

PARTIES

2. Bayer is a limited liability corporation organized under the laws of the State of Delaware, with its principal place of business at 555 White Plains Road, Tarrytown, New York, 10591.

3. Bayer's Animal Health division is located at 12707 Shawnee Mission Parkway, Shawnee Mission, Kansas, 66216.

4. Upon information and belief, defendant Pfizer Inc. ("Pfizer") is a corporation organized under the laws of Delaware, with its principal place of business at 235 E. 42nd Street, New York, New York, 10017.

5. According to Pfizer's website, available at http://www.pfizer.com/products/animal_health/animal_health.jsp (last checked January 26, 2012), Pfizer Animal Health is a "business unit of Pfizer" headquartered in Madison, New Jersey.

6. According to Pfizer's Form 10-Q Security Exchange Commission filing for the quarterly period ending October 2, 2011, available at <http://www.sec.gov/Archives/edgar/data/78003/000115752311006714/a50063064.htm>, (last checked January 26, 2012), Pfizer's Animal Health business unit "includes worldwide revenues and earnings, as defined by management, from products and services to prevent and treat disease in livestock and companion animals, including vaccines, paraciticides, and anti-infectives."

JURISDICTION AND VENUE

7. This is an action for declaratory relief, a temporary restraining order, preliminary and permanent injunctive relief, and for further relief based on patent infringement and active inducement of patent infringement under 35 U.S.C. § 271.

8. Jurisdiction and venue are proper in this district pursuant to 28 U.S.C. §§ 1331, 1338(a), 1391, 1400, and 2201.

9. Upon information and belief, Pfizer regularly transacts business within this district in a substantial, continuous and systematic way, including but not limited to, regularly shipping and selling products to businesses in Illinois and in this district, and those products include A180[®]; and Pfizer maintains offices in the State of Illinois and employs Illinois residents, including residents within this district who work for Pfizer's Animal Health unit. Pfizer has appointed an agent within this district, CT Corporation System, 208 S. LaSalle St., Suite 814, Chicago, IL 60604 to receive corporate correspondence, such as summons and service of process, on Pfizer's behalf.

10. Upon information and belief, Pfizer manufactures both A180[®] and ADVOCIN[™].

11. Pfizer is subject to personal jurisdiction in this Court by virtue of all the contacts in the district referenced above, including among other things, Pfizer's regular conduct of business in this district, in particular, its conduct of business related to A180[®], Pfizer's purposeful availment of the rights and benefits of Illinois law, and Pfizer's substantial, continuous, and systematic contacts with Illinois.

NATURE OF THE CASE

12. Bayer refers to and incorporates herein each of the preceding paragraphs 1-11 as if fully set forth herein.

13. U.S. Patent No. 5,756,506, entitled "Single High Dose Fluoroquinolone Treatment" (Exhibit A hereto), issued on May 26, 1998 to Bayer Corporation, as assignee of inventors Dennis D. Copeland, Kathleen M. Ewert, and Terry S. Wollen.

14. Bayer Corporation subsequently assigned the '506 patent to Plaintiff Bayer (Bayer HealthCare LLC).
15. Bayer is the current owner of the '506 patent.
16. Bayer will be substantially and irreparably harmed and damaged by Pfizer's infringement and active inducement of the infringement of the '506 patent.
17. Bayer markets and sells Baytril[®] 100, which is a single use high dose fluoroquinolone treatment for bovine respiratory disease ("BRD") covered by one or more claims of the '506 patent.
18. The '506 patent covers a process for treating a bacterial infection in cattle in need thereof comprising administering to said animal a pharmaceutically effective composition comprising a fluoroquinolone, an ester, or a salt thereof in one high dose, single treatment.
19. The '506 patent covers a composition with the fluoroquinolone danofloxacin.
20. The '506 patent has been listed in connection with Baytril[®] 100 in *FDA Approved Animal Drug Products*, also known as the "Green Book."
21. Bayer's Animal HealthCare Division sells Baytril[®] 100 pursuant to a New Animal Drug Application ("NADA") held by Bayer, which has been approved by the FDA.
22. In a January 23, 2012, email with the subject "Your range of BRD treatment options is growing," Dimitri Popov, Pfizer Animal Health's Marketing Manager for Beef Anti-Infectives, U.S. Cattle Team, announced that Pfizer "will be discontinuing the sale of A180[®] (*danofloxacin mesylate*) effective in January" and anticipates "ADVOCIN[™] product supplies will be available in February."
23. Mr. Popov's email states that Pfizer's ADVOCIN[™] is a "single-dose fluoroquinolone to treat cattle with bovine respiratory disease."

24. Mr. Popov's email further states that ADVOCIN™ would be a "[c]ost-effective alternative to Baytril."

25. On January 26, 2012, Pfizer hosted a conference call/webex "webinar" entitled "ADVOCIN Launch Plan." During the webinar, Dr. J.P. Pollreisz, D.V.M., Veterinary Operations, Pfizer Animal Health, explained that existing supplies of Pfizer's drug A180® can be used as a single high dose treatment for BRD.

