

**LITE DEPALMA GREENBERG & RIVAS, LLC**

Allyn Z. Lite  
Michael E. Patunas  
Two Gateway Center, 12th Floor  
Newark, New Jersey 07102  
(973) 623-3000

*Attorneys for Plaintiffs Teva Pharmaceutical  
Industries Ltd. and Teva Pharmaceuticals USA, Inc.*

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

TEVA PHARMACEUTICAL INDUSTRIES	:	
LTD. and TEVA PHARMACEUTICALS	:	
USA, INC.,	:	
	:	
Plaintiffs	:	Civil Action No.
	:	
v.	:	
	:	
USV LIMITED,	:	
	:	
Defendant.	:	
	:	

**COMPLAINT FOR DECLARATORY JUDGMENT**

For their Complaint against Defendant USV Limited (“Defendant”), Plaintiffs Teva Pharmaceutical Industries Ltd. (“Teva Ltd.”) and Teva Pharmaceuticals USA, Inc. (“Teva USA”; collectively, “Plaintiffs”) allege as to their own acts, and on information and belief as to the acts of others, as follows:

**THE PARTIES**

1. Teva Ltd. is a corporation organized under the laws of Israel, and maintains its principal place of business at 5 Basel Street, Petah Tiqva 49131, Israel.

2. Teva USA is a Delaware corporation with its principal place of business located at 1090 Horsham Road, North Wales, Pennsylvania, 19454-1090. Teva USA is a wholly-owned subsidiary of Teva Ltd.

3. On information and belief, Defendant is an Indian corporation based in Mumbai, India. On further information and belief, Defendant is engaged in the business of developing, manufacturing, and selling various pharmaceutical products, many of which are sold in New Jersey. On further information and belief, Defendant conducts its business in the United States through the use of a pharmaceutical supply agent called SST Corporation based in Clifton, New Jersey.

#### **NATURE OF THE ACTION**

4. This is an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and seeking injunctive relief under 35 U.S.C. §§ 281-283.

#### **JURISDICTION AND VENUE**

5. This Court has subject matter jurisdiction over this controversy under 28 U.S.C. §§ 1331 and 1338(a), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

6. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because this is a case of actual controversy within the Court's jurisdiction.

7. This Court has personal jurisdiction over Defendant because of, *inter alia*, Defendants' systematic, purposeful and continuous contacts in this District, including its sales of pharmaceutical products into the District and availment of the privilege of doing business in this District through its pharmaceutical supply agent SST Corporation.

8. Venue is proper in this judicial district based on 28 U.S.C. § 1400(b) and/or 28 U.S.C. § 1391(b), (c), and (d).

### FACTUAL BACKGROUND

#### The Patents in Suit

9. Teva Ltd. is the owner of all right, title and interest in United States Patent Nos. 6,699,997 (“the ‘997 Patent”), 6,710,184 (“the ‘184 Patent”), 7,056,942 (“the ‘942 Patent”), and 7,126,008 (“the ‘008 Patent”; collectively, “the patents in suit”) relating to, *inter alia*, various forms of a chemical compound known as carvedilol and processes for preparing various forms of carvedilol. One polymorphic form of carvedilol is known as “Form II.”

10. The ‘997 Patent was duly and legally issued by the United States Patent and Trademark Office (“PTO”) on March 2, 2004 for an invention entitled “Carvedilol.” A copy of the ‘997 Patent is attached as Exhibit A.

11. The ‘008 Patent was duly and legally issued by the PTO on October 24, 2006 for an invention entitled “Carvedilol.” A copy of the ‘008 Patent is attached as Exhibit B.

12. The ‘997 and ‘008 Patents claim processes for preparing carvedilol.

13. The ‘184 Patent was duly and legally issued by the PTO on March 23, 2004 for an invention entitled “Crystalline Solids of Carvedilol and Processes for Their Preparation.” A copy of the ‘184 Patent is attached as Exhibit C.

14. The ‘184 Patent claims processes for preparing carvedilol Form II.

15. The ‘942 Patent was duly and legally issued by the PTO on June 6, 2006 for an invention entitled “Carvedilol.” A copy of the ‘942 Patent is attached as Exhibit D.

16. The ‘942 Patent claims, *inter alia*, a hydrate form of carvedilol hydrochloride.

### **GlaxoSmithKline's Exclusivity**

17. Carvedilol is a pharmaceutical compound used in the treatment of congestive heart failure. It is the active pharmaceutical ingredient ("API") in the product sold by GlaxoSmithKline ("GSK") under the trade name COREG<sup>®</sup>. COREG<sup>®</sup> is included in the United States Food and Drug Administration's ("FDA") list of "Approved Drug Products With Therapeutic Equivalence Evaluations," also known as the "Orange Book."

18. The carvedilol compound is disclosed and claimed in U.S. Patent No. 4,503,067 ("the '067 Patent"), which is owned by GSK. The '067 Patent is listed in the FDA's Orange Book in association with COREG<sup>®</sup>. The '067 Patent expired on March 5, 2007.

19. Pursuant to 21 U.S.C. § 355a, GlaxoSmithKline was awarded a six-month period of pediatric exclusivity following the expiration of the '067 Patent. GlaxoSmithKline's pediatric exclusivity period extends from March 5, 2007 to September 5, 2007. Pursuant to this exclusivity, the FDA cannot grant final approval to any Abbreviated New Drug Application ("ANDA") holders for carvedilol during that period. The FDA may grant final approval to ANDA holders beginning immediately upon expiration of GSK's pediatric exclusivity period.

20. There are nine holders of ANDAs for carvedilol that have received tentative approval from the FDA. Final approval is expected to be granted to these ANDA holders shortly after the expiration of GSK's pediatric exclusivity period on September 5, 2007. Once each ANDA holder receives final approval, it may market carvedilol tablets in the United States.

### **Defendant's Imminent Infringement of the Patents in Suit**

21. Under the Act, ANDA holders must provide detailed information to the FDA about how the API to be used in their proposed generic products will be made. ANDA holders

may purchase API from a supplier instead of making API themselves. Suppliers of API typically are reluctant to disclose confidential information about their manufacturing processes to their customers and, instead, may submit this confidential information directly to the FDA in the form of a Drug Master File (“DMF”). ANDA filers who intend to purchase API from a given supplier may then reference the API supplier’s DMF in their ANDAs. Upon receiving an ANDA referencing a DMF, the FDA will separately review the DMF as part of the ANDA approval process. Accordingly, the act of filing a DMF indicates that the present intent of the DMF filer is to supply API in the United States.

22. On information and belief, Defendant has filed DMF No. 17487 for carvedilol API with the FDA.

23. On information and belief, Defendant plans and intends to supply carvedilol API to one or more third party ANDA holder(s), with the knowledge and intent that the third party ANDA holder(s) will engage in the commercial importation, manufacture, use, sale and/or offer for sale of generic carvedilol tablets in the United States.

24. On information and belief, Defendant plans and intends to supply carvedilol API to the third party ANDA holder(s) with the knowledge and intent that the third party ANDA holder(s) will engage in the activities described in paragraph 23 immediately upon receiving final approval of the ANDA(s) from the FDA, and that said approval will occur shortly after GSK’s pediatric exclusivity period expires on September 5, 2007.

25. On information and belief, Defendant plans and intends to supply carvedilol API to the third party ANDA holder(s) with the knowledge and intent that the third party ANDA

holder(s) will engage in the activities described in paragraph 23 prior to the expiration of the patents in suit.

