**19TH JUDICIAL DISTRICT COURT, PARISH OF EAST BATON ROUGE**

**STATE OF LOUISIANA**

**NO.** 637960 **DIVISION** __ **SECTION** SEC. 22

**STATE OF LOUISIANA,**

**by and through its ATTORNEY GENERAL JAMES CALDWELL**

**VERSUS**

**ASTRA ZENECA AB, ASTRAZENECA LP,**

**ASTRAZENECA PHARMACEUTICALS LP, AND AKTIBOLAGET HÄSSLE**

STATE

**FILED:** MAR 18 2015 BY DY CLERK OF COURT **DEPUTY CLERK**

Plaintiff State of Louisiana ("State" or "Plaintiff"), by and through its Attorney General James D. "Buddy" Caldwell, based upon information and belief and after an inquiry reasonable under the circumstances, for its Petition against Defendants, AstraZeneca AB, AstraZeneca LP, AstraZeneca Pharmaceuticals LP, and Aktiebolaget Hässle, ("Defendants") alleges as follows:

## I. NATURE OF THE ACTION

1. This Petition, on behalf of the State of Louisiana, alleges violations of Louisiana antitrust laws and the Louisiana Unfair Trade Practices Act arising from the manufacture, marketing, and sale of Toprol-XL® ("Toprol-XL"). The State purchased, paid, and/or provided reimbursement for Toprol-XL and its generic equivalent, metoprolol succinate.

2. As further explained below, this matter pertains to the intersection of three patents, the '318 patent, the '161 patent and the '154 patent. Among other things, the '318 patent contained claims regarding metoprolol succinate. The later filed and issued '161 and '154 patents contained claims that, as found by the district court and the Federal Circuit in *In re Metoprolol Succinate Patent Litigation*, 494 F.3d 1011, 1020-21 (Fed. Cir. 2007), were obvious from the '318 patent and hence should not have been applied for and issued. Furthermore, during the prosecution of the '161 and '154 patents, Defendants engaged in inequitable conduct before the PTO that would have also rendered the patents invalid were they not already invalid as a result of their obviousness in relation to the '318 patent.

3. Toprol-XL is an extended-release drug approved by the U.S. Food and Drug

Administration ("FDA") containing an active chemical compound used for the treatment of angina, hypertension and congestive heart failure.

4. Defendants prevented generic versions of Toprol-XL from entering the market, by, *inter alia*, improperly manipulating patent filings and filing baseless patent infringement lawsuits, thus unlawfully monopolizing and/or attempting to monopolize the domestic market for Toprol-XL and its generic bioequivalents.

5. Specifically, Defendants unlawfully obtained and manufactured a monopoly for Toprol-XL and metoprolol succinate through intentional omissions and misrepresentations to the U.S. Patent and Trademark Office ("PTO"). As alleged herein, Defendants obtained U.S. Patent 5,001,161 (the "'161 patent") and U.S. Patent 5,081,154 (the "'154 patent"), through inequitable conduct before the PTO, and caused them to be listed in the Orange Book (defined below), which enabled Defendants to falsely create and extend their market monopoly for Toprol-XL. In the absence of such conduct, the '161 and '154 patents would not have been issued. Defendants wrongfully protected their patent-enabled monopoly by filing sham patent infringement litigation, when they knew or should have known that the patents were unenforceable *ab initio*.

6. In addition to their invalidity based on Defendants' misconduct before the PTO, the '161 and '154 patents are invalid for obviousness-type double patenting over the earlier issued '318 patent and the '161 patent is not entitled to priority over the '318 patent.

7. As more fully described below, Defendants maintained patents for metoprolol succinate itself, as well as "sustained release" formulations of metoprolol succinate. Toprol-XL sales in 2005 were $1.29 billion, making it the number one revenue-producing betablocker (a specific type of drug used to treat hypertension), and AstraZeneca's top-selling drug by volume. Defendants' unlawful actions as described herein prevented generic versions of Toprol-XL from entering the United States market, thereby causing injury to Plaintiff.

8. As a result of Defendants' conduct, Plaintiff paid for Toprol-XL and its generic equivalent metoprolol succinate at prices significantly higher than what it would have paid if multiple competing and/or generic versions of Toprol-XL were on the market.

9. At least three generic drug manufacturers, KV Pharmaceutical Company ("KV")[1],

[1] KV later changed its name to Lumara Health before being acquired by AMAG Pharmaceuticals.

Andrx Pharmaceuticals, LLC and Andrx Corporation ("Andrx")[2] and Eon Labs, Inc. ("Eon") (collectively, the "generic manufacturers") filed separate Abbreviated New Drug Applications ("ANDAs") with the FDA requesting approval to market a generic version of Toprol-XL. In their applications, the generic manufacturers asserted that their products are bioequivalents to Toprol-XL and either: (i) do not infringe any patent owned by or licensed to Defendants; or (ii) that Defendants' underlying '161 and '154 patents for Toprol-XL are invalid. In response, Defendants, for the purpose of preventing generic competition, filed baseless patent infringements actions against the generic manufacturers, which prevented generic versions of Toprol-XL from timely entering the U.S. market.

10. Defendants instituted these baseless patent infringement suits to frustrate or delay market availability of generic bioequivalents and these actions prevented the FDA from granting final approval of generic manufacturers' ANDAs to manufacture, market and sell a generic version of Toprol-XL under the "Hatch-Waxman Amendments." Drug Price Competition and Patent Term Restoration Act of 1984; *see* Pub. L. No. 98-417, 98 Stat.1585 (1984 (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271 (e))). The Hatch-Waxman Amendments were intended to facilitate entry of generic drugs into the market, but Defendants have used the legislation to frustrate and delay less expensive, reasonably priced generic alternatives.

11. Defendants knew that under the Hatch-Waxman Amendments the mere filing of patent litigation, even groundless suits based on invalid or unenforceable underlying patents, would automatically prevent the FDA, for up to thirty months, from granting generic competitors final approval of an ANDA. Defendants' patents were ultimately determined invalid and unenforceable in Federal District Court[3] and the Federal Circuit Court of Appeals,[4] but their lawsuits nevertheless blocked generic competition for an extended period of time. Defendants' actions allowed them to unlawfully maintain their monopoly simply by listing the patents in the Orange Book and then filing and pursuing baseless patent infringement litigation against generic competitors.

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[2] Andrx was later acquired by Actavis plc.

[3] *In re Metoprolol Succinate Patent Litig.*, 2006 WL 120343 (E.D. Mo. Jan. 17, 2006) (holding that patents '161 and '154 were unenforceable due to Defendants' inequitable conduct before the PTO, were also invalid on the basis of double patenting, and that the '161 patent was invalid as anticipated, and not entitled to priority to the '318 patent).

[4] *In re Metoprolol Succinate Patent Litig.*, 494 F.3d 1011, 1020-21 (Fed. Cir. 2007) (affirming the district court's ruling on invalidity but reversing and remanding the question of inequitable conduct due to contested issues of material fact).

12. Such unscrupulous strategies by brand name companies have not gone unnoticed by federal competition authorities. For example, in 2002, the Chairman of the Federal Trade Commission ("FTC"), Timothy Muris ("Muris"), in a statement before a Congressional Subcommittee, noted that "an improper Orange Book listing strategy involves unilateral abuse of the Hatch-Waxman process itself to restrain trade." *See* Prepared Statement of The FTC Before the Committee on Energy and Commerce, Subcommittee on Health, United States House of Representatives ("FTC Statement"), at 9 (Oct. 9, 2002). Chairman Muris also explained that because "the FDA does not review patents presented for listing in the Orange Book . . . , an NDA filer acting in bad faith . . . [has the] power to . . . delay[] generic entry and potentially cost[] consumers millions, or even billions, of dollars without valid cause." FTC Statement at 10.

13. As a direct and proximate result of Defendants' unlawful scheme and anticompetitive conduct, Plaintiff has been deprived the benefits of free and unrestrained competition, by being denied the opportunity to choose between branded Toprol-XL and lower priced AB-rated generic alternatives. A generic version would have initially cost thirty percent (30%) to forty percent (40%) less than branded Toprol-XL. Instead, Plaintiff was forced to continue to pay supracompetitive prices for Toprol-XL, thereby causing it to sustain injury.

14. The State is accountable to its citizens and taxpayers for how it spends limited State resources, and it is empowered to pursue any party whose unlawful conduct caused the State to be overcharged and led to the unlawful obtainment of State funds.

15. Consequently, the State, by and through its Attorney General, brings this action to seek restitution and treble damages, via the enforcement powers of the Louisiana Attorney General as provided by Louisiana state laws and statutes, including but not limited to La. R.S. §§ 51:123, 51:128, 51:136, 51:137, 51:138, 51:1404, 51:1405, 51:1407, 51:1408, 51:1409, and 51:1414. Through this civil action, the State seeks to recover amounts paid by the State of Louisiana for illegally obtained funds due to Defendant's monopolistic actions and unfair and deceptive trade practices and acts. The State brings this action exclusively under the laws and statutes of Louisiana. No claims arising under the laws of the United States are asserted herein.

## II. PARTIES

### A. Plaintiff

16. This action is brought for and on behalf of the sovereign State of Louisiana, by and through its duly elected Attorney General, James D. "Buddy" Caldwell. The Attorney

General, as chief legal officer of the State, is statutorily authorized to initiate and prosecute any and all suits deemed necessary for the protection of the interests and rights of the State pursuant to La. R.S. §§ 13:5036, 51:128, 51:138, 51:1404, 51:1405, 51:1414 and related statutes and Louisiana law. Specifically, the Attorney General is authorized to initiate and prosecute suits to penalize conduct that constitutes unfair or deceptive trade practices and that monopolizes or restrains trade or commerce. The Attorney General is also charged with the duty to protect the fiscal and programmatic integrity of Louisiana's medical assistance programs from companies that engage in abusive practices. Plaintiff brings this action in its proprietary and/or sovereign capacity, which may include state departments, bureaus, agencies, political subdivisions, and other instrumentalities as purchasers of Toprol-XL (either directly, indirectly, or as assignees) or as purchasers under medical or pharmaceutical reimbursement programs.

**B. Defendants**

17. Defendant AstraZeneca AB is a company organized and existing under the laws of Sweden, with its principal place of business in Södertälje, Sweden.

18. Defendant AstraZeneca LP is a limited partnership organized under the laws of Delaware, with its principal place of business in Wilmington, Delaware. AstraZeneca LP holds an approved New Drug Application from the FDA for metoprolol succinate preparations with extended release, which it sells under the brand name Toprol-XL. AstraZeneca LP is a U.S. subsidiary of AstraZeneca PLC.

19. Defendant AstraZeneca Pharmaceuticals LP is a company organized and existing under the laws of Delaware, which distributes, markets, and sells pharmaceutical products including Toprol-XL throughout the United States. Its U.S. headquarters is located in Wilmington, Delaware. AstraZeneca Pharmaceuticals LP is a U.S. Subsidiary of AstraZeneca PLC, and was created as a result of a 1999 merger between Zeneca Pharmaceuticals and Astra Pharmaceuticals.

