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SOUTHERN ILLINOIS UNIVERSITY
NATIONAL HEALTH LAW MOOT COURT COMPETITION

Transcript of Record
Docket No. 11-1023

Supreme Court of the United States
October Term, 2011

PHARMEX, INC.,
Petitioner

v.

FAITH MBOLE, individually and on behalf of
all others similarly situated,
Respondent.

COMPETITION PROBLEM

In Conjunction with the National Health Law Moot Court Competition
which is
SPONSORED BY:

Southern Illinois University School of Law

Southern Illinois University School of Medicine,
Department of Medical Humanities

American College of Legal Medicine
and the ACLM Foundation

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW LINCOLN**

Faith Mbole,)	
individually and on behalf of)	
all others similarly situated,)	
Plaintiff,)	MEMORANDUM OPINION AND
)	ORDER
v.)	
)	Civil Case No. 09-1332
Pharmex, Inc.,)	
Defendant)	

LEE SMITH, District Judge

Plaintiff Faith Mbole brings this class-action lawsuit on her own behalf and on behalf of all other similarly situated Zinerian women who were subjects in a clinical trial of Atramine in the fall of 2002.¹ Mbole filed a complaint in the Federal District Court for the District of New Lincoln on January 23, 2009, against defendant Pharmex, Inc. The complaint alleged that Pharmex failed to inform the subjects of the clinical trial that Atramine was an experimental drug, that the experiment would involve a placebo, and that the drug could expose the women to life threatening risks. Pursuant to the Alien Tort Statute, 28 U.S.C. §1350 (2006), Mbole asserts that Pharmex violated an international law norm prohibiting nonconsensual human experimentation.²

¹ No issues about the propriety of the class action have been raised.

² Mbole has claimed that 1) no suit could be brought in Zineria because Zineria, as a new nation, has not yet developed a fully functioning judicial system; that 2) any so-called judiciary in Zineria would likely be unresponsive to the women’s claims because Pharmex and other U.S. pharmaceutical corporations provide medical supplies and equipment in exchange for access to research subjects in the Biango clinic; that 3) neither Zineria nor the state of Biango has developed statutes or regulations to govern human subjects research; that 4) litigating in Zineria could endanger the safety of witnesses; and that 5) the United States has provided an appropriate forum for their claims through the Alien Tort Statute. Pharmex filed a motion to dismiss on grounds of *forum non conveniens*. By separate Memorandum and Order, this Court denied that motion and the issue is no longer before the Court.

Pharmex filed a Rule 12(b)(6) motion to dismiss for failure to state a claim upon which relief can be granted. For the reasons set forth below, Pharmex's motion is GRANTED.

I. Facts

The following facts have been stipulated by the parties. Faith Mbole and other members of the class action are Zinerian women (or their legal representatives) who participated in an experiment conducted by Pharmex, Inc. All of the members of the class except Mbole currently reside in Zineria. Mbole currently lawfully resides in the United States. Pharmex, Inc., is a multinational pharmaceutical corporation headquartered in Corporate Village, New Lincoln, with subsidiaries on several continents including Africa where Zineria is located. In September, 2002, Pharmex conducted a trial of its new drug, Atramine, in Parrottown. Parrottown is located in the state of Biango in Zineria. Zineria itself was founded in 2001 after a generation of *coups d'etat*, civil war, and turmoil in the region. Atramine was being developed to treat the SX2 infection, a contagious, debilitating, and occasionally fatal disease which began to spread through several continents beginning in 2000.

SX2 infection began in the southern hemisphere and, while it affects both men and women, has been particularly devastating to women and girls. Specifically, SX2 is estimated to affect nearly 12% of the female Parrottown population, approximately three times the rate of male infection. The Zinerian government, in an attempt to address what was rapidly becoming a public health crisis in its new nation, was cooperating with nearby southern African nations to create an SX2 infection task force. It also began an SX2 public education campaign that urged residents to get treatment. But SX2 infection was beginning to affect populations in the northern hemisphere as well, where Pharmex planned to market Atramine after clinical trials were undertaken and approval was obtained from the Food and Drug Administration (FDA). SX2

most often results in paralysis and blindness and is occasionally fatal. Animal studies suggested that, although Atramine occasionally resulted in temporary cardiac arrhythmias and joint disease, it had significant potential not only to reduce the incidence of blindness resulting from SX2 infection, but also to save lives.

The literacy rate in Biango is among the lowest in the world. Neither boys nor girls go to school. The culture of the residents of Parrottown is an oral culture, and their language has no concept for “research” or “hypothesis.” Deference to a traditional council of elders is expected on matters that significantly affect community welfare. Women in Parrottown rarely have contact with those outside the culture. In an attempt to protect women, men mediate women’s contact with those outside the community when such contact is unavoidable.