26. On information and belief, Defendant plans and intends to import carvedilol API into the United States for sale to third party ANDA holder(s).

27. On information and belief, Defendant's carvedilol API infringes or will infringe one or more claims of the patents in suit, and/or is or will be made by a process that infringes one or more claims of the patents in suit. Accordingly, Defendant's plans and intentions to import and sell carvedilol API in the United States constitute imminent, threatened acts of infringement under 35 U.S.C. § 271, which give rise to an actual controversy over which the Court may exercise jurisdiction.

28. On information and belief, Defendant's plans and intentions to supply carvedilol API to third party ANDA holder(s) outside of the United States for incorporation into products that it knows will be imported and sold in the United States constitutes imminent, threatened inducement of infringement under 35 U.S.C. § 271, which gives rise to an actual controversy over which this Court may exercise jurisdiction.

29. Plaintiffs have made a reasonable effort to determine the chemical composition of Defendant's carvedilol API, as well as the processes by which Defendant's carvedilol API is or will be made. On May 8, 2007, Teva USA notified Defendant of the existence of the patents in suit and sought information allowing Plaintiffs to ascertain whether Defendant's API falls within the scope of one or more of the patents in suit, and/or whether Defendant's API is made pursuant to a process that falls within the scope of one or more of the patents in suit. In particular, Teva USA requested samples of all carvedilol API made pursuant to Defendant's DMF, and a detailed

description of all processes that will be used to manufacture Defendant's carvedilol API. Teva USA offered to enter into a confidentiality agreement to protect the confidentiality of any information disclosed by Defendant. Pursuant to this offer, Teva USA supplied a proposed confidentiality agreement to Defendant.

30. Defendant has not provided to Teva USA samples of Defendant's carvedilol API or the detailed information requested regarding the processes by which Defendant's carvedilol API is made, despite Teva USA's offer of confidentiality. Further, Plaintiffs have been unable to obtain samples of Defendant's API from a public source.

31. Without the requested information, Plaintiffs are unable to determine whether Defendant's API infringes one or more compounds claimed in the patents in suit, or whether the processes by which Defendant's API is made infringe one or more methods claimed in the patents in suit. For this reason, Plaintiffs cannot conclusively determine whether Defendant infringes each of the patents in suit unless and until Defendant provides samples of its API and discloses to Plaintiffs the processes by which the API is made.

32. In the absence of a sufficient response from Defendant, Plaintiffs have no choice but to resort to the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, the information required to confirm their beliefs as to infringement and to present the Court evidence that Defendant will infringe the patents in suit.

33. As a direct and proximate consequence of the planned and intended infringement by Defendant, Plaintiffs will be injured in their business and property rights unless the infringement is enjoined by the Court, and will suffer injury for which they are entitled to relief.

**COUNT I**

**Declaratory Judgment of Patent Infringement**

34. Plaintiffs repeat and reallege Paragraphs 1 through 33 of the Complaint as if fully set forth herein.

35. On information and belief, the importation, manufacture, use, sale and/or offer for sale by Defendant of its carvedilol API pursuant to DMF No. 17487 will infringe, either literally or under the doctrine of equivalents, one or more claims of the '997, '184, '942, and/or '008 Patents, or will contribute to or induce such infringement, under 35 U.S.C. § 271.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs Teva Ltd. and Teva USA respectfully request a judgment from the Court:

1. Declaring that the '997, '184, '942, and '008 Patents are valid and enforceable;
2. Declaring that Defendant will infringe, either literally or under the doctrine of equivalents, one or more claims of the '997, '184, '942, and/or '008 Patents, or will contribute to or induce such infringement, under 35 U.S.C. § 271;
3. Declaring that Defendant's infringement will be willful and that this is an exceptional case under 35 U.S.C. § 285;
4. Permanently enjoining Defendant, its officers, agents, servants and employees, and those persons in active concert or participation with any of them, from infringing the '997, '184, '942, and '008 Patents;
5. Awarding Plaintiffs their attorneys' fees, costs, and expenses; and

6. Awarding Plaintiffs such other relief that the Court deems proper, just and equitable.

**LITE DEPALMA GREENBERG & RIVAS, LLC**

Dated: June 22, 2007

/s/ Michael E. Patunas  
Allyn Z. Lite  
Michael E. Patunas  
Two Gateway Center, 12th Floor  
Newark, New Jersey 07102  
(973) 623-3000

*Attorneys for Plaintiffs Teva Pharmaceutical  
Industries Ltd. and Teva Pharmaceuticals USA, Inc.*

**LOCAL CIVIL RULE 11.2 CERTIFICATION**

Plaintiffs, by their attorneys, hereby certify that the matter in controversy is also the subject of the following actions:

<b><u>Caption</u></b>	<b><u>Docket No.Court</u></b>
<i>Teva Pharmaceutical Industries Ltd., et al. v. Ranbaxy Laboratories, Ltd., et al.</i>	Filed on 6/21/07 D.N.J.
<i>Teva Pharmaceutical Industries Ltd., et al. v. Dr. Reddy's Laboratories Inc., et al</i>	Filed on 6/21/07 D.N.J.
<i>Teva Pharmaceutical Industries Ltd., et al. v. Watson Pharmaceuticals, Inc.</i>	Filed on 6/21/07 D.N.J.
<i>Teva Pharmaceutical Industries Ltd., et al. v. Lupin Limited, et al.</i>	Filed on 6/21/07 D.N.J.
<i>Teva Pharmaceutical Industries Ltd., et al. v. MOEHS IBERICA, S.L</i>	Filed on 6/21/07 D.N.J.
<i>Teva Pharmaceutical Industries Ltd., et al. v. Orchid Pharmaceuticals, Inc. ,et al.</i>	Filed on 6/21/07 D.N.J.
<i>Teva Pharmaceutical Industries Ltd., et al. v. URQUIMA, S.A.</i>	Filed on 6/21/07 D.N.J.

I hereby certify that the following statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

Dated: June 22, 2007

/s/ Michael E. Patunas  
Michael E. Patunas

J. Mark Pohl, Esq. (JP-4457)  
PHARMACEUTICAL PATENT ATTORNEYS, LLC  
55 Madison Avenue, 4<sup>th</sup> floor  
Morristown, New Jersey 07960-7397  
Attorneys for Defendant

TEVA PHARMACEUTICAL  
INDUSTRIES LTD.

Plaintiff,

vs.

USV LIMITED

Defendant.

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

Civil Action No.

3:07-2911-GEB-JJH

**ANSWER**

Defendant for its Answer to the COMPLAINT, states as follows:

**JURISDICTION AND VENUE**

1. Defendant admits the allegations in Paragraph 1.
2. Defendant admits the allegations in Paragraph 2.
3. Defendant admits the allegations in Paragraph 3, except that Defendant denies that SST Corporation is Defendant's "agent" in the legal sense

of the word (*i.e.*, SST Corporation is an independent third-party distributor, and is not authorized to act on behalf of the Defendant).

4. Defendant denies that Title 35 of the United States Code provides a remedy for hypothetically-possible future acts.

5 **FACTUAL BACKGROUND**

5. Defendant denies that this Court has subject matter jurisdiction because:

(a) Defendant discontinued making carvedilol made pursuant to Drug Master File 17487 (the “accused product”) in January 2004, so this is not a “case or controversy.” *See* Exhibit F.