20. Defendant Aktiebolaget Hässle is a company organized and existing under the laws of Sweden, with its principal place of business in Mölndal, Sweden.

21. Defendants AstraZeneca AB, AstraZeneca LP, AstraZeneca Pharmaceuticals LP and Aktiebolaget Hässle are referred to collectively as "Astra" or "Defendants."

## III. JURISDICTION AND VENUE

22. This Court has jurisdiction over the State's claims because they arise exclusively

under Louisiana Law.

23. This Court has personal jurisdiction over each Defendant pursuant to La. C.C.P. Art. 6, La. R.S. §§ 13:3201, 51:128, 51:1407(A), 51:1418 and related statutes because each Defendant engages in consumer transactions within the State of Louisiana, purposefully directs and/or directed its actions toward the State of Louisiana, and/or has the requisite minimum contacts within the State of Louisiana needed to permit this Court to exercise jurisdiction.

24. Venue is proper in this judicial district pursuant to the La. C.C.P. Art. 42, La. R.S. §§ 51:131, 51:1407 and related statutes. Further, the State pays reimbursement through its Medicaid agency for prescription drugs dispensed in this Parish and throughout the State of Louisiana. The events giving rise to the claims herein arose, in substantial part, in this Parish.

## IV. LEGAL BACKGROUND

### A. The Regulation and Approval of Brand Name Drugs

25. The manufacture, marketing, distribution, and sale of prescription drugs is one of the most profitable industries in the United States. The U.S. market accounts for more than 40% of the world's prescription pharmaceutical revenue. The cost of prescription drugs in the United States has been rising at rates of approximately 15% - 20% per year. In 1997, over $97 billion worth of prescription drugs was dispensed in the United States. By 2008, that amount had risen to more than $230 billion.

26. Congress has enacted various laws designed to regulate the prescription drug industry and to address the growing health care and prescription drug costs.

27. Under the Food, Drug, and Cosmetic Act ("FDCA"), codified at 21 U.S.C. §§ 301-392, manufacturers who develop a new drug product must obtain the approval of the Food and Drug Administration ("FDA") to sell the new drug by filing a New Drug Application ("NDA").

28. The NDA approval process is typically a timely and expensive one. An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. § 355(a), (b).

29. The FDA publishes the patent information that it receives in a publication entitled "Approved Drug Products With Therapeutic Equivalence Evaluations," more commonly known as the "Orange Book," where it can be easily found and consulted by future applicants.

30. If, after its NDA is approved, the brand name drug manufacturer obtains a new

patent that claims the drug or method of its use, the manufacturer must supplement its NDA by submitting information on the new patent within thirty (30) days of issuance. 21 U.S.C. § 355(c)(2). The FDA then lists the new patent in a supplement to the Orange Book. The FDA is required to accept as true the patent information it obtains from patent holders.

**B. Generic Drugs**

31. To stem the rising cost of prescription drugs, Congress in 1984 amended the FDCA by adding the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. 21 U.S.C. § 355; 35 U.S.C. § 271(e). The Hatch-Waxman Amendments were designed to bring cheaper generic drugs to market faster, as the availability of generic drugs has been one of the most effective means of lowering the cost of prescription drugs.

32. Two primary goals motivated the enactment of the Hatch-Waxman Amendments. First, where a generic product could be developed that did not infringe any existing legitimate patent, Congress sought to expedite the entry of generic competitors and thereby reduce healthcare expenses nationwide. Second, Congress wanted to protect the incentive of pharmaceutical companies to create new and innovative products. The Hatch-Waxman Amendments achieved both goals, substantially advancing the rate of generic product launches, and ushering in an era of historic high profit margins for brand name pharmaceutical companies.

33. Under the terms of the FDCA and the Hatch-Waxman Amendments, a prospective generic manufacturer must demonstrate to the FDA that the generic drug it proposes to market is bioequivalent to the brand named drug. 21 U.S.C. § 355(j)(2)(A)(iv). The FDCA and Hatch-Waxman Amendments operate on the presumption that bioequivalent drug products contain identical amounts of the same active ingredients in the same route of administration and dosage form, meet applicable standards of strength, quality, purity and identity, and are therapeutically equivalent and may be substituted for one another.

34. Bioequivalency demonstrates that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart. 21 U.S.C. § 355(j)(8)(B). For drugs that are not intended to be absorbed into the bloodstream, the Hatch-Waxman Amendments provide that the FDA "may establish alternative, scientifically valid methods to show bioequivalence if the alternative

methods are expected to detect a significant difference between the drug and the listed drug in safety and therapeutic effect." 21 U.S.C. § 355(j)(8)(C); 21 C.F.R. § 320.24(b)(6).

35. Drugs proven to meet bioequivalence requirements through *in vivo* (clinical) and/or *in vitro* (laboratory) testing receive an "AB" rating from the FDA, indicating they are therapeutically equivalent to other drugs with the same rating in the same category.

36. Typically, manufacturers of AB-rated generic versions of brand name drugs price their drugs significantly below the brand name counterparts. Because of the price differential and certain institutional features of the pharmaceutical market which seek to capitalize on this price differential, AB-rated generic versions are rapidly and substantially substituted for their brand name counterparts.

37. As a counter-balance to the abbreviated approval procedure for bioequivalent generic drugs, the Hatch-Waxman Amendments streamlined the process for brand name manufacturers to enforce legitimate patents against infringement by generic manufacturers. Beyond traditional patent rights, the Hatch-Waxman Amendments also provide brand name manufacturers with several means to obtain legitimate protection from generic competition for set, and specifically limited, periods of time. For example, each approved NDA provides the owner of that drug with three years of exclusivity during which time no generic manufacturer can even seek approval of its proposed generic drug. 21 U.S.C. § 355(j)(5)(F)(iii). Brand name drugs or truly new or innovative drugs that make use of a never-before-approved chemical entity or moiety receive even more time: a "New Chemical Entity" exclusivity period of five years. 21 U.S.C. § 355(j)(5)(F)(ii).

38. Under the statutory regime enacted by Congress (*i.e.*, the Hatch-Waxman Amendments) and as found in most state legislatures (*i.e.*, Drug Product Selection laws), pharmacists in Louisiana may – and, in the case of Medicaid, must – substitute an AB-rated generic version of a drug for the brand name drug without seeking or obtaining permission from the prescribing doctor.[5] Congress and state legislatures actively encourage generic

[5] La. Admin Code, Title 46, Chapter 25, SubChapter B, Section 2511(B)(6) provides: Equivalent Drug Product Interchange

a. The pharmacist shall not select an equivalent drug product when the prescriber handwrites a mark in the check box labeled "Dispense as Written", or "DAW", or both, and personally handwrites his signature on a printed single signature line. Otherwise, the pharmacist may select an equivalent drug product, provided the patient has been informed of, and has consented to, the proposed cost saving interchange.

b. In the event an authorized prescriber has indicated that an equivalent drug product interchange is prohibited by handwriting a mark in the check box labeled "Dispense as Written", or "DAW", or both,

substitution of brand name drugs because of the enormous cost savings to purchasers and consumers.[6]

39. Once a physician writes a prescription for a brand name drug such as Toprol-XL, the prescription defines and limits the options to the named drug and its AB-rated generic equivalent(s). Only drugs which carry the FDA's AB generic rating in that category may be substituted by pharmacists for a physician's prescription for a brand name drug.

40. Generic competition enables the purchase of generic versions of brand name drugs at substantially lower prices–and results in reduced prices for, and thus savings on purchases of, the brand name drug (as the brand manufacturer lowers prices in an attempt to maintain market share). Prior to entry of AB-rated generic competition, however, brand name manufacturers can charge supra-competitive prices without losing all, or a substantial portion, of their brand name sales. Consequently, brand name drug manufacturers have strong incentives to delay the introduction of AB-rated generic competition into the market.

**C. The Regulatory Structure for Approval of Generic Drugs**

41. The Hatch-Waxman Amendments simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file a lengthy and costly NDA in order to obtain FDA approval. Instead, the FDA provides an expedited review process by which generic manufacturers file an abbreviated application (an "ANDA") which relies in substantial part on the scientific finding of safety and effectiveness included by the brand named manufacturer in the NDA for the same drug. 21 U.S.C. § 355(j).

42. For each patent applicable to the pioneer drug listed in the Orange Book, an ANDA applicant must certify whether the proposed generic drug would infringe the patent and, if not, why not, in accordance with the FDCA. 21 U.S.C. § 355(j)(2)(A)(vii).

43. As part of its application, an ANDA filer must make one of four certifications to the FDA:

1. That no patent for the pioneer drug has been filed with the FDA (a

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then a non-licensed, non-certified, or non-registered agent of the pharmacy shall not inquire as to a patient's desire for an equivalent drug product interchange.

c. For prescriptions reimbursable by Medicaid or Medicare, the authorized prescriber may only prohibit equivalent drug product interchange by handwriting the words "brand necessary" or "brand medically necessary" on the face of the prescription order or on a sheet attached to the prescription order.

[6] Federal and state legislatures also recognize that the economics of the pharmaceutical industry prevent generic manufacturers from engaging in the heavy promotion or "detailing" typically done by brand name manufacturers.

"Paragraph I Certification");

2. That the patent (or patents) for the pioneer drug has (or have) expired (a "Paragraph II Certification");
3. That the patent for the pioneer drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III Certification"); or
4. That the patent for the pioneer drug is invalid or will not be infringed upon by the proposed generic company's product (a "Paragraph IV Certification").

U.S.C. § 355(j)(2)(A)(vii).

44. In the case of a patent that has not yet expired, the ANDA applicant's only certification options are Paragraph III or IV certifications.

45. If an ANDA includes a Paragraph IV Certification, the applicant must notify the pioneer drug patent owner of the certification. 21 U.S.C. § 355(j)(2)(B).

46. An ANDA including a Paragraph IV Certification is considered a technical act of patent infringement. 35 U.S.C. § 271(e)(2)(A).

47. Upon receiving notification of a Paragraph IV certification, the brand name drug patent owner has forty-five (45) days under the Hatch-Waxman Amendments to initiate a patent infringement lawsuit against the ANDA applicant (the "45 day window"). If no lawsuit is initiated during the 45 day window, the process for FDA approval of the generic product continues. 21 U.S.C. § 355(j)(5)(B).

48. If the patent holder commences a patent infringement suit within the 45 day window, final FDA approval of the ANDA is automatically stayed until the earliest of: (a) the expiration of the patent; (b) the expiration of thirty (30) months from the patent holder's receipt of notice of the Paragraph IV Certification (the "30 month stay"); or (c) a final judicial determination of non-infringement or patent invalidity.

