

**UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT**

August Term, 2006

(Argued: July 12, 2007)

Decided: January 30, 2009)

Docket Nos. 05-4863-cv (L), 05-6768-cv (CON)

Rabi Abdullahi, individually and as the natural guardian and personal representative of the estate of her daughter Lubabatau Abdullahi, Salisu Abullahi, individually and as the natural guardian and personal representative of the estate of his son Abulliahi {Manufi} Salisu, Alasan Abdullahi, individually and as the natural guardian and personal representative of the estate of his daughter Firdausi Abdullahi, Ali Hashimu, individually and as the natural guardian and personal representative of the estate of his daughter Suleiman, Muhammadu Inuwa, individually and as the natural guardian and personal representative of the estate of his son Abdullahi M. Inuwa, Magaji Alh Laden, individually and as the natural guardian and personal representative of the estate of his son Kabiru Isyaku, Alhaji Mustapha, individually and as the natural guardian and personal representative of the estate of his daughter Asma`u Mustapha, Suleiman Umar, individually and as the natural guardian and personal representative of the estate of his son Buhari Suleiman, Zainab Abdu, a minor, by her mother and natural guardian, Haja Abdullahi, Haji Abdullahi, individually, Firdausi Abdullahi, a minor, by her father and natural guardian Abdullahi Madawaki, Abdullahi Madawaki, individually, Sani Abdullahi, a minor, by his father and natural guardian, Sani Abdullahi, Abdullahi Ado, a minor, by his mother and natural guardian, Aisha Ado, Aisha Ado, individually, Abdumajid Ali, a minor, by his father and natural guardian, Alhaji Yusuf Ali, Nura Muhammad Ali, a minor, by his father and natural guardian, Muhammad Ali, Muhammad Ali, individually, Umar Badamasi, a minor, by his father and natural guardian, malam Badamasi Zubairu, Malam Badamasi Zubairu, individually, Muhammadu Fatahu Danladi, a minor, by his father and natural guardian, Alhaji Danladi Ibrahim, Alhaji Danaldi Ibrahim, individually, Dalha Hamza, a minor, by his father and natural guardian malam Hamza Gwammaja, Malam Gwammaja, individually, Tasiu Haruna, a minor, by his guardian Mukhtar Saleh, Mukhtar Saleh, individually, Muhyiddeen Haasan, a minor, by his father and natural guardian, Tijjani Hassan, Tijjani Hassan, individually, Kawu Adamu Ibrahim, a minor, by his father and natural guardian, Malam Abamus Ibrahim Adamu, Alhaji Ibrahim Haruna, individually, Mallam Idris, individually, Yusuf Idris, a minor, by his father

and natural guardian, Idris Umar, Idris Umar, individually, Hafsat Isa, a minor, by her father and natural guardian, Isa Muhammed Isa, Isa Muhammed Isa, individually, Tajua Isa, a minor, by her father and natural guardian, Malam Isa Usman, Malam Isa Usman, individually, Hadiza Isyaku, a minor, by her father and natural guardian, Isyaki Shuaibu, Isyaku Shuaibu, individually, Zahra`u Jafaru, a minor, by her father and natural guardian, Jafaru Baba, Jafaru Baba, individually, Anas Mohammed, a minor, by his father and natural guardian, Malam Mohammed, Malam Mohammed, individually, Nafisatu Muhammed, a minor, by her mother and natural guardian, Yahwasu Muhammed, Yahwasu Muhammed, individually, Muhsinu Tijjani, a minor, by his father and natural guardian, Tijjani Hassan, Alhaji Yusuf Ali, Maryam Idris, a minor, by her father and natural guardian, Malam Idris, Ajudu Ismaila Adamu, individually and as parent and natural guardian of Yahaya Ismaica, minor, Malam Mohammed, individually and as parent and natural guardian of Bashir Mohammed, minor, Malam Yusab Ya`u Amale, individually and as parent and natural guardian of Suyudi Yusals Yu`a, minor, Malam Haruna Adamu, individually and as parent and natural guardian of Mohammed Tasi`u Haruna, minor, Zangon Kwajalawa, individually and as parent and natural guardian of Nuruddim Dauda, minor, Malam Dahauru Ya`y, individually and as parent and natural guardian of Rabi Dahuru, minor and as parent and natural guardian of Zainab Musa Dahuru, minor, Zangon Marikita, individually and as parent and natural guardian of Ismaila Musa, minor, Arhaji Muihammad Soja, individually and as parent and natural guardian and personal representative of Estate of Hamaza Achaji Muhammad, minor, deceased, Achaji Ibrahim Dankwalba, individually and as parent and natural guardian of Personal Representative of Est of Abdullahi Ibrahim, minor, Mallam Lawan, individually and as parent and natural guardian and personal representative of Est. of Aisha Lawan, minor, deceased, Alhaji Muhammed Tsohon Sojo, individually and as parent and natural guardian and personal representative of Est. of Unni Alhasi Muhammed, minor, Ismaila Zubairui, individually and as parent and natural guardian and personal representative of Est. of Mustapha Zubairu, minor, Deceased, Abubaker Musa, individually and as parent and natural guardian of Sa`adatu Musa, Minor, Mohamed Abdu, individually and as parent and natural guardian of Haruna Abdu, minor, Mallam Hassan, individually and as parent and natural guardian and personal representative of Est. of Sadiya Hassan, minor, deceased, Mallam Yakubu Umar, individually and as parent and natural guardian of, Mallam Samaila, individually and as parent and natural guardian of Adamu Samalia, minor, Musa Yahaya, individually and as parent and natural guardian of Ukhasa Musa, minor, Audu Ismaila Adamu, individually and as parent and natural guardian of Yashaya Samaila, Malam Musa Dahiru, individually and as parent, Malam Musa Zango, individually and as parent and natural guardian of Samaila Musa, minor, Mallam Alhassan Maihula, individually and as a parent and natural guardian of Najib Maihula, minor, Mallam Abdullah Gama, individually and as parent and natural guardian of Dankuma Gama, Minor, Dauda Nuhu, individually and as parent and natural guardian and personal representative of Est. of Hamisu Nuhu, minor, deceased, Mallam Abdullahi, individually and as parent and natural guardian and personal representative of Est. of Najaratu Adbullahi, minor, deceased, Malam Umaru Mohammed, individually and as parent and

natural guardian and personal representative of Est. of Sule Mohammed, minor, deceased, Mallam Nasiru, individually and as parent and natural guardian and personal representative of Est. of Yusuf Nasiru, minor, deceased, Yusuf Musa, individually and as parent and natural guardian and personal representative of Est. of Nafisatu Musa, minor, deceased, Mallam Muritala, individually and as parent and natural guardian and personal representative of Est. of Umaru Muritala, minor, deceased, Mallam Tanko, individually and as parent and natural guardian and personal representative of Est. of madina Tankol, minor deceased, Mallam Sheu, individually and as parent and natural guardian and personal representative of Est. of Madina Tankol, minor, deceased, Malam Kabiru Mohamed, individually and as parent and natural guardian and personal representative of Est. of Kabiru Mohamed, minor, deceased, Mallam Sule Abubakar, individually and as parent and natural guardian and personal representative of Est. of Fatima Abubaker, minor, deceased, Mallam Idris, individually and as parent and natural guardian and personal representative of Est. of Baba Idris, minor, deceased, Mallam Mohamed Bashir, individually and as parent and natural guardian and personal representative of Est. of Sani Bashir, minor, deceased, Ibrahim, individually and as parent and natural guardian and personal representative of Est. Hassan Ibrahim, minor, deceased, Alhaji Shuaibu, individually and as parent and natural guardian and personal representative of Est. of Masjbatu Shuaibu, minor, deceased, Mallam Abdullahi Sale, individually and as parent and natural guardian and personal representative of Est. of Shamisiya Sale, minor, deceased, Mallam Ibrahim Amyarawa, individually and as parent and natural guardian and personal representative of Est. of Yahaya Ibrahim, minor, deceased, Mallam Abdu Abubaker, individually and as parent and natural guardian and personal representative of Est. of Nasitu Abubaker, minor, deceased, Mallam Yusuf, individually and as parent and natural guardian and personal representative of Est. of Hodiza Yusuf, minor, deceased, Mallam Dauda Yusuf, individually and as parent and natural guardian and personal representative of Est. of Abubaker Sheu, minor, deceased, Maliam Mohammed Sheu, individually and as parent and natural guardian and personal representative of Est. of Mustapha Yakubu, minor, deceased, Alhaji Ubah, individually and as parent and natural guardian and personal representative of Est. of Maryam Ubah, minor, deceased, Mallam Mohamadu Jabbo, individually and as parent and natural guardian of Auwalu Mohamadu, Mallam Abdullah Adamu, individually and as parent and natural guardian and personal representative of Est. of Abdullah Adamu, minor,

Plaintiffs-Appellants,

v

Pfizer, Inc.,

Defendant-Appellee.

Before: POOLER, B.D. PARKER, and WESLEY, *Circuit Judges*.

Plaintiffs-Appellants appeal from judgments of the United States District Court for the Southern District of New York (Pauley, *J.*) dismissing complaints for lack of subject matter jurisdiction and on the ground of *forum non conveniens*. REVERSED and REMANDED.

Judge Wesley dissents in a separate opinion.

PETER SAFIRSTEIN (Elaine S. Kusel, Ann M. Lipton, Andrew Wilmar, and Tatiana Rodriguez, *on the brief*), MILBERG WEISS BERSHAD & SCHULMAN LLP, New York, NY, *for Plaintiffs-Appellants Rabi Abdullahi, et al.*

RICHARD ALTSCHULER (Ali Ahmad, Cheverly, MD, *on the brief*), ALTSCHULER & ALTSCHULER, West Haven, CT, *for Plaintiffs-Appellants Ajudu Ismaila Adamu, et al.*

STEVEN GLICKSTEIN (David Klingsberg, Maris Veidemanis, James D. Herschlein, and Julie B. du Pont, *on the brief*), KAYE SCHOLER LLP, New York, NY, *for Defendant-Appellee Pfizer, Inc.*

BARRINGTON D. PARKER, *Circuit Judge*:

This consolidated appeal is from the judgments of the United States District Court for the Southern District of New York (Pauley, *J.*) dismissing two complaints for lack of subject matter jurisdiction under the Alien Tort Statute, 28 U.S.C. § 1350 (“ATS”), and in the alternative, on the ground of *forum non conveniens*. Plaintiffs-Appellants Rabi Abdullahi and other Nigerian children and their guardians sued Defendant-Appellee Pfizer, Inc. under the ATS (“the *Abdullahi* action”). They alleged that Pfizer violated a customary international law norm prohibiting involuntary medical experimentation on humans when it tested an experimental antibiotic on children in Nigeria, including themselves, without their consent or knowledge. Plaintiffs-

Appellants Ajudu Ismaila Adamu and others, also children and their guardians who were part of Pfizer's Nigerian drug experiment, brought a similar action against Pfizer, alleging violations of the ATS, the Connecticut Unfair Trade Practices Act ("CUTPA"), and the Connecticut Products Liability Act ("CPLA") ("the *Adamu* action"). Pfizer moved to dismiss both actions for lack of subject matter jurisdiction and on the basis of *forum non conveniens*. The district court granted the motions and both sets of plaintiffs have appealed.

As explained below, we conclude: (1) that the district court incorrectly determined that the prohibition in customary international law against nonconsensual human medical experimentation cannot be enforced through the ATS; (2) that changed circumstances in Nigeria since the filing of this appeal require re-examination of the appropriate forum, albeit on the basis of a legal analysis different from that employed by the district court; and (3) that the district court incorrectly applied Connecticut's choice of law rules in the *Adamu* action. Consequently, we reverse and remand the cases to the district court for further proceedings.

BACKGROUND

A. Pfizer's Trovan Test in Nigeria

On review of a district court's grant of a motion to dismiss, we assume as true the facts alleged in the complaints, construing them in the light most favorable to the appellants. *See Vietnam Ass'n for Victims of Agent Orange v. Dow Chem. Co.*, 517 F.3d 104, 115 (2d Cir. 2008). The central events at issue in these cases took place in 1996, during an epidemic of bacterial

meningitis in northern Nigeria.¹ The appellants allege that at that time, Pfizer, the world's largest pharmaceutical corporation, sought to gain the approval of the U.S. Food and Drug Administration ("FDA") for the use on children of its new antibiotic, Trovafloxacin Mesylate, marketed as "Trovan." They contend that in April 1996, Pfizer, dispatched three of its American physicians to work with four Nigerian doctors to experiment with Trovan on children who were patients in Nigeria's Infectious Disease Hospital ("IDH") in Kano, Nigeria. Working in concert with Nigerian government officials, the team allegedly recruited two hundred sick children who sought treatment at the IDH and gave half of the children Trovan and the other half Ceftriaxone, an FDA-approved antibiotic the safety and efficacy of which was well-established. Appellants contend that Pfizer knew that Trovan had never previously been tested on children in the form being used and that animal tests showed that Trovan had life-threatening side effects, including joint disease, abnormal cartilage growth, liver damage, and a degenerative bone condition. Pfizer purportedly gave the children who were in the Ceftriaxone control group a deliberately low dose in order to misrepresent the effectiveness of Trovan in relation to Ceftriaxone. After approximately two weeks, Pfizer allegedly concluded the experiment and left without administering follow-up care. According to the appellants, the tests caused the deaths of eleven children, five of whom had taken Trovan and six of whom had taken the lowered dose of

¹ Bacterial meningitis is a serious and sometimes fatal infection of the fluids surrounding the spinal cord and the brain. Centers for Disease Control and Prevention, Meningococcal Disease: Frequently Asked Questions (May 28, 2008), <http://www.cdc.gov/meningitis/bacterial/faqs.htm>.

Ceftriaxone, and left many others blind, deaf, paralyzed, or brain-damaged.

Appellants claim that Pfizer, working in partnership with the Nigerian government, failed to secure the informed consent of either the children or their guardians and specifically failed to disclose or explain the experimental nature of the study or the serious risks involved. Although the treatment protocol required the researchers to offer or read the subjects documents requesting and facilitating their informed consent, this was allegedly not done in either English or the subjects' native language of Hausa. The appellants also contend that Pfizer deviated from its treatment protocol by not alerting the children or their guardians to the side effects of Trovan or other risks of the experiment, not providing them with the option of choosing alternative treatment, and not informing them that the non-governmental organization Médecins Sans Frontières (Doctors Without Borders) was providing a conventional and effective treatment for bacterial meningitis, free of charge, at the same site.²

The appellants allege that, in an effort to rapidly secure FDA approval, Pfizer hastily assembled its test protocol at its research headquarters in Groton, Connecticut, and requested and

² The appellants further allege that Pfizer failed to follow its protocol in ways that might have mitigated the harm suffered by the children. They contend that Pfizer violated the protocol by administering Trovan orally even though oral absorption is difficult for sick children; conducting no testing prior to administering the drug to determine whether Nigeria's strain of meningitis might be responsive to Trovan; failing to determine that the children in the test had meningitis; and failing to either exclude from the experiment children with liver or joint problems or to test for such problems, even though Trovan was known to exacerbate them. Although Pfizer's protocol called for children receiving Trovan to be switched to Ceftriaxone if they did not respond well to Trovan, Pfizer allegedly did not conduct regular blood tests of the children or switch those who suffered from Trovan-related side effects to Ceftriaxone.

received permission to proceed from the Nigerian government in March 1996. At the time, Pfizer also claimed to have secured approval from an IDH ethics committee. Appellants allege, however, that the March 1996 approval letter was backdated by Nigerian officials working at the government hospital well after the experiments had taken place and that at the time the letter was purportedly written, the IDH had no ethics committee.³ Appellants also contend that the experiments were condemned by doctors, including one on Pfizer's staff at the time of the Kano trial.

In 1998, the FDA approved Trovan for use on adult patients only. After reports of liver failure in patients who took Trovan, its use in America was eventually restricted to adult emergency care. In 1999, the European Union banned its use.

B. The Proceedings Below

In August 2001, the *Abdullahi* plaintiffs sued Pfizer under the ATS, alleging that the experiments violated international law. In September 2002, the district court granted Pfizer's motion to dismiss the *Abdullahi* claims on the ground of *forum non conveniens*, conditioned on Pfizer's consent to litigation in Nigeria. *Abdullahi v. Pfizer, Inc.*, No. 01 Civ. 8118 (WHP), 2002 WL 31082956, at *12 (S.D.N.Y. Sept. 17, 2002) ("*Abdullahi I*"). It found that Nigeria was an adequate alternative forum despite plaintiffs' contentions about corruption in the Nigerian court

³ A Nigerian physician who was the principal investigator for the test allegedly admitted that his office created the backdated approval letter when the FDA conducted an audit of the experiment in 1997.

system. *Id.* at *8-10. The district court denied Pfizer's motion to dismiss under Rule 12(b)(6), Fed. R. Civ. P., concluding that the plaintiffs adequately alleged that Pfizer's collusion with the Nigerian government made it a state actor. *Id.* at *5-6.

Meanwhile, another group of children and guardians involved in the Trovan experiment sued in the Federal High Court in Kano, alleging claims under Nigerian law. That case, *Zango v. Pfizer International, Inc.*, [2001] Suit No. FHC/K/CS/204/2001 (Nigeria), was dismissed in 2003 after plaintiffs voluntarily discontinued the suit following the removal from the bench of the first judge assigned to the action and the second judge's decision to decline jurisdiction for personal reasons. *Abdullahi v. Pfizer, Inc.*, No. 01 Civ. 8118 (WHP), 2005 WL 1870811, at *5 (S.D.N.Y. Aug. 9, 2005) ("*Abdullahi III*"). On appeal to this Court from the district court's dismissal in *Abdullahi I*, the *Abdullahi* appellants argued that the dismissal of the *Zango* litigation was a result of rampant corruption, which indicated that the Nigerian judicial system could not provide an adequate alternative forum for their action. Given an inconclusive record regarding the events leading to the dismissal of the *Zango* lawsuit, we vacated the judgment and remanded for further fact-finding on *forum non conveniens*. See *Abdullahi v. Pfizer, Inc.*, 77 F. App'x 48, 53 (2d Cir. 2003) (summary order) ("*Abdullahi II*").

In November 2002, following the dismissal of the *Zango* lawsuit, a number of the *Zango* plaintiffs filed the *Adamu* action. They alleged that in planning the Trovan experiment in Connecticut and in conducting the tests in Nigeria without informed consent, Pfizer violated the CUTPA, the CPLA, and the ATS. Eventually, the *Adamu* action was transferred to the Southern

District of New York and consolidated with the *Abdullahi* action. Pfizer then moved to dismiss both cases for failure to state a claim under the ATS and on the basis of *forum non conveniens*. It also moved to dismiss in *Adamu* on the ground that Connecticut choice of law principles require the application of Nigerian law, which bars suit under CUTPA and the CPLA.