(b) Defendant has already satisfied Plaintiff’s demand to provide samples of the accused product by providing Plaintiff<sup>1</sup> four samples of the accused product in 2003, so this case is moot. *See* Exhibit C.

(c) Defendant has withdrawn the Drug Master file at issue, so this case is moot. *See* Exhibit G.

(d) Adjudicating hypothetically-possible future infringement would require this Court to exceed its subject matter jurisdiction and promulgate an advisory opinion.

---

<sup>1</sup> The samples were delivered to Ivax Pharmaceuticals Inc., Plaintiff’s U.S. subsidiary. *See* Exhibits B and C.

6. Defendant denies this is “a case of actual controversy” for the reasons stated above.

7. Defendant denies this Court has personal jurisdiction over the Defendant because:

5 (a) SST Corporation is not Defendant’s “agent” (*see supra*).

(b) Defendant does not sell the accused product anywhere in The United States of America. *See* Exhibits F and G.

(c) Plaintiff failed to sufficiently serve process. *See* Exhibit E.

8. Defendant does not contest the allegations of Paragraph 8.

10 9. Defendant does not contest the allegations of Paragraph 9.

10. Defendant denies the ‘997 patent was “duly and legally issued.” To the contrary, the facts alleged in Plaintiff’s own Complaint contradict that conclusion. Defendant manufactured the accused product until January 2004. *See* Exhibit F. In so doing, Defendant used a manufacturing process which was  
15 invented not by Plaintiff, but by scientists at Boehringer Mannheim GmbH of Mannheim, Germany. *Id.* Boehringer Mannheim applied to patent the accused product on April 13, 1978. *See* Exhibit A at page 1, left column, item [30].  
Boehringer Mannheim’s patent application was published on October 31, 1979.

The Complaint alleges that the patents in suit cover the accused product.

20 *See infra at e.g., ¶ 27.* In so doing, the Complaint alleges that the patents in suit

cover a product which Boehringer Mannheim invented almost thirty years ago. The patents in suit cannot lawfully cover something which *another company invented*, nor something which has been *publicly known* for almost thirty years. Thus, accepting as true Plaintiff's allegations regarding the coverage of the patents in suit, the patents in suit cannot as a matter of law have been "duly and legally issued."

11. Defendant denies the allegations of Paragraph 11 for the reasons stated in Paragraph 10.

12. Defendant admits the allegations of Paragraph 12.

13. Defendant denies the allegations of Paragraph 13 for the reasons stated in Paragraph 10.

14. Defendant admits the allegations of Paragraph 14.

15. Defendant denies the allegations of Paragraph 15 for the reasons stated in Paragraph 10.

16. Defendant admits the allegations of Paragraph 16.

17. Defendant admits the allegations of Paragraph 17.

18. Defendant admits the allegations of Paragraph 18 (Contrary to Plaintiff's allegation, the '067 patent is not owned by GlaxoSmithKline Plc; that error is not, however, germane to this lawsuit.)

19. Defendant admits the allegations of Paragraph 19.

20. Defendant lacks sufficient information to admit or deny the allegations of Paragraph 20.

21. Defendant admits the allegations of the first five sentences of Paragraph 21. Defendant denies the last sentence of Paragraph 21 because it is contradicted by the undisputed factual record. Defendant filed Drug Master File 17487 on June 24, 2004. *See* Exhibit F. Since then, Defendant has neither made the accused product, nor sold it anywhere in the world. *Id.* Contrary to Plaintiff's representation to this Court, Defendant's Drug Master File 17487 has sat unused for over three years. *Id.* This fact - three years of idleness - directly contradicts Plaintiff's inference that filing a DMF indicates a "present intent" to supply API.

22. Defendant admits the allegations of Paragraph 22.

23. Defendant denies that it "plans and intends" to supply the accused product to anyone, anywhere in the world. Defendant last manufactured the accused product in January of 2004. *See* Exhibit F. Furthermore, Defendant has asked the U.S. Food & Drug Administration to withdraw Drug Master File 17487. *See* Exhibit G. Contrary to Plaintiff's factual representation to this Court, Plaintiff has neither *information* nor any objective basis for a *belief* that Defendant "plans and intends" to supply the accused product.

24. Defendant denies the allegations of Paragraph 24, because of the facts stated in Defendant's answer to Paragraph 23.

25. Defendant denies the allegations of Paragraph 25, because of the facts stated in Defendant's answer to Paragraph 23.

5 26. Defendant denies the allegations of Paragraph 26, because of the facts stated in Defendant's answer to Paragraph 23.

27. Defendant denies that the accused product "infringes or will infringe" the patents in suit. The accused product cannot as a matter of law infringe the patents in suit because Defendant does not make, use sell, offer to sell nor import the accused product in The United States. *See* Exhibits F and G.

10 The accused product cannot as a matter of law infringe the patents in suit because the accused product was made by a process invented by Boehringer Mannheim, not by Plaintiff. *See* Exhibit F.

15 The accused product cannot as a matter of law infringe the patents in suit because Plaintiff has already acknowledged in writing that the accused product is exempt from infringement as a matter of law. The Patent Statute says:

20 *It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention ... solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use and sale of drugs or veterinary biological products.*

See 35 U.S.C. § 271((e)(1) (emphasis mine). On February 14, 2003, Plaintiff executed an Assent agreeing that the accused product was “solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use and sale of drugs and will not be used and / or sold in a manner that infringes the claims of any United States patent.” See Exhibit B. By executing that written Assent, Plaintiff conceded that the accused product is exempt from infringement pursuant to 35 U.S.C. § 271((e)(1).

Defendant denies having any “plans and intentions to import and sell” the accused product into the United States. See Exhibit F.

Defendant denies that hypothetically-possible future acts, regardless of how “imminent,” constitute infringement under 35 U.S.C. § 271. Defendant denies that hypothetically-possible future acts of potential infringement constitute an “actual controversy.”

Defendant denies Plaintiff’s representation to this Court that its allegations are made “on information and belief,” because such pleading requires the signing attorney to have performed a reasonable pre-litigation investigation of the facts there alleged. In the immediate case, Plaintiff received four samples of the accused product in 2003. See Exhibits B and C. If Plaintiff had performed a reasonable pre-litigation investigation (*e.g.*, if Plaintiff had

analyzed those samples), then Plaintiff could have readily obtained information on whether the accused product was covered by the patents in suit. *See* Exhibit D. Plaintiff failed to do so. Plaintiff's allegations are therefore not based on *information*, but on *speculation*.

5           28. Defendant denies having "plans and intentions" to supply the accused product to anyone, anywhere. *See* Exhibit F. Defendant denies that hypothetically-possible future infringement, even if "imminent," would be actionable as a matter of law under 35 U.S.C. § 271. Defendant denies that hypothetically-possible future infringement, even if "imminent," would be a  
10 "case or controversy."

          29. Defendant denies that "Plaintiffs have made a reasonable effort to determine the chemical composition of" the accused product. Contrary to Plaintiff's representation to this Court, Plaintiff was sent four samples of the accused product: two samples on February 14, 2003, and two samples on  
15 September 29, 2003. *See* Exhibits B and C. Contrary to Plaintiff's representation to this Court, Plaintiffs have not "made a reasonable effort" to determine the chemical composition of those samples. *See* Exhibit D. to the contrary, Plaintiff has apparently made no effort at all to do so. *See id.*

          Defendant admits that Plaintiff requested samples of the accused product.  
20 Contrary to Plaintiff's representation to this Court, however, Plaintiff was in fact

sent four samples of the accused product: two samples on February 14, 2003, and two samples on September 29, 2003. *See* Exhibits B and C.

