

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

ASTRAZENECA UK LIMITED, IPR	:	
PHARMACEUTICALS, INC.,	:	
ASTRAZENECA AB, SHIONOGI	:	
SEIYAKU KABUSHIKI KAISHA, and	:	
THE BRIGHAM AND WOMEN'S	:	Civil Action No. 10-915-LPS
HOSPITAL, INC.,	:	
	:	Public Version
Plaintiffs,	:	Released March 23, 2012
	:	
v.	:	
	:	
WATSON LABORATORIES, INC. (NV)	:	
and EGIS PHARMACEUTICALS PLC,	:	
	:	
Defendants.	:	

Ford F. Farabow, Washington, DC; Charles E. Lipsey, Kenneth M. Frankel, and York M. Faulkner, Reston, VA; John D. Livingstone, Atlanta, GA; Mary K. Ferguson, Cambridge, MA; FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP.
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Attorneys for Plaintiffs.

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Attorneys for Defendants.

MEMORANDUM OPINION

March 13, 2012
Wilmington, Delaware.



STARK, U.S. District Judge:

I. INTRODUCTION

Presently before the Court are motions to dismiss filed by Defendant Watson Laboratories, Inc. (“Watson”) and EGIS Pharmaceuticals PLC (“EGIS”). (D.I. 56; D.I. 162) The Court held a hearing on both motions on January 13, 2012, in conjunction with the claim construction hearing. (D.I. 204) (“Tr.”) The Court further received post-hearing letter briefs relating to the impact of a recent Federal Circuit decision on the pending motions. (D.I. 232; D.I. 238) For the reasons set forth below, the Court will grant Watson’s motion to dismiss, and will grant-in-part and deny-in-part EGIS’s motion to dismiss.

II. BACKGROUND

A. The Parties and Patents-in-Suit

Plaintiffs AstraZeneca UK Limited, IPR Pharmaceuticals, Inc., AstraZeneca AB, and The Brigham and Women’s Hospital, Inc. (collectively, “AstraZeneca”) market rosuvastatin calcium under the brand name CRESTOR®, and hold the rights to three related patents: U.S. Patent No. RE37,314 (“the ’314 patent”); U.S. Patent No. 6,858,618 (“the ’618 patent”); and U.S. Patent No. 7,030,152 (“the ’152 patent”) (collectively, the “patents-in-suit”). The ’314 patent claims rosuvastatin compounds and pharmaceutical compositions containing such compounds; the ’618 and ’152 patents relate to methods of using rosuvastatin compounds to treat certain cardiovascular conditions.

In September 2010, Watson notified AstraZeneca that it had filed “Paper NDA” No. 202172 pursuant to Section 505(b)(2) of the Hatch-Waxman Act, 21 U.S.C. § 355, seeking FDA approval to market rosuvastatin zinc tablets. As part of its NDA filing, Watson included a

Paragraph IV certification as to the '314 patent, and filed a Section 505(b)(2)(B) Statement certifying that Watson would not seek FDA approval for the indications covered by the '618 and '152 patents. (D.I. 64 at 3; D.I. 77 at 5) As a result of the Section 505(b)(2)(B) Statement, Watson's paper NDA does not include any Paragraph IV certifications as to the '618 and '152 method patents.

EGIS is a Hungarian pharmaceutical company which, through a series of agreements and acquisitions, has partnered with Watson in a joint venture to develop and sell rosuvastatin zinc tablets in the United States. (D.I. 163 at 3-4; D.I. 185 at 3; D.I. 133) AstraZeneca contends that upon FDA approval of Watson's NDA, EGIS will be responsible for manufacturing rosuvastatin zinc active pharmaceutical ingredient ("API") and finished dosage form tablets in Hungary, for importation and sale by Watson in the United States. (D.I. 185 at 3-4; D.I. 133)