Although SX2 affects both men and women, because it has had such disproportionate affect on women, Pharmex initially undertook trials of Atramine on female-only subject groups. Before implementing the Atramine experiment, Pharmex sought and received written permission from the Biango state government to treat Parrottown patients for SX2 infection. Pharmex also sought and received approval from a newly constituted regional research ethics committee.³ On the advice of Zinerian national officials, Pharmex representatives met with the local council of elders, comprised of all males over age 40 in the Parrottown community, and asked for

³ The regional committee consisted of medical doctors and other health care professionals from several southern African nations, including a Catholic mission hospital located in Zineria. The members of the committee had been recruited and trained by a coalition of American hospitals and pharmaceutical companies interested in conducting drug trials in the area. This was done to satisfy FDA requirements regarding ethics review. Pharmex was a member of this coalition, but no allegations have been made that their representatives had any undue influence over the ethics committee. The ethics committee, being fairly new, had developed few formal procedures and generally gave at most cursory review of matters brought before it.

permission to use a new drug on infected women residing in the community. The council of elders gave Pharmex permission to proceed.

The trials were conducted in the Biango State Clinic, the only medical clinic, indeed the only medical facility, in Biango. In exchange for access to the community and for space to conduct the Atramine experiment in the overcrowded State Clinic, the Biango government received from Pharmex a substantial donation of medical equipment and supplies. This type of mutually beneficial exchange had begun with Pharmex's previous clinical trial of the drug Cetrivir at the Biango State Clinic in 2000, and has been part of Pharmex's work with other clinical trial sites in other contiguous African nations.

Pharmex staff and a local Biango physician recruited by Pharmex (who was not an employee of the Clinic) planned to conduct the Atramine experiment over the course of a 10 week period on 150 adult women at the Biango State Clinic. The precise ages of the experimental subjects are not known, but Pharmex's protocol required adult subjects under the age of 40. One-third of the subjects received Atramine, one-third received a placebo, and one-third received the World Health Organization-approved treatment, Triptivir.

Five women in the Atramine experiment suffered cardiac arrest and died within 48 hours of participating in the experiment; seven others began to suffer seizures and severe joint pain about two weeks into the experiment and have since become bedridden. Mbole experienced seizures and subsequently become paralyzed. Following an investigation by German journalists, reports of the testing were picked up by U.S. media as well as regional news media in Africa. Bomb threats from (an) individual(s) claiming to be "friends of Parrrottown" were received at Pharmex headquarters in the U.S., at Pharmex offices in Mexico and Brazil, and at several U.S. embassies in Africa. Pharmex terminated the trial before its planned ending.

II. Alien Tort Statute

This is a claim of first impression in this Circuit. Mbole brings suit under the Alien Tort Statute (ATS), which grants to federal courts original jurisdiction over “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.” 28 U.S.C. § 1350 (2006). In *Sosa v. Alvarez-Machain*, the United States Supreme Court determined that the ATS is jurisdictional only, that jurisdiction includes the ability to enforce only a small number of international norms recognized as part of eighteenth century common law, and that the standard for assessing whether any new cause of action brought under the ATS can be recognized by federal courts is that the international norm or rule must be specific, universal, and obligatory. *Sosa v. Alvarez-Machain*, 542 U.S. 692, 748 (2004) (quoting *In re Estate of Marcos Human Rights Litigation*, 25 F.3d 1467, 1475 9th Cir. 1994)).

To frame her ATS claim, Mbole relies on the Nuremberg Code; the Declaration of Helsinki; guidelines of the Council for International Organizations of Medical Services; Article 7 of the International Covenant on Civil and Political Rights; The Council of Europe’s Convention of Human Rights; the European Parliament’s Clinical Trial Directives of 2001; UNESCO’s Universal Declaration of Bioethics and Human Rights; and the Protocol to the African Charter on Human and Peoples’ Rights on the Rights of Women in Africa. Mbole alleges that nonconsensual medical experimentation violates the law of nations and, therefore, the laws of the United States. *See Abdullahi v. Pfizer, Inc.*, 562 F.3d 163, 184 (2d Cir. 2009) (holding that “prohibition on nonconsensual medical experimentation on human beings constituted a universally accepted norm of customary international law, and consequently an alleged violation thereof fell within jurisdiction of Alien Tort Statute”). We decline to consider these arguments,

because we find that there is no corporate liability under the ATS even for actions that violate international law.

III. Corporate Liability

The classic focus of international law is on states and nations, not private individuals or entities. Mbole may proceed with her claims only if she can establish the ATS allows for claims against corporations. In support of her argument that it does, Mbole first argues that the court should look to federal common law, which allows for tort liability of corporations, rather than to international law. She further argues that even if this Court looks to international law, there is universal support for holding corporations liable. The Court disagrees with both assertions.