Defendants admit that on May 10, 2007, Teva USA sent a letter. *See* Exhibit D. Defendant admits that Plaintiff's letter included a document titled, "Confidential Disclosure Agreement." *Id.* Contrary to Plaintiff's representation to this Court, however, Plaintiff did not offer to "protect the confidentiality of any information disclosed by Defendant." To the contrary, Plaintiff's "Confidential Disclosure Agreement" proposed that Defendant *wave* confidentiality. *See id.* at ¶¶ 2, 6, 7.

30. Defendant denies that it has not provided samples of the accused product to Plaintiff. Contrary to Plaintiff's factual representations to this Court, Defendant provided Plaintiff with two samples of the accused product on February 14, 2003, and two additional samples on September 29, 2003. *See* Exhibits B and C.

Defendant lacks information to admit or deny whether Plaintiff has "been unable to obtain samples of" the accused product from a public source. Defendant notes, however, that Plaintiff's allegation is not implausible because Defendant discontinued making the accused product in January 2004. *See* Exhibit F.

31. Defendant denies that Plaintiffs are “unable to determine” whether the accused product is covered by the patents in suit, because Plaintiff has had samples of the accused product since 2003. *See* Exhibits B and C. Defendant denies that Plaintiffs “cannot conclusively determine” whether the accused product is covered by the patents in suit because, contrary to Plaintiff’s factual representation to this Court, Plaintiff already has four samples of the accused product. *See* Exhibits B and C.

32. Defendant denies the “absence of a sufficient response” to Plaintiff; to the contrary, Defendant already provided Plaintiff with four samples of the accused product. *See* Exhibits B and C. Defendant denies that Plaintiff has “no choice but to resort to the judicial process and the aid of discovery” to obtain those samples, because Plaintiff already has them. *See* Exhibits B and C.

33. Defendant denies the existence of “planned and intended” future infringement. *See* Exhibits F and G. Defendant denies that Plaintiff has any legally-cognizable “business and property rights” prohibiting hypothetically-possible future infringement.

**FIRST COUNT**  
**Declaratory Judgment of Patent Infringement**

34. Defendant repeats its responses to Paragraphs 1-34 as if set forth herein at length.

35. Defendant denies the existence of any actionable “importation, manufacture, use, sale and/or offer for sale” of the accused product. *See* Exhibits F and G. Defendant denies any actionable manufacture of “carvedilol API pursuant to DMF No. 17487” because Defendant stopped making the  
5 accused product in January 2004 (before the patents in suit issued) and because Defendant has already asked the Food & Drug Administration to withdraw that Drug Master File. *See* Exhibits F and G. Defendant denies that the patents in suit can lawfully cover the accused product because the accused product was invented by Boehringer Mannheim GmbH, not Plaintiff. *See* Exhibit F ¶ 2.

10 Defendant states as follows:

**FIRST AFFIRMATIVE DEFENSE**

36. The Court lacks jurisdiction over the subject matter because of the facts above stated.

15 **SECOND AFFIRMATIVE DEFENSE**

37. The Court lacks jurisdiction over the Defendant because of the facts above stated.

**THIRD AFFIRMATIVE DEFENSE**

38. Service of process was insufficient. *See* Exhibit E.

**FOURTH AFFIRMATIVE DEFENSE**

39. The Complaint fails to state a claim upon which relief can be granted because of the facts above stated.

5 **FIFTH AFFIRMATIVE DEFENSE**

40. Plaintiff has already agreed in writing that the accused product is exempt from patent infringement under 35 U.S.C. § 271(e)(1). *See* Exhibit B.

**SIXTH AFFIRMATIVE DEFENSE**

10 41. Defendant has already provided four samples of the accused product to Plaintiff. *See* Exhibits B and C. The relief requested by Plaintiff (discovery compelling production of samples) is therefore barred by the doctrine of “accord and satisfaction.”

**SEVENTH AFFIRMATIVE DEFENSE**

15 42. In the Assent dated February 14, 2003, Plaintiff has granted a waiver, a release and / or a license to the patents in suit. *See* Exhibit B.

Defendant respectfully asks this Court to:

1. Dismiss Plaintiff's Complaint for lack of subject matter jurisdiction.

2. Dismiss Plaintiff's Complaint for lack of personal jurisdiction.

5 3. Dismiss Plaintiff's Complaint for insufficiency of service of process.

4. Dismiss Plaintiff's Complaint for failure to state a claim on which relief can be granted.

10 5. Find this case exceptional and award to Defendant its legal fees and costs of suit pursuant to 35 U.S.C. § 285.

6. Immediately enjoin Plaintiff from further delaying testing its samples of the accused product to determine whether any claim of the patents in suit covers the accused product.

15 7. Permanently enjoin Plaintiff from enforcing the patents in suit (and future related patents, if any) against the Defendant.

8. Find Plaintiff and its counsel in violation of F.R.C.P. Rule 11(c)(1)(A) and impose sanctions adequate to discourage Plaintiff and its counsel from repeating this behavior in the future.

9. Award Defendant such further relief as the Court deems just and proper.

PHARMACEUTICAL PATENT  
ATTORNEYS, LLC  
Attorneys for Defendant

By: \_\_\_\_\_/s/\_\_\_\_\_  
J. Mark Pohl (JP-4457)

Dated: Friday, July 13, 2007

Pharmaceutical Patent Attorneys, LLC  
*www.LicensingLaw.Net*

55 Madison Avenue, 4th floor (P 4014)  
Morristown, NJ 07960-7397 USA / Etats Unis

Practice limited to Domestic & International  
Pharmaceutical Patent law and licensing

20 July 2007

Mr. Michael E. Patunas, Esq.  
Lite, DePalma Greenberg & Rivas, LLC  
Two Gateway Center, 12<sup>th</sup> floor  
Newark, NJ 07102

BY PRIORITY MAIL WITH  
DELIVERY CONFIRMATION

Re: Teva Pharmaceutical Industries Ltd. v. USV Limited  
Docket No. 3:07-CV-02911-GEB-JJH

Dear Mr. Patunas :

Pursuant to F.R.C.P. Rule 11(c)(1)(A), enclosed find Defendant's motion for  
Sanctions.

Sincerely,  
PHARMACEUTICAL PATENT ATTORNEYS, LLC

/s/  
J. Mark Pohl  
Direct (973) 984-0076  
Mark.Pohl@LicensingLaw.Net

SD\USV\letterhead.doc

Pharmaceutical Patent Attorneys, LLC  
Telecopier +1 (973) 984 6159

J. Mark Pohl (JP-4457)  
PHARMACEUTICAL PATENT ATTORNEYS, LLC  
55 Madison Avenue, 4<sup>th</sup> floor  
Morristown, NJ 07960-7397  
(973) 984-0076  
Attorneys for Defendant

TEVA PHARMACEUTICAL  
INDUSTRIES, LTD.

Plaintiff,

vs.

USV, LIMITED

Defendant

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

Civil Action No.