B. AstraZeneca's Complaints Against Watson and EGIS

On October 26, 2010, AstraZeneca filed its original Complaint, asserting the '314 patent against Watson. (D.I. 1) AstraZeneca subsequently filed an Amended Complaint, adding Counts II and III, to additionally assert the '618 and '152 patents against Watson. (*See* D.I. 43; D.I. 52) On November 23, 2011, AstraZeneca filed its Second Amended Complaint, adding EGIS as a Defendant and asserting all three patents-in-suit against both Watson and EGIS. (D.I. 133) Thus, the Second Amended Complaint now asserts a total of nine Counts against Watson and EGIS. Counts I, II, and III, respectively, assert the '314, '618, and '152 patents against Watson. Counts IV, V, and VI, respectively, assert that EGIS will induce infringement of the '314, '618, and '152 patents upon FDA approval of Watson's NDA. Counts VII, VIII, and IX, respectively, seek declaratory judgments that EGIS will induce infringement of the '314, '618, and '152

patents upon FDA approval of Watson's NDA.

C. Watson's and EGIS's Motions to Dismiss

On June 8, 2011, Watson moved to dismiss Counts II and III of AstraZeneca's Amended Complaint for lack of subject matter jurisdiction and failure to state a claim. (D.I. 56) On December 22, 2011, EGIS moved to dismiss Counts IV-IX of the Second Amended Complaint for lack of subject matter jurisdiction and failure to state a claim. (D.I. 162)¹

III. LEGAL STANDARDS

A. Rule 12(b)(1) Motion to Dismiss for Lack of Subject Matter Jurisdiction

Federal Rule of Civil Procedure 12(b)(1) authorizes dismissal of a complaint for lack of jurisdiction over the subject matter. *See Samsung Electronics Co., Ltd. v. ON Semiconductor Corp.*, 541 F. Supp. 2d 645, 648 (D. Del. 2008). Motions brought under Rule 12(b)(1) may present either facial or factual challenges to the Court's subject matter jurisdiction.

In reviewing a facial challenge under Rule 12(b)(1), the standards relevant to Rule 12(b)(6) apply. In this regard, the Court must accept all factual allegations in the Complaint as true, and the Court may only consider the complaint and documents referenced in or attached to the complaint. *Gould Electronics, Inc. v. United States*, 220 F.3d 169, 176 (3d Cir. 2000). [In contrast, however,] [i]n reviewing a factual challenge to the Court's subject matter jurisdiction, the Court is not confined to the allegations of the complaint, and the presumption of truthfulness does not attach to the allegations in the complaint. *Mortensen v. First Fed. Sav. & Loan*, 549 F.2d 884, 891 (3d Cir. 1997). Instead, the Court may consider evidence outside the pleadings, including affidavits, depositions and testimony, to resolve any factual issues bearing on jurisdiction. *Gotha v. United States*, 115 F.3d 176, 179 (3d Cir. 1997).

¹Counts II and III against Watson are repeated in AstraZeneca's Second Amended Complaint, and EGIS's motion to dismiss incorporates by reference Watson's previous arguments to dismiss Counts II and III. (D.I. 163 at 1 n.1) It does not appear that any party has suggested that Watson's motion is mooted and needed to be formally renewed as a result of the filing of the Second Amended Complaint. Under these circumstances, the Court will treat Watson's motion to dismiss Counts II and III as being directed to the Second Amended Complaint.

Id.

Once the Court's subject matter jurisdiction over a complaint is challenged, Plaintiff bears the burden of proving that jurisdiction exists. *See Mortensen*, 549 F.2d at 891. "Dismissal for lack of subject-matter jurisdiction because of the inadequacy of the federal claim is proper only when the claim is so insubstantial, implausible, foreclosed by prior decisions of [the Supreme Court], or otherwise completely devoid of merit as not to involve a federal controversy." *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 89, 118 S.Ct. 1003, 140 L.Ed.2d 210 (1998) (internal quotation marks omitted).

B. Rule 12(b)(6) Motion to Dismiss for Failure to State a Claim

Evaluating a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) requires the Court to accept as true all material allegations of the complaint. *See Spruill v. Gillis*, 372 F.3d 218, 223 (3d Cir. 2004). "The issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1420 (3d Cir. 1997) (internal quotation marks omitted). Thus, the Court may grant such a motion to dismiss only if, after "accepting all well-pleaded allegations in the complaint as true, and viewing them in the light most favorable to plaintiff, plaintiff is not entitled to relief." *Maio v. Aetna, Inc.*, 221 F.3d 472, 481-82 (3d Cir. 2000) (internal quotation marks omitted).