49. The first filer of an ANDA with a Paragraph IV Certification is eligible for a 180-day period in which to market its generic version on an exclusive basis (the "180-day exclusivity period"). 21 U.S.C. § 355(j)(5)(B)(iv).

50. The 180-day exclusivity period is triggered by either: (a) commercial marketing of the generic product; or (b) a final court decision that the patent at issue is either invalid or not infringed.

51. Prior to the expiration of the 30 month stay, the FDA may grant "tentative"

approval of an ANDA once it determines that all criteria for "final" approval have been satisfied. 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd).

52. The Hatch-Waxman Amendments expressly permit the FDA to grant final approval to the first filed ANDA, and an ANDA applicant with FDA approval may market its generic product in the United States while the patent infringement lawsuit remains unresolved.

53. If a patent is listed in the Orange Book, the brand name drug patent holder need only file a patent infringement lawsuit within the 45 day window in order to block FDA approval of an ANDA applicant's generic drug from entering the market for up to 30 months.

**D. Improper Patent Listing in the Orange Book**

54. The FDA maintains and publishes the Orange Book, which lists all prescription drugs approved for use in the United States and the patents, if any, covering those drugs.

55. A patent is listable in the Orange Book only if the patent "claims the drug . . . or a method of using such drug" and the patent is one "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1). A patent that is unenforceable does not meet the criteria for listing in the Orange Book. Listing an unenforceable patent in the Orange Book is wrongful, improper, and an abuse of the Hatch-Waxman regulatory scheme.

56. Listing a patent in the Orange Book that is not properly listable can have significant anticompetitive consequences. As the United States Federal Trade Commission has stated, "the Orange Book listing scheme is susceptible to opportunistic behavior. The NDA holder can exploit the listing scheme by obtaining patents and listing them in the Orange Book to block FDA approvals of generic rivals for 30 months, even when the NDA holder does not reasonably expect the patents to ultimately hold up in court." *See* Analysis to Aid Public Comment in the Matter of Bristol-Myers Squibb Company, File Nos. 001 0221, 011 0046, and 021 0181.

57. The listing of a patent in the Orange Book is a private act undertaken by the NDA holder, which submits the patent to the FDA for listing in the Orange Book. The FDA acts in a purely ministerial manner, receiving the submission for the NDA holder and including that submission in the Orange Book. The FDA does not analyze the validity or enforceability

of the patent at issue, and the FDA does not analyze whether the patent is appropriately listable to the NDA at issue. Listing a patent in the Orange Book does not involve petitioning activity.

58. Moreover, the FDA has no administrative procedures for resolving listing disputes. If a party wishes to dispute a listing, it may notify the FDA of its basis for disagreement. 21 C.F.R. § 314.53(1). In response to such a notification, the FDA will simply request that the brand-name company confirm the correctness of the listed patent information. *Id.* Unless the brand-name company voluntarily "withdraws or amends its patent information in response to the FDA's request, the FDA will not change the patent information on the list." *Id.*

59. This unilateral ability of brand name companies to cause and maintain the listing of even the most manifestly inappropriate / unsustainable patents in the Orange Book creates an opportunity for an unscrupulous brand name manufacturer to wrongfully thwart a generic competitor from bringing a lower priced generic product to market. This wrongful conduct frequently leads to baseless patent infringement litigation and unmerited automatic 30 month stays of the FDA's consideration of the ANDAs. This delay prevents the entry of lower priced generic drugs.

**E. The Louisiana Medicaid Program**

60. The Louisiana Medicaid program is a state-administered program with federal matching funds that pays for medical care, including prescription drug benefits, for Louisiana's low-income and disabled citizens.

61. Louisiana Medicaid currently covers approximately 1,300,000 individuals.

62. Prescription drug benefits represent approximately 15% of Louisiana Medicaid's annual budget. Since 1991, the total annual cost of pharmacy-dispensed prescription drugs to Louisiana Medicaid has increased exponentially. Today, the total annual costs exceed $1 billion.

63. Louisiana Medicaid reimburses medical providers, including physicians and pharmacists, for drugs prescribed for, and dispensed to, Louisiana Medicaid recipients pursuant to statutory and administrative formulas.

64. Reimbursement for pharmacy-dispensed prescription drugs under the Louisiana Medicaid program is based on information supplied by Defendants. At all times relevant to this

action, Defendants were aware of the State of Louisiana's Medicaid drug reimbursement formulas and procedures for pharmacy-dispensed drugs, yet it continued its unlawful conduct in violation of Louisiana's antitrust and consumer protection laws.

65. Defendants caused Louisiana's medical assistance programs to pay more for metoprolol succinate products than they would otherwise have paid. Defendants' unlawful conduct deprived Louisiana's medical assistance programs of the benefits of competition that Louisiana's antitrust and consumer protection laws are intended to preserve.

## V. FACTUAL BACKGROUND

### A. The History of the Toprol-XL Related Patents

66. Defendants manufacture, market and sell "extended release" forms of the drug metoprolol succinate as "Toprol-XL."

67. Defendants contend two patents cover Toprol-XL and barred generic competition: U.S. Patent No. 5,001,161 (the "'161 patent") and U.S. Patent No. 5,081,154 (the "'154" patent").

68. Patent '161 relates to the "sustained release" form of metoprolol succinate. The application for the '161 patent was filed on March 25, 1988; it issued on March 19, 1991, and it was set to expire on March 19, 2008.

69. Patent '154's sole claim is for the composition of metoprolol succinate itself. The application for the '154 patent was filed on September 28, 1990; it issued on January 14, 1992, and it was set to expire on January 14, 2009.

70. As explained below, patents '154 and '161 were invalid when issued as a result of Defendants' misconduct before the PTO in the application process for these patents.

71. As explained further below, even if Defendants did not act improperly before the PTO in the application process for the '154 and '161 patents, they are invalid nonetheless for obviousness-type double patenting (non-statutory double patenting) based on claim 8 of the '318 patent, because the claims in the '161 patent and the '154 patents are a genus of the species described in claim 8 of the '318 patent and as anticipated by prior art.

#### 1. The '161 Patent

72. The "Abstract" of the '161 patent states that "[t]he present invention relates to metoprolol succinate, a new therapeutically active compound, and pharmaceutical preparations comprising this new compound."

73. The "Description of the Present Invention" states:

> This compound can, in order to be administered orally be treated in accordance with the method proposed in EP-A 1-0 040 590. Herein it has been proposed an oral pharmaceutical composition comprising a core containing a therapeutically active compound, which core has been coated with a layer comprising 10 to 85% by weight of an anionic polymer soluble at a pH above 5.5, and 15 to 90% by weight of a water insoluble polymer selected from the group of quarternary ammonium substituted acrylic polymers.
>
> . . .
>
> When dosing the ready made product a number of discrete, coated particles/granules corresponding to a therapeutical dose unit of the actual therapeutical compound is administered. When administering, in order to achieve a steady blood plasma level of the therapeutically active compound provided with a coating according to the present invention can be administered together with some particles/granules which are not coated.

74. The sole claim of the '161 patent is for "[a] sustained release pharmaceutical composition comprising metoprolol succinate together with a pharmaceutically acceptable carrier." The invention consisted of coated forms of metoprolol succinate that provide for extended release of the drug.

**2. The '154 Patent**

75. The sole claim in the '154 patent is for the composition of metoprolol succinate itself.

**3. The '318 Patent**

76. The '318 patent was applied for on January 10, 1985, and issued on October 25, 1988. It expired on October 25, 2005.[7]

77. The "Abstract" of the '318 patent states that "[t]he present invention relates to a new oral pharmaceutical composition having an improved release of the therapeutically active compound present therein, in the lower part of the gastro-intestinal duct . . . ."

78. The "Background of the Invention" states as follows:

> There exists an everlasting problem within pharmacy to be able to administer a therapeutically active compound as close as possible to the colon or preferably in the colon, in order to thereby to eliminate the risk of adverse influence on the active compound by the gastric juice, or to prevent irritation of the ventricular mucous membranes, or to obtain a therapeutically effect [sic] in the lower part of the gastrointestinal tract.

79. The "Object of the Invention" states as follows:

> It has now surprisingly been shown possible to be able to solve the aforesaid

[7] The application filed claimed priority to the Swedish Patent Application No. 84000845, which was filed on January 10, 1984, by Curt H. Appelgren and Eva C. Eskilsson, and published as European Patent Application EP148811 on July 17, 1985.

> problem by the present invention, which is a pharmaceutical composition in unit dosage form characterized by a core comprising a therapeutically active substance in the form of a weak base or a weak acid, on which core there is provided a first, inner layer of a diffusion membrane in the form of ethyl cellulose and/or a copolymer of polyethyl acrylate, methyl methacrylate, and trimethylammonium ethyl methacrylate chloride, and or which inner layer there is provided a second layer of at least one anionic polymer and/or fatty acid having a pk suba of 4.5 to 7, preferably 6 to 6.5.

80. The "Detailed Description of the Invention" provides in relevant part:

> By means of the present invention the core is protected against attack by gastric juice after ingestion by means of the outer layer comprising an anionic polymer and/or fatty acid having a pk suba of 4.5 to 7. When this outer layer has been removed by dissolution upon passage of the composition into the small intestine with its higher pH, a slow but controlled release of the therapeutically active compound from the core by diffusion through the diffusion membrane occurs due to the difference in concentrations on each side of said membrane. The release takes thereby place at such a rate that 80-90% of the therapeutically active compound has been released after 7 to 10 hrs, which means that the release can take place in a constant pH independent way, and thereby in a very reproducible way.

81. Claim 8 of the '318 patent is set forth below, along with the portions of claims 6 and 7 on which it is dependent:

> 6. Oral pharmaceutical composition having an improved release therefrom of a therapeutically active compound therein which is soluble in gastric juice, independent of its solubility, having a core comprising the therapeutically active compound, a first inner layer coating on the core, in the form of a diffusion membrane which is a mixture of ethyl cellulose and a copolymer of polyethyl methacrylate-methyl methacrylate-trimethyl ammonium ethylmethacrylate chloride, in a weight relationship between the monomers or the copolymer of 63 to 65:31.7 to 32.3:2.5 to 5, and a second outer layer coating on the inner layer of at least one anionic polymer having a pk suba of 4.5 to 7.
>
> 7. Pharmaceutical composition according to claim 6, wherein the therapeutically active compound in the core has a solubility in the pH range of 1 to 8 which exceeds 0.5 to 1 g per 100 ml.
>
> 8. *Pharmaceutical composition according to claim 7, wherein the active compound is quinidine sulphate, quinidine bisuphate, quinidine gluconate, quinidine hydrochloride, metoprolol tartrate, metoprolol succinate, metoprolol fumarate, or furosemide, 5- aminosalvcidic acid, propranolol or alprenolol or a pharmaceutically acceptable salt thereof, or a mixture thereof with another weak base, weak acid, or salt thereof having a pk suba of 1 to 8.* (emphasis added).

