2011

Section 5: Business

Institute of Bill of Rights Law at The College of William & Mary School of Law
V. Business

In This Section:

**New Case: 10-1150 Mayo Collaborative Services v. Prometheus Laboratories, Inc.**

Synopsis and Questions Presented

“PROMETHEUS: BOUND FOR CLARIFICATION OR CONFUSION?”
James W. Morando & Julie Wahlstrand

“MAJOR RULING FOR DOCTORS DUE”
Lyle Denniston

“CLINICAL METHOD CLAIMS DODGE A BULLET: PROMETHEUS v. MAYO”
Mr. James Mullen III, Ph.D., Matthew I. Kreeger & Yan Leychikis

“COURT BACKS PATENTS FOR DIAGNOSTIC TESTS”
Andrew Pollack

**New Case: 10-844 Caraco Pharmaceutical Laboratories, Ltd. v. Novo Nordisk A/S**

Synopsis and Questions Presented

“HIGH COURT TO HEAR GENERIC-DRUG CASE, REJECTS ABU GHRAIB CHALLENGE”
Brent Kendall

“NOVO NORDISK A/S v. CARACO PHARMACEUTICAL LABORATORIES, LTD. (FED. CIR. 2010)”
Kevin E. Noonan

**New Case: 10-1062 Sackett v. Environmental Protection Agency**

Synopsis and Questions Presented

“SUPREME COURT TO HEAR EPA WETLAND CASE”
Lawrence Hurley, Greenwire

“EPA BEATS BACK CONSTITUTIONAL CHALLENGE TO WATER ACT ENFORCEMENT SYSTEM”
Aaron Lovell

**New Case: 10-948 CompuCredit Corp. v. Greenwood**
Synopsis and Questions Presented

“RIGHTS OF THE SECOND-CHANCE CARDHOLDER”
Lyle Denniston

“NINTH CIRCUIT RULES THAT CONGRESS’S USE OF THE PHRASE “RIGHT TO SUE” PRECLUDED PARTIES FROM AGREETING TO ARBITRATE ANY DISPUTE”
Louis M. Solomon

“ARBITRATION AND CONSUMER PROTECTION”
Harvard Law Review Association

New Case: 10-1261 Credit Suisse Securities v. Simmonds

Synopsis and Questions Presented

“SUPREME COURT TO CONSIDER TIME LIMIT ON INSIDER-TRADING SUIT”
Brent Kendall

“HIGH COURT TO CONSIDER TIME LIMIT FOR DERIVATIVE CLAIMS”
Evan Weinberger

“SUPREME COURT GRANTS CERT IN YET ANOTHER SECURITIES CASE”
Kevin LaCroix

New Case: 10-1104 Minneci v. Pollard

Synopsis and Questions Presented

“NEW CURB ON BIVENS REMEDY”
Lyle Denniston

“PRISON INMATE MAY SUE EMPLOYEES OF PRIVATE FIRM, SAYS 9TH CIRCUIT”
Pat Murphy

“SHOULD PRIVATE PRISON GUARDS BE LIABLE UNDER BIVENS”
Shon R. Hopwood

New Case: 10-1491 Kiobel v. Royal Dutch Petroleum Co. (Looking Ahead)

Synopsis and Questions Presented

“MAJOR NEW CORPORATE CASE AT COURT”
Lyle Denniston

“CORPORATE EXECUTIVES: GET READY FOR A BILLION DOLLAR LAWSUIT”
Ben Kerschberg

p. 444
p. 455
p. 457
p. 458
p. 462
p. 475
p. 476
p. 478
p. 480
p. 498
p. 500
p. 501
p. 503
p. 523
p. 525
385
“FURTHER THOUGHTS ON TODAY’S SECOND CIRCUIT ATS DECISION ON CORPORATE LIABILITY”
Kenneth Anderson

Prometheus is the sole and exclusive patent holder for two patents that claim methods for determining the optimal dosage of a drug used to treat gastrointestinal illnesses. Prometheus' developed and marketed a test kit based on these patents. As the district court articulated the patents, they are for a three step process: 1) administering the drug; 2) determining the levels of a certain substance in the patient's bloodstream; 3) based on that determination, warning the doctor if a dosage adjustment is required. Mayo, a one-time purchaser of Prometheus' test kits, now seeks to develop a similar test. Mayo claims the patents are for unpatentable subject matter and thus invalid. The district court agreed with Mayo, holding the patents invalid because they assert a claim over natural phenomena resulting from a process of the human body. On first appeal, the Federal Circuit applied the machine-or-transformation test in holding the district court erred in this determination. Subsequently, the Supreme Court decided this test was not definitive in Bilski v. Kappos and remanded this case for further consideration. The Federal Circuit again concluded the district court erred, holding that Prometheus' patents were tied to a particular application of a naturally occurring phenomenon and thus patentable. The Federal Circuit characterized the patents as describing a series of transformative steps that optimize efficacy and reduce toxicity for a particular treatment method.

Question Presented: Whether 35 U.S.C. § 101 is satisfied by a patent claim that covers observed correlations between blood test results and patient health, so that the claim effectively preempts all uses of the naturally occurring correlations, simply because well-known methods used to administer prescription drugs and test blood may involve “transformations” of body chemicals.

PROMETHEUS LABORATORIES, INC., Plaintiff-Appellant,

v.

MAYO COLLABORATIVE SERVICES (doing business as Mayo Medical Laboratories) and Mayo Clinic Rochester, Defendants-Appellees.

United States Court of Appeals for the Federal Circuit

Decided December 17, 2010

[Excerpt; some footnotes and citations omitted.]

LOURIE, Circuit Judge.

This case returns to this court on remand from the Supreme Court for further consideration in light of the Court's decision in Bilski v. Kappos, 561 U.S. ——, 130 S.Ct. 3218, 177 L.Ed.2d 792 (2010). In Prometheus Laboratories, Inc. v. Mayo Collaborative Services, 581 F.3d 1336 (Fed.Cir.2009), we decided an appeal by Prometheus Laboratories, Inc. ("Prometheus") from a final judgment of the
United States District Court for the Southern District of California granting summary judgment of invalidity of U.S. Patents 6,355,623 ("the '623 patent") and 6,680,302 ("the '302 patent") under 35 U.S.C. § 101. We held that the district court erred as a matter of law in finding Prometheus's asserted medical treatment claims to be drawn to nonstatutory subject matter under this court's machine-or-transformation test, which we had held in In re Bilski, 545 F.3d 943 (Fed.Cir.2008), to be the definitive test for determining the patentability of a process under § 101. Following our decision in this case, the Supreme Court held that the machine-or-transformation test, although "a useful and important clue," was not the sole test for determining the patent eligibility of process claims. Based on that decision, the Court vacated and remanded our Prometheus decision. On remand, we again hold that Prometheus's asserted method claims are drawn to statutory subject matter, and we again reverse the district court's grant of summary judgment of invalidity under § 101.

BACKGROUND

Prometheus is the sole and exclusive licensee of the '623 and '302 patents, which claim methods for determining the optimal dosage of thiopurine drugs used to treat gastrointestinal and non-gastrointestinal autoimmune diseases. These drugs include 6-mercaptopurine ("6-MP") and azathiopurine ("AZA"), a pro-drug that upon administration to a patient converts to 6-MP, both of which are used to treat inflammatory bowel diseases ("IBD") such as Crohn's disease and ulcerative colitis....

Although drugs such as 6-MP and AZA have been used for years to treat autoimmune diseases, non-responsiveness and drug toxicity may complicate treatment in some patients. Accordingly, the patents claim methods that seek to optimize therapeutic efficacy while minimizing toxic side effects. As written, the claimed methods typically include two separately lettered steps: (a) "administering" a drug that provides 6-TG to a subject, and (b) "determining" the levels of the drug's metabolites, 6-TG and/or 6-MMP, in the subject. The measured metabolite levels are then compared to pre-determined metabolite levels, "wherein" the measured metabolite levels "indicate a need" to increase or decrease the level of drug to be administered so as to minimize toxicity and maximize treatment efficacy....

Claim 1 of the '623 patent is representative of the independent claims asserted by Prometheus in this case:

1. A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

(a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and

(b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,

wherein the level of 6-thioguanine less than about 230 pmol per $8 \times 10^8$ red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and

wherein the level of 6-thioguanine greater than about 400 pmol per $8 \times 10^8$ red blood cells indicates a
need to decrease the amount of said drug subsequently administered to said subject.

'623 patent claim 1 (emphases added).

Claim 1 of the '302 patent is substantially the same, with the addition of determining 6-MMP levels in addition to 6-TG levels. Claim 46 of the '623 patent dispenses with the "administering" step and claims only the "determining" step:

46. A method of optimizing therapeutic efficacy and reducing toxicity associated with treatment of an immune-mediated gastrointestinal disorder, comprising:

(a) determining the level of 6-thioguanine or 6-methylmercaptopurine in a subject administered a drug selected from the group consisting of 6-mercaptopurine, azathioprine, 6-thioguanine, and 6-methylmercaptopurine, said subject having said immune-mediated gastrointestinal disorder,

wherein the level of 6-thioguanine less than about 230 pmol per 8x10^8 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject, and

wherein the level of 6-thioguanine greater than about 400 pmol per 8x10^8 red blood cells or a level of 6-methylmercaptopurine greater than about 7000 pmol per 8x10^8 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

'623 patent claim 46 (emphases added).

Prometheus marketed a PROMETHEUS Thiopurine Metabolites test (formerly known as the PRO-PredictRx® Metabolites test) that used the technology covered by the patents in suit. Mayo Collaborative Services and Mayo Clinic Rochester (collectively, "Mayo") formerly purchased and used Prometheus's test, but in 2004, Mayo announced that it intended to begin using internally at its clinics and selling to other hospitals its own test. Mayo's test measured the same metabolites as Prometheus's test, but Mayo's test used different levels to determine toxicity of 6-TG and 6-MMP.

On June 15, 2004, Prometheus sued Mayo for infringement of '623 and '302 patents. Prometheus asserted independent claims 1, 7, 22, 25, and 46 of the '623 patent and independent claim 1 of the '302 patent. Prometheus also asserted several dependent claims that require either that the measurement of the metabolites be performed using high pressure liquid chromatography, or that the thiopurine drug used be one of four specified drugs.[..] Mayo rescinded its announcement shortly after Prometheus filed suit, and has yet to launch its test.

On November 22, 2005, the district court held on cross-motions for summary judgment that Mayo's test literally infringed claim 7 of the '623 patent. In its opinion, the court construed "indicates a need" to mean "a warning that an adjustment in dosage may be required." This construction did not require doctors to adjust drug dosage if the metabolite level reached the specified levels; rather, the court found the two "wherein" phrases to mean "that when the identified metabolites reach the specified level, the doctor is warned or notified that a dosage
adjustment may be required, if the doctor believes that is the proper procedure.”

On January 29, 2007, Mayo filed a motion for summary judgment of invalidity, arguing that the patents in suit are invalid because they claim subject matter unpatentable under 35 U.S.C. § 101. Specifically, Mayo contended that the patents impermissibly claim natural phenomena—the correlations between, on the one hand, thiopurine drug metabolite levels and, on the other hand, efficacy and toxicity—and that the claims wholly preempt use of the natural phenomena.

On March 28, 2008, the district court granted Mayo’s motion for summary judgment of invalidity under § 101. Prometheus Labs., Inc. v. Mayo Collaborative Servs., No. 04-CV-1200, 2008 WL 878910 (S.D.Cal. Mar. 28, 2008) (“Invalidity Opinion “). First, the court found that the patents only claimed the correlations between certain thiopurine drug metabolite levels and therapeutic efficacy and toxicity. The court reasoned that, as construed in the November 2005 summary judgment order, the claims have three steps: (1) administering the drug to a subject, (2) determining metabolite levels, and (3) being warned that an adjustment in dosage may be required. The court stated that the fact that the inventors framed the claims as treatment methods does not render the claims patent-eligible subject matter. Rather, the court found that the ‘‘administering’’ and ‘‘determining’’ steps are merely necessary data-gathering steps for any use of the correlations” and that “as construed, the final step—the ‘warning’ step (i.e., the ‘wherein’ clause)—is only a mental step.” The court noted that the warning step does not require any actual change in dosage and that “it is the metabolite levels themselves that ‘warn’ the doctor that an adjustment in dosage may be required.” With this understanding of the claims, the court concluded that the claims recited the correlations between particular concentrations of 6-TG and 6-MMP and therapeutic efficacy or toxicity in patients taking AZA drugs.

Second, the district court found that those correlations were natural phenomena, not patent-eligible inventions because the correlations resulted from a natural body process. The court stated that the inventors did not “invent” the claimed correlation; rather, “6-TG and 6-MMP are products of the natural metabolizing of thiopurine drugs, and the inventors merely observed the relationship between these naturally produced metabolites and therapeutic efficacy and toxicity.” Finally, the court determined that “[b]ecause the claims cover the correlations themselves, it follows that the claims ‘wholly pre-empt’ the correlations.” Thus, the court concluded that there was no genuine issue of material fact to be resolved as to whether the patents in suit were directed to statutory subject matter and found by clear and convincing evidence that the claims were invalid under § 101. On May 16, 2008, the district court entered final judgment, and Prometheus timely appealed.

On appeal, we reversed and upheld the asserted claims’ validity under what was at the time this court’s “definitive test” for determining whether a process is patentable subject matter under § 101: the machine-or-transformation test. Under the machine-or-transformation test, a claimed process is patent eligible if it (1) is tied to a particular machine or apparatus, or (2) transforms a particular article into a different state or thing. We held that both the “administering” and “determining” steps were transformative and not merely data-gathering steps under the second prong of the test, and as such the
claims did not wholly preempt the use of the recited correlations between metabolite levels and drug efficacy or toxicity.

Following our decision in *Prometheus*, the Supreme Court issued a decision rejecting the machine-or-transformation test as the sole, definitive test for determining the patent eligibility of a process under § 101. Instead, the Court declined to adopt any categorical rules outside the well-established exceptions for laws of nature, physical phenomena, and abstract ideas, and resolved the case based on its decisions in *Gottschalk v. Benson*, 409 U.S. 63, 93 S.Ct. 253, 34 L.Ed.2d 273 (1972), *Parker v. Flook*, 437 U.S. 584, 98 S.Ct. 2522, 57 L.Ed.2d 451 (1978), and *Diamond v. Diehr*, 450 U.S. 175, 101 S.Ct. 1048, 67 L.Ed.2d 155 (1981), holding that *Bilski*’s claims to methods of hedging risk are not patentable processes because they attempt to patent abstract ideas. The Court did not, however, reject the machine-or-transformation test, but rather characterized the test as “a useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under § 101.”

The Court then granted Mayo’s petition for certiorari, vacated our decision holding *Prometheus*’s method claims to cover patent-eligible subject matter under the machine-or-transformation test, and remanded the case for consideration in light of the Court’s *Bilski* decision. On September 1, 2010, we requested that the parties simultaneously submit briefs, without further oral argument, to address the effect of the Supreme Court’s decision in *Bilski* on the disposition of this case. In view of this additional briefing and the Supreme Court’s guidance in *Bilski*, we again hold that *Prometheus*’s method claims recite patentable subject matter under § 101.

DISCUSSION

We review the district court’s grant of summary judgment *de novo*. Summary judgment is appropriate if there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law. Whether a patent claim is directed to statutory subject matter is a question of law that we review *de novo*.

I.

The issue again before us is whether *Prometheus*’s method claims meet the requirements of § 101. The text of the statute provides that:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent thereof, subject to the conditions and requirements of this title.


The Supreme Court has consistently construed § 101 broadly. Most recently, in *Bilski*, the Court stated that by choosing expansive terms to specify four independent patent-eligible categories of inventions or discoveries—processes, machines, manufactures, and compositions of matter—and by modifying those terms with the comprehensive “any,” Congress plainly contemplated that § 101 would be given wide scope. “Congress took this permissive approach to patent eligibility to ensure that ‘ingenuity should receive a liberal encouragement.’”

Yet, it is equally well-established that § 101,
while broad, is not unlimited. "The Court's precedents provide three specific exceptions to § 101's broad patent-eligibility principles: 'laws of nature, physical phenomena, and abstract ideas.'" Although not compelled by the statutory text, the Court has held that "these exceptions have defined the reach of the statute as a matter of statutory stare decisis going back 150 years," and "[t]he concepts covered by these exceptions are 'part of the storehouse of knowledge of all men . . . free to all men and reserved exclusively to none[.]'"

The Supreme Court has also established that while a law of nature, natural phenomenon, or abstract idea cannot be patented, "an application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection." In making this determination, the Court has made clear that a claim must be considered as a whole; it is "inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis." Nonetheless, a scientific principle cannot be made patentable by limiting its use to a particular technological environment or by adding insignificant post-solution activity.

In light of the Supreme Court's decision in *Bilski*, patent eligibility in this case turns on whether Prometheus's asserted claims are drawn to a natural phenomenon, the patenting of which would entirely preempt its use as in *Benson or Flook*, or whether the claims are drawn only to a particular application of that phenomenon as in *Diehr*. We conclude they are drawn to the latter.

II.

We turn to the parties' arguments on remand. Prometheus argues that neither the Supreme Court's *Bilski* decision nor the Court's GVR Order compels a different outcome on remand, and therefore we should again reverse the district court's judgment of invalidity under § 101. Regarding *Bilski*, Prometheus contends that the Court held only that patents that do not satisfy the machine-or-transformation test are not necessarily unpatentable and did not overrule the long-established view that claims that satisfy the machine-or-transformation test, like Prometheus's, necessarily satisfy § 101. But regardless, Prometheus argues, its asserted claims not only satisfy the machine-or-transformation test, but also are not drawn to mere abstractions. Specifically, Prometheus argues that its asserted claims involve a particular transformation of a patient's body and bodily sample and use particular machines to determine metabolite concentrations in a bodily sample (e.g., via high pressure liquid chromatography), thus satisfying either prong of the machine-or-transformation test. Prometheus further argues that its claims also involve an application of a law of nature, not the law itself, because they recite specific means of treating specific diseases using specific drugs, and therefore do not preempt the abstract idea of calibrating drug dosages to treat disease.

Mayo argues that the Supreme Court in *Bilski* reaffirmed that preemption is the controlling standard for § 101 under the Court's *Benson, Flook, and Diehr* precedents and made clear that while a machine-or-transformation test may inform the analysis, that test is not outcome determinative. And, according to Mayo, under the governing preemption standard, Prometheus's claims are invalid because they preempt all practical use of naturally occurring correlations between metabolite levels and drug efficacy and any machine or
transformation present in the claims is merely insignificant post-solution activity. Mayo also asserts that the carefully considered opinion of three Justices—allegedly cited approvingly by five Justices in Bilski—rejected Prometheus’s machine-or-transformation argument for nearly identical claims in Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc., 548 U.S. 124, 138–39, 126 S.Ct. 2921, 165 L.Ed.2d 399 (2006), concluding that the claims do not cover a process for transforming a bodily sample, but rather merely instruct the user to obtain test results and think about them. Finally, Mayo claims that the Supreme Court’s decision to GVR our earlier decision in this case indicates that a different analysis is required of us on remand.

We disagree with Mayo. We do not think that either the Supreme Court’s GVR Order or the Court’s Bilski decision dictates a wholly different analysis or a different result on remand. In our pre-Bilski decision in this case, we held not only that Prometheus’s asserted claims recite transformative “administering” and “determining” steps, but also that Prometheus’s claims are drawn not to a law of nature, but to a particular application of naturally occurring correlations, and accordingly do not preempt all uses of the recited correlations. The Supreme Court’s decision in Bilski did not undermine our preemption analysis of Prometheus’s claims and it rejected the machine-or-transformation test only as a definitive test. The Court merely stated that “[I]t is clear that the Court of Appeals incorrectly concluded that this Court has endorsed the machine-or-transformation test as the exclusive test.” The Court stated that it had previously noted in Benson, 409 U.S. at 70, 93 S.Ct. 253, that “[t]he transformation and reduction of an article ‘to a different state or thing’ is the clue to the patentability of a process claim that does not include particular processes.” Thus, the Court did not disavow the machine-or-transformation test. And, as applied to the present claims, the “useful and important clue, an investigative tool,” leads to a clear and compelling conclusion, viz., that the present claims pass muster under § 101. They do not encompass laws of nature or preempt natural correlations.

III.

As before, we again hold that Prometheus’s asserted method claims recite a patent-eligible application of naturally occurring correlations between metabolite levels and efficacy or toxicity, and thus do not wholly preempt all uses of the recited correlations. As discussed below, the claims recite specific treatment steps, not just the correlations themselves. And the steps involve a particular application of the natural correlations: the treatment of a specific disease by administering specific drugs and measuring specific metabolites. As such, and contrary to Mayo’s assertions, the claims do not preempt all uses of the natural correlations; they utilize them in a series of specific steps. See Diehr, 450 U.S. at 187, 101 S.Ct. 1048 (“Their process admittedly employs a well-known mathematical equation, but they do not seek to preempt the use of that equation. Rather, they seek only to foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process.”). The inventive nature of the claimed methods stems not from preemption of all use of these natural processes, but from the application of a natural phenomenon in a series of steps comprising particular methods of treatment. Other drugs might be administered to optimize the therapeutic efficacy of the claimed treatment.
We similarly reaffirm that the treatment methods claimed in Prometheus’s patents in suit satisfy the transformation prong of the machine-or-transformation test, as they “transform an article into a different state or thing,” and this transformation is “central to the purpose of the claimed process.” The transformation is of the human body and of its components following the administration of a specific class of drugs and the various chemical and physical changes of the drugs’ metabolites that enable their concentrations to be determined. We thus have no need to separately determine whether the claims also satisfy the machine prong of the test.

Contrary to the district court and Mayo’s arguments on remand, we do not view the disputed claims as merely claiming natural correlations and data-gathering steps. The asserted claims are in effect claims to methods of treatment, which are always transformative when one of a defined group of drugs is administered to the body to ameliorate the effects of an undesired condition. More specifically, Prometheus here claimed methods for optimizing efficacy and reducing toxicity of treatment regimes for gastrointestinal and non-gastrointestinal autoimmune diseases that utilize drugs providing 6-TO by administering a drug to a subject. The invention’s purpose to treat the human body is made clear in the specification and the preambles of the asserted claims.

When administering a drug such as AZA or 6-MP, the human body necessarily undergoes a transformation. The drugs do not pass through the body untouched without affecting it. In fact, the transformation that occurs, viz., the effect on the body after metabolizing the artificially administered drugs, is the entire purpose of administering these drugs: the drugs are administered to provide 6-TG, which is thought to be the drugs’ active metabolite in the treatment of disease, to a subject. The fact that the change of the administered drug into its metabolites relies on natural processes does not disqualify the administering step from the realm of patentability. As Prometheus points out, quite literally every transformation of physical matter can be described as occurring according to natural processes and natural law. Transformations operate by natural principles. The transformation here, however, is the result of the physical administration of a drug to a subject to transform—i.e., treat—the subject, which is itself not a natural process. “It is virtually self-evident that a process for a chemical or physical transformation of physical objects or substances is patent-eligible subject matter.” The administering step, therefore, is not merely data-gathering but a significant transformative element of Prometheus’s claimed methods of treatment that is “sufficiently definite to confine the patent monopoly within rather definite bounds.”

Not all of the asserted claims, however, contain the administering step. That omission, which occurs in claims 46 and 53 of the 623 patent, does not diminish the patentability of the claimed methods because we also hold that the determining step, which is present in each of the asserted claims, is transformative and central to the claimed methods. Determining the levels of 6-TG or 6-MMP in a subject necessarily involves a transformation. Some form of manipulation, such as the high pressure liquid chromatography method specified in several of the asserted dependent claims or some other modification of the substances to be measured, is necessary to extract the metabolites from a bodily sample and determine their concentration. As stated by Prometheus’s expert, “at the end of the process, the human blood sample is no
longer human blood; human tissue is no longer human tissue.” That is clearly a transformation. In fact, Mayo does not dispute that determining metabolite levels in the clinical samples taken from patients is transformative, but argues that this transformation is merely a necessary data-gathering step for use of the correlations. On the contrary, this transformation is central to the purpose of the claims, since the determining step is, like the administering step, a significant part of the claimed method. Measuring the levels of 6-TG and 6-MMP is what enables possible adjustments to thiopurine drug dosage to be detected for optimizing efficacy or reducing toxicity during a course of treatment. The determining step, by working a chemical and physical transformation on physical substances, likewise sufficiently confines the patent monopoly, as required by the machine-or-transformation test.

A further requirement for patent-eligibility is ensuring that the involvement of the transformation in Prometheus’s claimed process is “not merely insignificant extraneous activity.” As made clear from the discussion above, the administering and determining steps are transformative and are central to the claims rather than merely insignificant extraneous activity.

The crucial error the district court made in reaching the opposite conclusion was failing to recognize that the first two steps of the asserted claims are not merely data-gathering steps. While it is true that the administering and determining steps gather useful data, it is also clear that the presence of those two steps in the claimed processes is not “merely” for the purpose of gathering data. Instead, the administering and determining steps are part of a treatment protocol, and they are transformative. As explained above, the administering step provides thiopurine drugs for the purpose of treating disease, and the determining step measures the drugs’ metabolite levels for the purpose of assessing the drugs’ dosage during the course of treatment.

Given the integral involvement of the administering and determining steps in Prometheus’s therapeutic methods, this case is easily distinguishable from prior cases that found asserted method claims to be unpatentable for claiming data-gathering steps and a fundamental principle. Perhaps the case that offers the closest comparison is In re Grams, 888 F.2d 835 (Fed.Cir.1989), but the asserted claims found unpatentable in that case are readily distinguished from those in the instant action. In Grams, the applicant claimed a process that involved (1) performing a clinical test on individuals and (2) based on the data from that test, determining if an abnormality existed and determining possible causes of any abnormality by using an algorithm. We found that this process was not drawn to patentable subject matter because the essence of the claimed process was the mathematical algorithm, rather than any transformation of the tested individuals. More specifically, the Grams process was unpatentable because “it was merely an algorithm combined with a data-gathering step,” i.e., performing a clinical test. The claims did not require the performing of clinical tests on individuals that were transformative—and thus rendering the entire process patentable subject matter—because the tests were just to “obtain data.” The patent and thus the court focused only on the algorithm rather than the clinical tests purported to be covered by the claims.

Here, unlike the clinical test recited in Grams, the administering and determining steps in Prometheus’s claimed methods are not “merely” data-gathering steps or
“insignificant extra-solution activity”; they are part of treatment regimes for various diseases using thiopurine drugs. As a result, the administering and determining steps are not insignificant extra-solution activity, and the claims are therefore not drawn merely to correlations between metabolite levels and toxicity or efficacy.

We agree with the district court that the final “wherein” clauses are mental steps and thus not patent-eligible per se. However, although they alone are not patent-eligible, the claims are not simply to the mental steps. A subsequent mental step does not, by itself, negate the transformative nature of prior steps. Thus, when viewed in the proper context, the final step of providing a warning based on the results of the prior steps does not detract from the patentability of Prometheus’s claimed methods as a whole. The data that the administering and determining steps provide for use in the mental steps are obtained by steps well within the realm of patentable subject matter; the addition of the mental steps to the claimed methods thus does not remove the prior two steps from that realm. No claim in the Prometheus patents claims only mental steps. Therefore, contrary to Mayo’s assertions, a physician who only evaluates the result of the claimed methods, without carrying out the administering and/or determining steps that are present in all the claims, cannot infringe any claim that requires such steps.

This analysis is consistent with In re Abele, 684 F.2d 902 (CCPA 1982). In Abele, a method claim called for the use of X-ray attenuation data, which necessarily involved production, detection, and display with a CAT scan. The method also called for use of an algorithm. We found that the claim was patentable because removal of the algorithm still left all the steps of a CAT scan in the claim; thus, the production and detection could not be considered “mere antecedent steps to obtain values for solving the algorithm. . . . We view the production, detection, and display steps as manifestly statutory subject matter, and are not swayed from this conclusion by the presence of an algorithm in the claimed method.” In the instant case, the presence of mental steps similarly does not detract from the patentability of the administering and determining steps.

As we explained in Bilski,

[I]t is inappropriate to determine the patent eligibility of a claim as a whole based on whether selected limitations constitute patent-eligible subject matter. After all, even though a fundamental principle itself is not patent-eligible, processes incorporating a fundamental principle may be patent-eligible. Thus, it is irrelevant that any individual step or limitation of such processes by itself would be unpatentable under § 101.

545 F.3d at 958 (citations omitted).

Such is the case here. Although the wherein clauses describe the mental processes used to determine the need to change the dosage levels of the drugs, each asserted claim as a whole is drawn to patentable subject matter. Although a physician is not required to make any upward or downward adjustment in dosage during the “warning” step, the prior steps provide useful information for possible dosage adjustments to the method of treatment using thiopurine drugs for a particular subject. Viewing the treatment methods as a whole, Prometheus has claimed therapeutic methods that determine the optimal dosage level for a course of
treatment. In other words, when asked the critical question, “What did the applicant invent?,” the answer is a series of transformative steps that optimizes efficacy and reduces toxicity of a method of treatment for particular diseases using particular drugs.

In light of the foregoing analysis, we hold that Prometheus’s asserted method claims satisfy the preemption test as well as the transformation prong of the machine-or-transformation test.

CONCLUSION

For the foregoing reasons, we reverse the judgment of the district court and remand to the court with instructions to deny Mayo’s motion for summary judgment that the asserted claims are invalid under § 101.

REVERSED and REMANDED
On June 20, 2011, the Supreme Court granted certiorari for the second time in *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, after having already granted certiorari last year, vacating and remanding to the Federal Circuit for further consideration in light of *Bilski*. The patent claims at issue in *Prometheus* are medical method claims directed at administering a drug to treat autoimmune disorders, and determining whether the metabolite level of the drug falls within a range correlated with efficacy but not toxicity.

One could speculate as to why the Supreme Court granted certiorari—and in fact many are guessing that it is a second chance at some of the same questions presented by *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.*, where the Supreme Court dismissed the writ as improvidently granted on procedural grounds, and the dissent rendered a substantive opinion. However, speculation as to the reasons the Supreme Court chose to weigh in is likely unproductive, particularly after *Microsoft v. i4i*, where assumptions about the Court’s purpose for granting certiorari did not hold true.

While it remains to be seen how the high Court will handle the issues presented, it is clear that the case provides the potential for the Court to clarify the patentable subject matter analysis, while at the same time hopefully avoiding the frequent problem of conflation between the threshold test for patentable subject matter and the separate requirement of novelty in patent law.

**Potential for Clarification**

*Prometheus* will present the Supreme Court with an opportunity to clarify the proper application of and relationship between the “machine-or-transformation” test and the “preemption” analysis for determining what falls within patentable subject matter under 35 U.S.C. §101. Are the two tests truly separate, or is the machine-or-transformation test merely a “useful and important clue” to inform the overarching preemption test? While the interplay between these tests was not fully addressed in *Bilski*, both were addressed in the Federal Circuit’s decision in *Prometheus* and are also a strong focus of the briefing on petition for certiorari.

The Federal Circuit held that Prometheus’s patent claims satisfied the machine-or-transformation test because the steps preceding use of the natural correlations (between metabolite levels and efficacy or toxicity) involve “transformations” of the human body (because enzymes transform the drug into metabolites whose concentrations can be determined). The Federal Circuit also held under the preemption test that Prometheus’s method claims recite a patent-eligible application (constituting specific treatment steps) of the correlations, and that this application is sufficiently limiting so that all uses of the naturally occurring correlation are not preempted.

In its certiorari petition, Mayo argued that the Federal Circuit got it wrong—that
Prometheus’s claims monopolize all uses of the natural correlations, and fail the preemption standard even if specific steps and natural “transformations” of body chemistry may lead up to those correlations. Addressing the Federal Circuit’s treatment of the two tests, Mayo’s petition argues that the “transformations” found by the Federal Circuit would only be relevant if they impose meaningful limitations on the claims such that the claims do not preempt all uses of the natural correlation, and that here “[t]hose bodily transformations in no way limit the uses that may be made of the admittedly natural correlations.”

Mayo’s arguments should require the Supreme Court to expand upon Bilski and further address the three Supreme Court precedents discussed therein (Benson, Flook, and Diehr) to clarify the relationship between the preemption standard and the machine-or-transformation test. While an abstract idea or law of nature cannot be patented, the Court has recognized that an application may deserve protection if it imposes meaningful limits. For example, in Benson the Court stated, in reversing the court below, that “The mathematical formula involved here has no substantial practical application except in connection with a digital computer, which means that if the judgment below is affirmed, the patent would wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself.” Thus, in Benson, tethering the claim to an application using a digital computer did not reduce the preemptive footprint of the claim because it did not provide meaningful limits. Mayo’s petition attempts to draw parallels to Benson, noting that the transformation steps recited provide no meaningful limitation because there is no utility for the correlation outside an application involving the human body.

Mayo will also seek to rely on Flook, where the applicant attempted to patent a procedure for monitoring the conditions during the catalytic conversion process in the petrochemical and oil-refining industries. In Flook, the only innovation was reliance on a mathematical algorithm, and the Court “rejected [t]he notion that post-solution activity, no matter how conventional or obvious in itself, can transform an unpatentable principle into a patentable process,” concluding that “the process at issue there was ‘unpatentable under § 101, not because it contain[ed] a mathematical algorithm as one component, but because once that algorithm [wa]s assumed to be within the prior art, the application, considered as a whole, contain[ed] no patentable invention.’” Mayo will seek to distinguish Diehr, also discussed in Bilski, where the patent at issue claimed a method for molding uncured synthetic rubber into cured precision products, using a mathematical formula to complete some of its steps using a computer. The Court in Diehr concluded that the claim fell within patentable subject matter because it was not an attempt to patent a mathematical formula, but instead a patent on the process of curing synthetic rubber that did not preempt all uses of the formula: “Their process admittedly employs a well-known mathematical equation, but they do not seek to pre-empt the use of that equation. Rather, they seek only to foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process. . . .”

The central policy behind § 101 is to prevent monopoly over natural phenomena or abstract ideas and keep these dedicated to the public domain. It is this concern with over-breadth that is at the heart of the § 101 inquiry, and drives the requirement that the
patentee tether the abstract idea or natural phenomenon to a real-world application that limits the scope of the claims. It therefore makes sense that the preemption analysis, which focuses directly on this over-breadth concern, should be the dominant analysis, and that the machine-or-transformation test is relevant only to the extent it informs the overarching preemption analysis by providing limitations on claims involving abstract ideas or natural phenomena. This use of the machine-or-transformation test to determine whether the claims are sufficiently limited so as to not monopolize all uses of a natural phenomenon is also consistent with the Court’s statement in *Bilski* that the machine-or-transformation inquiry, while not the sole test, serves as a “useful and important clue” to determine whether a claimed invention is a patent-eligible process.

The application of these analyses and the interplay between them as applied to particular facts remain unclear and present difficult issues for the lower courts. The decision in *Prometheus* has the potential to provide welcome clarification regarding the relationship between the preemption and “machine-or-transformation” tests following *Bilski*.

**Potential for Confusion**

*Prometheus* is also important because it presents the potential for confusion between the threshold patentable subject matter analysis under § 101 and the novelty analysis under §§ 102 and 103. As Justice Kennedy stated in *Bilski*, the § 101 patent-eligibility inquiry is a threshold condition on patentability separate from novelty and nonobviousness. Similarly, as former Chief Judge Michel noted in the Federal Circuit *Bilski* opinion, “Congress did not intend the ‘new and useful’ language of § 101 to constitute an independent requirement of novelty or non-obviousness distinct from the more specific and detailed requirements of §§ 102 and 103, respectively. . . . It is irrelevant to the § 101 analysis whether Applicants’ claimed process is novel or non-obvious.”

There is no doubt, however, that the issues of patentable subject matter and novelty are easily and frequently confused. Indeed, the question presented in *Prometheus* highlights this potential for confusion as it appears to conflate the threshold test for patentable subject matter under § 101 with what should be the separate requirement of novelty:

> “Whether 35 U.S.C. § 101 is satisfied by a patent claim that covers observed correlations between blood test results and patient health, so that the claim effectively preempts all uses of the naturally occurring correlations, simply because well-known methods used to administer prescription drugs and test blood may involve ‘transformations’ of body chemistry.” (emphasis added).

Notably, some of the Supreme Court’s own precedents, including *Flook*, contribute to the potential for confusion between the novelty and patentable subject matter analyses. For instance, *Flook* states that because the “algorithm was assumed to be within the prior art, the application, considered as a whole, contain[ed] no patentable invention.” Comparison of the patent claims to the prior art, however, is generally the purview of the novelty analysis, not patentable subject matter.

Admittedly, the preemption analysis invites a cursory, and likely necessary, inquiry into how commonplace the use of an application is, to determine whether that application provides sufficient limitation to avoid
preemption. That is, if the real-world application of an abstract idea is so widespread that it effectively provides no real limitation, such as the use of the computer in *Benson*, then all uses are preempted. Mayo argues along these lines that "those steps [relied upon by the Federal Circuit in upholding the patent] are well-known, are performed every day by countless medical personnel, and owe nothing at all to Prometheus" and thus that the recited steps provide no limitation to a monopoly on the natural correlation.

However, Mayo's arguments extend beyond this inquiry regarding limitation and go further to question the level of innovation, which unquestionably invites further confusion. In its petition for certiorari, Mayo argues that the steps needed to elicit the correlation, which the Federal Circuit found to be transformative, are not innovative:

"But these steps are simply the administration of the drug and the measurement of metabolite levels, *both of which had been known in the art for decades*. This was enough for the Federal Circuit to find patent-eligibility for a process that—*far from constituting any innovation*—is nothing more than the body's natural reaction to the ingestion of drugs, and a mental recognition of that natural reaction."

Prometheus points out the potential for confusion in its opposition to the petition, stating, "Mayo and its amici repeatedly try to import novelty analysis into §101 by arguing that the physical, transformative steps of the patents should be disregarded because those steps were previously well known in the art—and that without those steps all that remains is a mental step."

*Prometheus* thus poses an important question, which if left unanswered will lead to further confusion, and if answered without clarity could lead to further conflation of the doctrines: Does the specific application merely have to be limiting so as to avoid preemption, or does it also need to be novel, and non-obvious in order to constitute eligible patentable subject matter, so that it is not merely "post-solution activity"? Hopefully the Supreme Court will not succumb to the invitation to conflate the two questions and will instead answer this question so as to avoid further confusion.

It is difficult to know why the Supreme Court granted certiorari in *Prometheus*. However, the potential for the Court to answer critical questions about the interrelationship of the tests for patentable subject matter, and to either avoid further conflation or add to the confusion of the separate §101 and novelty inquiries, means this opinion will be one to watch for.
Six years after stepping into a major legal controversy over doctors’ medical diagnoses of how their patients react to varying drug doses, but then finding itself unable to decide, the Supreme Court agreed on Monday to try again. It granted review, with the decision to come in its next Term, on the scope of patent rights for a system of analyzing such patient reactions. The famous Mayo Clinic and its affiliated organizations brought the issue back to the Court, a year after the Justices ordered a lower court to take a new look at the issue.

At the center of the Mayo appeal is its claim that no patent should be issued on observations of how varying a dosage of a medicine alters the way a patient reacts. Those kinds of observations are what doctors do routinely, the Mayo group has contended, and bottling up that process in someone’s exclusive patent rights would stifle normal medical practice, and force doctors to spend time looking in legal files to see if they are infringing.

The Circuit Court for the Federal Circuit—the nation’s leading tribunal on patent rights—has twice upheld diagnostic method patents owned by Prometheus Laboratories, Inc., a company that makes medicines and devises diagnostic techniques. It has patents covering a process for analyzing blood tests to determine whether certain biological measures rise or fall, depending upon the amount of a drug the patient has been given. The claimed invention involves measuring the effects of synthetic drugs that are used to treat so-called autoimmune diseases—that is, disorders in which the body’s self-protective capacity reacts to something occurring naturally in the body, as if it were an adversary that had to be attacked. The drugs suppress that immune response.

Doctors are said to have difficulty determining just how much of such a synthetic drug to give a patient, because patients’ metabolism varies. So the doctor will prescribe varying dosages of a drug for suppressing an immune response, and then analyze blood tests to determine whether the dosage is too strong, or not strong enough. Prometheus’s patents involve a method that aids doctors in performing this kind of treatment analysis. It has prepared test kits for doctors who use the method.

Prometheus sued the Mayo Clinic and its affiliates, contending that they were using the kits in violation of Prometheus’s patent rights. Mayo at one point had a plan to produce its own kits, but, after being sued for infringement, it held off. Prometheus ultimately won in the Circuit Court, in a finding that the company’s invention had satisfied that court’s “machine-or-transformation” test for patent eligibility. The Mayo group failed in that court on its argument that the test was nothing more than observing a natural phenomenon—something that, ordinarily, is not patentable.

The legal fight between Prometheus and the Mayo group was an echo of an earlier fight that had reached the Supreme Court, between Laboratory Corp. of America and Metabolite Laboratories, involving a similar dispute over a method patent involving analysis of patient reactions. The Supreme Court agreed to hear that case in 2005, but the case ultimately was turned aside without
a decision, because of a question of whether the legal issue had been kept alive. Three Justices (Justice Stephen G. Breyer and two Justices no longer on the Court) dissented, arguing that the case raised a major issue over whether eligibility for patents on such diagnostic methods might inhibit doctors' use of their own medical judgment in treating patients.

After Mayo had lost to Prometheus in a closely similar dispute in the Federal Circuit in 2009, it took its case to the Supreme Court. After the Court had ruled in *Bilski v. Kappos* in June last year, overturning the Circuit Court's singular reliance on the machine-or-transformation test of patent eligibility, the Justices sent the Mayo case back to that tribunal for a second look. That resulted in a new decision, once again upholding Prometheus's patents. The Circuit Court said that the patents were valid as a form of transformation, since the test measured the change in the body chemistry of a patient after being given varying dosages of immune-suppressing drugs.