3:07-cv-02911-GEB-JJH

**MOTION FOR SANCTIONS FOR**  
**FRAUD ON THE COURT**

**TABLE OF CONTENTS**

**THE NATURE AND PROCEDURAL POSTURE OF THE PROCEEDINGS AND SUMMARY OF ARGUMENT .....1**

THE PATENTS IN SUITE CANNOT CLAIM THE ACCUSED PRODUCT BECAUSE THE ACCUSED PRODUCT IS IN THE PUBLIC DOMAIN..... 1

DEFENDANT CANNOT INFRINGE THE PATENTS IN SUIT BECAUSE DOES NOT EVEN MAKE THE ACCUSED PRODUCT ..... 2

PLAINTIFF FAILED TO PERFORM ANY PRE-LITIGATION INVESTIGATION TO DETERMINE WHETHER DEFENDANT EVEN MAKES THE ACCUSED PRODUCT..... 3

**PLAINTIFF’S FACTUAL CONTENTIONS LACK EVIDENTIARY SUPPORT UNDER FEDERAL RULE OF CIVIL PROCEDURE RULE 11(B)(3).....4**

PLAINTIFF KNOWINGLY MISREPRESENTED TO THIS COURT THE EXISTENCE OF PERSONAL JURISDICTION OVER THE DEFENDANT IN AN ATTEMPT TO KNOWINGLY DECEIVE THIS COURT ..... 4

PLAINTIFF TOLD THIS COURT THAT IT IS “UNABLE” TO OBTAIN SAMPLES OF THE ACCUSED PRODUCT, CONCEALING FROM THE COURT THE FACT THAT PLAINTIFF IN FACT HAS FOUR SAMPLES..... 6

PLAINTIFF HAD EVIDENCE THAT DEFENDANT DOES NOT MAKE THE ACCUSED PRODUCT, YET NONETHELESS TOLD THIS COURT OF “IMMINENT, THREATENED ACTS” OF INFRINGEMENT ..... 7

PLAINTIFF FAILED TO COMPARE THE PATENTS IN SUIT TO THE ACCUSED PRODUCT TO DETERMINE WHETHER THERE WAS ANY EVIDENCE OF INFRINGEMENT ..... 8

*Plaintiff Did Not Investigate Whether Defendant Even Makes The Accused Product..... 9*

*Plaintiff Has Not Compared The Claims Of Each Of The Patents In Suit To The Accused Product ..... 9*

*Plaintiff Neglected To Obtain A Written Opinion Of Patent Counsel Before Signing Its Complaint..... 10*

*Plaintiff Apparently Neglected To Read Its Own Patents Before Signing Its Complaint, Because One Of The Patents In Suit Does Not Even Relate To The Accused Product ..... 10*

**PLAINTIFF’S CLAIMS ARE NOT WARRANTED BY EXISTING LAW UNDER FEDERAL RULES OF CIVIL PROCEDURE RULE 11(B)(2).....11**

**PLAINTIFF FILED ITS COMPLAINT FOR AN IMPROPER PURPOSE IN VIOLATION OF FEDERAL RULES OF CIVIL PROCEDURE RULE 11(B)(1).....13**

    PLAINTIFF CONCEDES THAT THIS COURT DOES NOT HAVE PERSONAL JURISDICTION OVER THE DEFENDANT, YET PLAINTIFF NONETHELESS REFUSES TO WITHDRAW ITS COMPLAINT ..... 13

**SANCTIONS ARE MANDATORY ON THESE FACTS .....15**

    THIS COURT RETAINS JURISDICTION TO IMPOSE SANCTIONS AFTER THE COMPLAINT HAS BEEN DISMISSED..... 15

    SANCTIONS SHOULD BE PROPORTIONAL TO THE AMOUNT OF ILLICIT PROFIT WHICH PLAINTIFF WOULD HAVE MADE BY ILLEGITIMATELY MONOPOLIZING THE DOMESTIC MARKET FOR CARVEDILOL..... 16

    CONCLUSION ..... 19

**CERTIFICATE OF SERVICE.....19**

## TABLE OF AUTHORITIES

### CASES

<i>Amana Refrigeration, Inc. v. Quadlux, Inc.</i> , (Fed. Cir., 1999)-----	12
<i>Hernandez v. Joliet Police Department</i> , 197 F. 3d 256, 264 (7 <sup>th</sup> Cir., 1999)-----	13
<i>Martin v. Brown</i> , 63 F.3d 1252, 1264 (3 <sup>rd</sup> Cir., 1995). -----	18
<i>Morton Salt Co. v. Suppiger Co.</i> , 314 U.S. 488, 498 (1942) -----	14
<i>Sequa Corp. v. Cooper</i> , 245 F.3d 1036, 1037 (8 <sup>th</sup> Cir., 2001) -----	15
<i>View Engineering, Inc. v. Robotic Vision Systems, Inc.</i> , 208 F.3d 981 (Fed. Cir. 2000). -----	3, 8, 15

### STATUTES AND REGULATIONS

Fed. Rule Civ. Proc. Rule 11(b)-----	3, 7
Fed. Rule Civ. Proc. Rule 4(f)(1) -----	4

### OTHER AUTHORITIES

Lawrence H. Pretty, <u>Patent Litigation</u> (Sept. 2006) (PLI, NYC, publ.)-----	8
--	---

**THE NATURE AND PROCEDURAL POSTURE OF  
THE PROCEEDINGS AND SUMMARY OF  
ARGUMENT**

Plaintiff accuses Defendant of infringing Plaintiff's patents. Defendant, however, discontinued making the accused product over three years ago, before Plaintiff even obtained its patents. Defendant accordingly *cannot* infringe as a matter of law.

Defendant here requests sanctions because: (a) Plaintiff's Complaint misrepresents material facts; (b) Plaintiff failed to adequately investigate the factual basis of its Complaint; (c) Plaintiff's Complaint raises claims and legal contentions not warranted by law; and (d) Plaintiff prosecutes this lawsuit not to legitimately enforce limited patent rights, but to illegally attempt to monopolize the domestic market for non-infringing carvedilol.

**The Patents In Suite Cannot Claim The  
Accused Product Because The Accused  
Product Is In The Public Domain**

Carvedilol is a drug used to treat congestive heart failure. *See* Complaint at ¶ 17. It was invented by scientists at Boehringer Mannheim GmbH. *See* Exhibit A. Boehringer Mannheim patented carvedilol and how to make it. *See id.* at page 1, left column, item [30]. That patent expired on March 5, 2007. *See* Complaint ¶ 18. Carvedilol is therefore in the public domain. Anyone can make it, import it into the United States, and (subject to a soon to expire FDA marketing-exclusivity

period) market it. *See id.* at ¶ 19. Because carvedilol is in the public domain, the patents in suit cannot legally claim it as a matter of law.

**Defendant Cannot Infringe The Patents  
In Suit Because Does Not Even Make The  
Accused Product**

Defendant manufactured carvedilol made pursuant to Drug Master File 17487<sup>1</sup> until January 2004. *See* Exhibit F. Defendant discontinued making the accused product in January 2004. *Id.* Defendant cannot infringe the patents in suit, because Defendant *does not even make the accused product.* *See id.*

Plaintiff could have confirmed this by simply telephoning Defendant (or its US distributor) and asking whether Defendant still makes the accused product. This inquiry would have taken perhaps five minutes. Plaintiff did not bother. Rather, Plaintiff decided to sue first and ask questions later.

Federal Rule of Civil Procedure Rule 11(b) requires any lawyer who signs a Complaint to investigate whether the Complaint has a basis in fact and in law. Here, Plaintiff did not do so. To the contrary, Plaintiff did not even bother to investigate whether Defendant makes the accused product. This is not a “reasonable” pre-litigation investigation: this is no investigation at all.