**B. The '161 and '154 Patents Were Obtained Improperly Through Misconduct**

82. Patent applicants, including each individual associated with the filing or prosecution of a patent application in the PTO, are required to prosecute patent applications in the PTO with candor, good faith, and honesty. *See Semiconductor Energy Lab. Co., Ltd. v. Samsung Elecs. Co. Ltd.*, 204 F.3d 1368, 1373 (Fed. Cir. 2000); *Precision Instrument Mfg. Co. v. Automotive Maintenance Mach. Co.*, 324 U.S. 806, 818 (1945). This duty encompasses each inventor named in the application, each attorney or agent who prepares or prosecutes

the application, each person who executes a declaration for submission to the PTO during prosecution of the application, and every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, the assignee or with anyone to whom there is an obligation to assign the application. The duty of candor and good faith dealing includes a duty to disclose to the PTO all information known to such individuals which is material to the patentability of the claimed invention. (*See* 37 C.F.R. § 1.56). Breach of that duty constitutes inequitable conduct.

83. Inequitable conduct consists of an affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false or misleading material information, coupled with intent to deceive.

84. The actions and omissions of those associated with the filing and/or prosecution of the patents at issue here, as set forth below, constitute clear and convincing evidence of: (a) intent to deceive the Patent Office; and (b) inequitable conduct.

85. Prior to the PTO amending its rules in March 1992, information was deemed material if "a reasonable examiner would be substantially likely consider [it] important in deciding whether to allow an application to issue as a patent." *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1363 (Fed. Cir. 2003) (internal citations omitted). Subsequent to the PTO amending its rules, information is deemed material if it "establishes either 'a prima facie case of unpatentability' or 'refutes, or is inconsistent with a position the applicant takes.'" *Id.* at 1363-64 n.10. However, the new standard established by the PTO was not intended to "constitute a significant substantive break with the previous standard." *Hoffman-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1368 n.2 (Fed. Cir. 2003).

86. Defendants failed to disclose to the PTO material information that would have affected the patentability of the claims regarding Toprol-XL. Specifically the Defendants: (1) failed to disclose that they were involved in a lengthy contest over the inventorship of metoprolol; and (2) failed to name the correct inventors in their prosecution of the subject patents.

**C. The History of the Invention of Metoprolol Succinate**

87. In 1971, an Astra[8] scientist named Toivo Nitenberg synthesized metoprolol

[8] "Astra" includes Hassle, as the division of the company was named at this time.

succinate and the tartrate and sulfate salts of metoprolol. At that time, Astra chose to commercialize only the tartrate salts.

88. In the 1980s, Astra wanted to develop a formulation of metoprolol that could be used for once-daily dosage, which the tartrate salts could not. As a result, Astra formed a research group to develop an extended release formulation of metoprolol. This group included scientists Curt Appelgren and Eva Eskilsson.

89. In 1982, Appelgren (along with his Astra colleague Ulf Jonsson) met with Urban Stenhede, a chemist in Astra's Södertälje, Sweden facility. Appelgren and Jonsson asked Stenhede to manufacture metoprolol salts with lower solubility than the tartrate salts.

90. In turn, Stanhede asked Lars Lilljequist, a chemist, to manufacture metoprolol salts with lower solubility than in the tartrate salts. He did; Lilljequist synthesized metoprolol succinate.

91. Then, in December 1982, Appelgren left Astra to form Lejus Medical ("Lejus"), a Swedish pharmaceutical research and development company. Eskilsson joined him at Lejus a few months thereafter.

92. Lejus filed a patent application in Sweden (SE 8400085) for delayed and extended release dosage forms of pharmaceutical compositions, including metoprolol succinate, on January 10, 1984. Appelgren and Eskilsson were named as the inventors on the patent application. The Swedish patent was published on July 17, 1985, as EP 148811.

93. On January 1, 1985, Lejus filed the same application in the United States, Application No. 690,197 (the '197 application) which eventually issued as the '318 patent on October 25, 1988.

94. In July 1985, Astra became aware of the Swedish patent and maintained that it was improper in that: (1) metoprolol succinate was invented by its employee, Nitenberg, in 1971; and (2) Astra was also responsible for extended release formulations of metoprolol succinate.

95. At that time, Astra recognized that the publication of the patent on July 17, 1985 could, from that point forward, be cited as prior art and possibly invalidate later applications concerning metoprolol succinate, thereby threatening Astra's market position, as the invention was now known to the public.

96. On October 21, 1985, Astra filed an action with the Swedish Patent Office to transfer the inventions contained in EP 148811 that relate to metoprolol succinate to Astra. In its action, Astra claimed that Nitenberg was the actual inventor of metoprolol succinate and that Appelgren and Eskilsson only worked with preparations already invented by Nitenberg.

97. In the Fall of 1985, Astra advised Lejus that metoprolol succinate was invented by Nitenberg and Lejus agreed to file new patents on the metoprolol succinate inventions and assign the applications to Astra. Astra then withdrew its action with the Swedish Patent Office.

98. In January 1986, Lejus filed Swedish patent application 8600202-9, for metoprolol succinate inventions.

99. In February 1988, Astra again asserted its position to Lejus, that Nitenberg, and not Appelgren and Eskilsson, was the inventor of metoprolol succinate and that Nitenberg should be named as the inventor and Appelgren and Eskilsson named only as co-inventors for inventing a particular form of a pharmaceutical composition under the claim.

100. In March 1988, Lejus filed U.S. patent application 172,897 (application '897) (which eventually issued as the '161 patent) as a counterpart to Swedish patent application 8600202-9. The application claimed: (1) metoprolol succinate; and (2) "a pharmaceutical composition, characterized in that the active compound is metoprolol succinate." The application named only Appelgren and Eskilsson as inventors.

101. The '897 application was filed as a continuation in part of the '197 application, filed on January 10, 1985, in an effort to avoid the problem, previously identified by Astra, of the prior art of the published EP 148811 patent.

102. Thus, by filing the '897 application as a continuation in part of the '197 application, and by naming the identical inventors, Astra intended to reap the benefit of priority of the '897 application filing date.

103. In May 1988, Astra confirmed assignment of the Lejus European and United States patents to Astra. Again, Astra maintained that Nitenberg was the inventor of metoprolol succinate and that Appelgren and Eskilsson should be limited in their roles.

104. Nonetheless, during the prosecution of the '161 and '154 patents, Defendants failed to disclose to the PTO any facts relating to their action against Lejus in the Swedish Patent Office in October 1985, the assignment agreement reached between Astra and Lejus, or that

Nitenberg had made metoprolol succinate at Astra in 1971.

**D. The Effects of Defendants' Conduct**

105. Appelgren and Eskilsson were named as inventors, which, as is evidenced by their dispute with Lejus, was both untrue and material.

106. The issue of inventorship is highly material in the patent prosecution process.

107. The failure to disclose the dispute regarding inventorship of metoprolol succinate to the PTO was both material (i.e., there was a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent) and done with an intent to deceive the patent examiner. *See PerSeptive Biosys., Inc. v. Pharmacia Biotech. Inc.,* 225 F.3d 1315, 1321 (Fed. Cir. 2000) (disputes concerning inventorship are material information that needs to be disclosed) (citing Manual of Patent Examining Procedure § 2001.06(c) and § 2004).

108. Had Defendants disclosed material information concerning the ongoing dispute over inventorship of metoprolol succinate and/or that incorrect inventors were listed on the patent applications, this would have undoubtedly affected a reasonable patent examiner's decision to issue a patent.

109. Accordingly, the '161 and '154 patents were and are unenforceable *ab initio*, and Defendants at no time could have reasonably asserted a patent claim on the basis of these inequitably obtained patents. Nor could Defendants reasonably have believed that a claim of infringement of these patents could reasonably be asserted against a proposed generic manufacturer of Toprol-XL.

**E. Even if Defendants Acted Properly Before the PTO, the '161 and '154 Patents Are Nonetheless Invalid**

**1. The '161 and '154 Patents are invalid for double patenting over the '318 Patent**

110. The doctrine of non-statutory double patenting (also known as "obviousness-type" double patenting) prevents the issuance of a patent on claims that are nearly identical to claims in an earlier patent. This doctrine prevents an applicant from extending patent protection for an invention beyond the statutory term by claiming a slight variant.

111. When patent holders try to wrongfully extend the period of exclusivity by filing claims in a later patent that are not distinct from earlier claims, a court will invalidate the claims that are not patently distinct from an earlier patent because of obviousness-type double patenting.

*See Geneva Pharms., Inc. v. GlaxoSmithKline PLC,* 189 F. Supp. 2d 377, 381 (E.D. Va. 2002). A later patent is not patently distinct from an earlier claim if the later claim is obvious or inevitable in light of an earlier claim. If a later claim is anticipated by an earlier claim, there can be no patentable distinction. *Id.*

112. The doctrine of "obviousness-type double patenting" applies and "requires elimination of the extension of exclusivity by truncating the term of the second patent to issue, to coincide with the term of the first patent to issue." *Eli Lilly & Co. v. Barr Labs., Inc.,* 251 F. 3d 955, 957 (Fed. Cir. 2001).

113. A species/genus relationship is a type of double patenting wherein the second broader claim is held invalid because it is anticipated by, and, therefore, not patently distinct from an earlier species claim. Claim 8 of the '318 patent discloses a specific application from within the general scope of the '161 patent's claim. Thus, the '161 patent is invalid as a "genus" of claim 8's "species." *See In re Goodman,* 11 F.3d 1046, 1053 (Fed. Cir. 1993); *Eli Lilly & Co. v. Barr Labs., Inc.,* 251 F.3d 955, 971 (Fed. Cir. 2001); *Geneva Pharms., Inc. v. GlaxoSmithKline PLC,* 349 F.3d 137, 1383 (Fed. Cir. 2003) (defining a species and genus relationship as one in which the second broader claim is invalid because it is anticipated by, and, therefore, not patently distinct from, an earlier species claim, making it invalid double patenting).

114. Specifically, the claim in the '161 patent for "sustained release" formulations of metoprolol succinate is an obvious variant of claim 8. Claim 8 of the '318 patent is a particular type of a controlled release formulation of metoprolol succinate and the claim of the '161 patent is a broad generalized claim to controlled release formulations of metoprolol succinate.

115. The claim in the '154 patent is only for the metoprolol succinate compound, and thus clearly not patentable in light of claim 8. Likewise, the '154 patent, which claims any pharmaceutical compositions containing metoprolol succinate, is a genus of the species in claim 8 of the '318 patent.

**2. The '161 Patent is invalid as anticipated by prior art under 35 U.S.C. § 102(b)**

116. A claim in a later-filed patent application may claim priority to an earlier-filed patent application under 35 U.S.C. § 120 if the earlier application complies with the written description requirement of paragraph one of 35 U.S.C. § 112, which requires that the

specification "contain a written description of the invention, and of the manner and process of making and using it[.]" *See e.g., Tronzo v. Biomet, Inc.,* 156 F.3d 1154, 1158 (Fed. Cir. 1998) (to meet section 112's requirement, "the disclosure of the earlier application, the parent, must reasonably convey to one of skill in the art that the inventor possessed the later-claimed subject matter at the time the application was filed") (internal citations omitted).

