February 6, 2009

Introduction

On January 30, 2009, the U.S. Court of Appeals for the Second Circuit issued an opinion that should be noted by any company doing business internationally. In *Abdullahi v. Pfizer, Inc.*, Nos. 05-4863-cv (L), 05-6768-cv (CON), 2009 WL 214649 (2nd Cir. Jan. 30, 2009), the Second Circuit reversed the District Court's dismissal of two cases brought against the pharmaceutical company Pfizer under the Alien Tort Statute ("ATS"), 28 U.S.C. § 1350.[1] While the decision is particularly significant to pharmaceutical companies – given its holding that informed consent for human medical experimentation is a norm of customary international law – it is also significant for any company doing business overseas because it provides guidance on how courts, especially the Second Circuit Court of Appeals, may assess whether other international norms exist that could give rise to claims under the ATS. In addition, the case follows a growing trend in which courts are allowing ATS claims brought by foreign nationals against corporations for their actions overseas to move forward in U.S. courts.

Factual/Procedural Background

The *Pfizer* case arises out of the response to an outbreak of bacterial meningitis that occurred in the northern Nigerian town of Kano in 1996. The complaint alleges that at the time of the outbreak, Pfizer was in the process of testing a new antibiotic to treat bacterial meningitis, which was marketed under the name Trovan. Trovan had not yet been approved by the U.S. Food and Drug Administration ("FDA"), but Pfizer had clinical data pointing to its safety and potential effectiveness. Pfizer offered to go to Nigeria and treat the critically ill patients with both Trovan and Ceftriaxone, one of its FDA-approved drugs. Because Trovan was not approved by the FDA at the time, Pfizer sought and obtained a letter from the Nigerian Government and the Kano Infectious Disease Hospital ("IDH") seeking to allow Pfizer to administer Trovan. The FDA granted the request and approved Pfizer's use of Trovan at the IDH in Kano.

The patients treated by Pfizer were primarily children, some of whom received Trovan and others Ceftriaxone. The plaintiffs allege that Pfizer's administration of these drugs caused the deaths of eleven children and injuries to other children. Disputes subsequently arose as to whether Pfizer had obtained informed consent for the treatment from the children's parents or legal guardians.

In August 2001, a group of parents whose children were treated with Trovan sued Pfizer in the Southern District of New York under the ATS. The plaintiffs alleged that Pfizer violated international law by failing to inform parents of the risks associated with Trovan, by failing to obtain informed consent prior to treating children with Trovan, and by providing inadequate medical treatment. The plaintiffs

contended that these alleged actions constituted torts in violation of international law, as established by various international treaties, conventions, declarations, customs, and judicial decisions that address human medical experimentation.

In September 2002, the District Court granted Pfizer's motion to dismiss on *forum non conveniens* grounds, on the condition that Pfizer consent to litigate the claims in Nigeria. *Abdullahi v. Pfizer, Inc.*, No. 01 Civ. 8118, 2002 WL 31082956, at *12 (S.D.N.Y. Sept. 17, 2002). Following the plaintiffs' unsuccessful attempt to bring suit in Nigeria, the Second Circuit vacated the District Court's dismissal and remanded for further fact finding on the *forum non conveniens* issue. *Abdullahi v. Pfizer, Inc.*, 77 Fed. App'x 48, 53 (2nd Cir. 2003). Following remand, Pfizer moved to dismiss for failure to state a claim under the ATS and, alternatively, on *forum non conveniens* grounds. The District Court granted Pfizer's motion and held that the plaintiffs had failed to identify a source of international law that "provide[s] a proper predicate for jurisdiction under the ATS." *Abdullahi v. Pfizer, Inc.*, No. 01 Civ. 8118, 2005 WL 1870811, at *14 (S.D.N.Y. Aug. 9, 2005). Although the District Court also held that Nigeria was an adequate alternate forum and again dismissed on *forum non conveniens* grounds, Pfizer did not pursue this basis for dismissal in light of changed circumstances in Nigeria.

The Alien Tort Statute, passed by the First Congress in 1789, provides that "[t]he district court shall have original jurisdiction of any civil action by an alien for a tort only, committed in violation of the law of nations or a treaty of the United States." After laying virtually dormant for its first 200 years, the ATS has been increasingly used by plaintiffs' lawyers over the last 20 years to bring claims for compensation for various human rights violations that have occurred abroad. Until recently, federal courts had generally recognized ATS jurisdiction in only a very limited set of circumstances, primarily involving genocide and war crimes, state-administered torture, and the safe passage of vessels in international waters.

