunctive relief compelling FDA to adopt Teva's interpretation of the statute with respect to delisting of a patent that is the subject of a paragraph IV certification. The district court disagreed with FDA's arguments that, because FDA has yet to take final action on Teva's ANDAs, Teva's action was not ripe and Teva lacked standing. On the merits, however, the district court upheld FDA's reading of the statute.

Teva appealed. In a decision issued on March 2, 2010, a divided panel of this Court rejected FDA's arguments, and it ruled that Teva's action is ripe for judicial review and that Teva has standing. Op. 10-22. On the merits, the panel majority reversed the district court and held that the statutory provision that provides for forfeiture upon patent delisting cannot result in forfeiture because such a result is "inconsistent with, and thus foreclosed by, the statutory scheme." *Id*. at 3; see *id*. at 23-29. The Court therefore remanded the matter to the district court "for further proceedings not inconsistent with this opinion." *Id*. at 31. Judge Henderson dissented, concluding that "the issue Teva seeks to litigate – its statutory eligibility vel non to exclusively market generic versions of Cozaar and Hyzaar, brand name

drugs manufactured by Merck & Co., Inc. (Merck) – will not be ripe unless and until the [FDA] issues its final decision either granting or denying Teva's [ANDAs]." Dissent 1.

Teva now seeks immediate issuance of the mandate. The last remaining relevant patent protection for Merck's brand-name version of the drugs here at issue (plus a six-month period of "pediatric exclusivity" not here at issue) expires on April 6, 2010. Teva, which has received tentative approval for its ANDAs, believes that it should receive final FDA approval on that date, accompanied by the 180-day period of marketing exclusivity. Thus, Teva seeks issuance of the mandate no later than April 5, 2010, "so that the district court can enter an appropriate order pursuant to the Court's remand ***before*** FDA approves any competing losartan ANDAs on April 6." Motion at 3.

ARGUMENT

1. Pursuant to Fed. R. App. P. 40(a)(1), the government has 45 days, or until April 16, 2010, in which to petition for rehearing by the panel and/or the Court sitting *en banc*. That 45-day period "recognizes that the Solicitor General needs time to conduct a thorough review of the merits of a case before requesting a rehearing." Fed. R. App. P. 40, Advisory Committee Notes (1994 Amendment). See 28 C.F.R.

§ 0.20(b) (Solicitor General determines whether government will seek rehearing *en banc*).

Ordinarily, the mandate is not issued until seven days after the disposition of any rehearing petition. Fed. R. App. P. 41(b); Cir. R. 41(a)(1). The Court, however, "retain[s] discretion to direct immediate issuance of its mandate in an appropriate case," when a moving party demonstrates "good cause" for such action. Cir. R. 41(a)(1). Immediate issuance of the mandate is appropriate when the Court is satisfied that it would not change its decision upon rehearing or rehearing *en banc*, and "'there is no reasonable likelihood that the Supreme Court would grant review.'" *Johnson v. Bechtel Assocs. Prof'l Corp.*, 801 F.2d 412, 415 (D.C. Cir. 1986) (quoting *Ostrer v. United States*, 584 F.2d 594, 598 (2d Cir. 1978)).

Expedited issuance of the mandate has serious consequences. It "formally marks the end of appellate jurisdiction," and precludes an otherwise timely petition for rehearing, unless the would-be petitioner successfully moves for a recall of the mandate. *Id*. at 415-16. Thus, if the issuance of the mandate in this matter is expedited, it will preempt the Solicitor General's consideration of whether this Court's divided panel decision warrants further review, and, if she subsequently determines that rehearing *en banc* should be requested, it will necessitate a motion for recall of the mandate.

