IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ROXANE LABORATORIES, INC. *et al.*, Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants, and TEVA PHARMACEUTICALS USA, INC., Intervenor-Defendant.	Civil Action No. 10-00517 (Consolidated with Civil Action No. 10-00521)

PLAINTIFF ROXANE'S REPLY IN SUPPORT OF
ITS MOTION FOR PRELIMINARY INJUNCTION

Plaintiff Roxane Laboratories, Inc. ("Roxane") respectfully submits this reply brief in support of its motion for a preliminary injunction, and in response to the papers opposing its motion filed by defendant Food and Drug Administration ("FDA") and the Intervenor-Defendant Teva Pharmaceuticals USA, Inc. ("Teva").

An examination of the central points made by defendants demonstrates the flaws in their arguments and why the Court should rule for Roxane and Apotex, Inc. in this action.

1. The D.C. Circuit's Decision in *Teva* Is Not Binding on this Court.

Both FDA's and, especially, Teva's opposition papers seek to portray FDA – and by implication, this Court – as bound to award exclusivity to Teva based on the D.C. Circuit's decision in *Teva Pharms. USA, Inc. v. Sebelius*, 595 F.3d 1303 (D.C. Cir. 2010) ("*Teva*"), even

though that case involved patent delisting and this case involves the separate issue of patent expiration. (*E.g.,* Teva Mem. in Opp. to Pls.' Mots. for Prelim. Injunctive Relief ("Teva Opp.") at 22 ("FDA is bound by the law of this Circuit" to award Teva exclusivity); Defs.' Opp. to Mot. for Prelim. Inj. ("FDA Opp."). at 1-2).

This Court, however, has made clear in its order on the remand of the D.C. Circuit's *Teva* patent delisting decision, that *Teva* was *not* controlling on the patent expiration issue in the *Teva* case, and it is certainly not binding precedent in this case, since the patent expiration was not addressed in *Teva*. Order Granting Defs.' Mot. to Am. J. and the March 16, 2010 Order, 1:09-cv-1111-RCM (Mar. 26, 2010). Teva's claims to the contrary are simply wrong.[1]

2. <u>This Case Presents a New Issue for the Court to Decide, and It Should Approach This Issue with Reference to the Case Law on Standards of Statutory Interpretation in the Supreme Court and this Circuit.</u>

Teva wants this Court to believe that its hands are tied by the D.C. Circuit's decision in *Teva*. The argument goes as follows: same exclusivity, same forfeiture concept, same outcome. Unfortunately for Teva, which has successfully battled the delisting provision, only to find its 180-day exclusivity in jeopardy again, this case involves an entirely new and different issue:

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[1] Indeed, Teva's efforts in this regard extend to selectively quoting the *Teva* decision in an effort to convey the false impression that *Teva* addressed the forfeiture issue generally and not just forfeiture in the context of delisting. *Teva*'s actual language is as follows:

> The FDA's view turns [the patent delisting forfeiture provision] into a fundamentally different forfeiture trigger: it is satisfied when the patent targeted in a paragraph-IV filing 'is withdrawn by the' brand manufacturer, full stop – meaning that Congress has now explicitly provided for a scenario in which the brand maker can unilaterally deprive the generic of its exclusivity. The agency, however, offers *not a single cogent reason* why Congress might have permitted brand manufacturers to trigger subsection (CC) by withdrawing a challenged patent, outside the counterclaim scenario identified by Teva.

595 F.3d at 1317 (emphasis in original). On its face, this language relates specifically and exclusively to the delisting forfeiture provision. Teva, however, reverses and collapses the above sentences in its brief, at page 1 and again at page 23, to suggest - incorrectly - that the court was making a broader point about forfeiture and exclusivity:

namely, whether the plain meaning of the patent expiration forfeiture provision – not the delisting forfeiture provision – requires the interpretation reluctantly adopted by FDA. As explained above, the D.C. Circuit has not considered this issue, and there is no controlling authority – *Teva* or otherwise – that compels FDA's decision that expiration of the '075 patent did not cause Teva to forfeit its exclusivity.