The Second Circuit recently rejected similar claims that because United States common law permits corporate tort liability, federal courts have jurisdiction under the ATS to hear claims against United States corporations for violation of international law. *See Kiobel v. Royal Dutch Petroleum, Co.*, 621 F.3d 111 (2d Cir. 2010).⁴ That circuit reasoned the ATS conferred “jurisdiction over a limited number of offenses defined by *customary international law*,” and that courts must “look beyond rules of domestic law—however well-established they may be—to examine the specific and universally accepted rules that the nations of the world treat as binding *in their dealings with one another*.” *Id.* at 118 (footnote omitted). Thus, the issue is not whether the United States has recognized corporate liability as a norm, but whether corporations may be held liable as a matter of international law. *See id.*

⁴ While the Second Circuit held it lacked subject matter jurisdiction to hear the plaintiffs’ claims, we agree with the Federal District Court for the Southern District of Indiana that there is significant conflicting authority on that issue and that given the gravity of the matter, the better course of action is to assume this Court has jurisdiction to consider the issue on its merits. *See Flomo v. Firestone Natural Rubber Co.*, 744 F. Supp. 2d 810, 813 (S.D. Ind. 2010).

This Court finds *Kiobel's* reasoning persuasive in light of the Supreme Court's admonitions in *Sosa*. In *Sosa*, the Supreme Court instructed the lower federal courts to consider "whether international law extends the scope of liability for a violation of a given norm to the perpetrator being sued, if the defendant is a private actor such as a corporation or individual." *Sosa*, 542 U.S. at 732 n. 20. Justice Breyer's concurrence interpreted the court's opinion as requiring that "[t]he norm...extend liability to the type of perpetrator (e.g. a private actor) the plaintiff seeks to sue." *Id.* at 760 (Breyer, J. concurring). We must, therefore, turn to customary international law to determine whether there is a norm that extends liability to the alleged perpetrator in this case, a corporation.

We find no consensus in customary international law that the scope of liability is extended to corporations, particularly when no *jus cogens* violation is being alleged. International tribunals have declined to hold corporations liable since the Nuremberg era. No tribunal at Nuremberg had the jurisdiction to impose judgment on a corporation. The military tribunals established under Control Council Law No. 10 expressly defined liability under the law of nations as liability that could not be divorced from individual moral responsibility. *See Kiobel*, 621 F.3d at 135-36.⁵ Similarly, the charters establishing both the International Criminal Tribunal for the former Yugoslavia and the International Criminal Tribunal for Rwanda limited the jurisdiction of those tribunals to natural persons. *See Statute of the International Criminal Tribunal for the Former Yugoslavia*, S.C. Res. 827, U.N. Doc S/RES/827 (May 25, 1993)

⁵ The United States Military Tribunals, established under Control Council Law No. 10, prosecuted corporate executives for their role in violating customary international law during the Second World War, but not the corporate entities themselves. *See generally* Control Council Law No. 10, Punishment of Persons Guilty of War Crimes, Crimes Against Peace and Against Humanity, in 1 *Enactments and Approved Papers of the Control Council and Coordinating Committee, Allied Control Authority Germany* 306 (1945), available at http://www.loc.gov/rr/frd/Military_Law/Enactments/Volume-I.pdf (last visited Oct. 7, 2010).

(adopting U.N. Secretary-General, *Report Pursuant to Paragraph 2 of Security Council Resolution 808*, art. 6, U.N. Doc. S/25704 (May 3, 1993)).

Additionally, the 1998 Rome Statute of the International Criminal Court applies only to “natural persons.” Rome Statute of the International Criminal Court art. 25(1), July 17, 1998, 2187 U.N.T.S. 90, available at http://www.icc-cpi.int/NR/rdonlyres/EA9AEFF7-5752-4F84-BE94-0A655EB30E16/0/Rome_Statute_English.pdf (last visited Oct. 7, 2010). As recently as 2007, the United Nations Special Representative of the Secretary-General observed that a proposal had been debated that would have given the International Criminal Court (ICC) jurisdiction over legal persons (which would have included corporations) but that it was not adopted because of the unwillingness of some States to adopt binding human rights standards for corporations. U.N Human Rights Council, Report of the Special Representative of the Secretary-General, *Business and Human Rights: Mapping International Standards of Responsibility and Accountability for Corporate Acts*, ¶¶ 22, 44, U.N. Doc. A/HRC/4/035 (Feb. 9, 2007) available at http://ap.ohchr.org/documents/alldocs.aspx?doc_id=12900 (last visited Oct. 7, 2010).