2. This is not an appropriate case for expedited issuance of the mandate for several reasons. On the afternoon of March 8, 2010, a significant fact that bears directly on Teva's pending ANDAs (and that of any other manufacturer seeking to market the same generic drug) was informally brought to FDA's attention for the first time. According to information on PTO's website, the delisted Merck '075 patent at issue in this case actually "[e]xpired" on March 30, 2009, because of nonpayment of maintenance fees. See Exhibit A (pages from PTO website); see also 35 U.S.C. § 41(b); 37 C.F.R. § 1.362(g). On March 9, 2010, Apotex, Inc. (cross-appellant and an *amicus* in this proceeding), formally called this matter to FDA's attention. See Exhibit B (Letter from Apotex to FDA).[1]

The expiration of the Merck '075 patent has important, and potentially dispositive, consequences for this litigation. First, in determining whether to approve

[1] FDA does not correct patent information contained in the Orange Book unless and until the New Drug Application ("NDA") holder confirms the correction. See 21 C.F.R. § 314.53(f). Indeed, this Court and others have recognized FDA's "purely ministerial role" respecting "the veracity of the patent information supplied by NDA holders," describing this as a "commonsense policy." *Teva Pharms. USA, Inc. v. Leavitt*, 548 F.3d 103, 106 (D.C. Cir. 2008). Consistent with that ministerial role, FDA is currently in the process of obtaining direct confirmation from Merck that its '075 patent has expired, as PTO's records and other documents reflect. See Exhibit B, Attachment C (April 10, 2008, Letter from Merck to Apotex, stating that "as reflected in the publicly accessible records of the USPTO, Merck and DuPont disclaimed [the '075] patent on April 28, 2005," and "[a]fter that date, neither this patent nor any exclusionary right under it continued to exist").

Teva's pending ANDAs, FDA must now consider whether and how a forfeiture event *other than* the delisting of the '075 patent – namely, expiration of a patent that is the subject of a paragraph IV certification, see 21 U.S.C. § 355(j)(5)(D)(i)(VI) – affects Teva's (and any other applicant's) claim to 180-day marketing exclusivity. Thus, in acting on Teva's ANDAs, it may well be unnecessary for FDA to reach the forfeiture question and statutory interpretation issue that, in the government's view, Teva raised prematurely in this litigation.

Second, several critical underpinnings of the panel majority's holdings are now, at a minimum, in considerable doubt. The Court's decision states that the Merck '075 patent "does not expire until 2014." Op. 8.[2] However, according to the PTO, the '075 patent expired in March 2009, months before Teva filed this suit. See Exhibits A and B. But more important is the panel majority's statement, based on the representations of Teva's counsel at oral argument, that it is "virtually inconceivable" that "one or more of the statutory 'forfeiture events' other than a 'failure to market' might * * * deprive Teva of exclusivity before final approval." Op. 13 (citing Oral Argument Tr. at 29-30 (Dec. 7, 2009)). One of those "virtually inconceivable" events has, in fact, occurred, as FDA "caution[ed]" that it might, *ibid*., and as the dissent contemplated:

[2] The source of that statement appears to be Teva's briefs. See Teva Br. 20-21, 35; Teva Reply Br. 32.

> We do not know whether the FDA's final decision will approve Teva's ANDA[s] or what the FDA's reasoning will be if, as the majority forecasts, maj. op. at 11-13, it does not. The FDA may conclude Teva forfeited its eligibility upon Merck's delisting of its patents, as Teva and the majority insist it will, or *it may reject Teva's application [for marketing exclusivity] based on one of the other forfeiture provisions* * * *. Because the FDA has not yet issued its decision[,] we are unable to divine its substance.

Dissent 2-3 (emphasis added).