117. The '161 patent was not entitled to priority to the '318 patent application.

118. The specification contained in the '318 patent does not reasonably convey to one of skill in the art that the inventor of the '318 patent possessed the subject matter of the '161 patent at the time the '318 application was filed. In order to be entitled to a priority, the disclosure in the '318 patent would have been required to describe the '161 patent invention, including all of its limitations; this information is absent from the '318 patent.

119. The effective filing date for the '161 patent is March 25, 1988.

120. Swedish application 84000845, published July 17, 1985, is the parent of the '318 patent and the grandparent of the '161 patent. Because the species of sustained release metoprolol succinate that becomes claim 8 of the '318 patent in the Swedish application was published in July 1985, nearly three years before the March 1988 filing of the '161 patent application, the '161 patent is invalid under 35 U.S.C. § 102(b), which stands for the proposition that a person is entitled to a patent unless the invention was described in a printed publication more than one year before the patent application was filed in the United States.[9]

**3. Defendants' filing of a disclaimer of Claim 8 of the '318 Patent**

121. Claim 8 of Defendants' '318 patent, which issued on October 25, 1988 (expiring on October 25, 2005), claims, among other compounds, "metoprolol succinate."

122. The claims of the '161 and '154 patents also claim "metoprolol succinate," but were due to expire on March 18, 2008, which is more than 17 years after the issuance of the '318 patent.

123. Defendants knew that the Patent Act (as it existed when the '318 patent was filed)

[9] In addition, the '161 Patent was anticipated by U.S. Patent No. 4,957,745 (the "'745 patent"), which was issued from a continuation of the U.S. Patent application that claimed priority to Swedish Patent Application No. 8504721 , which was filed on October 11, 1985 (naming as inventors Ulf E. Jonsson, John A. Sandberg and John A. Sjogren) and published as UK Patent Application GB2,181,348 on April 23, 1987. The application for the '745 Patent was filed on February 14, 1989; it issued on September 18, 1990, and was set to expire on September 18, 2007. The '745 Patent includes another controlled release formulation of metoprolol succinate.

entitled them to only 17 years of patent protection for metoprolol succinate and that the Patent Act prohibited them from "double patenting" metoprolol succinate for the purpose of obtaining more than 17 years of patent protection. However, Defendants did not file any terminal disclaimers limiting the patent monopoly for metoprolol succinate to 17 years.

124. Because Defendants did not file terminal disclaimers for the '161 and '154 patents, they are invalid for obviousness-type double patenting due to claim 8 of the '318 patent, and Defendants knew this.

125. On November 21, 2003, Defendants filed a statutory disclaimer of Claim 8 of the '318 patent, effectively canceling the claim.

**4. Defendants' prior patent infringement litigation**

126. On January 17, 2006, the United States District Court for the Eastern District of Missouri, held that the '161 patent and the '154 patent were unenforceable due to Defendants' inequitable conduct before the PTO during the prosecution of the patents for failure to disclose a dispute concerning inventorship of metoprolol succinate and were also invalid on the basis of double patenting over the '318 patent. *In re Metoprolol Succinate Patent Litig.*, 2006 WL 120343 (E.D. Mo. Jan. 17, 2006).

127. The Court further held that the '161 patent was invalid as anticipated, and not entitled to priority to the '318 patent. *Id.* at *13.

128. On appeal, the Federal Circuit affirmed the invalidity ruling but reversed and remanded the question of inequitable conduct, concluding fact issues precluded summary judgment. *In re Metoprolol Succinate Patent Litig.*, 494 F.3d 1011, 1020-21 (Fed. Cir. 2007). The matter was remanded to the district court.

129. Following remand, the parties settled the dispute before the district court could revisit the question of inequitable conduct.

**F. Defendants' Improper Listing of Patents in the Orange Book**

130. Despite Defendants' knowledge that the '161 and '154 patents were invalid, Defendants caused the patents to be listed in the Orange Book as covering Toprol-XL in order to force generic applicants to submit Paragraph IV certifications to the listed patents, resulting in Defendants' ability to commence approval-blocking patent litigation against those generic applicants. Defendants did not withdraw the patents from the Orange Book even after being

provided with clear proof that they were improperly filed.

131. Defendants knew that under the Hatch-Waxman Amendments if they filed patent infringement actions in response to the Paragraph IV certifications (that Defendants knew would be triggered by their wrongful Orange Book listings), they would be able to delay FDA final approval of ANDAs filed by generic competitors, thereby barring generic entry for up to thirty (30) months.

132. Unfortunately, it has become common practice in the pharmaceutical industry for brand companies to flout FDA Regulations and list any and every patent they can in the Orange Book so as to force generic manufacturers to file Paragraph IV Certifications. *See Purepac Pharm. Co. v. Thompson,* 2002 WL 31 840631 at *14 ("while the regulations tell those parties what they are supposed to do, they do not actually keep non-conforming patents, submitted in violation of the rules, out of the Orange Book . . . A utopian rule does not automatically create a utopia").

133. Defendants' listing of the '161 and '154 patents was objectively and subjectively baseless. The improper listing of the patents in the Orange Book was an indispensable predicate act of Defendants' monopoly-preserving scheme, without which Defendants could not have instituted generic entry blocking patent litigation—the mere filing of which, regardless of underlying merit, automatically precluded the FDA from granting approval to the generic applicants for up to thirty months.

134. As a result, Defendants were able to do more than just block all generic applicants from getting FDA approval. By simply listing their patents and forcing the generic applicants to file Paragraph IV Certifications in response thereto, Defendants illegally secured for themselves an additional anti-competitive benefit – namely, the assurance that even when a generic would be finally introduced into the market, for a six-month period the number of generic competitors and the extent of price competition would still be substantially diminished – as a result of Defendants' misconduct.

135. As described above, it has become fairly established in the marketplace that after the expiration of the first generic's six months of exclusivity, and as more generics enter the market, prices drop significantly, resulting in dramatic savings for consumers. See FTC Statement at 18 (recognizing that generic price decreases, and the corresponding benefits to

consumers, occur when additional generic competitors enter the market after the expiration of the 180-day exclusivity period).

**G. Defendants' Sham Infringement Actions in Response to Generic Manufacturers' ANDAs**

136. KV, Andrx and Eon (the generic manufacturers) manufactured generic pharmaceutical products. They submitted ANDAs to obtain FDA approval for the manufacture and sale of a generic version of oral tablets of metoprolol succinate before the expiration of the '161 and '154 patents.

137. In conformity with the Hatch-Waxman Amendments, the generic manufacturers' ANDAs contained a Paragraph IV certification for the '161 and '154 patents, asserting that each is invalid, unenforceable and/or would not be infringed by their generic products.

138. Pursuant to 21 U.S.C. § 355(j)(2)(B)(i) and (ii), the generic manufacturers gave written notice to Defendants, via letter, that their ANDAs and the accompanying certifications had been filed with the FDA. In accordance with 21 U.S.C. § 355(j)(2)(B)(iv), the notices also set forth the legal and factual bases for their claims that the '161 and '154 patents were either invalid or would not be infringed by their ANDAs.

139. Knowing the '161 and '154 patents were invalid, Defendants commenced multiple patent-infringement suits in the U.S. District Court for the District of Delaware[10] against the following companies seeking to market generic, bioequivalent versions of Toprol-XL: KV, Andrx, and Eon. These cases are summarized in the following chart:

AstraZeneca's Sham Litigation Against Generic Manufacturers

| Manufacturer | Date Filed | District | Case Number |
|---|---|---|---|
| KV Pharmaceutical Co. | 5/6/2003<br>8/22/2003 | E. D. Missouri<br>E. D. Missouri | 4:03-cv-00592-RWS<br>4:03-cv-01169-RWS |
| Andrx Pharmaceuticals, LLC<br>Andrx Corporation | 2/5/2004 | D. Delaware | 1:04-cv-00080-SLR |
| Eon Labs, Inc. | 4/5/2004 | D. Delaware | 1:04-cv-00205-SLR |

140. Defendants' filing of the sham infringement actions resulted in the aforementioned 30-month automatic statutory stay of the FDA's authority to grant final marketing approval to the generic manufacturers for their ANDAs for metoprolol succinate. The

[10] The cases were subsequently transferred to the United States District Court for the Eastern District of Missouri by the Judicial Panel on Multi District Litigation.

FDA could not grant final marketing approval to the generic manufacturers until they prevailed in the infringement actions or until the expiration of 30 months, whichever came first.

141. In defense, the generic manufacturers asserted that the '161 and '154 patents were invalid, unenforceable and/or not subject to infringement by their formulation of Toprol-XL, and they counterclaimed.

142. Defendants knew that their infringement actions against the generic manufacturers were a sham, yet they maintained the actions and defended against counterclaims asserted by the generic manufacturers, for the improper purpose of maintaining a monopoly in the Relevant Markets and concealing by deceit that unlawful interference and monopoly maintenance.

143. Defendants continued to maintain the sham Orange Book listings, the sham infringement actions, and their sham defenses of the counterclaim knowingly, intentionally, affirmatively, with the purpose of unlawfully maintaining their monopoly in the Relevant Markets, and with the effect of affirmatively and continuously foreclosing the generic entry of Toprol-XL into the Relevant Markets.

144. Defendants' litigations were objectively baseless and commenced and maintained in bad faith, with the specific intent and subjective motivation to prevent the generic manufacturers from selling competing metoprolol succinate products. The litigations were predicated upon deceptive conduct before the PTO and the FDA and other such conduct, including during the patent infringement litigations. As Judge Sippel noted, during the litigation, Defendants "maintained a pattern of submitting witness declarations that contradict their own prior deposition testimony." *See In re Metoprolol Succinate Patent Litig.*, 2006 WL120343, at *21, and Footnote 1, *infra.*

145. On January 17, 2006, the United States District Court for the Eastern District of Missouri granted summary judgment to the generic manufacturers. In relevant part, the Court found, by clear and convincing evidence that:

a) the '161 patent and the '154 patent were unenforceable based on Astra's inequitable conduct in the prosecution of these patents in failing to disclose its material dispute with Lejus over the inventorship of metoprolol succinate to avoid invalidation by prior art;

b) the '161 patent and the '154 patent were invalid based on double

patenting over the '318 patent; and

c) the '161 patent was invalid as anticipated and not entitled to priority to the date of the filing of the '318 patent.

See *In re Metoprolol Succinate Patent Litig.*, 2006 WL 120343, at *25-26.

146. Defendants knew they could not expect success on the merits of these litigations, but utilized the Hatch-Waxman process to bar the generic manufacturers from entering the market.