Moreover, the fact the Torture Victim Protection Act of 1991 (TVPA) does not permit claims against corporations further undermines Mbole’s arguments that there is an established norm of corporate liability. See Pub. L. No. 102-256, 106 Stat. 73 (codified at 28 U.S.C. § 1350 note). The TVPA creates a civil damages remedy against “[a]n individual, who, under actual or apparent authority, or color of law, of any foreign nation . . . subjects an individual to torture . . . or . . . extrajudicial killing.” Id. § 2(a)(1)-(2). The TVPA “enacted to codify a classic (pre-*Sosa*) ATS claim.” *Flomo v. Firestone Natural Rubber Co.*, 744 F. Supp. 2d 810, 817 (S.D. Ind. 2010). While the TVPA was enacted pre-*Sosa*, it nonetheless provides some guidance to

indicate that when specifically considering the issue, Congress rejected corporate liability. *See id.*

The Second Circuit's decision in *Kiobel* extensively reviewed the sources of international law identified in Article 38 of the Statute of the International Court of Justice. *See Kiobel*, 621 F.3d at 132-45. After that extensive review, the court concluded that corporate liability is not a well-defined and universal norm of international law. *See id.* at 145. Even Judge Leval, in a strongly worded separate opinion arguing for corporate liability, agreed that "international law, of its own force, imposes no liabilities on corporations or other private juridical entities." *Id.* at 186 (Leval, J., concurring in judgment).

This Court concludes that corporate liability has simply not achieved the universal acceptance necessary in order to permit a claim under the ATS. To the contrary, international law has consistently refused to hold corporations liable. While Mbole might have been able to state claims against individual actors under the facts of this case, she has chosen instead to pursue Pharmex corporation. Unfortunately for Mbole, the ATS does not permit this claim.

III. Conclusion

Plaintiffs have failed to state a legally cognizable claim under the ATS. Defendant is entitled to dismissal of all of Plaintiff's claims.

ORDER

Defendant's motion for dismissal is GRANTED.

SO ORDERED

Lee Smith, District Judge
October 11, 2010

**IN THE UNITED STATES COURT OF APPEALS
FOR THE TWELFTH CIRCUIT**

No. 299-02-2011

**Faith Mbole, individually and on behalf of all others similarly situated,
Appellant,**

v.

**Pharmex, Inc.,
Appellee.**

Appeal from the United States Federal Court for the District of Lincoln,
Case No. 09-1332-CIV—Lee Smith, District Judge

Argued April 29, 2011 – Filed July 15, 2011

Before: Kohlmann, Chief Judge, Tanner, Dunphy, Circuit Judges.

Tanner, Circuit Judge:

This appeal arises out of litigation about whether the pharmaceutical company, Appellee Pharmex carried out nonconsensual experimentation on Zinerian women during the fall of 2002. A class of Zinerian women who died or were seriously disabled following the experiment, represented by Appellant Mbole, herself alleged to have been paralyzed by the experiment, allege pursuant to the Alien Tort Statute (ATS) that Pharmex violated international law prohibiting nonconsensual medical experimentation. Pharmex moved to dismiss plaintiff's complaint for failure to state a claim upon which relief may be granted. The Federal District Court for the District of New Lincoln found that there was no corporate liability under the ATS, and ordered dismissal of all claims. Mbole then filed an appeal of that dismissal.

We disagree with the district court that Mbole has failed to allege a claim upon which relief can be granted. We first find that corporations are proper parties under the ATS. We then find that Appellant Mbole has articulated a claim for violation of a norm of customary

international law prohibiting nonconsensual human experimentation. We therefore reverse the district court's order of dismissal and remand this matter for further proceedings consistent with this opinion.

The stipulated facts are set out in detail in the district court's opinion, and we will not repeat them here. Suffice it to say that Pharmex conducted an experimental drug trial on 150 women infected with SX2, all of whom were citizens of Parrottown, Biango State, Zineria, at the time. This drug trial had such disastrous results that the experiment was terminated early. Pharmex obtained the consent of the drug trial participants through the local council of elders, as was the custom in that region. Pharmex also received approval of its experiment from a regional medical research ethics committee. At no point, however, did Pharmex receive individual informed consent from the drug trial participants themselves. A class action suit was brought on behalf of several of those participants or their legal representatives (in the case of diseased participants), seeking compensation for their injuries under the ATS. We must now decide whether the claims asserted by these individuals can be pursued under that statute.

DISCUSSION

I. Corporate Liability under the Alien Tort Statute

In its entirety, the ATS provides that “[t]he district courts 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.” 28 U.S.C. § 1350 (2006). This language is derived with little alteration from the Judiciary Act of 1789, ch. 20, § 9(b), 1 Stat. 73 76-77. *Flores v. Southern Peru Copper Corp.*, 414 F.3d 233, 242 (2d Cir. 2003).