The district court granted the motions. *See Abdullahi III*, 2005 WL 1870811; *Adamu v. Pfizer, Inc.*, 399 F. Supp. 2d 495 (S.D.N.Y. 2005). In *Abdullahi III*, Judge Pauley held that while “[p]laintiffs correctly state that non-consensual medical experimentation violates the law of nations and, therefore, the laws of the United States,” they failed to identify a source of international law that “provide[s] a proper predicate for jurisdiction under the ATS.” 2005 WL 1870811, at *9, 14. Noting that “a decision to create a private right of action is one better left to legislative judgment in the great majority of cases,” he concluded that “[a] cause of action for Pfizer’s failure to get any consent, informed or otherwise, before performing medical experiments on the subject children would expand customary international law far beyond that contemplated by the ATS.” *Id.* at *13-14 (internal quotation marks omitted).

With regard to the *forum non conveniens* analysis, the district court declined to accept plaintiffs’ submissions concerning Pfizer’s alleged bribery of Nigerian officials on the ground that they were not based on personal knowledge. *Id.* at *16-17. Finding that the plaintiffs had failed to submit specific evidence that the Nigerian judiciary would be biased against its own citizens in an action against Pfizer, the district court alternatively held that Nigeria was an adequate alternate forum. *Id.* at *16, 18.

Several months later, the district court also granted Pfizer's motion to dismiss the *Adamu* case. *Adamu*, 399 F. Supp. 2d 495. It relied on its *Abdullahi III* decision to hold that the plaintiffs could not establish jurisdiction under the ATS. *Id.* at 501. The district court also incorporated the *forum non conveniens* analysis from *Abdullahi III* to find that Nigeria is an adequate forum. *Id.* at 504. Applying the public and private interest factors set forth in *Gulf Oil Corp. v. Gilbert*, 330 U.S. 501, 508-09 (1947), *superseded by statute on other grounds as recognized in Cowan v. Ford Motor Co.*, 713 F.2d 100, 103 (5th Cir. 1983), the court found that while public interest factors did not support either forum, private interest factors weighed in favor of dismissal. *Adamu*, 399 F. Supp. 2d. at 505-06. The district court also dismissed the *Adamu* plaintiffs' Connecticut law claims, concluding that, under Connecticut choice of law principles, the action was governed and barred by Nigerian law. *Id.* at 503.

The *Abdullahi* and *Adamu* plaintiffs appealed. Since then, a tectonic change has altered the relevant political landscape. In May 2007, the state of Kano brought criminal charges and civil claims against Pfizer, seeking over \$2 billion in damages and restitution.⁴ Around the same time, the federal government of Nigeria sued Pfizer and several of its employees, seeking \$7 billion in damages.⁵ None of these cases seek compensation for the subjects of the tests, who are

⁴ Tina Akannam, *Nigeria: Pfizer—Case Adjourned Till May 27*, Vanguard, April 30, 2008, <http://allafrica.com/stories/200804300470.html>; Joe Stephens, *Pfizer Faces Criminal Charges in Nigeria*, The Washington Post, May 30, 2007, at A10, available at <http://www.washingtonpost.com/wp-dyn/content/article/2007/05/29/AR2007052902107.html>.

⁵ Jonathan Clayton, *Pfizer Under Fire After Drug Trial*, TimesOnline, June 27, 2007, http://business.timesonline.co.uk/tol/business/industry_sectors/health/article1990908.ece;

the appellants before this Court. Pfizer then notified this Court that in light of these recent developments, which it believed required further consideration by the district court, it would not seek affirmance on the basis of *forum non conveniens*.

DISCUSSION

The district court dismissed both actions based on its determination that it lacked subject matter jurisdiction because plaintiffs failed to state claims under the ATS. We review dismissal on this ground *de novo*. *Rweyemamu v. Cote*, 520 F.3d 198, 201 (2d Cir. 2008). “To survive dismissal, the plaintiff[s] must provide the grounds upon which [their] claim rests through factual allegations sufficient ‘to raise a right to relief above the speculative level.’” *ATSI Commc’ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 127 S. Ct. 1955, 1965 (2007)).⁶

I. The Alien Tort Statute

The Alien Tort Statute, 28 U.S.C. § 1350, 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

Nigeria Sues Drugs Giant Pfizer, BBC News, June 5, 2007, <http://news.bbc.co.uk/2/hi/africa/6719141.stm>.

⁶ *Twombly* instituted a flexible “plausibility standard,” not limited to antitrust cases, which requires the amplification of facts in certain contexts. *Iqbal v. Hasty*, 490 F.3d 143, 155-58 (2d Cir. 2007).

law of nations or a treaty of the United States.” Included in the Judiciary Act of 1789, the statute provided jurisdiction in just two cases during the first 191 years after its enactment. *See Taveras v. Taveraz*, 477 F.3d 767, 771 (6th Cir. 2007). In the last thirty years, however, the ATS has functioned slightly more robustly, conferring jurisdiction over a limited category of claims.

We first extensively examined the ATS in *Filartiga v. Pena-Irala*, 630 F.2d 876 (2d Cir. 1980), where we held that conduct violating the law of nations is actionable under the ATS “only where the nations of the world have demonstrated that the wrong is of mutual, and not merely several, concern, by means of express international accords.” *Id.* at 888. Following *Filartiga*, we concluded that ATS claims may sometimes be brought against private actors, and not only state officials, *see Kadic v. Karadzic*, 70 F.3d 232, 239 (2d Cir. 1995), when the tortious activities violate norms of “universal concern” that are recognized to extend to the conduct of private parties—for example, slavery, genocide, and war crimes, *id.* at 240. This case involves allegations of both state and individual action. In *Flores v. Southern Peru Copper Corp.*, 414 F.3d 233 (2d Cir. 2003), we clarified that “the law of nations” in the ATS context “refers to the body of law known as customary international law,” which “is discerned from myriad decisions made in numerous and varied international and domestic arenas” and “does not stem from any single, definitive, readily-identifiable source.” *Id.* at 247-48. These principles are rejected in their entirety by our dissenting colleague. In *Flores*, we concluded that ATS jurisdiction is limited to alleged violations of “those clear and unambiguous rules by which States universally abide, or to which they accede, out of a sense of legal obligation and mutual concern.” *Id.* at 252.

Applying this standard, we held that the appellants' claim that pollution from mining operations caused lung disease failed to state a violation of customary international law. We reasoned that the "right to life" and the "right to health" were insufficiently definite to constitute binding customary legal norms and that there was insufficient evidence to establish the existence of a narrower norm prohibiting intranational pollution. *Id.* at 254-55.

In 2004, the Supreme Court comprehensively addressed the ATS for the first time in *Sosa v. Alvarez-Machain*, 542 U.S. 692. Justice Souter, writing for the majority, clarified that the ATS was enacted to create jurisdiction over "a relatively modest set of actions alleging violations of the law of nations" and with "the understanding that the common law would provide a cause of action." *Id.* at 720, 723. The Supreme Court confirmed that federal courts retain a limited power to "adapt[] the law of nations to private rights" by recognizing "a narrow class of international norms" to be judicially enforceable through our residual common law discretion to create causes of action. *Id.* at 728-29. It cautioned, however, that courts must exercise this power with restraint and "the understanding that the door [to actionable violations] is still ajar subject to vigilant doorkeeping," permitting only those claims that "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 [the Supreme Court has] recognized." *Id.* at 725, 729. These 18th-century paradigms consist of offenses against ambassadors, violations of the right to safe passage, and individual actions arising out of piracy. *Id.* at 724. The common theme among these offenses is that they contravened the law of nations, admitted of a judicial remedy,

and simultaneously threatened serious consequences in international affairs. *Id.* at 715. Lower courts are required to gauge claims brought under the ATS against the current state of international law, but are permitted to recognize under federal common law only those private claims for violations of customary international law norms that reflect the same degree of “definite content and acceptance among civilized nations” as those reflected in the 18th-century paradigms. *Id.* at 732-33. The Supreme Court in *Sosa* also counseled that “the determination whether a norm is sufficiently definite to support a cause of action should (and, indeed, inevitably must) involve an element of judgment about the practical consequences of making that cause available to litigants” in federal courts. *Id.*

In this way *Sosa* set a “high bar to new private causes of action” alleging violations of customary international law. *Id.* at 727. A federal court can recognize one only if a plaintiff identifies the violation of a norm of customary international law that, as defined by the sources of such law that United States courts “have long, albeit cautiously, recognized,” *id.* at 733-34 (referencing *The Paquete Habana*, 175 U.S. 677, 700 (1900)), is sufficiently specific, universal, and obligatory to meet the standards established by *Sosa*. *See Sosa*, 542 U.S. at 732 (citing with approval *Tel-Oren v. Libyan Arab Republic*, 726 F.2d 774, 781 (D.C. Cir. 1984) (Edwards, J., concurring), and *In re Estate of Marcos, Human Rights Litig.*, 25 F.3d 1467, 1475 (9th Cir. 1994)). Applying these principles, the Supreme Court held that the plaintiff, a Mexican national who sued a fellow Mexican national under the ATS for allegedly aiding in his illegal abduction by agents of the U.S. Drug Enforcement Agency, had failed to allege the violation of a customary

international law norm with the required precision. *Sosa*, 542 U.S. at 738. The Supreme Court found that the practical consequences of recognizing a general and broad customary international law prohibition of arbitrary detention in a case involving “a single illegal detention of less than a day, followed by the transfer of custody to lawful authorities and a prompt arraignment” would be “breathtaking” and inappropriate. *Id.* at 736, 738.

Since *Sosa*, this Court has reviewed three judgments dismissing claims under the ATS. In *Khulumani v. Barclay National Bank, Ltd.*, 504 F.3d 254 (2d Cir. 2007) (per curiam), we held that the ATS conferred jurisdiction over multinational corporations that purportedly collaborated with the government of South Africa in maintaining apartheid because they aided and abetted violations of customary international law. *Id.* at 260. In *Vietnam Ass’n for Victims of Agent Orange v. Dow Chemical Co.*, 517 F.3d 104 (2d Cir. 2008), we concluded that the ATS did not support a claim that the defendants violated international law by manufacturing and supplying Agent Orange and other herbicides used by the United States military during the Vietnam War. *Id.* at 123. We reasoned that the sources of law on which the appellants relied did not define a norm prohibiting the wartime use of Agent Orange that was both universal and sufficiently specific to satisfy the requirements of *Sosa*. *Id.* at 119-23. Similarly, in *Mora v. People of the State of New York*, 524 F.3d 183 (2d Cir. 2008), we held that the norm at issue—one that prohibits the detention of a foreign national without informing him of the requirement of consular notification and access under Article 36(1)(b)(3) of the Vienna Convention on Consular Relations—was insufficiently universal to support a claim under the ATS. *Id.* at 208-09.

Turning now to this appeal, and remaining mindful of our obligation to proceed cautiously and self-consciously in this area, we determine whether the norm alleged (1) is defined with a specificity comparable to the 18th-century paradigms discussed in *Sosa*, (2) is based upon a norm of international character accepted by the civilized world, and (3) is one that States universally abide by, or accede to, out of a sense of legal obligation and mutual concern.

A. The Prohibition of Nonconsensual Medical Experimentation on Humans

Appellants' ATS claims are premised on the existence of a norm of customary international law prohibiting medical experimentation on non-consenting human subjects. To determine whether this prohibition constitutes a universally accepted norm of customary international law, we examine the current state of international law by consulting the sources identified by Article 38 of the Statute of the International Court of Justice ("ICJ Statute"), to which the United States and all members of the United Nations are parties. *Flores*, 414 F.3d at 250; *see, e.g., United States v. Yousef*, 327 F.3d 56, 100-01 (2d Cir. 2003). Article 38 identifies the authorities that provide "competent proof of the content of customary international law."

Flores, 414 F.3d at 251. These sources consist of:

- (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, T.S. No. 993 [hereinafter ICJ Statute].

The appellants ground their claims in four sources of international law that categorically forbid medical experimentation on non-consenting human subjects: (1) the Nuremberg Code, which states as its first principle that “[t]he voluntary consent of the human subject is absolutely essential”; (2) the World Medical Association’s Declaration of Helsinki, which sets forth ethical principles to guide physicians world-wide and provides that human subjects should be volunteers and grant their informed consent to participate in research; (3) the guidelines authored by the Council for International Organizations of Medical Services (“CIOMS”), which require “the voluntary informed consent of [a] prospective subject”; and (4) Article 7 of the International Covenant on Civil and Political Rights (“ICCPR”), which provides that “no one shall be subjected without his free consent to medical or scientific experimentation.”⁷

The district court found that “non-consensual medical experimentation violates the law of

⁷ These sources are located respectively at (1) *United States v. Brandt*, 2 Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council No. 10, 181 (1949) [hereinafter Nuremberg Trials]; (2) World Med. Ass’n, *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*, art. 20, 22, G.A. Res. (adopted 1964, amended 1975, 1983, 1989, 1996, and 2000), <http://www.wma.net/e/policy/pdf/17c.pdf> [hereinafter Declaration of Helsinki]; (3) Council for International Organizations of Medical Services [CIOMS], *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, guideline 4 (3rd ed. 2002), *superseding id.* at guideline 1 (2nd ed. 1993); (4) International Covenant on Civil and Political Rights, art. 7, Dec. 19, 1966, 999 U.N.T.S. 171 [hereinafter ICCPR].

nations and, therefore, the laws of the United States” and cited the Nuremberg Code for support. *Abdullahi III*, 2005 WL 1870811, at *9. It then noted that “[w]hile federal courts have the authority to imply the existence of a private right of action for violations of *jus cogens* norms of international law, federal courts must consider whether there exist special factors counseling hesitation in the absence of affirmative action by Congress.” *Id.* (internal citations and quotation marks omitted). The district court then separately analyzed the four sources of international law that prohibit nonconsensual medical experimentation on humans and the Universal Declaration of Human Rights. *Id.* at *11-13. It found that with the exception of the Nuremberg Code, these sources contain only aspirational or vague language lacking the specificity required for jurisdiction. *Id.* at *12-13. It also determined that because the United States did not ratify or adopt any of these authorities except the ICCPR, and because even the ICCPR is not self-executing, none of them create binding international legal obligations that are enforceable in federal court. *Id.* at *11-13. Finally, the district court concluded that the plaintiffs failed to provide a proper predicate for ATS jurisdiction because none of the sources independently authorizes a private cause of action and the inference of such a cause of action is a matter best left to Congress. *Id.* at *13-14.⁸

The district court’s approach misconstrued both the nature of customary international law and the scope of the inquiry required by *Sosa*. It mistakenly assumed that the question of

⁸ The district court interchangeably refers to the ‘lack of jurisdiction’ or ‘lack of subject matter jurisdiction’ over plaintiffs’ claims, the plaintiffs’ failure to state an ATS claim, and their failure to identify a norm that permits the inference of a cause of action.

whether a particular customary international law norm is sufficiently specific, universal, and obligatory to permit the recognition of a cause of action under the ATS is resolved essentially by looking at two things: whether each source of law referencing the norm is binding and whether each source expressly authorizes a cause of action to enforce the norm. But *Sosa*, as we have seen, requires a more fulsome and nuanced inquiry. Courts are obligated to examine how the specificity of the norm compares with 18th-century paradigms, whether the norm is accepted in the world community, and whether States universally abide by the norm out of a sense of mutual concern. By eschewing this inquiry, the district court did not engage the fact that norms of customary international law are “discerned from myriad decisions made in numerous and varied international and domestic arenas” and “[do] not stem from any single, definitive, readily-identifiable source.” *Flores*, 414 F.3d at 247-48.

The district court also inappropriately narrowed its inquiry in two respects. First, it focused its consideration on whether the norm identified by the plaintiffs is set forth in conventions to which the United States is a party, and if so, whether these treaties are self-executing or executed by federal legislation. While adoption of a self-executing treaty or the execution of treaty that is not self-executing may provide the best evidence of a particular country’s custom or practice of recognizing a norm, *see Flores*, 414 F.3d at 257, the existence of a norm of customary international law is one determined, in part, by reference to the custom or practices of many States, and the broad acceptance of that norm by the international community. Agreements that are not self-executing or that have not been executed by federal legislation,

including the ICCPR, are appropriately considered evidence of the current state of customary international law. *See Khulumani*, 504 F.3d at 284 (Katzmann, J., concurring) (noting that “[w]hether a treaty that embodies [a norm of customary international law] is self-executing is relevant to, but is not determinative of, [the] question” of whether the norm permits ATS jurisdiction). A formal treaty, moreover, is not the lone primary source of customary international law. The ICJ Statute permits, and *Sosa* encourages, among other things, that courts consider “international custom, as evidence of a general practice accepted as law.” ICJ Statute, *supra*, at art. 38(1); *Sosa*, 542 U.S. at 734 (“[W]here there is no treaty, and no controlling executive or legislative act or judicial decision, resort must be had to the customs and usages of civilized nations.”) (quoting *The Paquete Habana*, 175 U.S. at 700).

Second, the district court’s consideration of whether each source of law creates binding legal norms failed to credit the fact that even declarations of international norms that are not in and of themselves binding may, with time and in conjunction with state practice, provide evidence that a norm has developed the specificity, universality, and obligatory nature required for ATS jurisdiction. *See Filartiga*, 630 F.2d at 883 (“[A non-binding] Declaration creates an expectation of adherence, and insofar as the expectation is gradually justified by State practice, a declaration may by custom become recognized as laying down rules binding upon the States.”) (internal quotation marks omitted). The district court should have considered a greater range of evidence and weighed differently the probative value of the sources on which the appellants relied.

In sum, it was inappropriate for the district court to forego a more extensive examination of whether treaties, international agreements, or State practice have ripened the prohibition of nonconsensual medical experimentation on human subjects into a customary international law norm that is sufficiently (i) universal and obligatory, (ii) specific and definable, and (iii) of mutual concern, to permit courts to infer a cause of action under the ATS. *See Sosa*, 542 U.S. at 732-35. We now proceed with such an examination.

i. Universality

The appellants must allege the violation of a norm of customary international law to which States universally subscribe. *See Sosa*, 542 U.S. at 732; *Vietnam Ass'n for Victims of Agent Orange*, 517 F.3d at 117. The prohibition on nonconsensual medical experimentation on human beings meets this standard because, among other reasons, it is specific, focused and accepted by nations around the world without significant exception.

The evolution of the prohibition into a norm of customary international law began with the war crimes trials at Nuremberg. The United States, the Soviet Union, the United Kingdom and France “acting in the interest of all the United Nations,” established the International Military Tribunal (“IMT”) through entry into the London Agreement of August 8, 1945. M. Cheriff Bassiouni et al., *An Appraisal of Human Experimentation in International Law and Practice: The Need for International Regulation of Human Experimentation*, 72 J. Crim. L. & Criminology 1597, 1640 & n.220 (1981) (internal quotation marks omitted). Annexed to the

London Agreement was the London Charter, which served as the IMT's Constitution. *See* Agreement for the Prosecution and Punishment of the Major War Criminals of the European Axis Powers, with annexed Charter of the International Military Tribunal art. 2, Aug. 8, 1945, 59 Stat. 1544, 82 U.N.T.S. 279. According to the Charter, the IMT had the “power to try and punish persons who, acting in the interests of the European Axis countries, whether as individuals or as members of organisations, committed,” among other offenses, war crimes and crimes against humanity. *Id.* at art. 6.