147. Throughout the course of the proceedings before the PTO and during the litigation of the infringement action, Defendants knowingly and willfully concealed the true facts about their misrepresentations to the PTO to wrongfully obtain the patents described herein and to wrongfully prevent and discourage lawful competition with their brand name product Toprol-XL.

## VI. RELEVANT MARKET

148. Direct proof exists that Defendants had monopoly power over the price of metoprolol succinate in the United States. Such direct evidence includes transactional data showing a significant, non-transitory decline in prices of metoprolol succinate immediately upon entry of generic versions of the drug. Such a significant, non-transitory decline in prices did not occur until generic entry into the market. This direct evidence of monopoly power obviates the need to define a relevant product market in assessing whether Defendants had monopoly power.

149. Defendants, as the only sellers of metoprolol succinate products in the United States, could and would impose a significant, non-transitory price increase without losing sufficient sales to render the price increase unprofitable, as demonstrated by their ability to profitably charge supra-competitive prices during the period in which they were without generic competition. There were no reasonably interchangeable drug products available to prescribing physicians for the indications for which metoprolol succinate is prescribed.

150. To the extent applicable to the claims alleged herein, the relevant product market is the market for the manufacture and sale of Toprol-XL, metoprolol succinate, and all generic bioequivalents rated "AB" by the FDA. The relevant geographic markets are the United States and its territories. At all relevant times, up to and including the present, Defendants' market share in the relevant product and geographic markets was 100%.

151. The relevant geographic market is the United States and its territories.

152. Prior to generic entry, Defendants held 100% market share in the relevant market. Following market entry by generic manufacturers and much less expensive generic versions of Toprol-XL, Defendants' market share for metoprolol succinate declined dramatically in a short period of time.

## VII. MARKET EFFECTS

153. Defendants' unlawful scheme and anticompetitive conduct, as herein alleged, had the purpose and effect of unreasonably restraining and injuring competition by protecting Toprol-XL from generic competition in the relevant market.

154. Had generic competitors been able to enter the relevant market and compete with Defendants, Plaintiff would have paid for lower-priced generics in place of the higher-priced brand name drug, resulting in far fewer dollars paid for metoprolol succinate products. Regulations generally permit - and sometimes even mandate - pharmacists to substitute generic drugs for their branded counterparts, unless the prescribing physician has directed that the branded product be dispensed. Similarly, many third-party payors of prescription drugs (e.g., managed care plans) encourage or insist on the use of generic drugs whenever possible, thus creating a ready market for generic products. Louisiana Medicaid requires the substitution of generic drugs whenever possible, unless the prescribing physician has specifically required the use of the brand name drug.

155. The initial entry of generic products generally leads to a significant erosion of a branded drug's sales within the first year as generic drugs can quickly and efficiently enter the marketplace at substantial discounts.

156. By preventing generic competitors from entering the market, Defendants injured Plaintiff by causing it to pay more for metoprolol succinate products than they otherwise would have paid. Defendants' unlawful conduct deprived Plaintiff of the benefits of competition that Louisiana's antitrust and consumer protection laws are intended to preserve.

## VIII. CLAIMS FOR RELIEF

### FIRST CLAIM FOR RELIEF

**Violations of the Louisiana Monopolies Act**

157. Plaintiff incorporates by reference the preceding allegations.

158. Defendants used willful and exclusionary means as part of an overall scheme described herein to improperly maintain and extend their monopoly power in the metoprolol succinate market, as described above. Defendants accomplished this scheme by filing invalid patents and meritless patent infringement claims against prospective generic manufacturers.

159. The goal, purpose and effect of Defendants' unlawful scheme and anticompetitive conduct was to prevent, delay, and/or minimize the success of the entry of AB-rated metoprolol succinate products into the market which would have sold in the United States, including Louisiana, at prices significantly below Defendants' prices for Toprol-XL.

160. The goal, purpose and effect of Defendants' unlawful scheme and anticompetitive conduct was also to maintain and extend its monopoly power with respect to metoprolol succinate. Defendants' illegal scheme enabled them to continue charging supra-competitive prices for metoprolol succinate without a substantial loss of sales.

161. The result of Defendants' unlawful scheme and anticompetitive conduct has been to obtain and extend their monopoly in the relevant markets for Toprol-XL and its bioequivalents. This course of conduct included, *inter alia*, the following acts: (i) the intentional omission of material facts from the PTO; (ii) the prosecution of sham patent litigation against generic competitors; and (iii) maintaining sham defenses to the counterclaim by the generic manufacturers.

162. As a result of Defendants' unlawful scheme and anticompetitive conduct, Plaintiff was compelled to pay, and did pay, more than it would have paid for metoprolol succinate products absent Defendants' conduct. But for Defendants' illegal conduct, competitors would have begun marketing generic versions of Toprol-XL well before they actually did.

163. Had manufacturers of generic metoprolol succinate entered the market and lawfully competed with Defendants in a timely fashion, Plaintiff would have substituted lower-priced generic metoprolol succinate for the higher-priced brand name Toprol-XL for some or all of its metoprolol succinate requirements, and/or would have paid lower net prices on its remaining Toprol-XL purchases or reimbursements.

164. Defendants have intentionally and wrongfully maintained their monopoly power in the relevant market in violation of La. Rev. Stat. §§ 51:121, *et seq.*, with respect to

purchases of and reimbursements for Toprol-XL in Louisiana by Plaintiff.

165. Plaintiff has been injured by reason of Defendants' antitrust violations alleged in this Petition. The State's injury consists of paying higher prices for Toprol-XL than it would have paid in the absence of those violations. This injury is of the type the antitrust and consumer protection laws of Louisiana were designed to prevent and flows from that which makes Defendants' conduct unlawful.

166. Pursuant to La. R.S. §§ 51:136, 51:137, 51:138 and related statutes, Defendants are liable to the State for restitution, in an amount to be determined at trial, and treble damages, arising out of Defendants' efforts to monopolize trade and/or commerce which had an effect in Louisiana, as well as reasonable attorney fees and costs.

167. Plaintiff seeks damages and multiple damages as permitted by law for its injuries by Defendants' violations of the aforementioned statutes.

## SECOND CLAIM FOR RELIEF

### Violations of the Louisiana Unfair Trade Practices Act

168. Plaintiff incorporates by reference the preceding allegations.

169. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of La. R.S. § 51:1401, *et seq.*

170. Plaintiff has been injured by reason of Defendants' anticompetitive, unfair or deceptive acts alleged in this Petition. The State's injury consists of paying higher prices for Toprol-XL than it would have paid in the absence of these violations. This injury is of the type the Louisiana Unfair Trade Practices Act was designed to prevent and directly results from Defendants' unlawful conduct.

171. Pursuant to La. R.S. §§ 51:1405, 51:14707, 51:1408, 51:1409, 51:1414 and related statutes, Defendants are liable to the State for restitution, in an amount to be determined at trial, arising out of Defendants' anticompetitive, deceptive and unfair methods, acts and trade practices.

## THIRD CLAIM FOR RELIEF

### Unjust Enrichment

172. In the alternative, Defendants have benefited from the monopoly profits on their sales of Toprol-XL resulting from the unlawful and inequitable acts alleged in this Petition.

173. Defendants' financial benefits resulting from their unlawful scheme and

anticompetitive conduct are traceable to overpayments for Toprol-XL by Plaintiff.

174. Plaintiff has conferred upon Defendants an economic benefit, in the nature of profits resulting from unlawful overcharges and monopoly profits, to the economic detriment of Plaintiff.

175. The economic benefit of overcharges and unlawful monopoly profits derived by Defendants through charging supra-competitive and artificially inflated prices for Toprol-XL is a direct and proximate result of Defendants' unlawful practices.

176. The financial benefits derived by Defendants rightfully belong to Plaintiff, as Plaintiff paid anticompetitive and monopolistic prices, inuring to the benefit of Defendants.

177. It would be inequitable for the Defendants to be permitted to retain any of the overcharges for Toprol-XL derived from their unfair and unconscionable methods, acts and trade practices alleged in this Petition.

178. Defendants should be compelled to disgorge for the benefit of Plaintiff all unlawful or inequitable proceeds received by them.

179. Plaintiff has no adequate remedy at law.

**JURY DEMAND**

180. Plaintiff, the State of Louisiana, hereby demands a trial by jury on all claims so triable pursuant to La. C.C.P. Art. 1731 and related statutes.

**PRAYER FOR RELIEF**

181. WHEREFORE, Plaintiff, the State of Louisiana, by and through its Attorney General James D. "Buddy" Caldwell, prays for relief as follows:

A. For judgment in favor of the State and against Defendants, under the Louisiana Monopolies Act, La. R.S. §§ 51:123, 51:128, 51:136, 51:137, 51:138, *et seq.*, for restitution for an amount to be determined at trial, and treble damages to the State, and for reasonable attorney fees and costs;

B. For judgment in favor of the State and against Defendants, under Louisiana's Unfair Trade Practices Act, La. R.S. § 51:1401, *et seq.*, for restitution to the State for an amount to be determined at trial, and for fees, attorney fees, costs, and expenses;

C. For judgment in favor of the State and against Defendants, under La. C.C. Art. 2298, that Defendants have been unjustly enriched, for costs, expenses, fees, and attorney fees;

D. For all damages sustained by the State in such amount as is proven at trial, together with prejudgment interest;

E. For all costs of these proceedings, fees, attorneys' fees, and expenses;

F. For jury trial; and

G. For any such relief as may be justified and which the State may be entitled to by law, and any further relief that this Court deems appropriate in favor of the State.

RESPECTFULLY SUBMITTED this 18th day of March, 2015.