To the contrary, it is incumbent upon the Court in this case, as it is in every case involving review of agency action, to employ the traditional tools of statutory construction available to it, and all of the case law in the Supreme Court and this Circuit regarding how the Court should use and balance the application of these tools, of which the focal point is always the plain language. *See Estate of Cowart v. Nicklos Drilling Co.*, 505 U.S. 469, 475 (1992) ("In a statutory construction case, the beginning point must be the language of the statute, and when a statute speaks with clarity to an issue judicial inquiry into the statute's meaning, in all but the most extraordinary circumstance, is finished."); *United States v. Ron Pair Enter., Inc.*, 489 U.S. 235, 241 (1989) ("The task of resolving the dispute over the meaning of [the statute] begins where all such inquiries must begin: with the language of the statute itself. In this case it is also where the inquiry should end, for where, as here, the statute's language is plain, the sole function of the courts is to enforce it according to its terms.") (internal citation and quotations omitted)); *Nat'l Public Radio, Inc. v. F.C.C.*, 254 F.3d 226, 230 (D.C. Cir. 2001) ("Because statutory language represents the clearest indication of Congressional intent, . . . we must presume that Congress meant precisely what it said. Extremely strong, this presumption is rebuttable only in the 'rare cases [in which] the literal application of a statute will produce a result demonstrably at

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There is "*not a single cogent reason* why Congress might have permitted . . . a scenario in which the brand maker can unilaterally deprive the generic of its exclusivity." (Emphasis in original.)

odds with the intentions of the drafters.'") (internal citation omitted) (quoting *United States v. Ron Pair Enter., Inc.*, 489 U.S. 235, 242 (1989)).

In addition, cases decided by the Supreme Court and this Circuit do not allow courts to use policy to override the plain language of a statute. *See Norfolk S. Ry. Co. v. Sorrell*, 549 U.S. 158, 171 (2007) ("[A] statute's remedial purpose cannot compensate for the lack of a statutory basis [in text]."); *Landstar Express Am., Inc. v. Fed. Mar. Comm'n*, 569 F.3d 493, 498 (D.C. Cir. 2009) ("[N]either courts nor federal agencies can rewrite a statute's plain text to correspond to its supposed purposes.").

There is no dispute here that Hatch Waxman expressly provides for forfeiture of generic exclusivity upon expiration – for any reason, with no qualification – of the patent that is the subject of the relevant paragraph IV certification. 21 U.S.C. § 355(j)(5)(D)(i)(VI) (stating "forfeiture event" occurs when "[a]ll of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have *expired*.") There is thus no reason based on the face of the statute to conclude that a patent that has expired due to a patent holder's failure to pay maintenance fees does not trigger forfeiture of 180-day exclusivity under Section 355(j)(5)(D)(i)(VI). *See McCarthy v. Bronson*, 500 U.S. 136, 139 (1991) (adopting an inclusive interpretation of what kinds of prisoner petitions are covered by 28 U.S.C. § 636(b)(1)(B) and noting that "the text of the statute does not . . . contain any language suggesting that prisoner petitions should be divided into subcategories"); *Conn. Nat'l Bank v. Germain*, 503 U.S. 249, 253-54 (1992) ("[C]ourts must presume that a legislature says in a statute what it means and means in a statute what it says there.") Teva concedes as much, (Teva Opp. at 22-23), and is forced to argue that the plain language should be disregarded in light of other factors. FDA has also unambiguously conceded the same. (FDA Opp. at 2 ("In [its] letter,

FDA noted that the plain language of the statute would result in forfeiture for patent expiration . . . ."); *id.* at 5 ("FDA agrees that, under the plain language of the statute, forfeiture would be appropriate in this case." (citing FDA Ltr. at 3-7)).[2]

Simply put, the statutory language plainly and unambiguously supports the conclusion that expiration of the '075 patent operated to deprive Teva of its exclusivity for generic losartan, and the policy articulated by Teva – to encourage generic companies to challenge patents in order to obtain 180-day exclusivity – is not sufficient to overcome the plain language of the statute. *Landstar Express Am., Inc. v. Fed. Mar. Comm'n*, 569 F.3d at 498 ("[N]either courts nor federal agencies can rewrite a statute's plain text to correspond to its supposed purposes.")

Nor is it true that even this policy is sacrosanct, as Teva would have it. Courts have repeatedly upheld FDA's interpretations of Hatch-Waxman that infringe upon the 180-day exclusivity incentive structure, as in the case of so-called "authorized generics" – generic drugs marketed by the brand company that could have been held not be covered by the 180-day exclusivity. *See Teva Pharms., Indus., Ltd. v. FDA*, 355 F. Supp. 2d 111, 117 (D.D.C. 2004) ("Nothing in the statute provides any support for the argument that the FDA can prohibit NDA holders from entering the market with a brand generic drug during the exclusivity period."); *see also Mylan Pharms., Inc. v. FDA*, 454 F.3d 270, 276 (4th Cir. 2006) ("Mylan would have us set aside the statutory language and instead give determinative weight to its asserted understanding of the congressional intent behind the statute. Mylan contends that [brand] authorized generics may not be sold during the 180-day exclusivity period because Congress sought to give the first-