***
On December 17, 2010, the U.S. Court of Appeals for the Federal Circuit confirmed that claims to clinical and diagnostic methods can constitute patent-eligible subject matter in its *Prometheus II* decision. This was one of the first Federal Circuit opinions applying the recent United States Supreme Court *Bilski* case, which interpreted the statutory requirements for patent eligibility under 35 U.S.C. § 101. In *Prometheus II*, the Federal Circuit essentially reaffirmed its earlier decision in *Prometheus I*, holding that the claims recite a patent-eligible application of naturally occurring correlations and do not wholly preempt all uses of such correlations. *Prometheus II* clarifies that after *Bilski*, clinical and diagnostic methods can still be patented.

LEGAL BACKGROUND

The scope of patentable subject matter is broadly outlined in Section 101 of the Patent Act, which states that “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.” However, the Supreme Court has specified three categorical exceptions to the broad principles of Section 101: “laws of nature, physical phenomena, and abstract ideas.” The Federal Circuit attempted to construct a bright-line rule, commonly referred to as the “machine-or-transformation” test. Under this test, a process claim satisfies Section 101 by showing that the “claim is tied to a particular machine,” or the “claim transforms an article into a different state or thing.” Although the Supreme Court regarded it as an “important clue or investigative tool” for establishing patentability, it rejected this test as the exclusive test for determining a patent-eligible subject matter because such interpretation unduly limits the statute.

PROMETHEUS I

Prometheus sued Mayo for infringement of U.S. Patents 6,355,623 and 6,680,302. The claims at issue are directed to methods of optimizing therapeutic efficacy for treatment of immune-mediated gastrointestinal disorders by a process of administering a drug to a patient, measuring the level of a metabolite of the drug in the patient following administration of the drug, and comparing the level of the metabolite to recited threshold values to determine whether the drug’s dosage needs to be adjusted.

The district court held the claims unpatentable under Section 101.8. The Federal Circuit reversed, holding that the claims-in-suit pass the machine-or-transformation test. Mayo filed a petition for a writ certiorari, arguing that the Federal Circuit’s reliance on the machine-or-transformation test as the “single determinant” of patentability conflicts with the Supreme Court’s preemption standard and reiterating its argument that Prometheus’s claims effectively preempt any correlations between metabolite levels.
and efficacy or toxicity. The Supreme Court granted certiorari, vacated [the] *Prometheus I* decision and remanded the case to the Federal Circuit for reconsideration in light of *Bilski*.

**PROMETHEUS II**

On remand, the Federal Circuit reviewed the district court’s grant of summary judgment de novo and again sided with Prometheus. In light of the Supreme Court’s decision in *Bilski*, the Federal Circuit framed the issue as “whether Prometheus’s asserted claims are drawn to a natural phenomenon, the patenting of which would entirely preempt its use as in *Benson* and *Flook*, or whether the claims are drawn only to a particular application of that phenomenon as in *Diehr*.” The Federal Circuit concluded that they are drawn to the latter.

The Federal Circuit rejected Mayo’s position that the Supreme Court’s decision to grant review, vacate the *Prometheus I* decision, and remand in view of *Bilski* (“GVR Order”) indicates that preemption should be used as the controlling standard for Section 101 instead of the machine-or-transformation test. The court stated that “[n]either the Supreme Court’s GVR Order [n]or the Court’s *Bilski* decision dictates a wholly different analysis or a different result on remand.” The Federal Circuit further noted that “[t]he Supreme Court’s decision in *Bilski* did not undermine our preemption analysis of Prometheus’s claims and it rejected the machine-or-transformation test only as a definitive test.”

As in *Prometheus I*, the Federal Circuit in *Prometheus II* noted that “Prometheus’s asserted method claims recite a patent eligible application of naturally occurring correlations between metabolite levels and efficacy or toxicity, and thus do not wholly preempt all uses of the recited correlations.” The court explained that “[t]he steps recite specific treatment steps, not just the correlations themselves,” and “involve a particular application of the natural correlations: the treatment of a specific disease by administering specific drugs and measuring specific metabolites.”

The Federal Circuit also reaffirmed that “the treatment methods claimed in Prometheus’s patents in suit satisfy the transformation prong of the machine-or-transformation test, as they ‘transform an article into a different state or thing,’ and the transformation is ‘central to the purpose of the claimed process.’” The court noted that the asserted treatment methods are always transformative when a drug is administered to ameliorate an undesired condition. While the court recognized that the transformation of the drug upon administration occurs according to natural processes, it emphasized that the act of drug administration itself is not a natural process. Consequently, the administration step is not merely data gathering but rather a transformative element of the claimed methods.

Additionally, the Federal Circuit held that the determining step, present in each of the asserted claims, is transformative and central to the claimed methods. This step necessarily entails some form of manipulation to extract the metabolites from a bodily sample and determine their concentration. The court noted that “[w]hile it is true that the administering and determining steps gather useful data, it is also clear that the presence of those two steps in the claimed processes is not ‘merely’ for the purpose of gathering data.” Because both steps are integral to the treatment protocol, they a transformative and central to the claimed methods.

Last, the Federal Circuit reiterated that the inclusion of a mental step does not destroy
the patentability of an otherwise patentable process claim. While agreeing with the district court that the final “wherein” clauses in Prometheus’s asserted claims are mental steps, the Federal Circuit stressed that “[a] subsequent mental step does not, by itself, negate the transformative nature of prior steps.” Because the administering and determining steps fall squarely within the realm of patentable subject matter, the mental steps that follow fail to remove the asserted claims as a whole from that realm. The Federal Circuit thus concluded that Prometheus’s asserted methods satisfy the preemption test as well as the transformation prong of the machine-or-transformation test.

CONCLUSION

The *Prometheus II* decision confirms that inventions that satisfy the machine-or-transformation test will continue to fare well in the *post-Bilski* world. Moreover, *Prometheus II* indicates that the purpose of a claimed method is central to patentability analysis, suggesting that claims directed, at least in part, to methods of therapeutic treatment may have an easier time passing muster under Section 101 than claims directed to purely diagnostic techniques.
Diagnostic tests used to determine whether a patient is getting the proper dose of a medicine can be patented, an appeals court ruled Friday in a closely watched decision.

The ruling is important to the emerging field of personalized medicine, which involves using tests—such as of a person’s genes or levels of chemicals in the bloodstream—to help predict whether a drug will be safe and effective for a particular patient.

But one question hanging over the field has been whether tests that correlate something in the body with a drug’s effectiveness and safety are mere observations of natural phenomena and therefore ineligible for patents.

The ruling Friday of the Court of Appeals for the Federal Circuit in Washington, which upheld patents owned by Prometheus Laboratories, would be good for companies wanting to develop and patent such so-called companion diagnostic tests.

“This decision will be welcomed by those working in the personalized medicine arena, which holds much promise for improving both the clinical efficacy and cost-efficiency of therapeutic treatments,” Courtenay Brinckerhoff, a Washington patent lawyer who was not involved in the case, said in an e-mail.

But the decision might be disliked by those who think patents on tests raise costs and impede medical progress.

The decision could bode well for Myriad Genetics. The same appeals court, which specializes in patent cases, will hear its appeal of a lower court decision that invalidated patents on the company’s genetic test, which analyzes gene mutations to predict whether a woman has a high risk of breast cancer.

Prometheus, based in San Diego, sells a test that helps determine the safest and most effective doses of a particular class of drugs used to treat inflammatory bowel diseases.

The drugs are broken down naturally in the body into other chemicals, and Prometheus’s test involves measuring the levels of those chemicals in the blood. If the concentration is above a certain level, the dose of the drug should be reduced to avoid side effects. If the concentration is below a certain level, the drug dose should be increased.

Prometheus sued the Mayo Clinic, which wanted to offer a competing test in its laboratory. A lower court in 2008 agreed with Mayo that Prometheus’s patents were invalid because the test involved merely gathering data and observing natural phenomena.

But the appeals court has now reversed that decision, saying that the test involved the application of a law of nature, not the law itself. The patent claims “do not encompass laws of nature or pre-empt natural phenomena,” Judge Alan D. Lourie wrote on behalf of a three-judge panel.

The judges ruled that Prometheus’s tests met the court’s “machine-or-transformation” standard—that something was patentable if it was tied to a particular machine or
involved the transformation of something into something else. In this case, the judges said, the transformation is of the drug into its metabolites in the body and of the body itself once it is given the drug.

"The asserted claims are in effect claims to a method of treatment, which are always transformative when one of a defined group of drugs is administered to the body to ameliorate the effects of an undesired condition," Judge Lourie wrote.

This is the second time the appeals court has ruled in this case and it has reached the same conclusion both times.

The first decision was vacated in June by the Supreme Court, when it issued a ruling in the so-called Bilski case covering whether methods of doing business could be patented. As part of that decision, the Supreme Court said that the machine-or-transformation test should not be the sole test used to determine patentability. And it asked the appeals court to re-examine its Prometheus decision.

But the appeals court said Friday that while the machine-or-transformation test might no longer be the exclusive test of patentability, it could still be used.

The case involving Myriad Genetics has attracted a lot of attention mainly because a district judge ruled in March that genes isolated from human chromosomes cannot be patented.

But the judge, Robert W. Sweet, also said that the analysis of the genes to see if a woman had a high risk of breast cancer could not be patented because it was an abstract mental process.

The Prometheus decision could bear on that second part of the Myriad case. However, in making his ruling, Judge Sweet took pains to differentiate Myriad’s test from that of Prometheus.
Caraco Pharmaceutical Laboratories, Ltd. v. Novo Nordisk A/S

10-844


In 2005, Caraco Pharmaceutical Laboratories sought to market a generic version of Novo’s diabetes treatment drug, Prandin. Caraco attempted to utilize the FDA’s abbreviated new drug application for doing so. This program expedites the approval process if generic manufacturers can show their proposed drug is bio-equivalent to a drug that has already received approval. If approved, the generic drug will be required to carry the same label as the brand-name version. Additionally, the accelerated program allows for generic manufacturers to assert they intend to market their drug for a non-patented usage, or a “carve-out.” If their carve-out is approved, generic manufactures can remove the portions of the label that do not apply to the use for which they intend to market their drug.

In response to Caraco’s intent to produce a generic version of Prandin, Novo brought a patent infringement claim. Caraco counterclaimed under the Hatch-Waxman Act, asserting their intent to seek a carve-out that would avoid what would otherwise be an infringement. Around this time, Novo amended its patent information on file with the FDA, broadening the use code associated with Novo’s patents and resulting in the denial of Caraco’s carve-out application. Caraco argues Novo’s new use code is overbroad and suggests that Novo holds patents for all three FDA-approved uses of the drug when in fact it holds a patent for only one.

Questions Presented: Whether the counterclaim provision of the Hatch-Waxman Act applies when (1) there is “an approved method of using the drug” that “the patent does not claim,” and (2) the brand submits “patent information” to the FDA that misstates the patent’s scope, requiring “correct[ion].”

NOVO NORDISK A/S and Novo Nordisk, Inc., Plaintiffs-Appellants,

v.

CARACO PHARMACEUTICAL LABORATORIES, LTD., and Sun Pharmaceutical Industries, Ltd., Defendants-Appellees.

United States Court of Appeals for the Federal Circuit

April 14, 2010

[Excerpt; some footnotes and citations omitted.]

Opinion for the court filed by Circuit Judge RADER. Concurring opinion filed by Circuit Judge CLEVENGER. Dissenting opinion filed by Circuit Judge DYK.

The United States District Court for the Eastern District of Michigan entered an injunction directing Novo Nordisk A/S and Novo Nordisk, Inc. (collectively, “Novo”) to
request the U.S. Food and Drug Administration ("FDA") to replace Novo's patent use code U-968 listing for Prandin® in the Orange Book with the former U-546 listing. Because Caraco Pharmaceutical Laboratories, Ltd. ("Caraco") does not have a statutory basis to assert a counterclaim requesting such injunctive relief, this court reverses and vacates the injunction.

I.


Title 21 prohibits sale of a new drug without FDA approval. To obtain that approval, a pioneering manufacturer must file a new drug application ("NDA"), containing clinical studies of the drug's safety and efficacy. As part of the NDA process, the manufacturer must also identify all patents that claim the drug or a method of use:

The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.


If the patent information described in subsection (b) of this section could not be filed with the submission of an application under subsection (b) of this section . . . , the holder of an approved application shall file with the Secretary the patent number and the expiration date of any patent which claims the drug for which the application was submitted or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.


The FDA has authority to promulgate regulations for the efficient enforcement of these provisions. Under those regulations, a pioneering manufacturer files with the FDA the patent number and the expiration date of any applicable patents by submitting Form 3542a ("Patent Information Submitted with the Filing of an NDA, Amendment, or Supplement") or Form 3542 ("Patent Information Submitted Upon and After Approval of an NDA or Supplement"). If the patent claims one or more methods of using the NDA drug, Forms 3542a and 3542 require a description of each of those processes. This description is commonly known as the "use code narrative." The FDA assigns a unique number, known as a "use code," to each description. The FDA publishes a list of drugs, along with the applicable patents and their associated use
codes, in its Approved Drug Products With Therapeutic Equivalence Evaluations, commonly known as the “Orange Book.”

A manufacturer that seeks to market a generic copy of these listed drugs may submit an abbreviated new drug application (“ANDA”). The ANDA process streamlines FDA approval by allowing the generic manufacturer to rely on the safety and efficacy studies of a drug already listed in the Orange Book upon a showing of bioequivalence.

As part of the ANDA process, a generic manufacturer must make a certification addressing each patent identified in the Orange Book pertaining to its drug. Specifically, the generic manufacturer must select one of four alternatives [(Paragraph Notifications)] permitting use of the patented product or process: (I) no such patent information has been submitted to the FDA; (II) the patent has expired; (III) the patent is set to expire on a certain date; or (IV) the patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug.

Often pharmaceutical formulations have multiple uses and applications. After expiration of the patent on the composition itself, only some of those uses may enjoy continued protection as patented methods. If a generic manufacturer wishes to seek FDA approval for a use not covered by a method-of-use patent for a listed drug, it must make a “section viii statement.” 21 U.S.C. § 355(i)(2)(A)(viii). Along with the section viii statement, the generic manufacturer must submit a proposed label to the FDA that does not contain the patented method of using the listed drug. When considering approval of these requests for a use not covered by a patent, the FDA relies on the applicable patent’s use code narrative to determine the scope of the patented method. The FDA approves the section viii statement only where there is no overlap between the proposed carve-out label submitted by the generic manufacturer and the use code narrative submitted by the pioneering manufacturer.

The Hatch-Waxman Act facilitates early resolution of disputes between pioneering and generic manufacturers. To achieve this objective, the Act makes a Paragraph IV certification into an act of patent infringement. A generic manufacturer that files a Paragraph IV certification must give notice to the patentee and the NDA holder and provide a detailed basis for its belief that the patent is invalid or not infringed. The patentee then has forty-five days to sue the generic manufacturer for infringement. If the patentee does not sue, the FDA may approve the ANDA. If the patentee sues, the FDA may not approve the ANDA until expiration of the patent, resolution of the suit, or thirty months after the patentee’s receipt of notice, whichever is earlier. The court entertaining this suit has discretion to order a shorter or longer stay if “either party to the action fail[s] to reasonably cooperate in expediting the action.”

The Hatch-Waxman Act enables a generic manufacturer in a Paragraph IV suit to assert a counterclaim challenging the accuracy of the “patent information” submitted to the FDA:

[The ANDA] applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) of this section on the ground that the patent does
not claim either—

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.


This counterclaim provision was not part of the original Hatch-Waxman Act. Rather the Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub.L. No. 108-173, 117 Stat.2066 (2003) added this counterclaim provision to permit challenges to patent information at the FDA. The interpretation of this counterclaim provision is the central issue in this case.

II.

Novo markets and distributes the drug repaglinide under the brand name PRANDIN. PRANDIN is an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes (non-insulin dependent diabetes mellitus). The FDA has approved PRANDIN for three uses: (1) repaglinide by itself (i.e., monotherapy); (2) repaglinide in combination with metformin; and (3) repaglinide in combination with thiazolidinediones (“TZDs”). Novo Nordisk, Inc. holds the approved NDA for PRANDIN.

The Orange Book lists two patents for PRANDIN. U.S. Patent No. RE 37,035 (the “035 patent”) claims, inter alia, the chemical composition of repaglinide. The 035 patent expired on March 14, 2009. U.S. Patent No. 6,677,358 (the ‘358 patent”) claims, inter alia, repaglinide in combination with metformin:

A method for treating non-insulin dependent diabetes mellitus (NIDDM) comprising administering to a patient in need of such treatment repaglinide in combination with metformin.

‘358 patent, claim 4.

The ’358 patent expires on June 12, 2018. Novo Nordisk A/S owns the ’358 patent. Novo does not own patents claiming the other two approved methods of using repaglinide to treat type 2 diabetes. The FDA initially assigned the ’358 patent the use code “U-546-Use of repaglinide in combination with metformin to lower blood glucose.”

On February 9, 2005, Caraco filed an ANDA for the drug repaglinide. The ANDA initially contained a Paragraph III certification for the 035 patent and a Paragraph IV certification for the 358 patent. On June 9, 2005, Novo initiated an infringement action against Caraco. In April 2008, Caraco stipulated that its ANDA would infringe the ’358 patent if it included a label that discussed the combination of repaglinide and metformin. At around the same time, Caraco submitted an amended ANDA with a Paragraph IV certification for the ’358 patent and a section viii statement declaring that Caraco was not seeking approval for the repaglinide-metformin combination therapy. The FDA indicated that it would approve Caraco’s proposed carve-out label. Novo moved for reconsideration on the ground that allowing the carve-out would render the drug less safe and effective.

On May 6, 2009, Novo submitted an amended Form 3542 for PRANDIN in
which Novo updated its use code narrative for the '358 patent. The FDA removed the use code U-546 from the Orange Book for PRANDIN and substituted the new use code "U-968-A method for improving glycemic control in adults with type 2 diabetes mellitus." The FDA then denied Novo’s request for reconsideration as moot in light of the new use code. According to the FDA, the factual predicate on which the FDA’s permissive carve-out determination had rested no longer applied. The FDA then disallowed Caraco’s section viii statement, because its proposed carve-out label overlapped with the use code U-968 for the '358 patent. As a result, Caraco’s current label now includes the repaglinide-metformin combination therapy, which is stipulated to infringe claim 4 of the '358 patent.

On June 11, 2009, Caraco amended its answer and counterclaim. Caraco added a counterclaim under 21 U.S.C. § 355(j)(5)(C)(ii), requesting an order requiring Novo to change the use code for the '358 patent in reference to PRANDIN from U-968 to U-546. Caraco claimed that the use code U-968 was overbroad because it incorrectly suggested that the '358 patent covered all three approved methods of using repaglinide even though it claimed only one approved method. Caraco also added a patent misuse defense, asserting that Novo misrepresented the scope of the '358 patent in its use code narrative.

On June 29, 2009, Novo moved to dismiss Caraco’s new counterclaim and to strike the patent misuse defense. The district court found that Novo had improperly filed an overbroad use code narrative for the '358 patent. On September 25, 2009, the district court entered the following injunction:

Novo Nordisk is hereby directed by mandatory injunction under 21 U.S.C. § 355(j)(5)(C)(ii)(1)(bb) to correct within twenty (20) days from the date of this Order and Injunction its inaccurate description of the '358 patent by submitting to FDA an amended Form FDA 3542 that reinstates its former U-546 listing for Prandin and describes claim 4 of the '358 patent in section 4.2b as covering the "use of repaglinide in combination with metformin to lower blood glucose."


Given the urgency of Novo’s situation, Novo filed a motion in this court for an expedited appeal from the district court’s order. This court granted Novo’s motion to expedite briefing. Novo also filed a motion for a stay of the injunction pending appeal and a stay of trial court proceedings. This court ordered a stay of the injunction pending disposition of this appeal but declined to stay trial court proceedings. Because the district court had jurisdiction under 28 U.S.C. §§ 1331 and 1338(e), this court has jurisdiction under 28 U.S.C. § 1292(c)(1).

III.

[The Court stated that the standard of review is generally abuse of discretion but no deference is given to lower court’s statutory construction.]
IV.

The Hatch-Waxman Act provides a limited counterclaim to a generic manufacturer in a Paragraph IV infringement action. The Act authorizes the generic manufacturer to assert a counterclaim "on the ground that the patent does not claim either (aa) the drug for which the application was approved; or (bb) an approved method of using the drug."

Novo and Caraco agree that the 358 patent claims only one of the three approved methods of using PRANDIN (i.e., repaglinide in combination with metformin). Novo asserts that the counterclaim is available only if the 358 patent does not claim any approved methods. Caraco argues that it is entitled to the counterclaim because the 358 patent does not claim two of the approved methods of PRANDIN use. In other words, Novo reads "an approved method" in the counterclaim statute as "any approved method" while Caraco reads it as "all approved methods."

This court detects no ambiguity in the statutory language. When an indefinite article is preceded and qualified by a negative, standard grammar generally provides that "a" means "any."

The rest of the counterclaim provision also does not support Caraco's interpretation. In the context of this case, the statutory language "an approved method of using the drug" refers to the approved methods of using the listed drug, PRANDIN. This language cannot refer to the methods of using Caraco's generic drug, because the FDA has not yet approved Caraco's ANDA. Therefore, the Hatch-Waxman Act authorizes a counterclaim only if the listed patent does not claim any approved methods of using the listed drug.

Although the statutory language on its face presents no ambiguities, this court nonetheless examines the legislative history to make sure that it does not contain any clear intent to the contrary. Before the amendment to the Hatch-Waxman Act in 2003, private litigants could not challenge FDA submissions at all. Novo and Caraco agree that the counterclaim provision responded to this court's decision in *Mylan Pharm., Inc. v. Thompson*, 268 F.3d 1323 (Fed.Cir.2002). In *Mylan*, the Orange Book listed a patent as covering the FDA-approved drug BuSpar. Mylan, a generic manufacturer, asserted that the patent "did not claim BuSpar or an approved method of using BuSpar." This court held that Mylan did not have a private cause of action to delist the allegedly irrelevant patent from the Orange Book. The 2003 amendment used exact language from Mylan in the new counterclaim provision. This choice of legislative language suggests that the 2003 Amendment sought to correct the specific issue raised in *Mylan*, i.e., to deter pioneering manufacturers from listing patents that were not related at all to the patented product or method. Thus, the language selected for this Amendment supports this court's interpretation that "an approved method" means "any approved method." A patent listing that covers one amongst several approved methods of using a formulation protects that patented method and thus bears a direct relation to the purpose of Orange Book listings. This court does not detect a situation such as the one occurred in *Mylan*.

This case also suggests that this court should address the relationship between section viii and the counterclaim provision. Section viii addresses scenarios where a patent claims at least one, but not all, approved methods of using a drug. This court recognizes that a broad use code covering all uses of a
pharmaceutical could require generic manufacturers to prove specifically that their use will not overlap with and infringe the patented use. This proof, under Hatch-Waxman procedures, will take the form of a Paragraph IV lawsuit. In that context, the generic may provide proof that their use will not cause infringement of the patented use. This court perceives that the Hatch-Waxman Act will thus ensure that a generic drug for non-patented purposes will not be used for patented purposes via a simple section viii certification. Instead, the generic manufacturer will need to alleviate the risk of infringement or induced infringement in a proceeding that fully tests for infringement and its implications, including potential health and safety risks. Thus, the Act again facilitates efficient resolution of disputes concerning potential overlapping of protected and unprotected uses. The Act seeks to strike a balance of the pioneering and generic manufacturers' interests.

As Judge Clevenger points out, Caraco's real complaint should lie with the FDA, not with Novo. Had it not been for the FDA’s regulatory action, Caraco could have asserted in a Paragraph IV lawsuit that its proposed labeling did not infringe the 358 patent. It was the FDA, not Novo, that tipped the careful balance in the favor of pioneering manufacturers.

V.

As further indication of balancing interests and creation of an efficient dispute resolution mechanism, this court notes that the Act, by its terms, does not allow generic manufacturers to counterclaim unless the listed patent bears no relation to the listed drug. To be more specific, the terms of the counterclaim provision do not authorize an order compelling the patent holder to change its use code narrative. The counterclaim provision states that a generic manufacturer can request an order compelling “the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c).” Subsection (b) requires a pioneering manufacturer to submit “the patent number and the expiration date of any patent . . . which claims a method of using such drug.” Subsection (c) states that “[i]f the patent information described in subsection (b) of this section could not be filed with the submission of an application,” the holder “shall file with the Secretary the patent number and the expiration date of any patent . . . which claims a method of using such drug.”

Thus, the Act defined the term “patent information” as “the patent number and the expiration date.” The reference in subsection (c) to “the patent information described in subsection (b)” could only mean the patent number and the expiration date, because no other “patent information” appears in the statute. Therefore, to maintain consistency in the statutory terms, “the patent information” in the counterclaim provision must also mean the patent number and the expiration date. Thus, the counterclaim provision only authorizes suits to correct or delete an erroneous patent number or expiration date. The authorization does not extend to the use code narrative. Once again, this careful use of language suggests that the Act facilitates efficient resolution of disputes over the potential overlap of patented and unpatented uses in the form of a Paragraph IV suit.

Approximately six months before the 2003 Amendment, the FDA promulgated a regulation concerning the “Submission of Patent Information” in which it requires a pioneering manufacturer to submit not only the patent number and the expiration date, but also the use code narratives and other
patent-related information on Forms 3542a and 3542. This regulation appeared to include the use code narrative under the broader heading of “patent information.” Although this regulation preceded the 2003 Amendment, it did not change the meaning of the statutory use of the term “patent information.” As this court has clarified, “[s]uch opaque timing observations hardly amount to a ‘most extraordinary showing of contrary intentions,’ especially when the language of the statute trumpets its meaning by itself.” The counterclaim provision does not mention the FDA regulations or in any way suggest adoption of a meaning for “patent information” broader than the express statutory definition. Moreover, this court owes “no deference is due to agency interpretations at odds with the plain language of the statute itself.” As discussed above, this broader definition would upset the careful balance that requires a full resolution of the potential infringement issues involved in overlapping patented and unpatented uses.

The legislative history does not add any clarity to the meaning of “patent information.” During the floor debate, Senators occasionally referred to the need to correct “patent information.” This court must read these statements to use the term “patent information” consistent with the express statutory definition. Accordingly, to preserve the Act’s careful balance and to enforce the language of the statute, the explicit definition of “the patent information” as “the patent number and the expiration date” controls.

VI.

Caraco argues that in case this court does not find that Caraco is entitled to a counterclaim, this court should affirm the district court’s injunction under the doctrine of patent misuse. Because the judicial doctrine of patent misuse creates an unusual circumstance where an infringer can escape the consequences of its infringing conduct because the victim of that tort may have used its patent rights to gain an unfair competitive advantage against an unrelated third party, this court examines such allegations with particularity. For instance, the doctrine may apply where the patentee’s misconduct toward unrelated parties amounted to unfair market benefits beyond the scope of the patent. In any event, in this case, the district court, apparently recognizing the rarity of this situation, expressly declined to address the doctrine of patent misuse. Without any finding to review, this court declines to adjudicate this issue in the first instance.

VII.

This court therefore reverses the district court’s grant of summary judgment on Caraco’s attempted, but unsuccessful, counterclaim and vacates the injunction ordering Novo to correct its use code for the ‘358 patent listed in the Orange Book for PRANDIN.

REVERSED and VACATED.

CLEVENGER, Circuit Judge, concurring.

I agree with Judge Rader’s analysis of the relevant statutory provisions in this case and therefore join the opinion he writes for the court. I am not as certain as Judge Rader that the ongoing Paragraph IV litigation will cleanly resolve the dispute between the parties.

The dissent masks the cause for the dispute between the parties. Novo did nothing that was illegal or forbidden. FDA voluntarily requested a change to the approved
indications for PRANDIN® which required Novo to use FDA’s new approved labeling. The change also permitted Novo to revise its use code as the relevant FDA form, “Patent Information Submitted Upon and After Approval of an NDA or Supplement,” expressly instructed Novo to “[s]ubmit the description of the approved indication or method of use that you propose FDA include as the ‘Use Code’ in the Orange Book.” Novo changed its use code to match the new PRANDIN® indication. Nothing in the record suggests that Novo is responsible for the labeling change, which, given the statutory and regulatory framework, happens to benefit Novo at Caraco’s expense.

If not for FDA’s request that Novo change its labeling to the present broad indication, everything would have worked properly under the relevant statutes. As Judge Rader notes, the “efficient dispute resolution mechanism” was in play. Caraco filed its ANDA for repaglinide, and by making its Paragraph IV certification had committed the statutory act of infringement. Novo followed with its infringement suit. Caraco was prepared to defend on the grounds that its proposed use of repaglinide would not induce infringement of the 358 patent. Caraco also filed a section viii statement in light of the then-approved labeling and use code for PRANDIN®, and proposed carve-out language in its labeling to signify its proposed noninfringing use of repaglinide. Caraco was thus set to get FDA approval to bring its generic drug to market and to defend itself in Novo’s Paragraph IV suit.

But FDA, acting independently, gummed up the works. By requiring a single broad indication for repaglinide as part of the approved labeling, FDA created a situation where Caraco can no longer assert that its proposed labeling does not infringe the 358 patent. It remains to be seen what impact FDA’s action will have on Caraco’s ability to defend itself in the ongoing Paragraph IV litigation; but FDA’s regulatory action threatens to impair Caraco’s ability to disprove infringement. FDA thus may have inadvertently upset the careful balance of interests represented by the efficient dispute resolution mechanism Congress created in the Hatch-Waxman Act.

The dissent’s fix would be to have United States District Courts dictate to FDA what indications should be used on the prescribed labeling for approved drugs, even though there is nothing illegal, or even incorrect, about Novo’s current use code. There is no basis for a counterclaim to correct or delete the patent information submitted by Novo. If a fix is in order under the circumstances of this case, it lies with the FDA and Congress to understand the consequences of changing the approved repaglinide labeling to a single broad indication, and corresponding use code, and to remedy the situation. Laying blame on Novo is wrong.

The counterclaim statute, which the dissent would expand beyond its literal reach, was designed to cure the situation presented in Mylan. Congress has not addressed the fact situation presented in this case. Congress is the appropriate entity to readjust, if necessary, the delicate balance it has struck between original drug manufacturers and their generic counterparts.

DYK, Circuit Judge, dissenting.

In 2003, Congress enacted the counterclaim provision of the Hatch-Waxman Act in order to prevent manipulative practices by patent holders with respect to the Orange Book listings. These practices were designed to delay the onset of competition from generic drug manufacturers. In my view, the majority, in reversing the district court, now
construes the statute contrary to its manifest purpose and allows the same manipulative practices to continue in the context of method patents. The amendment was designed to permit the courts to order correction of information published in the Orange Book, yet under the majority’s opinion, erroneous Orange Book method of use information cannot be corrected. I respectfully dissent.

I

** **

A

[The Court described the process for new drug approval (NDA) and the streamlined process for generic drug approval.]

Some NDA filers realized that they could block generic competition by making unwarranted claims to patent coverage, for example, by listing in the Orange Book a patent for a drug or method of use when in fact the patent was clearly inapplicable. The FDA repeatedly declined to police the Orange Book listings, and before the enactment of the counterclaim provision in 2003, we held that the courts could not do so through declaratory judgments.

Congress responded by enacting the counterclaim amendment as part of the “Greater Access to Affordable Pharmaceuticals Act” (“ Gregg-Schumer Bill”), enacted in 2003. . . .

[T]he amendment allows an ANDA applicant, who is defending against a patent infringement suit brought by the holder of the NDA, to assert a counterclaim to correct or delete the Orange Book “patent information submitted. . . . under subsection (b) or (c)” on the ground that the patent does not claim “the drug for which the application was approved” or “an approved method of using the drug.” We have not previously construed this provision. The majority now holds that the counterclaim provision is unavailable to correct erroneous method of use information in the Orange Book—on two separate grounds.

II

A

In my view, the majority has misconstrued the term “patent information submitted . . . under subsection (b) or (c).” In the majority’s view, method of use information is not “patent information.” The majority construes the term as limited to the patent number and expiration date: “[T]he Act defined the term ‘patent information’ as ‘the patent number and the expiration date.’” Majority Op. at 1366. There is, in fact, no definition of “patent information” in the statute, and in reaching this construction, the majority ignores critical statutory language. The statute requires the NDA applicant to file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.


Thus, the statute requires the NDA applicant to list patents claiming a drug or method of use “with respect to which a claim of patent infringement could reasonably be asserted.” In other words, the statute on its face contemplates that the scope of the patent
must be accurately described and that the patent must be related to the drug or method of use for which the NDA application is submitted. The statute does not require the listing of patent numbers and expiration dates in the abstract. It contemplates the description of the scope of the patent and of the relationship between the patent and the drug or the method of use; the description of that scope and relationship is itself "patent information." The statute requires that this information be published, stating that the Secretary "shall publish information submitted under the two preceding sentences."

Other provisions of the statute also contemplate that the ANDA filer will be able to understand the scope of the patent and to relate the patent information to the drug or drugs being claimed and the method or methods of use being claimed. Describing the scope of the patent and relating the listed patents to the drug or method of use is essential to the operation of the statute, as the basic idea of the patent listings in the Orange Book is to put ANDA applicants on notice regarding which listed drugs and methods of use may be copied and which drugs or method of use are patent protected, and to enable the ANDA filer to submit an appropriate certification as required by law. The statute requires an ANDA applicant to provide, as part of the application,

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section—

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted....

Id. § 355(j)(2)(A)(vii) (emphases added).

Similarly, the section viii certification provision also appears to contemplate that information submitted under subsection (b) or (c) will encompass information regarding the patented method of use. The statute directs the ANDA applicant to submit,

if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

Id. § 355(j)(2)(A)(viii).

The statute plainly contemplates that "patent information" will include information that describes the scope of the patent and that relates the patent to the drug or method of use.

B

Quite apart from the fact that the majority's limiting interpretation is inconsistent with the statutory language and structure, the
majority's interpretation is in my view untenable for other reasons.

First, the majority agrees that the counterclaim amendment was designed to overrule our decision in *Mylan*. In overruling *Mylan*, Congress viewed erroneous information as to the scope of the patent and its relationship to an approved drug or method of use as "patent information" that could be ordered corrected. The majority appears to suggest that the overruling of *Mylan* is limited to the precise facts of *Mylan*, namely, the situation in which correction of the error would require that the patent number be deleted entirely from the Orange Book. The overruling would not apply to a situation in which other erroneous Orange Book information is involved, for example, where the patent is erroneously listed with respect to a particular drug or method of use, but is properly listed elsewhere in the Orange Book. This ignores the context of the *Mylan* decision.

The first thing to understand is that the majority's description of the Orange Book likely bears no relationship to the actual document. The Orange Book is not a list of patents from which a particular patent could be excised. The Orange Book is a list of NDAs that associates particular patents with approved drugs or methods of use. Correction of an Orange Book listing does not strike a patent from a list, it strikes (or corrects) the listing that associates the patent with a particular NDA, approved drug, or method of use.

The problem in *Mylan* was that the Orange Book improperly described the scope of the patent and improperly related the patent to a drug and method of use not covered by the patent...

Thus, in *Mylan*, the accused infringer challenged the accuracy of the listing associating the patent with the approved method of use. Congress acted to provide a counterclaim action to correct such errors. Congress' concern with the proper listing of the patent in the Orange Book does not remotely suggest a myopic congressional focus on situations where the patent belonged nowhere in the Orange Book, as the majority suggests. Most significantly, viewing the overruling of *Mylan* as limited to complete delisting would be inconsistent with the explicit statutory language, which provides for correction of Orange Book information "on the ground that the patent does not claim the drug for which the application was approved." The statute thus must allow correction of a misdescription of patent scope that includes a drug not covered by the patent and erroneous information about the relationship between the patent and the drug, even if the patent is properly listed elsewhere in the Orange Book. In other words the scope of the patent and its relationship to the drug must be "patent information."

Moreover, if "patent information" includes information as to the scope of the patent with respect to the drug and the relationship between the patent number and the drug, it must also include Orange Book information describing the scope of a method of use patent and linking the method of use to the patent. There is no basis in the statutory language or statutory purpose for distinguishing between drug information and method of use information. Either both must be "patent information," or neither must be patent information. In my view, all Orange Book information is "patent information."

Second, at the time the counterclaim provision was enacted in 2003, the FDA had
adopted the Patent Listing Rule, making clear that the agency had adopted a broad interpretation of "patent information submitted . . . under subsection (b) or (c)." That interpretation is entitled to Chevron deference even if the language of the statute is ambiguous, and not (as I urge) plainly contrary to the majority's interpretation. By the time of the counterclaim amendment in 2003, the FDA had adopted detailed requirements for the submission of "patent information" for both drugs and methods. The 2003 rule, published as a proposed rule in the Federal Register in late 2002 and finalized six months before the counterclaim amendment, includes a section entitled "Submission of patent information" on the requirements for the listing of a patent in the Orange Book. The report accompanying the regulatory revision makes clear that the FDA is defining what constitutes "patent information" for purposes of subsections (b) and (c). Additionally, the report accompanying the Proposed Rule in 2002 confirms that the FDA's authority for the 2003 rule arises from not only the FDA's general authority to enforce the FDCA under 21 U.S.C. § 371, but also its authority to implement section 505 of the Hatch-Waxman Act, "including the patent listing and patent certification requirements" in section 505(b). The regulation itself provides that "patent information" includes 1) "[i]nformation on the drug substance (active ingredient) patent including . . . [w]hether the patent claims the drug substance that is the active ingredient in the drug product described in the new drug application or supplement," 2) "[i]nformation on the drug product (composition/formulation) patent including . . . [w]hether the patent claims the drug product for which approval is being sought," and 3) "[i]nformation on each method-of-use patent including . . . [w]hether the patent claims one or more methods of using the drug product for which approval is being sought and a description of each pending method of use or related indication and related patent claim of the patent being submitted."

The NDA applicant is thus not only required to submit the patent number and the expiration date as part of its application, but is also required to describe the scope of the patent and relate the drug substance, drug product, or method of use in question to the particular patent. Furthermore, the regulation requires an NDA holder or applicant to complete FDA Form 3542, which requires the applicant to identify whether the submitted patent claims a "drug substance," "drug product," or "method of use," and link such information to each patent for which information is being submitted. The information in this form provides the basis for the Orange Book listing.

Congress was well aware of this regulatory interpretation of "patent information" when it enacted the counterclaim provision. As Senator Schumer, one of the original sponsors of the amendment, stated, "The bill provides a critical complement to the work the FDA has done in clarifying its regulations on patent listing, but it goes much further." Additionally, in several places in the legislative history the FDA regulation is cited approvingly.

Quite apart from Chevron, it is well established that where, as here, Congress was specifically aware of the agency's interpretation of a statutory term at the time the statute was enacted, this is compelling evidence of legislative adoption of the agency's interpretation. This principle has been recognized by the Supreme Court for decades, both in the context of reenactment of existing statutes where statutory
terminology had been construed by the agency before the reenactment, and in the context of new legislation utilizing terminology that the agency had previously construed. Here, Congress utilized the FDA’s interpretation of “patent information” by enacting the Gregg-Schumer Bill with full awareness of the agency’s interpretation of the term, and the FDA’s interpretation is binding on us in construing the statute.

Third, the legislative history makes clear that Congress was concerned with correcting Orange Book information generally. The legislative history suggests a broad concern with preventing brand manufacturers from manipulating the patent listing system in the Orange Book in order to delay entry of generics into the market. The purpose of the statutory provision as reflected in the legislative history refers broadly to correction of Orange Book information, not just to correction of patent numbers and expiration dates. As Senator Schumer described it, “[T]he provisions enforce the patent listing requirements at the FDA by allowing a generic applicant, when it has been sued for patent infringement, to file a counterclaim to have the brand drug company delist the patent or correct the patent information in the FDA’s Orange Book.”

Under the circumstances, it seems to me that we must interpret the phrase “patent information submitted . . . under subsection (b) or (c)” to include Orange Book information that describes the scope of the patent and relates the patent number and expiration date to the drug or method of use and, in particular, that “patent information” submitted under subsections (b) and (c) must be interpreted to include the patent information required by the 2003 regulation, including method of use information.

III

In my view, the majority also errs by interpreting “an approved method of using the drug” in 21 U.S.C. § 355(j)(5)(C)(ii)(I)(bb) to mean “any” approved method of use approved in the patentee’s NDA. The majority’s approach here is fundamentally inconsistent with the Supreme Court’s admonition, in a recent opinion by Justice Scalia, that “[u]ltimately context determines meaning,” and the Court’s repeated instruction that “[i]n expounding a statute, we must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy.”

The evident purpose of the counterclaim provision is to allow for the correction of “patent information submitted . . . under (b) or (c).” In other words, as discussed above, the provision is designed to provide for correction of erroneous Orange Book information submitted by the NDA applicant or holder, including information with respect to patent coverage of both drugs and methods of use. That purpose is reflected in the language of the statute, which allows an ANDA applicant defending against an infringement action to “assert a counterclaim seeking an order requiring the [NDA] holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) of this section on the ground that the patent does not claim either (aa) the drug for which the application was approved; or (bb) an approved method of using the drug.” In other words, if the submitted Orange Book information claims patent coverage for an approved drug not covered by the patent or a method of use not covered by the patent, that information may be corrected.

422
Thus, the reference to "an approved method of using the drug" in subsection (bb) must refer to information in the Orange Book concerning "an approved method of using the drug." The majority's error lies in focusing on the relationship between the patent and the NDA (which is not Orange Book information), rather than the relationship between the patent and the Orange Book listing. Under the majority's view, no correction of erroneous Orange Book information is permitted so long as the patent covered any approved method of use covered by the NDA. The patent can be listed in the Orange Book as erroneously covering approved use A, despite the fact that the patent actually covers approved use B, and the counterclaim provision provides no mechanism for correction. This cannot be what Congress intended.