**JAMES D. "BUDDY" CALDWELL**
**ATTORNEY GENERAL FOR**
**THE STATE OF LOUISIANA**

James D. "Buddy" Caldwell (No. 02211)
Keetsie T. Gunnels (No. 12952)
Nicholas J. Diez (No. 31701)
Stacie Deblieux (No. 29142)
Office of the Attorney General, State of Louisiana
1885 North 3rd Street
Baton Rouge, Louisiana 70802

-and-

**SHOWS, CALI & WALSH, LLP**
E. Wade Shows (No. 7637)
628 St. Louis Street
Baton Rouge, LA 70802
Telephone: (225) 346-1461
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**SALIM-BEASLEY LLC**
Robert L. Salim (No. 11663)
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**MEADE LAW LLC**
John Alden Meade (No. 29975)
909 Poydras St., Suite 1600
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Telephone: (504) 799-3102
Facsimile: (504) 717-2846

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EAST BATON ROUGE PARISH
2015 MAR 18 AM 10:55
DEPUTY CLERK OF COURT

CIVIL
- 11-COMM. PROP. PARTITIONS
- 12-PUBLIC SERV. COMM.
- 13-OTHER PARTITIONS
- 14-OTHER
- 15-D.E.Q.
- 16-
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- 19-
- 20-
- 01-DAMAGES
- 02-CONTRACT
- 03-PRISONER SUIT
- 04-EXECUTORY PROCESS
- 05-SUIT ON NOTES
- 06-EVICTION
- 07-WORKMENS COMPENSATION
- 08-JUDICIAL REVIEW
- 09-PROPERTY RIGHTS
- 10-INJUNCTION MANDAMUS

**MOTLEY RICE LLC**
Joseph F. Rice (*pro hac vice* pending)
28 Bridgeside Road
Mt. Pleasant, SC 29464
Telephone: (843) 216-9159
Facsimile: (843) 216-9290

Michael M. Buchman (*pro hac vice* pending)
John A. Ioannou (*pro hac vice* pending)
Alex R. Straus (*pro hac vice* pending)
600 Third Avenue, 21st Floor
New York, NY 10016
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**MORROW MORROW RYAN & BASSETT**
James P. Ryan (No. 11560)
Pat Morrow (No. 9748)
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Opelousas, LA 70571
Telephone: (337) 948-4483
Facsimile: (337) 942-5234

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Facsimile: (504) 524-5763

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Baton Rouge, LA 70808
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Facsimile: (225) 923-0315

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**DAVILLIER LAW GROUP, LLC**
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Tonya Rhodes Jupiter (No. 23270)
1010 Common Street, Suite 2510
New Orleans, Louisiana 70112
Telephone: (504) 582-6998
Facsimile: (504) 582-6985

**PLEASE SERVE:**

**AstraZeneca LP**
Through its agent for service of process:
C T Corporation System
5615 Corporate Blvd., Ste. 400B
Baton Rouge, LA 70808

**AstraZeneca Pharmaceuticals LP**
Through its agent for service of process:
C T Corporation System
5615 Corporate Blvd., Ste. 400B
Baton Rouge, LA 70808

**19TH JUDICIAL DISTRICT COURT, PARISH OF EAST BATON ROUGE**

**STATE OF LOUISIANA**

**NO.___ DIVISION __ SECTION ___**

**STATE OF LOUISIANA,**
**by and through its ATTORNEY GENERAL JAMES CALDWELL**

***VERSUS***

**ASTRA ZENECA AB, ASTRAZENECA, LP, ASTRAZENECA PHARMACEUTICALS LP, AND AKTIBOLAGET HÄSSLE**

**FILED:** _____ _____
**DEPUTY CLERK**

**THE STATE OF LOUISIANA'S FIRST SET OF REQUESTS FOR THE PRODUCTION OF DOCUMENTS TO DEFENDANTS**

TO: AstraZeneca LP
Through its agent for service of process:
C T Corporation System
5615 Corporate Blvd., Ste. 400B
Baton Rouge, LA 70808

AstraZeneca Pharmaceuticals LP
Through its agent for service of process:
C T Corporation System
5615 Corporate Blvd., Ste. 400B
Baton Rouge, LA 70808

Pursuant to article 1461 of the Louisiana Rules of Civil procedure, plaintiff in the above-captioned proceeding, The State of Louisiana, by and through its Attorney General James D. "Buddy" Caldwell, propounds the following document requests upon defendants AstraZeneca LP and AstraZeneca Pharmaceuticals LP, (collectively, "Defendants"), with said documents to be produced within fifteen (15) days from the date of receipt thereof and served upon E. Wade Shows, Shows, Cali & Walsh, LLP, 628 St. Louis St., Baton Rouge, LA 70802. As used herein, the following instructions and definitions shall apply:



**DEFINITIONS**

As used herein, the terms listed below are defined as follows:

1. "You" or "your" shall mean each and all Defendants, both individually and collectively, and specifically includes, but is not limited to, any agents, attorneys, accountants, affiliates, consultants, representatives, predecessors, successors, employees, directors, or officers and any person or entity who acts, acted, or may have acted for or on behalf of you and any person or entity who has obtained information for you or on your behalf.

2. "Person" shall mean any natural person, firm partnership, association, proprietorship, joint venture, corporation, company governmental agency, or other organization or legal or business entity.

3. "Document" or "documents" shall mean any written, typed, recorded, or graphic matter, however produced, of any type or description, whether sent or received, including both sides of originals, known copies, and drafts, including but without limitation, papers, books, letters, correspondence, telegrams, bulletins, notices, announcements, instructions, charts, manuals, brochures, schedules, cables, messages, memoranda, notes, notations, notices, accountants' working papers, transcripts, minutes, agendas, reports, and recordings of telephone or other conversations, interviews, conferences, or other meetings, affidavits, statements, summaries, opinions, reports, studies, analyses, evaluations, contracts, agreements, surveys, maps, drawings, journals, statistical records, desk calendars, appointment books, diaries, lists, tabulations, sound recordings, computer printouts, data processing input and output, microfilms, and other records kept by electronic, photographic, or mechanical means, and things similar to any of the above, and any other documents within the meaning of the Louisiana Code of Civil Procedure, that is in your possession, custody, or control. Without limitation of the term "control" as used in the preceding sentence, a document is deemed to be in your "control" if you have the right to secure the document or a copy thereof from another person or public or private entity having actual physical possession thereof.

4. "Communication" shall be construed in its broadest sense and shall mean every manner or means of disclosure, transfer, or exchange, and every disclosure, transfer, or exchange of information, whether orally, face-to-face, or by telephone, mail personal delivery, electronic delivery, document or otherwise.

5. "Relating to" and "relate to" shall be construed in their broadest sense and shall mean directly or indirectly describing, setting forth, discussing, mentioning, commenting upon, supporting, contradicting, or referring to the subject or topic in question, either in whole or in part.

6. "All" includes the word "any" and "any" includes the word "all."

7. "Each" includes the word "every" and "every" includes the word "each."

8. "And" as well as "or" shall be construed either conjunctively or disjunctively as necessary in order to bring within the scope of these discovery requests any information which might otherwise be construed to be outside their scope.

9. The singular and masculine form of a noun or pronoun shall embrace the plural, the feminine, and/or the neuter, and vice versa.

10. "Direct Purchaser Action, " or "DP Action" means the action *In re: Metoprolol Succinate Direct Purchaser Antitrust Litigation*, case numbered 06-cv-00052, in the United States District Court for the District of Delaware.

11. "Indirect Purchaser Action" or "End-Payor Action" or "Indirect/End-Payor Action" means *In re: Metoprolol Succinate End-Payor Antitrust Litigation*, case number 06-cv-0071, in the United States District Court for the District of Delaware.

## INSTRUCTIONS

1. Where knowledge, information, or documents are requested, such requests include knowledge, information, or documents in the possession of your agents, representatives, and attorneys.

2. Where exact information cannot be furnished, estimated information is to be supplied. Where estimated information is used, the response should indicate this fact and an explanation should be given as to the basis of how the estimation was made and the

reason exact information was not furnished.

3. Where knowledge, information, or documents are requested, such requests include knowledge, information, or documents in the possession of your agents, representatives, and attorneys.

4. Unless the context of the Request requires otherwise, references to the single include the plural and references to gender include both masculine and feminine.

5. If any requested documents are not produced on the basis that the documents sought are not in your custody and/or control, the documents should be identified and the person or entity in whose custody you believe the documents can be found should likewise be identified.

6. If any document, communication, or other requested information of any type whatsoever is withheld on the basis that such information is privileged or confidential, please identify with specificity the document, communication, or other requested information as well as the basis for asserting privilege or confidentiality.

7. Each document called for in these Requests shall be produced in and with the file folder or other documents (e.g., envelope, file cabinet marker, label, etc.) in which such document was previously produced.

8. Documents responsive to these Requests shall be produced in the condition and order or arrangement in which they existed when these Requests were served.

9. Upon producing the requested documents, you shall indicate to which Request each document produced is responsive.

10. Documents produced in response to these Requests should be delivered to E. Wade Shows, Shows, Cali & Walsh, LLP, 628 St. Louis St., Baton Rouge, LA 70802, on or before fifteen (15) days after service of these Requests.

## REQUESTS FOR PRODUCTION

**REQUEST FOR PRODUCTION NO. 1:**

Please produce all Interrogatories and Requests for Admissions that you received from any party in the Direct Purchaser Action, and the Indirect Purchaser Action.

**REQUEST FOR PRODUCTION NO. 2:**

Please produce all responses and answers you provided to the discovery requests named in Request For Production No. 1 above.

**REQUEST FOR PRODUCTION NO. 3:**

Please produce all deposition transcripts and associated exhibits from the Direct Purchaser Action, and the Indirect Purchaser Action.

**REQUEST FOR PRODUCTION NO. 4:**

Please produce all summary judgment briefs and associated exhibits from the Direct Purchaser Action, and the Indirect Purchaser Action.

**REQUEST FOR PRODUCTION NO. 5:**

Please produce all trial transcripts, exhibits, and demonstratives from the Direct Purchaser Action, and the Indirect Purchaser Action.

RESPECTFULLY SUBMITTED this 18th day of March, 2015.

**JAMES D. "BUDDY" CALDWELL**
**ATTORNEY GENERAL FOR**
**THE STATE OF LOUISIANA**

James D. "Buddy" Caldwell (No. 02211)
Keetsie T. Gunnels (No. 12952)
Nicholas J. Diez (No. 31701)
Stacie Deblieux (No. 29142)
Office of the Attorney General, State of Louisiana
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Baton Rouge, Louisiana 70802

-and-

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Tonya Rhodes Jupiter (No. 23270)
1010 Common Street, Suite 2510
New Orleans, Louisiana 70112
Telephone: (504) 582-6998
Facsimile: (504) 582-6985

**CERTIFICATE OF SERVICE**

I do hereby certify that I have on this ___ day of March, 2015, served a copy of the foregoing pleading on all parties via service on their Registered Agent in Louisiana for Service of Process, located at CT Corporation System, 5615 Corporate Blvd, Suite 400B, Baton Rouge, LA 70808.

E. WADE SHOWS

PLEASE SERVE:

AstraZeneca LP
Through its agent for service of process:
C T Corporation System
5615 Corporate Blvd., Ste. 400B
Baton Rouge, LA 70808

AstraZeneca Pharmaceuticals LP
Through its agent for service of process:
C T Corporation System
5615 Corporate Blvd., Ste. 400B
Baton Rouge, LA 70808

2425-15-000951

# CITATION

**STATE OF LOUISIANA, BY AND THROUGH ITS ATTORNEY GENERAL JAMES CALDWELL**
**(Plaintiff)**

**vs.**

**ASTRA ZENECA AB, ET AL**
**(Defendant)**

**NUMBER C637960 SECTION 22**

**19th JUDICIAL DISTRICT COURT**

**PARISH OF EAST BATON ROUGE**

**STATE OF LOUISIANA**

**TO: ASTRAZENECA, LP**
**THROUGH ITS AGENT FOR SERVICE OF PROCESS:**
**C T CORPORATION SYSTEM**

GREETINGS:

Attached to this citation is a certified copy of the petition*. The petition tells you what you are being sued for.