Moreover, the panel majority was heavily influenced by the fact that FDA had previously interpreted and applied the delisting forfeiture event provision in connection with two other ANDAs for different drugs (acarbose and COSOPT). See, e.g., Op. 13 ("[W]e know precisely what the FDA thinks the answer is; and its resolution will almost certainly determine whether Teva is entitled to the exclusivity it claims"); *id*. at 17 ("It is clear what the FDA will do absent judicial intervention and what the effect of the agency's action will be"). But, in contrast to its interpretation of the delisting provision, FDA has not formally expressed an opinion on patent expiration as a forfeiture event under 21 U.S.C. § 355(j)(5)(D)(i)(VI). Even more important, Teva raised *only* the delisting issue and "Failure to market" forfeiture provision in this proceeding. See, e.g., Teva Compl., JA 37-39, 49-55, 57-62, 63 (Teva seeks declaration that "the Delisting Rule is in excess of FDA's statutory authority," and that "Teva has not, as of the date of the Court's order, forfeited its

right to 180-day exclusivity under 21 U.S.C. § 355(j)(5)(D)(i)(I)"); Teva Mot. for Prelim. Injunctive Relief, Civil Action No. 1:09-cv-01111-RMC, Doc. 5 (filed June 19, 2009) at 1 (Teva seeks declaration that "FDA's Delisting Rule is in excess of FDA's statutory authority," and that Teva has not "forfeited its right to 180-day exclusivity under 21 U.S.C. § 355(j)(5)(D)(i)(I) by virtue of the '075 patent's delisting"); *id*., Proposed Order, Doc. 5-7 at 1 (same). Thus, patent expiration as a forfeiture event under 21 U.S.C. § 355(j)(5)(D)(i)(VI) has not been litigated or addressed in this case *at all*.

The premises and reasoning of the panel majority's decision on the ripeness and standing issues are therefore seriously undermined by the fact that, according to PTO records, the Merck '075 patent expired almost a year ago. In addition, the question of statutory interpretation upon which both the district court and the panel majority here ruled may never have even reached the courts had Teva awaited FDA's action on its still-pending ANDAs before bringing suit. See Dissent 3 (noting that, given the uncertainty concerning what FDA's decision will ultimately be, "the court may not need to resolve the delisting/forfeiture issue after the FDA's final decision"). Thus, Teva's litigation may well have prompted an advisory opinion from this Court on a question of statutory interpretation.

3. Teva's claim (Mot. at 5) that immediate issuance of the mandate is "necessary to avoid irreparable harm to [it]" – i.e., the harm of 180 days of competition from one or more other generics that may be approved by FDA – is seriously undermined as well. That claim is based on Teva's belief that it is entitled to FDA approval of its ANDAs, with 180 days of market exclusivity, on April 6, 2010. But if FDA determines that Teva has forfeited such exclusivity for a reason unrelated to that addressed in this preemptive litigation, then Teva will suffer no harm, irreparable or otherwise. Teva cannot be harmed by the denial of something to which it is not entitled in the first place.

4. In light of (i) the apparent expiration of the '075 patent and its consequences; (ii) the dissent's foreshadowing of such events; (iii) the potential adverse impact from the panel majority's ripeness, standing, and statutory interpretation rulings on FDA's overall administration of the marketing exclusivity provisions of the FDCA; and (iv) the effect that marketing exclusivity and the corresponding delay in robust competition among generic drug manufacturers will have on consumers, this case is manifestly a serious candidate for further review. See *Johnson*, 801 F.2d at 415 (immediate issuance of mandate is warranted only when Court is satisfied that further review is unlikely). The Solicitor General's

consideration of this matter should therefore not be truncated and potentially foreclosed by the Court's expedited issuance of the mandate.[3]

CONCLUSION

Teva's motion for issuance of the mandate forthwith should be denied.

Respectfully submitted,

s/ Douglas N. Letter
DOUGLAS N. LETTER
(202) 514-3602

s/ Christine N. Kohl
CHRISTINE N. KOHL
(202) 514-4027

Attorneys, Appellate Staff
Civil Division, Room 7511
Department of Justice
950 Pennsylvania Avenue NW
Washington, DC 20530-0001

MARCH 2010

[3] Because the Court's decision was rendered just last week, the government's consideration of whether to seek panel and *en banc* rehearing is at an early stage. Moreover, because the government was the appellee, the Solicitor General has had no prior occasion to review this matter.