Moreover, the statutory language referring to "an approved method of using the drug" obviously refers, once again, to the terminology used in the 2003 Patent Listing Rule. That regulation required that for "each method of use patent" the NDA applicant submit certain information, including "[w]hether the patent claims one or more approved methods of using the approved drug product and a description of each approved method of use or indication and related patent claim of the patent being submitted." In other words, the regulation requires the patentee to relate the patent to the approved method of use. Subsection (bb) is directly concerned with correction of the Orange Book patent information relating the patent to the approved method of use.

Once the overall operation of the statutory scheme is understood, the text is clear. Webster's Third New International Dictionary describes "a" as being "used as a function word before a singular noun followed by a restrictive clause or other identifying modifier <a man who was here yesterday >." This definition appears before the definition of "a" as "any." As the example illustrates, "an" in this case may be the function word before the singular noun ("approved method of using the drug") conveying a particular identity through the use of a restrictive clause. The restrictive clause here is implicit—"an approved method of using the drug" logically refers to an approved method of use listed by the NDA holder in the Orange Book, as associated with the listed patent. Thus, "an" refers to a particular method of using the drug, that is, the particular approved method listed by the NDA holder in the Orange Book. This is the only interpretation of the statutory language that yields a result that is not plainly at variance with the purpose of the legislation as a whole. "As in all cases of statutory construction, our task is to interpret the words of these statutes in light of the purposes Congress sought to serve."

In short, the statute must be construed to read as follows:

(iii) Counterclaim to infringement action.—

(I) In general.—If an owner of the patent or the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) of this section on the ground that the patent does not claim either—
(aa) the [associated] drug for which the application was approved; or

(bb) an [associated] approved method of using the drug.

An error in an Orange Book use code, which covers an unpatented method of use, is subject to correction under a proper reading of the counterclaim provision.

IV

The facts in this case well illustrate the true manipulation that the counterclaim provision was designed to avoid. . . .

***

Novo acknowledges that monotherapeutic use of repaglinide is not covered by the '358 patent. But the use code claims that the patent does cover the monotherapy use. In my view, this is precisely the type of situation that Congress intended the counterclaim provision to address.

The concurrence blames the FDA for Caraco's predicament, adopting Novo's disingenuous argument that the FDA, and not Novo, was responsible for the change in the use code. The concurrence accuses the FDA of "gumm[ing] up the works. By requiring a single broad indication for repaglinide as part of the approved labeling, FDA created a situation where Caraco can no longer assert that its proposed labeling does not infringe the 358 patent." Concurring Op. at 1368. First, the FDA did not require a change in the use code. The FDA does not interpret patents or police the Orange Book listings, the very source of the problem that led to the counterclaim provision. The FDA role in administering the Orange Book is ministerial: it simply lists the patent information that it receives from brand manufacturers, expecting those parties to abide by the statutory and regulatory mandates.

Second, while the FDA did require a general change in oral diabetes drug labeling in November of 2007 that required a corresponding change in the PRANDIN label, there is absolutely nothing in the statute or regulations that required Novo to change the use code to track this new indication. The FDA did not direct or request that Novo change its use code to reflect the new indication, nor was Novo required under FDA regulations to make such a change. Indeed, in response to questioning at oral argument, Novo admitted this.

However, Novo argues that the labeling change required by the FDA in the "Indication" part of the label made the use code change appropriate. Novo argues that FDA Form 3542 allows them to submit either the method of use or the indication for the use code. That is partially correct, but the form also requires that the use code information refer to that portion of the label that relates to a patented use. An approved label, as in this case, may cover both patented uses and unpatented uses. Nothing in the FDA regulations or FDA Form 3542 suggests that the patentee may derive Orange Book use code information from that portion of the label referring to unpatented uses. Quite the contrary, the applicable regulations and FDA Form 3542 are clear that the patentee is required to utilize those portions of the label that refer to the patented use.

Here, the patentee did exactly what was expressly forbidden. For the proposed use code description submitted on the FDA Form 3542, Novo submitted the following: "A method for improving glycemic control in adults with type 2 diabetes mellitus." It thus utilized that portion of PRANDIN's
label that refers to the use of repaglinide standing alone to treat diabetes (an unpatented use), not to the use of repaglinide together with metformin (a patented use). There is no justification for using a portion of the label referring to an unpatented use to describe a patented use.

The manipulative nature of Novo’s actions is confirmed not only by the lack of justification for the change, but also by the timing of the change (two years after the labeling change was initiated by the FDA and immediately after the FDA approved Caraco’s section viii carve-out), and by its own admission that preventing approval of Caraco’s ANDA was part of the motivation for changing the use code. At oral argument, Novo conceded that the decision to change the use code was in part “a response to the section viii ruling ... in December 08 from FDA.”

V

Finally, the majority opinion suggests that the court’s restrictive interpretation of the counterclaim provision is not so bad because it does not leave Caraco without a remedy to correct the erroneous Orange Book listing. The majority is sanguine about the outcome, believing that forcing Caraco to defend the paragraph IV infringement suit will “facilitate[ ] efficient resolution of disputes concerning potential overlapping of protected and unprotected uses.” Majority Op. at 1365. In contrast, the concurrence doubts that there is a remedy in the infringement suit, and I agree. As the concurrence notes, “[b]y requiring a single broad indication for repaglinide as part of the approved labeling, FDA created a situation where Caraco can no longer assert that its proposed labeling does not infringe the ‘358 patent.” Concurring Op. at 1368. Indeed, Novo’s adoption of a broad use code for PRANDIN likely prevents Caraco from being able to disprove infringement in the paragraph IV lawsuit, because Caraco is now compelled to include information regarding the patented combination therapy in its label.

Nor would there be a remedy in a suit under the Administrative Procedure Act (“APA”). To be sure, we have held that an APA action could be brought to challenge FDA action in refusing to police use codes in the Orange Book, but at the same time we expressed no view as to whether such an action would succeed. To succeed in such an action, the ANDA applicant would have to establish that the FDA’s refusal to police use codes was arbitrary and capricious, or contrary to the statute. We have subsequently held that the FDA is under no statutory obligation to determine the correctness of particular patent listings in the Orange Book, and that nothing in the Hatch-Waxman Act requires the FDA to screen Orange Book submissions by NDA applicants and refuse those that do not satisfy the statutory requirements for listing. Moreover, the very enactment of the counterclaim provision assumed that no alternative remedy was available to an ANDA applicant challenging an Orange Book listing. Today’s decision strikingly limits the counterclaim provision with the consequence that, in all likelihood, the ANDA applicant is left without any remedy to correct an erroneous Orange Book listing with respect to a method of use patent. This cannot be what Congress intended.

***

In summary, the majority’s crabbed view of the statute sanctions an unjustified manipulation of the Orange Book. In this suit, Caraco seeks to compel Novo to correct the use code for PRANDIN, and to reinstate
the earlier U-546 use code describing the '358 patent as covering the "USE OF REPAGLINIDE IN COMBINATION WITH METFORMIN TO LOWER BLOOD GLUCOSE." Under the correct construction of the counterclaim provision, the district court properly held that Caraco was entitled to an order reinstating the former U-546 use code.

In holding that the counterclaim provision is unavailable, the majority's approach is notably inconsistent with the approach adopted by our sister circuit in another recent Hatch-Waxman Act case, *Teva Pharmaceuticals USA, Inc. v. Sebelius*, 595 F.3d 1303 (D.C.Cir.2010). There the court construed another provision of the 2003 amendments concerning the NDA holder's withdrawal of "patent information submitted under subsection (b) or (c)." 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC). The statute provided that if such information were "withdrawn by the holder of the application," the period of exclusivity of the ANDA first filer would be forfeited. The court held that only the withdrawal resulting from a successful counterclaim suit triggered a forfeiture and not a voluntary withdrawal. This was so because there was "not a single cogent reason why Congress might have permitted brand manufacturers to trigger subsection (CC) by withdrawing a challenged patent, outside the counterclaim scenario," and because of the strong policy of the statute favoring the 180-day marketing exclusivity period. Here the majority reaches a result that is unsupported by any cogent reason for leaving an ANDA applicant without a remedy to correct an erroneous Orange Book listing with respect to a method of use patent, and is directly contrary to the congressional purpose. I respectfully dissent.
The Supreme Court agreed on Monday to consider whether generic-drug makers can file certain legal counterclaims against branded-drug companies to get their cheaper, copycat medicines on the market.

At issue is whether the generics companies can challenge the way brand-name manufacturers describe their patents to the Food and Drug Administration. The generics say their brand rivals, if left unchecked, can describe their patents broadly in FDA submissions to shut out generic competition, even for unpatented uses of a drug.

The Supreme Court will consider an appeal by Caraco Pharmaceutical Laboratories, a unit of Sun Pharmaceutical Industries Ltd., which is seeking to introduce a generic version of Novo Nordisk A/S’s diabetes drug Prandin.

One Novo Nordisk patent on the drug compound has expired, but the company holds a second patent, which doesn’t expire until 2018, that involves the use of the drug in combination with another medicine.

The FDA has approved three uses for the drug. Caraco wants to introduce a generic version for the two uses that aren’t patented. The company says it can’t do so because Novo Nordisk’s description of its patent to the FDA is so broad that it forecloses the agency from approving a generic version of the drug.

A divided federal appeals court ultimately ruled last year that Caraco couldn’t file a legal counterclaim to challenge the way Novo described its patent to the FDA.

Novo said in a court brief that its FDA submission was correct and followed an agency directive concerning the labeling of oral diabetes drugs. It argued that the generic industry’s concerns were overblown and said the issue at the center of the case rarely arises.

The Obama administration urged the Supreme Court to hear Caraco’s appeal, arguing that the lower-court ruling was incorrect. Teva Pharmaceuticals USA, Mylan Pharmaceuticals Inc. and the Generic Pharmaceutical Association also filed briefs supporting Caraco, saying a loss would have serious adverse consequences for generics manufacturers.

The case is Caraco Pharmaceutical Laboratories v. Novo Nordisk, 10-844. Oral arguments will take place during the court’s next term, which begins in October.

***
On April 14th, the Federal Circuit rendered a decision construing statutory language in a rather straightforward and unremarkable (albeit not unanimous) opinion. But the statutory language at issue involved the 2003 Medicare Prescription Drug Improvement and Modernization Act, which amended the 1984 Drug Price Competition and Patent Term Restoration Act (colloquially known as the Hatch-Waxman Act), thus raising the opinion’s significance.

The statutory provisions at issue involve the requirements for listing patents claiming drug products or their uses in the Orange Book. The statute requires an innovator and approved New Drug Application (NDA) holder to identify these patents by patent number and expiration date. For patents claiming uses (more properly, methods of use) of a regulated drug, the FDA prescribes “use codes” which are published in the Orange Book as well.

For a use not covered by an Orange Book listed patent, a generic drug manufacturer who files an Abbreviated New Drug Application (ANDA) must submit a proposed label for the unpatented use as well as a statement under 21 U.S.C. § 355(j)(2)(A)(viii) (a “Section viii” statement) that the use does not infringe any listed patent. Approval of the ANDA requires that the proposed label does not overlap with any patented method (a “carve-out”).

As part of the litigation provisions of the Hatch-Waxman Act, an ANDA filer can file a counterclaim in ANDA litigation that challenges the accuracy of the patent information submitted by the innovator, on two grounds—either that the patent doesn’t claim the approved drug or an approved method for using the drug (which is defined by the use codes and the innovator drug label). This part of the law was enacted as part of the MMA amendments, in response to a Federal Circuit decision as discussed in the opinion and below, and is codified as 21 U.S.C. § 355(j)(5)(c)(ii)(I):

[The ANDA] applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) of this section on the ground that the patent does not claim either—

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

The case involves Novo Nordisk’s repaglinide drug product marketed as PRANDIN®. Novo listed two patents in the Orange Book associated with this drug: Reissue Patent No. RE37,035, which claims repaglinide drug product itself; this patent expired March 14, 2009. The other patent, U.S. Patent No.6,677,358, claims the method of using repaglinide in combination with metformin; this patent expires June 12, 2018. There are two other approved uses for
PRANDIN®: as monotherapy and in combination with thiazolidinediones (TZD’s); neither of these indications is claimed in any Orange Book listed patent. All indications are for treating Type 2 (adult-onset) diabetes.

Caraco filed an ANDA for generic repaglinide having a Paragraph III certification regarding the ‘035 patent and a Paragraph IV certification for the ‘358 patent, the latter leading to ANDA litigation pursuant to 35 U.S.C. § 271(e)(2). During the litigation, Caraco stipulated in that action that its ANDA would infringe the ‘358 patent if it included a label describing the combination of repaglinide and metformin, and at the same time submitting an amended ANDA with a Paragraph IV certification and a Section viii statement that its ANDA would not seek approval for the repaglinide + metformin combination. The “carve-out” label was acceptable to FDA.

However, at that time the FDA changed the use code associated with Novo’s PRANDIN® product. The original use code, U-546, specified the combination of repaglinide + metformin to lower blood glucose. The FDA changed this use code to U-968, for a method for improving glycemic control in adults with Type 2 diabetes.” This use code was not limited to the specific repaglinide + metformin combination, and indeed was not expressly limited to Novo’s drug (i.e., it could encompass metformin monotherapy). (There was some dispute between the majority and the concurring opinion, the concurrence asserting that the FDA changed the use code sua sponte which was not asserted in the majority opinion.)

This change in the use code caused the FDA to reject Caraco’s Section viii certification and “carve-out” label, requiring Caraco to include the repaglinide + metformin combination on its label. Since Caraco stipulated that this combination was an infringement, the FDA’s decision essentially mandated judgment for Novo absent a finding at trial of invalidity or unenforceability.

In response to the FDA’s determination, Caraco counterclaimed for an injunction to return the use code to U-546. The District Court granted summary judgment on this issue, granting Caraco the requested injunction. Specifically, the Court’s injunction ordered Novo to request the FDA to change the use code in the Orange Book for Prandin® from U-968 to its former U-546 listing.

The Federal Circuit granted Novo an expedited appeal and briefing schedule, and stayed the injunction pending the appeal. In its opinion, by Judge Rader joined by Judge Clevenger (with concurring opinions by Judge Clevenger and a dissenting opinion by Judge Dyk), the CAFC held that the statute contained no provisions permitting an ANDA defendant to request or a district court to grant such an injunction, reversing the decision and vacating the injunction.

The Federal Circuit characterizes the question as whether the statutory language of “an approved method” means “any approved method” (Novo) or “all approved methods” (Caraco). Novo contended that reciting one of the patented uses was sufficient to preclude the statutory counterclaim, while Caraco contended that reciting any unpatented use permits an ANDA defendant to assert the counterclaim.

In finding for Novo, the Court found “no ambiguity” in the language of the statute:

When an indefinite article is preceded and qualified by a negative,

The Court also says Caraco improperly focuses on its proposed uses:

[T]he statutory language "an approved method of using the drug" refers to the approved methods of using the listed drug, PRANDIN. This language cannot refer to the methods of using Caraco’s generic drug, because the FDA has not yet approved Caraco’s ANDA.

Thus, the Court concluded that Caraco can assert its counterclaim only if no patent listed in the Orange Book claims “any approved methods of using the listed drug.” That was not the case here.

The opinion also references the legislative history “to make sure that it does not contain any clear intent to the contrary.” It did not: the Court says that the counterclaim provisions of the statute addressed the Court’s own interpretation of the Hatch-Waxman Act to be devoid of a “private cause of action to delist an allegedly irrelevant patent from the Orange Book.” This intent was ascertained by the panel due to the use in the statute of “exact language” from the Mylan decision, the Court concluding that “[t]his choice of legislative language suggests that the 2003 Amendment sought to correct the specific issue raised in Mylan, i.e., to deter pioneering manufacturers from listing patents that were not related at all to the patented product or method.” Accordingly, the opinion found this legislative history to be consistent with its interpretation that “an approved method” means “any approved method,” because this interpretation “bears a direct relation to the purpose of Orange Book listings.”

The opinion also asserts that, under its interpretation, the combination of a Section viii certification and ANDA litigation will “ensure that a generic drug [approved] for non-patented purposes will not be used for patented purposes via a simple section viii certification.” This is consistent, the court contends, with the Hatch-Waxman Act’s purpose of striking “a balance [between] the pioneering and generic manufacturers’ interests.”

Finally, the Court held that the statute has no provisions permitting a generic drug maker to obtain an order from a court, like the injunction here, to compel a patent holder to change or modify its use code. The plain language of the statute authorizes the generic drug maker to “request an order compelling the holder to correct or delete the patent information submitted by the holder.” (The Court notes that “the patent information” under the statute is “the patent number and the expiration date.”) (Emphases in original). Put simply, “the patent information” does not include the use code narrative according to the plain language of the statute, and thus does not grant an ANDA challenger to obtain the injunction granted by the district court below.

This analysis is complicated by an FDA requirement, promulgated before passage of the amendments in 2003, that “a pioneering manufacturer . . . submit not only the patent number and the expiration date, but also the use code narratives and other patent-related information” on specific FDA forms. The panel refused to conclude that the regulation “change[d] the ordinary meaning of the statutory use of the term ‘patent information,’” citing the Court’s opinion in Wyeth v. Kappos that clear statutory meaning trumps any agency regulatory
interpretation. And the Court reminds us all that “no deference is due to agency interpretations at odds with the plain language of the statute itself.” Here, the legislative intent sheds no light on any relevance of the agency provisions to the plain meaning discerned by the panel.

Judge Clevenger concurred with the Court’s judgment, but in his view Novo merely reacted to a request by the FDA, and changed its use code narrative to match the new FDA use code. “FDA, acting independently, gummed up the works,” according to the judge.

Judge Dyk dissented, believing that the construction is contrary to the “manifest purpose” of the statute, allowing “the same manipulative practices” the statute was passed to prevent, i.e., “delay[ing] the onset of competition from generic drug manufacturers.” The dissent has a thorough explication of the Hatch-Waxman act and the 2003 Amendments, particularly with regard to what Judge Dyk characterizes as efforts by NDA filers to “block generic competition by making unwarranted claims to patent coverage, for example, by listing in the Orange Book a patent for a drug or method of use when in fact the patent was clearly inapplicable.”

Since the FDA “repeatedly declined to police Orange Book listings,” and the Federal Circuit refused to let ANDA filers use declaratory judgment jurisdiction to do so, Congress intervened by passing the 2003 amendments, including the Section viii certification provisions thereof.

Judge Dyk disagrees with majority on construing the term “patent information” to be limited to patent number and expiration date. According to Judge Dyk, this information is not required “in the abstract,”

“the statute on its face contemplates that the scope of the patent must be accurately described and that the patent must be related to the drug or method of use for which the NDA application is submitted.”

In context, the statute “contemplates the description of the scope of the patent and of the relationship between the patent and the drug or the method of use; the description of that scope and relationship is itself ‘patent information.’”

At least one source of the majority’s error, in Judge Dyk’s view, is their erroneous understanding of the Orange Book:

[T]he majority’s description of the Orange Book likely bears no relationship to the actual document. The Orange Book is not a list of patents from which a particular patent could be excised. The Orange Book is a list of NDAs that associates particular patents with approved drugs or methods of use. Correction of an Orange Book listing does not strike a patent from a list, it strikes (or corrects) the listing that associates the patent with a particular NDA, approved drug, or method of use.

Judge Dyk also disagreed with the majority’s treatment of the FDA’s regulations promulgated six months before enactment of the 2003 Amendments, stating that “Congress was well aware of this regulatory interpretation of ‘patent information’ when it enacted the counterclaim provision,” and citing portions of the legislative history illustrating this awareness (e.g., Senator Schumer’s statement that “[t]he bill provides a critical complement to the work the FDA has done in clarifying its regulations on patent listing,
but it goes much further.” Legislative and Regulatory Responses to the FTC Study on Barriers to Entry in the Pharmaceutical Marketplace: Hearing Before the S. Comm. on the Judiciary, 108th Cong. 19 (2003)). Judge Dyk believes that under circumstances where “Congress was specifically aware of the agency’s interpretation of a statutory term at the time the statute was enacted, this is compelling evidence of legislative adoption of the agency’s interpretation,” citing Supreme Court precedent to this effect (including United States v. Bd. of Comm’rs of Sheffield, Ala., 435 U.S. 110, 131-35 (1978); Cammarano v. United States, 358 U.S. 498, 510 (1959); and Hartley v. Comm’r, 295 U.S. 216, 220 (1935)). Judge Dyk also rejected the majority’s interpretation of the term “any” in the statute, citing (ironically in view of his Merck v. Integra decision) Justice Scalia’s admonition that, in construing a statute, “[u]ltimately context determines meaning,” citing Johnson v. United States, No. 08-6925, slip op. at 5 (U.S. Mar. 2, 2010). He illustrates this objection with the following hypothetical:

Under the majority’s view, no correction of erroneous Orange Book information is permitted so long as the patent covered any approved method of use covered by the NDA. The patent can be listed in the Orange Book as erroneously covering approved use A, despite the fact that the patent actually covers approved use B, and the counterclaim provision provides no mechanism for correction. This cannot be what Congress intended.

Judge Dyk’s dissent adds more confusion to the history of the change in use code for PRANDIN®; consistent with his view that NDA holders attempt to manipulate FDA rules to maximize the time generic drug manufacturers are kept off the market, in his description of the underlying facts Novo asked the FDA for the change in use codes, and Caraco submitted its “carve-out” labeling proposal at FDA’s behest. According to Judge Dyk:

Here, the patentee did exactly what was expressly forbidden. For the proposed use code description submitted on the FDA Form 3542, Novo submitted the following: “A method for improving glycemic control in adults with type 2 diabetes mellitus.” J.A. 673. It thus utilized that portion of PRANDIN’s label that refers to the use of repaglinide standing alone to treat diabetes (an unpatented use), not to the use of repaglinide together with metformin (a patented use). There is no justification for using a portion of the label referring to an unpatented use to describe a patented use.

The manipulative nature of Novo’s actions is confirmed not only by the lack of justification for the change, but also by the timing of the change (two years after the labeling change was initiated by the FDA and immediately after the FDA approved Caraco’s section viii carve-out), and by its own admission that preventing approval of Caraco’s ANDA was part of the motivation for changing the use code. At oral argument, Novo conceded that the decision to change the use code was in part “a response to the section viii ruling . . . in December ‘08 from FDA.”
“In summary, the majority’s crabbed view of the statute sanctions an unjustified manipulation of the Orange Book,” according to Judge Dyk. Perhaps hoping to provoke Supreme Court review, in the final portion of the dissent, Judge Dyk characterizes as “notably inconsistent” the majority’s view and the views of the D.C. Circuit court regarding what constituted whether the counterclaim is available under these circumstances.
Sackett v. Environmental Protection Agency

10-1062


Chantell and Michael Sackett own approximately one half acre of undeveloped land near Priest Lake in Idaho. In April of 2007, the Sacketts began filling in part of their land in preparation for construction of a dwelling. In November of 2007, the EPA issued a compliance order informing the Sacketts their land is a wet land subject to the Clean Water Act (CWA) and directing them to remove the fill and restore the land to its original condition or face fines. The Sacketts petitioned the EPA for a hearing to contest the determination of their land as a wet land but were denied. The Sacketts then brought an action in federal district court, challenging the compliance order as arbitrary and capricious under the Administrative Procedure Act and alleged violations of their due process rights as the order was issued without a hearing. The district court dismissed the case for lack of subject matter jurisdiction, holding that the CWA precludes judicial review of compliance orders before the EPA has commenced an enforcement action. On appeal, the Ninth Circuit affirmed the lower court, holding that Congress meant to preclude pre-enforcement judicial review of compliance orders in the interest of efficiency; the court also found no deprivation of the Sacketts' due process rights, holding that the CWA requires the EPA to prove alleged violations have actually occurred before assessing fines.

Questions Presented: (1) May petitioners seek pre-enforcement judicial review of the administrative compliance order pursuant to the Administrative Procedure Act, 5 U.S.C. §704? (2) If not, does petitioners' inability to seek pre-enforcement judicial review of the administrative compliance order violate their rights under the Due Process Clause?

Chantell SACKETT; Michael Sackett, Plaintiffs-Appellants, v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY; Steven L. Johnson, Administrator, Defendants-Appellees.

United States Court of Appeals for the Ninth Circuit

Filed September 17, 2010

[Excerpt; some footnotes and citations omitted.]

GOULD, Circuit Judge:

We determine whether federal courts have subject-matter jurisdiction to conduct review of administrative compliance orders issued by the Environmental Protection Agency pursuant to the Clean Water Act, 33 U.S.C. § 1319(a)(3), before the EPA has filed a lawsuit in federal court to enforce the compliance order. We join our sister circuits and hold that the Clean Water Act precludes pre-enforcement judicial review of administrative compliance orders, and that such preclusion does not violate due process.
Chantell and Michael Sackett ("the Sacketts") own a 0.63-acre undeveloped lot in Idaho near Priest Lake ("the Parcel"). In April and May of 2007, the Sacketts filled in about one-half acre of that property with dirt and rock in preparation for building a house.

On November 26, 2007, the EPA issued a compliance order against the Sacketts. The compliance order alleged that the Parcel is a wetland subject to the Clean Water Act ("CWA") and that the Sacketts violated the CWA by filling in their property without first obtaining a permit. The compliance order required the Sacketts to remove the fill material and restore the Parcel to its original condition. The compliance order states that "[v]iolation of, or failure to comply with, the foregoing Order may subject Respondents to (1) civil penalties of up to $32,500 per day of violation . . . [or] (2) administrative penalties of up to $11,000 per day for each violation."

The Sacketts sought a hearing with the EPA to challenge the finding that the Parcel is subject to the CWA. The EPA did not grant the Sacketts a hearing and continued to assert CWA jurisdiction over the Parcel. The Sacketts then filed this action in the United States District Court for the District of Idaho seeking injunctive and declaratory relief. They challenged the compliance order as (1) arbitrary and capricious under the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(2)(A); (2) issued without a hearing in violation of the Sacketts' procedural due process rights; and (3) issued on the basis of an "any information available" standard that is unconstitutionally vague.

The district court granted the EPA's Federal Rule of Civil Procedure 12(b)(1) motion to dismiss the Sacketts' claims for lack of subject-matter jurisdiction. It concluded that the CWA precludes judicial review of compliance orders before the EPA has started an enforcement action in federal court. The Sacketts filed a Federal Rule of Civil Procedure 59(e) motion for clarification and reconsideration that was also denied. The Sacketts appealed. We have jurisdiction pursuant to 28 U.S.C. § 1291.

II

We review de novo the dismissal of a complaint for lack of subject-matter jurisdiction.

The EPA has determined that the Sacketts discharged pollutants into the waters of the United States in violation of the CWA. When the EPA identifies a CWA violation, it has three main civil enforcement options. First, it can assess an administrative penalty. When the EPA assesses an administrative penalty, the alleged violator is entitled to "a reasonable opportunity to be heard and to present evidence," the public is entitled to comment, and any assessed penalty is subject to immediate judicial review. Second, the EPA can initiate a civil enforcement action in federal district court. Third, the EPA can issue, as it did here, an administrative "compliance order."

A compliance order "is a document served on the violator, setting forth the nature of the violation and specifying a time for compliance with the Act." The EPA derives its power to issue compliance orders from 33 U.S.C. § 1319(a)(3), which states:

Whenever on the basis of any information available to him the Administrator finds that any person is in violation of section 1311, 1312, 1316, 1317, 1318, 1328, or 1345 of
this title, . . . he shall issue an order requiring such person to comply with such section or requirement, or he shall bring a civil action in accordance with [33 U.S.C. § 1319(b)].

To enforce a compliance order, the EPA must bring an enforcement action in federal court under 33 U.S.C. § 1319(b). The compliance order issued against the Sacketts exposed them to potential court-imposed civil penalties not to exceed $32,500 “per day for each violation” of the compliance order. In assessing the amount of the penalty, courts “shall consider the seriousness of the violation or violations, the economic benefit (if any) resulting from the violation, any history of such violations, any good-faith efforts to comply with the applicable requirements, the economic impact of the penalty on the violator, and such other matters as justice may require.”

The Sacketts argue that compliance orders are judicially reviewable prior to the EPA filing an enforcement action in federal court. The CWA, however, does not expressly provide for pre-enforcement judicial review of compliance orders. The Sacketts argue that federal courts are nonetheless authorized to conduct pre-enforcement review of compliance orders pursuant to the APA. Under the APA, “[a]gency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review.” Agency action is not reviewable under the APA, however, where the relevant statute “preclude[s] judicial review.”

Whether the CWA precludes pre-enforcement review of compliance orders is an issue of first impression in our circuit. We begin with the presumption favoring judicial review of administrative action.

That presumption is overcome, however, “whenever the congressional intent to preclude judicial review is fairly discernible in the statutory scheme.” “Whether and to what extent a particular statute precludes judicial review is determined not only from its express language, but also from the structure of the statutory scheme, its objectives, its legislative history, and the nature of the administrative action involved.” The CWA does not expressly preclude pre-enforcement judicial review of such compliance orders. So we must consider the other factors identified by the Supreme Court to determine whether the CWA impliedly precludes pre-enforcement judicial review.

In this assessment, we do not work from a blank slate. Every circuit that has confronted this issue has held that the CWA impliedly precludes judicial review of compliance orders until the EPA brings an enforcement action in federal district court. The reasoning of these courts is persuasive to us, as well as the broad uniformity of consensus on this issue.

First, we look to the structure of the statutory scheme and the nature of the administrative action involved. Here, Congress gave the EPA a choice of “issu[ing] an order requiring such person to comply with such section or requirement, or . . . bring[ing] a civil action in [district court].” Authorizing pre-enforcement judicial review of compliance orders would eliminate this choice by enabling those subject to a compliance order to force the EPA to litigate all compliance orders in court. Such a result would be discordant with the statutory scheme.

Moreover, no sanctions can be imposed, or injunctions issued, for noncompliance with a compliance order until the EPA brings a
civility enforcement action in district court. Given that an enforcement action gives an opportunity for judicial consideration of the compliance order, we infer that Congress intended that all challenges to the compliance order be brought in one proceeding.

In addition, by contrast to how it treated compliance orders, Congress set forth an explicit mechanism for judicial review of administrative penalties assessed by the EPA for CWA violations. Congress’s express grant of judicial review for administrative penalties helps to persuade us that the absence of a similar grant of judicial review for compliance orders was an intentional omission that must be respected.

Second, we look to the objectives of the statutory scheme. Here, courts have concluded that compliance orders, like pre-enforcement administrative orders in other environmental statutes, are meant to "allow EPA to act to address environmental problems quickly and without becoming immediately entangled in litigation." This goal of enabling swift corrective action would be defeated by permitting immediate judicial review of compliance orders.

Third, we consider the legislative history of the CWA. The enforcement provisions of the CWA were modeled on enforcement provisions in the Clean Air Act ("CAA"), and many courts have relied on similar provisions in the CAA in concluding that the CWA precludes pre-enforcement judicial review of compliance orders. During the enactment of the CAA, the Conference Committee which reconciled the House and Senate versions of the CAA deleted a provision in the Senate’s version of the bill that would have expressly provided for pre-enforcement review of CAA administrative compliance orders. At least one court has inferred from this deletion that it was intended to preclude pre-enforcement judicial review of compliance orders. Such an inference is not unassailable. Nevertheless, and subject to the general caution with which we must view all legislative history not adopted by both houses and enacted as law, that inference is supported by the structure of the CWA and its statutory language discussed above.

In view of the above considerations, we hold that a congressional intent to preclude pre-enforcement judicial review of compliance orders is "fairly discernible in the statutory scheme."

III

The Sacketts argue that CWA compliance orders must be judicially reviewable before enforcement because preclusion of pre-enforcement review violates their due process rights. They rely on the Eleventh Circuit’s opinion in Tennessee Valley Authority v. Whitman, 336 F.3d 1236 (11th Cir.2003) [hereinafter TVA], in which that court identified constitutional problems with a similar compliance-order provision in the CAA[.] The Eleventh Circuit concluded that the complete preclusion of judicial review of compliance orders issued under the CAA would raise serious constitutional questions where compliance orders, “if ignored, lead[ ] automatically to the imposition of severe civil penalties and perhaps imprisonment.” The chief problem with the CAA, as the Eleventh Circuit saw it, was that a compliance order could be issued by the EPA “on the basis of any information available” without any hearing, and that the CAA made civil and criminal penalties dependent on violations of compliance orders whether or not there was an actual violation of the CAA.
If the CWA is read in the literal manner the Sacketts suggest, it could indeed create a due process problem. Like the CAA, the CWA permits the EPA to issue compliance orders "on the basis of any information available," which presumably includes "a staff report, newspaper clipping, anonymous phone tip, or anything else that would constitute "any information[]." And according to the plain text of the enforcement provision, "any person who violates any order issued by the Administrator under [33 U.S.C. § 1319(a)], shall be subject to a civil penalty . . . for each violation." Thus, the Sacketts' reading of the CWA suggests they risk substantial financial penalties for violating the compliance order, even if they did not violate the CWA, if the EPA establishes in an enforcement proceeding that the compliance order was validly issued based on "any information available."

We decline to interpret the CWA in this manner. The civil penalty provision of the CWA is "not a model of clarity." Although the term "any order" in 33 U.S.C. § 1319(d) could be interpreted to refer to all compliance orders issued on the basis of "any information available," the term could also be interpreted to refer only to those compliance orders that are predicated on actual, not alleged, violations of the CWA, as found by a district court in an enforcement action according to traditional civil evidence rules and standards of proof.

Mindful of the Supreme Court's repeated instruction that "every reasonable construction must be resorted to, in order to save a statute from unconstitutionality," we believe that the latter interpretation is the better interpretation of "any order" in § 1319(d). The EPA is authorized only "to commence a civil action for appropriate relief, including a permanent or temporary injunction, for any violation for which [the EPA] is authorized to issue a compliance order." Read carefully, this provision does not authorize the EPA to bring enforcement actions for mere violations of compliance orders. Rather, to enforce a compliance order, the EPA must bring an action alleging a violation of the CWA itself. Given that the CWA does not empower the EPA to bring an enforcement action on the basis of a violation of a compliance order alone, it follows that a court cannot assess penalties for violations of a compliance order under § 1319(d) unless the EPA also proves, by a preponderance of the evidence, that the defendants actually violated the CWA in the manner alleged. Under this interpretation, if the EPA does not prove that the CWA was actually violated, the compliance order is unenforceable, even if it was validly issued on the basis of "any information available."

We therefore hold that the term "any order" in § 1319(d) refers only to orders predicated on actual violations of the CWA as identified by a district court in an enforcement proceeding according to traditional rules of evidence and standards of proof.

The Sacketts further allege that forcing them to wait until the EPA brings an enforcement action "ignores the realities of [their] circumstances," because of the "frightening penalties" they risk accruing by refusing to comply. The increase in penalties from noncompliance with an administrative order not subject to immediate judicial review, however, does not necessarily constitute a due process violation. Rather, statutory preclusion of pre-enforcement judicial review of administrative orders violates due process only when the "practical effect of coercive penalties for noncompliance [is] to foreclose all access to the courts" so that "compliance is sufficiently onerous and coercive penalties sufficiently potent that a
constitutionally intolerable choice might be presented.”

We are not persuaded that the potential consequences from violating CWA compliance orders are so onerous so as to “foreclose all access to the courts” and create a “constitutionally intolerable choice.” We reach this conclusion for two reasons. First, the CWA has a permitting provision. The Sacketts could seek a permit to fill their property and build a house, the denial of which would be immediately appealable to a district court under the APA. If the Sacketts were denied a permit and then took an appeal, they could challenge whether their property is subject to the jurisdiction of the CWA. Therefore, rather than completely foreclosing the Sacketts’ ability to use their property or challenge CWA jurisdiction, the CWA channels judicial review through the affirmative permitting process.

Second, the civil penalties provision is committed to judicial, not agency, discretion. The amount of the penalty for noncompliance with a CWA compliance order is to be determined by a court and is determined on the basis of six factors: (1) the seriousness of the violation, (2) the economic benefit resulting from the violation, (3) any history of CWA violations, (4) good-faith efforts to comply, (5) the economic impact of the penalty on the violator, and (6) such other matters as justice may require. Any penalty ultimately assessed against the Sacketts would therefore reflect a discretionary, judicially determined penalty, taking into account a wide range of case-specific equitable factors, and imposed only after the Sacketts have had a full and fair opportunity to present their case in a judicial forum.

We therefore hold that precluding pre-enforcement judicial review of CWA compliance orders does not violate due process.

IV

In conclusion, we hold that it is “fairly discernable” from the language and structure of the Clean Water Act that Congress intended to preclude pre-enforcement judicial review of administrative compliance orders issued by the EPA pursuant to 33 U.S.C. § 1319(a)(3). We further interpret the CWA to require that penalties for noncompliance with a compliance order be assessed only after the EPA proves, in district court, and according to traditional rules of evidence and burdens of proof, that the defendants violated the CWA in the manner alleged in the compliance order. Thus we do not see any sharp disconnect between the process given a citizen and the likely penalty that can be imposed under the CWA. Under these circumstances, preclusion of pre-enforcement judicial review does not violate the Sacketts’ due process rights. The district court properly dismissed this case for lack of subject-matter jurisdiction.

AFFIRMED.
The Supreme Court decided today to take up a challenge to U.S. EPA’s authority to issue compliance orders under the Clean Water Act without allowing an immediate hearing on the underlying issue.

At issue are efforts by Chantell and Michael Sackett to build a house on a half-acre parcel near Priest Lake, Idaho.

After they began earth-moving work, the Sacketts were halted by EPA, which said the property fell within the jurisdiction of Section 400 of the Clean Water Act. The landowners were in violation after they placed fill material into wetlands, EPA said.

The order prevented further construction work on the site and required the Sacketts to restore the wetlands.

The Sacketts—backed by the Pacific Legal Foundation (PLF), a conservative Sacramento, Calif.-based group that focuses on property rights—filed suit in the District of Idaho, but a federal judge dismissed their request that they be able to contest the order.

The 9th U.S. Circuit Court of Appeals agreed with the district judge’s conclusion.

The court held that the Sacketts’ due process rights were not violated because those subject to compliance orders have an opportunity to go to court if EPA commences an enforcement action.

The Supreme Court will consider whether the Sacketts’ should be able to contest a compliance order before the enforcement proceedings and, if not, whether that would violate their due process rights.

The Sacketts’ lawyers argue that the use of compliance orders puts their clients and others in an “impossible situation” because they “must either run the risk of ruinous penalties or imprisonment” or essentially buy their right to judicial review by entering the permitting process.

That could cost $200,000, they say.

PLF attorney Damien Schiff said the case raises important property rights and due process questions.

“When government seizes control of your land and you disagree with the justification, shouldn’t you be allowed your day in court?” he said in a statement.

The Obama administration stated in its brief that appeals courts have “uniformly concluded” that the Clean Water Act provisions in question do not violate the due process clause because EPA must file suit in federal court if it wants to enforce compliance.

In some ways, the Sacketts’ claim mirrors one made by General Electric Co. over whether it could challenge EPA administrative orders requiring companies to clean up sites containing hazardous materials. Earlier this month, the Supreme Court declined to take up that case.

The justices will hear arguments in the Sackett case in the 2011 court term, which begins in October.
A federal appeals court has found that the system for judicial review of Clean Water Act (CWA) compliance orders does not constitute a violation of due process, though the plaintiffs in the case are considering options to challenge the ruling, including a possible appeal to the Supreme Court.

The U.S. Court of Appeals for the 9th Circuit ruled Sept. 17 in Sackett v. EPA that the CWA "precludes pre-enforcement judicial review of administrative compliance orders, and that such preclusion does not violate due process," according to the court’s opinion, which notes that it joins other circuit courts in holding that view. The ruling is available on InsideEPA.com.

While the plaintiffs have made no decisions about their next steps, they could consider a rehearing in the 9th Circuit, request review from the Supreme Court, or both, according to a lawyer involved with the case. A petition to the high court could focus on the conflict between the 9th Circuit’s opinion and a high-profile decision in the 11th Circuit on how to interpret compliance order language in the Clean Air Act, which includes enforcement provisions similar to the CWA.

The Pacific Legal Foundation (PLF), a conservative legal organization that is representing the plaintiffs, has previously sought to have the Supreme Court reconsider key environmental law arguments after conservative Chief Justice John Roberts and Justice Samuel Alito were appointed to the high court.

In Sackett, a couple building a house on a plot of land on the shore of Priest Lake, ID, received a compliance order from EPA saying the land contained wetlands covered by the CWA and that the couple violated the act by not obtaining a permit before starting the project. In the order, the agency required the plaintiffs to fully restore the preexisting wetlands before applying to the Army Corps of Engineers for a permit. The plaintiffs requested an administrative hearing with EPA to challenge the agency finding that the land is a wetland covered by the CWA.

When EPA did not grant the hearing, the plaintiffs filed suit in the U.S. District Court for the District of Idaho, arguing that the compliance order was arbitrary and capricious, was issued without a hearing in violation of their due process rights and was issued "on the basis of an 'any information available' standard that is unconstitutionally vague," according to the opinion. The district court granted an EPA motion to dismiss the case for lack of subject matter jurisdiction.

In the appeal, the plaintiffs argued that a 2003 decision by the 11th Circuit in Tennessee Valley Authority (TVA) v. Whitman found constitutional problems with the compliance orders issued under the Clean Air Act. Disagreements between the circuits on how to interpret the compliance order statutes could also form the basis for further appeals.

In TVA, the court ruled that the air act’s enforcement "scheme for administrative
compliance orders was unconstitutional to the extent that severe civil and criminal penalties can be imposed for noncompliance with the terms of an administrative compliance order. The court found that the orders "are legally inconsequential and do not constitute final agency action."

The plaintiffs say this is an issue because an order could be issued "on the basis of any information available"—including an anonymous tip or newspaper article—without an administrative hearing, and civil and criminal penalties, including fines and jail time, under the act depend on violation of the compliance order regardless of whether the Clean Air Act was actually violated. The CWA could have similar implications, the plaintiffs say.