[2] To the extent that FDA argues that its decision awarding exclusivity is entitled to deference under *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), no such deference is warranted here – both because the statutory text regarding forfeiture of exclusivity upon patent expiration is unambiguous and also because FDA's decision here is not the product of reasoned decision making, but rather is based on its self-professed need to follow a judiciary decision by which it was not bound and with which it does not agree. *See Holland v. Nat'l Mining Ass'n*, 309 F.3d 808, 817 (D.C. Cir. 2002) (no deference where agency believed it had no choice but to apply judicial interpretation and believed that it was effectively "coerced" into doing so).

filing paragraph IV ANDA applicant the sole right to sell a generic drug during that period. . . . Mylan points to no textual ambiguity of the sort that would ordinarily lead us to consult materials outside the statute's four corners."); *id.* at 276 ("Although the introduction of an authorized generic may reduce the economic benefit of the 180 days of exclusivity awarded to the paragraph IV ANDA applicant, § 355(j)(5)(B)(iv) gives no legal basis for the FDA to prohibit the encroachment of authorized generics on that exclusivity.").

While we recognize that the Panel in *Teva* took a different approach in interpreting the delisting forfeiture provision, this Court is not bound by that panel's approach, nor would a different panel of the D.C. Circuit be bound.[3] Application of the statutory construction principles enunciated in the case law of this Circuit leads to one conclusion: the plain meaning of the patent expiration forfeiture provision requires that the Court order FDA to deny Teva 180-day exclusivity. Indeed, a ruling by the D.C. Circuit in *this case* overturning FDA's decision to award Teva exclusivity on the basis of the unambiguous statutory text is not only not foreclosed by the *Teva* decision, but is a real possibility.[4]

[3] As noted by FDA, the Solicitor General's office is considering whether to seek rehearing of that decision. (FDA Opp. at 2 n.1.)

[4] It is worth noting that many, indeed most, of the Supreme Court cases cited by Teva at 22-23 of its opposition papers in support of FDA's decision to ignore clear statutory language regarding patent expiration actually decline to adopt narrowing constructions of statutory terms where there is no qualifying language used with those terms. *E.g. Robinson v. Shell Oil Co.*, 519 U.S. 337, 343 (1997) (interpreting the term "employee" in provisions of Title VII of the Civil Rights Act to include both past and current employees and noting that where the Congress meant that term to mean just current employees, "'employee' refers unambiguously to a current employee . . . ."); *Estate of Cowart v. Nicklos Drilling Co.*, 505 U.S. 469, 477 (1992) (interpreting the term "entitled to compensation" in the Longshore and Harbor Workers' Compensation Act's to not be limited to cases in which the claimant had secured a judicial determination of liability and relying on "the natural reading of the statute . . . ."); *McCarthy v. Bronson,* 500 U.S. 136, 139 (1991) (adopting an inclusive interpretation of what kinds of prisoner petitions are covered by 28 U.S.C. § 636(b)(1)(B) and noting that "the text of the statute does not . . . contain any language suggesting that prisoner petitions should be divided into subcategories."); *SEC v. C.M. Joiner Leasing Corp.*, 320 U.S. 344, 351 (1943) (adopting broad interpretation of the term "securities" under the Securities Act of 1933 and noting that "we cannot read out of the statute [] generally descriptive designations merely because more specific ones have bee used to reach some kinds of documents."); *Atl. Cleaners & Dyers, Inc. v. United States*, 286 U.S. 427 (1932) (inclusive interpretation of the term "restraint of trade" for purposes of determining scope of the Sherman Antitrust Act).

3. The Reasoning of the *Teva* Panel Does Not Apply to the Patent Expiration Issues Before this Court.

The Panel in *Teva* held that FDA could not permit Merck to unilaterally delist its patent and cause Teva to forfeit its 180-day exclusivity. In doing so, the Court determined that regardless of the plain language of the statute, FDA's interpretation of the delisting forfeiture provision could not be squared with the structure of the statute. *Teva*, 595 F.3d at 1317. The reasoning of the Panel in *Teva* does not apply to this case for three important reasons.

