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9 Attorneys for Plaintiffs
10 Merck Sharp & Dohme Corp. and
Intervet Inc.

11 UNITED STATES DISTRICT COURT
12 SOUTHERN DISTRICT OF CALIFORNIA
13

14
15 MERCK SHARP & DOHME CORP.
and INTERVET INC.

16 Plaintiffs,
17 vs.

18 MED-PHARMEX, INC.,
19 Defendants.

CASE NO.: '15CV1905 BTM KSC

**COMPLAINT FOR PATENT
INFRINGEMENT**

1 **NATURE OF THE ACTION**

2 1. This is an action for patent infringement arising under the patent
3 laws of the United States of America, Title 35, United States Code, against
4 Defendant Med-Pharmex, Inc. (“Med-Pharmex”). This action relates to
5 Abbreviated New Animal Drug Application (“ANADA”) No. 200-536 filed by
6 Med-Pharmex with the U.S. Food and Drug Administration (“FDA”) for approval to
7 market Mometavet®, a proposed generic copy of Mometamax® otic suspension,
8 prior to expiration of U.S. Patent No. 6,127,353 (the ’353 patent).

9 **PARTIES**

10 2. Merck Sharp & Dohme Corp. (collectively with Intervet Inc., “Merck”
11 and/or “Plaintiff”) is a New Jersey corporation with its principal place of business at
12 2000 Galloping Hill Road, Kenilworth, New Jersey 07033.

13 3. Intervet Inc., doing business as Merck Animal Health, is a Delaware
14 corporation with its principal place of business at 2 Giralda Farms, Madison, New
15 Jersey 07940.

16 4. On information and belief, Med-Pharmex is incorporated in California
17 and maintains a principal place of business at 2727 Thompson Creek Road, Pomona,
18 CA 91767.

19 **JURISDICTION AND VENUE**

20 5. This action arises under the patent laws of the United States of
21 America, Title 35, United States Code, and jurisdiction is founded on Title 28,
22 United States Code §§ 1331 and 1338(a).

23 6. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

24 7. This Court has jurisdiction over Med-Pharmex because, upon
25 information and belief, Med-Pharmex is a California corporation.

26 8. This Court also has jurisdiction over Med-Pharmex because, inter alia,
27 this action arises from actions of Med-Pharmex directed toward California, and
28 Med-Pharmex has purposefully availed itself of the rights and benefits of California

1 law by engaging in systematic and continuous contacts with California. Upon
2 information and belief, Med-Pharmex regularly and continuously transacts business
3 within the State of California, including by selling products in California, either on
4 its own or through affiliates. Upon information and belief, Med-Pharmex derives
5 substantial revenue from the sale of those products in California and has availed
6 itself of the privilege of conducting business within the State of California.

7 9. For these reasons, and for other reasons that will be presented to the
8 Court if jurisdiction is challenged, the Court has personal jurisdiction over Med-
9 Pharmex.

10 **BACKGROUND**

11 10. On October 3, 2000, the '353 patent, entitled MOMETASONE
12 FUROATE MONOHYDRATE, PROCESS FOR MAKING SAME AND
13 PHARMACEUTICAL COMPOSITIONS, duly and legally issued to Pui-Ho Yen,
14 Charles Eckhart, Teresa Etlinger, and Nancy Levine. The '353 patent is currently
15 scheduled to expire on October 3, 2017, with pediatric exclusivity through April 3,
16 2018. The '353 patent discloses and claims novel form(s) of mometasone furoate
17 monohydrate (also designated $9\alpha,21$ -dichloro- 16α -methyl- $1,4$ -pregnadiene- $11\beta,17\alpha$ -
18 diol- $3,20$ -dione- 17 -($2'$ -furoate) monohydrate) and novel pharmaceutical
19 compositions thereof. A copy of the '353 patent is attached to this First Amended
20 Complaint as Exhibit 1.

21 11. Merck is the owner through assignment of the '353 patent.

22 12. Intervet Inc., currently doing business as Merck Animal Health and
23 formerly known as Intervet/Schering-Plough Animal Health, is the sponsor of New
24 Animal Drug Application No. ("NADA") 141-177, covering Mometamax® otic
25 suspension.

26 13. Merck's Mometamax® otic suspension is extremely successful and is
27 widely used in California and throughout the United States to treat ear infections in
28 dogs.

1 14. The publication *FDA Approved Animal Drug Products* (commonly
2 known as the “Green Book”) identifies animal drug products approved on the basis
3 of safety and effectiveness by the FDA under the Federal Food, Drug, and Cosmetic
4 Act (FFDCA). Merck has listed the ’353 patent in the Orange Book as covering its
5 Mometamax® otic suspension.

6 15. On information and belief, Med-Pharmex has filed an ANADA with
7 the FDA for a generic copy of Mometamax® otic suspension (ANADA No. 200-
8 536). On information and belief, Med-Pharmex’s ANADA contains a certification
9 that the ’353 patent is not infringed by ANADA No. 200-536. Notice of that
10 certification, but not the certification, was transmitted to Merck on or after July 16,
11 2015.

12 16. Merck has requested additional information regarding Med-Pharmex’s
13 ANADA No. 200-536 and/or samples of Med-Pharmex’s proposed generic copy,
14 but such materials have not been provided to Merck under reasonable conditions
15 that would allow evaluation of the ANADA and/or associated samples before the
16 filing of the original complaint in this action.

17 17. Upon information and belief, Med-Pharmex’s proposed generic copy
18 would contain mometasone furoate in such a form that would infringe the ’353
19 patent.

20 18. On information and belief, Med-Pharmex filed ANADA No. 200-536
21 because Med-Pharmex seeks to enter the lucrative market for Mometamax® otic
22 suspension created by Merck.