Summarizing the argument, the 9th Circuit says, "the Sacketts' reading of the CWA suggests that they risk substantial financial penalties for violating the compliance order, even if they did not violate the CWA, if the EPA establishes in an enforcement proceeding that the compliance order was validly issued based on 'any information available.'"

But the 9th Circuit reads the CWA more broadly in a way that avoids the constitutional problems raised by the 11th Circuit, and concludes that the due process rights would not be affected. "Although the term 'any order' . . . could be interpreted to refer to all compliance orders issued on the basis of 'any information available,' the term could also be interpreted to refer only to those compliance orders that are predicated on actual, not alleged, violations of the CWA, as found by a district court in an enforcement action according to traditional civil evidence rules and burdens of proof," according to the opinion.
This appeal presents the question, *inter alia*, as to whether the word "sue," as used in the Credit Repair Organization Act ("CROA"), means "arbitrate." Or, perhaps the question is, as Alice put it: "whether you can make words mean so many different things?" We conclude that Congress meant what it said in using the term "sue," and that it did not mean "arbitrate." We affirm the order of the district court denying the Credit Providers' motion to compel arbitration.

CompuCredit marketed a subprime credit card under the brand name Aspire Visa to consumers with low or weak credit scores through massive direct-mail solicitations and the internet. CompuCredit marketed the card and the cards were issued by Columbus Bank and Trust (collectively "Credit Providers").

Greenwood and her fellow plaintiffs ("Consumers") allege CompuCredit
marketed the card by representing to consumers it could be used to “rebuild your credit,” “rebuild poor credit,” and “improve your credit rating.” Consumers allege the promotional materials noted there “was no deposit required,” and that consumers would immediately receive $300 in available credit when they received the card. In fact, they allege, Credit Providers charged a $29 finance charge, a monthly $6.50 account maintenance fee, and a $150 annual fee, assessed immediately against the $300 limit before the consumer received the card. In aggregate, the card had $257 in fees the first year. Although the promotional material mentioned the fees, it did so in small print amidst other information in the advertisement, and not in proximity to its representations that no deposit was required. Consumers each applied for and received an Aspire card, and were charged these fees. Consumers allege the Credit Providers’ actions constitute several violations of the CROA and of California’s Unfair Competition Law.

Before receiving the Aspire Visa credit card, each Consumer received a mailing entitled “Pre-Approved Acceptance Certificate.” The Acceptance Certificate includes the following paragraph:

By signing, I request an Aspire Visa card and ask that an account be opened for me. I certify that everything I have stated in the Acceptance Certificate is true and accurate to the best of my knowledge. I have read and agree to the be bound by the “Summary of Credit Terms” and “Terms of Offer” printed on the enclosed insert, which insert includes a discussion of arbitration applicable to my account, and is incorporated here by reference.

One Consumer mailed in her acceptance, one applied over the internet, and the other applied over the phone.

The “Terms of Offer” states:

Important—The agreement you receive contains a binding arbitration provision. If a dispute is resolved by binding arbitration, you will not have the right to go to court or have the dispute heard by a jury, to engage in pre-arbitration discovery except as permitted under the code of procedure of the National Arbitration Forum (“NAF”), or to participate as part of a class of claimants relating to such dispute. Other rights available to you in court may be unavailable in arbitration.

The “Summary of Credit Terms” contains the following:

ARBITRATION PROVISION
(AGREEMENT TO ARBITRATE CLAIMS)

Any claim, dispute or controversy (whether in contract, tort, or otherwise) at any time arising from or relating to your Account, any transferred balances or this Agreement (collectively, “Claims”), upon the election of you or us, will be resolved by binding arbitration pursuant to this Arbitration Provision and the Code of Procedure (“NAF Rules”) of the National Arbitration Forum (“NAF”) in effect when the Claim is filed. If for any reason the NAF cannot, will not or ceases to serve as arbitration administrator, we will substitute another nationally recognized arbitration organization utilizing a similar code of procedure.
Upon such an election, neither you nor we will have the right to litigate in court the claim being arbitrated, including a jury trial, or to engage in prearbitration discovery except as provided under NAF Rules. In addition, you will not have the right to participate as representative or member of any class of claimants relating to any claim subject to arbitration. Except as set forth below, the arbitrator’s decision will be final and binding. Other rights available to you in court might not be available in arbitration.

The agreement also provides, “This Agreement, and your Account, and any claim, dispute or controversy (whether in contract, tort or otherwise) . . . are governed by and construed in accordance with applicable federal law and the laws of Georgia.”

Consumers brought this action in federal district court, and the Credit Providers moved to compel arbitration of Consumers’ CROA claims. The district court held the arbitration clause in the Credit Providers’ Aspire Visa credit card agreements was invalid and void under the CROA’s prohibition of the waiver of a consumer’s right to sue in court, and denied the motion to compel arbitration. The district court also denied the Credit Providers’ Motion for Leave to File Motion for Reconsideration. The Credit Providers filed a timely interlocutory appeal challenging the denial of the motion to compel arbitration.

We review the denial of a motion to compel arbitration de novo.

II

The district court correctly concluded that the arbitration agreement was void because the CROA specifically prohibits provisions disallowing any waiver of a consumer’s right to sue in court for CROA violations.

A

We employ our usual methodology in statutory construction. As always, our starting point is the plain language of the statute. “[W]e examine not only the specific provision at issue, but also the structure of the statute as a whole, including its object and policy.” If the plain meaning of the statute is unambiguous, that meaning is controlling and we need not examine legislative history as an aid to interpretation unless “the legislative history clearly indicates that Congress meant something other than what it said.” If the statutory language is ambiguous, we consult legislative history.

In this context, we also note that Congress has manifested a “liberal federal policy favoring arbitration agreements.” Specifically, the Federal Arbitration Act declares that “[a] written provision in ... a contract evincing a transaction involving commerce to settle by arbitration a controversy thereafter arising out of such contract or transaction . . . shall be valid, irrevocable, and enforceable, save upon such grounds as exist at law or in equity for the revocation of any contract.”

The Supreme Court has held that “[h]aving made the bargain to arbitrate, the party should be held to it unless Congress itself has evinced an intention to preclude a waiver of judicial remedies for the statutory rights at issue.” “[I]f Congress intended the substantive protection afforded by a given statute to include protection against waiver of the right to a judicial forum, that intention would be deducible from text or legislative history.” More recently, the Supreme Court has reiterated that the Congressional intent
to preclude waiver "will be discoverable in the text of the [statute], its legislative history, or an 'inherent conflict' between arbitration and the [statute's] underlying purposes." The burden is on the party opposing arbitration to show that Congress intended to preclude a waiver of judicial remedies for the statutory rights at issue.

B

With these principles in mind, we turn to the Credit Reporting Organization Act. The CROA expressly identifies four rights, which appear in the disclosures section of the statute, 15 U.S.C. § 1679c. The first two rights concern rights that consumers have in relation to credit bureaus, which are not implicated by this suit. The third and fourth rights specifically concern rights that consumers have in relation to credit repair organizations. The third right directly addresses the Consumers' argument: "You have a right to sue a credit repair organization that violates the Credit Repair Organization Act." In addition, each credit repair organization is required to (1) inform the consumer of his or her right to sue, (2) provide such information to the consumer in a separate document containing a verbatim copy of an eight-paragraph text specified by Congress, which enumerates the "right to sue," (3) obtain from the consumer a signature confirming receipt of such information, and (4) keep such signed confirmations on file for two years from the date of signing. The disclosure document must be provided to every consumer "before any contract or agreement between the consumer and the credit repair organization is executed."

The CROA also contains a non-waiver provision, phrased in unusually comprehensive and precise language: "Any waiver by any consumer of any protection provided by or any right of the consumer under this subchapter (1) shall be treated as void; and (2) may not be enforced by any Federal or State court or any other person."

Thus, the plain language of the CROA provides consumers with the "right to sue." The "right to sue" means what it says. The statute does not provide a right to "some form of dispute resolution," but instead specifies the "right to sue." The act of suing in a court of law is distinctly different from arbitration. The right to sue protected by the CROA cannot be satisfied by replacing it with an opportunity to submit a dispute to arbitration.

Where terms are not defined within a statute, they are accorded their plain and ordinary meaning. The plain and ordinary meaning of terms can be deduced through reference sources, including Black's Law Dictionary and general usage dictionaries.

To sue is "[t]o institute a lawsuit against (another party)." For "lawsuit," Black's directs us to "suit," which is defined as: "[a]ny proceeding by a party or parties against another in a court of law." The plain meaning of the phrase "right to sue" thus clearly involves the right to bring an action in a court of law.

By contrast, "arbitration" is "[a] method of dispute resolution involving one or more neutral third parties who are usu[ally] agreed to by the disputing parties and whose decision is binding." Arbitration is one of several mechanisms of "alternative dispute resolution," which is "[a] procedure for settling a dispute by means other than litigation, such as arbitration or mediation." The Corpus Juris Secundum underscores that "[a]rbitration is not a judicial proceeding either at common law or under statutes. It is a proceeding separate from
litigation based upon its underlying purpose of encouraging dispute resolution *without result to the courts*, and may be characterized as an alternative to litigation.”

As a matter of parlance, reference, and common sense, we cannot conclude that when Congress used the word “sue,” it really meant “arbitrate.” The district court correctly read the statute, and determined that the consumer’s statutory right to sue could not be waived.

III

The Credit Providers raise a number of counter-theories, none of which is persuasive.

A

Credit Providers first argue that, by placing the “right to sue” in the mandatory “Disclosures” section of the statute, thus *requiring* it be explicitly stated to all consumers, does not actually create a right to sue as the terms are ordinarily understood. Under such a reading, Congress, whose purpose in enacting the statute included protecting consumers from misinformation, drafted a statute which requires credit repair organizations to misinform consumers about a fictional right. Under Defendant’s interpretation, Congress was requiring that consumers be told a lie: that they possessed a non-existent right. We should “avoid, if possible, a [statutory] interpretation that would produce ‘an absurd and unjust result which Congress could not have intended.’” We do not believe Congress was playing Humpty Dumpty with the statute, and we decline to accept the Credit Providers’ invitation to go down that particular rabbit hole.

B

The Credit Providers characterize the language stating “you have the right to sue” in Section 1679c as merely a simplified shorthand for the more “complicated” right to bring a claim under Section 1679g. This is actually a two-step argument. First, Credit Providers argue the “right to sue” language should not be examined independently because it is merely a “simplified” restatement for consumers of the “substantive” rights embodied in the rest of the statute, particularly Section 1679g, which sets out the punishments available for violations of the Act. Second, Credit Providers argue the more general language of Section 1679g does not preclude arbitration.

We disagree. We must, if possible, interpret a statute such that all its language is given effect, and none of it is rendered superfluous. Under Credit Providers’ interpretation, the “right to sue” language, indeed, the entire “Disclosures” section, becomes superfluous and insignificant, merely a restatement of other sections of the statute that expand upon the rights set out in Section 1679c. We decline to adopt such a reading.

In addition, Credit Providers argue the language “right to sue” was used in the Section because it is more “understandable” to the average consumer than a broader phrase such as the “right to bring a claim.” This is despite the fact that, according to Credit Providers, Congress meant to give consumers that latter right, rather than the former. If the purpose of the “Disclosures” was to communicate to consumers their right to sue or to proceed using some form of alternative dispute resolution, the phrase
"right to sue" is a phrase particularly likely to cause confusion, and lead consumers to misunderstand their rights under the CROA. We see no reason to interpret the language in a way that goes against the purpose even Credit Providers have ascribed to it. The language actually chosen by Congress should be given effect because it is plain and clear on its face, and we “presume that [the] legislature says in a statute what it means and means in a statute what it says there.”

The extremely broad anti-waiver provision in the CROA protects the enumerated “right to sue,” by treating as void “[a]ny waiver by any consumer of any protection provided by or any right of the consumer under this subchapter . . . .” The Act further provides that “[a]ny attempt by any person to obtain a waiver from any consumer of any protection provided by or any right of the consumer under this subchapter shall be treated as a violation of this subchapter.” The plain language of the statute demonstrates that the waiver provision applies to the previously enumerated “right to sue.” First, the use of the word “any” to describe which rights are covered is “expansive language [that] offers no indication whatever that Congress intended” to limit a statute’s reach. Thus, we read the term “any right of the consumer” to apply to all the rights in the statute, including the “right to sue.” Second, Congress’s consistent use of the word “right” indicates the waiver prohibition applies to the “right to sue,” as identical words in a statute should be given a consistent and identical meaning throughout the statute. Therefore, we conclude that Congress meant what it said. Accordingly, the non-waiver provision invalidates any waiver of the right to sue.

We are also not convinced by Credit Providers’ argument regarding the language in 15 U.S.C. § 1679f(a). The section states a consumer waiver of any right or protection “may not be enforced by any Federal or State court or any other person.” Credit Providers argue the “any other person” language demonstrates Congress intended arbitrators to be able to decide CROA claims. First, we do not think this language leads to such a clear and unilateral conclusion. For example, it is foreseeable that a credit repair organization would institute arbitration proceedings against a consumer for collection of the organization’s fees under its contract with the consumer. The CROA creates various non-waivable consumer rights and protections other than the right to sue. In an arbitration collection proceeding, one of the other non-waivable consumer rights or protections could arise. The “any other person” language of Section 1679f(a) assures that these rights and protections would be preserved in an arbitration instituted by a credit repair organization or debt collection agency. It is consistent with a consumer’s explicitly stated non-waivable right to sue. Given the plain language creating such a right, we do not find this language requires a different conclusion.

In addition, the statutory language underscores the central role of courts in enforcement of the statute in § 1679g. This section, which sets out available damages for violations of the CROA, repeatedly refers only to “courts” as the enforcement mechanism. For example, punitive damages may be assessed in “such additional amount as the court may allow” and lays out factors that “the court shall consider.” Thus, the language in the remainder of the statute supports the plain reading of the text creating the right to sue, rather than requiring a different outcome.

We agree with other courts that the “CROA’s non-waiver of rights provisions,
combined with its proclamation of a consumer's right to sue, represent precisely the expression of congressional intent required by the Supreme Court to find that a waiver of judicial remedies is precluded. "Congress did not intend to void all waivers of rights under the Act, and require consumers to sign a congressionally mandated enumeration of their rights under the Act, only to permit those very same rights to waived mere moments later upon the signing an agreement such as the one in question here." We agree with the district court that "[i]f we recognize that CROA voids all waivers of 'any right of the consumer' and mandates that any waiver of the right to sue is void strikes the court as embracing an unhealthy regard for the federal policy favoring arbitration." Thus, we hold the plain language of the CROA prohibits enforcement of the arbitration agreement.

IV

We realize this decision is in conflict with that of two of our sister circuits, but we are unpersuaded by the reasoning of those cases. See Gay v. CreditInform, 511 F.3d 369 (3d Cir.2007); Picard v. Credit Solutions, Inc., 564 F.3d 1249 (11th Cir.2009). Both Gay and Picard give surprisingly little regard to the "right to sue" language in the statute, and rely upon reasoning in Supreme Court cases that are distinguishable from the situation here. As Picard essentially follows and adopts the reasoning in Gay, we will not deal with the two cases separately.

Gay dispatches with the explicit language creating a consumer's "right to sue" in a mere footnote. The court states that since the section does not specify the forum for resolution of the dispute, it does not support the argument that it provides a "judicial, rather than an arbitral, forum for CROA violations." As discussed in more detail above, this ignores the plain meaning of the word "sue." The Third Circuit continues that even if "sue" implies the availability of a judicial forum (which we believe it does), use of the word "would not mean that the organization could not assert defenses that it had to such an action including the right to invoke a contractual arbitration provision to change the forum." This ignores completely the anti-waiver clause of the statute. The anti-waiver clause explicitly states that any waiver of any right by the consumer "shall be treated as void" and "may not be enforced by any Federal or State court...." Thus, the organization might assert the defense of the contractual arbitration provision, but the Court is explicitly forbidden from enforcing this waiver of the right to sue.

Gay also relies upon analogies to several Supreme Court arbitration cases that we find unavailing. The Third Circuit first analogized the issue to the one the Supreme Court considered in Shearson/Am. Express, Inc. v. McMahon, 482 U.S. 220, 107 S.Ct. 2332, 96 L.Ed.2d 185 (1987), when it determined whether Section 29(a) of the Exchange Act prohibited arbitration agreements. Section 27 of the Act provides, "The district courts of the United States ... shall have exclusive jurisdiction of violations of this chapter or the rules and regulations thereunder, and of all suits in equity and actions at law brought to enforce any liability or duty created by this chapter or the rules and regulations thereunder." Section 29(a) of the Act declares void "[a]ny condition, stipulation, or provision binding any person to waive compliance with any provision of the Act." The plaintiffs in McMahon argued that Section 29(a) prohibited waiver of the Section 27 right to bring suit in a federal district court.

As pointed out by the court in McMahon,
the Exchange Act's anti-waiver provision, § 29(a),

forbids [ ] enforcement of agreements to waive "compliance" with the provisions of the statute. But § 27 itself does not impose any duty with which persons trading in securities must "comply." By its terms, § 29(a) only prohibits waiver of the substantive obligations imposed by the Exchange Act. Because § 27 does not impose any statutory duties, its waiver does not constitute a waiver of "compliance with any provision" of the Exchange Act under § 29(a).

McMahon, 482 U.S. at 228, 107 S.Ct. 2332. In summary, because the Exchange Act only prohibits waivers of compliance with its substantive obligations and the mandate of a judicial forum is not a substantive obligation, the Exchange Act does not preclude arbitration agreements.

Applying McMahon, the Third Circuit observed that "the section [of the CROA] in which this anti-waiver provision appears is entitled 'Noncompliance with this subchapter.'" The Third Circuit reasoned that the CROA's anti-waiver provision only "extend[s] to rights premised on the imposition of statutory duties." Because the right to sue in a judicial forum is not a statutory duty under the CROA, the court concluded that the anti-waiver provision did not apply to it. However, the plain text of 15 U.S.C. § 1679f encompasses waivers of "any protection" or "any right" under the CROA-categories which are much broader than mere noncompliance. "[H]eadings and titles are not meant to take the place of the detailed provisions of the text," and where the plain text of the statute is unambiguous, "the heading of a section cannot limit the plain meaning of the text." Here, because the text of § 1679f(a) is not ambiguous, we need not turn to the title of the section to clarify its meaning. Further, the substantive-procedural distinction has no application to the CROA. Unlike the Exchange Act, the CROA grants consumers the "right to sue." Vesting jurisdiction to hear a claim in a particular court is quantitatively different from a statute that expressly provides for a right to sue. Thus, § 1679f's prohibition on waivers may not be limited to "compliance" with the CROA, and McMahon does not apply.

We are also not persuaded that the other Supreme Court cases regarding the availability of arbitration require allowing arbitration in this case. For instance, in Mitsubishi Motors Corp. v. Soler Chrysler-Plymouth, Inc., 473 U.S. 614, 105 S.Ct. 3346, 87 L.Ed.2d 444 (1985), the Supreme Court considered whether the language in 15 U.S.C. § 15(a) rendered antitrust claims non-arbitrable in the context of an international commercial dispute. In relevant part, § 15(a) provides that "any person who shall be injured in his business or property by reason of anything forbidden in antitrust laws may sue therefor in any district court of the United States." The Court held that this section did not evidence a congressional intent to preclude Sherman Act claims from being arbitrable, emphasizing that the Federal Arbitration Act and the Convention on the Recognition of Enforcement of Foreign Arbitral Awards favor arbitration for disputes in international commerce. The Court concluded that it was important "to subordinate domestic notions of arbitrability to the international policy favoring commercial arbitration." The present case differs in that it does not contain an international component. More importantly, the CROA contains express language which precludes waiving "any right of the

451
consumer." A plain reading of the statute dictates that one of those rights is the "right to sue a credit repair organization that violates" the CROA. The Sherman Act does not contain similar non-waiver language, and thus does not apply to this situation.

In *Gilmer v. Interstate/Johnson Lane Corp.*, 500 U.S. 20, 29, 111 S.Ct. 1647, 114 L.Ed.2d 26 (1991), the Supreme Court considered whether an arbitration agreement in a securities registration application could be avoided on the theory that arbitration "deprives claimants of the judicial forum provided for by the [Age Discrimination in Employment Act (ADEA)]." The ADEA contains the following non-waiver provision: "any individual may not waive any right or claim under this Act unless the waiver is knowing and voluntary." However, the ADEA does not explicitly provide for a "right to sue." Rather, the ADEA takes a "flexible approach to resolution of claims. The EEOC for example, is directed to pursue 'informal methods of conciliation, conference, and persuasion,' which suggests that an out-of-court dispute resolution, such as arbitration, is consistent with the statutory scheme established by Congress."

Contrary to the ADEA, the CROA specifically grants access to a judicial forum and a right to sue, and reveals no such "flexibility" toward alternative methods of dispute resolution. Moreover, in contrast to language in the ADEA that permits "knowing and voluntary" waiver of statutory rights, the CROA proscribes any "waiver by any consumer of any protection provided by or any right of the consumer under this title" irrespective of a consumer's knowledge or intent. Thus, *Gilmer* is also inapplicable here.

Finally, in *Green Tree Fin. Corp.-Ala. v. Randolph*, 531 U.S. 79, 80, 121 S.Ct. 513, 148 L.Ed.2d 373 (2000), the Supreme Court considered whether claims under the Truth in Lending Act (TILA) were arbitrable. The party challenging arbitration did not "contend that the TILA evinces an intention to preclude a waiver of judicial remedies." Instead, plaintiffs challenged arbitration because the costs and fees would be prohibitive. The Court, finding no showing regarding prohibitive costs was made, rejected the argument. Here, arbitration is challenged on the ground that the CROA evinces an intention to preclude a waiver of judicial remedies. *Green Tree* simply does not apply.

V

The CROA gives consumers the "right to sue," and prevents any waiver of "any right" under the statute. We find this sufficient to demonstrate Congress intended that consumers cannot waive their right to sue under the CROA, and instead submit to arbitration. Therefore, we affirm the district court's holding that the forced arbitration clause is void and the court's denial of the motion to compel arbitration of the CROA claims.

AFFIRMED.

TASHIMA, Circuit Judge, dissenting:

Because I disagree with the majority's conclusion that Congress intended to preclude a waiver of a judicial forum for claims under the Credit Repair Organizations Act ("CROA"), I respectfully dissent.

As the majority acknowledges, Congress has manifested "a liberal federal policy favoring arbitration agreements." Under the Federal Arbitration Act, courts should enforce
arbitration agreements involving statutory claims ""unless Congress itself has evinced an intention to preclude a waiver of judicial remedies for the statutory rights at issue."" Congress’ intent to preclude a waiver of judicial remedies must be shown by the statute’s text, its legislative history, or an inherent conflict between arbitration and the statute’s underlying purpose. Plaintiffs bear the burden of showing that Congress intended to preclude a waiver of a judicial forum for CROA claims.

The majority concludes that the plain language of 15 U.S.C. § 1679c(a) provides consumers with the “right to sue,” that the right to sue implies a judicial forum, and that 15 U.S.C. § 1679f prohibits any waiver of this right. (Maj. Op. at 1208.) I submit, however, that the plain language of § 1679c(a) does not confer this right upon consumers, and neither the CROA nor its legislative history shows that Congress intended to preclude a waiver of judicial remedies.

All that § 1679c(a) requires is that a credit repair organization provide consumers with the following written disclosure:

You have a right to dispute inaccurate information in your credit report....

You have a right to obtain a copy of your credit report....

You have a right to sue a credit repair organization that violates the Credit Repair Organization Act. This law prohibits deceptive practices by credit repair organizations.

You have the right to cancel your contract with any credit repair organization for any reason within 3 business days from the date you signed it....


This section does not purport to create any substantive rights, including the right to sue. Rather, its sole purpose is to set forth a disclosure statement to be communicated verbatim to consumers.

Each of the rights referred to in § 1679c(a) is separately conferred within Chapter 41 of Title 15, thus indicating that Congress included § 1679c(a) to advise consumers of relevant rights provided for elsewhere in the CROA. See Rex v. CSA-Credit Solutions of America, Inc., 507 F.Supp.2d 788, 798-99 (W.D.Mich.2007) (“The inclusion of separate sections actually providing the substantive rights indicates that the language in the disclosures in § 1679c does not create any rights. Rather, the language in § 1679c only sets forth the phrasing that is to be used in advising consumers of their rights under other sections of Chapter 41 of Title 15.”).

For example, 15 U.S.C. § 1681i provides a consumer with the right to dispute inaccurate information in his credit report, 15 U.S.C. § 1681j provides a consumer with the right to obtain a copy of his credit report, and 15 U.S.C. § 1679g(a) provides a consumer with the right to cancel a contract with a credit repair organization within three business days.

The “right to sue” listed in § 1679c(a) is provided for in 15 U.S.C. § 1679g, which establishes civil liability for violations of the CROA. Because § 1679g provides for civil liability, a consumer ordinarily has the “right to sue” a credit repair organization which violates the CROA. Nowhere in the CROA, however, does Congress mandate a judicial forum for enforcement of the CROA’s substantive provisions. The
disclosure language in § 1679c(a), while recognizing a right to sue, does not itself confer that right. Because § 1679c(a) does not establish any rights, but only requires credit repair organizations to make a written disclosure to consumers, the disclosure statement’s mention of a “right to sue” cannot be the basis of a non-waivable right under 15 U.S.C. § 1679f.

In addition, 15 U.S.C. § 1679f indicates that Congress intended that CROA claims to be enforceable outside a judicial forum. It provides that “[a]ny waiver . . . of any protection . . . or any right . . . under this subchapter . . . may not be enforced by any Federal or State court or any other person.” By including “or any other person” in the same sentence that lists Federal and State courts as appropriate for CROA claims, Congress clearly indicated that arbitrators, mediators, and other third parties may decide CROA claims. This language indicates that Congress contemplated a role for arbitrators in enforcing CROA claims. On the other hand, the majority’s suggestion that the references to “the court” in § 1679g support a right to sue in court, does not overcome the “liberal federal policy favoring arbitration agreements.” Such language merely indicates Congress’ expectation that the question of civil liability will normally be resolved in a judicial forum. It does not confer a non-waivable right to a judicial forum.

Finally, the mere mention of a “right to sue” does not necessarily mean the right to sue in court, especially given the lack of other statutory language supporting this interpretation. The only other circuits to have ruled on this issue are in agreement. See Picard v. Credit Solutions, Inc., 564 F.3d 1249, 1255 (11th Cir.2009) (“Although CROA requires credit repair organizations to inform consumers of their right to a private cause of action, such does not preclude arbitration under CROA”); Gay, 511 F.3d at 377 n. 4 (“[15 U.S.C. § 1679c(a) ] does not specify the forum for the resolution of the dispute and therefore does not support [the] argument that the CROA provides a consumer with the right to bring suit in a judicial, rather than an arbitral, forum for CROA violations.”). We should not lightly create a circuit split on an issue of national application on the basis of the flimsy evidence on which the majority relies. We should be “hesitant to create such a split, and we should do so only after the most painstaking inquiry” and only if required by the “unambiguously expressed intent of Congress.”

The majority does not even address whether the legislative history of the CROA or any inherent conflict between arbitration and the statute’s underlying purpose may form a basis for prohibiting waiver of the judicial forum. Nothing cited by Plaintiffs suggests that Congress actually considered the issue of arbitrability of CROA claims, and the legislative history does not establish that Congress intended CROA claims to be non-arbitrable. In addition, there is no inherent conflict between arbitration and CROA’s underlying purpose because Plaintiffs may enforce their rights under the substantive provisions of CROA even if compelled to arbitrate.

Because neither the plain text of the statute, its legislative history, nor any inherent conflict between the purpose of CROA and arbitration shows that Congress intended to preclude a waiver of judicial remedies, I would reverse the district court’s order and remand with instructions to compel arbitration.
In the wake of the Great Recession, America has a good many consumers who would like—and may need—to have credit cards, but they are higher risk, or “sub-prime” borrowers. There has been, for some years, a financial industry to serve them: the community of “credit repair organizations” willing to give those consumers a second chance. Congress took steps, back in 1996, to make sure such consumers were not duped, adding the Credit Repair Organizations Act as a title in the Consumer Credit Protection Act. On Monday, the Supreme Court agreed to spell out what legal remedies that law provides: a right to sue, or only a right to go to arbitration? The appeals courts are split on the issue.

The Court granted review of *CompuCredit Corp., et al., v. Greenwood, et al.* (10-948), a challenge to a Ninth Circuit Court ruling that the 1996 law guarantees a right to sue, and will not allow the consumer to waive that right even though obliged, by a credit card agreement, to take any dispute to arbitration. The case will be heard and decided in the Court’s next Term, starting Oct. 3.

As a general matter, consumer advocates would rather have the chance to sue, instead of going to arbitration, on the theory that they can do better in court—especially since the Supreme Court has been in the process of discouraging group arbitration by a number of consumers with the same commercial complaint. Businesses, though, prefer arbitration, because they fear risks of being taken before a jury in a position to award sympathetic damages, and that risk may force them to settle. Arbitration, too, is a less expensive process than a court case.

Both sides thus have a keen interest in the new case, the latest in a series of disputes the Court has taken on in the past several terms to clarify the role of arbitration in consumer disputes.

The case involves a “sub-prime credit card” that CompuCredit Corp. marketed under the brand name, “Aspire Visa.” It promoted the card, especially to high-risk, poor-credit consumers, through mass mailings and Internet advertising. One of the issuers of the card was a Georgia bank, Columbus Bank and Trust (recently taken over and now a part of Synovus Bank, a Florida-based regional banking firm).

Wanda Greenwood and several other consumers obtained the cards from the bank. They later would say they were attracted because no deposit was required and there was a promise that they would immediately have $300 in credit available to them. Later, after they were signed up, they discovered that a total of $257 in first-year fees were being charged. Although those fees are spelled out in the fine print, the consumers contended that they did not get proper notice of those fees. The card agreements they entered in order to get the cards required them to arbitrate any disputes.

Their lawsuit, including some Californians, was filed as a class-action case in a federal court in San Francisco, relying on the 1996 federal law and on California state law (as to the Californians in the class; the California-
related issues are no longer involved in the case). The lawsuit contended that the card agreement deceived them about the fees that would be charged in the first year.

Under the federal law, credit repair organizations are required to make a number of disclosures to their potential customers, including a statement that “you have a right to sue.” That is a part of a civil liability section of the law, that specifies that any person who fails to obey the law is liable for damages. Another provision says that “any waiver by any consumer of any protection provided by or any right of the consumer . . . shall be treated as void.”

CompuCredit and the bank asked the District Court to compel arbitration of the dispute over the entry fees, citing the binding arbitration clause in the card agreements. The judge refused, ruling that claims under the Credit Reporting Organizations Act were not subject to arbitration. The Ninth Circuit Court agreed, declaring: “We conclude that Congress meant what it said in using the term ‘sue,’ and that it did not mean ‘arbitrate.’” Noting that other Circuit Courts had ruled the arbitration agreement had to be enforced, the Ninth Circuit panel said it disagreed.

CompuCredit and Synovus Bank, in their petition to the Supreme Court, relied heavily upon the fact that the Circuit Courts are split on the issue. They contended that the Ninth Circuit’s decision conflicts with Congress’s preference for arbitration of commercial disputes, under the Federal Arbitration Act.
Our most recent post, on 11/12/10, analyzed the First Circuit’s efforts to uphold private parties’ freedom to contract with each other concerning the forum and law to govern their international dispute. By way of contrast, a recent decision by the Ninth Circuit Court of Appeals, Greenwood, et al. v. CompuCredit Corp, et al., No. 09-15906 (9th Cir. 8/17/10), also addressed the freedom of contract issue. Here, however, the Court of Appeals found that Congress had precluded the right of private parties to agree to arbitrate their disputes rather than having to litigate them in court. The decision creates a conflict with two other Courts of Appeals and is important in the context of international litigation, where parties frequently believe they have the right to determine for themselves whether to contract to arbitrate or initiate litigation in court to resolve any disputes.

CompuCredit involved claims by consumers under the Credit Repair Organization Act (CROA), in particular the rights granted to consumers in the disclosure section of the CROA, 15 U.S.C. 1679c. One of the rights provided: “You have the right to sue a credit repair organization that violates the” CROA (emphasis supplied).

In the agreements that CompuCredit made with consumers, there was an explicit right, and obligation, to arbitrate. The District Court held that the obligation to arbitrate was invalid and denied a motion to compel arbitration. An immediate, interlocutory appeal was proper.

In affirming, the Court of Appeals recognized the strong and “liberal federal policy favoring arbitration agreements” (quoting Gilmer v. Interstate/Johnson Lane Corp., 500 U.S. 20 (1991)). Nonetheless, the Circuit determined that there was no reasonable way the phrase “right to sue” could include arbitration. Said the Court of Appeals: “The plain language of the CROA provides consumers with the ‘right to sue,’ 15 U.S.C. § 1679c. The ‘right to sue’ means what it says. The statute does not provide a right to ‘some form of dispute resolution’, but instead specifies the ‘right to sue’. The act of suing in a court of law is distinctly different from arbitration.”

The Court of Appeals acknowledged that its decision was in conflict with the holdings of two other Circuit Court decisions (from the Third and Eleventh Circuits). And, of the three member panel deciding this appeal, one, Circuit Judge Tashima, dissented, believing that the language Congress used, “right to sue”, did not preclude a waiver of a judicial forum for the resolution of disputes. With the panel itself unable to agree, one might ask if the conclusion of the majority was so clear as to preclude any other interpretation, and if an alternative interpretation was reasonable, whether the strong policy in favor both of freedom of contract and in particular of resolving disputes by arbitration might not have permitted a different outcome.
Congress passed the Credit Repair Organizations Act (CROA) to assist consumers in making informed decisions and to protect consumers from unfair or deceptive practices when dealing with companies that purport to help rebuild credit. The CROA augments the Consumer Credit Protection Act with additional nonwaivable consumer protections, including a mandatory precontractual disclosure of consumers’ rights when contracting with a credit repair organization. Recently, in *Greenwood v. CompuCredit Corp.*, the Ninth Circuit denied a request to compel arbitration based on a predispute arbitration agreement, holding that the CROA’s mandatory disclosure term “right to sue” creates a substantive, nonwaivable right that precludes arbitration. While the decision marks an additional step toward limiting the federal policy favoring arbitration for claims involving consumer rights, the Ninth Circuit limited arbitration by adopting a narrow definition of “sue” that the Supreme Court has rejected. As a result of this definition, the Ninth Circuit effectively created a mandatory rule that goes beyond what advocates of consumer protection support by banning arbitration of CROA claims.

The CROA requires that credit repair organizations—businesses that offer to “improv[e] any consumer’s credit record”—provide consumers with a specific written disclosure statement. The third paragraph of this mandatory disclosure statement tells the consumer, “You have a right to sue a credit repair organization.” In addition, the CROA creates civil liability for “[a]ny person who fails to comply with any provision of this subchapter.” Moreover, a waiver of “any protection provided by or any right of the consumer under this subchapter . . . may not be enforced by any Federal or State court or any other person.”

CompuCredit marketed a subprime credit card called the Aspire Visa, issued by Columbus Bank and Trust, to consumers with “low or weak credit scores,” claiming the card “could be used to rebuild your credit, rebuild poor credit, and improve your credit rating.” Despite the assertion made in CompuCredit’s advertisements that the credit card offered an immediate $300 line of credit with “no deposit required,” CompuCredit charged consumers $257 in fees during the first year against their line of credit, including “a $29 finance charge, a monthly $6.50 account maintenance fee, and a $150 annual fee.” Before receiving the credit card, each consumer received and agreed to the “Terms of Offer” and “Summary of Credit Terms” under the “Pre-Approved Acceptance Certificate,” which included a “binding arbitration provision” requiring “[a]ny claim, dispute or controversy . . . [to] be resolved by binding arbitration.”

Wanda Greenwood and her fellow plaintiffs, each of whom had opened an Aspire Visa card, brought suit in the Northern District of California against CompuCredit and Columbus Bank and Trust, alleging violations of the CROA. The defendants moved to compel arbitration based on the Pre-Approved Acceptance Certificate. The district court denied the motion to compel arbitration. While the Federal Arbitration Act (FAA) requires a district court to
compel arbitration when “1) there exists a valid agreement to arbitrate; and 2) the dispute falls within its terms,” Judge Wilken found the arbitration agreement at issue void because the text of the CROA created a “right to sue” that cannot be waived. Noting the “federal policy favoring arbitration,” Judge Wilken distinguished the ‘right to sue’ and non-waiver language used in CROA [as] different in important respects from other statutory language at issue in the relevant Supreme Court precedents. While the statutes at issue in those cases contain jurisdictional provisions granting access to federal courts, the CROA establishes the “right to sue,” which precludes arbitration, in a section of the statute that imposes a substantive duty of disclosure.

The Ninth Circuit affirmed. Writing for the panel, Judge Thomas held that the plain language of the CROA created a right to sue in a judicial forum that could not be waived. Stating that the policy favoring arbitration can only be overcome by “[c]ongressional intent to preclude waiver” found in the statute’s text, legislative history, or “inherent conflict between arbitration and the [statute’s] underlying purposes,” Judge Thomas read the mandatory disclosure section of the CROA as creating an unambiguous “right to sue” in a court that the broad antiwaiver provision plainly covers by protecting “any right of the consumer.” Judge Thomas determined that the “right to sue . . . cannot be satisfied by replacing it with an opportunity to submit a dispute to arbitration” because the “plain and ordinary meaning” of “sue” does not include arbitration. Using legal dictionaries, Judge Thomas argued that the plain meaning of “sue” involves litigation “in a court of law” whereas the plain meaning of “arbitration” constitutes “dispute resolution without result to the courts.”

The Ninth Circuit also dismissed the alternative interpretation of the CROA adopted by the Third and Eleventh Circuits, distinguishing the Supreme Court precedents relied upon by those courts. First, Judge Thomas rejected the argument that the mandatory disclosure section does not create a substantive right to sue in court as well as the argument that the “right to sue” actually refers to the broader right to bring a claim established in § 1679g. Reading the statute with Congress’s purpose of “protecting consumers from misinformation” in mind, Judge Thomas reasoned that the defendants’ interpretations of the “right to sue” would either nonsensically “misinform consumers about a fictional right” or render “the entire ‘Disclosures’ section . . . superfluous.” Judge Thomas then held that the “any other person” language in § 1679f(a)—the CROA’s antiwaiver provision—does not evince a congressional intent to allow arbitration of CROA claims because a consumer can raise CROA counterclaims in an arbitration proceeding initiated by a credit repair organization, and the arbitrator, or “person,” in that proceeding cannot enforce a waiver of the consumer’s CROA protections. Recognizing that the court’s reading of the CROA “is in conflict with that of two . . . sister circuits,” both of which allowed arbitration of CROA claims, Judge Thomas highlighted the fact that the other circuits “g[a]ve surprisingly little regard to the ‘right to sue’ language” in the mandatory disclosure section and consequently to the difference between that language, which creates a substantive right, and the jurisdictional provisions of other statutes that the Supreme Court found could be waived.

Judge Tashima dissented. Although he disagreed with the majority’s interpretation of the text of CROA and lamented the creation of a circuit split, his dissent used
the same inquiry as the majority. Beginning with the text of the CROA, Judge Tashima argued that the mandatory disclosure section does not “create any substantive rights, including the right to sue,” a reading supported by the fact that other sections of Title 15 separately confer the rights mentioned in the mandatory disclosure statement. Since the civil liability section does not “mandate a judicial forum,” the “right to sue” does not mean the right to sue in court. Judge Tashima found further support for his reading of the CROA in the “any other person” language of the waiver provision, which “clearly indicate[s] that arbitrators . . . may decide CROA claims,” and in the Third and Eleventh Circuit decisions. After dismissing the majority’s argument that the text unambiguously demonstrates a ban on arbitration, Judge Tashima then noted the lack of legislative history and argued that “there is no inherent conflict between arbitration and CROA’s underlying purpose.”

The Ninth Circuit made three necessary determinations in order to find a ban on arbitration in the CROA. First, “the plain and ordinary meaning” of “sue” precludes arbitration. Second, Congress created a substantive “right to sue” in the mandatory disclosure section of the CROA that is distinct from the procedural civil liability provision. Finally, the antiwaiver provision of the CROA covers the substantive “right to sue.” Whether the CROA precludes or allows consumer-initiated arbitration therefore depends primarily on the decision to define “sue” either narrowly or broadly. While the Ninth Circuit supported its narrow definition of “sue” with “parlance, reference, and common sense,” the definition fails to adopt the Supreme Court’s view that arbitration is simply another forum for adjudication. As a result of the dichotomy created between “sue” and “arbitrate,” the Ninth Circuit effectively created a mandatory rule banning arbitration of CROA claims in proceedings initiated by consumers. By removing consumers’ ability to commit to binding arbitration, the court contravened consumer protection’s purpose and the CROA’s purpose of aiding consumer choice.

In defining “sue” narrowly, the Ninth Circuit failed to follow Supreme Court precedent interpreting similar language in other statutes. Since the CROA and its legislative history do not mention arbitration, the Ninth Circuit relied exclusively on the plain meaning of the word “sue” found in legal reference texts to distinguish “sue” from “arbitrate.” While “sue” could be defined broadly as bringing a claim in any forum, the Ninth Circuit defined “the right to sue” narrowly as “[t]he act of suing in a court of law [which] is distinctly different from arbitration” and “cannot be satisfied by . . . arbitration.” The Ninth Circuit’s definition therefore conflicts with the Supreme Court’s view of an arbitration agreement as “a specialized kind of forum-selection clause.” The Court in Rodriguez de Quijas v. Shearson/American Express, Inc. implicitly accepted that “arbitration is merely a form of trial to be used in lieu of a trial at law.” The Ninth Circuit previously recognized this definition, interpreting the ability to “bring suit . . . in any district court” granted by the Federal Communications Act as lacking the “strong showing of congressional intent” necessary to “bar[] the arbitral forum” even though it bars state and tribal forums.