---

<sup>1</sup> Defendant calls this the “accused product,” Plaintiff calls it “Defendant’s API.”

More troubling than Plaintiff's negligence, however, is Plaintiff's recitation in its Complaint of allegations which are false, *and which Plaintiff knew were false at the time Plaintiff gave that document to this Court.*

**Plaintiff Failed To Perform Any Pre-Litigation Investigation To Determine Whether Defendant Even Makes The Accused Product**

Before a lawyer signs a Complaint, the lawyer must conduct an investigation "reasonable under the circumstances." *See* F.R.C.P. Rule 11(b); *View Engineering, Inc. v. Robotic Vision Systems, Inc.*, 208 F.3d 981 (Fed. Cir. 2000).

A lawyer's signature on a Complaint is a certification to the reviewing court of three things:

1. The allegations and other factual contentions in the Complaint have evidentiary support, *see* F.R.C.P. Rule 11(b)(3).
2. The claims and other legal contentions of the complaint are warranted by law, *see* F.R.C.P. Rule 11(b)(2).
3. The Complaint is not presented for an improper purpose such as to harass or to violate antitrust law; *see* F.R.C.P. Rule 11(b)(1).

In the instant case, Plaintiff violates all three rules. We discuss each rule in turn.

**PLAINTIFF’S FACTUAL CONTENTIONS LACK  
EVIDENTIARY SUPPORT UNDER FEDERAL  
RULE OF CIVIL PROCEDURE RULE 11(B)(3)**

The allegations and other factual contentions in the Complaint lack evidentiary support. Rather, Plaintiff’s allegations are directly contradicted by the evidence of record. In the immediate case, Plaintiff both *knowingly misrepresents* facts and *negligently fails to investigate* facts. We discuss each in turn.

Plaintiff knowingly misrepresents several material facts. Plaintiff knowingly misrepresents: (a) the existence of personal jurisdiction over the defendant; (b) Plaintiff’s possession of samples; and (c) the existence of “imminent, threatened acts of infringement.” We discuss each in turn.

**Plaintiff Knowingly Misrepresented To  
This Court The Existence Of Personal  
Jurisdiction Over The Defendant In An  
Attempt To Deceive This Court**

Defendant is an Indian company. For this Court to exercise personal jurisdiction over Defendant, Plaintiff must properly serve process. *See* Rule 4(f)(1) (noting that non-U.S. Defendants may be served pursuant to The Hague Convention on the Service Abroad).

Plaintiff did not, however, attempt to serve process. To the contrary, Plaintiff concedes that it did not attempt to serve process *at all*. Plaintiff says:

“Teva filed (but did not serve) the referenced action against USV for infringement of Teva’s carvedilol patents. Teva provided USV with a courtesy copy of its complaint.”

*See* Exhibit J at page 1; Exhibit E. Plaintiff recognizes that it has neither effected, nor even attempted, sufficient service of process. *Id.*

By recognizing that service of process is non-existent, Plaintiff recognizes that this Court cannot have personal jurisdiction over the Defendant. Plaintiff nonetheless certifies *the exact opposite* to this Court:

“This Court has personal jurisdiction over Defendant”

*See* Complaint ¶ 7. This misrepresentation is important because it shows that Plaintiff knows that this Court lacks personal jurisdiction over the Defendant and cannot lawfully adjudicate this case, yet Plaintiff nonetheless tries to mislead this Court into hearing this case anyway. Plaintiff exposes this Court to the prospect of wasting its resources adjudicating this case, only to face an embarrassing reversal on appeal for lack of jurisdiction. Plaintiff’s misrepresentation is sanctionable under Rule 11(b)(3).

**Plaintiff Told This Court That It Is  
“Unable” To Obtain Samples Of The  
Accused Product, Concealing From The  
Court The Fact That Plaintiff In Fact Has  
Four Samples**

Plaintiff says that Ivax Pharmaceuticals, Inc. is its U.S. subsidiary. Exhibit J at page 2. In contrast, Defendant has no U.S. subsidiary; Defendant distributes products in the U.S. via a third party wholesaler, SST Corporation of Clifton, New Jersey.

On February 14, 2003, SST Corporation shipped two 50 gram samples of the accused product to Plaintiff. *See* Exhibit B, C. On September 29, 2003, SST shipped two more 50 gram samples of the accused product to Plaintiff. *Id.* Plaintiff has therefore had four samples of the accused product in its possession, custody and control for over three years.

Plaintiff’s Complaint, however, tells this Court *the exact opposite*. In justifying why this Court should hear this case, Plaintiff tells this Court:

“Defendant has not provided to Teva USA samples of Defendant’s carvedilol API ... Further, Plaintiffs have been unable to obtain samples of Defendant’s API from a public source”

*See* Complaint ¶ 30. Plaintiff tells this Court that Plaintiff has “no choice but to resort to the judicial process” to obtain samples. *Id.* at ¶ 32.

Plaintiff intentionally conceals from this Court the fact that Plaintiff already has four samples of the accused product. Plaintiff attempts to mislead this Court into adjudicating a moot dispute. This is sanctionable under Rule 11(b)(3).

**Plaintiff Had Evidence That Defendant Does Not Even Make The Accused Product, Yet Nonetheless Told This Court Of “Imminent, Threatened Acts” Of Infringement**

Plaintiff alleges that “Plaintiffs have been unable to obtain samples of Defendant’s API from a public source.” *See* Complaint ¶ 30. This is false because Plaintiff already has four samples. *See* Exhibit B, C.

It may, however, be difficult to obtain further samples from a public source *at the present time*, because Defendant discontinued the accused product almost four years ago. *See* Exhibit F. Defendant therefore no longer distributes samples.

Plaintiff’s inability to obtain samples from a public source *at the present time* intimates that there might not be infringement, because an inability to obtain samples indicates that the accused product may no longer exist.

Despite having this evidence indicating that the accused product might not even exist, Plaintiff told this Court the exact opposite, saying that “imminent, threatened acts of infringement” would occur “shortly after” September 5, 2007. *See e.g.*, Complaint at ¶¶ 24, 27. Defendant’s representation to this Court of

“imminent, threatened” infringement,” despite having evidence to the contrary, is sanctionable under Rule 11(b)(2).

**Plaintiff Did Not Bother To Compare The Patents In Suit To The Accused Product To Determine Whether There Was Any Evidence Of Infringement**

Rule 11 prohibits Plaintiff from pleading facts which Plaintiff knows are false. Rule 11, however, requires more, and requires Plaintiff to actively investigate the correctness of its factual allegations. *See* F.R.C.P. Rule 11(b).

This duty to investigate is quite demanding in the context a patent infringement suit. In a patent infringement suit, the patent owner must compare the patents in suit to the accused product, to determine whether objective evidence of infringement exists. *See e.g., View Engineering, Inc. v. Robotic Vision Systems, Inc.*, 208 F.3d 981, 985 (Fed. Cir. 2000). This is the “bare minimum” investigation:

“Rule 11 .. must be interpreted to require the law firm to, at a bare minimum, apply the claims of each and every patent that is being brought into the lawsuit to the accused device and conclude that there is a reasonable basis for a finding of infringement of at least one claim of each patent so asserted.”