CERTIFICATE OF SERVICE

I hereby certify that on March 11, 2010, I filed and served the foregoing "Appellees' Opposition to Appellant's Emergency Motion to Issue Mandate Forthwith" through the Court's CM/ECF system and transmitted four paper copies of this Opposition to the Court by messenger.

s/ *Christine N. Kohl*
Christine N. Kohl
Counsel for Appellees

EXHIBIT A

United States Patent and Trademark Office

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08/371,937 POLYMORPHS OF LOSARTAN AND THE PROCESS FOR THE PREPARATION OF FORM II OF LOSARTAN

Select New Case | Application Data | Transaction History | Continuity Data | Fees | Published Documents | Address & Attorney/Agent

Bibliographic Data

Application Number:	08/371,937	Customer Number:	-
Filing or 371 (c) Date:	01-12-1995	Status:	Patent Expired Due to NonPayment of Maintenance Fees Under 37 CFR 1.362
Application Type:	Utility	Status Date:	03-30-2009
Examiner Name:	SPRINGER, DAVID B	Location:	FILE REPOSITORY (FRANCONIA)
Group Art Unit:	1201	Location Date:	08-13-2009
Confirmation Number:	4230	Earliest Publication No:	-
Attorney Docket Number:	19157CA	Earliest Publication Date:	-
Class / Subclass:	548/252	Patent Number:	5,608,075
First Named Inventor:	GORDON C. CAMPBELL JR. , WILMINGTON, DE (US)	Issue Date of Patent:	03-04-1997

Title of Invention: POLYMORPHS OF LOSARTAN AND THE PROCESS FOR THE PREPARATION OF FORM II OF LOSARTAN

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Select New Case | Application Data | Transaction History | Continuity Data | Fees | Published Documents | Address & Attorney/Agent

Transaction History

Date	Transaction Description
03-30-2009	Expire Patent
07-06-2005	Post Issue Communication - Dedicate Life of Patent to Public/Disclaimers
03-04-1997	Recordation of Patent Grant Mailed
01-27-1997	Issue Notification Mailed
08-30-1996	Miscellaneous Incoming Letter
11-20-1995	Issue Fee Payment Verified
11-22-1996	Drawing(s) Processing Completed
11-19-1996	Drawing(s) Matched to Application
08-12-1996	Drawing(s) Received at Publications
07-16-1996	Mailroom Date of Drawing(s)
01-12-1996	Information Disclosure Statement (IDS) Filed
01-12-1996	Information Disclosure Statement (IDS) Filed
08-22-1995	Mail Notice of Allowance
08-22-1995	Notice of Allowance Data Verification Completed
01-12-1995	Preliminary Amendment
07-28-1995	Case Docketed to Examiner in GAU
02-10-1995	Application Captured on Microfilm

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- *If you experience technical difficulties or problems with this application, please report them via e-mail to Electronic Business Support or call 1 800-786-9199.*

EXHIBIT B

BUC & BEARDSLEY, LLP
919 EIGHTEENTH STREET, N.W.
SUITE 600
WASHINGTON, D.C. 20006-5503

WRITER'S TELEPHONE
202-736-3620

TELEPHONE
202-736-3600
FACSIMILE
202-736-3608

March 9, 2010

Gary J. Buehler, R. Ph.
Office of Generic Drugs
HFD-600
7519 Standish Place
Rockville, Maryland 20855

Dear Mr. Buehler:

We write on behalf of our client, Apotex, Inc., to bring to your attention certain patent information of relevance in connection with Teva v. Sebelius, No. 09-528 (D.C.Cir. Mar. 2, 2010) and the approval of Apotex, Inc.'s pending ANDAs referencing Hyzaar and Cozaar. Specifically, Teva Pharmaceuticals USA, Inc. has claimed an entitlement to 180-day exclusivity as a result of its certification to Merck's U.S. Patent No. 5, 608, 075 ("the '075 patent"). That patent, however, has expired. In fact, according to the United States Patent & Trademark Office ("USPTO"), the '075 patent expired at least as of March 30, 2009. The patent expired as a matter of law pursuant to 35 U.S.C. § 41(b) for failure to pay maintenance fees. Attachment A is a printout of the USPTO's Patent Application Information and Retrieval website reflecting that the '075 patent expired. Attachment B is a copy of the USPTO Official Gazette dated April 21, 2009 which, on page 5, reports that the '075 patent expired.

As Merck & Co., Inc., the patent holder, disclaimed the '075 patent in 2005 (Attachment C) and requested some time ago that this patent be delisted from the Orange Book altogether, it is not surprising that Merck did not update patent expiration information.

We have no objection to the public dissemination of this letter, or the information contained herein.

Sincerely,

Carmen M. Shepard
Kate C. Beardsley

cc: Elizabeth H. Dickinson, Esq.
Office of Chief Counsel
PKLN-671
5600 Fishers Lane
Rockville, Maryland 20857

Office of Generic Drugs
OGD Document Room
Attention: Orange Book Staff
7500 Standish Place
Rockville, MD 20855

ATTACHMENT

B

Notice of Expiration of Patents Due to Failure to Pay Maintenance Fee

Notice of Expiration of Patents Due to Failure to Pay Maintenance Fee

35 U.S.C. 41 and 37 CFR 1.362(g) provide that if the required maintenance fee and any applicable surcharge are not paid in a patent requiring such payment, the patent will expire at the end of the 4th, 8th or 12th anniversary of the grant of the patent depending on the first maintenance fee which was not paid.

According to the records of the Office, the patents listed below have expired due to failure to pay the required maintenance fee and any applicable surcharge.

PATENTS WHICH EXPIRED ON March 4, 2009 DUE TO FAILURE TO PAY MAINTENANCE FEES

Patent Number	Application Number	Issue Date
5,606,745	08/589,803	03/04/97
5,606,747	08/490,421	03/04/97
5,606,755	08/417,518	03/04/97
5,606,765	08/523,166	03/04/97
5,606,772	08/382,694	03/04/97
5,606,782	08/424,715	03/04/97
5,606,783	08/527,030	03/04/97
5,606,784	08/472,112	03/04/97
5,606,791	08/123,428	03/04/97
5,606,796	08/335,794	03/04/97
5,606,797	08/494,368	03/04/97
5,606,811	08/432,427	03/04/97
5,606,815	08/557,674	03/04/97
5,606,833	08/295,939	03/04/97
5,606,834	08/509,148	03/04/97
5,606,835	08/285,320	03/04/97
5,606,838	08/448,260	03/04/97
5,606,840	08/582,620	03/04/97
5,606,841	08/428,712	03/04/97
5,606,842	08/625,676	03/04/97
5,606,846	08/304,226	03/04/97
5,606,848	08/238,167	03/04/97
5,606,855	08/448,397	03/04/97
5,606,860	08/422,547	03/04/97
5,606,877	08/423,757	03/04/97
5,606,895	08/287,390	03/04/97
5,606,897	08/577,332	03/04/97
5,606,898	08/447,616	03/04/97
5,606,906	08/590,271	03/04/97
5,606,915	08/418,214	03/04/97
5,606,923	08/371,818	03/04/97
5,606,940	08/576,277	03/04/97
5,606,944	08/618,316	03/04/97
5,606,953	08/392,885	03/04/97
5,606,955	08/516,053	03/04/97