The Ninth Circuit attempted to distinguish the Supreme Court precedents upholding arbitration of statutory claims. The court’s discussion of Shearson/American Express, Inc. v. McMahon and Rodriguez de Quijas, the two Supreme Court cases addressing the issues closest to those in Greenwood, focused on the application of antiwaiver.
provisions to substantive rights, such as the CROA's "right to sue," but not to procedural, jurisdictional provisions. However, even if the CROA creates a substantive "right to sue," that right bars arbitration only if the court rejects the equivalence of arbitration and adjudication in court, adopting the "judicial hostility" and "outmoded presumption of disfavoring arbitration proceedings" Congress sought to eliminate with the FAA. The Ninth Circuit also ignored the Supreme Court's lengthy discussions in McMahon and Rodriguez de Quijas equating arbitration with judicial suit. The court missed the critical preliminary step of defining "sue" correctly and, as a result, relied on an outmoded distinction between "sue" and "arbitrate" to find the CROA bars arbitration.

While the Ninth Circuit's holding addressed only predispute arbitration agreements, the decision effectively creates a mandatory rule against arbitration of CROA claims in any proceeding initiated by a consumer. By holding that "Congress intended that consumers cannot waive their right to sue under the CROA, and instead submit to arbitration," the Ninth Circuit left open the possibility that the statute similarly precludes postdispute arbitration agreements. Postdispute, a consumer can ordinarily choose to enter into an arbitration agreement to resolve CROA claims; however, submitting to arbitration requires an agreement to be bound by the result of the arbitration. Since Greenwood held that a consumer cannot waive his or her CROA right to sue in a court, a consumer can void a postdispute arbitration agreement by asserting this CROA "right to sue." Consumers therefore cannot meaningfully submit to arbitration, whereas credit repair organizations can continue to enforce arbitration agreements in proceedings they initiate.

The mandatory rule against arbitration effectively created by the narrow definition of "sue" contravenes the purpose of the CROA and goes further than consumer protection advocates and legislation support. The CROA aims to aid consumer contracting by "ensur[ing] that prospective buyers ... are provided with the information necessary to make an informed decision." While consumers have little power to choose arbitration in the context of predispute arbitration agreements, they have a better bargaining position postdispute when deciding whether to submit to arbitration. Proponents of consumer protection legislation support banning predispute arbitration agreements in consumer contracts because the forced arbitration clause harms the consumer's ability to contract freely. Therefore, the issue with arbitration agreements is not the outmoded view that arbitration fails to afford consumers the same protections as a judicial proceeding, which the Ninth Circuit focused on by defining "sue" as distinct from "arbitrate," but rather the elimination of the consumer's choice in predispute agreements. Effectively banning postdispute arbitration also eliminates the consumer's ability to choose.

Plaintiff Vanessa Simmonds brought 54 derivative complaints under Section 16(b) of the Securities and Exchange Act of 1934. Simmonds alleged numerous instances of short-swing trading practices surrounding IPOs of corporations in which she held stock. Accordingly, Simmonds sought disgorgement of profits obtained as a result of these transactions. Before bringing her claim, Simmonds sent “demand letters” to the companies involved, insisting they assert their rights under 16(b) and file their own claims in this matter. When the corporations elected not to do so, Simmonds brought these complaints. The district court dismissed 30 of the complaints for deficiencies in the demand letters and the remaining 24 as time-barred due to a two-year statute of limitations. The Ninth Circuit affirmed the dismissal of the deficient complaints but reversed the dismissal of those the district court found time-barred. The court interpreted the two-year statutory period as tolled until the disputed transactions had been disclosed in mandatory Section 16(a) reports to the SEC, rather than running from the time the transactions took place.

Question Presented: Does the two-year statute of limitations established in Section 16(b) of the Securities and Exchange Act of 1934, which requires statutory insiders to disgorge profits from short-swing transactions in publicly traded issuer securities, begin to run if the targeted insider has failed to comply with its obligations under Section 16(a) of the Act to disclose short-swing trading activity in reports filed with the SEC? (Roberts, C.J., recused).
allege that the Defendant-Appellee investment banks (collectively, Underwriters) violated Section 16(b) by engaging in prohibited "short-swing" transactions in connection with the Initial Public Offerings (IPOs) of the fifty-four Defendant-Appellee corporations (collectively, Issuing Companies) between 1999 and 2000. Simmonds seeks disgorgement of the Underwriters’ alleged short-swing trading profits.

We affirm the district court’s conclusion (rendered in the thirty cases in which the issue was raised) that Simmonds failed to present an adequate demand letter to the Issuing Companies prior to filing her lawsuits, and we remand these cases to the district court to dismiss the complaints with prejudice. We reverse the district court’s conclusion that the remaining twenty-four cases are barred by Section 16(b)’s two-year statute of limitations, and we remand these cases to the district court so that all defendants, including the Underwriters, have a full opportunity to contest the adequacy of Simmonds’s demand letters with respect to the remaining twenty-four cases.

FACTUAL AND PROCEDURAL BACKGROUND

In her First Amended Complaints (Complaints), Simmonds alleges that while the Underwriters were acting as lead underwriters on the Issuing Companies’ IPOs, they coordinated their activities with the Issuing Companies’ officers, directors, and principal shareholders (collectively, Insiders) in order to obtain financial benefits from post-IPO increases in the Issuing Companies’ stock prices. Simmonds alleges that the Insiders entered “lock-up agreements” with the Underwriters that prevented the Insiders from offering or selling their stock for 180 days following the IPO. The purpose of the lock-up agreements was to “collectively hold[ ] . . . and refrain[ ] from selling” the Insiders’ shares, and the Underwriters and Insiders intended to receive financial benefits by selling these shares into an inflated market after the lock-up agreements expired. In order to create this inflated market, the Underwriters and Insiders allegedly agreed to release the IPO to the general public at a discount to the price that “they knew to be the likely aftermarket price range . . . based on clear indications of IPO and aftermarket demand.” The Underwriters also allegedly inflated the post-IPO share prices by engaging in a practice known as “laddering”—in exchange for giving their customers access to IPO allocations, the Underwriters required their customers (including the Issuing Companies’ Insiders) to purchase shares “at progressively higher prices” following the IPO. Finally, Simmonds asserts that the Underwriters engaged in “improper research-related activities that were designed to inflate the market price” of the shares. According to Simmonds, these allegations establish that the Underwriters and Insiders acted as a group and coordinated their conduct with respect to acquiring the Issuing Companies’ stock, holding the stock, and disposing of the stock “so as to share in the profits gained in the aftermarket following the IPO.”

Simmonds alleges that the Underwriters had three types of “direct or indirect pecuniary interest[s]” in the Issuing Companies’ stock that allowed the Underwriters to “profit[ ] from purchases and sales, or sales and purchases” of that stock. (The Complaints define these transactions as the operative “Short-Swing Transactions” for purposes of these lawsuits.) First, the Underwriters “shar[ed] in the profits of customers to whom they made IPO allocations” of the Issuing Companies’ stock. Second, the
Underwriters “allocated shares of [the Issuing Companies’] stock to executives and other high-level insiders of other companies, both private and public, from which [the Underwriters] expected to receive new or additional investment banking business in return.” Finally, the Underwriters “created the opportunity for other members of the [group] to derive personal financial benefits from the sale of the [the Issuing Companies’] stock into an inflated market, in an effort by [the Underwriters] to obtain future investment banking business from [the Issuing Companies].”

In her Complaints, Simmonds seeks to compel the Underwriters to disgorge the profits they received from these “Short-Swing Transactions.” Simmonds alleges that prior to filing the Complaints, she submitted demand letters insisting that the Issuing Companies seek this relief directly (as is their right under Section 16(b)). When more than sixty days had lapsed after she sent the demand letters, Simmonds filed the Complaints at issue in this appeal.

The Underwriters jointly filed a motion to dismiss Simmonds’s Complaints under Fed.R.Civ.P. 12(b)(6). The Underwriters contended that Simmonds’s claims were time-barred, that Simmonds’s Complaints failed to state a cause of action under Section 16(b), and that the Underwriters are protected by various exemptions from Section 16(b). Thirty of the Issuing Companies (collectively, Moving Issuers) filed a separate motion to dismiss under Fed.R.Civ.P. 12(b)(1) and Fed.R.Civ.P. 12(b)(6). The Moving Issuers argued that Simmonds’s claims were time-barred and that Simmonds lacked standing because she failed to submit adequate demand letters to the Issuing Companies prior to filing suit.

The district court granted the Moving Issuers’ Fed.R.Civ.P. 12(b)(1) motions to dismiss based on the inadequacy of Simmonds’s demand letters, and granted the Underwriters’ Fed.R.Civ.P. 12(b)(6) motions to dismiss based on the two-year statute of limitations. In re Section 16(b) Litig., 602 F.Supp.2d 1202, 1211-18 (W.D.Wash.2009). The court did not address the Underwriters’ remaining arguments regarding the merits of Simmonds’s allegations and the scope of the Underwriters’ exemptions from Section 16(b). The court dismissed without prejudice the thirty actions resolved by the Moving Issuers’ Fed.R.Civ.P. 12(b)(1) motions. The court dismissed the remaining twenty-four cases with prejudice in light of its ruling on the statute of limitations.

Simmonds filed a timely appeal, and the thirty Moving Issuers filed timely cross-appeals requesting that the district court’s dismissals of their cases be entered with prejudice rather than without prejudice. We granted the parties’ joint motion to consolidate the cases on appeal pursuant to Fed. R.App. P. 3(b)(2).

JURISDICTION AND STANDARD OF REVIEW

Ordinarily, “[a] dismissal of a complaint without prejudice is not a final order.” However, the district court’s orders in these cases are final and appealable because “leave to amend was not specifically allowed and [Simmonds] cannot amend [her] complaint to defeat the statute of limitations bar” as construed by the district court. Accordingly, we have jurisdiction pursuant to 28 U.S.C. § 1291.

We review the district court’s dismissal for failure to comply with the demand requirement for abuse of discretion. We review the district court’s dismissal on
statute of limitations grounds de novo. We refrain from reviewing issues not addressed by the district court.

DISCUSSION

"Congress enacted Section 16(b) as part of the Exchange Act to prevent corporate insiders from exploiting their access to information not generally available to others." Section 16(b) requires corporate insiders to disgorge any trading profits they obtain in any "short-swing" transaction, which is defined as "a coupled purchase-and-sale, or sale-and-purchase, completed within six months." There are four basic elements of a Section 16(b) claim: "(1) a purchase and (2) a sale of securities (3) by an officer or director of the issuer or by a shareholder who owns more than ten percent of any one class of the issuer's securities (4) within a six-month period."

The purpose of the rule is not to punish specific instances of wrongdoing or remedy harms suffered by particular individuals. Rather, the law is "aimed at protecting the public" by preventing corporate insiders from exploiting inside information at the expense of ordinary investors. In order to fulfill this purpose, Section 16(b) "is a blunt instrument, at once both over- and under-inclusive." It "is over-inclusive in that it imposes strict liability regardless of motive, including trades not actually based on inside information," and "[i]t is underinclusive in that there is no liability for trades made on inside information if more than six months transpire between purchase and sale."

This appeal focuses on a pair of procedural prerequisites to filing a Section 16(b) lawsuit: the demand requirement, and the statute of limitations. Shareholders may only file a Section 16(b) suit after requesting that the issuing company take appropriate action against its insiders. If sixty days pass after a shareholder demand has been made without the issuing company resolving the matter (either informally or via lawsuit), shareholders may file suit on the issuing company's behalf. However, shareholders must file their suit within two years of the transactions at issue, subject to the tolling rules described in greater detail infra.

A. Demand Requirement

Section 16(b) provides in relevant part that all insider short-swing trading profits "shall inure to and be recoverable by the issuer," and "[s]uit to recover such profit may be instituted at law or in equity in any court of competent jurisdiction by the issuer, or by the owner of any security of the issuer in the name and in behalf of the issuer if the issuer shall fail or refuse to bring such suit within sixty days after request or shall fail diligently to prosecute the same thereafter. . . ." The issuing company's right to recover the insider's trading profits "is simply an application of an old principle in the law that if you are an agent and you profit by insider information concerning the affairs of your principal, your profits go to your principal."

Section 16(b) does not set forth any additional details regarding the nature and scope of this statutory demand requirement. In light of this Congressional silence, we turn to state law for guidance. The Supreme Court has explained that "where a gap in the federal securities laws must be bridged by a rule that bears on the allocation of governing powers within the corporation, federal courts should incorporate state law into federal common law unless the particular state law in question is inconsistent with the policies underlying the federal statute." Kamen v. Kemper Fin. Servs., Inc., 500 U.S. 90, 108, 111 S.Ct. 1711, 114 L.Ed.2d 152 (1991). Applying this broad principle in the context
of the Investment Company Act of 1940, the Kamen Court held that "the contours of the demand requirement" (in that case, the standards governing demand futility) must be determined by the law of the state of incorporation.

Here, the adequacy of Simmonds's Section 16(b) demand letters is disputed in the thirty cases involving the Moving Issuers, all of which are Delaware corporations. In light of the principles articulated in Kamen, these thirty demand letters must be analyzed in accordance with Delaware law, unless there is a conflict between Delaware law and federal law that "would frustrate specific objectives" of Section 16 and the Exchange Act. Our task under Kamen is the same as in any case decided under state law after Erie R.R. Co. v. Tompkins, 304 U.S. 64, 58 S.Ct. 817, 82 L.Ed. 1188 (1938). We must "approximate state law as closely as possible in order to make sure that the vindication of the state right is without discrimination because of the federal forum." Accordingly, we must follow the Delaware Supreme Court's pronouncements, or, if the Delaware Supreme Court has not addressed the question, "we must predict how the Court will decide the issue, based on decisions of Delaware courts, decisions from other jurisdictions, treatises and restatements." In other contexts, we have relied on the Delaware Court of Chancery's decisions as accurate statements of Delaware law, and we note that there are particularly compelling reasons for following the Delaware Court of Chancery's decisions because it is widely recognized as the nation's leading authority on corporate law issues[.]

The Delaware Supreme Court has explained that the demand requirement exists "first to insure that a stockholder exhausts his intracorporate remedies, and then to provide a safeguard against strike suits." "The purpose of pre-suit demand is to assure that the stockholder affords the corporation the opportunity to address an alleged wrong without litigation, to decide whether to invest the resources of the corporation in litigation, and to control any litigation which does occur." These justifications are not unique to Delaware. The Supreme Court has repeatedly highlighted these points, as have our sister circuits, and leading commentators have approved. As we have previously stated, the demand rule "is not merely a technical or unimportant requirement." Rather, it flows from "the general rule of American law . . . that the board of directors controls a corporation." Indeed, the policies animating shareholder demands are particularly relevant in the Section 16(b) context. "Anecdotal evidence suggests that well over 90 percent of all Section 16(b) claims are settled privately, without any lawsuit being filed." This figure would almost certainty be lower if Section 16(b) did not contain a demand requirement, as shareholder demands allow boards to investigate the allegations and resolve matters without resorting to costly and burdensome litigation.

To give effect to these general policies, the Delaware Chancery has required that demand letters "specifically state: (i) the identity of the alleged wrongdoers, (ii) the wrongdoing they allegedly perpetrated and the resultant injury to the corporation, and (iii) the legal action the shareholder wants the board to take on the corporation's behalf." Furthermore, "the party asserting that a demand was made . . . bear[s] the burden of proof. . . ." These requirements flow directly from the underlying justifications for the demand requirement: "[i]t is essential that the communication contain these three elements to enable the board to perform its duty to make a good
faith investigation of claims of alleged wrongdoing, and, where appropriate, to rectify the misconduct.” We believe that this is a correct statement of Delaware law as it would be decided by the Delaware Supreme Court. This standard was announced by a vice chancellor who was later elevated to the state supreme court, and, more importantly, this standard has been uniformly followed in subsequent Chancery decisions. Accordingly, under Kamen and our general Erie jurisprudence, we apply this legal standard (and the Delaware courts’ applications of it) except where it “frustrate[s] specific objectives” of Simmonds’s federal cause of action.

Here, the thirty demand letters at issue in the Moving Issuers’ motion (all of which were identical in all material respects) stated the following pertinent facts. “[T]he Company’s IPO underwriters, in addition to certain of its officers, directors and principal shareholders, as identified in the IPO prospectus . . . coordinated their efforts for the purpose of acquiring, holding, and/or disposing of securities of the Company,” obtained beneficial ownership of shares amounting to more than 10% of the company’s outstanding common stock in the year following the IPO, “engaged in purchases and sales of Company within periods of less than six months during” that year, and failed to report those transactions as required by Section 16(a). Simmonds “demand[ed] that the board of directors prosecute a claim against” those persons “for violations of § 16(b) of the Securities Exchange Act of 1934,” in order to “compel[ ] [them] to disgorge the profits they made through purchases and sales of Company stock.”

In response to twenty-five of the thirty Moving Issuers’ requests for additional information, Simmonds explained that “the challenged transactions involved the activities of the lead underwriters, the other IPO underwriters, and the officers, directors and principal shareholders of the Company . . . related to improper IPO allocation (so-called ‘laddering’ and ‘spinning’) and research and stock rating activities during the Relevant Period. As you are aware, information regarding these activities is readily available at court, law firm and SEC websites.”

Simmonds’s initial demand letters satisfied the first part of the Delaware test for demand adequacy, which requires the shareholder to state “the identity of the alleged wrongdoers.” In FLI Deep Marine v. McKim, the plaintiff’s demand letter stated that “‘certain employees, officers and directors of [the company] and others’” had diverted and misappropriated the company’s assets. The Court of Chancery stated that this letter was sufficient to satisfy the first prong of Yaw. Simmonds’s demand letters identify the alleged wrongdoers with a similar level of precision as in the FLI Deep Marine plaintiff’s demand letter. Specifically, Simmonds’s letters identified “the Company’s IPO underwriters, in addition to certain of its officers, directors and principal shareholders, as identified in the IPO prospectus.” Although the Moving Issuers contend that their respective prospectuses listed between eleven and fifty-one underwriters, officers, and directors, and we acknowledge that this is a close question, we follow the Court of Chancery’s approach in FLI Deep Marine. Because Simmonds’s demand letters identified a closed set of alleged wrongdoers, we agree with the district court that “the demand letters in this case sufficiently identify the alleged wrongdoers.”

Simmonds’s letters failed, however, to satisfy the second and third prongs of the
Delaware test for demand adequacy, which require the shareholder to identify the “wrongdoing . . . allegedly perpetrated” and “the legal action the shareholder wants the board to take on the corporation’s behalf.” Simply put, Simmonds’s demand letters presented factual theories that vary significantly from the facts alleged in the Complaints. Her demand letters claimed that the Underwriters directly bought and sold the Issuing Companies’ shares, and accordingly requested that the Issuing Companies seek disgorgement of the Underwriters’ trading profits. In contrast, her Complaints do not allege that the Underwriters directly participated in buying and selling the Issuing Companies’ stock, and instead seek disgorgement of the profits the Underwriters received through their investment banking operations.

According to the Complaints, the Underwriters violated Section 16(b) when they profited indirectly through their customers’ purchases and sales of the Issuing Companies’ shares. Specifically, the Complaints allege that the Underwriters engaged in “Short-Swing Transactions” when (1) their existing customers purchased and sold the issuing company’s stock, (2) they obtained new banking customers in exchange for giving other companies’ insiders favorable consideration in the issuing company’s IPO, and (3) they obtained additional banking business from the issuing company in exchange for helping the issuing company’s insiders profit from their own company’s IPO. The Complaints assert that these “Short-Swing Transactions” violated Section 16(b), and request disgorgement of profits obtained through these “Short-Swing Transactions.” None of these alleged transactions is referenced in any way in the original demand letters submitted to the Moving Issuers. The garden-variety Section 16(b) claim made out in these demand letters bears no resemblance to the elaborate scheme described in Simmonds’s Complaints.

Even if we consider Simmonds’s follow-up letters to twenty-five of the Moving Issuers, she failed to identify the wrongful acts “clearly and specifically.” The follow-up letters noted that the “challenged transactions . . . [are] related to improper IPO allocation (so-called ‘laddering’ and ‘spinning’) and research and stock rating activities.” Simmonds’s conclusory references to “laddering,” “spinning,” and “research and stock rating,” were vague and ambiguous, as was her open ended reference to “court, law firm and SEC websites,” and completely failed to provide sufficiently detailed information to permit the boards to conduct a good faith inquiry into the alleged wrongdoing.

Moreover, because the demand letters and the Complaints contain distinct factual assertions, the demand letters also failed to set forth “the legal action the shareholder wants the board to take on the corporation’s behalf.” The demand letters requested that the Moving Issuers “compel[ ]” the Underwriters and other group members to “disgorge the profits they made through purchases and sales of [the issuing company’s] stock.” The Complaints, on the other hand, do not mention the Underwriters’ direct trading profits, and instead seek disgorgement of the profits the Underwriters received through their investment banking operations.

The Court of Chancery has noted that demand letters must be sufficiently specific to “enable the board to perform its duty to make a good faith investigation of claims of alleged wrongdoing[ ] and . . . to rectify the misconduct” at issue in a subsequent lawsuit. The court further noted that “to
require a board to investigate claims asserted ambiguously . . . would not be an efficient use of corporate resources, because the board would lack the information necessary to make a good faith inquiry.” Simmonds’s demand letters were particularly inadequate because they described a different course of conduct than the one she described in her Complaints. And clearly, Simmonds’s demand letters could have led directors to investigate facts (the Underwriters’ purchases and sales of Issuing Company stock) that were only marginally related to the issues ultimately raised in the Complaints (the Underwriters’ customers’ purchases and sales of Issuing Company stock, and associated profit-sharing agreements between the Underwriters and their customers).

We are not persuaded by Simmonds’s argument that the Moving Issuers subjectively understood what she meant in her demand letters. Delaware case law sets forth an objective standard for assessing the adequacy of a demand and does not inquire whether the board of directors had independent knowledge of relevant information. To the extent that Simmonds’s argument has been addressed by any courts, it has been soundly rejected. For example, the Third Circuit has rejected a shareholder’s argument that a conclusory demand was adequate because “the directors were in a better position than the shareholders to make the investigation necessary to uncover wrongdoers.” In the related context of demand refusal, the Delaware Supreme Court rejected the argument that “[t]he board has better access to the relevant facts” and plaintiffs should therefore be relieved of their burden to show that the board’s refusal was improper.

Simmonds’s argument is an end-run around Delaware’s requirement that shareholders make reasonably specific demands, and were we to adopt Simmonds’s proposed approach, Delaware’s demand standard would be eviscerated. Plaintiffs in derivative actions often seek relief for a corporate insider’s wrongdoing. If the demand requirements were relaxed on account of insiders’ subjective knowledge, then shareholders would never have to “clearly and specifically” describe their assertions in a demand letter. To the extent that Simmonds believed that relevant information was “readily available at court, law firm and SEC websites” as she claimed in her follow-up letters, it was her burden under Delaware law to distill the relevant facts and present them to the board. Delaware law does not allow shareholders to forego pre-suit investigations in an attempt to shift information-gathering costs onto the corporation, and this rule is not clearly incompatible with Section 16 and the Exchange Act.

As an alternative to her argument that her demand letters were adequate, Simmonds contends that the demand requirement should be excused as futile. However, Delaware courts have repeatedly held that a shareholder concedes that a demand is not futile by submitting a demand to the board. “Delaware law could hardly be clearer” in holding that shareholders may not invoke the futility exception after submitting a demand to the board.

We hold that the thirty demand letters in the record fail to satisfy the demand requirement under Delaware law. Accordingly, we affirm the district court’s order granting the Moving Issuers’ motions to dismiss the thirty cases to which they are parties.

B. Statute of Limitations

The district court dismissed the cases
involving the remaining twenty-four issuers (that is, the Issuing Companies that did not join the Moving Issuers' Motion to Dismiss) on account of the statute of limitations. Section 16(b) provides that “no ... suit shall be brought more than two years after the date such profit was realized” from the alleged short-swing transactions. 15 U.S.C. § 78p(b). We have previously issued a thorough decision interpreting this provision, Whittaker v. Whittaker Corp., 639 F.2d 516 (9th Cir. 1981), and we are bound by our prior holding.

In Whittaker, a corporate insider engaged in prohibited short-swing transactions between December 1965 and December 1970. The corporation sought disgorgement in January 1971 without filing a lawsuit. The insider paid the full amount requested, but later filed suit against the corporation seeking to recover some of the money he had paid. In the lawsuit, he argued that Section 16(b)’s statute of limitations barred the corporation from retaining any amounts that he had obtained from short-swing transactions prior to January 1969 (that is, two years prior to the time that the corporation requested that he disgorge his profits). The district court agreed with the insider, and “found that various corporate officers had information which put the Corporation on notice throughout the relevant trading period” between 1965 and 1970. Based on this factual finding, the district court allowed the corporation to recover the insider’s profits only for the two years prior to the disgorgement request.

On appeal, we explained that there were three competing approaches to Section 16(b)’s statute of limitations: (1) a “strict” approach under which the statute is treated as a statute of repose—that is, a firm bar that is not subject to tolling; (2) a “notice” or “discovery” approach like the one that had been applied by the district court, “under which the time period is tolled until the Corporation had sufficient information to put it on notice of its potential § 16(b) claim”; and (3) a “disclosure” approach “under which the time period is tolled until the insider discloses the transactions at issue in his mandatory § 16(a) reports.” After thoroughly analyzing the merits of the competing interpretations, we held unequivocally that “the disclosure interpretation is the correct construction of § 16.” Under this approach, “an insider’s failure to disclose covered transactions in the required § 16(a) reports tolls the two year limitations period for suits under § 16(b) to recover profits connected with such a non-disclosed transaction. The two-year period for § 16(b) begins to run when the transactions are disclosed in the insider’s § 16(a) report.” Accordingly, we reversed the district court’s use of the “notice” approach and held that the corporation could recover all of the insider’s short-swing profits, even those obtained long after the corporation was on notice of the insider’s trading.

In this case, the Defendants advance various arguments in an attempt to distinguish Whittaker. All of these arguments are variations on a single theme—Simmonds knew or should have known of the alleged wrongful conduct many years before she filed her Complaints. But despite the Defendants’ arguments, the central holding of our opinion in Whittaker—both in our legal analysis and our application of the law to the facts of that case—is that the Section 16(b) statute of limitations is tolled until the insider discloses his transactions in a Section 16(a) filing, regardless of whether the plaintiff knew or should have known of the conduct at issue. We recently restated this holding in Roth v. Reyes, 567 F.3d 1077 (9th Cir.2009), in which we concluded that the statute of limitations begins to run when the
insider files a Section 16(a) report even if the contents of the filing inaccurately claim an exemption that does not actually apply. We explained that the basic act of filing a Section 16(a) report satisfies Whittaker’s disclosure requirement and “supports the goals of disclosure and transparency” underlying Section 16.

The Defendants advance four specific points in support of their general theory that Whittaker can be distinguished. First, they argue that Whittaker does not apply because Simmonds knew or should have known of the relevant facts sometime around 2001. By that time, much of the information described in the Complaints had been publicly disclosed in court filings, news reports, and the Issuing Companies’ IPO registration filings. The Defendants contend that “[w]hen a party is aware of the necessary facts to bring a claim, there is no excuse for any delay beyond the statute of limitations period, let alone a delay of six years.” However, this theory was plainly rejected in Whittaker. Our Whittaker decision reversed the district court’s conclusion that the statute of limitations began to run at the time that “various corporate officers had information which put the Corporation on notice” of the insider’s short-swing trades. The Defendants’ “notice” argument is an unpersuasive attempt to revive a theory that we considered and rejected nearly thirty years ago.

Second, the Defendants argue that the Section 16(b) limitations period should not be tolled indefinitely unless the defendant actively “conceal[s] the facts necessary to trigger a Section 16(b) lawsuit.” This theory overlooks the footnote in Whittaker in which we explained that “[t]he failure to disclose in § 16(a) reports, whether intentional or inadvertent, is deemed concealment, thus triggering the traditional equitable tolling doctrine of fraudulent concealment.” That conclusion was further bolstered by our emphasis on creating a rule that can be “mechanically calculated from objective facts,” which would be undermined if courts were required to conduct case-specific inquiries into the insiders’ state of mind about their failure to file Section 16(a) reports.

Third, the Defendants contend that Whittaker does not apply in this case because the Underwriters are exempt from Section 16(a) reporting requirements under the SEC’s underwriting and market-making exemptions. However, this argument finds no support in Whittaker’s bright-line rule. In any event, were we to follow the Defendants down this line of argument, we would soon find ourselves deciding the substantive merits of the parties’ dispute. The question of whether or not the Underwriters are exempt from filing Section 16(a) reports is identical to the question of whether they may be held liable under Section 16(b). We refrain from adopting an approach that “would merge the tolling doctrine with the substantive wrong....”

Finally, the Defendants argue that Whittaker does not apply because it involved a corporation that was seeking disgorgement, rather than an outside shareholder as in the instant case. They assert that we should adopt different lines of analysis depending on whether the plaintiff is an issuing company or is an outside shareholder such as Simmonds. However, our decision in Whittaker created a blanket rule that applies in all Section 16(b) actions. A key component of our reasoning was that Section 16(a) notices allow the company’s shareholders—who “are likely to be outsiders, minority holders”—to obtain the information necessary to bring a Section 16(b) action. Nothing in Whittaker’s logic or
reasoning would allow us to distinguish between issuing companies and outside shareholders, and we refrain from adopting such a strained interpretation of our precedent.

In short, the fundamental holding of Whittaker is that Section 16(b)'s two-year statute of limitations begins to run from the time that the defendant files a Section 16(a) disclosure statement. Because Simmonds alleges that the Defendants did not file any Section 16(a) reports, we conclude that Simmonds's claims are not time-barred. Accordingly, the district court's decision on this ground is reversed.

C. Cross-Appeal

In their cross-appeal, the Underwriters contend that the district court erred by dismissing the thirty cases involving the Moving Issuers without prejudice on account of Simmonds's inadequate demand. They argue that these dismissals should have been with prejudice because Simmonds's claims are time-barred. Although we disagree that Simmonds's claims are time-barred, we agree that the district court should have dismissed the thirty Complaints against the Moving Issuers with prejudice on account of her failure to satisfy the Section 16(b) demand requirement in those cases.

We have previously held that a complaint may be dismissed with prejudice on account of the plaintiff's failure to satisfy the demand requirement, and various other circuits have reached the same conclusion. Although the district court dismissed Simmonds's thirty Complaints against the Moving Issuers "without prejudice," our decision to convert the dismissal is not unprecedented. In a derivative action in which the shareholder failed to show demand futility, the First Circuit sua sponte converted the district court's dismissal from "without prejudice" to "with prejudice." In re Kauffman Mut. Fund Actions, 479 F.2d 257, 267 (1st Cir.1973). The court explained that the plaintiff was barred from relitigating the issues decided in that action, and accordingly the dismissal should have been entered with prejudice rather than without.

We agree with the First Circuit's approach in Kauffman. Simmonds is barred from relitigating issues relating to the adequacy of the demand letters she sent to the thirty Moving Issuers and the follow-up letters she sent to twenty-five of the Moving Issuers. As with any issue litigated fully on the merits, shareholders may not endlessly relitigate the adequacy of their pre-suit demand. Accordingly, we vacate the district court's order dismissing without prejudice the thirty cases involving the Moving Issuers, and the district court is instructed to dismiss these thirty cases with prejudice.

In the twenty-four cases that were improperly dismissed as time-barred and in which the Issuing Companies did not join the Moving Issuers' Motion to Dismiss, the district court is directed to permit the Underwriters and Issuing Companies to seek dismissal on account of Simmonds's failure to comply with the demand requirement. We note that our discussion in this opinion will almost certainly resolve the twenty remaining cases involving issuers incorporated in Delaware. (We express no opinion regarding the four cases involving non-Delaware issuers.) However, as Simmonds's demands letters to those companies are not in the record, we leave it to the district court to address those cases in the first instance. We note that four of the cases involve issuers incorporated in jurisdictions other than Delaware (two issuers are incorporated in California, one in Washington, and one in Bermuda). We
direct the district court to analyze the adequacy of those demand letters in accordance with the choice-of-law principles articulated in Kamen—namely, the court should apply the demand requirements of California, Washington, and Bermuda law, unless those requirements "would frustrate specific objectives" of Section 16 and the Exchange Act.

CONCLUSION

We AFFIRM the district court's conclusion that Simmonds's demand letters to the thirty Moving Issuers were inadequate under Delaware law, REVERSE the district court's conclusion that all of Simmonds's claims are time-barred, and VACATE the district court's dismissal orders as to the thirty Moving Issuers with instructions that the district court dismiss these thirty cases with prejudice on account of Simmonds's failure to satisfy Delaware's demand requirement. We REMAND the remaining twenty-four cases (that is, the cases involving the twenty-four Issuing Companies that did not join the Moving Issuers' Motion to Dismiss) with instructions for the district court to allow the Underwriters and Issuing Companies to file an appropriate motion to challenge the adequacy of Simmonds's demand letters under Delaware, California, Washington, and Bermuda law, unless that law conflicts with Section 16(b). Costs are awarded to the Appellees.

AFFIRMED IN PART, REVERSED IN PART, VACATED IN PART, AND REMANDED IN PART.

M. SMITH, Circuit Judge, specially concurring:

The statutory text of Section 16(b) provides that "no such suit shall be brought more than two years after the date such profit was realized." 15 U.S.C. § 78p(b). In my view, "no suit" means no suit, and "two years after the date such profit was realized" means two years after the insider's final profitable transaction, regardless of when—or even if—a Section 16(a) report is filed. The text of the statute sets a firm bar against Section 16(b) suits filed more than two years after the transaction is completed. Accordingly, I agree with the Supreme Court's dictum that Section 16(b) "sets a 2-year . . . period of repose." Lampf, Pleva, Lipkind, Prupis & Petigrow v. Gilbertson, 501 U.S. 350, 360 n. 5, 111 S.Ct. 2773, 115 L.Ed.2d 321 (1991).

This straightforward textual reading is further confirmed by comparing the language of Section 16(b) with the language of the other statutes of limitations in our securities laws. The Court in Lampf explained that language such as Section 16(b)’s "no such suit shall be brought" creates periods of repose that are not subject to tolling. In addition, the general securities fraud statute of limitations added by the Sarbanes-Oxley Act of 2002, 116 Stat. 801, provides that securities fraud suits "may be brought not later than . . . 5 years after such violation." 28 U.S.C. § 1658(b)(2). The Supreme Court recently noted that this provision "gives defendants total repose" after five years. There is little meaningful distinction between the language of 28 U.S.C. § 1658(b)(2) and Section 16(b)—one provides that suits "may be brought not later than . . . 5 years after such violation," and the other provides that "no such suit shall be brought more than two years after the date such profit was realized." To me, this nearly identical language should "give[e] defendants total repose" under both statutes.

There are numerous reasons why Congress would elect to create a firm two-year period of repose for Section 16(b) actions. Although there is no direct evidence of Congress's intent, the legislative history has left behind an intriguing clue. When the
Senate and House of Representatives passed their respective bills that later became the Exchange Act, the House of Representatives's version did not even provide for a private right of action under Section 16(b), whereas the Senate's version provided a right of action but omitted a statute of limitations. It is reasonable to infer that the House negotiators, in reaching a compromise with the Senate over the inclusion of a private right of action, might have bargained to include a stringent statute of limitations to circumscribe that right of recovery.

Admittedly, the legislative history is inconclusive, but a restrictive statute of limitations is eminently logical. Section 16(b) imposes an inflexible penalty on corporate insiders even if they are not at fault and third parties are unharmed. As Section 16(b)'s critics have noted, its disgorgement provision “is little more than a trap for the unwary.” It makes no sense to allow individuals to be hauled into court years—or even decades—after they unintentionally violate Section 16. Our holding in Whittaker creates the possibility that “a claim that affects long-settled transactions might hang forever over honest persons.” Whittaker could lead to the anomalous situation in which a corporate officer who mistakenly calculates the six-month short-swing period can be compelled to disgorge his trading profits decades after the fact, whereas a culpable officer who engages in fraudulent insider trading becomes immune from civil suit after five years as long as his trades were spaced more than six months apart. I fail to see the logic behind such a result, and I fear that Whittaker failed to foresee such anomalies.

I note that Whittaker was motivated by the well-intentioned concern that corporate insiders could avoid Section 16(b) liability if they flout Section 16(a)’s reporting requirements. However, I do not believe that this concern warrants the creation of never-ending liability for corporate directors, officers, and shareholders. The Exchange Act is a comprehensive statute that was designed to address various types of wrongdoing. It is inappropriate for us to use Section 16(b), which prohibits certain types of insider trading, to enforce the policies of Section 16(a), which requires disclosure of insider trading. The Exchange Act creates more than adequate enforcement mechanisms for enforcing Section 16(a)’s disclosure requirements. If the insiders do not file their reports, they may be held professionally, civilly, or criminally liable for failing to do so. And if the insiders withhold their Section 16(a) reports in order to profit from inside information, they may be subjected to Rule 10b-5 securities fraud actions.

Ultimately, I believe that Whittaker’s cure is worse than the disease it intended to address. I would have preferred to adopt any one of the three alternatives to Whittaker: the statute of repose approach, Lampf, 501 U.S. at 360 n. 5, 111 S.Ct. 2773, the actual notice approach, Litzler, 362 F.3d at 208, or the hybrid approach that tolls the statute in cases of “fraud or concealment,” id. at 208 n. 5 (Jacobs, J., concurring). Of these three approaches, the statutory text and statutory structure clearly point toward the repose approach. Were it not for Whittaker, I would hold that Section 16(b) suits may not be brought more than two years after the short-swing trades take place.

Despite these concerns, I am compelled to follow Whittaker. See Miller v. Gammie, 335 F.3d 889, 899 (9th Cir.2003) (en banc). Accordingly, I concur with the panel’s decision.
The U.S. Supreme Court agreed Monday to hear an appeal by several investment banks seeking to enforce strict time limits on when a plaintiff can file one type of insider-trading lawsuit.

At issue are claims that the banks, as underwriters of “hot” initial public offerings 10 years ago, impermissibly reaped “short-swing” insider profits from aftermarket gains of those stocks.

The case involves a single plaintiff’s challenge to the banks’ actions in 54 IPOs. The plaintiff, Vanessa Simmonds, alleged in 54 separate complaints that the banks shared in the profits of customers who received IPO allocations and sold their shares on the open market at higher prices. The suits also claim the banks strategically allocated IPO shares to customers who would return the favor by giving the banks more business.

Simmonds holds stock in the companies that issued shares through the disputed IPOs. She sent those companies letters demanding that they sue the underwriting banks for disgorgement of ill-gotten profits. When the companies declined, she invoked a provision of the Securities Exchange Act that allowed her to sue the banks herself.

The banks say the suits should be thrown out because they were filed after a two-year time limit. A San Francisco-based federal appeals court said the suits were not too late because the time limit had been postponed.

The appeals court, however, dismissed 30 of Simmonds’ lawsuits on other legal grounds. The other 24 remain alive, though the appeals court suggested many of those have deficiencies also.

Banks appealing to the Supreme Court included Bank of America Corp. (BAC) and subsidiaries of Citigroup Inc. (C), Credit Suisse Group (CS, CSGN.VX), Deutsche Bank AG (DB, DBK.XE), Goldman Sachs Group (GS), J.P. Morgan Chase & Co. (JPM) and Morgan Stanley (MS).

The case is Credit Suisse Securities v. Simmonds, 10-1261. Oral arguments will take place during the court’s next term, which begins in October.
The U.S. Supreme Court on Monday agreed to hear a group of investment banks' challenge to a Ninth Circuit ruling in a case involving initial public offerings with broader implications for shareholder derivative suits brought after the statute of limitations codified in federal securities laws.

The high court agreed to hear an appeal of a December decision reviving 24 lawsuits that were part of a consolidated securities action over initial public offerings of 54 companies in the late 1990s on the grounds that a lower court incorrectly dismissed them with prejudice based on the underwriters' assertion that the two-year statute of limitations had elapsed for the claims. The suits alleged that the underwriters engaged in prohibited short-swing transactions.

In their petition for certiorari, the underwriters argued that the 30-year-old rule on which the Ninth Circuit relied, established in a 1981 case called Whittaker v. Whittaker Corp., was out of step with established precedents in the Second Circuit and needed to be resolved by the Supreme Court.

The rule states that the two-year statute of limitations on derivative claims is tolled until a shareholder files the necessary forms notifying a company of wrongdoing, even if the company is already aware of the wrongdoing.

"Because the issuers on whose behalf this case was brought and their shareholders had actual notice of the underlying facts for at least six years before this lawsuit was filed, these complaints would have been time-barred if brought in the Second Circuit," the underwriters said in their cert petition, filed in April. "Certiorari is warranted based on that conflict alone."

Bank of America Corp., JPMorgan Chase & Co., Credit Suisse Securities (USA) LLC, Morgan Stanley, Goldman Sachs Group Inc., Deutsche Bank AG and Citigroup Inc., among others, were the petitioners.

At the same time, the Supreme Court rejected a cert petition filed by Vanessa Simmonds, the named plaintiff in the consolidated securities, who appealed the Ninth Circuit's affirmation of the district court's dismissal of the remaining 30 lawsuits on the grounds that she did not comply with presentation requirements under Section 16(b) of the Securities Exchange Act.

According to her petition, the Ninth Circuit ruled Simmonds' demand letters did not state with sufficient specificity that the investment banks and company insiders issuing their first batch of public stock turn over ill-gotten gains.

The letters, the appeals court said, clearly failed to satisfy the adequacy standards that compelled Simmonds to state the alleged wrongdoing the shareholder targeted and the legal action the shareholder intended to take
prior to filing the suits.

Simmonds argues that such specificity was not required under Section 16(b) claims, noting that several scholars have argued that such demand letters are traditionally only one page long and written in general terms.

Jeffrey I. Tilden, a partner at Gordon Tilden Thomas & Cordell LLP representing Simmonds, said he was disappointed in the high court’s split cert rulings, but vowed to fight on the statute of limitations question.