View Engineering, 208 F.3d at 986. The patent owner must apply each asserted claim of each asserted patent to the accused product, to determine whether infringement exists. The patent owner must do this analysis *before* filing its Complaint. *Id.* This analysis is “extremely important” because it protects

defendants from incurring the significant cost required to defend against baseless infringement allegations. *Id.* This pre-litigation analysis usually takes the form of a written opinion of counsel. *See generally* Lawrence H. Pretty, Patent Litigation § 2.1.2 (Sept. 2006) (Pract. Law Inst., New York City, publ.).

*Plaintiff Did Not Investigate  
Whether Defendant Even Makes  
The Accused Product*

In the immediate case, the Plaintiff failed on several counts. First, Plaintiff failed to investigate whether Defendant even makes the accused product; Plaintiff did not even telephone Defendant (nor its US distributor) to ask. This is not a reasonable investigation: this is no investigation at all.

*Plaintiff Has Not Compared The  
Claims Of Each Of The Patents In  
Suit To The Accused Product*

Second, Plaintiff has not made any effort at all to determine whether the patents in suit cover the accused product. *See e.g.*, Complaint at ¶ 31. Plaintiff has had these samples for three years. *See* Exhibit B, C. Plaintiff has nonetheless neglected to compare these samples to any of the patents in suit, to see whether or not infringement exists. *Cf. e.g.*, Complaint ¶ 30. This failure violates Rule 11. *See View Engineering* at 986.

Plaintiff Neglected To Obtain A  
Written Opinion Of Patent  
Counsel Before Signing Its  
Complaint

Third, Plaintiff apparently failed to obtain a written opinion of counsel before filing its Complaint. *Cf. e.g.*, Complaint ¶ 30 (Plaintiff did not determine whether infringement exists before filing the Complaint).

Plaintiff's failure to obtain an opinion of patent counsel is not surprising, because Plaintiff does not dispute<sup>2</sup> that carvedilol is in the public domain, so the patents in suit cannot legally claim it as a matter of law.

Plaintiff Apparently Neglected To  
Read Its Own Patents Before  
Signing Its Complaint, Because  
One Of The Patents In Suit Does  
Not Even Relate To The Accused  
Product

Fourth, had Plaintiff bothered to read its own patents, it would have seen that at least one of the patents in suit relates to a different product. (!)

The accused product is carvedilol. Carvedilol is a heart drug approved by the Food & Drug Administration to treat congestive heart failure. *See* Complaint at ¶ 17.

---

<sup>2</sup> On July 18, 2007, Defendant told Plaintiff that carvedilol is in the public domain, so "anyone in the world" has the right to import it. *See* Exhibit L. Defendant asked Plaintiff, "If you disagree, please explain why." *Id.* Plaintiff has not, however, voiced any disagreement.

In contrast, one of the patents asserted by Plaintiff is “the ‘942 patent.” *See* Complaint ¶ 9. The ‘942 patent, however, does not claim carvedilol. *See* Exhibit K. Rather, the ‘942 patent claims a *hydrochloric acid-based* modification of carvedilol called “carvedilol hydrochloride hydrate.” *Id.* at col. 16, line 33. Carvedilol hydrochloride hydrate is not the same as carvedilol. To the contrary, the Food and Drug Administration does not recognize carvedilol hydrochloride hydrate as safe to treat congestive heart failure nor, on information and belief, safe to treat *anything*. Therefore, importing carvedilol would not - indeed, that *could not* - infringe the ‘942 patent because the ‘942 patent covers a different chemical.

Plaintiff’s *failure to ask* if Defendant makes the accused product, Plaintiff’s failure to obtain a pre-litigation *opinion of counsel*, its failure to even informally *compare the patents in suit* to the accused product, and Plaintiff’s apparent failure to even *read its own patents* indicates that Plaintiff failed to do a pre-litigation investigation.

**PLAINTIFF’S CLAIMS ARE NOT WARRANTED  
BY EXISTING LAW UNDER FEDERAL RULES  
OF CIVIL PROCEDURE RULE 11(B)(2)**

Rule 11(b)(2) prohibits Plaintiff from raising claims and legal contentions which are not “warranted by existing law.” In the instant case, Plaintiff does just that, asking this Court for relief not warranted by - indeed, *expressly rejected by* - existing law.

The Complaint (at page 8) asks this Court to order the patents in suit “valid and enforceable.” That relief is not, however, available under existing law. Patents are presumed “valid and enforceable” by statute. *See* 35 U.S.C. § 282. Because a patent is presumed valid, a Court cannot (redundantly) order a patent “valid”; rather, a Court can only adjudicate whether the evidence before it rebuts or fails to rebut the presumption of validity.

Plaintiff asks that this Court find that the Defendant will in the future do something which will in the future infringe the patents in suit. *See* Complaint ¶ 2 (“Defendant will infringe”), ¶ 3 (“Defendant’s infringement will be willful”). Relief against hypothetically possible future infringement, however, is not a claim warranted under existing law. To the contrary, the Court of Appeals for the Federal Circuit has already addressed this type of claim *and rejected it*. *See e.g., Amana Refrigeration, Inc. v. Quadlux, Inc.*, (Fed. Cir., 1999) (“The residual possibility of a future infringement suit based on [the alleged infringer’s] future acts is simply too speculative a basis for jurisdiction.”).

Before a Plaintiff signs a Complaint, it must perform “basic legal research” to determine whether its claims are supported by law. *See Hernandez v.*

*Joliet Police Department*, 197 F. 3d 256, 264 (7<sup>th</sup> Cir., 1999). In the instant case, Plaintiff's law firm<sup>3</sup> failed to comply.

**PLAINTIFF FILED ITS COMPLAINT FOR AN  
IMPROPER PURPOSE IN VIOLATION OF  
FEDERAL RULES OF CIVIL PROCEDURE RULE  
11(B)(1)**

**Plaintiff Concedes That This Court Does  
Not Have Personal Jurisdiction Over The  
Defendant, Yet Plaintiff Nonetheless  
Refuses To Withdraw Its Complaint**

Plaintiff concedes that it did not attempt service of process on the Defendant. *See supra* at 4-5. Plaintiff should therefore recognize that this Court does not enjoy personal jurisdiction over the Defendant.

Defendant has thus repeatedly invited Plaintiff to unconditionally withdraw its Complaint. *See* Exhibit H. Plaintiff refuses. *See* Exhibit J. Rather, Plaintiff insists that Defendant agree to not import carvedilol, *even if that carvedilol is made by a non-infringing process*. *See* Exhibit J. Further, despite the fact that the patents in suit will expire in several years, Plaintiff insists that Defendant agree to not import carvedilol *forever*. *Id.*

---

<sup>3</sup> N.B.: The Court may sanction both Plaintiffs and its law firm for their factual misrepresentations. *See* Rule 11(b)(c). Those sanctions may be both monetary and non-monetary. *See* Rule 11(b)(c)(2). The Court may also sanction both Plaintiffs and its law firm for arguing a legal position not “warranted by law,” albeit can only impose *monetary* sanctions on the law firm. *See* Rule 11(c)(2)(A).

In the instant case, Plaintiff demands that Defendant not import *non-infringing* carvedilol, and do so *beyond the term* of the patents in suit. See Exhibit J. The immediate lawsuit is not a legitimate effort to enforce specific patent rights. Rather, Plaintiff and its law firm are attempting to monopolize the market in a *non-infringing* product, public-domain carvedilol. Plaintiff enforces the patents in suit beyond their scope. This is “patent misuse.” See *e.g.*, *Morton Salt Co. v. Suppiger Co.*, 314 U.S. 488, 498 (1942).