The ATS is a unique jurisdictional provision in American law. As Judge Henry J. Friendly, a distinguished student and practitioner of international law before his appointment to

the federal bench, wrote, the ATS “is a kind of legal Lohengrin ... no one seems to know whence it came.” *IIT v. Vencap, Ltd.*, 519 F.2d 1001, 1015 (2d Cir. 1975). The ATS lay largely dormant for nearly 200 years. In 1980, the statute was revived by the Second Circuit, which held that the United States had jurisdiction in a lawsuit brought by two Paraguayans charging former Paraguayan official Americo Peña-Irala, then residing in the U.S., with the torture and wrongful death of their family member, Joelito Filartiga. *Filartiga v. Pena-Irala*, 630 F.2d 876 (2d Cir. 1980). Since *Filartiga*, aliens have used the ATS to pursue a variety of international human rights cases in United States federal courts. After 1997, when Burmese villagers brought an ATS suit against the United States oil company Unocal Corporation and its subsidiary Union Oil Company of California for complicity in forced labor, rape, and murder, numerous ATS lawsuits have also been brought against United States corporations. *Doe v. Unocal Corp.*, 963 F. Supp. 880 (C.D. Cal. 1997), *aff’d in part and rev’d in part*, 395 F.3d 932 (9th Cir. 2002).

Corporate liability under the ATS was in fact assumed, until this past year when the Second Circuit issued its decision in *Kiobel v. v. Royal Dutch Petroleum, Co.*, 621 F.3d 111 (2d Cir. 2010). In *Kiobel*, that court concluded it lacked subject matter jurisdiction over claims against corporations because it found no universal norm of international law that permitted such claims. *Id.* at 149. As the Seventh Circuit has more recently pointed out in overruling the lower court opinion in *Flomo v. Firestone Natural Rubber Co.* relied upon by the district court in this case, however, while “[i]nternational law imposes substantive obligations[,] the individual nations decide how to enforce them.” *Flomo v. Firestone Natural Rubber Co.*, No. 10-3675, 2011 WL 2675924 at *5 (7th Cir. July 11, 2011). Thus, *Kiobel* is mistaken in looking to international rather than domestic law to determine the scope of corporate liability. *See id.* at *5-6. Civil corporate liability is long established in United States law for actions such as those

alleged in this case, in which there is no question that the actions were directed and supported by the corporation. *See id.* at *6 (noting the standard of corporate liability).

Mbole has, therefore, stated a claim over which the court has jurisdiction. Whether she has stated a claim upon which relief can be granted depends on whether the Pharmex's actions violate a norm of customary international law that is sufficiently "specific, universal, and obligatory." *See Sosa*, 542 U.S. at 732. For that reason, we will consider that issue not addressed by the court below.

II. Violation of CIL Prohibiting Nonconsensual Human Experimentation.

We now turn to the merits of Mbole's international law claims. Despite a flurry of ATS suits, appellate review of ATS suits has been uncommon, and the Supreme Court has given detailed consideration to the ATS only once, in *Sosa v. Alvarez-Machain*, 542 U.S. 692 (2004). The *Sosa* Court, citing *The Paquete Habana*, affirmed that the domestic law of the United States recognizes the law of nations. *Sosa*, 542 U.S. at 730 (citing *The Paquete Habana*, 175 U.S. 677, 700 (1900)). The Court concluded, however, that any claim based on the present-day law of nations under the ATS should rest on a norm of international character accepted by the civilized world and defined with a specificity comparable to the features of the recognized eighteenth century paradigms – that is, the three common law international law wrongs identified by Blackstone, "violation of safe conducts, infringement of the rights of ambassadors, and piracy." *Id.* at 725-26. Despite this cautionary note, the Court left the door "ajar" to some international human rights litigation in federal courts, "subject to vigilant doorkeeping" by the courts. *Id.* at 729. Courts may recognize new actionable rules based on evolving principles of international law. *Id.* at 714.

Mbole claims that Pharmex’s conduct violated the “law of nations” —commonly referred to as “international law” or, when limited to non-treaty law, as “customary international law.” Mbole does not claim any violation of a United States treaty; rather she alleges a violation of customary international law. Sources identified by Article 38 of the Statute of the International Court of Justice as authorities providing “competent proof of the content of customary international law” include:

- (a) international conventions, whether general or particular, establishing rules expressly recognized by the contesting states;
- (b) international custom, as evidence of a general practice accepted as law;
- (c) the general principles of law recognized by civilized nations;
- (d)... judicial decisions and the teachings of the most highly qualified publicists of the various nations, as subsidiary means for the determination of rules of law.

Statute of the International Court of Justice, art. 38(1), June 26, 1945, 59 Stat. 1055, 1060. When consensus has been reached among these authorities about a norm that is universal, specific and obligatory, *Sosa* permits federal jurisdiction under the ATS. *Sosa*, 542 U.S. at 738.

We are therefore called upon to determine whether any norm of international law is sufficiently (i) universal and obligatory, (ii) specific and definable, and (iii) of mutual concern, to permit a cause of action under the ATS when human experimentation is conducted based on community consent rather than individualized consent. We must be clear that in this case, we are not addressing a situation in which there has been no permission of any kind (other than that of government officials) granted. All parties to this appeal, as well as our dissenting colleague, agree that a cognizable norm would clearly have been violated in that context. Instead, we address the more narrow question asked here—whether human experimentation conducted without individualized consent, but with community consent, meets the *Sosa* jurisdictional standard. We find that it does.

