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IN THE UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

AIDS HEALTHCARE FOUNDATION, a California Non-Profit Corporation, Plaintiff, v. GLAXOSMITHKLINE PLC, etc., et al., Defendant.	CV 03-2792 TJH BRIEF OF AMICUS CURIAE STATE OF CALIFORNIA IN SUPPORT OF AIDS HEALTHCARE FOUNDATION'S OPPOSITION TO GLAXOSMITHKLINE'S MOTION FOR PARTIAL SUMMARY JUDGMENT JUDGE TERRY J. HATTER

INTEREST OF AMICUS CURIAE STATE OF CALIFORNIA

The State of California places a high value on the preservation of open and competitive markets for prescription drugs. The Attorney General serves as a representative of the public interest, defending the interests of consumers in a variety of contexts, and is responsible to the public for the enforcement of antitrust law. This position of special public trust imposes upon the Attorney General a unique duty to represent the public interest in cases where the resolution of a legal dispute between private parties has important implications for the marketplace and

threatens serious harm to open competition and the benefits it provides to consumers. This special public trust encompasses a duty to represent the public interest for all of California's citizens, including the estimated 50,000 Californians living with AIDS.

The Attorney General has a particularly compelling interest in this matter because resolution of the issues presented will affect numerous controversies of public importance. The impact of this decision may be wide-ranging. Fair competition law and patent law, in proper balance, both foster innovation. Fair competition law and patent law out of balance may have the perverse effect of thwarting competition.

This case arises out of the events surrounding the development, patenting, and commercial production of zidovudine ("AZT") from the 1960's to the present. The parties, a non-profit AIDS service and advocacy organization (the AIDS Healthcare Foundation or "AHF") and a large multi-national pharmaceutical company (GlaxoSmithKline plc or "Glaxo"), both agree that it is the conduct – and the antitrust and patent implications of that conduct—of employees of Burroughs-Welcome Company (Glaxo's predecessor at interest) before the United States Patent and Trademark Office ("the PTO") and the Food and Drug Administration ("FDA") that is the focus of this motion for partial summary judgment.

Glaxo maintains that an antitrust claim based on the procurement of patents cannot go forward without a genuine issue of material fact as to fraud, that there is none, and that partial summary judgment should be granted. AHF asserts that the

standard for summary judgment has not been met and that there are important disputed material facts. The State of California submits that much of the nominal dispute over material facts is, in fact, a dispute over the legal significance of material omissions before the PTO.

The Attorney General of California submits this amicus brief to support the proposition that material omissions from information submitted to the PTO and in supplementary submissions to the Food and Drug Administration's Orange Book ("the Orange Book") may give rise to crucial elements of an antitrust claim. The material omissions at issue in this motion for partial summary judgment are the lynchpins to a powerful antitrust claim. The factual dispute over the characterization of these material omissions – as intentional, grossly negligent, inadvertent error, or honest mistake -- is not appropriately resolved by a summary judgment motion.

QUESTION PRESENTED

Should this Court grant partial summary judgment on the issue of AZT patent validity when the validity determination turns on factual issues surrounding the nature and content of material omissions from information submitted to the PTO and supplementary submissions to the Orange Book.

ARGUMENT

Material omissions from information submitted to the PTO and the FDA's Orange Book may give rise to crucial elements of an antitrust claim brought to correct an allegedly anti-competitive market effect resulting from the use of a fraudulently obtained patent to influence the marketplace.

Both parties to this litigation advance readings of *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965) ("*Walker Process*"). *Walker Process* represents an exception to the general immunity from antitrust prosecution a patent holder enjoys and is invoked here by AHF. The exemption developed out of the recognition that the integrity of the patent system depends upon the candor of the patent applicant.

Although "[t]he patent fraud proscribed by *Walker* is extremely circumscribed", *Argus Chem.Corp. v. Fibre Glass-Evercoat Co.*, 812F.2d 1381 (Fed.Cir.1987), the Federal Circuit has reiterated that a patentee may be denied its exemption from the antitrust laws if the patentee obtained the patent by knowingly and willfully misrepresenting material facts. *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F. 3d 1059, 1068-69 (Fed. Cir. 1998).

A valid *Walker Process* fraud claim requires proof that the patentee acted intentionally to deceive the government and that the patent under dispute would not have been issued but for the patentee's fraud. 1 Herbert Hovenkamp et al., *Intellectual Property and Antitrust* § 11.2, at 11-7 at 11-7 (2003). "[T]he gravamen of a *Walker Process* claim is not punishment for misrepresentation, but an action to correct an anticompetitive market effect resulting from the use of the patent to influence the marketplace." 1 Herbert Hovenkamp et al., *Intellectual Property and Antitrust* § 11.2, at 11-10.1 (2003).

A *Walker Process* fraud claim, in part, takes the material omissions made in the relative obscurity of the patent prosecution process and exposes them to the light of day as it

tests possible anti-competitive market effects resulting from those material omissions. The State of California, infrequently a party to patent prosecutions, has a particular concern that such material omissions be afforded the most searching of factual scrutiny when evaluating a *Walker Process* fraud claim. It is precisely because the patent application and prosecution process has historically been so impenetrable[1/] that a *Walker Process* claim is not ripe for partial summary judgment.

Because the public interest in fair and open competition in pharmaceutical markets is so important, an antitrust claim that challenges the very integrity of AZT's patent acquisition as well as the integrity of the market for Glaxo-patented AZT itself is also very important. As the PTO explicitly does not investigate duty of disclosure issues and does not reject applications on that basis, there is a great public interest in a thorough factual exposition of antitrust claims based on allegations of these kinds of material omissions. *See* United States Patent and Trademark Office, *Manual of Patent Examining Procedure §* 2001.06 (8th ed. 2001), *available at* http://www.uspto.gov/web/offices/pac/mpep/mpep.htm.

CONCLUSION

The State of California recognizes the public policy determinations that underly the need for finality in the issuance of a patent. A patent, once granted, enjoys a legal presumption

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[1/] *See* Federal Trade Commission, "To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy" (2003) at 7 , *available at* http://www.ftc.gov . ("Until recently, third parties could only bring certain relevant documents to the attention of, and, in limited circumstances, file a written protest with, an examiner or to request the PTO Director to reexamine a patent.")

of validity. This is coupled with a high standard of proof for those who seek to challenge the validity of a patent. This combination of a favorable presumption and a high standard of proof more than protect Glaxo from unproductive litigation going forward. The public interest in striking the appropriate balance between promoting innovation and promoting fair competition can best be vindicated here by denying Glaxo's motion for partial summary judgment.

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Respectfully submitted,

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