However, "[t]o survive a motion to dismiss, a civil plaintiff must allege facts that 'raise a right to relief above the speculative level on the assumption that the allegations in the complaint are true (even if doubtful in fact).'" *Victaulic Co. v. Tieman*, 499 F.3d 227, 234 (3d Cir. 2007) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 127 S.Ct. 1955, 1965, 167 L.Ed.2d 929

(2007)). While heightened fact pleading is not required, “enough facts to state a claim to relief that is plausible on its face” must be alleged. *Twombly*, 127 S.Ct. at 1974. At bottom, “[t]he complaint must state enough facts to raise a reasonable expectation that discovery will reveal evidence of [each] necessary element” of a plaintiff’s claim. *Wilkerson v. New Media Technology Charter School Inc.*, 522 F.3d 315, 321 (3d Cir. 2008) (internal quotation marks omitted). Nor is the Court obligated to accept as true “bald assertions,” *Morse v. Lower Merion School Dist.*, 132 F.3d 902, 906 (3d Cir. 1997) (internal quotation marks omitted), “unsupported conclusions and unwarranted inferences,” *Schuylkill Energy Resources, Inc. v. Pennsylvania Power & Light Co.*, 113 F.3d 405, 417 (3d Cir. 1997), or allegations that are “self-evidently false,” *Nami v. Fauver*, 82 F.3d 63, 69 (3d Cir. 1996).

IV. DISCUSSION

A. Watson’s Motion to Dismiss Section 271(e)(2) Counts II and III

The Court first will address Watson’s motion to dismiss Counts II and III, which allege infringement of the ’618 and ’152 patents under Section 271(e)(2). Both the ’618 and ’152 patents were asserted, and subsequently dismissed, during prior litigation brought by AstraZeneca against different generic drug manufacturers who also sought FDA approval to market generic CRESTOR®. *See AstraZeneca Pharms. LP v. Apotex Corp.*, 2010 WL 5376310 (D. Del. Dec. 22, 2010). AstraZeneca subsequently appealed those dismissals to the Federal Circuit, and that appeal remained pending at the time of the parties’ briefing of the instant motions, as well as at the time of the Court’s hearing on these motions.²

²In their briefing, both sides generally agreed that AstraZeneca’s Federal Circuit appeal involved essentially the same operative facts at issue here, with Watson urging the Court to grant Watson’s motion to dismiss on that basis, and AstraZeneca conversely asking this Court to await

The Federal Circuit recently resolved AstraZeneca’s appeal, issuing an opinion affirming the dismissal of the ’618 and ’152 patents. *See AstraZeneca Pharms. LP v. Apotex Corp.*, No. 2011-1182, --F.3d--, 2012 WL 400306 (Fed. Cir. Feb. 9, 2012) (“*AstraZeneca-Crestor*”). The Federal Circuit concluded that AstraZeneca’s assertion of the ’618 and ’152 patents failed to state a claim under Section 271(e)(2) because the generic drug manufacturer defendants had not sought FDA approval for the method of use indications covered by the ’618 and ’152 patents. Specifically, the Federal Circuit held that “a patented method of using a drug can only be infringed under § 271(e)(2) by filing an ANDA that seeks approval to market the drug for *that use*.” *Id.* at *6 (emphasis added). The Federal Circuit explained that the Hatch-Waxman Act “allows generic manufacturers to limit the scope of regulatory approval they seek – and thereby forego Paragraph IV certification and a § 271(e)(2) infringement suit – by excluding patented indications from their ANDAs.” *Id.* at *7.