A. Universality

The district court properly noted the foremost authorities supporting the norm prohibiting nonconsensual human experimentation. Each of these authorities prohibits nonconsensual experimentation, as do laws, regulations, and guidelines in over 100 countries. *See* U.S. Department of Health and Human Services Office for Human Research Protections, *International Compilation of Human Research Protections* (2011 Edition), available at <http://www.hhs.gov/ohrp/international/intlcompilation/hspcompilation-v20101130.pdf> (last visited June 30, 2011). We examine below four international authorities that make it particularly clear that substituting the community consent or permission of a “council of elders” for that of an adult woman is part of that same prohibition: the World Medical Association’s Declaration of Helsinki; The Council for International Organizations of Medical Sciences’ International Ethical Guidelines for Biomedical Research Involving Human Subjects; The United Nations Educational Scientific and Cultural Organization’s Universal Declaration of Bioethics and Human Rights; and the African Union’s Protocol to the African Charter on Human and Peoples’ Rights on the Rights of Women in Africa.

For example, the World Medical Association’s Declaration of Helsinki, adopted in 1964 and subsequently amended, states in part: “Participation by competent individuals as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no competent individual may be enrolled in a research study unless he or she freely agrees.” World Medical Association, *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects* ¶ B(22), (1964, last amended 2008), available at <http://www.wma.net/en/30publications/10policies/b3/17c.pdf> (last visited June 30, 2011). Similar provisions can be found in Guideline 4 of the *International Ethical Guidelines for*

Biomedical Research Involving Human Subjects, issued by the Council for International Organizations of Medical Sciences, a nongovernmental organization under the auspices of the World Health Organization . See Council for International Organizations of Medical Sciences (CIOMS), *Guidelines for Biomedical Research Involving Human Subjects*, Guideline 4 (2002), available at http://www.cioms.ch/publications/layout_guide2002.pdf (last visited June 30, 2011). Commentary on Guideline 4 elaborates on the role of cultural considerations in human subjects research and makes clear that “[i]n no case . . . may the permission or a community leader or other authority substitute for individual informed consent.” *Id.* at 32.

Specific to the rights of women, Commentary to Guideline 16, “Individual consent of women,” provides that “[i]n research involving women of reproductive age, whether pregnant or non-pregnant, only the informed consent of the woman herself is required for her participation. In no case should the permission of a spouse or partner replace the requirement of individual informed consent. *Id.* at 73. Similarly, the Organization of African Unity’s (now African Union) Protocol seeks to prohibit all medical and scientific experiments on women without their prior informed consent: “States Parties shall take appropriate and effective measures to: . . . prohibit all medical or scientific experiments on women without their informed consent.” See Protocol to the African Charter on Human and Peoples' Rights on the Rights of Women in Africa, art. 4(2)(h) (adopted July 11, 2003), available at http://www.achpr.org/english/info/women_en.html (last visited June 30, 2011).

Provisions similar to the above can also be found in the General Conference of the United Nations Educational Scientific and Cultural Organization’s Universal Declaration on Bioethics and Human Rights. See United Nations, Educ., Scientific & Cultural Org. (UNESCO), *Universal Declaration on Bioethics and Human Rights*, art. 6, 12, U.N. Doc. SHS/EST/BIO/06/1 (2005),

available at <http://unesdoc.unesco.org/images/0014/001461/146180E.pdf> (last visited June 30, 2011).

Pharmex's alleged conduct lies at the core of the international prohibition articulated by these authorities. None of the documents on which this norm rests permits an exception from individualized consent for women. In fact, four authorities specifically prohibit such an exception. Though an exception from individualized consent for women may at one time in human history have been acceptable, it clearly is not today.

B. Specificity

Sosa requires that a norm be no “less definite [in] content...than the historical paradigms familiar when [the ATS] was enacted.” *Sosa*, 542 U.S. at 732. Comparing degrees of definiteness is a difficult task. Nevertheless, the norm prohibiting nonconsensual human experimentation is, as the Second Circuit observed, even more concrete than those eighteenth century paradigms. *Abdullahi v. Pfizer, Inc.*, 562 F.3d 163, 184 (2d Cir. 2009) In recognizing a norm such as the prohibition against nonconsensual experimentation, it is not necessary to specify every category of nonconsent to which individuals might be subjected at the hands of researchers, or every category of human subjects whose rights may be violated. Courts have widely held that “categorical specificity” is not required before an international norm is cognizable under the ATS. *See Bowoto v. Chevron Corp.*, 557 F.Supp.2d 1080, 1093 (N.D. Cal. 2008) (denying summary judgment of claims of cruel, human and degrading treatment even though “[t]here is no widespread consensus regarding the elements of [cruel, human and degrading treatment]”).