You must EITHER do what the petition asks OR, within fifteen (15) days after you have received these documents, you must file an answer or other legal pleading in the office of the Clerk of Court at 300 North Boulevard, Baton Rouge, Louisiana.

If you do not do what the petition asks, or if you do not file an answer or legal pleading within fifteen (15) days, a judgment may be rendered against you without further notice.

This citation was issued by the Clerk of Court for East Baton Rouge Parish on **26-MAR-2015**.

THE CLERK OF THE PARISH OF EAST BATON ROUGE, LA. SEAL

Dianna J. Manning

*Deputy Clerk of Court for*
**Doug Welborn, Clerk of Court**

**Requesting Attorney: JAMES DAVID CALDWELL**

Also attached are the following documents:
**PETITION; REQUESTS FOR PRODUCTION OF DOCUMENTS**

---

**SERVICE INFORMATION:**

Received on the _____ day of _____, 20____ and on the _____ day of _____, 20_____, served on the above named party as follows:

**CT CORPORATION SYSTEMS:** By tendering same to the within named, by handing same to _____.

**DUE AND DILIGENT:** After diligent search and inquiry, was unable to find the within named _____ or his domicile, or anyone legally authorized to represent him.

**RETURNED:** Parish of East Baton Rouge, this _____ day of _____, 20_____.

SERVICE: $_____
MILEAGE $_____
TOTAL: $_____

_____
Deputy Sheriff

**CITATION - 2425**

EBR2904372

**2425-15-000952**

# CITATION

**STATE OF LOUISIANA, BY AND THROUGH ITS ATTORNEY GENERAL JAMES CALDWELL**
**(Plaintiff)**

**vs.**

**ASTRA ZENECA AB, ET AL**
**(Defendant)**

**NUMBER C637960 SECTION 22**

**19th JUDICIAL DISTRICT COURT**

**PARISH OF EAST BATON ROUGE**

**STATE OF LOUISIANA**

**TO: ASTRAZENECA PHARMACEUTICALS LP**
**THROUGH ITS AGENT FOR SERVICE OF PROCESS:**
**C T CORPORATION SYSTEM**

GREETINGS:

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This citation was issued by the Clerk of Court for East Baton Rouge Parish on **26-MAR-2015.**

THE CLERK OF THE PARISH OF EAST BATON ROUGE, LA 1935

Dianna J. Manning

*Deputy Clerk of Court for*
**Doug Welborn, Clerk of Court**

**Requesting Attorney: JAMES DAVID CALDWELL**

Also attached are the following documents:
**PETITION; REQUEST FOR THE PRODUCTION OF DOCUMENTS**

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**SERVICE INFORMATION:**

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**CT CORPORATION SYSTEMS:** By tendering same to the within named, by handing same to _____.

**DUE AND DILIGENT:** After diligent search and inquiry, was unable to find the within named _____ or his domicile, or anyone legally authorized to represent him.

**RETURNED:** Parish of East Baton Rouge, this _____ day of _____, 20_____.

SERVICE: $_____
MILEAGE $_____
TOTAL: $_____

_____
Deputy Sheriff

**CITATION - 2425**

EBR2904374

2425-15-000952

# CITATION

**STATE OF LOUISIANA, BY AND THROUGH ITS ATTORNEY GENERAL JAMES CALDWELL**
**(Plaintiff)**

**vs.**

**ASTRA ZENECA AB, ET AL**
**(Defendant)**

**NUMBER C637960 SECTION 22**

**19th JUDICIAL DISTRICT COURT**

**PARISH OF EAST BATON ROUGE**

**STATE OF LOUISIANA**

**TO: ASTRAZENECA PHARMACEUTICALS LP**
**THROUGH ITS AGENT FOR SERVICE OF PROCESS:**
**C T CORPORATION SYSTEM**

GREETINGS:

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This citation was issued by the Clerk of Court for East Baton Rouge Parish on **26-MAR-2015**.

THE CLERK OF COURT OF THE PARISH OF EAST BATON ROUGE, STATE OF LOUISIANA

Dianna J. Mouning

*Deputy Clerk of Court for*
**Doug Welborn, Clerk of Court**

**Requesting Attorney: JAMES DAVID CALDWELL**

Also attached are the following documents:
**PETITION; REQUEST FOR THE PRODUCTION OF DOCUMENTS**

MAR 30 2015

---

**SERVICE INFORMATION:**

I made service on the named party through the CT Corporation by tendering a copy of this document to ☐ ANTOINE PIERCE ☐ DENIS ☐ TREVOR GAROUTTE ☐ UNIVERSITY CALLOUET

Received on the _____ day of _____, 20____ and on the _____ day of _____, 20____, served on the above named party as follows:

**CT CORPORATION SYSTEMS:** By tendering same to the within named, by handing same to _____.

**DUE AND DILIGENT:** After diligent search and inquiry, was unable to find the within named _____ or his domicile, or anyone legally authorized to represent him.

Deputy Sheriff, Parish of East Baton Rouge, Louisiana

**RETURNED:** Parish of East Baton Rouge, this _____ day of _____, 20____.

SERVICE: $_____
MILEAGE $_____
TOTAL: $_____

_____
Deputy Sheriff

**CITATION - 2425**

FILED
MAR 30 2015
DEPUTY CLERK OF COURT

EBR2746940

EBR2904374

2425-15-000951

# CITATION

**STATE OF LOUISIANA, BY AND THROUGH ITS ATTORNEY GENERAL JAMES CALDWELL**
**(Plaintiff)**

**vs.**

**ASTRA ZENECA AB, ET AL**
**(Defendant)**

**NUMBER C637960 SECTION 22**

**19th JUDICIAL DISTRICT COURT**

**PARISH OF EAST BATON ROUGE**

**STATE OF LOUISIANA**

**TO: ASTRAZENECA, LP**
**THROUGH ITS AGENT FOR SERVICE OF PROCESS:**
**C T CORPORATION SYSTEM**

GREETINGS:

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This citation was issued by the Clerk of Court for East Baton Rouge Parish on **26-MAR-2015**.

THE CLERK OF THE PARISH OF EAST BATON ROUGE, LA. SEAL 1846

Diana J. Manning
*Deputy Clerk of Court for*
**Doug Welborn, Clerk of Court**

**Requesting Attorney: JAMES DAVID CALDWELL**

Also attached are the following documents:
**PETITION; REQUESTS FOR PRODUCTION OF DOCUMENTS**

---

**SERVICE INFORMATION:**

MAR 30 2015
I made service on the named party through the CT Corporation
4 DEPUTIES ANTOINE PIERCE
by tendering a copy of this document to TREVOR GAROUTTE
by tendering same to HENRY CAILLOUET
Deputy Sheriff, Parish of East Baton Rouge, Louisiana

Received on the _____ day of _____, 20____ and on the _____ day of _____, 20____, served on the above named party as follows:

**CT CORPORATION SYSTEMS:** By tendering same to the within named _____ by handing same to _____.

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SERVICE: $_____
MILEAGE $_____
TOTAL: $_____

_____
Deputy Sheriff

**CITATION - 2425**

FILED
MAR 30 2015
DEPUTY CLERK OF COURT

EBR2746939

EBR2904372

KEAN | MILLER LLP
ATTORNEYS AT LAW

BRADLEY C. MYERS, PARTNER
PH 225.382.3421 DIRECT FAX 225.215.4021
BRAD.MYERS@KEANMILLER.COM

April 13, 2015

POSTED
APR 14 2015

*Via Hand Delivery*

Honorable Doug Welborn
Clerk of Court - 19th JDC
East Baton Rouge Parish
Governmental Building
222 St. Louis Street
Baton Rouge, LA 70821-1991

Re: State of Louisiana by and through its Attorney General James Caldwell
v. Astra Zeneca AB, et al., Civil Action No. 637,960, Section 22
19th JDC, East Baton Rouge Parish, Louisiana

Dear Mr. Welborn:

Enclosed is an original and one copy of an Unopposed Motion and Order for Extension on behalf of Astra Zeneca AB, AstraZeneca LP, AstraZeneca Pharmaceuticals LP and Akitbolaget Hässle ("AstraZeneca"). Please file the motion in the above reference case and return a date-stamped copy to our courier.

Enclosed is our firm check in the amount of $27.00 to cover the filing costs.

Thank you for your assistance in this matter. If you have any questions, please feel free to contact me.

Very truly yours,

Bradley C. Myers

EBR2899717

/jtb
osures

James D. "Buddy" Caldwell (w/enc.)
E. Wade Shows (w/enc.)
Robert L. Salim (w/enc.)

REC'D C.P.
APR 14 2015

REC'D C.P.
APR 22 2015

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Allan Kanner (w/enc.)
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T. Allen Usry (w/enc.)
Michael G. Bagneris (w/enc.)

19th JUDICIAL DISTRICT COURT

PARISH OF EAST BATON ROUGE

STATE OF LOUISIANA

COST OK Amt. 27.

APR 13 2015

BY c#027276 SP
DY CLERK OF COURT

STATE OF LOUISIANA
BY AND THROUGH ITS ATTORNEY
GENERAL JAMES CALDWELL

CIVIL ACTION NO.: 637,960

VERSUS

SECTION: 22

ASTRA ZENECA AB, ASTRAZENECA LP, ASTRAZENECA PHARMACEUTICALS LP AND AKITBOLAGET HÄSSLE

**UNOPPOSED MOTION AND ORDER FOR EXTENSION**

Upon motion of Astra Zeneca AB, AstraZeneca LP, AstraZeneca Pharmaceuticals LP and Akitbolaget Hässle ("AstraZeneca") (appearing herein solely for the purpose of this motion for extension and reserving all rights and defenses), for an extension of time until May 1, 2015, to move, plead, or otherwise respond to the Petition; that this is the first extension requested, that plaintiff's counsel, E. Wade Shows, has no objection and consents to this extension and that this extension will not unduly delay the progress of this matter;

**IT IS ORDERED** that Astra Zeneca AB, AstraZeneca LP, AstraZeneca Pharmaceuticals LP and Akitbolaget Hässle be and are hereby granted an extension of time until the 1st day of May, 2015, within which to move, plead or otherwise respond to the Petition.

EBR2899718

FILED
EAST BATON ROUGE PARISH, LA
2015 APR 13 PM 4:07
DEPUTY CLERK OF COURT

Baton Rouge, Louisiana, this 21 day of April, 2015.

JUDGE TIMOTH KELLEY
19TH Judicial District Court

Respectfully Submitted by:

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REC'D C.P.

APR 14 2015 REC'D C.P.

APR 22 2015



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**CERTIFICATE OF SERVICE**

I hereby certify that a copy of the above and foregoing Unopposed Motion and Order for Extension has been served by United States Mail, postage prepaid and properly addressed to the following counsel of record:

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FILED
EAST BATON ROUGE PARISH, LA
2015 APR 13 PM 4:07
DEPUTY CLERK OF COURT

Baton Rouge, Louisiana, this 13th day of April, 2015.

Bradley C. Myers



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