First, as discussed in Roxane's Memorandum in Support of Motion for Preliminary Injunction ("Roxane's Memorandum") at 13-17, when Congress enacted the forfeiture amendment provisions to Hatch-Waxman in 2003, the term "expired," unlike the concept of patent delisting, already had a meaning in the patent law that is in direct conflict with the meaning of "expired" that FDA has adopted in this case. The statute setting forth the requirements for payment of fees to maintain a patent expressly provides that non-payment of such fees causes a patent to "expire." 35 U.S.C. § 41(b). FDA has adopted the exact opposite interpretation of that provision in this case. The very act that results in patent expiration under the patent code – non-payment of maintenance fees – is interpreted by FDA as not being a patent expiration under the FFDCA that triggers forfeiture of 180-day exclusivity.

A term that appears in different statutes should be interpreted to mean the same thing in each statute. *See Nat'l Treasury Employees Union v. Chertoff*, 452 F.3d 839, 857-58 (D.C. Cir. 2006) ("There is a presumption that Congress uses the same term consistently in different statutes.") (collecting cases); *see also Hawaiian Airlines, Inc. v. Norris*, 512 U.S. 246, 254 (1994). The term "expired" is fundamentally a concept of patent law and not of Hatch Waxman or the FFDCA and, as such, is without ambiguity and not susceptible to different meanings. As the Supreme Court noted in *General Dynamics Land Systems v. Cline*, a case cited by Teva,

"[t]he presumption of uniform usage . . . relents [footnote omitted] when a word used has several commonly understood meanings among which a speaker can alternate in the course of an ordinary conversation, without being confused or getting confusing. 'Age' is that kind of word." 540 U.S. 581, 595-96 (2004). "Expiration" is not that kind of word.

Moreover, Congress could not have intended for FDA's interpretation of the term "expired," one which is essential to the functioning of the patent law, to trump the USPTO's interpretation of that term. That term is not a "technical patent-law concept[]", (Teva Opp. at 24), but instead a core principle of the patent code. While the life of any patent has a ceiling, the ability for a patent to remain unexpired until the last date allowed for under the code, is entirely conditioned on the payment of maintenance fees. 35 U.S.C. § 41(b) (patent will expire if maintenance fees are not paid when required); 35 U.S.C. § 154 (a)(2) (term of patent is subject to payment of fees). It is this bedrock principle of patent law that Congress adopted when it injected the concept of patent expiration into Hatch-Waxman, and there is no basis for finding that it intended to assign the term expiration an inconsistent meaning. *See, e.g.*, *Athlone Indus., Inc. v. Consumer Prod. Safety Comm'n*, 707 F.2d 1485, 1491 (quoting *Morissette v. United States*, 342 U.S. 246, 263 (1952) ("[W]hen Congress uses a legal term it presumably adopts 'the meaning its use will convey to the judicial mind unless otherwise instructed.'"). In determining Congress's intent in Hatch-Waxman, FDA should have used the long standing interpretation of the term "expired" that Congress had previously adopted in the patent law, and its failure to do so is a basis for overturning the agency's decision in this case.

Second, the impact of an FDA decision awarding exclusivity to Teva despite an *expired* patent would broadly undermine the administrative structure and implementation of Hatch-Waxman in a way that awarding exclusivity in spite of a *delisted* patent would not. As noted in

Roxane 's Memorandum, FDA regulations implementing Hatch-Waxman require an applicant to "amend a submitted certification if, at any time before the effective date of the approval of the application, the applicant learns that the submitted certification is no longer accurate." 21 CFR § 314.94(a)(12)(viii)(C)(1). This regulation, if FDA's reading of Hatch-Waxman were upheld, would be nullified in significant part, in that the certification amendment requirement would no longer exist in many patent expiration cases. Moreover, the need to distinguish between different types of patent expiration for purposes of determining exclusivity awards would require FDA, in the context of such awards, to make determinations of substantive patent law (*i.e.*, the basis for a particular patent's expiration) – an area that the Courts have recognized FDA has long been loath to enter. *See aaiPharma Inc. v. Thompson*, 296 F.3d 227, 241 (4th Cir. 2002); *see also Watson Pharms., Inc. v. Henney*, 194 F. Supp. 2d 442, 445 (D. Md. 2001) ("[FDA] has no expertise – much less any statutory franchise – to determine matters of substantive patent law."); *see also* 59 Fed. Reg. 50338, 50345 (Oct. 3, 1994) ("FDA does not have the resources or the expertise to review patent information for its accuracy and relevance to an NDA.").