26. During the webinar, Dr. Pollreisz said, "any A180 that you currently have on the shelf can be used now at the single-dose regimen, can be used at 8 milligrams per kilogram or 2 milliliter per 100 pounds one time subcutaneously with four-day withdrawal of treatment of BRD. It is the same NADA. We have received approval. So you are good to go even with A180 at that single-dose regimen at this point in time."

27. During the webinar, Dr. Pollreisz also said that Pfizer would continue to study the use of ADVOCIN™ in "some phase four studies in the design and in the works to continue to support this brand."

28. Also during the webinar, Pfizer's Mr. Popov explained that ADVOCIN™ would be introduced at the February 1st, 2012, National Cattle Industry Convention and National Cattlemen's Beef Association trade show, that the pricing for ADVOCIN™ would be revealed at the show, and that ADVOCIN™ would be readily available in mid-February.

29. At the conclusion of the webinar, Mr. Popov specifically stated: "pricing on this product will be disclosed next week. And as far as -- it was mentioned NCBA is the official launch time at which point we will have producers be aware of this product in our trade booth. At this point just veterinarians are aware as part of our 'first to know' initiative in communicating to veterinarians on prescription drugs first. And as far as product availability to

end users, we expect that to happen the week of February 13th is what we're aiming for and should be readily available."

30. At the conclusion of the webinar, Pfizer displayed a slide with an advertisement for its promotional campaign for ADVOCIN™. This advertisement included the slogans "ADVOCIN™ vs. Baytril" and "ADVOCIN Packs A Cost-Effective Knockout:"

ADVOCIN is the Fast-acting, Cost-effective Alternative to Baytril

BATTLE OF THE BRD ANTIMICROBIALS

COMPETING FOR
★ SPEED ★
and
COST-EFFECTIVENESS

INTRODUCING
ADVOCIN™ vs. **BAYTRIL®**

WITHDRAWAL TIME: 4 DAYS WITHDRAWAL TIME: 28 DAYS

GET READY FOR THE HEAD-TO-HEAD MATCHUP OF THE SEASON:
NEW ADVOCIN™ (danofloxacin mesylate) FROM PFIZER ANIMAL HEALTH
IS THE COST-EFFECTIVE ALTERNATIVE TO BAYTRIL® (enrofloxacin).

★ ★ ADVOCIN PACKS A COST-EFFECTIVE KNOCKOUT. ★ ★

IMPORTANT SAFETY INFORMATION: FEDERAL LAW PROHIBITS THE EXTRA-LABEL USE OF ALL FLUOROQUINOLONES INCLUDING ADVOCIN™ IN FOUR SPECIFIC ANIMALS. NOT FOR USE IN CATTLE. INTENDED FOR ORAL PRODUCTION OR IN CALVES TO BE PROCESSED FOR VEAL. ADVOCIN HAS A PRE-SCREENED WITHDRAWAL TIME OF FOUR DAYS.

ADVOCIN™
(danofloxacin mesylate)

3 KEY MESSAGES:

- Single injection FQ
- Cost-effective alternative to Baytril
- 4 day withdrawal time

Pfizer 31

31. ADVOCIN™ is FDA approved for treating BRD, a bacterial infection in cattle, by administering a subcutaneous injection to the animal of the fluoroquinolone danofloxacin mesylate in a single high dose treatment.

32. Upon information and belief, Pfizer is aware of the '506 patent.

33. Upon information and belief, Pfizer's actions have been willful and deliberate and in disregard of Bayer's lawful rights under the '506 patent.

34. Unless enjoined, Pfizer's marketing, offers to sell, and sales of ADVOCINTM will cause irreparable harm to Bayer by permanently eroding Baytril[®] 100 price and market share, and by damaging Bayer's goodwill.

COUNT ONE: INFRINGEMENT OF THE '506 PATENT

35. Bayer refers to and incorporates herein each of the preceding paragraphs 1-34 as if fully set forth herein.

36. Upon information and belief, Pfizer's manufacture, use, offers to sell, and sales of ADVOCINTM infringe one or more claims of the '506 patent.

37. Upon information and belief, Pfizer has manufactured, used, and offered to sell, and/or sold ADVOCINTM knowing that these acts infringe the '506 patent.

38. Bayer has suffered and will continue to suffer irreparable harm and other damages as a result of Pfizer's infringement of the '506 patent.

COUNT TWO: ACTIVE INDUCEMENT OF INFRINGEMENT OF THE '506 PATENT

39. Bayer refers to and incorporates herein each of the preceding paragraphs 1-38 as if fully set forth herein.

40. Upon information and belief, Pfizer's manufacture, use, offers to sell, and sales of Pfizer's A180[®] for use in a single high dose infringe one or more claims of the '506 patent.