This is precisely what Watson has done with respect to its paper NDA. That is, Watson has filed a Section 505(b)(2)(B) Statement certifying that it is not seeking FDA approval for the indications covered by the ’618 and ’152 patents. Thus, for the same reasons stated by the Federal Circuit in its recent *AstraZeneca-Crestor* opinion, Counts II and III also fail to state a viable claim under Section 271(e)(2) against Watson.³

The Court has considered the parties’ letter submissions explaining their respective

the Federal Circuit’s ruling. (D.I. 64 at 4, 7; D.I. 77 at 1-2, 6-7)

³The parties agree that, for purposes of deciding Defendants’ motions to dismiss, there is no meaningful distinction between the ANDAs and Section viii statements at issue in *AstraZeneca-Crestor*, and Watson’s paper NDA and Section 505(b)(2)(B) Statement at issue in the instant litigation. (D.I. 64 at 10; D.I. 77 at 5; D.I. 232 at 3 n.1)

positions concerning the impact of the Federal Circuit's *AstraZeneca-Crestor* decision on the Defendants' instant motions to dismiss. In its letter, AstraZeneca argues that the Federal Circuit's decision is not dispositive with respect to Counts II and III, because the Second Amended Complaint in this case specifically alleges that Watson's Section 505(b)(2)(B) Statement was erroneous or improper, a scenario the Federal Circuit expressly declined to address in its opinion. (D.I. 232 at 3-4) (citing *AstraZeneca-Crestor*, 2012 WL 400306 at *8) However, the Court agrees with Watson that AstraZeneca's arguments amount to essentially the same type of conclusory and speculative allegations rejected by the Federal Circuit in its *AstraZeneca-Crestor* opinion. *See generally* 2012 WL 400306 ("Because Appellees have submitted ANDAs seeking approval to market rosuvastatin calcium for uses that are not subject to AstraZeneca's '618 and '152 method of use patents, AstraZeneca does not state a claim for infringement of these patents under § 271(e)(2)."). Accordingly, again, the Court will grant Watson's motion to dismiss.

B. EGIS's Motion to Dismiss Section 271(e)(2) Counts IV, V, and VI

The Section 271(b) induced infringement Counts IV, V, and VI asserted against EGIS are based on the underlying Section 271(e)(2) Counts I, II, and III asserted against Watson. (*See* D.I. 185 at 6-7) Thus, dismissal of AstraZeneca's Section 271(e)(2) Counts II and III requires dismissal of the corresponding Section 271(b) Counts V and VI against EGIS for failure to state a claim. *See BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1380 (Fed. Cir. 2007) ("[I]nducement of infringement requires a predicate finding of direct infringement.").

The Court now turns to Count IV. Count IV alleges that EGIS will induce infringement of the '314 patent upon FDA approval of Watson's NDA. The Court is unpersuaded by EGIS's

various arguments for dismissing Count IV.

As an initial matter, subject matter jurisdiction over Count IV is supported by the Federal Circuit's recent *AstraZeneca-Crestor* decision. *See* 2012 WL 400306, at *5 ("AstraZeneca alleged that the . . . ANDA filings infringed its listed patents under § 271(e)(2), and nothing more was required to establish the district court's subject matter jurisdiction."). To the extent EGIS still maintains that subject matter jurisdiction is lacking because FDA approval of Watson's NDA is too remote and speculative to establish an Article III case or controversy (D.I. 163 at 15), the Federal Circuit's precedent holds otherwise.⁴ *See Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1331-32 (Fed. Cir. 2003) ("While a section 271(e)(2) induced infringement claim may be speculative, it is not sufficiently so to contravene the case or controversy requirement."); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1571 (Fed. Cir. 1997) (holding that district court had properly exercised jurisdiction over Glaxo's declaratory judgment claim where defendant was "systematically attempting to meet the applicable regulatory requirements while preparing to import its product.")⁵

⁴The present controversy is distinguishable from the facts at issue in this Court's dismissal of AstraZeneca's Section 271(a) declaratory judgment claims involving the '314 patent in another action. *See In re Rosuvastatin Calcium Patent Litigation*, 2008 WL 5046424 (D. Del. Nov. 24, 2008), adopted by *AstraZeneca Pharms. LP v. Aurobindo Pharma Ltd.*, 2009 WL 483131 at *3 (D. Del. Feb. 25, 2009). In that case, both the Section 271(e)(2) and the Section 271(a) declaratory judgment counts were filed at the same time, against the same generic manufacturers, and were based on the same facts; both claims also sought the same relief. *Id.* at *12-13. Here, by contrast, the various counts against EGIS were brought well after the original Complaint and are directed to a different entity; they do not present the same remoteness and redundancy concerns that informed the Court's prior ruling.