The IMT tried 22 “major” Nazi war criminals leaving “lower-level” war criminals, including “[l]eading physicians . . . and leading German industrialists,” to be tried in subsequent trials by U.S. military tribunals acting “under the aegis of the IMT.” United States Holocaust Memorial Museum, *War Crimes Trials*, Holocaust Encyclopedia (2008), <http://www.ushmm.org/wlc/article.php?lang=en&ModuleId=10005140>. The law that authorized the creation of the U.S. military tribunals, Control Council Law No. 10, was enacted in 1945 by the Allied Control Council, *see id.*, an authority through which the London Agreement signatories exerted joint-control over Germany, *see* Encyclopedia Britannica, *Germany*, Encyclopedia Britannica Online (2009), <http://search.eb.com/eb/article-58214>. Control Council Law No. 10 stated that its purpose was to “give effect to the terms of . . . the London Agreement . . . and the [London] Charter,” and “to establish a uniform legal basis in Germany for the prosecution of war criminals.” Allied Control Council No. 10, preamble, (Dec. 20, 1945), <http://avalon.law.yale.edu/imt/imt10.asp>. Law No. 10 expressly incorporated the London

Agreement, identifying it as an “integral part[] of this Law.” *Id.* at art. I. Law No. 10 also authorized military tribunals of the occupying powers to prosecute individuals for the same crimes over which the IMT had jurisdiction, including war crimes and crimes against humanity, *see id.* at arts. II-III, and made military tribunal prosecutions subject to the IMT’s right of first refusal, *see id.* at art. III. Consequently, the U.S. military tribunals effectively operated as extensions of the IMT, *see* Telford Taylor, *Final Report to the Secretary of the Army on the Nuernberg War Crimes Trials Under Control Council Law No. 10* 7, 107 (1949) [hereinafter *Report on Nuernberg War Crimes Trials*], available at http://www.loc.gov/r/r/frd/Military_Law/pdf/NT_final-report.pdf (explaining that “the trials under Law No. 10 were to be a means of carrying out such ‘declarations of criminality’ . . . as the International Military Tribunal might make” and that “[t]he first [IMT] trial and the 12 following [military tribunal] trials . . . form a single sequence based on common principles”), and Control Council Law No. 10 served to implement the commitments undertaken in the London Agreement, *see id.* at 7 (noting that “the two documents supplemented each other” and “[m]ajor criminals not tried under the one could be tried under the other”).

In August 1947, Military Tribunal 1, staffed by American judges and prosecutors and conducted under American procedural rules, *see* George J. Annas, *The Nuremberg Code in U.S. Courts: Ethics versus Expediency in The Nazi Doctors and the Nuremberg Code* 201, 201 (George J. Annas & Michael A. Grodin eds., 1992), promulgated the Nuremberg Code as part of the tribunal’s final judgment against fifteen doctors who were found guilty of war crimes and

crimes against humanity for conducting medical experiments without the subjects' consent, *Brandt*, 2 Nuremberg Trials, at 181-82. Among the nonconsensual experiments that the tribunal cited as a basis for their convictions were the testing of drugs for immunization against malaria, epidemic jaundice, typhus, smallpox and cholera. *Id.* at 175-178. Seven of the convicted doctors were sentenced to death and the remaining eight were sentenced to varying terms of imprisonment. *Id.* at 298-300. The tribunal emphasized that

[i]n every single instance appearing in the record, subjects were used who did not consent to the experiments; indeed, as to some of the experiments, it is not even contended by the defendants that the subjects occupied the status of volunteers.

Id. at 183. The judgment concluded that “[m]anifestly human experiments under such conditions are *contrary to the principles of the law of nations* as they result from usages established among civilized peoples, from the laws of humanity, and from the dictates of public conscience.” *Id.* (emphasis added and internal quotation marks omitted). The Code created as part of the tribunal’s judgment therefore emphasized as its first principle that “[t]he voluntary consent of the human subject is absolutely essential.” *Id.* at 181.

The American tribunal’s conclusion that action that contravened the Code’s first principle constituted a crime against humanity is a lucid indication of the international legal significance of the prohibition on nonconsensual medical experimentation. As Justices of the Supreme Court have recognized, “[t]he medical trials at Nuremberg in 1947 deeply impressed *upon the world* that experimentation with unknowing human subjects is morally and legally unacceptable.” *United States v. Stanley*, 483 U.S. 669, 687 (1987) (Brennan, J., concurring in part and dissenting in part)

(emphasis added); *see also id.* at 709-10 (O'Connor, J., concurring in part and dissenting in part).

Moreover, both the legal principles articulated in the trials' authorizing documents and their application in judgments at Nuremberg occupy a position of special importance in the development of bedrock norms of international law. United States courts examining the Nuremberg judgments have recognized that "[t]he universal and fundamental rights of human beings identified by Nuremberg—rights against genocide, enslavement, and other inhumane acts . . .—are the direct ancestors of the universal and fundamental norms recognized as *jus cogens*," from which no derogation is permitted, irrespective of the consent or practice of a given State. *Siderman de Blake v. Republic of Arg.*, 965 F.2d 699, 715 (9th Cir. 1992) (cited in *Sampson v. F.R.G.*, 250 F.3d 1145, 1150 (7th Cir. 2001)). As Telford Taylor, who served as an assistant to Justice Robert Jackson during his time as Chief Prosecutor for the IMT and then became Chief Counsel for War Crimes on the Nuremberg trials held under the authority of Control Council Law No. 10, explained, "Nuernberg was based on enduring [legal] principles and not on temporary political expedients, and this fundamental point is apparent from the reaffirmation of the Nuernberg principles in Control Council Law No. 10, and *their application and refinement* in the 12 judgments rendered under that law during the 3-year period, 1947 to 1949." Taylor, *Report on Nuernberg War Crimes Trials*, at 107 (emphasis added).

Consistent with this view, the Code's first principle has endured: "[S]ignificant world opinion has not come to the defense of the nature or manner in which the experiments were conducted in the Nazi concentration camps." Bassiouni et al., *supra*, at 1641. Rather, since

Nuremberg, states throughout the world have shown through international accords and domestic law-making that they consider the prohibition on nonconsensual medical experimentation identified at Nuremberg as a norm of customary international law.⁹

In 1955, the draft International Covenants on Human Rights was revised to add a second sentence to its prohibition of torture and cruel, inhuman or degrading treatment or punishment. The addition provided that “[i]n particular, no one shall be subjected without his free consent to medical or scientific experimentation involving risk, where such is not required by his state of physical or mental health.” Annotations on the text of the draft International Covenants on Human Rights, at 31, U.N. GAOR, 10th Sess., Annexes, agenda item 28 (II), U.N. Doc. A/2929 (July 1, 1955). The clause was later revised to offer the simpler and sweeping prohibition that “no

⁹ The Fourth Geneva Convention, which entered into force in 1950 and provides protection to civilians in the time of war, elaborates on the application of the norm during armed conflict. Article 32 of the convention prohibits civilian or military agents of the state parties from conducting “medical or scientific experiments not necessitated by the medical treatment of the protected person.” Geneva Convention Relative to the Protection of Civilian Persons in Time of War art. 32, Aug. 12, 1949, 6 U.S.T. 3516, 75 U.N.T.S. 287. According to the commentary, “[p]rotected persons must not in any circumstances be used as ‘guinea pigs’ for medical experiments.” *Commentary on the Geneva Conventions of 12 August 1949: IV Geneva Convention Relative to the Protection of Civilian Persons in Time of War* 224 (Oscar Uhler & Henri Coursier eds., 1958). This commentary explains that the prohibition is directly related to the first principle of the Nuremberg Code since “[i]n prohibiting medical experiments on protected persons, the Diplomatic Conference wished to abolish for ever the criminal practices from which thousands of persons suffered in the death camps of the [second] world war.” The practices involved human medical experiments that were objectionable because they were nonconsensual. See *Brandt*, 2 Nuremberg Trials, at 183. The convention is legally-binding on 194 states that have ratified it without reservation to Article 32. See International Committee of the Red Cross, Geneva Conventions of 12 August 1949 State Parties, Signatories, Reservations and Declarations, <http://www.icrc.org/ihl.nsf/WebSign?ReadForm&id=375&ps=P>.

one shall be subjected without his free consent to medical or scientific experimentation.” ICCPR, *supra*, at art. 7. This prohibition became part of Article 7 of the ICCPR, which entered into force in 1976, and is legally binding on the more than 160 States-Parties that have ratified the convention without reservation to the provision.¹⁰ By its terms this prohibition is not limited to state actors; rather, it guarantees individuals the right to be free from nonconsensual medical experimentation by any entity—state actors, private actors, or state and private actors behaving in concert.

Its status as a norm that states conceive as legally binding—and therefore part of customary international law—is confirmed by Article 2 of the accord, which requires that “[e]ach State Party . . . undertake[] to respect and to ensure to all individuals within its territory and subject to its jurisdiction the rights recognized in the present Covenant.” ICCPR art. 2(1). The international community’s recognition in the ICCPR of its obligation to protect humans, regardless of the source of the action, is powerful evidence of the prohibition’s place in customary international law.

It is clear that, as the court mentioned in *Sosa*, the Universal Declaration of Human Rights and the ICCPR themselves could not establish the relevant, applicable rule of international law in

¹⁰ Although certain States-Parties to the ICCPR have made reservations or declarations with respect to Article 7’s prohibition of torture and cruel, inhuman or degrading treatment or punishment, we are not aware of any similar qualification by a State-Party to the prohibition of medical or scientific experimentation without the free consent of human subjects. See Office of the United Nations High Commissioner for Human Rights, International Covenant on Civil and Political Rights, Declarations and Reservations, <http://www2.ohchr.org/english/bodies/ratification/docs/DeclarationsReservationsICCPR.pdf>.

that case. *Sosa*, 542 U.S. at 754. Nonetheless, the ICCPR, when viewed as a reaffirmation of the norm as articulated in the Nuremberg Code, is potent authority for the universal acceptance of the prohibition on nonconsensual medical experimentation. As we discuss below, *see infra* pp. 28-30, the fact that the prohibition on medical experimentation on humans without consent has been consciously embedded by Congress in our law and reaffirmed on numerous occasions by the FDA demonstrates that the United States government views the norm as the source of a binding legal obligation even though the United States has not ratified the ICCPR in full.¹¹

 In 1964, the World Medical Association adopted the Declaration of Helsinki, which enunciated standards for obtaining informed consent from human subjects. It provided that in clinical research combined with professional care, “[i]f at all possible, consistent with patient psychology, the doctor should obtain the patient’s freely given consent after the patient has been given a full explanation,” and that non-therapeutic clinical research on a person “cannot be undertaken without his free consent, after he has been fully informed.” World Med. Ass’n, *Declaration of Helsinki: Code of Ethics of the World Medical Association*, art. III(3a), G.A. Res. (1964), <http://www.pubmedcentral.nih.gov/picrender.fcgi?artid=1816102&blobtype=pdf>. The Declaration has since been amended five times. The informed consent provision now provides

¹¹ *Khulumani* makes clear that treaties that the United States has neither signed nor ratified—let alone treaties like the ICCPR that the United States has signed but not ratified—may evidence a customary international law norm for ATS purposes where the treaty has been ratified widely and it is clear that the reason for the United States’s failure to subscribe to the treaty was unrelated to the particular norm in question. *See Khulumani*, 504 F.3d at 276, 276 n.9 (Katzmann, J., concurring).

that “subjects must be volunteers and informed participants in the research project.” Declaration of Helsinki, *supra*, at art. 20. The Declaration also requires that “[i]n any research on human beings, each potential subject must be adequately informed of the aims, methods, . . . anticipated benefits and potential risks of the study, and the discomfort it may entail” and that researchers “obtain the subject’s freely-given informed consent, preferably in writing.” *Id.* at art. 22.

Although the Declaration itself is non-binding, since the 1960s, it has spurred States to regulate human experimentation, often by incorporating its informed consent requirement into domestic laws or regulations. *See* Delon Human & Sev S. Fluss, The World Medical Association’s Declaration of Helsinki: Historical and Contemporary Perspectives, 8-11 (July 24, 2001) (fifth draft), http://www.wma.net/e/ethicsunit/pdf/draft_historical_contemporary_perspectives.pdf (describing legal and regulatory developments in Australia, Belgium, Brazil, China, Israel, Japan, New Zealand, Norway, Switzerland, and the United States following the Declaration of Helsinki). Currently, the laws and regulations of at least eighty-four countries, including the United States, require the informed consent of human subjects in medical research.¹² That this conduct has been the subject of domestic legislation is not, of course, in and of itself proof of a norm. *See Flores*, 414 F.3d 249. However, the incorporation of this norm into

¹² The Department of Health and Human Services has compiled the laws, regulations, and guidelines governing human subjects research in eighty-four countries. *See* Office of Human Research Prot., Dep’t of Health & Human Servs., International Compilation of Human Subject Research Protections (2008), <http://www.hhs.gov/ohrp/international/HSPCompilation.pdf>. It is uncontested that all of the countries identified in this compilation require informed consent to medical experimentation.

the laws of this country and this host of others is a powerful indication of the international acceptance of this norm as a binding legal obligation, where, as here, states have shown that the norm is of mutual concern by including it in a variety of international accords.

The history of the norm in United States law demonstrates that it has been firmly embedded for more than 45 years and—except for our dissenting colleague—its validity has never been seriously questioned by any court. Congress mandated patient-subject consent in drug research in 1962. Bassiouni et al., *supra*, at 1624 (citing 21 U.S.C. § 355(i) (1976)). In response, the FDA promulgated its first regulations requiring the informed consent of human subjects. Tellingly, the sources on which our government relied in outlawing non-consensual human medical experimentation were the Nuremberg Code and the Declaration of Helsinki, which suggests the government conceived of these sources’ articulation of the norm as a binding legal obligation. Bassiouni et al., *supra*, at 1625-26 (citing 21 C.F.R. § 310.102(h) (1980)).¹³ Today,

¹³ The importance of informed consent to medical experimentation was reinforced with the passage of the National Research Act in 1974, which established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. See National Research Act, Pub. L. 93-348, 88 Stat. 342 (codified as amended in scattered sections of 42 U.S.C.). This body issued the *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* in 1979, which identifies basic ethical principles governing biomedical and behavioral research on human subjects and requires informed consent. Nat’l Comm’n for the Prot. of Human Subjects of Biomedical & Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, part C (1) (1979), available at <http://ohsr.od.nih.gov/guidelines/belmont.html#goc>. Soon afterwards, the Department of Health, Education and Welfare (later renamed the Department of Health and Human Services) promulgated stricter regulations for ensuring informed consent in research conducted or supported by federal departments or agencies. See U.S. Dep’t of Health & Human Servs., *Guidelines for the Conduct of Research Involving Human Subjects at the National Institutes of Health*, 17-18 (5th ed. 2004),

FDA regulations require informed consent to U.S. investigators' research, whether conducted domestically or in a foreign country, to support applications for the approval of new drugs. *See* 21 C.F.R. §§ 50.20, 50.23-.25, 50.27, 312.20, 312.120 (2008); 45 C.F.R. §§ 46.111, 46.116-.117 (2008).

The importance that the United States government attributes to this norm is demonstrated by its willingness to use domestic law to coerce compliance with the norm throughout the world. United States law requires that, as a predicate to FDA approval of any new drug, both American and foreign sponsors of drug research involving clinical trials, whether conducted here or abroad, procure informed consent from human subjects. 21 C.F.R. §§ 312.20, 312.120 (2008); *see also* Dep't of Health & Human Servs., Office of Inspector Gen., *The Globalization of Clinical Trials* 5 (2001), <http://www.oig.hhs.gov/oei/reports/oei-01-00-00190.pdf>. Sponsors conducting research under an Investigational New Drug Application ("IND") are obligated to adhere to FDA regulations, which require informed consent. 21 C.F.R. § 312.20 (2008); *The Globalization of Clinical Trials*, *supra*, at 5. Prior to April 2008, sponsors conducting research under non-IND guidelines were obligated to adhere to the ethical principles of the 1989 version of the Declaration of Helsinki or the host country's regulations, whichever offered greater protection to the human subject. 21 C.F.R. § 312.120 (2007); *The Globalization of Clinical Trials*, *supra*, at 5. The April 2008 revisions to the non-IND guidelines reaffirmed the informed consent requirement. Human

<http://ohsr.od.nih.gov/guidelines/GrayBooklet82404.pdf> (referencing 45 C.F.R. pt. 46, subpt. A (1981)).

Subject Protection: Foreign Clinical Studies Not Conducted Under an Investigational New Drug Application, 73 Fed. Reg. 22,800, 22,801, 22,803, 22,804, 22,816 (Apr. 28, 2008) (codified at 21 C.F.R. pt. 312). Foreign clinical studies not conducted under an IND must now comply with the Good Clinical Practice guidelines (“GCP”) promulgated by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, 62 Fed. Reg. 25,692 (May 9, 1997), which require informed consent to medical experimentation. 21 C.F.R. § 312.120 (2008).

Additional international law sources support the norm’s status as customary international law. The European Union embraced the norm prohibiting nonconsensual medical experimentation through a 2001 Directive passed by the European Parliament and the Council of the European Union. The Directive accepted the informed consent principles of the 1996 version of the Declaration of Helsinki. Council Directive 2001/20/EC, preamble (2), 2001 O.J. (L 121) 37 (EC) [hereinafter 2001 Clinical Trial Directive]. It also required member States to adopt rules protecting individuals incapable of giving informed consent and permitting clinical trials only where “the trial subject or, when the person is not able to give informed consent, his legal representative has given his written consent after being informed of the nature, significance, implications and risks of the clinical trial.” *Id.* at art. (1), (2)(d). The Directive further required all member States to implement by 2004 domestic laws, regulations, and administrative provisions to comply with its informed consent requirements. *Id.* at art. 22(1).

_____ Since 1997, thirty-four member States of the Council of Europe have also signed the

Convention on Human Rights and Biomedicine, a binding convention and a source of customary international law. 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. 5, 15-16, *opened for signature* Apr. 4, 1997, E.T.S. No. 164, <http://conventions.coe.int/Treaty/en/Treaties/html/164.htm> [hereinafter Convention on Human Rights and Biomedicine]; Convention on Human Rights and Biomedicine, Chart of Signatures and Ratifications as of Aug. 8, 2008, <http://conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=164&CM=8&DF=8/8/2008&CL=ENG>. It provides that an “intervention in the health field may only be carried out after the person concerned has given free and informed consent to it” and that the informed consent of human subjects is required for their involvement in medical research. Convention on Human Rights and Biomedicine, *supra*, at art. 5.¹⁴ In 2005, the General Conference of the United Nations Educational, Scientific and Cultural Organization (UNESCO) adopted the Universal Declaration on Bioethics and Human Rights, which requires “the prior, free, express and informed consent of the person concerned” for research-oriented treatments. Universal Declaration on Bioethics and Human Rights, UNESCO Gen. Conf. Res., at art. 6, 33rd Sess., 33 C/Resolution 36, (Oct. 19, 2005).