The Second Circuit placed disclosure of information about the placebo design of an experiment at the fringe of the norm, along with best practices for conducting informed consent procedures when the subject of the experiment is illiterate. *Abdullahi*, 562 F.3d at 185. But

disagreements about what information to disclose and how to disclose it do not affect the fact that women of all cultures are included within the core of the norm requiring disclosure to, and consent from, the subject. When a prohibition is cognizable under the ATS, as is the norm prohibiting nonconsensual medical experimentation, the proscription is not dependent on attributes possessed by the potential victim. The international law norm prohibiting nonconsensual experimentation permits no exception for women or other socially or culturally disadvantaged groups, no matter what the local cultural practice.

C. Mutual Concern

For a norm to become part of customary law, states must universally abide by, or accede to, it out of a sense of legal obligation and mutual concern. *See Sosa*, 542 U.S. at 732-35, *Flores*, 414 F.3d at 248. Offshoring of pharmaceutical experimentation is a recent development that can profoundly affect the relations among the United States (where most of the largest pharmaceutical corporations are headquartered), the nations that host their clinical trials, and, in an increasingly interconnected world, other nations. The alleged violation of the norm prohibiting nonconsensual experimentation by Pfizer in Kano, Nigeria in 1996, which was attributed as a major factor in a subsequent outbreak of polio across much of Africa as well as the Middle East, amply illustrates this global interconnectedness. *See Abdullahi*, 562 F.3d at 186 (recounting published reports regarding the consequences of Pfizer's actions in Nigeria).

The geographic and political impact of Pharmex's Atramine experiment has, fortunately, been more contained. Nonetheless, the alleged conduct caused threats of violence in several nations and has jeopardized relations between the United States and Zineria. For these reasons, Mbole has alleged conduct by Pharmex that violates an international law norm to which nations adhere out of a sense of legal obligation and mutual concern

CONCLUSION

Based on the foregoing, we REVERSE the District Court's dismissal of the complaint and REMAND for further proceedings.

Dunphy, J., concurring and dissenting:

I concur in judgment with Part I of the Court's opinion but respectfully dissent from Part II.

I. Corporate Liability under the ATS

I believe the majority incorrectly concludes that corporate liability under the ATS is a matter of domestic, rather than international, law. The ATS remedies violations of the law of nations, and the law of nations must support corporate liability. However, I agree that civil corporate liability is universally established and that the district court may properly consider the merits of Mbole's claims. I believe, like Judge Posner in *Flomo v. Firestone Natural Rubber Co.*, that the Second Circuit in *Kiobel* focused too much on whether there is criminal corporate liability under international law. I believe Judge Posner correctly articulates the basis for finding an international norm supporting civil corporate liability and I would adopt his reasoning in total.

II. The Prohibition on Nonconsensual Human Experimentation

Although I believe the lower court had jurisdiction over Mbole's claims, I would not remand the case because I believe she has not alleged a cognizable ATS claim. As my colleagues acknowledge, the Supreme Court has set the bar high for claims to be actionable under the ATS. *Sosa v. Alvarez-Machain*, 542 U.S. 692 (2004). The question of whether there is a claim under the ATS turns on whether the alleged conduct—not the general characteristics of the claim—violates international norms that are specific, universal and obligatory. *See Doe v. Qi*, 349 F. Supp 2d 1258, 1278 (N.D. Cal. 2004) (finding that alleged human rights violations

committed by local government officials of PRC were sufficiently attributable to the government of China so as to constitute an act of state.). Pharmex’s alleged conduct, though not ideal, does not qualify as a violation of this norm prohibiting nonconsensual experimentation.

Pharmex sought and received consent from the Parrottown’s village elders, as well as approval from a regional research ethics committee—steps recommended by experts in the ethics of international health research.⁶ Although the consent Pharmex obtained could not be considered ideal by Western standards, it was a form of consent. And although Pharmex did not disclose the placebo-controlled design of the experiment, disclosure of that information clearly is at the fringes of the norm. *Abdullahi*, 562 F.3d at 185. n.15. Therefore Pharmex’s alleged conduct does not implicate a prohibition on nonconsensual experimentation that is actionable under the ATS.

The prohibition on nonconsensual experimentation proscribes only egregious conduct, such as Pfizer’s alleged failure to seek or secure the consent of either the Nigerian children or their guardians for its 1996 Trovan experiment. *Abdullahi*, 562 F.3d at 169.⁷ Pharmex’s alleged wrongdoing in Zineria pales in comparison to Pfizer’s alleged conduct in Nigeria. The allegations against Pharmex may describe less than ideal conduct, but not conduct that rises to

⁶ Individual informed consent is today viewed as ethically insufficient in international health research. Obtaining consent from the community was a necessary, if not entirely sufficient, step in carrying out the Atramine experiment. *See, e.g.*, David Buchanan, et al., *Assuring Adequate Protections in International Health Research: A Principled Justification and Practical Recommendations for the Role of Community Oversight*, Public Health Ethics 1, no. 3 (2008) 246-257 (asserting that individual informed consent and research ethics committee review should be supplemented by required community oversight of health research conducted in international settings).