⁵Although *Glaxo* involved a declaratory judgment claim, the Article III analysis is the same for both declaratory judgment and non-declaratory judgment claims. *See MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 126-27 (2007) (noting that "the phrase 'case of actual controversy' in the [Declaratory Judgment] Act refers to the type of 'Cases' and 'Controversies'

EGIS contends that the Section 271(e)(2) induced infringement claims of Count IV are improperly directed against activities protected by the Section 271(e)(1) safe harbor. (D.I. 163 at 9-13) This argument is again contrary to the Federal Circuit’s prior decisions. *See Forest Labs., Inc. v. Ivax Pharms., Inc.*, 501 F.3d 1263, 1272 (Fed. Cir. 2007) (rejecting dissenting opinion’s position that Section 271(e)(1) safe harbor precluded injunctive relief against generic manufacturer’s development partner); *Glaxo*, 110 F.3d at 1571 (“[T]he district court properly exercised its discretion to hear Glaxo’s declaratory judgment action, even though that action was premised in part on actions protected under § 271(e)(1).”).

Finally, EGIS contends that *Allergan* narrowly permits Section 271(e)(2) induced infringement claims only under limited circumstances involving the assertion of method of use patents against an actual ANDA or paper NDA filer, but does not allow the assertion of composition patents such as the ’314 patent against a development partner like EGIS. (D.I. 162 at 18-19; D.I. 192 at 5) This overlooks the Federal Circuit’s decision in *Forest*, which stated, “Section 271(e)(2) may support an action for induced infringement” without limitation as to any particular types of patents or defendants. 501 F.3d at 1272. In upholding an injunction that included the ANDA filer’s development partner, the Federal Circuit in *Forest* concluded that an “inquiry into induced infringement focuses on the party accused of inducement as the prime mover in the chain of events leading to infringement.” *Id.* Here, AstraZeneca has adequately alleged in its Second Amended Complaint that EGIS is a prime mover responsible for the events that will lead to Watson’s eventual FDA approval. Thus, EGIS’s motion to dismiss Count IV

that are justiciable under Article III”).

will be denied.⁶

C. EGIS's Motion to Dismiss Declaratory Judgment Counts VII, VIII, and IX

Counts VII, VIII, and IX seek a declaratory judgment that EGIS will induce infringement of the patents-in-suit upon FDA approval of Watson's NDA. Because the declaratory judgment claim of Count VII is duplicative of Count IV, with both counts alleging that EGIS will induce infringement of the '314 patent upon FDA approval of Watson's paper NDA, the Court will exercise its discretion to dismiss Count VII.⁷

Counts VIII and IX, respectively, seek declaratory judgments that EGIS will induce infringement of the '618 and '152 patents upon FDA approval of Watson's NDA. In the Court's view, although Counts VIII and IX allege a sufficiently "imminent" controversy for the same reasons explained in connection with Count IV, they fail to present a controversy of sufficient "reality" for purposes of Article III, and therefore must be dismissed for lack of subject matter jurisdiction.

Whether a declaratory judgment claim presents an Article III case or controversy depends on "whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy *and reality*

⁶The Court will also deny EGIS's 12(b)(6) motion to dismiss Count IV for failure to state a claim. EGIS contends that "AstraZeneca has not alleged any predicate act of direct infringement in support of the inducement counts against EGIS." (D.I. 163 at 16-17) To the contrary, the Court agrees with AstraZeneca that the Second Amended Complaint adequately alleges induced infringement against EGIS based on underlying acts of direct infringement by Watson. (*See* D.I. 133 at ¶¶ 33, 94-96)

