



2. DRL is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 2, and therefore denies them.

3. DRL is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 3, and therefore denies them.

4. DRL denies that Promius is, in all circumstances, an agent of DRL Inc. and DRL Ltd., and, for purposes of this action, admits the remaining allegations of paragraph 4.

5. DRL denies that DRL Inc. is, in all circumstances, an agent of DRL Ltd., and, for purposes of this action, admits the remaining allegations of paragraph 5.

6. DRL admits the allegations of paragraph 6.

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

7. Answering paragraph 7 of the complaint, DRL admits that Plaintiffs purport to allege claims of patent infringement arising under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.*, as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, in asserting the patents-in-suit (collectively U.S. Patent Nos. 7,211,267; 7,232,572; 8,603,506; 7,749,532; 8,206,740; 8,394,405; 8,394,406; 8,470,364; and 8,709,478), but DRL denies that Plaintiffs have a legally sufficient, valid, or meritorious claim against DRL under those provisions.

#### **JURISDICTION AND VENUE**

8. DRL admits that this Court purportedly has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a), but DRL denies that Plaintiffs have a valid or meritorious claim against DRL under those provisions.

9. DRL admits the allegations of paragraph 9 as to DRL Inc.; DRL denies that this district is a proper venue for the present dispute with regard to DRL Ltd. or Promius; but DRL does not contest venue in this district for the purposes of this action.

10. Answering paragraph 10 of the complaint, DRL admits that this Court has personal jurisdiction over DRL, Inc.; DRL denies that this Court has personal jurisdiction over DRL Ltd. or Promius, but DRL does not contest personal jurisdiction in this Court for the purposes of this action; DRL admits that it filed NDA No. 208286 with the U.S. Food & Drug Administration (“FDA”), and DRL admits that it is intending to commercialize, manufacture, use, and/or sell the DRL’s NDA Product before the expiration of the patents-in-suit, throughout the United States, including in the State of Delaware, following approval of DRL’s NDA Product by the FDA; DRL denies the remaining allegations of paragraph 10.

11. DRL admits that Promius is a subsidiary of DRL Inc. and DRL Ltd., but denies that Promius is an agent of DRL Inc. and DRL Ltd. and thus denies the remaining allegations of paragraph 11.

12. DRL denies that DRL Inc., in all circumstances, is an agent of DRL Ltd., but otherwise admits that DRL Inc. submitted DRL’s NDA No. 208286 to the FDA on behalf of DRL Ltd.

13. DRL denies the allegations in paragraph 13.

14. DRL is without knowledge or information sufficient to form a belief as to the truth of Plaintiffs’ assertion of an estimated potential of U.S. sales of DRL’s NDA Product and whether Promius may have any involvement in any such commercialization, and therefore denies the allegations of paragraph 14.

15. DRL denies the allegations of paragraph 15.

16. DRL admits that Promius is organized and existing under the laws of the State of Delaware. DRL otherwise denies the allegations of paragraph 16, but DRL does not contest personal jurisdiction over Promius for the purposes of this action.

17. DRL denies the allegations of paragraph 17, but DRL does not contest personal jurisdiction over DRL Inc. and DRL Ltd. for the purposes of this action.

18. DRL admits the allegations of paragraph 18 as to DRL Inc., but DRL denies the allegations of paragraph 18 as to DRL Ltd.

19. DRL admits that Promius is a subsidiary of DRL Inc. and DRL Ltd., and DRL admits that Promius sells branded dermatologic pharmaceutical products, but denies that Promius is an agent of DRL Inc. and DRL Ltd. and thus denies the remaining allegations of paragraph 19.

20. DRL denies that DRL Ltd. directs the operations, management and activities of Promius and DRL Inc. in the United States, and thus denies the allegations of paragraph 20.

21. Answering paragraph 21 of the complaint, DRL denies that it can be deemed to have availed itself of the protections afforded by the Court by having asserted compulsory counterclaims in this judicial district in other, unrelated cases; DRL admits that it has asserted compulsory counterclaims in this jurisdiction; and otherwise admits the allegations of paragraph 21.

### **THE PATENTS-IN-SUIT**

22. DRL is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 22, and therefore denies them.

23. DRL admits the allegations of paragraph 23, but denies that the '267 Patent was duly and legally issued.

24. DRL is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 24, and therefore denies them.

25. DRL admits the allegations of paragraph 25, but denies that the '572 Patent was duly and legally issued.

26. DRL is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 26, and therefore denies them.

27. DRL admits the allegations of paragraph 27, but denies that the '506 Patent was duly and legally issued.

28. DRL is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 28, and therefore denies them.

29. DRL admits the allegations of paragraph 29, but denies that the '532 Patent was duly and legally issued.

30. DRL admits the allegations of paragraph 30 insofar as TCD is listed as the current owner in the USPTO assignment database, but is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 30, and therefore denies them.

31. DRL admits the allegations of paragraph 31, but denies that the '740 Patent was duly and legally issued.

32. DRL admits the allegations of paragraph 32 insofar as TCD is listed as the current owner in the USPTO assignment database, but is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 32, and therefore denies them.

33. DRL admits the allegations of paragraph 33, but denies that the '405 Patent was duly and legally issued.

34. DRL admits the allegations of paragraph 34 insofar as TCD is listed as the current owner in the USPTO assignment database, but is without knowledge or information sufficient to

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