23 **COUNT I**

24 19. Each of the preceding paragraphs is incorporated as if fully set forth
25 herein.

26 20. On information and belief, Med-Pharmex filed ANADA No. 200-536
27 to obtain approval under the FFDCA to engage in the commercial manufacture, use,
28 or sale of a drug product that is claimed in the ’353 patent, before the expiration of

1 the '353 patent. On information and belief, Med-Pharmex has committed an act of
2 infringement under 35 U.S.C. § 271 (e)(2)(B), and Med-Pharmex will further
3 infringe at least one claim of the '353 patent by making, using, offering to sell, and
4 selling its generic copies of Mometamax® otic suspension in the United States
5 and/or importing such copies into the United States unless enjoined by the Court.

6 21. On information and belief, when Med-Pharmex filed ANADA No. 200-
7 536 seeking approval to market a generic copy of Mometamax® otic suspension
8 before the expiration of the '353 patent, Med-Pharmex was aware of the existence of
9 the '353 patent and that the filing of ANADA No. 200-536 constituted an act of
10 infringement of that patent.

11 22. On information and belief, Med-Pharmex acted without a reasonable
12 basis for a good faith belief that it would not be liable for infringing the '353 patent.

13 23. If Med-Pharmex is not enjoined from engaging in the marketing and
14 sale of its proposed generic copy of Mometamax® otic suspension prior to the
15 expiration of the '353 patent and all other relevant exclusivities, Merck will suffer
16 substantial and irreparable harm for which there is no remedy at law.

17 **COUNT II**

18 24. Each of the preceding paragraphs is incorporated as if fully set forth
19 herein.

20 25. On information and belief, Med-Pharmex filed ANADA No. 200-536
21 to obtain approval under the FFDCA to engage in the commercial manufacture, use,
22 or sale of a drug product which is claimed in the '353 patent, before the expiration
23 of the '353 patent. On information and belief, Med-Pharmex has committed an act
24 of infringement under 35 U.S.C. § 271 (e)(2)(B), and Med-Pharmex will further
25 contribute to the infringement of others of at least one claim of the '353 patent.

26 26. In any event, to the extent that Med-Pharmex contends that it will not
27 directly infringe the '353 patent by the manufacture, use, or sale of the product
28 described in ANADA No. 200-536, the mometasone furoate in Med-Pharmex's

1 product constitutes a material part of the invention of the '353 patent because the
2 mometasone furoate will be present in Med-Pharmex's product in such a form and
3 under such conditions so as to infringe the '353 patent during storage during the
4 proposed shelf life of such product and/or at the time of the use of such product.

5 27. Med-Pharmex has knowledge of the '353 patent, as evidenced by at
6 least its identification of the '353 patent in connection with its filing of ANADA No.
7 200-536.

8 28. On information and belief, Med-Pharmex has or will have knowledge
9 that if it were to receive approval from the FDA to market the product described in
10 ANADA No. 200-536 and made said product available for sale and/or use during
11 the proposed shelf life of the product, such activities would result in the sale and/or
12 use of an infringing article that is not a staple article or commodity of commerce
13 suitable for substantial noninfringing use, but rather is especially made and/or
14 adapted for use in the direct infringement of the '353 patent by another.

15 29. On information and belief, Med-Pharmex acted without a reasonable
16 basis for a good faith belief that it would not be liable for contributing to the
17 infringement the '353 patent.

18 30. If Med-Pharmex is not enjoined from engaging in the marketing and
19 sale of its proposed generic copy of Mometamax® otic suspension prior to the
20 expiration of the '353 patent and all other relevant exclusivities, Merck will suffer
21 substantial and irreparable harm for which there is no remedy at law.

22
23 **REQUESTED RELIEF**

24 WHEREFORE, Plaintiff Merck respectfully seeks the following relief:

25 a) That judgment be entered that Defendant Med-Pharmex has directly
26 infringed and/or contributed to the infringement of the '353 patent by submitting
27 ANADA No. 200-536;

28

1 b) That a permanent injunction be issued under 35 U.S.C. § 271(e)
2 restraining or enjoining Defendant Med-Pharmex, its officers, agents or attorneys or
3 employees, and those acting in privity or concert with them, from engaging in the
4 commercial manufacture, use, offer to sell, or sale within the United States, or
5 importation into the United States, of any chemical entity and/or therapeutic
6 composition, covered by the '353 patent for the full term thereof, including the
7 applicable pediatric exclusivity, and from contributing to such activities;

8 c) That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the
9 effective date of any approval of ANADA No. 200-536 be a date which is not earlier
10 than the expiration date of the asserted patent, including the applicable pediatric
11 exclusivity;

12 d) That this is an exceptional case under 35 U.S.C. § 285 and that
13 judgment be entered for costs and reasonable attorney fees to be awarded to Merck;
14 and

15 e) That this Court award such other and further relief as the Court may
16 deem proper and just under the circumstances.

17 DATED: August 28, 2015

QUINN EMANUEL URQUHART &
SULLIVAN, LLP

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20 *By/s/ Amar L. Thakur*

21 Amar L. Thakur
22 Attorneys for Merck Sharp & Dohme Corp.
23 and Intervet Inc.
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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true copy of the following document has been served on August 28, 2015 to all counsel of record who are deemed to have consented to electronic service via the Court’s CM/ECF system per Civil Local Rule 5.4:

COMPLAINT FOR PATENT INFRINGEMENT

Any other counsel of record will be served by electronic mail, facsimile, and/or overnight delivery.

I declare under penalty of perjury under the laws of United States that the foregoing is true and correct and that this proof of service was executed on August 28, 2015 at Los Angeles, California.

/s/ Amar L. Thakur

Amar L. Thakur