⁷ The protocol in *Abdullahi* required researchers to offer or read documents to the subjects that would have requested and facilitated their informed consent. *Abdullahi*, 562 F.3d at 169-70. The plaintiffs alleged this was never done, either in English or the subject’s native language. *Id.*

the level of a violation of the universally recognized international law prohibiting nonconsensual experimentation.

As in *Sosa*, the question here is not so much whether the prohibition exists, but more whether the conduct is sufficient to fall within the scope of the norm. *Sosa* concluded that the conduct alleged did not breach the norm invoked. *Sosa*, 542 U.S. 692 at 762. Because there is no established international norm prohibiting all experimentation except that to which the subject has given individualized consent, the majority has attempted to create a new norm, into the scope of which Pharmex's alleged conduct might fall. Several of the authorities upon which the majority relies postdate the events at issue, however, specifically the 2003 African and the 2005 UNESCO documents. These cannot be the basis for the supposed norm in this case, regardless.

Other authorities relied upon by the majority actually permit consent by someone other than the subject of the experiment. For example, the Helsinki Declaration referenced by the majority states in part, "For a research subject who is legally incompetent, physically or mentally incapable of giving consent or is a legally incompetent minor, the investigator must obtain informed consent from the legally authorized representative in accordance with applicable law." *Declaration of Helsinki*, at ¶ B(27). The Convention for the Protection of Human Rights and Dignity of the Human Being permits numerous exceptions to the majority's proposed prohibition on experimentation without the individual's consent— including minors and adults without the capacity to consent. See Council of Europe, *Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine* art. 6, Apr. 4, 1997, E.T.S. No. 164, available at <http://conventions.coe.int/Treaty/EN/Treaties/html/164.htm> (last visited June 30, 2011).

Experiments on those with serious mental disorders and those in an emergency situation may be carried out without any consent at all. *See id.* art.7, 8.

Even in the United States, the general requirements for informed consent found in the Department of Health and Human Services regulations permit consent by someone other than the subject of the experiment. *See* 45 C.F.R. § 46.116 (2010). Further, the current Director of the Office for Human Research Protections admitted only a few years ago that there is no consensus among U.S. states about the criteria for determining whether an adult person is or is not capable of personally deciding whether to participate in research. *See* Jerry Menikoff and Edward P. Richards, *What the Doctor Didn't Say: The Hidden Truth About Medical Research* Oxford University Press, 149-154 (2006). The authorities on which the majority depends therefore recognize and make accommodation for the fact that an “ideal” consent cannot always be obtained from research subjects. Having recognized this reality, they do not insist, as the majority would, on each subject’s personal consent. Neither the community consent that Pharmex allegedly relied upon nor consent by a legally authorized representative that these authorities urge researchers to rely upon is the precise equivalent of the consent of the individual subject of the experiment; but each is *a form of* consent, designed to accommodate the perceived vulnerabilities of experimental subjects.

Disregarding *Sosa*’s warnings, the majority has taken the incautious step of creating a new norm because Pharmex’s alleged conduct simply did not fall within the scope of the norm that is “firmly established.” The majority’s rule regarding individual consent may represent an ideal. Agreements or declarations that are merely aspiration, however, are of “little utility” in discerning norms of customary international law. *Sosa*, 542 U.S. at 734. Women’s individual consent may, at some point, evolve into a settled rule of international law. In order for a norm to

have “ripened ... into ‘a settled rule of international law,’” however, it must command “the general assent of civilized nations.” *Filartiga*, 630 F.2d at 881 (quoting *The Paquete Habana*, 175 U.S. 677, 694(1900)). At this point, such a norm does not command that level of assent. At best, the majority’s norm is aspirational. At worst, it is the result of judicial imperialism. No nation or culture, however, is free to impose its own rules upon others, in the name of applying international law.

In summary, a prohibition on completely nonconsensual experimentation would be actionable under the Alien Tort Statute, but Mbole has not made that allegation. She has alleged conduct that violated a norm the majority has created: a prohibition on experimentation that has community or surrogate consent. The authorities the majority relies upon to create this new norm do not uniformly indicate that such a norm satisfies the requirements of *Sosa*. Mbole has not stated a claim upon which relief can be granted and I would uphold dismissal of her claims on this basis alone.

Supreme Court of the United States

Pharmex, Inc., Petitioner

v.

Faith Mbole, individually
and on behalf of all others
similarly situated, Respondent

No. 11-1023

July 26, 2011

Petition for writ of certiorari to the Twelfth Circuit Court of Appeals is granted limited to the following Questions:

1. Whether there is corporate liability under the Alien Tort Statute.
2. Whether nonconsensual human experimentation when community consent but not individual consent has been given may be the basis for a claim under the Alien Tort Statute.

IT IS SO ORDERED.