This history illustrates that from its origins with the trial of the Nazi doctors at Nuremburg

¹⁴ States-Parties to the Convention on Human Rights and Biomedicine are also required to afford “appropriate judicial protection” to prevent or end infringements of the rights protected by the Convention, including the right to informed consent to medical experimentation. Convention on Human Rights and Biomedicine, *supra*, at art. 23.

through its evolution in international conventions, agreements, declarations, and domestic laws and regulations, the norm prohibiting nonconsensual medical experimentation on human subjects has become firmly embedded and has secured universal acceptance in the community of nations. Unlike our dissenting colleague’s customary international law analysis, which essentially rests on the mistaken assumption that ratified international treaties are the only valid sources of customary international law for ATS purposes, *see* Dissent at 19-20, we reach this conclusion as a result of our review of the multiplicity of sources—including international conventions, whether general or particular, and international custom as identified through international agreements, declarations and a consistent pattern of action by national law-making authorities—that our precedent requires us to examine for the purpose of determining the existence of a norm of customary international law. Our dissenting colleague’s reasoning fails to engage the incompatibility of nonconsensual human testing with key sources of customary international law identified in Article 38 of the ICJ’s statute, most importantly international custom, as evidence of a general practice accepted as law, as well as the general principles of law recognized by civilized nations. *See supra* p. 15.

ii. Specificity

Sosa requires that we recognize causes of action only to enforce those customary international law norms that are no “less definite [in] content . . . than the historical paradigms familiar when [the ATS] was enacted.” *Sosa*, 542 U.S. at 732. The norm prohibiting nonconsensual medical experimentation on human subjects meets this requirement. In *United*

States v. Smith, 18 U.S. (5 Wheat) 153, 159-61 (1820), Justice Story found that “whatever may be the diversity of definitions, . . . all writers concur, in holding, that robbery or forcible depredations upon the sea . . . is piracy.” *Id.* at 161. We have little trouble concluding that a norm forbidding nonconsensual human medical experimentation is every bit as concrete—indeed even more so—than the norm prohibiting piracy that Story describes, or interference with the right of safe conducts and the rights of ambassadors, which together are the paradigmatic norms identified in *Sosa*. *Id.* at 724. The Nuremberg Code, Article 7 of the ICCPR, the Declaration of Helsinki, the Convention on Human Rights and Biomedicine, the Universal Declaration on Bioethics and Human Rights, the 2001 Clinical Trial Directive, and the domestic laws of at least eighty-four States all uniformly and unmistakably prohibit medical experiments on human beings without their consent, thereby providing concrete content for the norm.¹⁵ The appellants allege that Pfizer knowingly and purposefully conducted such experiments on a large scale. Whatever uncertainty may exist at the margin is irrelevant here because appellants allege a complete failure on the part of Pfizer and the Nigerian government to inform appellants of the existence of the Trovan experiments. These allegations, if true, implicate Pfizer and the Nigerian government in conduct

¹⁵ At the fringe, disagreement exists over certain aspects of informed consent including, for example, the way to best secure consent from illiterate or otherwise vulnerable populations, *see, e.g.*, Daniel W. Fitzgerald et al., *Comprehension During Informed Consent in a Less-Developed Country*, 360 *The Lancet* 1301, 1301-02 (2002), and whether informed consent is possible in double-blind experiments in which some subjects are given placebos, *see, e.g.*, Timothy S. Jost, *The Globalization of Health Law: The Case of Permissibility of Placebo-Based Research*, 26 *Am. J. L. & Med.* 175, 183-86 (2000). These debates do not disturb the specificity of the basic norm at issue or the unanimity of world opinion against medical experimentation on human subjects without their consent.

that is at the core of any reasonable iteration of the prohibition against involuntary medical experimentation. While the prohibition in question applies to the testing of drugs without the consent of human subjects on the scale Pfizer allegedly conducted, we do not suggest that it would extend to instances of routine or isolated failures by medical professionals to obtain informed consent, such as those arising from simple negligence. The allegations in the complaints involve anything but a doctor's routine or erroneous failure to obtain such consent from his patient.

iii. Mutual Concern

Customary international law proscribes only transgressions that are of “mutual” concern to States—“those involving States’ actions performed . . . towards or with regard to the other.” *Flores*, 414 F.3d at 249 (differentiating matters of “mutual” concern from those of “several” concern, in which “States are separately and independently interested”). Conduct that States have prohibited through domestic legislation is also actionable under the ATS as a violation of customary international law when nations of the world have demonstrated “by means of express international accords” that the wrong is of mutual concern. *Filartiga*, 630 F.2d at 888. An important, but not exclusive, component of this test is a showing that the conduct in question is “capable of impairing international peace and security.” *Flores*, 414 F.3d at 249. Appellants have made both of these showings.

As we have seen, States throughout the world have entered into two express and binding international agreements prohibiting nonconsensual medical experimentation: the ICCPR and the

Convention on Human Rights and Biomedicine. The entry of over 160 States into these agreements and the European Union's passage of the 2001 Clinical Trial Directive demonstrates that States have not only acted independently to outlaw large-scale, nonconsensual drug testing on humans, but they have also acted in concert to do so. In other words, acting out of a sense of mutual concern, "the nations [of the world] have made it their business, both through international accords and unilateral action," to demonstrate their intention to eliminate conduct of the type alleged in the complaints. *Filartiga*, 630 F.2d at 889.

The administration of drug trials without informed consent on the scale alleged in the complaints poses a real threat to international peace and security. Over the last two decades, pharmaceutical companies in industrialized countries have looked to poorer, developing countries as sites for the medical research essential to the development of new drugs. See James V. Lavery, *Putting International Research Ethics Guidelines to Work for the Benefit of Developing Countries*, 4 Yale J. Health Pol'y L. & Ethics 319, 320-21 (2004); The Globalization of Clinical Trials, *supra*, at 8.¹⁶ Pharmaceutical companies recognize the potential benefits of drug trials to poor nations and have sought to promote access to medicines and health care in underserved populations through philanthropy and partnership with governments and NGOs. See, e.g., PhRMA, Press Releases: Worldwide Pharmaceutical Industry Launches Global Health Progress

¹⁶ In the United States, for example, the number of foreign clinical investigators conducting drug research under an IND increased sixteen-fold in the 1990s. Globalization of Clinical Trials, *supra*, at 6.

Initiative to Expand Efforts to Improve Health in Developing Countries (April 16, 2008), http://www.phrma.org/news_room/press_releases/global_health_progress_initiative_launched_to_improve_health_in_developing_countries/ (describing initiative by worldwide pharmaceutical industry to “further access to medicines; build capacity of health workers in developing nations; advocate for global action to address health challenges; and continue R&D to develop new tools to fight diseases that plague the developing world”); PhRMA, Profile2008: Pharmaceutical Industry 42 (2008), <http://www.phrma.org/files/2008%20Profile.pdf> (describing contributions by American pharmaceutical companies to the promotion of global access to medicines and health care). This trend offers the possibility of enormous health benefits for the world community. Life-saving drugs can potentially be developed more quickly and cheaply, and developing countries may be given access to cutting edge medicines and treatments to assist underresourced and understaffed public health systems, which grapple with life-threatening diseases afflicting their populations.¹⁷

¹⁷ These benefits are well acknowledged. See, e.g., Remigius N. Nwabueze, *Ethical Review of Research Involving Human Subjects in Nigeria: Legal and Policy Issues*, 14 Ind. Int'l & Comp. L. Rev. 87, 102 (2003) (recognizing that clinical trials at times provide the only access to innovative and effective health care in developing countries); David Wendler, et al., *The Standard of Care Debate: Can Research in Developing Countries Be Both Ethical and Responsive to those Countries' Health Needs?*, 94 Am. J. Pub. Health 923, 923 (2004) (noting dramatic inequalities in health care world-wide and the potential of drug research to better care for the world's poor).

Doctors Without Borders, the WHO, and other international health organizations, for example, have called for increased corporate research interest in developing countries. Sonia Shah, *Globalizing Clinical Research*, The Nation, June 13, 2002, at 3, <http://www.thenation.com/doc/20020701/shah>. Ruth Faden, a bioethicist at Johns Hopkins,

The success of these efforts promises to play a major role in reducing the cross-border spread of contagious diseases, which is a significant threat to international peace and stability. The administration of drug trials without informed consent on the scale alleged in the complaints directly threatens these efforts because such conduct fosters distrust and resistance to international drug trials, cutting edge medical innovation, and critical international public health initiatives in which pharmaceutical companies play a key role. This case itself supplies an exceptionally good illustration of why this is so. The Associated Press reported that the Trovan trials in Kano apparently engendered such distrust in the local population that it was a factor contributing to an eleven month-long, local boycott of a polio vaccination campaign in 2004, which impeded international and national efforts to vaccinate the population against a polio outbreak with catastrophic results.¹⁸ According to the World Health Organization, polio originating in Nigeria triggered a major international outbreak of the disease between 2003 and 2006, causing it to

stated, “What we need, if anything, is more health research in the developing world, not less.” *Id.* An HIV researcher observed that even when companies test drugs geared for patients in the developed world through trials in developing countries, the testing “brings benefits to the patients. They get special attention and potential therapy.” *Id.*

¹⁸ Salisu Rabi, *Pfizer Asks Nigeria Court to Dismiss Case*, The Associated Press, July 4, 2007, http://origin.foxnews.com/printer_friendly_wires/2007Jul04/0,4675,NigeriaPfizer,00.html (reporting that the boycott of the Kano polio vaccination program is believed to have “set back global eradication” of polio and to have “caus[ed] an outbreak that spread the disease across Africa and into the Middle East”). The boycott also impaired the efforts of American pharmaceutical companies to contribute to polio eradication by donating over 130 million doses of polio vaccine to sixteen African countries since 1997. PhRMA, *Global Partnerships: Humanitarian Programs of the Pharmaceutical Industry in Developing Nations* 4 (2004), http://www.phrma.org/files/Global_Partnerships_2004.pdf.

spread across west, central, and the Horn of Africa and the Middle East, and to re-infect twenty previously polio-free countries.¹⁹

The administration of drug trials without informed consent poses threats to national security by impairing our relations with other countries. Seven of the world's twelve largest pharmaceutical manufacturers – a group that includes Pfizer – are American companies. *Global 500*, Fortune, July 21, 2008,

<http://money.cnn.com/magazines/fortune/global500/2008/industries/21/index.html>.

Consequently, American companies are likely to be sponsors of medical experiments on human subjects abroad.²⁰ As this case illustrates, the failure to secure consent for human experimentation has the potential to generate substantial anti-American animus and hostility. Unsurprisingly, as noted above, *see supra* p. 30, our government actively attempts to prevent this practice in foreign countries. For example, federal law requires that data generated from testing on human subjects

¹⁹ World Health Organization, *Poliomyelitis in Nigeria and West/Central Africa*, June 18, 2008, http://www.who.int/csr/don/2008_06_18/en/.

Other examples of the link between the cross-border spread of contagious disease and international peace and stability come to mind, such as the outbreak of anti-U.S. riots in South Korea as a result of fear that imported American beef will spread mad cow disease to that country. *See* Choe Sang-Hun, *South Korea Lifts Ban on U.S. Beef*, New York Times, June 26, 2008, <http://www.nytimes.com/2008/06/26/world/asia/26korea.html>.

²⁰ FDA data suggests the industry trend is to use foreign research to support applications for new drug approvals in the United States. Since 1990 there has been an explosion in the number of foreign clinical investigators conducting drug research that sponsors use for this purpose. In 1990, there were 271 foreign investigators conducting research in 28 countries in the FDA database. By 1999, the number had grown to 4,458 investigators working in 79 countries. Globalization of Clinical Trials, *supra*, at i.

abroad that is used to seek regulatory approval for a given drug must, at minimum, be the result of testing conducted consistent with the requirements of informed consent. Consequently, the US government denies access to the US market for any new drug unless the drug's research data is generated in a manner consistent with the customary international law norm prohibiting drug trials on human subjects without informed consent.

For these reasons, we hold that the appellants have pled facts sufficient to state a cause of action under the ATS for a violation of the norm of customary international law prohibiting medical experimentation on human subjects without their knowledge or consent. In such an instance, ATS jurisdiction exists over plaintiffs' claims. The district court determined that the norm existed, but concluded that because no single source recognizing the norm was legally binding on the United States and created a private cause of action, it could not infer such a right under the ATS. Presumably, on this basis, it simultaneously held that there was no subject matter jurisdiction over plaintiffs' claims. Under *Sosa*, this approach was not correct. *Sosa* makes clear that the critical inquiry is whether the variety of sources that we are required to consult establishes a customary international law norm that is sufficiently specific, universally accepted, and obligatory for courts to recognize a cause of action to enforce the norm. Nothing in *Sosa* suggests that this inquiry can be halted if some of the sources of international law giving rise to the norm are found not to be binding or not to explicitly authorize a cause of action.

_____ We believe that the issues raised by this appeal regarding customary international law are framed by our analysis and by that of our dissenting colleague. He contends that our analysis is

created from “whole cloth.” Dissent at 1. We believe that his approach to customary international law is unselfconsciously reactionary and static. The approach does not accommodate itself to the normative world that, by their commitments and conduct over the past fifty years, states—including our own— have shown they believe to exist.

B. State Action

A private individual will be held liable under the ATS if he “acted in concert with” the state, i.e., “under color of law.” *Kadic*, 70 F.3d at 245. In making this determination, courts look to the standards developed for finding state action in claims brought under 42 U.S.C. § 1983. *Id.* Under § 1983, state action may be found when “there is such a ‘close nexus between the State and the challenged action’ that seemingly private behavior ‘may be fairly treated as that of the State itself.’” *Brentwood Acad. v. Tenn. Secondary Sch. Athletic Ass’n*, 531 U.S. 288, 295 (2001) (quoting *Jackson v. Metropolitan Edison Co.*, 419 U.S. 345, 351 (1974)). That nexus may exist “where a private actor has operated as a willful participant in joint activity with the State or its agents,” *Gorman-Bakos v. Cornell Coop. Extension of Schenectady County*, 252 F.3d 545, 551-52 (2d Cir. 2001) (quoting *Loce v. Time Warner Entertainment Advance/Newhouse Partnership*, 191 F.3d 256, 266 (2d Cir. 1999)), or “acts together with state officials or with significant state aid,” *Kadic*, 70 F.3d at 245. Pfizer meets this test.

The Appellants have alleged that the Nigerian government was involved in all stages of the Kano test and participated in the conduct that violated international law. They allege that the

Nigerian government provided a letter of request to the FDA to authorize the export of Trovan, arranged for Pfizer's accommodations in Kano, and facilitated the nonconsensual testing in Nigeria's Infectious Disease Hospital ("IDH") in Kano. Despite overcrowding due to concurrent epidemics, the Nigerian government extended the exclusive use of two hospital wards to Pfizer, providing Pfizer with control over scarce public resources and the use of the hospital's staff and facilities to conduct the Kano test, to the exclusion of MSF.

This unlawful conduct is alleged to have occurred in a Nigerian facility with the assistance of the Nigerian government and government officials and/or employees from the IDH and Aminu Kano Teaching Hospital. Pfizer's research team in Kano was comprised of three American physicians, Dr. Abdulhamid Isa Dutse (a physician in the Aminu Kano Teaching Hospital), and three other Nigerian doctors. The American and Nigerian members of Pfizer's team allegedly jointly administered the Kano test. Finally, in addition to assisting with the Kano test, Nigerian officials are alleged to have conspired to cover up the violations by silencing Nigerian physicians critical of the test and by back-dating an "approval letter" that the FDA and international protocol required to be provided prior to conducting the medical experiment. In addition to these allegations, the Adamu plaintiffs explicitly allege that the Nigerian government "was intimately involved and contributed, aided, assisted and facilitated Pfizer's efforts to conduct the Trovan test," "acted in concert with Pfizer," and, according to a Nigerian physician involved in the Trovan experimentation, appeared to "back[]" the testing. At the pleading stage, these contentions meet the state action test because they adequately allege that the violations occurred

as the result of concerted action between Pfizer and the Nigerian government.

II. Forum Non Conveniens

As an alternative to dismissal for failure to state a claim under the ATS, the district court dismissed the actions on the ground of *forum non conveniens*. Appellants raised this issue on appeal. Ordinarily, we review a *forum non conveniens* dismissal for abuse of discretion. *Norex Petroleum Ltd. v. Access Indus., Inc.*, 416 F.3d 146, 153 (2d Cir. 2005). Since filing this appeal, however, Pfizer has notified the Court that in light of recent developments, in particular the initiation of proceedings by the federal government of Nigeria and the state of Kano against Pfizer and certain of its employees, it would not seek affirmance of the judgment on the basis of *forum non conveniens*. The appellants agreed and also requested that the issue be remanded. We accede to this request.

Although we are not now called upon definitively to review the district court's application of *forum non conveniens*, in view of the frequency with which this issue has arisen and remained unsettled in this case, we offer additional guidance to assist the parties and the district court. The three-step analysis set forth in *Iragorri v. United Techs. Corp.*, 274 F.3d 65, 71-75 (2d Cir. 2001) (en banc), applies. In this litigation, the second step of the analysis, which requires the district court to consider the adequacy of the alternative forum, is pivotal. Dismissal is not appropriate if an adequate and presently available alternative forum does not exist. *Norex*, 416 F.3d at 159. A forum in which defendants are amenable to service of process and which permits litigation of the

dispute is generally adequate. *Id.* at 157. Such a forum may nevertheless be inadequate if it does not permit the reasonably prompt adjudication of a dispute, if the forum is not presently available, or if the forum provides a remedy so clearly unsatisfactory or inadequate that it is tantamount to no remedy at all. *Piper Aircraft Co. v. Reyno*, 454 U.S. 235, 254-55 & n.22 (1981); *USHA (India), Ltd. v. Honeywell Int'l, Inc.*, 421 F.3d 129, 136 (2d Cir. 2005); *Norex*, 416 F.3d at 160.

The defendant bears the burden of establishing that a presently available and adequate alternative forum exists, and that the balance of private and public interest factors tilts heavily in favor of the alternative forum. *USHA (India), Ltd.*, 421 F.3d at 135; *PT United Can Co. v. Crown Cork & Seal Co., Inc.*, 138 F.3d 65, 74 (2d Cir. 1998). Absent a showing of inadequacy by a plaintiff, “considerations of comity preclude a court from adversely judging the quality of a foreign justice system.” *PT United Can Co.*, 138 F.3d at 73. Accordingly, while the plaintiff bears the initial burden of producing evidence of corruption, delay or lack of due process in the foreign forum, the defendant bears the ultimate burden of persuasion as to the adequacy of the forum. *See, e.g., Norex*, 416 F.3d at 159-160.

When the district court granted Pfizer’s motion, it identified the pivotal issue as whether the plaintiffs produced sufficient evidence to show that Nigeria is an inadequate alternative forum. *Abdullahi III*, 2005 WL 1870811, at *15. Having found that they had not, it concluded that Nigeria was an adequate forum. *Id.* at *16-18. In so doing, the district court omitted an analysis of whether Pfizer discharged its burden of persuading the court as to the adequacy and present availability of the Nigerian forum and improperly placed on plaintiffs the burden of proving that

the alternative forum is inadequate. *Cf. DiRienzo v. Philip Servs. Corp.*, 294 F.3d 21, 30 (2d Cir. 2002) (holding that it is error not “to hold defendants to their burden of proof” of the *Gilbert* factors). On remand, the district court will have an opportunity to reassess this issue, as well as the relationship between Fed. R. Civ. P. 44.1 and the Federal Rules of Evidence.