Furthermore, Plaintiff has recently instituted in this Court about ten other actions against other drug manufacturers. Tellingly, Plaintiff’s various Complaints recite a similar inability to obtain samples, allege similar “imminent, threatened future infringement” - and display similar indicia of a failure to do a pre-litigation investigation. Enforcing the patents in suit beyond their scope against a number of manufacturers of non-infringing carvedilol is not merely patent misuse, but is apparently a criminal violation the Sherman Antitrust Act by Plaintiff *and its law firm*. This is the most “improper purpose” imaginable under Rule 11(b)(1), and should be sanctioned accordingly.

## **SANCTIONS ARE MANDATORY ON THESE FACTS**

Rule 11 says that “a court *may* ... impose an appropriate sanction.” *See* Rule 11(c) (emphasis mine). The Court of Appeals for the Federal Circuit interprets this to mean that a court “*shall*” impose sanctions when a patent owner signs an infringement Complaint without “a substantiated belief” that infringement exists. The Federal Circuit says:

“Rule 11 imposes a duty on attorneys to certify that they have conducted a reasonable inquiry and have determined that any papers filed with the court are well-grounded in fact, legally tenable, and ‘not interposed for any improper purpose.’ An attorney who signs the paper without such a substantiated belief ‘shall’ be penalized by ‘an appropriate sanction.’”

*See View Engineering, Inc. v. Robotic Vision Systems, Inc.*, 208 F.3d 981, 986 (Fed. Cir. 2000), *quoting Cooter & Gell*, 496 U.S. at 393. In the instant case, Plaintiff filed a Complaint which is nether *well-grounded in fact*, nor *legally tenable*, and appears to be *interposed for an improper purpose*.

### **This Court Retains Jurisdiction To Impose Sanctions After The Complaint Has Been Dismissed**

This Court retains jurisdiction to impose sanctions even after the Complaint has been dismissed. *See e.g., Sequa Corp. v. Cooper*, 245 F.3d 1036, 1037 (8<sup>th</sup> Cir., 2001).

**Sanctions Should Be Proportional To The Amount Of Illicit Profit Which Plaintiff Would Have Made By Illegitimately Monopolizing The Domestic Market For Carvedilol**

Sanctioning false representations, frivolous legal argument and harassment lawsuits is “necessary to act as a future deterrent to attorneys considering filing suit without first performing a reasonable inquiry as to the existence of a valid claim.” *View Engineering, Inc. v. Robotic Vision Systems, Inc.*, 208 F.3d 981, 984 (Fed. Cir. 2000). In the instant case, Plaintiff has filed the immediate suit without performing an inquiry, and appears to have filed a large number of similarly baseless suits in this Court.

In this situation, the appropriate amount of sanctions should be not less than the illegitimate profit Plaintiff would have made by monopolizing the domestic market for non-infringing carvedilol. This amount is calculated as follows:

In calendar year 2005, carvedilol sales in the United States were \$1,043,000,000. *See* Exhibit M. Carvedilol is currently marketed in the United States by GlaxoSmithKline plc. *See* Complaint ¶ 17, *see also* Exhibit M. On information and belief, GlaxoSmithKline does not disclose profitability figures for carvedilol specifically. GlaxoSmithKline, however, has an average overall gross margin of 86%. *See* Exhibit M. Assuming that the profit margin for carvedilol is in line with the company-wide average profit margin, in 2005, carvedilol generated approximately  $\$1,043,000,000 * 86\% = \$896,980,000$  in gross profit.

Plaintiff here is attempting to monopolize the future annual profit stream for carvedilol. The aggregate value of this future profit stream is the annual profit (C) divided by the market capitalization rate (r) less the expected growth rate (g):

$$PV = C/(r - g)$$

See e.g., Richard Brealey *et al.*, Principles of Corporate Finance at 31 (1984) (McGraw-Hill, publ.). Here, annual profit (C) = \$896,980,000. We can conservatively assume that the annual profit does not grow; thus  $g = 0$ .

The market capitalization rate (r) is simply the reciprocal of the price : earnings ratio (or “P/E ratio”). See *id.* at 54. GlaxoSmithKline does not disclose a P/E ratio for carvedilol specifically. GlaxoSmithKline, however, has a company-wide aggregate P/E ratio of 14.9. See Exhibit M. Assuming that the capitalization rate for carvedilol is in line with the company-wide average rate:

$$r = 1/(\text{P/E Ratio}) = 1/14.9 = 6.7\%$$

This means that the value of the future annual gross profits for carvedilol in the United States is:

$$PV = \$896,980,000/(6.7\% - 0) = \$896,980,000/(6.7\%) = \underline{\underline{\$13,365,002,000.00}}$$

This is a rather large sum. It perhaps explains why Plaintiff so readily filed, and so aggressively prosecutes, its baseless lawsuits. Given this amount of potential profit, Plaintiff may consider sanctions - even extraordinarily large sanctions - to be an acceptable cost of doing business.

While Plaintiff's baseless lawsuits may therefore be rational *financially*, they ignore a non-financial, *ethical* obligation by its lawyers to this Court to not prosecute improper litigation. Defendant thus respectfully asks this Court to consider the magnitude of Plaintiff's illicit profit, and impose as sanctions a percentage of Plaintiff's illicit profit, which percentage the Court in its discretion believes sufficient to deter Plaintiff and its law firm from attempting to monopolize the market for carvedilol and other public-domain pharmaceutical products.

Plaintiff may argue that it was careless, but did not act in bad faith. That defense is belied by Plaintiff's knowing failure to even attempt service of process, and by Plaintiff's insistence on maintaining this suit even after being told that Defendant does not make the accused product.

That defense also fails to save Plaintiff, because Rule 11 establishes an objective standard of reasonableness under the circumstances. *See Martin v. Brown*, 63 F.3d 1252, 1264 (3<sup>rd</sup> Cir., 1995). A finding of "bad faith" is not required. *Id.*



UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

TEVA PHARMACEUTICAL	:	
INDUSTRIES LTD. and TEVA	:	
PHARMACEUTICALS USA, INC.,	:	Civil Action No.07-2911 (GEB)
	:	
Plaintiffs	:	
	:	
v.	:	
	:	
USV LIMITED,	:	
	:	
Defendant.	:	

**STIPULATION OF DISMISSAL**

Pursuant to Rule 41(a) of the Federal Rules of Civil Procedure, the parties, by their undersigned counsel, hereby stipulate and agree that the above-captioned action, including all claims, counterclaims, and third-party claims asserted therein, is dismissed, without prejudice. Defendant also hereby stipulates and agrees to waive any and all motions for sanctions. Each party shall bear its own fees, costs, and expenses.

This stipulation may be executed and filed in counterparts, with each such counterpart constituting an original.

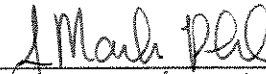
**LITE DEPALMA GREENBERG & RIVAS, LLC**



Allyn Z. Lite  
Michael E. Patunas  
Two Gateway Center, 12th Floor  
Newark, New Jersey 07102-5003  
(973) 623-3000

*Attorneys for Teva Pharmaceutical Industries Ltd. & Teva Pharmaceuticals USA, Inc.*

**PHARMACEUTICAL PATENT ATTORNEYS, LLC**



J. Mark Pohl (JP-4457)  
55 Madison Avenue, 4<sup>th</sup> Floor  
Morristown, NJ 07960-7397

*Attorneys for USV Limited*