In 2004, the U.S. Supreme Court, in its only case to date that explores the parameters of the ATS, cautioned courts that "any claim based on the present-day law of nations [must] rest on a norm of international character accepted by the civilized world and defined with a specificity comparable to the features of the 18th-century paradigms we have recognized." *Sosa v. Alvarez-Machain*, 542 U.S. 692, 724 (2004). The Supreme Court, however, gave lower courts little guidance on exactly how to conduct such an analysis. In deciding that the ATS confers a cause of action for the failure to obtain informed consent for human medical experimentation, the majority in the *Pfizer* case set forth a framework that could make it easier in the future to assert new causes of action against private actors under the ATS.

Both the *Pfizer* majority and the dissent agreed that there are three criteria that must be satisfied before a violation of international law can be actionable under the ATS: the international norm must be "(1) specific and definable, (2) universally adhered to out of a sense of legal obligation, and (3) a matter of mutual concern [among States]." *Abdullahi*, 2009 WL 214649, at *22.

There was sharp disagreement, however, on whether the norm against non-consensual medical experimentation meets these requirements. In deciding that this norm is universal and obligatory, the majority relied on a review of various international treaties, conventions, declarations, customs, and judicial decisions that address human medical experimentation, including the International Covenant on Civil and Political Rights, the World Medical Association's Declaration of Helsinki, the guidelines of the Council for International Organizations of Medical Sciences, and the Nuremberg Code. The majority found that it was appropriate to take into account such a wide range of sources in ATS cases because customary international law "does not stem from any single, definitive, readily-identifiable source." *Id.* at *4 (quoting *Flores v. S. Peru Copper Corp.*, 414 F.3d 233, 247-48 (2nd Cir. 2003)).

As the dissent pointed out, though, the majority did not examine the evidentiary weight of these sources, or how they compared with the evidence of customary international law that had been deemed sufficient to sustain an ATS action in prior cases. For example, some of the sources relied upon by the majority are agreements among countries in a specific region of the world. Other sources only address human experimentation carried out by governments and do not speak to experimentation by private parties. Still others are not self-executing; that is, by their terms they do not create private rights of action. Yet others did not come into force until after Pfizer's activities in Nigeria. Thus, in the dissent's view, the majority went too far in finding that these sources give rise to an ATS cause of action against private actors for non-consensual human medical experimentation.

In addition, the dissent argued that norms of customary international law must not only be universally accepted, but must also touch on matters of "mutual" concern. The dissent contended that while the failure to obtain a patient's informed consent may be reprehensible, it does not "threaten serious consequences in international affairs" and is thus not of "mutual" concern to all nations. *Abdullahi*, 2009 WL 214649 at *35-36. Ultimately, the dissent cautions that the majority's "ability to pick and choose from [a] seemingly limitless menu of [international] sources presents a real threat of 'creative interpretation.'" *Id.* at *24 (quoting *Flores*, 414 F.3d at 248).

If other courts follow the majority's approach, it would not be surprising if additional causes of action are allowed to proceed under the ATS – even in areas where Congress has ratified treaties and other international agreements with the explicit understanding that they do not create private rights of action.

Given the current uncertainty about the scope of actionable conduct under the ATS, particularly with respect to how courts will interpret the various sources of international law that plaintiffs are sure to rely upon in future cases, companies must keep a close eye on ATS cases as they percolate through the courts. Companies should also take a proactive approach to protect themselves from becoming targets of ATS actions by exercising particular caution when dealing with foreign governments that have less-than-stellar human rights records, and should generally

become familiar with the various treaties, international agreements, and codes of conduct that could be applied to their business activities abroad.

For more information, contact :

Arvin Maskin at (212) 310-8098 or arvin.maskin@weil.com,
Caitlin Halligan at (212) 310-8535 or caitlin.halligan@weil.com, or
Konrad Cailteux at (212) 310-8904 or konrad.cailteux@weil.com.

1 The *Abdullahi* appeal is a consolidated appeal of two cases brought by separate groups of plaintiffs against Pfizer raising many of the same issues. Both groups of plaintiffs allege that Pfizer's actions in Nigeria violated international law and seek to invoke jurisdiction under the Alien Tort Statute.