FDA's decision similarly disables the regulation governing correction of patent information errors. *See* 21 C.F.R. § 314.53(f). That regulation requires FDA to publish in the Orange Book the patent information that is confirmed as correct by the new drug application ("NDA") holder. *Id.* Under its decision in this case, however, FDA will no longer be following this regulation in cases where the NDA holder confirms that the patent has expired due to failure to pay maintenance fees because it will not change the Orange Book to reflect that expiration. To do otherwise would be inconsistent with its decision to treat the patent as not having expired for purposes of its 180-day exclusivity determination. FDA's decision requires it to read out yet another long standing requirement in another of its regulations.

In short, any analysis of the impact on the Hatch-Waxman "structure" of an award of exclusivity to Teva here – despite the '075 patent's expiration – must also take into account the destabilizing and unwanted effects of this award on that structure. There are no such similar consequences in the delisting context.

Third, unlike the panel in *Teva*, this Court does not have any prior D.C. Circuit precedent on the patent expiration forfeiture provision with which it must square its opinion in this case. In *Teva*, the Court of Appeals was driven by its prior decision on delisting in *Ranbaxy Laboratories Ltd. v. Leavitt*, 469 F.3d 120 (D.C. Cir. 2006), in which, prior to enactment of the Medicare Modernization Act of 2003 ("MMA"), it had invalidated an FDA policy that allowed brand manufacturers to deprive generic manufacturers of 180-day marketing exclusivity by delisting their patents. There are no prior opinions on patent expiration and generic exclusivity that require FDA to preserve 180-day exclusivity despite expiration of a patent. To the contrary, the pre-MMA case law is in Roxane's favor, and holds that 180-day exclusivity cannot survive patent expiration. *See Dr. Reddy's Labs., Inc. v. Thompson*, 302 F. Supp. 2d 340, 355-57 (D.N.J. 2003) (recognizing that it was permissible for the FDA to deny a grant exclusivity to a paragraph IV filer, even though the filer had exposed itself to litigation, and in fact litigated a patent infringement suit, because the patent had expired and the paragraph IV certification should have been changed to a paragraph II certification); *see also Ranbaxy Labs., Ltd. v. FDA*, 307 F. Supp. 2d 15, 19 ("[A]t [that] 'magic moment' of midnight on January 29, 2004, [when the patent expired], Ranbaxy's Paragraph IV certification was no longer accurate and no longer valid because the patent to which it related had expired."), *aff'd*, 96 Fed. Appx. 1 (D.C. Cir. 2004) (unpublished) ("The district court also properly affirmed the FDA's conclusion that, upon

expiration of Pfizer's patent on January 29, 2004, Ranbaxy's 'Paragraph IV' certification became invalid . . . .").

In summary, whether or not the *Teva* court correctly interpreted the delisting forfeiture provision, a similar interpretation of the patent expiration forfeiture provision is inconsistent not only with the unambiguous statutory text, but with the structure and meaning both of the patent statute *and* of the Hatch-Waxman framework as set forth in FDA's regulations.

4. Roxane Has Demonstrated that It Will Suffer Irreparable Harm if the Court Does Not Enter a Preliminary Injunction.

In its opposition papers, FDA relies on the general rule that monetary injuries are generally not a sufficient basis for a finding of irreparable harm. FDA Opp. at 8-9. While this may be true, there are exceptions to this rule, and, as discussed in Roxane's opening brief, several of those exceptions are present here and support Roxane's claim of irreparable harm. Roxane Mem. at 17-21. FDA makes no effort to address the application of these exceptions to this case, or even to acknowledge that they exist.

For its part, Teva fails to address the irreparable harm prong altogether, other than to say that *it* will be irreparably harmed if FDA's decision is reversed. Teva. Opp. at 35-37. However, Teva too ignores the more intangible and less quantifiable injuries that Roxane would also suffer as a result of not being among the first on the market for generic losartan, and that Teva - which will be among the first on the market no matter what – will not suffer here. Roxane Opp. at 21-22. At most, Teva's argument results in a standoff on the issue of irreparable harm, which throws the preliminary injunction argument back to the merits issue. *See Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1326 (D.C. Cir. 1998) (holding in generic drug approval case that decision on the "likelihood of success prong" is dispositive because, in part, competing claims of irreparable harm and injury to the public interest are "a wash.").

5. Conclusion

For the foregoing reasons, in addition to those in its original motion papers, Roxane respectfully submits that the Court should grant its motion for a preliminary injunction.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies that on this 1st day of April, 2010, he caused a copy of the foregoing **PLAINTIFF ROXANE'S REPLY IN SUPPORT OF ITS MOTION FOR PRELIMINARY INJUNCTION** to be served upon the following attorneys by electronic mail and through this Court's ECF filing system:

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