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**UNITED STATES DISTRICT COURT**

**DISTRICT OF NEVADA**

PACIRA PHARMACEUTICALS, INC.

Plaintiff,

v.

RESEARCH DEVELOPMENT  
FOUNDATION,

Defendant.

CASE NO.:

**COMPLAINT FOR DECLARATORY  
JUDGMENT**

**JURY TRIAL DEMANDED**

Plaintiff Pacira Pharmaceuticals, Inc. ("Pacira") seeks a declaratory judgment against Defendant Research Development Foundation ("RDF") that Pacira owes no royalties to RDF with respect to Pacira's EXPAREL® product made after December 24, 2021.

### NATURE OF THE ACTION

1. This is an action for a declaratory judgment pursuant to the Federal Declaratory Judgments Act, 28 U.S.C. §§ 2201–2202, and Rule 57 of the Federal Rules of Civil Procedure.

2. Pacira produces EXPAREL® (bupivacaine liposome injectable suspension), approved by the Food and Drug Administration (FDA) in 2011. EXPAREL® is a first-of-its-kind, single dose local anesthetic administered at the time of surgery to control pain and reduce or eliminate the use of opioids for acute postsurgical pain. The active ingredient in EXPAREL®, bupivacaine, is encapsulated in multivesicular liposomes allowing for gradual release of bupivacaine over time as the lipid membranes are absorbed, prolonging the action of bupivacaine.

3. Pacira, under its former names DepoTech Corporation (“DepoTech”) and SkyePharma Inc. (“Skye”), and RDF are signatories to an Assignment Agreement dated February 9, 1994 (the “1994 Agreement”) and an Amendment Agreement dated April 15, 2004 (the “2004 Amendment”) (collectively the “Agreements”).

4. The purpose of the 1994 Agreement was for RDF to assign certain experimental technology and intellectual property to Pacira for it to pursue commercialization and, in exchange, Pacira would make certain royalty payments to RDF under certain conditions. At the time, there was no EXPAREL® product. Instead, during the 1990s, the only Pacira product subject to royalties under the 1994 Agreement was DepoCyt®, which was a cytotoxic anticancer drug. Specifically, DepoCyt® was a cytarabine liposome injection used for the intrathecal treatment of lymphomatous meningitis. Pacira ceased manufacturing DepoCyt® in 2017.

5. A dispute arose in 2003 regarding the scope of the products for which Pacira would owe royalties under the 1994 Agreement. The execution of the 2004 Amendment was an attempt to clarify and resolve the dispute.

6. The 2004 Amendment requires Pacira to pay royalties on products embodying particularly defined inventions that are claimed in certain patents or patent applications for only as long as those particular patents or patent applications are unexpired.

7. However, Pacira and RDF now dispute the interpretation of the 2004 Agreement in conjunction with the 1994 Agreement.

8. It is clear that under the terms of the Agreements, Pacira does not owe any royalties to RDF with respect to Pacira's EXPAREL® product manufactured after December 24, 2021. Specifically, all of the patents encompassing the technology relevant to the Agreements will have expired after December 24, 2021, meaning that Pacira will therefore no longer have an obligation to pay RDF any royalties on Pacira's EXPAREL® product.

9. Despite the plain language in the Agreements, the common-sense interpretation of their terms, and what both parties intended when those Agreements were signed, RDF maintains that, under its interpretation of the terms of the Agreements, Pacira will continue to owe royalties to RDF with respect to Pacira's EXPAREL® product made after December 24, 2021. RDF maintains this position despite the fact that Pacira has independently, and at its own great expense, developed a novel, patented process for making a novel bupivacaine encapsulated multivesicular liposome product, which will be sold as EXPAREL®. RDF also maintains this position despite the fact that all patents relevant to the Agreements will expire on December 24, 2021.

10. Accordingly, Pacira now seeks a declaratory judgment that Pacira does not owe any royalties to RDF with respect to Pacira's EXPAREL® product made after December 24, 2021, under the terms of the Agreements. In the alternative, Pacira seeks a declaratory judgment that any terms of the Agreements that would require Pacira to pay a royalty to RDF with respect to Pacira's EXPAREL® product made after December 24, 2021 are unenforceable as unconscionable and in violation of public policy.

## THE PARTIES

11. Pacira is a California corporation with its principal place of business at 5 Sylvan Way, Suite 300, Parsippany, New Jersey 07054.

12. On information and belief, RDF is a Nevada corporation with its principal place of business at 402 North Division Street, Carson City, NV 89703.