“The petition granted addresses an issue that has been long settled in the Ninth Circuit, nationally and in the mind of the [U.S. Securities and Exchange Commission], and we look forward to addressing it,” he said.

Counsel for the underwriters, Christopher Landau of Kirkland & Ellis LLP, could not be immediately reached for comment.

Chief Justice John Roberts recused himself from the decisions on the two cert petitions, according to the Supreme Court.

During a 10-day span in October 2007, Simmonds, then a 22-year-old college student, sued the banks and 54 companies that made IPOs in 1999 and 2000. Many of the defendant companies were part of the dot-com boom, and included TiVo Inc., Audible Inc. and Priceline.com Inc.

Simmonds—whose father, Robert Simmonds, works as a securities plaintiffs attorney—sought disgorgement of profits from the underwriters on behalf of the nominal defendant issuers under Section 16(b), which creates strict liability for company insiders who buy and sell stock in their own company within a six-month period without disclosure.

* * *
"Supreme Court Grants Cert in Yet Another Securities Case"

The D & O Diary
June 27, 2011
Kevin LaCroix

Years from now, when the history of the Roberts Court is finally written, I hope that the historians will be able to explain why during the first dozen years of the 21st century, the U.S. Supreme Court seemed so eager to take up securities cases. But whatever the reason, on June 27, 2011, on the final day of a term in which the Court heard three different securities cases, the Supreme Court granted petition for writ of certiorari to hear yet another securities case next term.

The case is styled as Credit Suisse Securities (USA) LLC v. Simmonds and the question that the Supreme Court will address has to do with the interpretation and application of the statute of limitations in Section 16(b) of the '34 Act, relating to so-called "short swing profits." Here is the Question Presented in the case:

Whether the two-year time limit for bringing an action under Section 16(b) of the Securities Exchange Act of 1934, 15 U.S.C. § 78p(b), is subject to tolling, and, if so, whether tolling continues even after the receipt of actual notice of the facts giving rise to the claim.

The litigation arises out of the IPO laddering scandal from the dot com era. The plaintiff filed fifty-four related derivative complaints under Section 16(b) in connection with 54 IPOs in 1999 and 2000. The gist of the plaintiff’s allegation is that the supposed arrangement whereby the underwriters had arranged for post-IPO stock purchases of the issuers’ securities at progressively higher prices ("laddering") constituted prohibited short-swing profits. The plaintiff seeks to compel the underwriter defendants to disgorge their profits.

The District Court granted the defendants’ motions to dismiss. As to thirty of the cases, the district court granted the dismissal motion as to thirty of the companies based upon the inadequacy of the derivative demand letters the plaintiff had sent to the issuer companies. The District Court dismissed the remaining twenty-four cases on the basis of Section 16(b)'s two year statute of limitations. The plaintiff appealed.

In a December 2, 2010 opinion (as amended on January 18, 2011) written by Judge Milan Smith a three-judge panel the Ninth Circuit affirmed the district court’s ruling as to the demand letters, but reversed the district court as to the statute of limitations issue. The specific issue the Ninth Circuit addressed was whether the two-year statute of limitations is a strict statute of repose, or whether it is a "notice" or "discovery" statute that is tolled until the claimant has sufficient information to be put on notice.

The Ninth Circuit, following its own prior precedent, held that the two-year statute operates as a "notice" statute, and the running of the statute is tolled until there has been adequate disclosure of the trade. Because the statute begins to run only when the defendant files a Section 16(a) disclosure statement, and because the defendants did not file a Section 16(a) statement, the Ninth

478
Circuit held that the claims are not time-barred.

In an unusual twist, Judge Smith, the author of the opinion for the three judge panel, added an additional opinion “specially concurring” in the result and expressing his view that the two-year statute of limitations is a statute of repose, and that were it not for the prior Ninth Circuit precedent on which the court relied in deciding this case, he would have voted that the Section 16(b) cases could not be brought more than two years after the short-swing trades took place.

The defendants affected by the Court’s ruling on the statute of limitation filed a petition for a writ of certiorari with the United States Supreme Court and on June 27, 2011, the Court granted the petition.

Discussion

There was a time when the Supreme Court rarely took up securities cases. That time is long passed. The Court is not only routinely taking up securities cases, but it is even taking up routine matters—this is the second securities-related statute of limitations case the Court has taken up recently. Just last year the Court dealt with statute of limitations issues in the Merck case.

The Court has only just accepted this case and it has not yet been briefed, much less argued. The Supreme Court does not explain why it takes up the cases it takes up. But I have to say that it doesn’t seem very likely that the Supreme Court took up this case to affirm the Ninth Circuit’s holding. I have no idea how five or more votes on this case will line up, but if I had to predict I would guess that the Court will say that two-year statute of limitations in Section 16(b) operates as a statute of repose.

It seems that Judge Smith’s unusual appended opinion specially concurring in the holding but in effect dissenting from the Ninth Circuit’s precedent operated like an entreaty to the Supreme Court to clean up the situation.

The one wild card is that Chief Justice Roberts may not participate in this case. The Court’s June 27 order specifies that Roberts did not participate in consideration of the cert petition. He may be conflicted out, perhaps as a result of his prior activities while in private practice. If Roberts does not participate, the conservative majority that lined up together this past term on the Janus Capital and Wal-Mart Stores case may not be able to put together the five votes to control the outcome. In which case, the outcome of the Supreme Court review may be too close to call.

But in any event, next October we will enter yet another Supreme Court term with at least one securities case on the Court’s docket. I know for sure at least one blog post I will be writing somewhere between next October and next June.
Minneci v. Pollard

Ruling Below: Pollard v. The GEO Group, Inc., 629 F.3d 843 (9th Cir. 2010) cert. granted, 131 S. Ct. 2449, 179 L. Ed. 2d 1208 (U.S. 2011).

Defendant GEO Group maintains private prisons in contract with the federal government. Plaintiff Richard Lee Pollard alleges that while incarcerated at one of the defendant’s prisons, he fractured both elbows in a slip-and-fall accident. Pollard claims that he was then forced to wear a jumpsuit and restraint device that caused him severe pain and that no alternative arrangements were made while he was unable to feed or bathe himself in the following weeks. Pollard filed a claim against the prison (later removed due the Supreme Court’s holding in Correctional Services Corp. v. Malesko) and individual prison employees, asserting Eighth Amendment violations and seeking money damages under Bivens. The district court dismissed the claim, holding that GEO employees did not act under the color of federal law and that the existence of alternative state remedies precluded a Bivens action. The Ninth Circuit reversed the lower court on this issue, holding that the mere availability of alternative state law remedies does not preclude a Bivens action and that under the public function test, the GEO employees were acting under the color of federal law for the purposes of Bivens.

Question Presented: Whether the Court should imply a cause of action under Bivens v. Six Unknown Named Agents of Federal Bureau of Narcotics, against individual employees of private companies that contract with the federal government to provide prison services, when the plaintiff has adequate alternative remedies for the harm alleged and the defendants have no employment or contractual relationship with the government.

Richard Lee POLLARD, Plaintiff-Appellant,

v.

THE GEO GROUP, INC., Erroneously Sued as Wackenhut Corrections Corporation, dba Taft Correctional Institution; Margaret Minneci; Jonathan E. Akanno; Robert Spack; Bob D. Steifer; Becky Maness, Defendants-Appellees.

United States Court of Appeals for the Ninth Circuit


[Excerpt; some footnotes and citations omitted.]

PAEZ, Circuit Judge:

Plaintiff-Appellant Richard Lee Pollard, a federal inmate, appeals the district court’s order dismissing his Eighth Amendment claims against employees of a private corporation operating a federal prison under contract with the Bureau of Prisons. This appeal presents the question of whether the implied damages action first recognized in Bivens v. Six Unknown Named Agents of Federal Bureau of Narcotics, 403 U.S. 388, 91 S.Ct. 1999, 29 L.Ed.2d 619 (1971), allows a federal prisoner to recover for violations of his constitutional rights by employees of private corporations operating
federal prisons. We conclude that it does.

I. BACKGROUND

The GEO Group, Inc. (GEO), under contract with the federal Bureau of Prisons (BOP), has operated the Taft Correctional Institution (TCI) since December 1997. Pollard is a federal inmate who, in 2001 and 2002, was incarcerated at TCI. During his imprisonment, Pollard slipped on a cart left in a doorway and had to be seen by the prison's medical staff. He was x-rayed, diagnosed with possible fractures of both elbows, and placed in a bilateral sling. He was then referred to an orthopedic clinic outside the prison.

Before transporting Pollard to the clinic, a GEO employee directed him to don a jumpsuit. Pollard told the employee that putting his arms through the sleeves of the jumpsuit would cause him excruciating pain, but he was nonetheless required to put it on. Two employees also forced Pollard to wear a "black box" mechanical restraint device on his wrists despite Pollard's complaints about severe pain. An outside orthopedist diagnosed Pollard with serious injuries to his elbows and recommended that his left elbow be put into a posterior splint for approximately two weeks. Upon returning to TCI, Pollard was told that, due to limitations in staffing and facilities, his elbow would not be put into a posterior splint. Pollard claims that, in the following weeks, he was unable to feed or bathe himself and that the GEO employees failed to make alternative arrangements for him. He further alleges that he was required to return to work before his injuries had healed and was again forced to wear the "black box" restraint when returning to the outside orthopedic clinic for a follow-up appointment.

Pollard subsequently filed a pro se complaint in the United States District Court for the Eastern District of California, alleging violations of his Eighth Amendment rights and seeking money damages under Bivens. His first amended complaint named GEO and eight individuals as defendants. Seven of these individuals were employees of GEO at the time of Pollard's injuries. The eighth, Marshall Lewis, was a doctor employed by the Pacific Orthopedic Medical Group, which GEO had hired to treat Pollard. GEO was subsequently dismissed from the suit due to the Supreme Court's holding in Correctional Services Corp. v. Malesko, 534 U.S. 61, 122 S.Ct. 515, 151 L.Ed.2d 456 (2001), that private prison corporations are not subject to Bivens liability.

Pollard's suit against the remaining defendants was assigned to a magistrate judge for screening pursuant to 28 U.S.C. § 1915A(a). The Magistrate Judge issued proposed findings and a recommendation that Pollard's suit be dismissed under 28 U.S.C. § 1915A(b)(1) for failure to state a claim. Specifically, the Magistrate Judge concluded that a Bivens cause of action was not available to Pollard for two reasons: (1) state law provided him with alternative remedies for his injuries in the form of a tort action for negligence or medical malpractice; and (2) although under contract with the federal government, the GEO employees did not act under color of federal law. Pollard did not file objections to the Magistrate Judge's recommendation, and the district court adopted it in full and dismissed Pollard's complaint.

Shortly thereafter, Pollard, now represented by counsel, filed a motion to vacate the judgment. That motion requested that the
dismissal be vacated for the limited purpose of allowing Pollard to assert objections to the Magistrate Judge’s findings and recommendation, thereby preserving his right to appeal. The district court did not rule on the motion. Pollard ultimately filed a timely notice of appeal, which was served on the Acting Executive Assistant at TCI, but not on any of the individually named defendants personally. Before this court, only five of the original eight individual defendants filed an opposition brief.

We review de novo a district court’s grant of a motion to dismiss under 28 U.S.C. § 1915A.

II. PROCEDURAL CHALLENGES

III. DISCUSSION

We turn to the merits of this appeal. The district court dismissed Pollard’s suit pursuant to 28 U.S.C. § 1915A(b)(1) for failure to state a claim. Specifically, the Magistrate Judge’s findings and recommendation concluded that a Bivens action was not available to Pollard because: (1) the GEO employees do not act under color of federal law; and (2) Pollard could pursue a claim for damages against the GEO employees under state tort law. We address these issues in turn and conclude that (1) the GEO employees act under color of federal law for purposes of Bivens liability and (2) the availability of a state tort remedy does not foreclose Pollard’s ability to seek redress under Bivens. We recognize that the former holding directly conflicts with the Fourth Circuit’s holding in Holly v. Scott, 434 F.3d 287, 294 (4th Cir.2006), and the latter conflicts with both Holly and the Eleventh Circuit’s holding in Alba v. Montford, 517 F.3d 1249, 1254 (11th Cir.2008). We discuss our disagreement with our sister circuits infra.

1. Federal Action

In Bivens, the Supreme Court recognized an implied cause of action under the Fourth Amendment for injury caused “by a federal agent acting under color of his authority. . . .” 403 U.S. at 389, 91 S.Ct. 1999. It is widely accepted that Bivens provides a cause of action only against an official “acting under color of federal law.” Thus, the threshold question presented here is whether the GEO employees can be considered federal agents acting under color of federal law in their professional capacities. We conclude that they can.

We note at the outset that the one federal court of appeal to have directly addressed the question—the Fourth Circuit—has held that employees of private corporations operating federal prisons are not federal actors for purposes of Bivens. Holly, 434 F.3d at 294. In Holly, as in this case, the defendants were employees of GEO, which the Fourth Circuit described as “a wholly private corporation in which the federal government has no stake other than a contractual relationship.” Reasoning that “[a]pplication of Bivens to private individuals simply does not find legislative sanction,” the Holly majority held that the GEO employees were not federal actors for purposes of Bivens.

Neither the Supreme Court nor our court has squarely addressed whether employees of a private corporation operating a prison under contract with the federal government act under color of federal law. That said, we have held that private defendants can be sued under Bivens if they engage in federal action. In determining whether a private individual has engaged in federal action, we
have looked to "state action" principles developed by the Supreme Court in suits brought under 42 U.S.C. § 1983.

Other circuits have also recognized the similarity of the § 1983 and Bivens doctrines. Indeed, even the Supreme Court has recognized a connection between the two doctrines, although at a high level of abstraction.

In the § 1983 context, we have recognized a number of tests for identifying state action. For our purposes, the most applicable is the "public function" test: a private entity may engage in state action where it exercises "powers traditionally exclusively reserved to the State." In West v. Atkins, the Supreme Court applied a variation of that test in concluding that private correctional employees under contract with North Carolina were amenable to suit under § 1983 for failing to render constitutionally adequate medical care. See 487 U.S. 42, 49-51, 108 S.Ct. 2250, 101 L.Ed.2d 40 (1988).

The Court found state action present in the § 1983 action because the defendant exercised power "possessed by virtue of state law and made possible only because the wrongdoer is clothed with the authority of state law." Ten years before West, the Court had recognized an obligation on the part of state correctional employees "to provide medical care for those whom it is punishing by incarceration." In finding such an obligation under the Constitution, the Estelle Court reasoned that "[a]n inmate must rely on prison authorities to treat his medical needs; if the authorities fail to do so, those needs will not be met."

Similarly, in evaluating whether a prison physician employed as an independent contractor was amenable to suit under § 1983, the West Court stated:

If [the physician] misused his power by demonstrating deliberate indifference to [the prisoner's] serious medical needs, the resultant deprivation was caused, in the sense relevant for state-action inquiry, by the State's exercise of its right to punish [the prisoner] by incarceration and to deny him a venue independent of the State to obtain needed medical care.


In reaching this conclusion, the Court noted that "[i]t is only those physicians authorized by the State to whom the inmate may turn" and that "[u]nder state law, the only medical care [the prisoner] could receive for his injury was that provided by the State." The Court rejected the notion that, because the physician was an independent contractor rather than a direct employee of the prison, the state action analysis would change. Instead, the Court held that, "[w]hether a physician is on the state payroll or is paid by contract, the dispositive issue concerns the relationship among the State, the physician, and the prisoner." Thus, the Court concluded, because the private employee was "fully vested with state authority to fulfill essential aspects" of the state's duty to provide medical care to state prisoners, he was fulfilling a public function and was therefore amenable to § 1983 liability.

In our view, there is no principled basis to distinguish the activities of the GEO employees in this case from the governmental action identified in West. Pollard could seek medical care only from the GEO employees and any other private physicians GEO employed. If those employees demonstrated deliberate indifference to Pollard's serious medical
needs, the resulting deprivation was caused, in the sense relevant for the federal-action inquiry, by the federal government's exercise of its power to punish Pollard by incarceration and to deny him a venue independent of the federal government to obtain needed medical care. On this point, West is clear.

The Fourth Circuit does not share our understanding of West. The Holly majority concluded that West's reasoning does not apply to privately operated federal prisons because the relationship among the state, the physician and the prisoner is "very different in this case, where the correctional facility is privately run, than in West . . . , where the state itself was directly responsible for managing the prison." Curiously, the Fourth Circuit's reading of West suggests that independent contractors are state actors when directly hired by the state, but that employees of an independent contractor are not state actors because they are not hired by the state. We cannot subscribe to such an illogical reading of West. As Judge Motz noted in her concurrence in Holly, West itself rejected the notion that "by adding an additional layer, the government can contract away its constitutional duties." Instead, West makes clear that "[c]ontracting out care 'does not relieve' the government of its 'constitutional duty' to provide adequate care or 'deprive inmates of the means to vindicate their Eighth Amendment rights.'"

Nor do we find convincing the Fourth Circuit's reliance on Richardson v. McKnight, 521 U.S. 399, 117 S.Ct. 2100, 138 L.Ed.2d 540 (1997). Contrary to the Fourth Circuit's holding, that case does not stand for the proposition that private prison employees never act under color of federal or state law. Indeed, the Court in Richardson expressly noted that it did "not address[ ] whether the defendants are liable under § 1983 even though they are employed by a private firm." Rather, the Court there addressed only the question of whether private prison guards at state prisons are entitled to qualified immunity when sued for constitutional violations, not whether those guards acted under color of federal or state law. As other cases confirm, the immunity question is fundamentally distinct from the governmental action question we encounter here.

In Richardson, the Court explained that qualified immunity applies only where "a tradition of immunity was so firmly rooted in the common law . . . that Congress would have specifically so provided had it wished to abolish the doctrine." The Court noted that, although private individuals had operated correctional facilities in the 18th and 19th centuries, those individuals did not historically enjoy qualified immunity. Because there was therefore no "firmly rooted' tradition of immunity applicable to privately employed prison guards," those private guards were not entitled to qualified immunity.

Contrary to the Fourth Circuit's understanding, the Richardson Court's observation that private individuals "were heavily involved in prison management during the 19th century," does not mean that private prison guards exercise a power that is not "traditionally exclusively reserved to the State" under the public function test for identifying state action. The Holly majority looked to the "operation of the prison, not the fact of [the prisoner's] incarceration," to conclude that private prison guards did not perform a traditionally public function. The Holly majority, however, does not provide, nor can we identify, any support for such a distinction. The relevant function here is not prison management, but rather incarceration.
of prisoners, which of course has traditionally been the State’s “exclusive prerogative.” West reflects this understanding that the relevant function is incarceration, explaining that a prisoner’s injury from inadequate medical care would be “caused, in the sense relevant for state-action inquiry, by the State’s exercise of its right to punish [the prisoner] by incarceration.”

Likewise, in the § 1983 context, our sister circuits have routinely recognized that imprisonment is a fundamentally public function, regardless of the entity managing the prison. The Fifth Circuit, for example, has held that “confinement of wrongdoers—though sometimes delegated to private entities—is a fundamentally governmental function. These [private] corporations and their employees are therefore subject to limitations imposed by the Eighth Amendment.” Likewise, the Sixth Circuit has held that private prison employees “perform[ ] the ‘traditional state function’ of operating a prison.” And, in his dissent in Richardson, Justice Scalia, joined by three other Justices, noted that “private prison management firms, who perform the same duties as state-employed correctional officials, . . . exercise the most palpable form of state police power.”

In accord with West and other federal courts of appeal, we hold that there is but one function at issue here: the government’s power to incarcerate those who have been convicted of criminal offenses. We decline to artificially parse that power into its constituent parts—confinement, provision of food and medical care, protection of inmate safety, etc.—as that would ignore that those functions all derive from a single public function that is the sole province of the government: “enforcement of state-imposed deprivation of liberty.” Because that function is “traditionally the exclusive prerogative of the [government],” it satisfies the “public function” test under Rendell-Baker.

Finally, we note that in Malesko, the Supreme Court explicitly left open the possibility that private prison employees could act under color of federal law and therefore face Bivens liability. The Court, in holding that a corporate entity operating a federal prison could not be subject to Bivens liability, noted that “the question whether a Bivens action might lie against a private individual is not presented here.” Malesko, 534 U.S. at 65, 122 S.Ct. 515. The dissent, authored by Justice Stevens, confirmed that this question remained open:

The Court recognizes that the question whether a Bivens action would lie against the individual employees of a private corporation like Correctional Services Corporation (CSC) is not raised in the present case. Both CSC and [Malesko] have assumed Bivens would apply to [private prison employees], and the United States as amicus maintains that such liability would be appropriate under Bivens. . . . [T]he reasoning of the Court’s opinion relies, at least in part, on the availability of a remedy against employees of private prisons.

Id. at 79 n. 6, 122 S.Ct. 515 (Stevens, J., dissenting) (internal citation omitted).

Thus, despite the contrary holding in the Fourth Circuit, we conclude that the GEO employees act under color of federal law for purposes of Bivens liability.

2. Availability of a Bivens Remedy

Even where defendants have engaged in federal action, we do not always allow
Bivens suits to go forward. We begin with a review of the Supreme Court's evolving Bivens jurisprudence to help illuminate when we will recognize an implied right of action against individuals engaged in federal action.

In Bivens, the Supreme Court "recognized for the first time an implied private action for damages against federal officers alleged to have violated a citizen's constitutional rights." In the years following Bivens, the Court recognized a Bivens cause of action on only two occasions. In Davis v. Passman, 442 U.S. 228, 248-49, 99 S.Ct. 2264, 60 L.Ed.2d 846 (1979), the Court held that the plaintiff stated a cause of action for money damages against her former employer, a member of the United States Congress, for employment discrimination in violation of the Due Process Clause of the Fifth Amendment. The following year, in Carlson v. Green, 446 U.S. 14, 24, 100 S.Ct. 1468, 64 L.Ed.2d 15 (1980), the Court held that a federal inmate could bring suit for money damages against federal prison officials under the Eighth Amendment.

Since Carlson and Davis, the Supreme Court has "consistently refused to extend Bivens liability to any new context or new category of defendants." Indeed, the Court has "rejected invitations to extend Bivens "in every new factual and legal context presented after Carlson. Although Bivens remains intact, it is apparent that the era Justice Scalia referred to as the "heady days in which [the Supreme] Court assumed common-law powers to create causes of action" is no more.

The Court's most recent consideration of whether to extend Bivens distills its prior three decades of jurisprudence into a two part test:

[O]ur consideration of a Bivens request follows a familiar sequence, and on the assumption that a constitutionally recognized interest is adversely affected by the actions of federal employees, the decision whether to recognize a Bivens remedy may require two steps. In the first place, there is the question whether any alternative, existing process for protecting the interest amounts to a convincing reason for the Judicial Branch to refrain from providing a new and freestanding remedy in damages. But even in the absence of an alternative, a Bivens remedy is a subject of judgment: the federal courts must make the kind of remedial determination that is appropriate for a common-law tribunal, paying particular heed, however, to any special factors counselling hesitation before authoring a new kind of federal litigation.


Applying Wilkie's two-part test, we hold that a Bivens cause of action is available here.

a. Application of the Wilkie Two-Part Test

***

(i) Wilkie Part One: Alternative Existing Processes

The GEO employees argue that because Pollard can pursue a state law negligence action for damages, he has an "alternative, existing process" for protecting his interests
and thus should not be afforded a *Bivens* remedy. The Magistrate Judge agreed, stating in his recommendation and findings that “[i]n light of the existing alternative remedies available to [Pollard], the court finds that extending *Bivens* would not provide [Pollard] with an otherwise nonexistent cause of action.” Neither the Ninth Circuit nor the Supreme Court has ever addressed whether the existence of a state remedy, alone, is sufficient to displace the *Bivens* remedy. We conclude that the mere availability of a state law remedy does not counsel against allowing a *Bivens* cause of action.

In evaluating whether alternative, potential remedies preclude a *Bivens* action, the Court has consistently stressed that only remedies crafted by Congress can have such a preclusive effect. For example, in *Carlson*, the Court held that where “defendants show that Congress has provided an alternative remedy which it explicitly declare[s] to be a substitute for recovery directly under the Constitution and view[s] as equally effective,” no *Bivens* remedy is available. Likewise, in *Bush v. Lucas*, the Court held that the *Bivens* remedy for an alleged First Amendment violation was precluded by an “elaborate remedial system that has been constructed step by step” by Congress.

In *Malesko*, however, the Court implicitly suggested that non-congressionally created remedies might displace *Bivens*. There, the Court noted that it had consistently declined to extend *Bivens* except where the extension would “provide an otherwise nonexistent cause of action against individual officers alleged to have acted unconstitutionally, or [would] provide a cause of action for a plaintiff who lacked any alternative remedy for harms caused by an individual officer’s unconstitutional conduct.” The GEO employees, like the Fourth and Eleventh Circuits, place great weight on this “any alternative remedy” language. They argue that it shows that state tort law can preclude a *Bivens* remedy. *Wilkie*, however, demonstrates that this reads too much into the Court’s words in *Malesko*.

In *Wilkie*, the Court made clear that the mere existence of an alternative state remedy, alone, did not preclude a *Bivens* action. There, the Court noted that the plaintiff had “alternative, existing” remedies for the alleged violation of his Fifth Amendment rights, including state tort remedies, administrative claims against the Bureau of Land Management, and tort claims under the Federal Tort Claims Act. Even though the plaintiff undoubtedly had a “tort remedy” available to him, the Court concluded that because “the forums of defense and redress open to [the plaintiff] are a patchwork, an assemblage of state and federal, administrative and judicial benches applying regulations, statutes and common law rules,” “[i]t would be hard to infer that Congress expected the Judiciary to stay its *Bivens* hand, but equally hard to extract any clear lesson that *Bivens* ought to spawn a new claim.” Thus, the mere existence of a potential state law claim did not suffice to preclude a *Bivens* action.

Instead, the *Wilkie* opinion requires that we not simply inquire into the existence of alternative remedies generally, but rather that we ask whether “any alternative, existing process for protecting the interest amounts to a convincing reasons for the Judicial Branch to refrain from providing a new and freestanding remedy in damages.” For two reasons, state court remedies, alone, do not amount to such a “convincing reason.”

First, as *Wilkie* implies and the Court has repeatedly recognized, we consider
alternative remedies because the judicially created *Bivens* remedy should yield to congressional prerogatives under basic separation of powers principles. So too has this circuit recognized the importance of deferring to Congress in this arena.

Second, the Court has recognized that the policy “obviously” motivating *Bivens* was “that the liability of federal officials for violations of citizens’ constitutional rights should be governed by uniform rules.” In *Carlson*, the Court made a point of noting that the plaintiff’s action would have failed under the survivorship law of the forum state. The Court emphasized that “only a uniform federal rule of survivorship will suffice to redress the constitutional deprivation here alleged and to protect against repetition of such conduct.” As we recently noted in *Castaneda v. United States*, 546 F.3d 682, 701 (9th Cir.2008), *overruled on other grounds by Hui v. Castaneda*, ___ U.S. ___, 130 S.Ct. 1845, 176 L.Ed.2d 703 (2010), “the remedies we and the Supreme Court have held to preclude *Bivens* . . . applied uniformly throughout the republic.” Although *Castaneda* is no longer good law, this observation was not addressed by the Supreme Court and comports with our analysis of the Court’s *Bivens* jurisprudence. If we were to allow state tort law to preclude a *Bivens* action for Pollard and similarly situated prisoners, the liability of federal officials for constitutional violations would no longer be governed by uniform rules. The substance, procedural requirements, and remedies of state tort law—especially with regard to causes of action for negligence and medical malpractice—vary widely from state to state. For example, assuming Pollard were to bring a claim for medical malpractice under California law, the cap on his non-economic damages would be $250,000. But, under Oregon law (where Pollard was transferred in the midst of this litigation), Pollard’s medical malpractice claim would not be subject to the state’s non-economic damages cap. Likewise, the statute of limitations for bringing his suit under California law would be three years after the date of his injury or one year after he discovered the injury, whichever came first. But Oregon law would require Pollard to bring his suit within two years of discovering the injury. We need not belabor the obvious point that state tort remedies are anything but “uniform.”

The *Bivens* inquiry turns in part on “bedrock principles of separation of powers,” but concluding that a *Bivens* cause of action must yield to state tort law does little to demonstrate deference to congressional prerogatives. Thus, we conclude that state remedies alone are insufficient to displace a *Bivens* remedy under the first prong of the *Wilkie* test.

(ii) *Wilkie* Part Two: “Special Factors Counselling Hesitation”

*Wilkie*’s second step requires us to “weigh[] reasons for and against the creation of a new cause of action, the way common law judges have always done.” In other words, we must look to any “special factors counselling hesitation before authorizing a new kind of federal litigation.” The Court has emphasized that we must differentiate “special” factors from “any” factors. Although the Court has never compiled an exhaustive list of these “special” factors, some that the Court has previously considered include: (1) whether it is feasible to create a workable cause of action, (2) whether extending the cause of action would undermine *Bivens*’s deterrence goals, (3) whether an extension of *Bivens* would impose asymmetric liability costs on privately operated facilities as compared to
government-operated facilities, and (4) whether unique attributes of an area, like the military, give reason to infer that congressional inaction is deliberate. As the Court has already recognized a Bivens cause of action for inmates in government-run federal prisons, it appears that prisons do not have the types of unique attributes that counseled against recognizing a Bivens action for claims against the military in Chappell. Nor did the Court allude to any such unique attributes in Malesko. Thus, we address only the first three of these considerations.

(a) Feasibility

Pollard alleges a basic Eighth Amendment cause of action under Bivens. Since Carlson, courts have regularly recognized this type of action against federal prison officials, and the applicable standards are clear. There is no need for the district court to craft new standards or remedies to address Pollard’s claims. Accordingly, there are no feasibility concerns that would counsel hesitation under Wilkie.

By contrast, the regime the GEO employees propose—allowing a Bivens cause of action to go forward only where a plaintiff would otherwise have no alternative remedy—would likely be difficult to administer. The Eighth Amendment protects against conditions of confinement that “involve the wanton and unnecessary infliction of pain . . . [or are] grossly disproportionate to the severity of the crime warranting imprisonment.” But many acts meeting that standard may not be covered by state tort law. For example, a prison inmate deprived of access to a toilet for several days would have a strong case against prison officers under Bivens. But, although tort law imposes a duty on those with custody of another to protect that person “against unreasonable risk of physical harm,” it is unclear whether deprivation of a toilet would amount to “physical harm.” Likewise, it is unclear whether a deprivation of outdoor exercise would amount to a tort violation, despite our conclusion that such deprivation constitutes an Eighth Amendment violation in certain circumstances.

Nor is it apparent whether a prisoner could recover under state law for the denial of “basic necessities such as socks, toilet paper, and soap.” Although a district court considering a constitutional claim based on such injuries stated that the plaintiff had “adequate state tort remedies available . . . including, but not limited to, negligence and wantonness,” we find it somewhat less obvious which theory of state tort law, if any, would provide the plaintiff in that case with an opportunity for relief. A plaintiff might also seek to recover under an intentional infliction of emotional distress theory of recovery, but that cause of action has its own problems given that prison disciplinary measures regularly cause emotional distress by design.

These are not isolated examples, and the inquiry becomes even more complicated when a prisoner alleges an Eighth Amendment violation as the result of a combination of factors that may not, on their own, constitute a violation of state tort law. Indeed, this very problem of identifying whether state common law provides a remedy is likely to arise any time constitutional and state common law regulate similar conduct in different ways.

The dissent argues that these obvious difficulties are irrelevant because Pollard’s injuries are “certainly . . . covered by state tort law.” Dissenting Op. at 875. But this decision will have implications far beyond Pollard’s suit. Under the GEO employees’
proposed framework, as adopted by the dissent, in each case a court would need to identify whether state remedies provide relief for the plaintiff’s particular claim. While in some instances that may prove an easy task, in others, like those identified above, it may be quite difficult. For questions of first impression, it would require a federal court to examine: (1) state common law, (2) state statutes, (3) state administrative regulations, (4) state constitutional provisions, (5) procedural requirements attendant to each alternative claim (including statutes of limitations, exhaustion requirements, etc.), and (6) the existence of a cause of action to enforce state law. Furthermore, under the GEO employees’ proposed framework, courts would potentially need to consider whether a plaintiff’s claims would be frustrated by any viable defenses under state law. For example, a privately operated prison might assert the “government contractor” defense if sued under state tort law. Thus, unless such defenses are assessed prior to dismissing a Bivens action because of alternative state remedies, a prisoner in a privately operated facility may be foreclosed from relief, even though a prisoner housed in a governmentally run prison would have a cause of action. But, in the context of prisoner litigation, a court would often be required to make these types of determinations before the defendant has asserted any defenses or made any filing whatsoever (as was the case here). It is also worth noting that, in light of the ever-rising percentage of federal inmates incarcerated in private prison facilities, federal courts would be increasingly asked to make these types of determinations.

In sum, a Bivens cause of action for prisoners’ Eighth Amendment claims would be fairly straightforward to apply. By contrast, it would be difficult to administer a regime where Bivens claims were allowed to proceed only when state law would offer no remedy. While these observations are by no means dispositive of the question here presented, under Wilkie we are bound to consider them in deciding whether to allow a “new” cause of action to proceed, “the way common law judges have always done.”

(b) Deterrence

The Court has also looked to whether extending Bivens would undermine the “core purpose” of an implied cause of action: deterring individual officers from committing constitutional violations. Allowing a Bivens action to go forward here would not undermine that core purpose.

In Meyer, the Court declined to extend Bivens to permit suit against a federal agency, reasoning that plaintiffs could be expected to always choose to sue the federal agency over an individual who could assert qualified immunity as an affirmative defense. 510 U.S. at 485, 114 S.Ct. 996. To the extent that aggrieved parties would have “less incentive to bring a damages claim against individuals, ‘the deterrent effects of the Bivens remedy would be lost.’” Thus, Meyer concluded that allowing a Bivens claim against federal agencies “would mean the evisceration of the Bivens remedy, rather than its extension.”

In Malesko, the Court echoed this reasoning in concluding that allowing Bivens suits to proceed against private prison corporations would undermine the deterrent effects of Bivens. According to the Court, “if a corporate defendant is available for suit, claimants will focus their collection efforts on it, and not the individual directly responsible for the alleged injury.” Thus, recognizing that corporations would likely
bear the lion’s share of responsibility for *Bivens* damages if subject to an implied cause of action under the Constitution, the Court concluded that the deterrence goals of *Bivens* would be undermined by such an extension. Whatever deterrent effect a suit against a corporation may have, the Supreme Court explicitly rejected the notion that corporate deterrence is relevant to the core deterrence goals of *Bivens*.

The instant case does not present the same problems. It simply cannot be disputed that allowing *Bivens* suits against private prison employees would not undermine *Bivens*’s goal of deterring unconstitutional acts by individuals. The dissent argues that state tort remedies are “superior” to a *Bivens* remedy here, Dissenting Op. at 871, and that allowing Pollard to bring a *Bivens* action would not serve *Bivens*’ goal of deterrence, Dissenting Op. 875-76. We disagree. It is true that state tort remedies may often serve to deter unconstitutional conduct, and that it may be easier to prevail on such a claim than on an Eighth Amendment *Bivens* claim. Indeed, in an action to recover damages for personal injuries under state tort theories such as negligence or medical malpractice, the plaintiff would not be required to prove deliberate indifference, as required to establish an Eighth Amendment violation. But while we acknowledge that the elements of a state tort claim may not be as demanding, we are not prepared to say that *Bivens* would have no marginal deterrent effect against individual employees of GEO.

For instance, in some states, a prisoner in Pollard’s position must submit a declaration by a physician attesting that the suit is not frivolous. It is unclear how a prisoner like Pollard, who filed this claim *in forma pauperis*, would be able to secure such a declaration. The Eleventh Circuit in *Alba* concluded that a similar certification requirement in Georgia did not render the inmate’s state remedies ineffective because it merely placed him in “the same shoes as anyone else in Georgia filing a professional malpractice claim,” under “no stricter rules than the rest of Georgia’s residents.” But federal courts have long recognized that inmates proceeding *pro se* are not in the “same shoes” as other citizens.

Additionally, *Bivens* may allow for recovery of greater damages in some cases than a state tort law remedy. As discussed *infra*, were Pollard to bring a claim for medical malpractice under California law, there would be a cap on the amount of non-economic damages he could recover. There is no similar cap on non-economic damages under *Bivens*. Thus, for a truly egregious case of neglect or abuse, a medical professional at a privately operated prison would face significantly greater liability under *Bivens* than state tort law. Furthermore, to be entitled to punitive damages under California law, a plaintiff must demonstrate “oppression, fraud, or malice.” By contrast, once a plaintiff has successfully met the “deliberate indifference” standard under the Eighth Amendment—requiring that the conduct be “wanton,” there is little more that such a plaintiff would need to prove to establish a convincing argument for an award of punitive damages. These significant differences in the potential liability faced by privately operated federal prisons are prime examples of the “marginal deterrence” that *Bivens* offers. Thus, we do not find that this “special factor” counsels hesitation.

(c) Asymmetrical Liability Costs

The Court has also expressed concerns about imposing asymmetric liability costs on privately operated facilities as compared to government-operated facilities. We are
equally concerned about issuing a decision that will yield disparate rights and remedies among inmates in private and public prisons. Unfortunately, under the current *Bivens* regime, asymmetries may remain irrespective of whether we recognize or deny a *Bivens* cause of action here.

Unlike officers employed by public prisons, the GEO employees may not be entitled to qualified immunity, and as a result, prisoners asserting claims against them may be able to recover more often than their counterparts in governmentally run prisons. We need not decide the issue of qualified immunity here.

On the other hand, if we conclude that Pollard cannot bring a suit under *Bivens*, then only inmates in public prisons will be able to vindicate their constitutional rights. Prisoners would thereby have entirely different rules governing their rights depending upon whether they are incarcerated in a public or private prison (and, for that matter, in which state the private prison is located). This outcome is equally undesirable. As asymmetries will persist irrespective of the outcome of this case, this consideration does not counsel hesitation in recognizing a *Bivens* remedy here.

IV. CONCLUSION

We conclude that Pollard’s suit under *Bivens* against the GEO employees for alleged violations of his Eighth Amendment rights should be allowed to proceed. We reach that conclusion because (1) the GEO employees act “under color of federal law” for purposes of *Bivens* liability; and (2) a faithful application of Wilkie’s two-part test counsels that state tort remedies alone are insufficient to displace *Bivens* and there are no “special factors counselling hesitation” in allowing Pollard’s suit to proceed. We therefore reverse and remand to the district court for further proceedings consistent with this opinion. To the extent Pollard’s appeal seeks to challenge the district court’s dismissal of GEO from the lawsuit, we affirm the district court’s disposition as to that issue.

AFFIRMED IN PART, REVERSED IN PART, REMANDED.

RESTANI, Judge, concurring in part and dissenting in part:

I agree that the district court properly dismissed GEO from the lawsuit and that employees of a private corporation operating a federal prison are federal government actors. I conclude, however, that we would err by creating a split in the law of the various circuits by holding that a prisoner may maintain a cause of action under *Bivens* ... against such employees where adequate state law remedies exist. Until now, the federal circuits that have addressed the issue have held correctly that a prisoner may not maintain such an action. The evolution of the U.S. Supreme Court’s *Bivens* jurisprudence confirms that this Court should follow their lead.

I. The Supreme Court has limited *Bivens* to cases in which no alternative remedy is available against the federal actor who committed the wrong.

The majority overlooks the reality that the Supreme Court has recognized *Bivens* causes of action only where federal officials, by virtue of their position, enjoy impunity, if not immunity, from damages liability because of gaps or exemptions in statutes or in the common law....
The Supreme Court has only extended *Bivens* twice, “to provide an otherwise nonexistent cause of action against *individual officers* alleged to have acted unconstitutionally, or to provide a cause of action for a plaintiff who lacked *any alternative remedy* for harms caused by an individual officer’s unconstitutional conduct.”

[The Court then summarizes *Davis* and *Carlson*.]

Thus, the Supreme Court has recognized *Bivens* claims only “for want of other means of vindication,” as “*Davis* had no other remedy, *Bivens* himself was not thought to have an effective one, and in *Carlson* the plaintiff had none against Government officials.” As the majority notes, the Court has set forth two-step test to determine whether to recognize new *Bivens* actions. Since *Carlson*, however, the Court has “consistently refused to extend *Bivens* liability to any new context or new category of defendants.”

II. The justifications for recognizing *Bivens* actions do not apply here.

A. Adequate alternative remedies are available to Pollard.

Here, ordinary state tort remedies for negligence or medical negligence against the GEO employees are an adequate, alternative, existing process for protecting Pollard’s interest. Where, as here, the plaintiff has an alternative remedy against a federal official alleged to have acted unconstitutionally, the Supreme Court has “consistently rejected invitations to extend *Bivens*.” Unlike *Bivens*, in which alternative state tort remedies were inadequate because the plaintiff’s lack of resistance to the federal agents foreclosed a trespass action, Pollard’s “claim of negligence or deliberate indifference requires no resistance to official action.” Additionally, employees of private prison corporations do not enjoy impunity or immunity as to damages because of gaps or exemptions in statutes or in the common law.

In fact, as the majority concedes, tort remedies for negligence and medical negligence may be even more easily obtained than remedies under *Bivens* for an Eighth Amendment violation “because the heightened ‘deliberate indifference’ standard of Eighth Amendment liability would make it considerably more difficult for [a plaintiff] to prevail than on a theory of ordinary negligence.” Thus, Pollard does not lack effective remedies because his “alternative remedies are at least as great, and in many respects greater, than anything that could be had under *Bivens*.” The state tort remedies for negligence or medical negligence are therefore a more than adequate alternative, existing process for protecting Pollard’s interest.