III. Choice of Law

The district court dismissed the *Adamu* plaintiffs’ claims under the Connecticut Unfair Trade Practices Act and the Connecticut Products Liability Act on the ground that Connecticut choice of law principles applied and called for the application of Nigerian law. *Adamu*, 399 F. Supp. 2d at 501-03. “We review the district court’s choice of law *de novo*.” *Fin. One Pub. Co. Ltd. v. Lehman Bros. Special Fin., Inc.*, 414 F.3d 325, 331 (2d Cir. 2005).

The district court correctly determined that Connecticut choice-of-law rules applied because it was obligated to apply the state law that would have been applicable if the case had not been transferred from Connecticut to New York. *See Van Dusen v. Barrack*, 376 U.S. 612, 639 (1964). Under Connecticut law, *lex loci delicti*, “the doctrine that the substantive rights and obligations arising out of a tort controversy are determined by the law of the place of injury,” typically applies. *O’Connor v. O’Connor*, 201 Conn. 632, 637 (1986). *Lex loci delicti* would require the application of Nigerian law because the *Adamu* plaintiffs’ injuries are alleged to have occurred there. Connecticut, however, has conspicuously retreated from a rigid application of the doctrine. The Connecticut Supreme Court held that *lex loci delicti* does not apply to a tort claim

when doing so would undermine expectations of the parties or an important state policy, produce an arbitrary and irrational result, or where “reason and justice” counsel for the application of a different principle. *Id.* at 637, 648, 650. In such cases, Connecticut courts are required to apply the “most significant relationship” analysis set forth in the Restatement (Second) of Conflict of Laws §§ 6 & 145 (1971) [hereinafter Restatement (Second)]. *O’Connor*, 201 Conn. at 649-50.

Section 145 (1) of the Restatement provides that “[t]he rights and liabilities of the parties with respect to an issue in tort are determined by the local law of the state which, with respect to that issue, has the most significant relationship to the occurrence and the parties under the principles stated in § 6.” Restatement (Second) § 145(1). Section 6(2), in turn, provides that where a state is not guided by a statutory directive on choice of law,

the factors relevant to the choice of the applicable rule of law include

- (a) the needs of the interstate and international systems,
- (b) the relevant policies of the forum,
- (c) the relevant policies of other interested states and the relative interests of those states in the determination of the particular issue,
- (d) the protection of justified expectations,
- (e) the basic policies underlying the particular field of law,
- (f) certainty, predictability and uniformity of result, and
- (g) ease in the determination and application of the law to be applied.

Restatement (Second) § 6(2). The Connecticut Supreme Court has determined that Section 145(2) provides courts with guidance regarding the evaluation of the policy choices set out in Sections 145(1) and 6(2). *O’Connor*, 201 Conn. at 652. Section 145(2) assists with the application of the principles of Section 6 to tort cases by calling for consideration of:

- (a) the place where the injury occurred,

- (b) the place where the conduct causing the injury occurred,
- (c) the domicil, residence, nationality, place of incorporation and place of business of the parties, and
- (d) the place where the relationship, if any, between the parties is centered.

Restatement (Second) § 145(2). These factors are “to be evaluated according to their relative importance with respect to the particular issue.” *Id.*

The district court correctly decided to apply Sections 6 and 145 of the Restatement rather than *lex loci delicti*. It applied the factors in Section 145(2) to determine whether Connecticut or Nigeria has the most significant relationship to the conduct at issue, which it identified as “Pfizer’s failure to inform the children or their parents about the potential problems with Trovan, and the administration of Trovan and low dosage of Ceftriaxone.” *Adamu*, 399 F. Supp. 2d at 503 (citations omitted). It reasoned that “the Nigerian contacts to this litigation are stronger than Connecticut’s” and noted in particular that both the plaintiffs’ injuries and Pfizer’s alleged conduct occurred in Nigeria, that the plaintiffs were Nigerian residents, and that “the parties’ relationship is centered” in Nigeria. *Id.* It determined that most of the factors of Section 145(2) point toward applying Nigerian law and that the “sole basis” for the applicability of Connecticut law was that “Pfizer performed research and development with respect to Trovan and planned the experiment in Connecticut.” *Id.* For these reasons, it concluded that Nigeria’s interests were superior and that its law should apply. *Id.*

Although the district court correctly identified some of the pertinent factors, it ultimately erred in its application of the “most significant relationship” test because it did not factor into its Section 145(2) analysis the integral factors set out in Section 6(2). It did not, for example, discuss “the relevant policies of the forum” or “the relevant policies of other interested states and the

relative interests of those states in the determination of the particular issue.” Restatement (Second) § 6(2)(b)-(c). Nor did it analyze what “justified expectations” existed that could have prompted Pfizer reasonably to believe that its conduct in Connecticut would not expose it to Connecticut law, or how Pfizer would have been disadvantaged by litigating these claims in Connecticut. *Id.* § 6(2)(d). Finally, the district court did not evaluate its own ability to determine and apply Connecticut, as opposed to Nigerian, law. *Id.* § 6(2)(g). For these reasons, we vacate the dismissal of the state law claims and remand to the district court for further consideration.

CONCLUSION

For the foregoing reasons, we REVERSE the judgments of the district court and REMAND for further proceedings.

1 WESLEY, *Circuit Judge*, dissenting:

2 The majority has undertaken to define a “firmly established” norm of international law,
3 heretofore unrecognized by any American court or treaty obligation, on the basis of materials
4 inadequate for the task. In deviating from our settled case law, the majority *identifies* no norm of
5 customary international law, it creates a new norm out of whole cloth. Because the majority’s
6 analysis misconstrues – rather than vindicates – customary international law, I respectfully
7 dissent.

8 Proceeding with “extraordinary care and restraint,” *Flores v. S. Peru Copper Corp.*, 414
9 F.3d 233, 248 (2d Cir. 2003), this Court has upheld jurisdiction under the Alien Tort Statute, 28
10 U.S.C. § 1350 (“ATS”), in only a handful of cases alleging violations of the most firmly
11 established international law norms, *see Kadie v. Karadzic*, 70 F.3d 232, 241-43 (2d Cir. 1995)
12 (genocide and war crimes); *Amerada Hess Shipping Corp. v. Argentine Republic*, 830 F.2d 421,
13 426 (2d Cir. 1987), *rev’d on other grounds*, 488 U.S. 428 (1989) (free passage of neutral ship in
14 international waters); *Filartiga v. Pena-Irala*, 630 F.2d 876, 878 (2d Cir. 1980) (state-
15 administered torture). In *Sosa v. Alvarez-Machain*, the Supreme Court identified three such
16 “paradigmatic” norms, namely “violation of safe conducts, infringement of the rights of
17 ambassadors, and piracy.” 542 U.S. 692, 724 (2004). Rather than declare that list exhaustive for
18 purposes of the ATS, the Court held that “any claim based on the present-day law of nations
19 [must] rest on a norm of international character accepted by the civilized world and defined with a
20 specificity comparable to the features of the 18th-century paradigms we have recognized.” *Id.* at
21 725. Accordingly, we are charged with “vigilant doorkeeping” when reviewing ATS claims to
22 ensure that they rest on “a narrow class of international norms” comparable to the paradigms

1 identified by the Supreme Court. *Id.* at 729.

2 The majority identifies three criteria that must be satisfied before a violation of
3 international law can be actionable under the ATS: that the norm is (1) specific and definable, (2)
4 universally adhered to out of a sense of legal obligation, and (3) a matter of mutual concern,
5 namely a matter “involving States’ actions performed towards or with regard to the other.”
6 *Flores*, 414 F.3d at 249 (internal quotation and alterations omitted). I agree with the
7 methodology used by the majority to determine whether a norm falls within the jurisdictional
8 grant of the ATS, but I do not agree with their conclusion that a norm against non-consensual
9 medical experimentation on humans by private actors is (1) universal and obligatory or (2) a
10 matter of mutual concern.

11 The majority relies on eight sources of customary international law to support its
12 determination that a norm against non-consensual medical experimentation on humans by private
13 actors is universal and obligatory. However, this evidence falls far short of the quantum
14 necessary to establish the existence of such a norm: (1) the International Covenant on Civil and
15 Political Rights has been described by the Supreme Court as a “well-known international
16 agreement[] that despite [its] moral authority, ha[s] little utility,” in defining international
17 obligations, *Sosa*, 542 U.S. at 734, and moreover, it does not apply to private actors, such as the
18 Defendant in this action; (2) the Council of Europe’s Convention on Human Rights and
19 Biomedicine – a regional convention – was not ratified by the most influential nations in the
20 region, such as France, Germany, Italy, the Netherlands, Russia and the United Kingdom, and it
21 was promulgated on April 4, 1997, one year *after* the conduct at issue in this litigation; (3) the
22 UNESCO Universal Declaration of Bioethics and Human Rights of 2005 and (4) the European

1 Parliament Clinical Trial Directive of 2001 both also post-date the relevant time period by
2 several years; (5) the Declaration of Helsinki issued by the World Medical Association, a private
3 entity, and (6) the International Ethical Guidelines for Research Involving Human Subjects
4 promulgated by the Council for International Organizations for Medical Sciences, another private
5 entity, “express[] the sensibilities and the asserted aspirations and demands of some countries or
6 organizations” but are not “statements of universally-recognized legal obligations,” *Flores*, 414
7 F.3d at 262; (7) states’ domestic laws, which, unsupported by express international accords, are
8 not “significant or relevant for purposes of customary international law,” *id.* at 249; and (8) the
9 so-called Nuremberg Code, a statement of principles that accompanied a criminal verdict,
10 possesses at best “subsidiary” value as a judicial decision, Statute of the International Court of
11 Justice art. 38, June 26, 1945, 59 Stat. 1031, 33 U.N.T.S. 993 (“ICJ Statute”). Taken together,
12 this evidence falls short of charting the existence of a universal and obligatory international norm
13 actionable against non-government actors under the ATS.¹

14 In support of its determination that non-consensual medical experimentation by private
15 actors is a matter of mutual concern, the majority reasons that non-consensual medical
16 experiments breed distrust of medical interventions and thereby accelerate the spread of
17 infectious diseases across international borders. It is not enough, however, that tortious conduct
18 could create some sort of international consequence. In order for conduct to be a matter of
19 mutual concern, it must “threaten[] serious consequences in international affairs.” *Sosa*, 542
20 U.S. at 715. Such is the case when an ambassador is assaulted, for example, because the assault

¹ Even if we were to conclude that such a norm applied to state actors and that private entities could be held liable if they act under color of law, Plaintiffs have not pleaded sufficient state involvement to impose liability on Pfizer under that theory. *See* Part III *infra*.

1 “impinge[s] upon the sovereignty of the foreign nation and if not adequately redressed could rise
2 to an issue of war.” *Id.* Non-consensual medical experimentation by private actors simply does
3 not present the same grave risk of serious consequences in international affairs and is therefore
4 not a matter of mutual concern.

5 For these reasons, I conclude that non-consensual medical experimentation by private
6 actors, though deplorable, is not actionable under international law and would therefore affirm
7 the district court’s dismissal of Plaintiffs’ complaints.

8 DISCUSSION

9 I. Universal and Legally Obligatory Adherence

10 In order for a principle to become a norm of customary international law, states must
11 universally abide by it out of a sense of legal obligation, and not merely aspiration. *See Flores*,
12 414 F.3d at 248. It might seem obvious, but before one can determine whether a principle is
13 universally followed, one must define the principle in question. Like domestic law, international
14 law is not a monolith – a unitary set of rules applying indiscriminately to all actors that come
15 within its reach. To the contrary, international law consists of rules that govern only states, rules
16 that apply to private parties – individuals and corporations – and other rules that regulate both
17 evenhandedly. *See, e.g.*, Restatement (Third) of Foreign Relations of the United States § 101
18 (1987) (“Restatement (Third)”). As a result, the Supreme Court has required courts deciding
19 whether a principle is a customary international law norm to consider “whether international law
20 extends the scope of liability for a violation of a given norm to the perpetrator being sued, if the
21 defendant is a private actor such as a corporation or individual.” *Sosa*, 542 U.S. at 732 n.20; *see*
22 *also id.* at 760 (Breyer, J., concurring) (“The norm must extend liability to the type of perpetrator

1 (e.g., a private actor) the plaintiff seeks to sue.”).

2 The majority lists the norm at issue here as the prohibition of “medical experimentation
3 on non-consenting human subjects,” Maj. Op. at 15, and proceeds to analyze that norm without
4 regard to the alleged violator, *see id.* at 15-40. Put another way, the majority’s analysis would be
5 no different if Plaintiffs had sued the Nigerian government, instead of, or in addition to, Pfizer.
6 Such a broad, simplified definition ignores the clear admonitions of the Supreme Court – and
7 conflicts with prior decisions of this Court – that a customary international law norm cannot be
8 divorced from the identity of its violator. The majority’s analysis omits this critical
9 consideration. As a result, the majority opinion presents only half of the equation. To my mind,
10 the majority should have asked whether customary international law prohibits *private actors*
11 from medical experimentation on non-consenting human subjects. That question must be
12 answered in the negative.

13 A. *The Majority’s Sources of Customary International Law*

14 In *Flores*, we explained some of the difficulties inherent in determining what offenses
15 violate customary international law:

16 Customary international law is discerned from myriad decisions made in
17 numerous and varied international and domestic arenas. Furthermore, the relevant
18 evidence of customary international law is widely dispersed and generally
19 unfamiliar to lawyers and judges. These difficulties are compounded by the fact
20 that customary international law . . . does not stem from any single, definitive,
21 readily-identifiable source.

22 414 F.3d at 247-48. We have consistently looked to the ICJ Statute as the starting point for
23 determining the proper sources of international law. *See, e.g., id.* at 250-51; *United States v.*
24 *Yousef*, 327 F.3d 56, 100-03 (2d Cir. 2003). That statute lists: (1) “international conventions,
25 whether general or particular, establishing rules expressly recognized by the contesting states”;

1 (2) “international custom, as evidence of general practice accepted as law”; (3) “the general
2 principles of law recognized by civilized nations”; and, in certain circumstances (4) “judicial
3 decisions and the teachings of the most highly qualified publicists of the various nations, as
4 subsidiary means for the determination of rules of law.” ICJ Statute art. 38.

5 The ability to pick and choose from this seemingly limitless menu of sources presents a
6 real threat of “creative interpretation.” *Flores*, 414 F.3d at 248; *see also Amerada Hess*, 830 F.2d
7 at 429 (Kearse, J., dissenting). To mitigate this risk, and to prevent courts from becoming “
8 roving commission[s],” *Flores*, 414 F.3d at 262, we have, in our cases, methodically assessed
9 the weight and relative influence of not only each class of sources listed in the ICJ Statute, but
10 many individual sources within each class. The near-infinite list of international law sources
11 makes adherence to this precedent of paramount importance, for our analysis demonstrates that
12 not every source of international law carries equal weight.

13 Instead of following and applying our framework, the majority substitutes in its place a
14 compelling narrative. Over the course of only a few pages, the majority employs several sources
15 that it believes demonstrate a customary norm against medical experimentation by non-state
16 entities and weaves them together to reach its conclusion. *See* Maj. Op. at 15-35. Nowhere does
17 the majority examine these sources in the context required by *Sosa*. The majority does not
18 discuss the weight of these sources, how they collectively demonstrate a customary norm, or how
19 evidence supporting that norm compares with our ATS precedent. Had they done so, I am
20 hopeful that my colleagues would reach the same conclusion that I do – that medical
21 experimentation by private actors, while reprehensible, is not actionable under international law.

22 1. Treaties & Conventions

1 In *Flores*, we noted that treaties are the strongest evidence of customary international law
2 because they “create *legal obligations* akin to contractual obligations on the States parties to
3 them.” 414 F.3d at 256. “[W]e look primarily to the formal lawmaking and official actions of
4 States . . . as evidence of the established practices of States.” *Yousef*, 327 F.3d at 103. But not all
5 treaties are equal. Although “[a]ll treaties that have been ratified by at least two States
6 provide *some* evidence of the custom and practice of nations . . . a treaty will only constitute
7 *sufficient proof* of a norm of customary international law if an overwhelming majority of States
8 have ratified the treaty.” *Flores*, 414 F.3d at 256. Moreover, the “evidentiary weight to be
9 afforded to a given treaty varies greatly depending on (i) how many, and which, States have
10 ratified the treaty, and (ii) the degree to which those States actually implement and abide by the
11 principles set forth in the treaty.” *Id.* at 256-57. For instance, treaties ratified by the United
12 States are of greater evidentiary value if they are either self-executing or executed through acts of
13 Congress. *See, e.g., id.* at 257; *Khulumani v. Barclay Nat’l Bank Ltd.*, 504 F.3d 254, 284 (2d Cir.
14 2007) (Katzmann, J., concurring).

15 The majority relies primarily on two treaties.

16 a. International Covenant on Civil and Political Rights

17 The International Covenant on Civil and Political Rights, Dec. 9, 1966, S. Exec. Doc. E,
18 95-2, 999 U.N.T.S. 171, 6 I.L.M. 368 (ratified by the United States June 8, 1992) (“ICCPR”)
19 “guarantees a broad spectrum of civil and political rights to individuals within signatory nations.”
20 *United States v. Duarte-Acero*, 296 F.3d 1277, 1282 (11th Cir. 2002). One of those rights – to be
21 free of non-consensual medical or scientific experimentation – is stated in Article 7.

22 The ICCPR is not appropriate evidence of customary international law for at least two

1 reasons. First, the Supreme Court in *Sosa* explicitly described the ICCPR as a “well-known
2 international agreement[] that, despite [its] moral authority, ha[s] *little utility* under the standard
3 set out in this opinion,” because the “United States ratified [it] on the express understanding that
4 it was not self-executing and so did not itself create obligations enforceable in the federal
5 courts.” 542 U.S. at 734-35 (emphasis added).

6 Second, whatever limited weight the ICCPR has with regard to state action, it does
7 nothing to show that a norm prohibiting involuntary medical experimentation applies to non-state
8 entities. In citing its seemingly universal language, the majority overlooks the ICCPR’s
9 operative section, which requires that “[e]ach State Party . . . undertake[] to respect and to ensure
10 to all individuals within its territory and subject to its jurisdiction the rights recognized in the
11 present Covenant.” ICCPR art. 2(1). Thus, despite its broad text, the ICCPR by its own terms,
12 only governs “the relationship between a State and the individuals within the State’s territory.”
13 *Duarte-Acero*, 296 F.3d at 1283. Because the ICCPR only creates obligations flowing from a
14 state to persons within its territory, a non-state actor cannot be said to have violated it. Thus, the
15 ICCPR was relevant in *Filartiga* (decided before the Supreme Court limited its utility), in the
16 context of state-administered torture of one of its citizens in contravention of one of the rights
17 guaranteed by states in the ICCPR. *See* 630 F.2d at 884. But whatever its evidentiary value had
18 Plaintiffs sued the Nigerian government, the ICCPR clearly has none where the question is
19 whether international law includes a norm actionable against a *private corporation*.

20 b. Convention on Human Rights and Biomedicine

21 The second treaty cited by the majority is the Convention on Human Rights and
22 Biomedicine, Apr. 4, 1997, E.T.S. No. 164 (the “Convention”), promulgated by the Council of

1 Europe. *See* Maj. Op. at 31-32. Articles 5² and 16³ of the Convention require that the subject of
2 scientific research give his or her informed consent, which may be withdrawn at any time.