⁷During the hearing, counsel for AstraZeneca conceded that each of Counts IV-VI and their respective counterpart Counts VII-IX were largely redundant of one another, and acknowledged that AstraZeneca did not need to assert both Counts for any of the three patents. (Tr. at 80)

to warrant the issuance of a declaratory judgment.” *MedImmune*, 549 U.S. at 127 (emphasis added). Assessing the “reality” requirement of Article III requires analysis of “whether . . . the potentially infringing subject of the declaratory-judgment suit was substantially *fixed*, particularly with respect to its potentially-infringing characteristics, on the date the complaint was filed.” *Sierra Applied Scis., Inc. v. Advanced Energy Indus., Inc.*, 363 F.3d 1361, 1379 (Fed. Cir. 2004). Thus, the “greater the variability of the subject of a declaratory-judgment suit, particularly as to its potentially infringing features, the greater the chance that the court’s judgment will be purely advisory.” *Id.*

Here, the “potentially infringing subject” is Watson’s proposed NDA label. AstraZeneca alleges that Watson’s label will cause doctors and patients to use Watson’s rosuvastatin zinc product for the indications covered by the ’618 and ’152 patents, notwithstanding Watson’s Section 505(b)(2)(B) Statement. As AstraZeneca has argued in its own letter submission, however, Watson’s proposed label has not remained substantially fixed over time, and in fact previously has been altered by Watson with respect to information relating to the ’618 and ’152 patents, in an apparent effort to protect itself from the very same induced infringement allegations now asserted by AstraZeneca. (D.I. 232 at 3) Thus, as AstraZeneca’s own arguments and evidence demonstrate, Watson’s label remains “fluid and indeterminate” and, thus, does not provide the basis for a justiciable Article III controversy of sufficient “reality.” *Sierra*, 363 F.3d at 1379. Accordingly, the Court will dismiss Counts VIII and IX for lack of subject matter jurisdiction.⁸

⁸The potentially fluid nature of Watson’s label is a key distinction between this case and *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042 (Fed. Cir. 2010), cited by AstraZeneca in its letter submission. (D.I. 232 at 4) There, Apotex had obtained final FDA approval at the time of

Finally, even if Counts VIII and IX did present a justiciable Article III controversy, the Court would nonetheless exercise its discretion to dismiss them. The Federal Circuit’s recent *AstraZeneca-Crestor* opinion appears to contemplate a narrow Hatch-Waxman cause of action, which is inconsistent with permitting a count asserting infringement based on something Defendants do not seek to do, and will have no legal authority to do (or to induce others to do). Moreover, under the circumstances of the instant case, the Court agrees with Watson that this case began as a narrow dispute about infringement of the ’314 patent and should remain so. In this regard, the Court can maintain the current schedule and provide a timely resolution of the dispute among the parties that gave rise to this litigation.⁹

AstraZeneca’s declaratory judgment action and motion for preliminary injunction. *Id.* at 1047. There was a sufficiently real controversy because the information in Apotex’s label was substantively fixed by the time of Apotex’s anticipated launch, which supported AstraZeneca’s 271(b) allegations notwithstanding Apotex’s Section viii statement. Additionally, the label in *Apotex* contained step-by-step instructions leading directly to infringement, an allegation that is absent here.

⁹AstraZeneca further suggests that “in the interests of conserving the Court’s and parties’ resources and avoiding prejudice to the parties,” the Court should separate trial on the ’314 patent from trial on the ’618 patent and ’152 patents. (D.I. 232 at 2) As the Court is dismissing the counts relating to the latter two patents, AstraZeneca’s suggestion is moot. Additionally, Plaintiffs “propose to amend their pleadings to assert Counts II and III as declaratory judgment claims for induced infringement against Watson.” (D.I. 232 at 5) The Court agrees with Defendants that a request for such relief – if AstraZeneca continues to seek it – must come through a formal motion and briefing. (D.I. 238 at 3)

V. CONCLUSION

For the foregoing reasons, the Court will grant Watson's motion to dismiss Counts II and III of the Second Amended Complaint for failure to state a claim. The Court also will grant EGIS's motion to dismiss Counts V and VI for failure to state a claim, and Counts VIII and IX for lack of subject matter jurisdiction. The Court will deny EGIS's motion to dismiss Count IV and will exercise its discretion to dismiss Count VII as duplicative of Count IV. An appropriate order follows.