B. The availability of tort remedies is a convincing reason to refrain from recognizing a new damages remedy.

The availability of a superior alternative remedy is a convincing reason for the Judicial Branch to refrain from providing a new, freestanding damages remedy. Courts are reluctant to recognize new *Bivens* actions, which are implied without any Congressional authority, because “[s]o long as the plaintiff ha[s] an avenue for some redress, bedrock principles of separation of powers foreclose[ ] judicial imposition of a new substantive liability.” “The dangers of overreaching in the creation of judicial
remedies are particularly acute where such remedies are unnecessary." Because a Bivens action is unnecessary against the employees of a private prison corporation, we should not recognize such an action.

III. The availability of a state tort remedy may preclude a Bivens action.

The majority's conclusion that the availability of state remedies is not a convincing reason for the judiciary to refrain from recognizing a Bivens remedy is based on the faulty premises that remedies that preclude Bivens must (1) be crafted by Congress and (2) "appl[y] uniformly throughout the republic." The first is wrong because the Supreme Court actually has considered remedies not crafted by Congress, and Malesko itself is one instance in which the Court declined to recognize a Bivens action because of state remedies. The second is wrong because the need for uniformity is not particularly compelling where the persons who harmed the plaintiff are private employees of a private entity.

A. The Supreme Court has declined to recognize a Bivens action because of state remedies.

Recent Supreme Court precedent makes clear that a state tort remedy may be an alternative, existing process that precludes recognition of a Bivens action. In Malesko, the Court "consider[ed] availability of state tort remedies in refusing to recognize a Bivens remedy." The Court also has "rejected the claim that a Bivens remedy should be implied simply for want of any other means for challenging a constitutional deprivation in federal court." Thus, an alternative remedy need not be a federal remedy.

There is some tension between Malesko and other recent Supreme Court cases, and Carlson, which suggested that the only kind of alternative remedy that could defeat a Bivens claim was one provided by Congress "which it explicitly declared to be a substitute for recovery directly under the Constitution and viewed as equally effective." The tension, however, can be resolved by understanding the Carlson formulation as a "test for express Bivens preemption" by a statute. Malesko, which did not involve any statute, did not discuss this test. The Supreme Court has determined that alternative remedies that are not expressly authorized by Congress and are not an equally effective substitute nonetheless may preclude a Bivens remedy. More recently, in a case in which express statutory preemption was not at issue, the Supreme Court has stated that it will not recognize a new Bivens action if "any alternative, existing process for protecting the interest amounts to a convincing reason for the Judicial Branch to refrain." Finally, even if Carlson and Malesko are truly irreconcilable, we should follow the most recent Supreme Court precedent, Malesko.

The majority's statement that in Wilkie, the existence of an alternative state remedy alone was not sufficient to preclude a Bivens action, Maj. Op. at 861, is misleading. Rather, in Wilkie, the Supreme Court considered that the plaintiff had "an administrative, and ultimately a judicial, process for vindicating virtually all of his complaints" for torts, improper criminal charges, unfavorable agency actions, and other offensive behavior by the Bureau of Land Management. The Court, however, found that the plaintiff functionally did not have a remedy for his true complaint regarding the agency's course of dealing as a whole because "the forums of defense and redress open to [the plaintiff] are a patchwork, an assemblage of state and
federal, administrative and judicial benches applying regulations, statutes and common law rules.” It is too much of a stretch to infer, as the majority does, that if the plaintiff had merely complained of one or more torts, the Court would have reached the same result. To the contrary, the Court noted that “when the incidents are examined one by one, [the plaintiff’s] situation does not call for creating a constitutional cause of action for want of other means of vindication.” Further, the Wilkie Court concluded that, even where the remedies available are a patchwork, the need for a Bivens remedy is not particularly compelling, as “[t]he question whether [an] action for violations by federal officials of federal constitutional rights should be governed by uniform rules” and that “[t]he question whether [an] action for violations by federal officials of federal constitutional rights should be left to the vagaries of the laws of the several States admits of only a negative answer in the absence of a contrary congressional resolution.” Specifically, the Court concluded that a uniform federal rule of survivorship for Eighth Amendment Bivens claims was necessary where one state’s law would permit survival of the claims but another would not. Essentially, state law previously had dictated whether the prisoner’s claim died with him.

Here, however, the need for uniformity of rules is much less compelling. First, although employees of a private corporation operating a federal prison may be government actors, they are not federal officials and do not have the same immunities as federal officials. Second, ordinary negligence and medical negligence causes of action are already universally available against employees of a private corporation operating a federal prison, and the elements of such common law-derived causes of action are fundamentally the same in every state.

Unlike in Carlson, no individual state law forecloses or extinguishes such actions altogether, although many states have enacted various procedural hurdles and limits on non-economic damages in medical malpractice suits. The majority points to the differences between the California and Oregon statutes of limitations and the fact that Pollard’s medical malpractice claim would be subject to a non-economic damages cap under California law but not under Oregon law. Maj. Op. at 862-63. These differences, however, should not be determinative, as an alternative remedy need not provide complete relief for the plaintiff. Rather, as the Eleventh Circuit has held, “[t]hat state procedural rules complicate the filing of a lawsuit does not mean that a plaintiff lacks any alternative remedy for harms caused by an individual officer’s unconstitutional conduct,” and procedural hurdles in filing a state action do not “render state relief unavailable in the same vein in which the Supreme Court held it to be unavailable in Bivens.”

IV. Special factors also counsel hesitation in recognizing a new Bivens action.

The availability of an adequate alternative remedy should end the analysis. The court need not look at other special factors, such as whether extending the cause of action
would: (1) be feasible, (2) serve Bivens's deterrence goals, or (3) impose asymmetric liability costs. In any event, these factors do counsel hesitation here and certainly do not counsel in favor of recognizing a new Bivens action, as the majority suggests.

A. Case-by-case Bivens determinations are feasible.

First, although a Bivens action under the Eighth Amendment for prisoners is a workable cause of action that is recognized already, allowing a Bivens action to go forward only where a plaintiff would otherwise have no alternative remedy is not unduly complicated. Rather, the Supreme Court appears to prefer case-by-case determinations of whether adequate alternative remedies exist to a blanket determination that Bivens is available to an entire class of plaintiffs. Thus, the Supreme Court has invited federal courts to determine whether an alleged Eighth Amendment violation has a state law analogue and apply Bivens only if there is no such state analogue.

Further, the current system of determining whether a state analogue exists is easy to administer because there is unlikely to be an instance in which an Eighth Amendment violation by a private prison employee is not a tort. An Eighth Amendment violation requires a "sufficiently serious" condition and "deliberate indifference" to inmate health or safety. Tort law similarly imposes a duty of care on jailers or prison employees to protect the life and health of prisoners in their custody and protect the prisoners from foreseeable harm or unreasonable risk of physical harm. Breach of this duty may give rise to a negligence claim.

The majority does not contend that the acts alleged here fall into the category of acts that violate the Eighth Amendment but are not covered by state tort law, and that is not the case. California, Oregon, and every other state recognize the torts of negligence and medical negligence. The tort of negligence also covers Pollard's allegation that the prison employees deprived him of food while his arms were in casts, as numerous cases recognize that the keeper of a jail has a common law duty to provide prisoners with food.

There is no reason to think that either federal preemption or the government contractor defense, which the majority mentions, is applicable here. No federal law expressly or impliedly preempts or directly conflicts with a state tort of negligence or medical malpractice here, and federal law does not occupy the field governing private corrections employees' actions. The government contractor defense is not likely to apply because there is no indication that the United States directed the GEO employees' treatment of Pollard.

Because the conduct at issue here certainly is covered by state tort law, the other examples the majority posits that may violate the Eighth Amendment of the Constitution but may not be covered by tort law are inapposite. In any event, I am not convinced that any of these acts—denying a prisoner access to a toilet and thus exposing the prisoner to human waste for thirty-six hours, depriving a prisoner of basic necessities, completely depriving a prisoner of outdoor exercise for a period of years, and exposing a prisoner to other unhygienic conditions—would not be covered by tort law. Rather, each act involves a clear breach of the duty of reasonable care and would unreasonably jeopardize a prisoner's health.

B. Recognizing a Bivens action here would not deter individual officers.
Second, as the majority recognizes, state tort liability deters private prison officials from wrongdoing and may even provide more relief for Pollard than the Eighth Amendment would because the deliberate indifference standard for Eighth Amendment claims creates a high bar to hurdle. Maj. Op. at 866-67. This undermines the deterrence analysis. Because “[t]he purpose of Bivens is to deter individual federal officers from committing constitutional violations,” the purpose of Bivens is not served where, as here, state law already allows for compensatory and punitive damages for the same conduct. In such an instance, a Bivens action is unnecessary. Further, it is difficult to see how potential procedural differences in state laws or between the state and federal law would figure into deterrence as a practical matter. As discussed supra, the court should hesitate to create an unnecessary judicial remedy.

C. Declining to recognize a Bivens action here would avoid concerns about asymmetrical liability costs.

Finally, declining to recognize a Bivens action here would avoid the concerns that the Supreme Court has expressed about imposing asymmetrical liability costs. Although declining to recognize a Bivens action would perpetuate an existing public-private asymmetry because Bivens actions are permitted against federal prison employees but not private prison employees, declining to create a Bivens action would not “impose costs on one wrongdoer and not another.” By contrast, recognizing that a plaintiff may pursue both a Bivens action and a tort action against private prison employees may impose asymmetrical liability costs, as a plaintiff currently may assert tort claims against private prison employees, while Bivens actions allow for recovery from federal employees where the FTCA otherwise bars tort claims against them. Indeed, as the majority notes, plaintiffs may be able to recover from private prison employees more often than from federal prison employees because private prison employees may not be entitled to qualified immunity.

V. Conclusion

I would join with other circuits in concluding that a Bivens cause of action is not available against employees of privately-run prison corporations where, as here, state tort laws provide a remedy. Accordingly, I respectfully dissent in part.
In the 40 years since the Supreme Court first created a right to sue a federal official for a violation of someone’s constitutional rights, it has been very sparing in allowing later attempts to expand that right. In fact, it has only twice added new options to file such lawsuits—and the last of those was approved 31 years ago. On Monday, the Court took on a new test case on the issue, but the chances are, it did so to once more stop a further expansion. This time, it will be confronting a constitutional claim for damages not against a public official, but against private individuals working under government contract—potentially, a far-reaching new option to sue.

The basic decision at issue is the Justices’ ruling in 1971, in Bivens v. Six Unknown Federal Narcotics Agents, in which the Court for the first time opened the federal courthouses to a type of lawsuit not authorized by any federal statute, but created solely by court decree—a right to sue for a claimed violation of one’s constitutional rights, when there was no other available remedy.

In the beginning, in Bivens, the Court authorized a constitutional lawsuit seeking $15,000 in damages against six narcotics agents who forced their way into a New York City apartment without a warrant, threatened to arrest the entire family, searched the apartment unit from end to end, then took the father into custody and subjected him to a “visual strip search.” The father, Webster Bivens, had no other remedy for this alleged Fourth Amendment violation, the Court concluded.

Eight years later, in Davis v. Passman, the Court allowed a Bivens-type lawsuit against a member of Congress for alleged sexual harassment of a female staff member. In the last such ruling, in Carlson v. Green in 1980, the Court permitted a mother to sue a public officer of a prison after her prisoner son had died, allegedly because prison officials failed to provide proper medical care for his chronic asthma. The Court has had multiple requests since then to add new categories of Bivens claims, but regularly has refused to do so.

Last June, the Ninth Circuit Court added a new Bivens-type claim: it ruled that a prison inmate, Richard Lee Pollard, could sue a group of private individuals working under contract as prison guards for Wackenhut Corrections Corp., the operator of the federal prison in Taft, Calif. Pollard contended that he broke his elbow in a fall after tripping over a cart left in a hallway, but that prison guards required him to make use of the arm in painful ways in taking him to and from an outside clinic for treatment, refused to provide a splint for the injury though a doctor had prescribed one, and was required to return to work at a prison job before he had healed fully. (Wackenhut has since become a part of GEO Corp.)

The Circuit Court remarked that “neither the Supreme Court nor our court has squarely addressed whether employees of a private corporation operating a prison under contract with the federal government act under color of federal law.” It went on to rule that their actions were as if they had been federal employees, and the fact that the
prisoner could have sued under California state law did not deprive him of a federal constitutional remedy. Over the dissent of eight judges, the Circuit Court refused to reconsider the ruling en banc.

On Monday, the Supreme Court agreed to review the decision, in the case of Minneci, et al., v. Pollard (docket 10-1104).

At this stage, the Court does not explain why it will hear a case, but the ruling by the Ninth Circuit conflicts directly with decisions of two other Circuit Courts (the Fourth and the Eleventh), and involves the creation of a perhaps wide expansion of the Bivens decision. The private organization, DRI, which seeks to curb civil liability in general, told the Court in a separate amicus brief that the Ninth Circuit ruling “takes Bivens into uncharted territory by exposing private employees to an unprecedented form of personal liability,” and potentially may extend Bivens-type liability well beyond the prison setting, given how common it is for private employees to work under contract for federal agencies.

***
A federal prison inmate could seek damages for a violation of his constitutional rights from the employees of a private company that operated the facility, the 9th Circuit has ruled in reversing judgment.

The plaintiff was an inmate at a federal prison in California. A private company operated the facility under a contract with the government.

The plaintiff filed a Bivens claim against seven employees of the private contractor, alleging that his Eighth Amendment rights were violated by their failure to provide appropriate medical treatment for broken elbows he suffered in a fall.

The defendants argued that a Bivens claim cannot be maintained against the employees of a private company.

But the court decided that the employees in this case could be considered federal agents acting under color of federal law for the purpose of a Bivens claim.

The court said that there was “no principled basis” to distinguish the activities of the private employees in this case from governmental action.

“[The plaintiff] could seek medical care only from the [contractor’s] employees and any other private physicians [the contractor] employed. If those employees demonstrated deliberate indifference to [the plaintiff’s] serious medical needs, the resulting deprivation was caused, in the sense relevant for the federal-action inquiry, by the federal government’s exercise of its power to punish [the plaintiff] by incarceration and to deny him a venue independent of the federal government to obtain needed medical care,” the court said.

It noted a contrary decision from the 4th Circuit.
"Should Private Prison Guards Be Liable Under Bivens?"

The CockleBur
May 27, 2011
Shon R. Hopwood

The Supreme Court granted certiorari last week almost assuredly to reverse a Ninth Circuit ruling creating a Bivens action for prisoners wanting to sue prison personnel at privately-run correctional facilities. The case is Minneci, et al., v. Pollard, No. 10-1104.

After having read the lower court decision and cert-stage briefs, I am of the opinion that there is a .001 percent chance the Supreme Court will uphold the Ninth Circuit's judgment.

Not only does the current Court take a dim view of creating implied causes of action, some members of the Court also generally discount claims that prisoners who suffer abuse are entitled to any Eighth Amendment protection, and they would prefer that the federal judiciary stay out of squabbles over prison conditions, period. So I am not hopeful that the Court will give federal prisoners another forum to sue prison employees.

But even I—someone who advocates for holding prisoner personnel accountable for their wrongdoing—acknowledge that a Bivens action in this case makes little sense. The prisoner in this case was serving federal time in a privately-owned prison and had a superior state negligence remedy; one that would not involve navigating the difficult "deliberate indifference" standard or qualified immunity. If I was a prisoner plaintiff, I would much rather bring my claim in state court.

Since the prisoner had an alternative remedy, there is no chance ... the Court will allow an extension of Bivens. Let's just hope the Court doesn't feel the need to retreat or overrule Bivens because that would have drastic consequences for the growing federal prison population.

The privatization of prisons has become a recent news item. It appears that Florida is closing a deal to privatize the entire state prison system. The private prison industry is touting the deal as "an important milestone," most likely because Florida has the nation's third largest prison system.

I wonder what the incentive is for private companies to provide job training and rehabilitation programs which would help prevent inmates from returning to very prisons that make them money.

In Maine, there is a debate over a bill that would allow a private prison company to construct a 100 million dollar prison. When one of the State Senators was asked to defend the bill, he forthrightly pronounced:

"I don't know much about prisons, but I do know about jobs and I know that the people I represent need more and better jobs. I could pretend this bill is all about prisons, but it is really a jobs bill. It is time those of us in Augusta stopped pretending that everything is all right and started doing more to create a climate where the jobs we need can be created."

Creating jobs by incarcerating his constituents? It sounds like a solid policy to me.
Thankfully there are two sides to this argument: "Opponents argued that a prison should not be used as an economic development tool and cited studies that reportedly show private prisons do not save states money. Religious leaders opposed the bill on moral grounds."

Even the number one argument for privatizing prisons is being questioned, this time in a story by the *New York Times*.

"There's a perception that the private sector is always going to do it more efficiently and less costly," said Russ Van Vleet, a former co-director of the University of Utah Criminal Justice Center. "But there really isn't much out there that says that's correct."
Kiobel v. Royal Dutch Petroleum Co.

10-1491

Ruling Below: Kiobel v. Royal Dutch Petroleum Co., 621 F.3d 111 (2d Cir. 2010) reh'g denied, 642 F.3d 268 (2d Cir. 2011).

The Plaintiffs in this case are individuals seeking to hold a series of corporations civilly liable under the Alien Tort Statute (ATS) for alleged human rights violations in Nigeria. Plaintiffs claim defendant corporations aided and abetted the Nigerian government’s violations of international law. The district court dismissed the claims as falling outside the subject matter jurisdiction of the ATS. The Second Circuit affirmed, holding that corporations, as juridical rather than natural persons, cannot be subject to suit under the ATS. The majority noted that suits under the ATS require liability under international law and defined international law as essentially a universal norm observed by all nations. They observed that nothing in the history of international law, authoritative treaties, or scholarly works supports the idea that corporate liability is a universally approved notion and thus falls outside of international law and therefore the ATS. The concurrence characterized the issue differently, finding the international community to be purposely silent on the issue of corporate liability. Judge Leval reasoned that this silence is a result of international law being structured to define broad prohibitions and leave enforcement of these prohibitions up to individual nations. Judge Leval regarded the ATS as a decision by the United States to enforce international law by allowing civil suits against persons, which under U.S. legal doctrine include corporations.

Questions Presented: (1) Whether the issue of corporate civil tort liability under the Alien Tort Statute ("ATS"), 28 U.S.C. § 1350, is a merits question, as it has been treated by all courts prior to the decision below, or an issue of subject matter jurisdiction, as the court of appeals held for the first time. (2) Whether corporations are immune from tort liability for violations of the law of nations such as torture, extrajudicial executions or genocide, as the court of appeals decisions provides, or if corporations may be sued in the same manner as any other private party defendant under the ATS for such egregious violations, as the Eleventh Circuit has explicitly held.


United States Court of Appeals for the Second Circuit

Decided September 17, 2010

[Excerpt; some footnotes and citations omitted.]
JOSE A. CABRANES, Circuit Judge:

Once again we consider a case brought under the Alien Tort Statute ("ATS"), 28 U.S.C. § 1350, a jurisdictional provision unlike any other in American law and of a kind apparently unknown to any other legal system in the world. Passed by the first Congress in 1789, the ATS lay largely dormant for over 170 years. Judge Friendly called it a "legal Lohengrin"—"no one seems to know whence it came." Then, in 1980, the statute was given new life, when our Court first recognized in Filartiga v. Pena-Irala that the ATS provides jurisdiction over (1) tort actions, (2) brought by aliens (only), (3) for violations of the law of nations (also called "customary international law" including, as a general matter, war crimes and crimes against humanity-crimes in which the perpetrator can be called "hostis humani generis, an enemy of all mankind."

Since that time, the ATS has given rise to an abundance of litigation in U.S. district courts. For the first fifteen years after Filartiga—that is, from 1980 to the mid-1990s—aliens brought ATS suits in our courts only against notorious foreign individuals; the first ATS case alleging, in effect, that a corporation (or "juridical" person) was an "enemy of all mankind" apparently was brought as recently as 1997.

Such civil lawsuits, alleging heinous crimes condemned by customary international law, often involve a variety of issues unique to ATS litigation, not least the fact that the events took place abroad and in troubled or chaotic circumstances. The resulting complexity and uncertainty—combined with the fact that juries hearing ATS claims are capable of awarding multibillion-dollar verdicts—has led many defendants to settle ATS claims prior to trial. Thus, our Court has published only nine significant decisions on the ATS since 1980 (seven of the nine coming in the last decade), and the Supreme Court in its entire history has decided only one ATS case.

Because appellate review of ATS suits has been so uncommon, there remain a number of unresolved issues lurking in our ATS jurisprudence-issues that we have simply had no occasion to address in the handful of cases we have decided in the thirty years since the revival of the ATS. This case involves one such unresolved issue: Does the jurisdiction granted by the ATS extend to civil actions brought against corporations under the law of nations?

Plaintiffs are residents of Nigeria who claim that Dutch, British, and Nigerian corporations engaged in oil exploration and production aided and abetted the Nigerian government in committing violations of the law of nations. They seek damages under the ATS, and thus their suit may proceed only if the ATS provides jurisdiction over tort actions brought against corporations under customary international law.

A legal culture long accustomed to imposing liability on corporations may, at first blush, assume that corporations must be subject to tort liability under the ATS, just as corporations are generally liable in tort under our domestic law (what international law calls "municipal law"). But the substantive law that determines our jurisdiction under the ATS is neither the domestic law of the United States nor the domestic law of any other country. By conferring subject matter jurisdiction over a limited number of offenses defined by customary international law, the ATS requires federal courts to look beyond rules.

---

3 In this opinion we use the terms "law of nations" and "customary international law" interchangeably.
of domestic law—however well-established they may be—to examine the specific and universally accepted rules that the nations of the world treat as binding in their dealings with one another. As Judge Friendly carefully explained, customary international law includes only "those standards, rules or customs (a) affecting the relationship between states or between an individual and a foreign state, and (b) used by those states for their common good and/or in dealings inter se."

Our recognition of a norm of liability as a matter of domestic law, therefore, cannot create a norm of customary international law. In other words, the fact that corporations are liable as juridical persons under domestic law does not mean that they are liable under international law (and, therefore, under the ATS). Moreover, the fact that a legal norm is found in most or even all "civilized nations" does not make that norm a part of customary international law. As we explained in Filartiga:

> [T]he mere fact that every nation's municipal [i.e., domestic] law may prohibit theft does not incorporate "the Eighth Commandment, 'Thou Shalt not steal' . . . into the law of nations." It is 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, that a wrong generally recognized becomes an international law violation within the meaning of the [ATS].

Accordingly, absent a relevant treaty of the United States—and none is relied on here—we must ask whether a plaintiff bringing an ATS suit against a corporation has alleged a violation of customary international law. The singular achievement of international law since the Second World War has come in the area of human rights, where the subjects of customary international law—i.e., those with international rights, duties, and liabilities—now include not merely states, but also individuals. This principle was most famously applied by the International Military Tribunal at Nuremberg. . . .

From the beginning, however, the principle of individual liability for violations of international law has been limited to natural persons—not "juridical" persons such as corporations—because the moral responsibility for a crime so heinous and unbounded as to rise to the level of an "international crime" has rested solely with the individual men and women who have perpetrated it. As the Nuremberg tribunal unmistakably set forth in explaining the rationale for individual liability for violations of international law: "Crimes against international law are committed by men, not by abstract entities, and only by punishing individuals who commit such crimes can the provisions of international law be enforced."

After Nuremberg, as new international tribunals have been created, the customary international law of human rights has remained focused not on abstract entities but on the individual men and women who have committed international crimes universally recognized by the nations of the world. This principle has taken its most vivid form in the recent design of the International Criminal Court ("ICC"). Although there was a proposal at the Rome Conference to grant the ICC jurisdiction over corporations and other "juridical" persons, that proposal was soundly rejected, and the Rome Statute, the

---

14 630 F.2d at 888 (quoting Vencap, 519 F.2d at 1015) (alteration omitted).
ICC’s constitutive document, hews to the tenet set forth in Nuremberg that international norms should be enforced by the punishment of the individual men and women who violate them.

In short, because customary international law imposes individual liability for a limited number of international crimes—including war crimes, crimes against humanity (such as genocide), and torture—we have held that the ATS provides jurisdiction over claims in tort against individuals who are alleged to have committed such crimes. As we explain in detail below, however, customary international law has steadfastly rejected the notion of corporate liability for international crimes, and no international tribunal has ever held a corporation liable for a violation of the law of nations.

We must conclude, therefore, that insofar as plaintiffs bring claims under the ATS against corporations, plaintiffs fail to allege violations of the law of nations, and plaintiffs’ claims fall outside the limited jurisdiction provided by the ATS.

We emphasize that the question before us is not whether corporations are “immune” from suit under the ATS: That formulation improperly assumes that there is a norm imposing liability in the first place. Rather, the question before us, as the Supreme Court has explained, “is whether international law extends the scope of liability for a violation of a given norm to the perpetrator being sued, if the defendant is a private actor such as a corporation or individual.” Looking to international law, we find a jurisprudence, first set forth in Nuremberg and repeated by every international tribunal of which we are aware, that offenses against the law of nations (i.e., customary international law) for violations of human rights can be charged against States and against individual men and women but not against juridical persons such as corporations. As a result, although customary international law has sometimes extended the scope of liability for a violation of a given norm to individuals, it has never extended the scope of liability to a corporation.

We pause briefly to acknowledge and reply to the separate opinion of our colleague, Judge Leval. As an initial matter, we are perplexed by Judge Leval’s repeated insistence that there is no “basis” for our holding because “[n]o precedent of international law endorses” it. See, e.g., Concurring Op. 151. In an ATS suit, we may apply only those international norms that are “specific, universal, and obligatory.” As a result, the responsibility of establishing a norm of customary international law lies with those wishing to invoke it, and in the absence of sources of international law endorsing (or refuting) a norm, the norm simply cannot be applied in a suit grounded on customary international law under the ATS. Thus, even if there were, as Judge Leval claims, an absence of sources of international law addressing corporate liability, that supposed lack of authority would actually support our holding. By contrast, to support Judge Leval’s proposed rule, there would need to be not only a few, but so many sources of international law calling for corporate liability that the norm could be regarded as “universal.” As it happens, no corporation has ever been subject to any form of liability under the customary international law of human rights, and thus the ATS, the remedy Congress has chosen, simply does not confer jurisdiction over suits against corporations.

Although Judge Leval condemns our holding, he in fact agrees with much of our opinion. He concedes, for example, that “[i]t is true that international law, of its own
force, imposes no liabilities on corporations or other private juridical entities.” Concurring Op. 186[.] He similarly has “no quarrel” with the “premise[ ]” that international law is “the place to look” to determine whether corporations can be held liable for violations of international law. He concludes, however, that international law does not supply an answer to that question. In his view, the question of corporate liability is merely a matter of “remedy” that “international law leaves . . . to the independent determination of each State.”

We agree with Judge Leval that whether to enact a civil remedy for violations of customary international law is a matter to be determined by each State; the United States has done so in enacting the ATS. But the ATS does not specify who is liable; it imposes liability only for a “violation of the law of nations,” and thus it leaves the question of the nature and scope of liability—who is liable for what—to customary international law. As we explain in detail below, therefore, whether a defendant is liable under the ATS depends entirely upon whether that defendant is subject to liability under customary international law. It is inconceivable that a defendant who is not liable under customary international law could be liable under the ATS.

We will not embark on a lengthy tangent in response to Judge Leval’s many “hypothetical cases,” Concurring Op. 159, in which corporations would not, under our holding, be liable under the ATS. We note only that nothing in this opinion limits or forecloses suits under the ATS against the individual perpetrators of violations of customary international law—including the employees, managers, officers, and directors of a corporation—as well as anyone who purposefully aids and abets a violation of customary international law. Nor does anything in this opinion limit or foreclose criminal, administrative, or civil actions against any corporation under a body of law other than customary international law—for example, the domestic laws of any State. And, of course, nothing in this opinion limits or forecloses legislative action by Congress.

**BACKGROUND**

These cross-appeals come to us from the United States District Court for the Southern District of New York (Kimba M. Wood, Judge ). At this stage of the proceedings, we accept as true all nonconclusory factual allegations relevant to this decision.

I. Factual Background

Plaintiffs, who are, or were, residents of the Ogoni Region of Nigeria, allege that defendants Royal Dutch Petroleum Company (“Royal Dutch”) and Shell Transport and Trading Company PLC (“Shell”), through a subsidiary named Shell Petroleum Development Company of Nigeria, Ltd. (“SPDC”), aided and abetted the Nigerian government in committing human rights abuses directed at plaintiffs. Royal Dutch and Shell are holding companies incorporated respectively in the Netherlands and the United Kingdom. SPDC is incorporated in Nigeria. All defendants are corporate entities—that is, “juridical” persons, rather than “natural” persons.

[The Court described local resistance to SPDC’s activities and the alleged assistance SPDC rendered to the government in violently quelling that resistance.]
Plaintiffs brought claims against defendants under the ATS for aiding and abetting the Nigerian government in alleged violations of the law of nations. Specifically, plaintiffs brought claims of aiding and abetting (1) extrajudicial killing; (2) crimes against humanity; (3) torture or cruel, inhuman, and degrading treatment; (4) arbitrary arrest and detention; (5) violation of the rights to life, liberty, security, and association; (6) forced exile; and (7) property destruction.

II. Procedural History

***

DISCUSSION

***

As we have explained above, this appeal presents a question that has been lurking for some time in our ATS jurisprudence. Since our first case upholding claims brought under the ATS in 1980, our Court has never directly addressed whether our jurisdiction under the ATS extends to civil actions against corporations. We have, in the past, decided ATS cases involving corporations without addressing the issue of corporate liability. But that fact does not foreclose consideration of the issue here. As the Supreme Court has held, “when questions of jurisdiction have been passed on in prior decisions sub silentio,” the Court “has never considered itself bound when a subsequent case finally brings the jurisdictional issue before [it].” The same rule applies here.

In answering the question presented we proceed in two steps. First, we consider which body of law governs the question—international law or domestic law—and conclude that international law governs. Second, we consider what the sources of international law reveal with respect to whether corporations can be subject to liability for violations of customary international law. We conclude that those sources lead inescapably to the conclusion that the customary international law of human rights has not to date recognized liability for corporations that violate its norms.

I. Customary International Law Governs Our Inquiry

The ATS grants federal district courts jurisdiction over claims “by an alien for a tort only, committed in violation of the law of nations or a treaty of the United States.” 28 U.S.C. § 1350. In 2004, the Supreme Court held in Sosa that the ATS is a jurisdictional statute only; it creates no cause of action. Justice Souter explained, because its drafters understood that “the common law would provide a cause of action for the modest number of international law violations with a potential for personal liability at the time.” Indeed, at the time of its adoption, the ATS “enabled federal courts to hear claims in a very limited category defined by the law of nations and recognized at common law.” These included “three specific offenses against the law of nations addressed by the law of England [and identified by Blackstone]: violation of safe conducts, infringement of the rights of ambassadors, and piracy”—each a rule “binding individuals for the benefit of other individuals[, which] overlapped with the norms of state relationships.”

The Supreme Court did not, however, limit the jurisdiction of the federal courts under the ATS to those three offenses recognized by the law of nations in 1789. Instead, the Court in Sosa held that federal courts may recognize claims “based on the present-day law of nations” provided that the claims rest
on "norm[s] of international character accepted by the civilized world and defined with a specificity comparable to the features of the 18th-century paradigms [the Court had] recognized."

The Supreme Court cautioned 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 the federal courts." The Court also observed that "a related consideration is whether international law extends the scope of liability for a violation of a given norm to the perpetrator being sued, if the defendant is a private actor such as a corporation or an individual." We conclude—based on international law, Sosa, and our own precedents—that international law, and not domestic law, governs the scope of liability for violations of customary international law under the ATS.

A. International Law Defines the Scope of Liability for Violations of Its Norms

International law is not silent on the question of the subjects of international law—that is, "those that, to varying extents, have legal status, personality, rights, and duties under international law and whose acts and relationships are the principal concerns of international law." Nor does international law leave to individual States the responsibility of defining those subjects. Rather, "[t]he concept of international person is . . . derived from international law."

That the subjects of international law are determined by international law, and not individual States, is evident from the decisions of the International Military Tribunal at Nuremberg ("Tribunal") in the aftermath of the Second World War. The significance of the judgment of the Tribunal and the judgments of the tribunals established by the Allied Control Council pursuant to Council Control Law No. 10 (Dec. 20, 1945), was not simply that it recognized genocide and aggressive war as violations of international law. The defining legal achievement of the Nuremberg trials is that they explicitly recognized individual liability for the violation of specific, universal, and obligatory norms of the customary international law of human rights.

***

B. Sosa and Our Precedents Require Us to Look to International Law to Determine the Scope of Liability

In Sosa the Supreme Court instructed the lower federal courts to consider "whether international law extends the scope of liability for a violation of a given norm to the perpetrator being sued, if the defendant is a private actor such as a corporation or individual." That language requires that we look to international law to determine our jurisdiction over ATS claims against a particular class of defendant, such as corporations. That conclusion is reinforced by Justice Breyer's reformulation of the issue in his concurring opinion: "The norm [of international law] must extend liability to the type of perpetrator (e.g., a private actor) the plaintiff seeks to sue."

The Supreme Court's instruction to look to international law to determine the scope of liability under the ATS did not involve a revolutionary interpretation of the statute—in fact, it had long been the law of this Circuit. In Filartiga, we had looked to international law to determine our jurisdiction and to delineate the type of defendant who could be sued. Likewise, in
Kadic v. Karadžić, 70 F.3d 232 (2d Cir.1995) (Newman, J.), and in Judge Harry T. Edwards’s notable concurring opinion in Tel-Oren v. Libyan Arab Republic, 726 F.2d 774, 775 (D.C.Cir.1984) (Edwards, J., concurring)—both cited with approval by the Supreme Court in Sosa—international law provided the rules by which the court decided whether certain conduct violated the law of nations when committed by non-state actors. In Kadic, we held that a private actor could be liable under the law of nations for genocide, war crimes, and crimes against humanity, 70 F.3d at 239-41, but in Tel-Oren, Judge Edwards expressed the view that a private actor could not be liable for torture under the ATS, 726 F.2d at 791-95 (Edwards, J., concurring); see also, e.g., Flores, 414 F.3d at 254-66 (looking to customary international law for the applicable norms).

Since Sosa, we have continued to adhere to the method prescribed in Sosa footnote 20 by looking to customary international law to determine both whether certain conduct leads to ATS liability and whether the scope of liability under the ATS extends to the defendant being sued. As recently as our decision of 2009 in Presbyterian Church, this same panel (including Judge Leval) declared that “footnote 20 of Sosa, while nominally concerned with the liability of non-state actors, supports the broader principle that the scope of liability for ATS violations should be derived from international law.” 582 F.3d at 258 (footnote omitted)[.] In Presbyterian Church, we looked to international law to determine the circumstances in which aiders and abettors could be liable for violations of the customary international law of human rights. We did so because “[r]ecognition of secondary liability is no less significant a decision than whether to recognize a whole new tort in the first place.” Thus, our holding today is consistent with Presbyterian Church, where we looked to international law to determine not only what conduct is cognizable under the ATS, but also the identity of the persons to whom that conduct is attributable (in that case, aiders and abettors).

Our interpretation of Sosa is also consistent with Judge Katzmann’s separate opinion in Khulumani, 504 F.3d at 264 (Katzmann, J., concurring), which this same panel (including Judge Leval) adopted as the law of the Circuit in Presbyterian Church[.] In Khulumani, Judge Katzmann observed that aiding and abetting liability—much like corporate liability—“does not constitute a discrete criminal offense but only serves as a more particularized way of identifying the persons involved’ in the underlying offense.” Judge Katzmann further explained that “[w]hile [footnote 20 of Sosa] specifically concerns the liability of non-state actors, its general principle is equally applicable to the question of where to look to determine whether the scope of liability for a violation of international law should extend to aiders and abettors.” He therefore concluded that “to assure itself that it has jurisdiction to hear a claim under the [ATS], [a court] should first determine whether the alleged tort was in fact ‘committed in violation of the law of nations,’ and whether this law would recognize the defendants’ responsibility for that violation.”

Significantly, it was only because we looked to international law that we were able to recognize a norm of aiding and abetting liability under the ATS. In Khulumani, Judge Katzmann declined to rely on the usual presumption against aiding and abetting liability that applies in the interpretation of domestic statutes. See Cent. Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A., 511 U.S. 164, 182,
II. Corporate Liability Is Not a Norm of Customary International Law

To attain the status of a rule of customary international law, a norm must be “specific, universal, and obligatory.” Defining such norms “is no simple task,” as “[c]ustomary international law is discerned from myriad decisions made in numerous and varied international and domestic arenas.” The sources consulted are therefore of the utmost importance. . . .

***

In this Circuit we have long recognized as authoritative the sources of international law identified in Article 38 of the Statute of the International Court of Justice (“ICJ Statute”). Article 38 provides in relevant part:

1. The Court, whose function is to decide in accordance with international law such disputes as are submitted to it, shall apply:

   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. subject to the provisions of Article 59, judicial decisions and the teachings of the most highly qualified publicists [i.e., scholars or “jurists”] of the various nations, as subsidiary means for the determination of rules of law.

With those principles in mind, we consider whether the sources of international law reveal that corporate liability has attained universal acceptance as a rule of customary international law.

A. International Tribunals

Insofar as international tribunals are established for the specific purpose of imposing liability on those who violate the law of nations, the history and conduct of those tribunals is instructive. We find it particularly significant, therefore, that no international tribunal of which we are aware has ever held a corporation liable for a violation of the law of nations.

I. The Nuremberg Tribunals

[The Court discussed the London Charter’s grant of jurisdiction only over natural persons and its grant of the authority to declare a corporation criminal for evidentiary purposes.]

Echoing the London Charter’s imposition of liability on natural persons only, the subsequent United States Military Tribunals, established under Control Council Law No. 10, prosecuted corporate executives for their role in violating customary international law during the Second World War, but not the corporate entities themselves. This approach to liability can be seen most clearly in the tribunal’s treatment of the notorious I.G. Farben chemical company (“I.G. Farben”). [The Court described Farben’s partnership with the Nazi state, how that partnership made possible many of the Nazi war crimes and crimes against humanity, and how the Farben corporation was expressly declared not before the tribunal and not subject to criminal penalties.]

In declining to impose corporate liability under international law in the case of the most nefarious corporate enterprise known to the civilized world, while prosecuting the men who led I.G. Farben, the military tribunals established under Control Council Law No. 10 expressly defined liability under the law of nations as liability that could not be divorced from individual moral responsibility. It is thus clear that, at the time of the Nuremberg trials, corporate liability was not recognized as a “specific, universal, and obligatory” norm of customary international law.

We turn now to international tribunals convened since Nuremberg to determine whether there is any evidence that the concept of corporate liability has coalesced into a “specific, universal, and obligatory” norm.

2. International Tribunals Since Nuremberg

Since Nuremberg, international tribunals have continually declined to hold corporations liable for violations of customary international law. For example, the charters establishing both the International Criminal Tribunal for the former Yugoslavia (“ICTY”) and the International Criminal Tribunal for Rwanda, or (“ICTR”) expressly confined the tribunals’ jurisdiction to “natural persons.”

The commentary contained in the Report of the Secretary-General of the United Nations on the ICTY reveals that jurisdiction over corporations was considered but expressly rejected: “[T]he ordinary meaning of the term ‘persons responsible for serious violations of international humanitarian law’ would be natural persons to the exclusion of
juridical persons.” Moreover, unlike the International Military Tribunal at Nuremberg, the ICTY lacked the authority to declare organizations “criminal.” Thus, to the extent that the International Military Tribunal at Nuremberg possessed some limited authority to declare corporations criminal—which, as explained above, operated merely as an evidentiary rule for later trials imposing liability on individuals—subsequent tribunals have not retained that procedure.

More recently, the Rome Statute of the ICC also limits that tribunal’s jurisdiction to “natural persons.” Significantly, a proposal to grant the ICC jurisdiction over corporations and other “juridical” persons was advanced by the French delegation, but the proposal was rejected. As commentators have explained, the French proposal was rejected in part because “criminal liability of corporations is still rejected in many national legal orders” and thus would pose challenges for the ICC’s principle of “complementarity.” The history of the Rome Statute therefore confirms the absence of any generally recognized principle or consensus among States concerning corporate liability for violations of customary international law.

In sum, modern international tribunals make it abundantly clear that, since Nuremberg, the concept of corporate liability for violations of customary international law has not even begun to “ripen[ ]” into a universally accepted norm of international law.

B. International Treaties

39 “Complementarity” is the principle, embodied in the Rome Statute, by which the ICC declines to exercise jurisdiction over a case that is simultaneously being investigated or prosecuted by a State having jurisdiction over it.

Treaties “are proper evidence of customary international law because, and insofar as, they create legal obligations akin to contractual obligations on the States parties to them.” Although all treaties ratified by more than one State provide some evidence of the custom and practice of nations, “a treaty will only constitute sufficient proof of a norm of customary international law if an overwhelming majority of States have ratified the treaty, and those States uniformly and consistently act in accordance with its principles.” Moreover, as one distinguished scholar of international law has explained:

The ordinary treaty by which two or more states enter into engagements with one another for some special object can very rarely be used even as evidence to establish the existence of a rule of general law; it is more probable that the very reason of the treaty was to create an obligation which would not have existed by the general law, or to exclude an existing rule which would otherwise have applied.

Brierly, ante, at 57 (emphases added).

That a provision appears in one treaty (or more), therefore, is not proof of a well-established norm of customary international law.

One district court in our Circuit erroneously overvalued the importance of a number of international treaties in finding that corporate liability has attained the status of customary international law. None of the treaties relied upon in the district court’s 2003 Presbyterian Church opinion have been ratified by the United States, and most of them have not been ratified by other
States whose interests would be most profoundly affected by the treaties’ terms. Those treaties are therefore insufficient—considered either individually or collectively—to demonstrate that corporate liability is universally recognized as a norm of customary international law.