5,607,816	08/531,853	03/04/97
5,607,824	08/281,398	03/04/97
5,607,827	08/531,714	03/04/97
5,607,834	08/420,443	03/04/97
5,607,835	08/473,589	03/04/97
5,607,847	08/275,053	03/04/97
5,607,857	08/489,859	03/04/97
5,607,862	08/497,731	03/04/97
5,607,863	08/163,860	03/04/97
5,607,865	08/381,425	03/04/97
5,607,869	08/595,369	03/04/97
5,607,885	08/636,970	03/04/97
5,607,887	08/367,265	03/04/97
5,607,888	08/452,939	03/04/97
5,607,894	08/487,847	03/04/97
5,607,904	08/421,224	03/04/97
5,607,911	08/635,630	03/04/97
5,607,920	08/278,617	03/04/97
5,607,924	08/469,177	03/04/97
5,607,925	08/333,017	03/04/97
5,607,935	08/232,029	03/04/97
5,607,955	08/431,425	03/04/97
5,607,958	08/394,757	03/04/97
5,607,959	08/495,509	03/04/97
5,607,960	08/532,573	03/04/97
5,607,961	08/517,999	03/04/97
5,607,962	08/591,329	03/04/97
5,607,967	08/330,518	03/04/97
5,607,971	08/413,797	03/04/97
5,607,995	08/583,218	03/04/97
5,607,996	08/318,395	03/04/97
5,608,017	08/449,250	03/04/97
5,608,028	08/189,984	03/04/97
5,608,029	08/402,067	03/04/97
5,608,035	08/190,788	03/04/97
5,608,041	08/591,565	03/04/97
5,608,042	08/594,487	03/04/97
5,608,057	08/518,303	03/04/97
5,608,058	08/189,700	03/04/97
5,608,059	08/356,187	03/04/97
5,608,060	08/351,469	03/04/97
5,608,063	08/412,409	03/04/97
5,608,075	08/371,937	03/04/97
5,608,079	08/473,509	03/04/97
5,608,080	08/424,504	03/04/97

5,608,082	08/281,639	03/04/97
5,608,095	08/637,968	03/04/97
5,608,096	08/580,417	03/04/97
5,608,109	08/350,462	03/04/97
5,608,119	08/463,896	03/04/97
5,608,128	08/495,662	03/04/97
5,608,154	08/397,969	03/04/97
5,608,157	08/544,591	03/04/97
5,608,160	08/627,740	03/04/97
5,608,167	08/390,980	03/04/97

ATTACHMENT

C

Mary J. Morry
Assistant Counsel
Intellectual Property Litigation
Fax 732 594 6200
Tel 732 594 1935
Email mary_morry@merck.com

Merck & Co., Inc.
P. O. Box 2000
126 Lincoln Avenue
Rahway, NJ 07065-0907

April 10, 2008

VIA COURIER
Shashank Upadhye, Esq.
Vice-President, Global Intellectual Property
Apotex Corp.
150 Signet Drive
Toronto, Ontario M9L 1T9
Canada

Re: Apotex Notification of Certification
Regarding U.S. Patent No. 5,608,075
ANDA No. 90-150 for Hydrochlorothiazide/ Losartan Potassium
12.5mg/50mg; 12.5mg/100mg and 25mg/100mg

Dear Mr. Upadhye,

We are in receipt of your letter of March 19, 2008 in connection with the above-referenced ANDA.

This is to inform you that Merck will not bring suit against Apotex Corp. based on the above mentioned U.S. Patent No. 5,608,075. As noted in your letter, and as reflected in the publicly accessible records of the USPTO, Merck and DuPont disclaimed this patent on April 28, 2005. After that date, neither this patent nor any exclusionary right under it continued to exist. Accordingly, Merck and DuPont have forever relinquished any right to sue any entity, including Apotex, for infringement of this patent. Furthermore, in 2005 Merck made a request to the FDA that it remove this patent from the Orange Book.

Very truly yours,

Mary J. Morry
MJM:emm

Upadhye-04-10-08
Lit P-MJM-IP Cases
IP05-1208