3 The first problem with the majority's reliance on the Convention is that it is a regional
4 agreement not signed by the most influential states in the region. Membership in the Council of
5 Europe is limited to European states. *See* Statute of the Council of Europe, art. 4, May 5, 1949,
6 E.T.S. No. 1. It is difficult to see how the Convention demonstrates the *universality* of the
7 medical experimentation principle when its signatories are limited to one continent. The
8 majority also notes that the Convention has been signed by thirty-four states, *see* Maj. Op. at 31,
9 but overlooks that it has only been ratified by twenty-two, and a treaty only evidences the

² Article 5 – General rule

An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks. The person concerned may freely withdraw consent at any time.

³ Article 16 – Protection of persons undergoing research

Research on a person may only be undertaken if all the following conditions are met:

- i. there is no alternative of comparable effectiveness to research on humans;
- ii. the risks which may be incurred by that person are not disproportionate to the potential benefits of the research;
- iii. the research project has been approved by the competent body after independent examination of its scientific merit, including assessment of the importance of the aim of the research, and multidisciplinary review of its ethical acceptability;
- iv. the persons undergoing research have been informed of their rights and the safeguards prescribed by law for their protection;
- v. the necessary consent as provided for under Article 5 has been given expressly, specifically and is documented. Such consent may be freely withdrawn at any time.

1 customs and practices of states that have ratified it. *Flores*, 414 F.3d at 256. Lastly, and perhaps
2 more importantly, the Convention is lacking even as evidence of a European norm, since it has not
3 been ratified by the more influential European states, including France, Germany, Italy, the
4 Netherlands, Russia and the United Kingdom, and a treaty's evidentiary value increases along
5 with the influence in international affairs of the states that have ratified it. *See id.* at 257;
6 Convention on Human Rights and Biomedicine, Chart of Signatures and Ratifications as of
7 December 23, 2008,
8 [http://conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=164&CM=8&DF=12/23/2008&](http://conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=164&CM=8&DF=12/23/2008&CL=ENG)
9 [CL=ENG](http://conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=164&CM=8&DF=12/23/2008&CL=ENG) ("Convention Ratifications Chart").

10 A second, more fundamental problem with the majority's reliance on the Convention is
11 that it was promulgated *after* the conduct at issue here. I know of no authority for an
12 international *ex post facto* definition of the law of nations by later signed treaties. *Cf. Vietnam*
13 *Ass'n for Victims of Agent Orange v. Dow Chem. Co.*, 517 F.3d 104, 118 (2d Cir. 2008) ("The
14 United States did not ratify the 1925 Geneva Protocol until 1975. Accordingly, the Protocol
15 cannot be said to have constituted 'a treaty of the United States,' 28 U.S.C. § 1350, during the
16 period relevant to this appeal."). Plaintiffs allege that the Trovan testing occurred in March and
17 April of 1996, but the Convention was not opened for signature until April 4, 1997, and did not
18 bind any state until Slovakia's ratification on January 15, 1998. *See Flores*, 414 F.3d at 256 ("A
19 State only becomes bound by – that is, becomes a party to – a treaty when it ratifies the treaty.");
20 Convention Ratifications Chart. The Convention is without import to this inquiry. Two other
21 post-1996 sources cited by the majority, the 2005 UNESCO Universal Declaration on Bioethics
22 and Human Rights and the 2001 European Parliament Clinical Trial Directive share equal

1 evidentiary irrelevance for the same reason.

2 2. Multinational Declarations of Principle

3 Plaintiffs and the majority cite several multinational declarations, including the World
4 Medical Association’s Declaration of Helsinki and the International Ethical Guidelines for
5 Research Involving Human Subjects promulgated by the Council for International Organizations
6 of Medical Sciences (“CIOMS Guidelines”), as additional evidence that the prohibition against
7 non-consensual medical experimentation applies to non-state actors. In doing so, the majority
8 somehow overlooks our decisions in *Flores* and *Yousef*.

9 In *Flores*, plaintiffs sought to demonstrate customary international law by reference to
10 multinational declarations. In response, we noted that a declaration, “which may be made by a
11 multinational body, or by one or more States, customarily is a ‘mere general statement of policy
12 [that] is unlikely to give rise to . . . obligation[s] in any strict sense.’” 414 F.3d at 262 (quoting *I*
13 *Oppenheim’s International Law* 1189 (Sir Robert Jennings & Sir Arthur Watts, eds., 9th ed.
14 1996)) (alterations in original). “Such declarations are almost invariably political statements –
15 expressing the sensibilities and the asserted aspirations and demands of some countries or
16 organizations – rather than statements of universally-recognized legal obligations.” *Id.* As a
17 result, we concluded that “such declarations *are not proper evidence of customary international*
18 *law.*” *Id.* (emphasis added).

19 In *Flores*, the declarations we rejected were put forth by international governmental
20 bodies, the Organization of American States and the United Nations Conference on Environment
21 and Development. *Id.* at 263. Here, the two declarations embraced by the majority were put
22 forward by entirely private organizations – hardly evidence of the state of international law. The

1 Declaration of Helsinki was adopted by the World Medical Association, a group comprised not of
2 member states, but of physicians and private national medical associations. “The World
3 Medical Association (WMA) is an international organization representing physicians. . . . [and]
4 has always been an independent confederation of free professional associations.” See The World
5 Medical Association, “About the WMA,” <http://www.wma.net/e/about/index.htm>. The express
6 terms of the Declaration of Helsinki make it abundantly clear that it is hortatory, and not
7 obligatory: “The World Medical Association (WMA) has developed the Declaration of Helsinki
8 as a statement of ethical principles” See World Med. Ass’n, *Declaration of Helsinki:
9 Ethical Principles for Medical Research Involving Human Subjects* art. A(1), June 1964.
10 Similarly, CIOMS is “an international non-governmental, non-profit organization.” CIOMS,
11 “What is CIOMS?,” http://www.cioms.ch/jan2008_what_is_cioms.pdf.

12 Treating these well-meaning, aspirational, but private, declarations as sources of
13 international law runs counter to our observation in *Yousef* that “no private person – or group of
14 men and women such as comprise the body of international law scholars – creates the law.” 327
15 F.3d at 102. This is so for good reason. As we have seen in our ATS jurisprudence,
16 international custom gives rise to legally enforceable obligations. To include the political
17 statements of private organizations in the select and conscribed group of sources capable of
18 creating international law would enfranchise non-democratic, unaccountable entities with
19 governmental authority. As a result, these declarations are “not proper evidence of customary
20 international law.” *Flores*, 414 F.3d at 262.

21 The majority focuses its lens on one line in *Filartiga* for the proposition that a
22 “declaration may by custom become recognized as laying down rules binding upon the States.”

1 Maj. Op. at 19 (quoting *Filartiga*, 630 F.2d at 883). In *Filartiga*, we were discussing a *United*
2 *Nations declaration*, which though not binding, “creates an expectation of adherence” because it
3 “specif[ies] with great precision the obligations of member nations.” 630 F.2d at 883. The
4 declarations relied on by the majority were not put forth by a governmental body such as the
5 United Nations but by wholly private organizations, incapable of creating legally binding
6 obligations.

7 3. State Practice

8 The majority also points to the great number of states that, in their respective domestic
9 laws, require informed consent in medical research. That many countries have prohibited private
10 actors from conducting medical experiments or treatments without informed consent is certainly
11 commendable and worthy of praise, but not “significant or relevant for purposes of customary
12 international law.”⁴ See *Flores*, 414 F.3d at 249. For it is only when states prohibit domestic
13 action as a result of “express international accords” that a wrong becomes a violation of
14 customary international law. See *Filartiga*, 630 F.2d at 888 (quoting *IIT v. Vencap, Ltd.*, 519 F.2d
15 1001, 1015 (2d Cir. 1975) (Friendly, J.)). No such international accord exists here.

16 Moreover, “substantive uniformity” among states’ domestic laws is only a starting point
17 for demonstrating international custom through individual state practice, which should also
18 reflect a “procedural” consensus among states on how that behavior should be prosecuted –
19 criminally and civilly. See *Sosa*, 542 U.S. at 761-62 (Breyer, J, concurring). As Justice Breyer
20 noted in his *Sosa* concurrence, the states of the world have reached both substantive and
21 procedural agreement with respect to only a handful of certain international law norms made

⁴ Reliance on states’ domestic laws also raises questions of mutuality, discussed *infra* at Part II.

1 actionable against non-state entities. *See id.*; Part I(B) *infra*. Non-consensual medical testing is
2 not among them.

3 4. The Nuremberg Code

4 The majority centers its analysis around the Nuremberg Code, but, in the process,
5 critically misstates its genesis and status in international law. *See* Maj. Op. at 20-24. Because the
6 Code is a *sui generis* source of international law, its context is vital to understanding what it
7 is – and what it is not.

8 The Nuremberg trials are unquestionably one of this country’s greatest and most enduring
9 contributions to the field of international law. As early as 1943, the Allied powers contemplated
10 bringing Nazi war criminals to justice after the conclusion of the Second World War. At the
11 October 1943 Moscow Conference, the United States, United Kingdom and Soviet Union issued

12 a joint “Statement on Atrocities,” warning that:

13 At the time of granting of any armistice to any government which may be set up in
14 Germany, those German officers and men and members of the Nazi party who have
15 been responsible for or have taken a consenting part in the above atrocities,
16 massacres and executions will be sent back to the countries in which their
17 abominable deeds were done in order that they may be judged and punished
18 according to the laws of these liberated countries and of free governments which
19 will be erected therein.

20 Moscow Declaration Statement of Atrocities, Oct. 30, 1943, 9 U.S. Dept of State Bull. 310
21 (signed by President Roosevelt, Prime Minister Churchill and Premier Stalin). The statement
22 added that German criminals “whose offenses have no particular geographical localization . . .
23 will be punished by joint decision of the government of the Allies.” *Id.*

24 Following victory in Europe and the surrender of Germany, the Allies executed the
25 London Charter on August 8, 1945, establishing an International Military Tribunal to try the

1 “major war criminals,” London Charter, Agreement for the Prosecution and Punishment of the
2 Major War Criminals of the European Axis, art. 3, Aug. 8, 1945, 59 Stat. 1544, 82 U.N.T.S. 279,
3 and leaving the door open for other war criminals to be tried in any other “national or occupation
4 court” that might be established, *id.* art. 6. Alongside the London Charter, the Allies
5 promulgated the Charter of the International Military Tribunal and formed a four-member
6 tribunal with one member appointed by each of the Allies, with jurisdiction over “the major war
7 criminals” accused of committing three crimes: crimes against peace,⁵ war crimes,⁶ and crimes
8 against humanity.⁷ Charter of the International Military Tribunal, arts. 2, 6, Aug. 8, 1945, 59
9 Stat. 1544, 82 U.N.T.S. 279. It was the International Military Tribunal that conducted the
10 celebrated trial that resulted in the convictions of 19 of 22 defendants, including high-ranking
11 Nazi officials Hermann Goering, Rudolf Hess, and Karl Doenitz. *See generally* Robert H.
12 Jackson, Final Report to the President on the Nuremberg Trials (Oct. 7, 1946). But the
13 Nuremberg Code was adopted by a different tribunal in a different trial.

⁵ “Crimes Against Peace” were defined as “planning, preparation, initiation or waging of a war of aggression, or a war in violation of international treaties, agreements or assurances, or participation in a common plan or conspiracy for the accomplishment of any of the foregoing.” Charter of the International Military Tribunal art. 6(a).

⁶ “War Crimes” were defined as “violations of the laws or customs of war. Such violations shall include, but not be limited to, murder, ill-treatment or deportation to slave labor or for any other purpose of civilian population of or in occupied territory, murder or ill-treatment of prisoners of war or persons on the seas, killing of hostages, plunder of public or private property, wanton destruction of cities, towns or villages, or devastation not justified by military necessity.” Charter of the International Military Tribunal art. 6(b).

⁷ “Crimes Against Humanity” were defined as “murder, extermination, enslavement, deportation, and other inhumane acts committed against any civilian population, before or during the war; or persecutions on political, racial or religious grounds in execution of or in connection with any crime within the jurisdiction of the Tribunal, whether or not in violation of the domestic law of the country where perpetrated.” Charter of the International Military Tribunal art. 6(c).

1 Four months after the London Charter established the International Military Tribunal, the
2 Allied Control Council, the joint allied entity that governed post-war Germany, enacted Control
3 Council Law No. 10, which authorized each of the occupying Allies, within its own “Zone of
4 Occupation,” to arrest and prosecute “persons within such Zone suspected of having committed a
5 crime,”⁸ subject to a right of first refusal by the International Military Tribunal. Allied Control
6 Council Law No. 10 art. III, §§ 1,3 (Dec. 20, 1945), *in 1 Trials of War Criminals Before the*
7 *Nuernberg Military Tribunals Under Control Council Law No. 10*, XVIII (William S. Hein &
8 Co., Inc. 1997) (1949), *available at* [http://www.loc.gov/rr/frd/Military_law/pdf/NT_war-](http://www.loc.gov/rr/frd/Military_law/pdf/NT_war-criminals_Vol-I.pdf)
9 [criminals_Vol-I.pdf](http://www.loc.gov/rr/frd/Military_law/pdf/NT_war-criminals_Vol-I.pdf) (“*1 Trials of War Criminals*”).

10 The first of the American trials arising under Control Council Law No. 10 was the
11 “Medical Case” against German doctors. On October 25, 1946, the American Office of Military
12 Government for Germany enacted General Order 68, constituting Military Tribunal 1, comprised
13 of three American military judges and one alternate judge. *Id.* at 5. That same day, Brigadier
14 General Telford Taylor, Chief of Counsel for War Crimes, signed an indictment in *United States*
15 *v. Karl Brandt, et al.* charging 23 defendants with war crimes, crimes against humanity, and
16 conspiracy, and charging 10 of the defendants with membership in the “SS,” an organization
17 declared criminal by the International Military Tribunal. *Id.* at 8-18. These charges were
18 premised, primarily, on the defendants’ forced medical experiments, which constituted war
19 crimes when performed on prisoners of war, and crimes against humanity when conducted on
20 Nazi concentration camp prisoners.

⁸ In addition to the three crimes listed in the Charter of the International War Tribunal, Control Council Law No. 10 added a fourth – “Membership in categories of a criminal group or organization declared criminal by the International Military Tribunal.” Control Council Law No. 10 art. II, § (d).

1 At the conclusion of the Medical Case, 16 of the 23 defendants were convicted of one or
2 more of the charges, and seven were ultimately sentenced to death. Along with their verdict, the
3 military judges enumerated ten principles that came to be known as the Nuremberg Code, the
4 first of which states that in medical experiments, the “voluntary consent of the human subject is
5 absolutely essential.” *2 Trials of War Criminals Before the Nuernberg Military Tribunals Under*
6 *Control Council Law No. 10*, 181 (William S. Hein & Co., Inc. 1997) (1949), available at
7 http://www.loc.gov/rr/frd/Military_law/pdf/NT_war-criminals_Vol-II.pdf (“*2 Trials of War*
8 *Criminals*”).

9 My colleagues contend that the Code flowed naturally from the principles of law
10 espoused in the London Charter. They are quite right, of course, that Control Council Law No. 10
11 was modeled after the London Charter and the American and International military tribunals
12 shared largely the same general international law and procedural frameworks. The London
13 Charter identified and defined certain international law offenses – Crimes Against Humanity,
14 Crimes Against Peace, and War Crimes – while each of the twelve trials before the American
15 military tribunal concerned a unique and horrific context for the commission of those crimes,
16 ranging from medical experimentation on prisoners to the use of slave labor. For example, the
17 definitions of Crimes Against Humanity and War Crimes under which the Nazi doctors were
18 tried in the Medical Case were virtually identical to those of the London Charter. However, the
19 majority overlooks the fact that the Nuremberg Code dealt not with these general principles of
20 law, but instead with the very specific issue of permissible medical experimentation. The ethical
21 principles espoused in the Code had no forebears in either the London Charter or the judgment of
22 the International Military Tribunal. They were developed exclusively in the Medical Case.

1 I recite this history not to suggest that the Nuremberg Code is not an extraordinary or
2 groundbreaking document, but rather to demonstrate the difficulty inherent in measuring its
3 evidentiary weight, as it does not fit neatly into any of the categories this Court has identified for
4 sources of international law. For one thing, the Code was developed by the United States
5 military and announced by an American military court. *See United States v. Stanley*, 483 U.S.
6 669, 687 (1987) (Brennan, J., dissenting). Certainly, the Code is not a treaty and did not
7 immediately bind any state. Under the framework of the ICJ Statute – and, accordingly, this
8 Court – because it was part of a criminal verdict, its closest analogue is a judicial decision, but
9 judicial decisions are only “subsidiary,” rather than primary, sources of customary international
10 law. *See* ICJ Statute art. 38; Maj. Op. at 15. I agree with my colleagues that the Code has had
11 significant import – influence that continues to this day. The Code surely has evidentiary value
12 in our inquiry, but there is nothing to indicate that the Code establishes a norm of international
13 law prohibiting non-consensual medical experimentation or treatment by private actors, or
14 compensates for the virtually non-existent evidentiary value of the other sources cited by the
15 majority.

16 Conscious of our obligation to measure the weight of the sources of international law in
17 the aggregate, what is the sum of the sources that serve as the cornerstone of the majority’s
18 conclusion? The ICCPR, characterized by the Supreme Court as being of “little utility,” *Sosa*,
19 542 U.S. at 734, which, in any event, does not apply to private actors; a pair of private
20 organizations’ declarations that our Circuit precedent tells us “are not proper evidence of
21 customary international law,” *Flores*, 414 F.3d at 262; one regional convention and two multi-
22 national declarations that post-date the critical time period and are thus completely irrelevant;

1 states' domestic laws untethered to any international agreement that we are told is not
2 "significant or relevant for purposes of customary international law," *id.* at 249; and the
3 Nuremberg Code, a document whose evidentiary value is unclear.

4 Simply put, the evidence here does not compare with the sources put forward in the few
5 cases where we have held a principle to be a norm of customary international law. Exercising
6 "extraordinary care and restraint," *see id.* at 248, we have only upheld ATS jurisdiction in cases
7 where the evidence of customary international law was entirely overwhelming.⁹ In *Filartiga*, we
8 were persuaded by the fact that the "international consensus surrounding torture has found
9 expression in *numerous* international treaties and accords." 630 F.2d at 883 (emphasis added).
10 There, the State Department – "the political branch with principal responsibility for conducting
11 the international relations of the United States," *Flores*, 414 F.3d at 262 – had expressly
12 announced that the prohibition against torture had ripened into a norm of customary international
13 law.¹⁰ *Filartiga*, 630 F.2d at 884. In *Kadic*, we observed that genocide was included in section
14 404 of the Restatement and that the Convention on the Prevention and Punishment of the Crime
15 of Genocide had been ratified by more than 120 nations, including the United States, 70 F.3d at

⁹ The majority purports to include our recent decision in *Khulumani v. Barclay National Bank Ltd.*, 504 F.3d 254 (2d Cir. 2007) (per curiam) in this select group, stating that it "held that the ATS conferred jurisdiction over multinational corporations that purportedly collaborated with the government of South Africa in maintaining apartheid because they aided and abetted violations of customary international law." Maj. Op. at 13-14. To the contrary, *Khulumani* did not confer jurisdiction and did not make any determination on whether plaintiffs had stated a violation of international law. It merely held that the district court erred in concluding that the ATS did not convey jurisdiction for "aiding and abetting violations of customary international law," and remanded for consideration of whether plaintiffs had alleged such a violation that the defendants could have been liable for aiding and abetting. *See Khulumani*, 504 F.3d at 260.