41. Upon information and belief, Pfizer has manufactured, used, offered to sell, and/or sold A180[®] for use in a single high dose knowing that these acts actively induce infringement of the '506 patent.

42. Upon information and belief, Pfizer personnel, including Dr. Pollreisz, have encouraged the use of A180[®] in ways that infringe the '506 patent.

43. Bayer has suffered and will continue to suffer irreparable harm and other damages as a result of Pfizer's inducement of infringement of the '506 patent.

**COUNT THREE: DECLARATORY JUDGMENT OF INFRINGEMENT
OF THE '506 PATENT**

44. Bayer refers to and incorporates herein each of the preceding paragraphs 1-43 as if fully set forth herein.

45. Upon information and belief, Pfizer's manufacture, use, offers to sell, and sales of ADVOCIN[™] will infringe one or more claims of the '506 patent.

46. Upon information and belief, after receiving FDA approval, Pfizer has used ADVOCIN[™] in a manner that infringes one or more claims of the '506 patent.

47. Upon information and belief, Pfizer will continue to use ADVOCIN[™] in a manner that infringes one or more claims of the '506 patent.

48. There is a substantial, imminent, and continuing controversy with respect to Pfizer's use of ADVOCIN[™] as single high-dose treatment for BRD.

49. Bayer will suffer irreparable harm and other damages as a result of Pfizer's imminent infringement of the '506 patent through its use of ADVOCIN[™].

**COUNT FOUR: DECLARATORY JUDGMENT OF ACTIVE INDUCEMENT
OF INFRINGEMENT OF THE '506 PATENT**

50. Bayer refers to and incorporates herein each of the preceding paragraphs 1-49 as if fully set forth herein.

51. Upon information and belief, Pfizer's manufacture, use, offers to sell, and sales of ADVOCIN™ will infringe one or more claims of the '506 patent.

52. Upon information and belief, the facts set forth above show that Pfizer has undertaken meaningful steps in preparation of its ADVOCIN™ launch, that Pfizer intends for ADVOCIN™ to take sales directly from Bayer's Baytril® 100 by actively inducing use of ADVOCIN™ in a manner that infringes the '506 patent, and that there is a substantial and imminent danger that Pfizer will actively induce infringement of the '506 patent.

53. Bayer will suffer irreparable harm and other damages as a result of Pfizer's plans actively to induce the use of ADVOCIN™ in a manner that infringes the '506 patent.

REQUEST FOR RELIEF

WHEREFORE, Bayer requests that the Court enter judgment in its favor and against Pfizer as follows:

- (a) A judgment that Pfizer has infringed the '506 patent through its manufacture, use, offers to sell, and sales of ADVOCIN™;
- (b) A judgment that Pfizer has actively induced infringement of the '506 patent through its communications about A180™;
- (c) A declaratory judgment that Pfizer's imminent use of ADVOCIN™ infringes the '506 patent;
- (d) A declaratory judgment that Pfizer's imminent launch of ADVOCIN™ will actively induce infringement of the '506 patent, and will contribute to the infringement by others of the '506 patent;
- (e) A judgment declaring that making, using, selling, offering for sale, marketing, or distributing ADVOCIN™, or any product which infringes the '506 patent, prior to the expiration date of the '506 patent, will actively induce infringement of, and will contribute to the infringement by others of, the '506 patent;
- (f) An order preliminarily and permanently enjoining Pfizer, and all persons acting in concert with Pfizer, from infringing, actively inducing the infringement of, or contributing to the infringement by others of, the '506 patent through the making, using, selling, offering for sale, marketing or distributing of ADVOCIN™, or any

product the use of which infringes the '506 patent, prior to the expiration of the '506 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

- (g) A declaration that this is an exceptional case and an award of attorney's fees pursuant to 35 U.S.C. § 285;
- (h) An order awarding Bayer costs and expenses in this action; and
- (i) Such further and other relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Bayer hereby demands a jury trial for all issues so triable.

DATED: January 30, 2012

Respectfully submitted,
BAYER HEALTHCARE LLC

By: /s/ Katherine G. Minarik
Katherine G. Minarik

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CERTIFICATE OF SERVICE

I, Katherine G. Minarik, an attorney, hereby certify that a true and correct copy of the foregoing document entitled **VERIFIED COMPLAINT** was electronically filed with the Clerk of the Court for the Northern District of Illinois using the CM/ECF System on January 30, 2012.

By: /s/ Katherine G. Minarik
Katherine G. Minarik

VERIFICATION

I, Cary R. Christensen, DVM, on behalf of Bayer HealthCare LLC, verify under penalty of perjury that the foregoing allegations of fact contained in this **Verified Complaint** are true and correct and those factual matters which are stated upon information and belief are believed to be true and correct.

Cary Christensen, DVM

Cary R. Christensen, DVM

State of Kansas

County of Johnson

Subscribed to and sworn before me
this 30th day of January, 2012

Janis G. Wright

Notary Public