## JURISDICTION AND VENUE

13. This action arises under the Declaratory Judgment Act, 28 U.S.C. § 2201 et seq.

14. An immediate, real, and justiciable controversy exists between Pacira and RDF as to whether Pacira owes royalties to RDF with respect to Pacira's EXPAREL® product made after

1 December 24, 2021, under the terms of the Agreements. Because this action presents an actual  
2 controversy with respect to Pacira's and RDF's rights and obligations under the Agreements, the Court  
3 may grant the declaratory relief sought pursuant to 28 U.S.C. § 2201 et seq.

4 15. This Court has subject matter jurisdiction over this action pursuant  
5 28 U.S.C. § 1332(a)(1) because it is a dispute between citizens of different states and the amount in  
6 controversy exceeds \$75,000.00, exclusive of interest and costs.

7 16. This Court has personal jurisdiction over RDF. Among other things, on information  
8 and belief, RDF is a Nevada corporation with its principal place of business in this District.  
9 Additionally, under the 2004 Amendment, RDF agreed that jurisdiction for any dispute regarding the  
10 Agreements would be in Nevada.

11 17. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) at least because RDF  
12 resides in this District. Additionally, under the 2004 Amendment, RDF agreed that venue for any  
13 dispute regarding the Agreements would be in Nevada.

#### 14 **FACTUAL BACKGROUND**

##### 15 **I. The 1994 Agreement**

16 18. Pacira, under its former name DepoTech, and RDF are signatories to the  
17 1994 Agreement.

18 19. Under the 1994 Agreement, RDF assigned DepoTech certain "Assigned Proprietary  
19 Property," giving DepoTech the exclusive rights to, among other things, make, manufacture, and sell  
20 products employing the Assigned Proprietary Property. By its own terms, the 1994 Agreement  
21 assigned "no other, further, or different property or rights" except for those provided in the  
22 1994 Agreement.

23 20. Under the 1994 Agreement, DepoTech was to pay RDF, during the term of the  
24 1994 Agreement, a royalty on Gross Revenues, where Gross Revenues was a defined term.

25 21. The term Gross Revenue was defined to include "charges actually collected by  
26 DepoTech from sales, rental, lease, licensing, maintenance, or production of a Product," where Product  
27 was a defined term.  
28

1           22.     The term Product was defined to mean “a product or portion of a product that where  
2 made, used or sold embodies an invention there claimed, or which is specifically intended to be used  
3 to practice a method or process there claimed in an Assigned Patent (or a patent application if the  
4 resulting Letters Patents would constitute an ‘Assigned Patent’ hereunder) and which is manufactured  
5 and sold by or for DepoTech (or its licensees),” where Assigned Patent was a defined term.

6           23.     The term Assigned Patent was defined to mean “the United States of America and  
7 Foreign Patents included within Proprietary Property and any division, reissue, continuation or  
8 extension thereof,” where Proprietary Property was a defined term.

9           24.     The term Proprietary Property was defined to mean “developments, patent rights,  
10 copyrights, as well as all patent applications, techniques, methods, processes, apparatus, products,  
11 data, trade secrets, confidential information, improvements thereto, modifications thereof, and  
12 Know-How, whether patentable or not, related to the technology described in Exhibit 1 hereto,” where  
13 Exhibit 1 included a description of Proprietary Property.

14           25.     Exhibit 1 to the 1994 Agreement included within Proprietary Property the patented  
15 technology of “Multivesicular Liposomes having a Biologically Active Substance Encapsulated  
16 therein the Presence of a Hydrochloride,” “Heterovesicular Liposomes,” “Cyclodextrin Liposomes  
17 Encapsulating Pharmacologic Compounds and Methods for their Use,” and “Uniform Spherical  
18 Multilamellar Liposomes of Defined and Adjustable Size Distribution” described in certain patents  
19 and patent applications.

## 20     **II.     The 2003 Dispute**

21           26.     In 2003, a dispute arose between RDF and Pacira, then operating under the name Skye,  
22 as to the scope of certain payment obligations under the 1994 Agreement.

23           27.     The 2003 dispute included a dispute over the scope of products and related patents for  
24 which royalties were owed to RDF under the 1994 Agreement.

25           28.     For example, RDF and Skye disputed whether Skye was required to pay royalties to  
26 RDF under the terms of the 1994 Agreement in connection with multivesicular liposome (“MVL”)   
27 technology that does not encapsulate a biologically active substance in the presence of a hydrochloride  
28 (“No HCl Technology”).

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