¹⁰ Indeed, the Supreme Court later declared that in ATS actions, "federal courts should give serious weight to the Executive Branch's view of the case's impact on foreign policy." *Sosa*, 542 U.S. at 733 n.21.

1 240-42, while international criminalization of war crimes was established by four Geneva
2 Conventions, ratified by more than 180 nations, including the United States, *id.* at 242-43. In
3 *Amerada-Hess*, it was similarly obvious that Argentina’s Falkland War attack on an American
4 ship violated one of the oldest customary international law norms. 830 F.2d at 423-24. We cited
5 a variety of international accords establishing the right of a neutral ship to free passage. *Id.* at
6 424. After tracing the norm to Blackstone, we concluded that it was “beyond controversy that
7 attacking a neutral ship in international waters . . . violates international law.” *Id.*

8 In those cases, the evidence of international acceptance of each norm with respect to each
9 defendant was “clear and unambiguous.” *Flores*, 414 F.3d at 252. In each case, the nations of
10 the world gathered to ratify in universal numbers treaties that specifically prohibited genocide,
11 war crimes, torture, and attacks on neutral ships – not in generalized human rights agreements
12 but in accords with those discrete norms as their exclusive subjects.

13 My colleagues contend that I look only to the presence (or, in this case, the absence) of a
14 globally ratified treaty as the exclusive source of an international law norm. Far from it – we
15 have held that customary international law “does not stem from any single, definitive, readily-
16 identifiable source.” *Id.* at 248. However, the great weight of ATS jurisdiction must rest upon a
17 foundation sturdy enough to support it. Just as it would be error to stubbornly require one source
18 of sufficient strength to bear that burden on its own, the majority is equally mistaken in its
19 attempt to employ a series of extraordinarily weak sources to secure a purported norm of
20 customary international law. Our case law makes clear that even when viewed collectively, these
21 sources are incapable of carrying the weight placed upon them by my colleagues.

22 B. *Restatement § 404*

1 Nor does Plaintiffs’ purported norm resemble the select few norms for which
2 international law extends liability to private actors. Although the law of nations in general does
3 not “confine[] its reach to state action,” *see Kadic*, 70 F.3d at 239, courts must still consider
4 whether the specific norm at issue does. In *Kadic*, we noted that the Restatement (Third) of
5 Foreign Relations Law of the United States differentiates between “those violations that are
6 actionable when committed by a state¹¹ and a more limited category of violations” that apply with
7 equal force to private actors. *Id.* at 240 (citing Restatement (Third) §§ 404, 702). Section 404 of
8 the Restatement authorizes universal criminal jurisdiction over non-state entities “for certain
9 offenses recognized by the community of nations as of universal concern, such as piracy, slave
10 trade, attacks on or hijacking of aircraft, genocide, war crimes, and perhaps certain acts of
11 terrorism, even where [no other basis of jurisdiction] is present.”¹² Universal jurisdiction, not to
12 be confused with universal acceptance of a norm for ATS purposes, “permits a State to prosecute

¹¹ Section 702 provides:

A state violates international law if, as a matter of state policy, it practices, encourages, or condones

- (a) genocide,
- (b) slavery or slave trade,
- (c) the murder or causing the disappearance of individuals,
- (d) torture or other cruel, inhuman, or degrading treatment or punishment,
- (e) prolonged arbitrary detention,
- (f) systematic racial discrimination, or
- (g) a consistent pattern of gross violations of internationally recognized human rights.

¹² The Court explained its application of a criminal law provision to a civil statute by noting that a comment to section 404 “permits states to establish appropriate civil remedies such as the tort actions authorized by the [ATS].” *Kadic*, 70 F.3d at 240 (citation omitted). More specifically, “jurisdiction on the basis of universal interests has been exercised in the form of criminal law, but international law does not preclude the application of non-criminal law on this basis, for example, by providing a remedy in tort or restitution for victims of piracy.” Restatement (Third) § 404 cmt. b.

1 an offender of any nationality for an offense committed outside of that State and without contacts
2 to that State.” *Yousef*, 327 F.3d 56 at 103.

3 The plaintiffs in *Kadic* alleged that Radovan Karadzic, the “president” of the self-
4 proclaimed republic of Srpska violated several international law norms, notably bans on
5 genocide, war crimes and torture. 70 F.3d at 236-37. Treating Karadzic as a non-state actor, we
6 reviewed not only the Restatement, but a host of relevant international accords, leading us to
7 conclude that by their own terms, the norms prohibiting genocide and war crimes applied to
8 private individuals, while torture and summary execution “are proscribed by international law
9 only when committed by state officials or under color of law.” *Id.* at 241-43. We added that the
10 “‘color of law’ jurisprudence of 42 U.S.C. § 1983 is a relevant guide to whether a defendant has
11 engaged in official action for purposes of jurisdiction under the [ATS].” *Id.* at 245.

12 Five years later, we again determined whether an international law norm applied only to
13 state actors. *See Bigio v. Coca-Cola Co.*, 239 F.3d 440 (2d Cir. 2000). Building on *Kadic*, we
14 held that ATS jurisdiction over a non-governmental entity requires the violation of a norm “listed
15 as an ‘act of universal concern’ in § 404 or . . . sufficiently similar to [those] acts for us to treat
16 them as though they were incorporated into § 404 by analogy,” or conduct committed under color
17 of law. *Id.* at 448. In affirming the district court’s dismissal, we determined that the act at issue
18 – discriminatory expropriation of property – is much more like the acts listed in section 702 than
19 those in section 404, and that the complaint did not allege that Coca-Cola acted in concert with
20 Egyptian state officials. *Id.* at 447-49. However, unlike in *Kadic*, we saw no need to look
21 beyond the Restatement to any sources of international law in order to conclude that the norm did
22 not apply to non-state entities. *Compare id.* at 448, *with Kadic*, 70 F.3d at 241-43. It is equally

1 clear that section 404 of the Restatement does not reveal a norm of customary international law
2 prohibiting non-consensual medical experimentation by *private actors*.

3 To reiterate, section 404 lists only five specific acts for which universal criminal
4 jurisdiction over private actors exists: piracy, genocide, slave trade, war crimes, and attacks on
5 aircrafts. *See also Vietnam Ass'n for Victims of Agent Orange*, 517 F.3d at 116 (describing these
6 five as comprising “the list of principles that may be said to have ripened into universally
7 accepted norms of international law” (internal quotation marks omitted)). If anything, this Court
8 has been even more stringent, holding that in spite of the Restatement, federal courts could not
9 try an alleged airline bomber under customary international law principles of universal
10 jurisdiction.¹³ *See Yousef*, 327 F.3d at 103-08. Regardless, there is no dispute that none of the
11 five acts in section 404 encompasses non-consensual medical experimentation. Instead,
12 Plaintiffs argue that it is “sufficiently similar” to those acts to support its application to a private
13 corporation.¹⁴ *See Bigio*, 239 F.3d at 448. This Court has never had occasion to consider what
14 types of acts are “sufficiently similar” to the section 404 acts except to conclude in *Bigio* that

¹³ Yousef was charged with placing a bomb aboard a Philippine Airlines jet flying from the Philippines to Japan. 327 F.3d at 81, 88. After holding that customary international law could not support universal jurisdiction, we observed that “treaties may diverge broadly from customary international law,” *id.* at 108, and upheld jurisdiction under 18 U.S.C. § 32, the statute implementing the “extradite or prosecute” provision of the Montreal Convention for the Suppression of Unlawful Acts Against the Safety of Civil Aviation (Sabotage) art. 7, Sept. 23, 1971, 24 U.S.T. 565, 974 U.N.T.S. 177 (“The Contracting State in the territory of which the alleged offender is found shall, if it does not extradite him, be obliged, without exception whatsoever and whether or not the offence was committed in its territory, to submit the case to its competent authorities for the purpose of prosecution.”), *id.* at 108-10.

¹⁴ I note the tension between our holding in *Bigio* that acts can, at least in theory, be incorporated into § 404 by analogy for ATS purposes, *see* 239 F.3d at 448, and our statement in *Yousef* that the “strictly limited set of crimes subject to universal jurisdiction cannot be expanded by drawing an analogy between some new crime . . . and universal jurisdiction’s traditional subjects” for purposes of exercising criminal jurisdiction, *see* 327 F.3d at 103-04.

1 discriminatory expropriation was not among them. *Id.* For similar reasons, neither is non-
2 consensual medical experimentation.

3 Universal jurisdiction originated with prosecutions of piracy more than 500 years ago.
4 *See Yousef*, 327 F.3d at 104; *United States v. Lei Shi*, 525 F.3d 709, 723 (9th Cir. 2008). As we
5 explained in *Yousef*, piracy is universally punishable not because it is uniquely heinous but
6 “because of the threat that piracy poses to orderly transport and commerce between nations and
7 because the crime occurs statelessly on the high seas.” 327 F.3d at 104. By 1822, it was beyond
8 “doubt . . . that vessels and property in the possession of pirates may be lawfully seized on the
9 high seas by [any] person, and brought in for adjudication.” *United States v. the La Jeune*
10 *Eugenie*, 26 F. Cas. 832, 843 (C.C.D. Mass. 1822) (No. 15,551); *see also United States v. Smith*,
11 18 U.S. (5 Wheat) 153, 163 (1820) (Story, J.) (discussing the bases for universal jurisdiction over
12 piracy).

13 Private actors trading slaves (as opposed to those engaging in slavery in general) are
14 subject to universal criminal jurisdiction because the early treaties that formed the basis for
15 customary international law considered the slave trade akin to piracy. For example, the 1841
16 Treaty of London provided that:

17 Their Majesties the Emperor of Austria, the King of Hungary and Bohemia, the
18 King of Prussia, and the Emperor of all the Russias, engage to prohibit all trade in
19 slaves, either by their respective subjects, or under their respective flags, or by
20 means of capital belonging to their respective subjects; and *to declare such traffic*
21 *piracy*. Their Majesties further declare that any vessel which may attempt to carry
22 on the Slave Trade, shall, by that fact alone, lose all right to the protection of their
23 flag.

24 Treaty for the Suppression of the African Slave Trade art. I, Dec. 20, 1841, 92 Consol. T.S. 437
25 (emphasis added), *reprinted in* M. Cherif Bassiouni & Edward M. Wise, *Aut Dedere Aut*

1 *Judicare: The Duty to Extradite or Prosecute in International Law* 132-33 (1995); *see also*
2 Kenneth C. Randall, *Universal Jurisdiction Under International Law*, 66 *Tex. L. Rev.* 785, 798
3 (1988) (“Currently, states can recognize universal jurisdiction over slave trading by . . .
4 customary law.”). Although we declined to hold in *Yousef* that the principle had ripened into a
5 customary norm, attacks on airliners logically fit into this class because, like the high seas,
6 airspace is stateless and extraterritorial.

7 After World War II, universal criminal jurisdiction was extended to private actors –
8 including many of the Nazi defendants prosecuted under Control Council Law No. 10 – accused
9 of crimes against humanity such as war crimes and genocide because, like piracy, ““there is . . . a
10 lack of any adequate judicial system operating on the spot where the crime takes place – in the
11 case of piracy it is because the acts are on the high seas and in the case of war crimes because of a
12 chaotic condition or irresponsible leadership in time of war.”” *Yousef*, 327 F.3d at 105 (quoting
13 Willard B. Cowles, *Universality of Jurisdiction Over War Crimes*, 33 *Cal. L. Rev.* 177, 194
14 (1945)); *see also Flores*, 414 F.3d at 244 n.18 (“Customary international law rules proscribing
15 crimes against humanity, including genocide, and war crimes, have been enforceable against
16 individuals since World War II.”)..

17 In *Yousef*, we concluded that these acts share two common traits: they “(1) are universally
18 condemned by the community of nations, and (2) by their nature occur either outside of a State or
19 where there is no State capable of punishing, or competent to punish, the crime.” 327 F.3d at
20 105.

21 Non-consensual medical experimentation is not “sufficiently similar” to these crimes to
22 warrant its incorporation into section 404 by analogy. Plaintiffs acknowledge that the acts listed

1 in section 404 share “a particular quality of crossing international boundaries,” a quality that they
2 argue that medical experimentation shares “because of the universal uses of medical research and
3 the common practice of physicians to travel to crisis areas to deliver humanitarian aid.” But the
4 mere crossing of an international border does not give rise to universal jurisdiction over non-state
5 actors. We made this clear in *Yousef*, where we rejected universal jurisdiction over an individual
6 accused of bombing of an aircraft leaving the Philippines for Japan. 327 F.3d at 98, 103. As we
7 held, universal criminal jurisdiction over private actors is only appropriate for acts which, “by
8 their nature,” are beyond state sovereignty. *Id.* at 105. Here, Pfizer’s alleged actions occurred
9 exclusively within Nigeria, and medical experimentation is not a crime which, by its nature, is
10 incapable of state punishment. Plaintiffs’ argument to the contrary is belied by the state and
11 federal civil and criminal actions pending against Pfizer in Nigeria. *See* Maj. Op. at 9.

12 As in *Bigio*, medical experimentation more closely resembles the acts for which only
13 state actors may be held responsible. Plaintiffs compare medical experimentation with slavery.
14 Yet, under the Restatement, while anyone may be prosecuted for engaging in the slave trade,
15 slavery itself is only actionable against state actors. *See* Restatement (Third) § 702(b) (“A state
16 violates international law if, as a matter of state policy, it practices, encourages, or condones . . .
17 slavery . . .”). Medical experimentation resembles slavery in its grievous exploitation of
18 unconsenting and unwilling subjects; it also resembles torture in its infliction of horrific physical
19 and emotional pain. However, both the Restatement and this Court have recognized that the
20 norm against torture reaches only state actors. *See Kadie*, 70 F.3d at 243-44; Restatement (Third)
21 § 702(d); *see also* Convention Against Torture and Other Cruel, Inhuman or Degrading
22 Treatment or Punishment art 1, Dec. 10, 1984, S. Treaty Doc. No. 100-20, 1465 U.N.T.S. 85

1 (“CAT”) (defining torture as being “inflicted by or at the instigation of or with the consent or
2 acquiescence of a public official or other person acting in an official capacity.”).¹⁵

3 One of the fundamental attributes of sovereignty is a state’s authority to exercise criminal
4 jurisdiction over persons accused of committing crimes within its territory. The crimes listed in
5 section 404 are not the extraordinary exceptions because they are singularly reprehensible or
6 deserving of condemnation. Few would argue that piracy, for which private actors may be
7 prosecuted universally but which requires neither an act of violence nor the infliction of physical
8 injury,¹⁶ is more heinous than torture or slavery, practices made actionable only against state
9 entities. Rather, by definition, these crimes occur in locations where, or during times when,
10 sovereignty, and *a fortiori* criminal jurisdiction, are incapable of being exercised. Because
11 medical experimentation is entirely *intranational* and fully subject to domestic criminal
12 jurisdiction, it is not “sufficiently similar” to those acts listed in section 404, and cannot be
13 incorporated by analogy as to reach private, non-state actors.

14 The defendants in the Medical Case were not charged with conducting non-consensual
15 medical tests per se. Rather, those tests, when conducted on prisoners of war and members of a
16 discrete civilian population imprisoned in concentration camps, constituted “war crimes” and
17 “crimes against humanity,” offenses for which customary international law has imposed
18 individual responsibility. *See Flores*, 414 F.3d at 244 n.18. Unlike the Defendant in this action,
19 the Nazi doctors convicted by the American military tribunal were not private actors. Each

¹⁵ It should be noted that while universal criminal jurisdiction under the CAT does exist for torturers, those torturers must, by definition, be state actors. *See* CAT arts. 4, 7, 8.

¹⁶*See, e.g.*, United Nations Convention on the Law of the Sea part VII, art. 101, Dec. 10, 1982, S. Treaty Doc. No. 103-39, 1833 U.N.T.S. 3 (stating that piracy may consist of “any illegal acts of violence or detention, or any act of depredation”)

1 convicted defendant held a position of authority in either the medical services or the military of
2 the Third Reich.¹⁷ See *1 Trials of War Criminals* 29. Moreover, the atrocities for which they
3 were convicted victimized state prisoners in state-administered concentration camps, according to
4 the Indictment, “for the benefit of the German Armed Forces.” *Id.* at 11-14. It is difficult to
5 imagine a more egregious example of the violation of a customary international law norm or a
6 more appropriate case for ATS jurisdiction.

7 The majority today authorizes the exercise of ATS jurisdiction over an entirely private
8 corporation for violating a previously unrecognized norm of international law. In doing so, my
9 colleagues accept proof far weaker than in any other case where this Court has identified a norm
10 of customary international law, and, apparently, overlook the fact that this purported norm in no
11 way resembles those few norms enforceable against private entities. When tasked by the
12 Supreme Court with “vigilant doorkeeping” to ensure that the list of actionable international
13 norms remains “narrow,” *Sosa*, 542 U.S. at 729, we must be no less demanding than we have
14 been in the past. Under that standard, the evidence put forward by Plaintiffs does not establish a
15 norm of customary international law actionable against private actors. I believe that the
16 majority’s decision departs from our settled case law and lowers considerably our previously high
17 bar for ATS jurisdiction.

18 II. **Mutuality**

¹⁷ All but three of the 23 defendants were doctors. *1 Trials of War Criminals* 29. The three that were not were colonels or senior colonels in the Nazi SS. *1 Trials of War Criminals* 8, 29. Of the 20 doctors, all but one “held positions in the medical services of the Third Reich.” *1 Trials of War Criminals* 29. The lone exception, Adolf Pokorny, a specialist in skin and venereal diseases, was acquitted of all charges. *1 Trials of War Criminals* 10; *2 Trials of War Criminals* 292-94

1 There are many principles on which most states of the world community agree. Most find
2 support and enforcement in the richly diverse legal systems in place around the globe. But
3 universal acceptance as a normative principle is not enough to gain entrance into the “law of
4 nations.” The norm must not only be universal, it must touch on matters that are “of mutual, and
5 not merely several, concern.” *Filartiga*, 630 F.2d at 888. Matters are of mutual concern when
6 they “affect[] the relationship between states or between an individual and a foreign state, and
7 [are] used by those states for their common good and/or dealings inter se.” *IIT*, 519 F.2d at 1015.
8 On the other hand, matters of several concern are those “in which States are separately and
9 independently interested.” *Flores*, 414 F.3d at 249. For example, as we noted in *Flores*,
10 “murder of one private party by another, universally proscribed by the domestic law of all
11 countries . . . is not actionable under the [ATS] as a violation of customary international law
12 because ‘the nations of the world’ have not demonstrated that this wrong is of mutual, and not
13 merely several, concern.” *Id.* (quotation marks omitted). The majority concludes that non-
14 consensual medical experimentation by one private party on another is a matter of mutual
15 concern. I disagree.

16 We have consistently held that the best evidence that states consider a matter to be of
17 mutual concern is the fact that they have agreed to be bound “by means of express international
18 accords.” *Filartiga*, 630 F.2d at 888; *see Flores*, 414 F.3d at 249; *Khulumani*, 504 F.3d at 274
19 n.7 (Katzmann, J., concurring). The majority points to the ICCPR, the Convention on Human
20 Rights and Biomedicine, and the 2001 Clinical Trial Directive as evidence that “States
21 throughout the world have entered into . . . express and binding international agreements
22 prohibiting nonconsensual medical experimentation.” *See Maj. Op.* at 35. But those agreements

1 fail to demonstrate mutuality for the same reason they fail to demonstrate universality – the
2 ICCPR does not address acts by non-state actors and the other two were not in force at the time
3 of the alleged misconduct. Whatever international consensus has been reached as to non-
4 consensual medical experimentation by private actors has not yet “found expression in numerous
5 treaties and accords,” *cf. Filartiga*, 630 F.2d at 883. The majority cites no worldwide, multi-
6 continental, universally applicable “Convention Against Medical Experimentation,” because, at
7 the moment, none exists. That fact alone distinguishes this case from *Filartiga*, *Amerada-Hess*,
8 and *Kadic*.

9 In the absence of a binding global treaty, the majority seeks to demonstrate mutuality of
10 concern by describing the downstream effects of non-consensual medical experimentation. In
11 essence, the majority contends that non-consensual medical experiments feed distrust among
12 their victims, which, in turn, engenders a general reluctance to seek future medical attention or
13 vaccination, which, in turn, helps accelerate the spread of infectious diseases across international
14 borders. *See* Maj. Op. at 36-39. Indeed, I would concede that the majority may be quite right.
15 But a smaller, more interdependent world community has not been employed by the Supreme
16 Court (or any other court to my knowledge) to convert claims such as those presented here into
17 violations of the law of nations. In fact, the majority’s theory would be no different when
18 evaluating the medical malpractice of Pfizer’s research physicians or the strict products liability
19 for its allegedly defective drug, but malpractice and products liability are among the
20 quintessential subjects of domestic law.

21 It is not enough that a wrong could create international ramifications; in order for it to be
22 a matter of mutual concern, it must “threaten[] serious consequences in international affairs.”

1 *Sosa*, 542 U.S. at 715. The Supreme Court listed three historical mutual wrongs as guideposts to
2 frame this inquiry: infringement of the rights of ambassadors, the violation of safe conducts and
3 piracy. *Id.* at 715, 720. An assault against an ambassador “impinged upon the sovereignty of the
4 foreign nation and if not adequately redressed could rise to an issue of war.” *Id.* at 715. The
5 18th century safe-conduct document was the historical equivalent of the modern passport, “which
6 entitles a bearer with a valid visa to safe passage to, within, and out of a foreign land pursuant to
7 a treaty or an agreement negotiated by his or her sovereign and the host sovereign.” *Taveras v.*
8 *Taveraz*, 477 F.3d 767, 773 (6th Cir. 2007) (quoting Thomas H. Lee, *The Safe-Conduct Theory*
9 *of the Alien Tort Statute*, 106 Colum. L. Rev. 830, 874 (2006)). Thus, “the purpose of the
10 doctrine of safe conducts under the law of nations is to protect the safety and security of the
11 person and property of the journeying alien bearing the safe conduct privilege (and consequently
12 to preserve commercial and diplomatic relationships between the alien’s host and home
13 countries).” *Id.* at 773-74. This is still true today – a passport issued by the United States
14 contains an official request from the Secretary of State to an authority of another sovereign state:
15 “The Secretary of State of the United States of America hereby requests all whom it may concern
16 to permit the citizen/national of the United States named herein to pass without delay or
17 hindrance and in case of need to give all lawful aid and protection.” Breaches of customary
18 international law impair the normal expectations that nations have in dealing with other nations.
19 They must threaten serious consequences in international affairs because the norms were, and
20 still are, the foundation for states’ formal relationships with one another.

21 Piracy does not fit squarely with the other two *Sosa* historical paradigms, but the threat to
22 international affairs posed by piracy needs no detailed exegesis. Suffice it to say that one of the

1 young Republic’s first military tests was its campaign against the Barbary Pirates, *see, e.g.*, Act
2 For the Protection of the Commerce and Seamen of the United States Against the Tripolitan
3 Cruisers, ch. IV, § 2, 2 Stat. 129, 130 (1802) (authorizing President Jefferson to instruct the
4 armed forces to “seize and make prize of all vessels, goods and effects, belonging to the Bey of
5 Tripoli . . . and also to cause to be done all such other acts of precaution or hostility as the state of
6 war will justify, and may, in his opinion, require.”), and piracy continues to threaten serious
7 consequences in international affairs today, *see* S.C. Res. 1851, ¶ 2, U.N. Doc. S/RES/1851 (Dec.
8 16, 2008) (calling upon states “to take part actively in the fight against piracy and armed robbery
9 at sea off the coast of Somalia”).

10 We have accepted no lesser showing in our case law. The threat posed by genocide is so
11 great that states are empowered to request “the competent organs of the United Nations to take
12 such action under the Charter of the United Nations as they consider appropriate for the
13 prevention and suppression of acts of genocide.” Convention on the Prevention and Punishment
14 of the Crime of Genocide art. 8, Dec. 9, 1948, 102 Stat. 3045, 78 U.N.T.S. 277. The Geneva
15 Conventions collectively establish, and obligate contracting parties to follow, the laws of war –
16 almost by definition a matter of international affairs. *See Kadic*, 70 F.3d at 242-43. On the other
17 hand, because international law does not define torture to include acts by private entities,
18 torturous conduct by non-state actors – while criminalized domestically – is not a matter of
19 mutual concern. *Id.* at 243-44.

20 Demonstrating that a wrong is a matter of mutual concern must necessarily be difficult.
21 The Supreme Court has only opened the door for ATS jurisdiction over a “narrow set of
22 violations of the law of nations, admitting of a judicial remedy and at the same time threatening

1 serious consequences in international affairs.” *Sosa*, 542 U.S. at 715. The nations of the world
2 have not yet demonstrated that non-consensual medical experimentation by non-state actors “is
3 of mutual, and not merely several, concern, by means of express international accords.”
4 *Filartiga*, 630 F.2d at 888. Nor does it threaten serious consequences in international affairs in
5 the same manner or to the same extent as the historical paradigms listed by the Supreme Court or
6 their modern counterparts identified by this Court. Without either showing, I cannot agree with
7 the majority that non-consensual medical experimentation *by private actors* is a matter of mutual
8 concern.

9 III. State Action

10 The fact that medical experimentation by private actors is not a subject of customary
11 international law does not end the inquiry. If international law supports state liability but not
12 private liability, a private actor may still be liable if he or she “acted under color of law.” In that
13 regard, we are told to employ our 42 U.S.C. § 1983 jurisprudence in the inquiry. *See Bigio*, 239
14 F.3d at 448; *Kadic*, 70 F.3d at 245. As an initial matter, this requires that the law of nations
15 includes a norm actionable against states, which, in the instant case, is far from certain. But even
16 assuming, for argument’s sake, that international law prohibits states from conducting non-
17 consensual medical tests, Plaintiffs have not demonstrated that Pfizer acted under the color of
18 law.

19 This issue requires a bit of procedural context. In 2002, Pfizer moved to dismiss
20 Plaintiffs’ complaint in *Abdullahi* on the grounds that (1) Plaintiffs had not alleged that Pfizer
21 was a state actor, and (2) the alternate ground of forum non conveniens. *See Abdullahi v. Pfizer,*
22 *Inc.*, No. 01 Civ. 8118, 2002 WL 31082956, at *12 (S.D.N.Y. Sept. 17, 2002). Judge Pauley

1 granted the forum non conveniens motion, but denied the state action motion, concluding that
2 Plaintiffs “sufficiently allege[d] that the former Nigerian government and Pfizer were joint
3 participants in the Trovan treatment.” *Id.* at *6. Plaintiffs appealed the district court’s dismissal,
4 and Pfizer cross-appealed from the court’s denial of its motion to dismiss on state action. *See*
5 *Abdullahi v. Pfizer, Inc.*, 77 Fed. Appx. 48 (2d Cir. 2003). On appeal, we vacated the district
6 court’s judgment of dismissal, and did not reach Pfizer’s cross-appeal, noting that our
7 intervening decision in *Flores* might have some application on remand. *Id.* at 53. Back before
8 Judge Pauley, Pfizer filed a new motion to dismiss, arguing that Plaintiffs failed to state a claim
9 under the substantially different ATS landscape which now included the Supreme Court’s
10 decision in *Sosa* and our decision in *Flores*. *See Abdullahi v. Pfizer, Inc.*, No. 01 Civ. 8118,
11 2005 WL 1870811, at *3 (S.D.N.Y. Aug. 9, 2005). Both of these decisions made clear that the
12 identity of the defendant is a critical component of whether a principle is a norm of customary
13 international law. Without addressing or affirming its previous conclusion finding sufficient
14 allegations of state action, the district court granted Pfizer’s motion to dismiss, holding that
15 medical experimentation was not actionable under the law of nations. *Id.* at *18. On appeal to
16 this Court, both parties addressed the issue of state action in their briefs. The majority concludes
17 that Plaintiffs’ allegations of state action were sufficient to defeat a motion to dismiss. *See Maj.*
18 *Op.* at 41-43. I cannot agree.

19 In their twin complaints, which total 628 paragraphs, Plaintiffs make only four allegations
20 concerning the role of the Nigerian government in the Trovan experiments: (1) in order for the
21 FDA to authorize the export of Trovan, “Pfizer obtained the required letter of request from the
22 Nigerian government”; (2) the government “arrang[ed] for Pfizer’s accommodation in Kano”; (3)

1 the government acted “to silence Nigerian physicians critical of [Pfizer’s] test”; and (4) the
2 government “assign[ed] Nigerian physicians to assist in the project.”¹⁸ Elsewhere in their
3 complaints, Plaintiffs note in conclusory fashion that a Nigerian doctor did not publicly object to
4 the Trovan study because it “seemed to have the backing of the Nigerian government.”

5 In their brief to this Court, Plaintiffs seek to bolster their complaints by describing the
6 role of “Nigerian government doctors” at the allegedly government-owned hospital that hosted
7 the study. However, the portions of the complaints that they cite do not support their
8 contentions. Nowhere in their complaints did Plaintiffs allege that the hospital was, in fact,
9 government owned or administered, nor did they allege that the four Nigerian doctors working
10 with Pfizer were employed by the government, and our review of a decision to grant a motion to
11 dismiss “is limited to the facts as asserted within the four corners of the complaint” and any
12 attached documents. *McCarthy v. Dun & Bradstreet Corp.*, 482 F.3d 184, 191 (2d Cir. 2007).

13 These bare allegations are plainly insufficient to survive a motion to dismiss for lack of
14 state action. The Supreme Court’s case law on state action is hardly a model of clarity, but
15 certain principles are well-settled. As a threshold matter, the conduct alleged attributable to the
16 state must be defined with the requisite specificity. “When analyzing allegations of state action,
17 we begin ‘by identifying the specific conduct of which the plaintiff complains,’” *Tancredi v.*
18 *Metro. Life Ins. Co.*, 316 F.3d 308, 312 (2d Cir. 2003) (quoting *Am. Mfrs. Mut. Ins. Co. v.*
19 *Sullivan*, 526 U.S. 40, 51 (1999)), and in most cases, a finding of state action “must be premised
20 upon the fact that the State is *responsible*” for that specific conduct, *Horvath v. Westport Library*

¹⁸ Plaintiffs also initially allege that the government backdated a letter of approval for the test, but then allege that the letter was in fact created by a “Nigerian physician whom Pfizer says was its principal investigator.”

1 *Ass'n*, 362 F.3d 147, 154 (2d Cir. 2004) (internal quotation omitted). Determining state action in
2 these cases “requires tracing the activity to its source to see if that source fairly can be said to be
3 the state.” *Leshko v. Servis*, 423 F.3d 337, 340 (3d Cir. 2005); *see also Hedges v. Yonkers*
4 *Racing Corp.*, 918 F.2d 1079, 1082-83 (2d Cir. 1990). As we recently stated, when confronted
5 with a motion to dismiss, it “is not enough . . . for a plaintiff to plead state involvement in *some*
6 *activity* of the institution alleged to have inflicted injury upon a plaintiff; rather, the plaintiff must
7 allege that the state was involved with the *activity that caused the injury* giving rise to the
8 action.” *Sybalski v. Indep. Group Home Living Program, Inc.*, 546 F.3d 255, 257-58 (2d Cir.
9 2008) (internal quotations omitted).

10 Here, that activity was not, as the majority apparently concludes, conducting the Trovan
11 trials in general, but rather administering the drug without informed consent. Although Plaintiffs
12 allege that the Nigerian government requested the import of Trovan and arranged for Pfizer’s
13 accommodations and some medical staff in Kano, they do not allege that the government or any
14 government employee played any role in either administering Trovan without consent or deciding
15 to do so in the first instance. The Supreme Court has described “the typical case raising a
16 state-action issue” as one in which “a private party has taken the decisive step that caused the
17 harm to the plaintiff, and the question is whether the State was sufficiently involved to treat that
18 decisive conduct as state action.” *NCAA v. Tarkanian*, 488 U.S. 179, 192 (1988). Plaintiffs have
19 not alleged any facts that would indicate that the answer here is “yes.”

20 Plaintiffs’ complaints are more noteworthy for what they do not allege than what they do.
21 They have not suggested that Pfizer was exercising any delegated state authority, *cf. West v.*
22 *Atkins*, 487 U.S. 42 (1988), or that the Nigerian government “knowingly accept[ed] the benefits

1 derived from [the unlawful] behavior,” *Tarkanian*, 488 U.S. at 192. Plaintiffs have not alleged
2 that Pfizer *conspired* with government officials to deprive the subjects of their rights, *cf. Fries v.*
3 *Barnes*, 618 F.2d 988, 991 (2d Cir. 1980), nor have they alleged that the Nigerian government
4 exercised any coercive power over Pfizer, *cf. Brentwood Acad. v. Tenn. Secondary Sch. Athletic*
5 *Ass’n*, 531 U.S. 288, 296 (2001). In fact, Plaintiffs did not allege that any Nigerian government
6 officials even knew about the non-consensual tests, because if Nigerian government doctors were
7 somehow involved in the study, Plaintiffs did not specify what role, if any, they played.

8 The case of *Beanal v. Freeport-McMoRan, Inc.*, 969 F. Supp. 362 (E.D. La. 1997), *aff’d*
9 197 F.3d 161 (5th Cir. 1999), is instructive. In *Beanal*, plaintiffs seeking to recover under the
10 ATS sought to establish state action on the basis of the Indonesian military’s involvement in
11 allegedly actionable conduct. The court rejected that argument, holding that plaintiffs had not
12 “alleged whether the military personnel helped enforce Freeport’s policies or merely observed . . .
13 the violative conduct.” *Id.* at 378. Broad conclusory statements of state involvement are not
14 sufficient to establish state action; “there must be some allegation indicating that the troops jointly
15 cooperated in the conduct, jointly participated in the conduct, influenced the conduct or played an
16 integral part in the deprivation of human rights.” *Id.* at 379. The same is true here.¹⁹ Plaintiffs’
17 allegations are inadequate.

18 Even without alleging that the State “coerced or even encouraged” the act complained of,
19 Plaintiffs can still survive a motion to dismiss if “the relevant facts show pervasive entwinement

¹⁹ The case relied upon by the district court is entirely distinguishable. *See Nat’l Coal. Gov’t of the Union of Burma v. Unocal, Inc.*, 176 F.R.D. 329 (C.D. Cal. 1997). There, plaintiffs survived a motion to dismiss by alleging that Unocal and the Burmese government were joint venturers and partners in a pipeline, with the Burmese government retaliating against protesters with military action and forced labor imposed by the Burmese military with Unocal’s knowledge. *Id.* at 348. There, as opposed to here, the state committed the unlawful acts.

1 to the point of largely overlapping identity between the State and the entity that the plaintiff
2 contends is a state actor.” *Horvath*, 362 F.3d at 154 (quotation omitted). This line of cases
3 revolves around the relationship between the state and the actor, as opposed to the specific act.
4 Showing “overlapping identity” is highly uncommon, and most often arises where a private actor
5 is performing one of the few functions traditionally and exclusively reserved to the state or is
6 controlled by a state entity. State assistance by itself is insufficient – the relevant question is
7 whether the *decisionmakers* were ostensibly state actors. We answered that question in the
8 affirmative in *Horvath*, where half of the putatively private defendant’s trustees were state
9 appointees. *Id.* at 153. But the assistance alleged by Plaintiffs – helping to procure a ward in a
10 hospital and arranging for the assistance of a handful of doctors – is not enough to clear this
11 hurdle. Using government property, government staff, and even government funds does not
12 make a private entity a state actor when its decisions are made independently of the state. *See*
13 *Yeo v. Town of Lexington*, 131 F.3d 241, 254 (1st Cir. 1997) (en banc).

14 Plaintiffs’ generalized allegations (unsupported by factual allegations) that the
15 government acted to silence critics of the test are no more helpful. They do not allege who these
16 government officials were, how they acted to silence critics, or when in the sequence of events
17 this conduct occurred. Such a “merely conclusory allegation that a private entity acted in concert
18 with a state actor does not suffice to state a § 1983 claim against the private entity.” *Ciambriello*
19 *v. County of Nassau*, 292 F.3d 307, 324 (2d Cir. 2002).

20 At most, Plaintiffs’ complaints alleged that the Nigerian government acquiesced to or
21 approved the Trovan program in general without knowing its disturbing details. That it approved
22 the program is hardly surprising – in the midst of a widespread epidemic, the Nigerian

1 government likely welcomed help from every entity offering it, but “[m]ere approval of or
2 acquiescence in the initiatives of a private party is not sufficient to justify holding the State
3 responsible for those initiatives.” *Blum v. Yaretsky*, 457 U.S. 991, 1004-05 (1982). Plaintiffs
4 have not demonstrated that Pfizer acted “under the color of law” such that it can be held liable
5 for the Nigerian government’s alleged violation of the “law of nations.”

6 *****

7 Plaintiffs’ allegations paint a vivid picture of the unspeakable pain and suffering of
8 dozens of innocent children. The issue on this appeal, however, is not whether Pfizer’s alleged
9 conduct was “wrong,” or even whether it is legally actionable, but whether it falls within both the
10 “narrow class” of international norms for which ATS jurisdiction exists, and the even smaller
11 subset of those norms actionable against non-state actors. Our Court and the Supreme Court
12 have made it pellucidly clear that ATS jurisdiction must be reserved only for acts that the nations
13 of the world collectively determine interfere with their formal relations with one another –
14 including those rare acts by private individuals that are so serious as to threaten the very fabric of
15 peaceful international affairs. I cannot agree with my colleagues that Pfizer’s alleged conduct
16 poses the same threat or is so universally and internationally proscribed as to fit within that
17 narrow class.

18 I respectfully dissent.