Even if those specialized treaties had been ratified by an “overwhelming majority” of states, as some recent treaties providing for corporate liability have been—the fact that those treaties impose obligations on corporations in the context of the treaties’ particular subject matter tells us nothing about whether corporate liability for, say, violations of human rights, which are not a subject of those treaties, is universally recognized as a norm of customary international law. Significantly, to find that a treaty embodies or creates a rule of customary international law would mean that the rule applies beyond the limited subject matter of the treaty and to nations that have not ratified it. To construe those treaties as so-called “law-making” treaties—that is, treaties that codify existing norms of customary international law or crystallize an emerging rule of customary international law—would be wholly inappropriate and without precedent.

As noted above, there is no historical evidence of an existing or even nascent norm of customary international law imposing liability on corporations for violations of human rights. It cannot be said, therefore, that those treaties on specialized questions codify an existing, general rule of customary international law. Nor can those recent treaties, in light of their limited number and specialized subject matter, be viewed as crystallizing a norm of customary international law (which they generally cannot), it would be inappropriate to do so in this case in light of the recent express rejection in major multilateral treaties of a norm of corporate liability in the context of human rights violations.

Finally, the few specialized treaties imposing liability on corporations have not had such influence that a general rule of corporate liability has become a norm of customary international law. . . .

***

For a treaty provision to attain the status of a norm of customary international law, the ICJ [has] explained, “[i]t would in the first place be necessary that the provision concerned should, at all events potentially, be of a fundamentally norm-creating character such as could be regarded as forming the basis of a general rule of law.” Provisions on corporate liability in a handful of specialized treaties cannot be said to have a “fundamentally norm-creating character.” Moreover, as the history of the Rome Statute demonstrates, “still unresolved controversies as to the exact meaning and scope of this notion” of corporate liability “raise further doubts as to the potentially norm-creating character of the rule.” Accordingly, provisions imposing corporate liability in some recent specialized treaties have not established corporate liability as a norm of customary international law.

In reaching the contrary conclusion in Presbyterian Church, the judge to whom the case was originally assigned in the district court acknowledged that “most treaties do not bind corporations” but reasoned that “[i]f corporations can be liable for unintentional torts such as oil spills or nuclear accidents, logic would suggest that
they can be held liable for intentional torts such as complicity in genocide, slave trading, or torture." In addition to the reasons discussed above, the district court's conclusion was flawed by its use of an improper methodology for discerning norms of customary international law: customary international law does not develop through the "logical" expansion of existing norms. Rather, as the Supreme Court has explained, it develops, if at all, through the custom and practice "among civilized nations... gradually ripening into a rule of international law."

***

We conclude, therefore, that the relatively few international treaties that impose particular obligations on corporations do not establish corporate liability as a "specific, universal, and obligatory" norm of customary international law. Although those treaties suggest a trend towards imposing corporate liability in some special contexts, no trend is detectable outside such narrow applications in specialized treaties, and there is nothing to demonstrate that corporate liability has yet been recognized as a norm of the customary international law of human rights.

C. Works of Publicists

Although the works of publicists (i.e., scholars or "jurists") can be a relevant source of customary international law, "[s]uch works are resorted to by judicial tribunals, not for the speculations of their authors concerning what the law ought to be, but for trustworthy evidence of what the law really is."

In light of the evidence discussed above, it is not surprising that two renowned professors of international law, Professor James Crawford and Professor (now Judge) Christopher Greenwood, forcefully declared in litigation argued before this panel on the same day as this case that customary international law does not recognize liability for corporations that violate its norms. According to Professor Crawford, "no national court [outside of the United States] and no international judicial tribunal has so far recognized corporate liability, as opposed to individual liability, in a civil or criminal context on the basis of a violation of the law of nations or customary international law." Even those who favor using the ATS as a means of holding corporations accountable for human rights violations reluctantly acknowledge that "the universe of international criminal law does not reveal any prosecutions of corporations per se."

Together, those authorities demonstrate that imposing liability on corporations for violations of customary international law has not attained a discernible, much less universal, acceptance among nations of the world in their relations inter se. Because corporate liability is not recognized as a "specific, universal, and obligatory" norm, it is not a rule of customary international law that we may apply under the ATS. Accordingly, insofar as plaintiffs in this action seek to hold only corporations liable for their conduct in Nigeria (as opposed to individuals within those corporations), and only under the ATS, their claims must be dismissed for lack of subject matter jurisdiction.

III. The Concurring Opinion

Judge Leval concedes that "international law, of its own force, imposes no liabilities on corporations or other private juridical entities." Concurring Op. 186. In other words, despite his perplexing but forceful contentions otherwise, Judge Leval does not
disagree with Part II of our opinion. What he disputes is our conclusion in Part I that customary international law supplies the rule of decision.

Judge Leval admits that international law is “the place to look” to “determine whether a corporation can be held civilly liable for a violation of international law,” but he maintains that we must accept corporate liability based on principles of domestic law unless “the law of nations [has] spoken on the question [and] provided that acts of corporations are not covered by the law of nations[].” He then contends that the law of nations has not, in fact, spoken on the question and that corporate liability is therefore a matter of “remedy” that “international law leaves . . . to the independent determination of each State.” In doing so Judge Leval dismisses as a source of authoritative guidance the fact that no international tribunal has ever been accorded jurisdiction over corporations because those tribunals have been charged only with the prosecution of crimes. Finally, Judge Leval accuses us of rejecting corporate civil liability under the ATS merely because there is no norm of corporate civil liability in customary international law, and he argues that this reasoning is inconsistent with our endorsement of individual liability under the ATS.

Judge Leval’s criticisms distort our holding and betray several fundamental misunderstandings of customary international law. First, Judge Leval attempts to shift to us the burden of identifying a norm of customary international law that supports our “rule.” But it is entirely inappropriate to begin, as Judge Leval apparently begins, with a presumption that a violation of customary international law can be attributed to any defendant unless, and until, a norm of customary international law declares otherwise. This reasoning turns customary international law on its head. Customary international law arises from the customs and practices “among civilized nations . . . gradually ripening into a rule of international law.” Accordingly, the responsibility lies with those who seek to demonstrate that “international law extends the scope of liability for a violation of a given norm to the perpetrator being sued.” Judge Leval produces no evidence that international law extends the scope of liability to corporations, and, in fact, he concedes that it does not. Concurring Op. 186 (“It is true that international law, of its own force, imposes no liabilities on corporations or other private juridical entities.”). In any event, although it is not our burden, we have little trouble demonstrating the absence of a norm of corporate liability in customary international law.

Second, Judge Leval dismisses the fact that international tribunals have consistently declined to recognize corporate liability as a norm of customary international law; he does so by inventing a distinction between civil and criminal liability in customary international law, that is contrary to our ATS jurisprudence. As Judge Katzmann explained in his separate opinion in Khulumani, “[t]his distinction finds no support in our case law, which has consistently relied on criminal law norms in establishing the content of customary international law for purposes of the [ATS].” 504 F.3d at 270 n. 5. Unlike U.S. domestic law, “international law does not maintain [a] kind of hermetic seal between criminal and civil law.” Indeed, Judge Katzmann was able to conclude that the scope of customary international law reaches those who aid and abet violations of international law only by looking to the
charters of—and the law applied by—the very same international tribunals that Judge Leval ignores. Judge Leval explicitly endorsed Judge Katzmann’s reasoning in *Khulumani* by joining the unanimous panel opinion in *Presbyterian Church*, which expressly adopted Judge Katzmann’s rule as the law of our Circuit. *Presbyterian Church*, 582 F.3d at 258. Apparently, Judge Leval would have us look to international criminal tribunals only when they supply a norm with which he agrees.

Third, Judge Leval distorts our analysis by claiming that we hold “that the absence of a universal practice among nations of imposing civil damages on corporations for violations of international law means that under international law corporations are not liable for violations of the law of nations.” Concurring Op. 152 (emphasis added). That is not our holding. We hold that corporate liability is not a norm that we can recognize and apply in actions under the ATS because the customary international law of human rights does not impose any form of liability on corporations (civil, criminal, or otherwise).

Finally, and most importantly, Judge Leval incorrectly categorizes the scope of liability under customary international law—that is, who can be liable for violations of international law—as merely a question of remedy to be determined independently by each state. As we explained above, the subjects of international law have always been defined by reference to international law itself. Judge Leval is therefore wrong to suggest that “international law takes no position” on the question of who can be liable for violations of international law.

Although international law does (as Judge Leval explains) leave remedial questions to States, the liability of corporations for the actions of their employees or agents is not a question of remedy. Corporate liability imposes responsibility for the actions of a culpable individual on a wholly new defendant—the corporation. In the United States, corporate liability is determined by a body of rules determining which actions of an employee or agent are to be imputed to the corporation. In this important respect, corporate liability is akin to accessorial liability, which is a subject of international law not left to individual States.

The potential for civil damages under the ATS arises only if customary international law recognizes that a particular class of defendant is a subject of international law in the first place. Contrary to Judge Leval’s suggestion, therefore, individual liability under the ATS is wholly consistent with our holding today. Congress chose in the ATS to grant jurisdiction over torts committed “in violation of the law of nations,” and since the Nuremberg trials, customary international law has recognized individual liability for the violation of international human rights. Thus, the ATS merely permits courts to recognize a remedy (civil liability) for heinous crimes universally condemned by the family of nations against individuals already recognized as subjects of international law. To permit courts to recognize corporate liability under the ATS, however, would require, at the very least, a different statute—one that goes beyond providing jurisdiction over torts committed “in violation of the law of nations” to authorize suits against entities that are not subjects of customary international law.

CONCLUSION

The ATS provides federal district courts jurisdiction over a tort, brought by an alien only, alleging a “violation of the law of nations or a treaty of the United States.”
When an ATS suit is brought under the “law of nations,” also known as “customary international law,” jurisdiction is limited to those cases alleging a violation of an international norm that is “specific, universal, and obligatory.”

No corporation has ever been subject to any form of liability (whether civil, criminal, or otherwise) under the customary international law of human rights. Rather, sources of customary international law have, on several occasions, explicitly rejected the idea of corporate liability. Thus, corporate liability has not attained a discernable, much less universal, acceptance among nations of the world in their relations inter se, and it cannot not, as a result, form the basis of a suit under the ATS.

Acknowledging the absence of corporate liability under customary international law is not a matter of conferring “immunity” on corporations. It is, instead, a recognition that the States of the world, in their relations with one another, have determined that moral and legal responsibility for heinous crimes should rest on the individual whose conduct makes him or her “hostis humani generis, an enemy of all mankind.” Nothing in this opinion limits or forecloses suits under the ATS against a corporation’s [individuals] or any other person who commits, or purposefully aids and abets, violations of international law. Moreover, nothing in this opinion limits or forecloses corporate liability under any body of law other than the ATS—including the domestic statutes of other States—and nothing in this opinion limits or forecloses Congress from amending the ATS to bring corporate defendants within our jurisdiction. Corporate liability, however, is simply not “accepted by the civilized world and defined with a specificity comparable to the features of the 18th-century paradigms” recognized as providing a basis for suit under the law prescribed by the ATS—that is, customary international law.

We do not know whether the concept of corporate liability will “gradually ripen[ ] into a rule of international law.” It can do so, however, only by achieving universal recognition and acceptance as a norm in the relations of States inter se. For now, and for the foreseeable future, the Alien Tort Statute does not provide subject matter jurisdiction over claims against corporations.

To summarize, we hold as follows:

(1) Since Filartiga, which in 1980 marked the advent of the modern era of litigation for violations of human rights under the Alien Tort Statute, all of our precedents—and the Supreme Court’s decision in Sosa, 542 U.S. at 732 n. 20 [124 S.Ct. 2739]—require us to look to international law to determine whether a particular class of defendant, such as corporations, can be liable under the Alien Tort Statute for alleged violations of the law of nations.

(2) The concept of corporate liability for violations of customary international law has not achieved universal recognition or acceptance as a norm in the relations of States with each other. See Vencap, 519 F.2d at 1015. Inasmuch as plaintiffs assert claims against corporations only, their complaint must be dismissed for lack of subject matter jurisdiction.

Accordingly, the September 29, 2006 order of the District Court is AFFIRMED insofar as it dismissed some of plaintiffs’ claims against the corporate defendants and REVERSED insofar as it declined to dismiss plaintiffs’ remaining claims against the corporate defendants.
LEVAL, Circuit Judge, concurring only in the judgment:

The majority opinion deals a substantial blow to international law and its undertaking to protect fundamental human rights. According to the rule my colleagues have created, one who earns profits by commercial exploitation of abuse of fundamental human rights can successfully shield those profits from victims' claims for compensation simply by taking the precaution of conducting the heinous operation in the corporate form. Without any support in either the precedents or the scholarship of international law, the majority take the position that corporations, and other juridical entities, are not subject to international law, and for that reason such violators of fundamental human rights are free to retain any profits so earned without liability to their victims.

[Characterizes the majority as creating a rule, in opposition to the objectives of international law, that shield corporations from liability for human rights abuses.]

Since Filartiga v. Pena-Irala, 630 F.2d 876 (2d Cir.1980), was decided in 1980, United States courts, acting under the Alien Tort Statute (ATS), which was passed by the First Congress in 1789, have been awarding compensatory damages to victims of human rights abuses committed in violation of the law of nations. Many supporters of the cause of human rights have celebrated the Filartiga line of cases as an important advance of civilization. Not all, however, have viewed those cases with favor. Some see them as unwarranted meddling by U.S. judges in events that occurred far away, applying a body of law that we did not make, in circumstances carrying a potential, furthermore, to interfere with the President's conduct of foreign affairs. In 2004, a substantial minority of the Supreme Court, in Sosa v. Alvarez-Machain, 542 U.S. 692, 124 S.Ct. 2739, 159 L.Ed.2d 718, would have essentially nullified the ATS and overturned the Filartiga line, by ruling that the ATS did no more than give courts jurisdiction, and that, absent further legislation establishing a legal claim, courts acting under ATS had no authority to grant any substantive relief. The majority of the Supreme Court, however, rejected that argument. The Court ruled that under the ATS, federal courts could award damages for violations of the law of nations. For those who believe the Filartiga - Sosa line represents a meaningful advance in the protection of human rights, the majority's decision here marks a very bad day.

To understand this controversy, it is important to understand exactly what is the majority's rule, how it functions, and in what circumstances. To begin, their rule relates to the most abhorrent conduct-those acts that violate norms of the international law of human rights. The ATS gives U.S. courts jurisdiction to award tort damages to aliens who are victims of such atrocities. According to the majority, in cases where the norms of the law of nations were violated by a corporation (or other juridical entity), compensatory damages may be awarded under the ATS against the corporation's employees, natural persons who acted in the corporation's behalf, but not against the corporation that commanded the atrocities and earned profits by committing them. The corporation, according to my colleagues, has not violated international law, and is indeed incapable of doing so because international law does not apply to the conduct of corporations. Accordingly, a corporation which has earned profits by abuse of fundamental human rights-as by slave trading-is free to retain those profits without liability.
... No precedent of international law endorses this rule. No court has ever approved it, nor is any international tribunal structured with a jurisdiction that reflects it. (Those courts that have ruled on the question have explicitly rejected it.) No treaty or international convention adopts this principle. And no work of scholarship on international law endorses the majority's rule. Until today, [the majority's] concept had no existence in international law.

The majority contend, nevertheless, that unambiguous jurisprudence "lead[s] inescapably" to their conclusion. Maj. Op. 125. However, the reasoning that supports the majority's argument is, in my view, illogical, misguided, and based on misunderstandings of precedent.

The argument depends on its observation that international criminal tribunals have been established without jurisdiction to impose criminal punishments on corporations for their violations of international law. From this fact the majority contend an inescapable inference arises that international law does not govern corporations, which are therefore free to engage in conduct prohibited by the rules of international law with impunity.

There is no logic to the argument. The reasons why international tribunals have been established without jurisdiction to impose criminal liability on corporations have to do solely with the theory and the objectives of criminal punishment, and have no bearing on civil compensatory liability. The view is widely held among the nations of the world that criminal punishments (under domestic law, as well as international law) are inappropriate for corporations. This view derives from two perceptions: First, that criminal punishment can be theoretically justified only where the defendant has acted with criminal intent—a condition that cannot exist when the defendant is a juridical construct which is incapable of having an intent; and second, that criminal punishments are pointless and counterproductive when imposed on a fictitious juridical entity because they fail to achieve the punitive objectives of criminal punishment. For these reasons many nations in their domestic laws impose criminal punishments only on natural persons, and not on juridical ones. In contrast, the imposition of civil liability on corporations serves perfectly the objective of civil liability to compensate victims for the wrongs inflicted on them and is practiced everywhere in the world. The fact that international tribunals do not impose criminal punishment on corporations in no way supports the inference that corporations are outside the scope of international law and therefore can incur no civil compensatory liability to victims when they engage in conduct prohibited by the norms of international law.

The majority next contend that international law does not distinguish between criminal and civil liability. This is simply incorrect. International law distinguishes clearly between them and provides differently for the different objectives of criminal punishment and civil compensatory liability.

The majority then argue that the absence of a universal practice among nations of imposing civil damages on corporations for violations of international law means that under international law corporations are not liable for violations of the law of nations. This argument is as illogical as the first and is based on a misunderstanding of the structure of international law. The position
of international law on whether civil liability should be imposed for violations of its norms is that international law takes no position and leaves that question to each nation to resolve. International law, at least as it pertains to human rights, consists primarily of a sparse body of norms, adopting widely agreed principles prohibiting conduct universally agreed to be heinous and inhumane. Having established these norms of prohibited conduct, international law says little or nothing about how those norms should be enforced. It leaves the manner of enforcement, including the question of whether there should be private civil remedies for violations of international law, almost entirely to individual nations. While most nations have not recognized tort liability for violations of international law, the United States, through the ATS, has opted to impose civil compensatory liability on violators and draws no distinction in its laws between violators who are natural persons and corporations. The majority's argument that national courts are at liberty to award civil damages for violations of international law solely against natural persons and not against corporations has no basis in international law and, furthermore, nullifies the intention of international law to leave the question of civil liability to be decided separately by each nation.

The majority's asserted rule is, furthermore, at once internally inconsistent and incompatible with Supreme Court authority and with our prior cases that awarded damages for violations of international law. The absence of a universally accepted rule of international law on tort damages is true as to defendants who are natural persons, as well as to corporations. Because international law generally leaves all aspects of the issue of civil liability to individual nations, there is no rule or custom of international law to award civil damages in any form or context, either as to natural persons or as to juridical ones. If the absence of a universally accepted rule for the award of civil damages against corporations means that U.S. courts may not award damages against a corporation, then the same absence of a universally accepted rule for the award of civil damages against natural persons must mean that U.S. courts may not award damages against a natural person. But the majority opinion concedes (as it must) that U.S. courts may award damages against the corporation's employees when a corporation violates the rule of nations. Furthermore, our circuit and others have for decades awarded damages, and the Supreme Court in Sosa made clear that a damage remedy does lie under the ATS. The majority opinion is thus internally inconsistent and is logically incompatible with both Second Circuit and Supreme Court authority.

If past judges had followed the majority's reasoning, we would have had no Nuremberg trials, which for the first time imposed criminal liability on natural persons complicit in war crimes; no subsequent international tribunals to impose criminal liability for violation of international law norms; and no judgments in U.S. courts under the ATS, compensating victims for the violation of fundamental human rights.

The rule in cases under the ATS is quite simple. The law of nations sets worldwide norms of conduct, prohibiting certain universally condemned heinous acts. That body of law, however, takes no position on whether its norms may be enforced by civil actions for compensatory damages. It leaves that decision to be separately decided by each nation. The ATS confers on the U.S. courts jurisdiction to entertain civil suits for violations of the law of nations. In the United States, if a plaintiff in a suit under
the ATS shows that she is the victim of a tort committed in violation of the norms of the law of nations, the court has jurisdiction to hear the case and to award compensatory damages against the tortfeasor. That is what the Supreme Court explained in *Sosa*. No principle of domestic or international law supports the majority’s conclusion that the norms enforceable through the ATS—such as the prohibition by international law of genocide, slavery, war crimes, piracy, etc.—apply only to natural persons and not to corporations, leaving corporations immune from suit and free to retain profits earned through such acts.

I am in full agreement that *this* Complaint must be dismissed. It fails to state a proper legal claim of entitlement to relief. The Complaint alleges that the Appellants—the parent holding companies at the apex of the huge Royal Dutch Shell international, integrated oil enterprise—are liable under the ATS on the theory that their actions aided the government of Nigeria in inflicting human rights abuses on the Ogoni peoples in the jungles of Nigeria. The allegations fall short of mandatory pleading standards. We recently held in *Presbyterian Church of Sudan v. Talisman Energy, Inc.*, 582 F.3d 244 (2d Cir.2009), that liability under the ATS for aiding and abetting in a violation of international human rights lies only where the aider and abettor acts with a purpose to bring about the abuse of human rights. Furthermore, the Supreme Court ruled in *Ashcroft v. Iqbal*, — U.S. —, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009), that a complaint is insufficient as a matter of law unless it pleads specific facts supporting a plausible inference that the defendant violated the plaintiff’s legal rights. Putting together these two rules, the complaint in this action would need to plead specific facts that support a plausible inference that the Appellants aided the government of Nigeria with a purpose to bring about the Nigerian government’s alleged violations of the human rights of the plaintiffs. As explained in greater detail below, see infra Part VII, the allegations of the Complaint do not succeed in meeting that test. I therefore agree with the majority that the claims against the Appellants must be dismissed, but not on the basis of the supposed rule of international law the majority have fashioned.

***

CONCLUSION

For the foregoing reasons, I agree with the majority that all of the claims pleaded against the Appellants must be dismissed. I cannot, however, join the majority’s creation of an unprecedented concept of international law that exempts juridical persons from compliance with its rules. The majority’s rule conflicts with two centuries of federal precedent on the ATS, and deals a blow to the efforts of international law to protect human rights.
Lawyers for 12 individuals seeking to hold major oil companies legally responsible for human rights abuses in Nigeria in the 1990s have asked the Supreme Court to overturn a federal appeals court’s ruling that corporations are immune to such claims in U.S. courts. The new petition, in the high visibility case of *Kiobel, et al., v Royal Dutch Petroleum, et al.*, raises what may be the hottest international law issue now affecting business firms.

In essence, the case is a kind of ultimate test of what Congress meant when, as part of the first federal courts law in 1789, it gave U.S. courts the authority to hear claims by foreign nationals that they were harmed by violations of international law. The case also seeks to test what the Supreme Court understood the law to mean in its ruling seven years ago in *Sosa v. Alvarez-Machain*, an international abduction case.

The law at issue is the Alien Tort Statute, a law that dates from the first Congress but has grown in importance at the center of a wave of lawsuits over the past three decades—lawsuits that were originally aimed at individuals, and then began targeting corporations in 1997.

The Second Circuit Court, in a ruling last September that aroused hard feelings among the judges on the panel and on the *en banc* Court, became the first court to rule that ATS does not apply at all to corporations, but only to individuals. The panel split 2-1, and the *en banc* Court divided 5-5 in refusing to reconsider the panel result.

Challenging that outcome, the new appeal argued: “Corporate tort liability was part of the common law landscape in 1789 and is firmly entrenched in all legal systems today. The notion that corporations might be excluded from liability for their complicity in egregious human rights violations is an extraordinary and radical concept.”

Invoking the grievous memory of atrocities by the I.G. Farben industrial complex in Nazi Germany, the petition asserted that “there is nothing in the ATS’s history or purpose, the common law of the 18th Century, or international law that supports” the Second Circuit conclusion.

While many lawyers and legal scholars interpret the Supreme Court’s 2004 ruling in *Sosa* to mean that the Court drew no distinction between corporations and individuals sued under ATS, the *Sosa* decision itself was a primary source of authority claimed by the Second Circuit panel for its conclusion that corporations are immune. The other main authority for the panel’s ruling was its perception of the absence of corporate defendants in international crimes tribunal cases.

The *Kiobel* petition seeks to put two questions before the Justices. It is conceivable that, if the Court were to grant the first of the two questions, it might not reach the ultimate question of corporate liability, at least in an initial round of review. That is because the first issue is whether the Circuit Court should have reached the issue of corporate immunity at all.
In fact, the petition suggested that the Justices should consider summarily overturning the Circuit Court on a basic procedural point, and then send the case back to the Circuit Court to decide on the legal issues of liability that the Nigerian challengers had raised in what was a pre-trial appeal.

As the case moved up from a federal District Court, neither side had raised the issue of whether ATS applied to corporations. That question was not decided by the District judge, and was not an issue that the judge sent up to the Circuit Court. But the Circuit Court panel majority, without deciding any of the issues sent up on appeal, opted on its own to conclude that it had no jurisdiction to decide the case because ATS simply did not apply to corporations.

Challenging that conclusion in arguing the first question in the new petition, the Nigerians’ counsel contended that the question of ATS’s reach is an issue on the legal merits, not a jurisdictional question. If it is treated as a jurisdictional question, the petition predicted, virtually every significant issue in an ATS case from now on will be turned into a question of the court’s authority, “enabling any Circuit panel to render decisions on virtually any issue without prior notice, briefing, or decision in the district court.” Moreover, it said, every corporation sued under such a legal understanding would seek to make every question one of jurisdiction.

The second question posed in the petition is what it describes as the merits question: whether corporations are immune from tort liability for war crimes, crimes against humanity, and other human rights abuses perhaps even amounting to genocide, or are they as liable as any private individual would be under ATS.

On that point, the petition said, there is a direct conflict between rulings of the Second Circuit and the Eleventh Circuit. In addition, it argued, other Circuit Courts have considered ATS suits against corporations without questioning whether they are covered.

Moreover, according to the petition, the issue of corporate liability under ATS is now under review in three other federal appeals courts—the D.C., Seventh and Ninth Circuits.

“Today,” the petition said, “corporations may be sued under the ATS for their complicity in egregious international human rights violations in Miami or Atlanta, but not in New York or Hartford. This is contrary to the congressional intent that the ATS ensure uniform interpretation of international law in federal courts in cases involving violations of the law of nations.”

The three companies involved in the case—Royal Dutch Petroleum Co., Shell Transport and Trading Co., and Shell Petroleum Development Co. of Nigeria Ltd.—will have a chance to respond to the petition before the Justices act on it. It is also possible that the Justices may seek the views of the federal government before acting.

There is no set timetable for the Court to act on the case, but it is a certainty that no action will come until the next Term, starting in October.
I recently spoke with the Managing Counsel of a publicly traded multinational corporation with a market cap well over $150 billion and operations on every continent. Although he had read a recent federal court of appeals opinion about the Alien Tort Statute ("ATS"), he admitted that he had little idea what it meant for his company in either the short or long term. In *Kiobel v. Royal Dutch Petroleum*, the Second Circuit held that corporations cannot be held liable for violations of customary international law under the ATS, thereby reversing a well-established trend of aliens suing corporate entities in U.S. federal courts for alleged human rights violations. However, *Kiobel* is hardly, as some observers have incorrectly hailed it, the blockbuster opinion that spells the end of the multi-billion dollar ATS litigation industry. On the contrary, those same suits will still proceed, but their cross-hairs will shift from corporations to the individuals who serve them.

A Look Back: How Corporations Came to Be Sued by Aliens in Federal Court

The ATS is a relic of the Federal Judiciary Act of 1789 that was intended to allow non-U.S. citizens to seek redress in American courts for violations of the law of nations (i.e., customary international law) such as piracy, attacks on ambassadors, and violations of rights of safe passage. The ATS remained dormant for 200 years until 1980, when the Second Circuit revived it in *Filartiga v. Pena-Irada*, a sweeping opinion that held that the ATS confers jurisdiction over tort actions brought by aliens (only) for violation of customary international law including war crimes against humanity. *Filartiga* gave rise to an abundance of litigation in federal district courts limited to suits against individuals, thereby reflecting one of the major trends in the international human rights movement of the post-WWII era. In 1999, however, federal courts began to allow hundreds of ATS suits alleging that a corporation—a "juridical" person—could also be an enemy of mankind.

*Kiobel* and the Resurgence of Individual Liability under the ATS

The Second Circuit’s recent opinion in *Kiobel* has closed for now the window used by plaintiffs to sue corporations under the ATS. However, it simultaneously turned the clock back 30 years by encouraging plaintiffs once again to target corporate directors and executives for such billion dollar suits. These suits will now become the norm among groups and plaintiffs’ lawyers putatively advocating under the aegis of human rights.

In *Kiobel*, residents of Nigeria claimed that Dutch, British, and Nigerian corporations that were engaged in oil exploration aided and abetted the Nigerian government in committing violations of customary international law. They sought damages under the ATS. The federal district court allowed their claims with respect to aiding and abetting arbitrary arrest and detention; crimes against humanity; and torture or cruel, inhuman, and degrading treatment. These claims were fair game. In light of the importance of the issues at stake, the trial
court voluntarily certified its entire order for interlocutory (i.e., provisional) appeal to the Second Circuit.

The Second Circuit held that corporations cannot be held liable for violations of customary international law. The court reasoned that the scope of liability—"who is liable for what"—must be determined by "specific, universal, and obligatory" norms of international (not domestic) law and that "corporate liability is not a discernible—much less a universally recognized—norm of customary international law." At the same time, the Court explicitly reminded both plaintiffs and individual corporate officers and directors alike that "nothing in [its] opinion limits or forecloses suits under the ATS against the individual perpetrators of violations of customary international law—including the employers, managers, officers, and directors of a corporation. . . ." Indeed, no one questions that individual liability for alleged violations of human rights—including for violations committed by those individuals' corporations—is precisely the sort of "specific, universal, and obligatory" norm that the Second Circuit and other federal courts recognize.

The Nuremberg Trials: The Root of Individual Liability in the International Human Rights Movement

The court accorded particular weight to no less than the Nuremberg Tribunals. The Tribunals explicitly refused to hear any claims against corporate defendant I.G. Farben, which, in close participation with the Nazi State, manufactured Zykon B, an insecticide knowingly used as a lethal asphyxiating agent in the gas chambers at Auschwitz, yet charged its individual executives with war crimes. The principle invoked by the Second Circuit in Kiobel was stated poignantly by Justice and U.S. Chief Prosecutor at Nuremberg Robert H. Jackson 75 years ago: "Crimes against international law are committed by men, not by abstract entities, and only by punishing individuals who commit such crimes can the provisions of international law be enforced."

Some suits brought under the ATS are legitimate. Yet corporate counsel generally deem the jurisdictional reach of the statute as having given rise to little more than a cottage industry of thousands of frivolous suits filed in often successful attempts to obtain 9-figure verdicts rather than face the uncertainty of complex, newsworthy trials with the specter of billion dollar jury verdicts.

A Final Word of Caution: Re-Aiming Litigation Cross-Hairs on Individual Directors, Officers, Managers, and Employees

Kiobel does nothing to deter the trend described above. On the contrary, the Second Circuit guides plaintiffs to their new—yet very old and once familiar—targets of choice: individual directors, officers, managers, and employees of those same corporations. Corporate executives and general counsel must institute proactive policies based on a detailed understanding of the ATS and relevant precedent in order to keep their companies far from suspicion while doing business abroad—and thereby keeping themselves from being named as individual defendants in lengthy cases with devastating costs.
I’ve now had a chance to read a little more closely the decision, majority and concurrence, in *Kiobel v. Royal Dutch Petroleum* (issued today by a 2nd Circuit panel of Judge Cabranes writing for himself and Judge Wood, and a concurrence in the judgment by Judge Leval). On second reading, it still looks to me like a blockbuster opinion, both because of the ringing tone of the Cabranes decision and the equally strong language of a concurrence that, on the key point of corporate liability, amounts to a dissent. With circuits having gone different directions on this issue, this perhaps tees up a SCOTUS review that would revisit its last, delphic pronouncement on the Alien Tort Statute in Sosa v. Alvarez-Machain. Here are a few thoughts that add to, but also partly revise and extend, things I said in my earlier post today.

Let me start by trying to sum up the gist of the majority opinion and its reasoning. (I am reconstructing it in part, in my own terms and terminology, and looking to basic themes, rather than tethering myself to the text of the opinion here.) The Cabranes opinion sets out the form of the ATS, that single sentence statute, as having a threshold part, which is established by international law (treaties of the United States and the law of nations, or customary international law), and a substantive part, which is the imposition of civil tort liability as a matter of US domestic law. It does not use quite those terms, but it seems to me to set up the statute in a way that I’ve sometimes characterized as a “hinge,” in which something has to “swing” between the threshold and the substantive command once the threshold is met. The question has been whether the threshold that serves as a hinge to swing over to connect and kick start the substantive part of the ATS, so to speak, the US domestic tort law substance, must be international law.

The ATS cases in various district courts and circuit courts have gone various directions on this, and indeed some of the early cases did not seem to recognize that there is a threshold part and a substance part. One sizable group of more recent cases have gone the direction of saying that even if the threshold has to be the law of nations or treaties of the United States, it is satisfied if there is some body of conduct that constitutes a violation of it (and further meets the requirements under Sosa). Call this conduct the “what” of this threshold requirement in the ATS. But what about the “who” of the conduct? Do the legal qualities of the alleged perpetrator of the violative conduct matter? Two possible answers are:

One is: if there is conduct, then the status under international law of whoever is alleged to have done it is not relevant. The existence of a “what” is enough, and the “who” is merely to show that this named defendant did it; further consideration of the juridical qualities of the defendant is irrelevant.

Alternatively, but to the same result of allowing a claim to go forward, even if it does matter, it is answered by looking to US domestic law in order to determine that it is an actor that can be held liable under the
ATS. Thus, under this latter view, a corporation could be such a party alleged to have engaged in conduct violating international law (and further meeting the Sosa standard). Why? Because it is enough that US civil law recognizes that a corporation is a legal person that can be held to legal accountability. So, for example, Judge Weinstein declared flatly in the Agent Orange litigation that notwithstanding weighty opinion that corporations are not subjects of liability in international law, well, as a matter of policy, they are so subject in US domestic law and that fact about US law will be enough to meet the threshold of the ATS international law violation. Put in my terminology, the “hinge” to an ATS claim can be met by an actor determined to be liable under US, rather than international law, standards. If there is conduct—the “what” under international law, such as genocide or slavery, meeting the Sosa standard—the question of “who” is subject to the ATS will be determined by the rules of US domestic law. The US domestic rules accept the proposition of a corporation being so subject, hence a claim will lie under the ATS.

The Second Circuit majority sharply rejects that view. It says that in order for the threshold of the ATS to be met, there must be a violation of international law. Conduct might very well violate international law, but for there to be a violation, it must be conduct by something that is recognized as being subject to liability in international law. If it is not something that is recognized or juridically capable of violating international law and being liable for it, then the conduct—whatever else it might be—is not actually a violation of international law by that party. States can violate international law, are subjects of international law, and can be liable under international law. Individuals under some circumstances can violate (a relatively narrow list of things in) international law, can be subjects of it, and can be liable under international law. But what about juridical persons, artificial persons—corporations? The opinion says flatly that corporations are not liable under international law—not even to discern a rule, let alone a rule that would meet the standards of Sosa. To reach this conclusion, the opinion walks through the history of arguments over corporate liability since WWII, ranging from Nuremberg to the considered refusal of the states-party to include corporations in the Rome Statute of the International Criminal Court.

By that point, the court has done two things. One, it has rejected the view that it is enough to find that US domestic law accepts corporate liability, and that it can be used to satisfy the threshold of an international law violation in the ATS. The hinge has to be international law; the threshold must answer both “what” and “who” as a matter of international law, with no reach to US domestic law. Hence, given that you can’t rely on US domestic law to reach it, then to satisfy the threshold, you have to show that it exists in international law as a treaty or customary norm (and then add to that the further burden of Sosa). Two, then, as to that latter requirement, the court says, no, it is not the case that a corporation meets the requirements of liability under the current state of customary international law or treaty law. The majority opinion accepts that if the international law threshold is met, then US domestic law in the ATS itself flips into civil tort mode. But you can’t get there without an international law violation on its own terms—and that means that there must be a “what” of conduct that violates international law and a “who” in the sense of an actor that, on international law’s own terms, is regarded as juridically capable of violating it.
It is important to note that this is all logically prior to Sosa’s requirements. What the Second Circuit has held here regarding corporate liability is not driven by Sosa at all. Sosa says that even if a claim satisfies the requirement of a violation of international law, the nature of the violation must meet a set of additional criteria—criteria that are established not as a matter of international law, but as matter of US Constitutional law imposed by the Court upon international law as considered in US courts to ensure, for domestic law reasons, that these ATS claims are, so to speak, really serious ones. The Second Circuit holding on corporate liability does not rest on the Sosa criteria; it never gets to them because it says that, quite apart from being “really serious” kinds of international law violations, the party alleged to have violated them must in the first place be a party capable in international law itself of violating them, in the sense of bearing legal liability. Only if the “who” is met, in other words, do the Sosa requirements come up as a further, domestic-law burden on the “what” of the claims.

This leaves an important point, however—one that is not so relevant to this case, but which will presumably be deeply relevant in other settings, perhaps in a SCOTUS case on this. On this I am somewhat less certain as to the court’s meaning, and will re-read the case and perhaps revise my views. At this point however, I’d say this. As the opinion observes, the nature of the ATS is to create in US domestic law a civil action in tort, premised upon meeting an international law threshold. However, it is a liability in tort—a remedy in tort—for violations that have to be international law violations themselves. We are now back at the “what.” The violations have to be international law violations (done by a “who” capable of being liable); once those violations of international law are met (and then further meeting the Sosa burdens as a kind of further threshold requirement in domestic law), then a tort remedy is available.

Even if the “who” is an individual person—capable of violating at least some actionable things in international law, including meeting the Sosa standard—as a matter of international law today, all the violations are criminal. They are all international crimes. International law recognizes no regime of civil liability in international law imposed upon persons; the violations that exist are such criminal acts as war crimes, crimes against humanity, genocide, and a few others that would meet the Sosa requirements.

To cut to the chase, the point is that nowhere in this list is there anything that looks like an environmental tort, because there is no international law of tort. And what many ATS cases seek to do is create out of the putty of American tort law a regime of international civil liability that, alas, does not exist. The court seems to recognize this implicitly, I think, although the holding about corporate liability does not turn on it. Let me step beyond the case, however, to the implication of this second point in practical terms.

Where ATS plaintiffs seek to state a claim (and even leaving aside the question of “who”) there is a large and logically independent problem, in many instances, of how plaintiffs can succeed in plausibly pleading a “what,” given the short list of things for which individuals can be liable. First off, they are all criminal. Particularly following Sosa, they are all criminal and all at the approximate level of serious war crimes and genocide. Whereas the actual substantive acts that plaintiffs wish to sue over, if they could be honest about it in the pleadings, are environmental torts—perhaps very serious ones, but not genocide or war
crimes. The only way into the ATS, given that the threshold “what” are all the most serious international crimes in the canon, has the perverse result that plaintiffs or, anyway, their lawyers, today utterly and routinely submit pleadings alleging war crimes, genocide, crimes against humanity, etc., at every turn.

Speaking for myself, anyway, this is not a good thing from the standpoint of convincing anyone outside the US civil tort process that the US is serious about these crimes. Trying to leverage the ATS into a global civil liability system in a sort of Jerry-rigged, spliced together, bits of US and bits of international law, arrangement that has precedential value only in US District Courts, and only by citing each other—well, it seems like a bad idea. I’m no fan of creating such a global system of civil tort liability, heaven knows, but if I were, I’d think this perhaps the worst of all worlds as a way of going about it.

But given the “whats” that can be plead, the result is inevitably a form of defining deviancy down. Defendants in these suits from outside the United States in particular seem often stunned that American courts so freely entertain allegations of the most serious crimes possible. In my personal experience, corporate defendants, in particular, often believe that they must fight to the wall even for things that in other circumstances they might be willing to negotiate as “ordinary” issues of labor rights, environmental claims, etc. Part of it is simply calculation—if they settle, they risk being forever characterized as having settled claims of … genocide, crimes against humanity, etc., in what was actually a fairly routine labor rights dispute in the developing world. But part of it, again in my experience, is that senior executives take this really personally; it is a slur on them and they won’t settle, not if the claims are war crimes rather than argument over ground water contamination. I agree with them and think that those who see the ATS as somehow promoting the universal rule of law should consider the many ways in which it instead promotes cynicism about international human rights claims in their most serious form, or at least the meaning of human rights claims in US courts.

That said on my own part, the Cabranes opinion is careful to emphasize that the Second Circuit has accepted that in appropriate cases, there can be aiding and abetting and secondary liability. The standard is a demanding one, to be sure, under the Second Circuit’s own holdings. In addition, the opinion emphasizes that individuals are, of course, liable in international law for certain serious crimes. Which goes to a question that Kevin Jon Heller posed in the comments, and on which I do not regard myself as expert. What is the big deal about this decision on corporate liability, if the same claims can simply be refiled against corporate officers and executives and other individuals? Why is the loss of corporate level liability such a big deal? I don’t regard myself as sufficiently expert in litigation to say definitively, and I welcome expert answers. However, for what it is worth, everyone I’ve dealt with on either side in these cases thinks it is a very big deal, in terms of what has to be proved as well as damages. I leave this to those more knowledgeable than I—but I have never had any sense that anyone in this practice area thought it was a red herring, although perhaps people will re­think it.

The majority opinion as well as Judge Leval’s concurrence both say quite a lot about the parlous issue of authority in answering the vexed questions of what constitutes customary international law. The role of experts, scholars, and “publicists” in
the traditional term is discussed in both opinions. Certainly in the majority, professors do not come off so well, despite the fact that the Cabranes opinion leans heavily on declarations by Professor James Crawford and then-Professor (now Justice) Christopher Greenwood in speaking to the content of customary international law. Without saying so in so many words, it seems clear that the court took into account that these are both globally important defenders of “international law” in its received sense, and not merely American academics; the court seemed implicitly to use them as an anchor for suggesting that international law needed to be tested, not merely within the parochial precincts of the US District Courts, citing each other in a gradually upward cascade of precedents, increasingly sweeping but also increasingly removed from sources of “international” law outside themselves, but against something genuinely international.

One can, of course, dispute whether Crawford and Greenwood are the right sources for that. But the opinion perhaps seemed to sense that ATS doctrines are increasingly sweeping but increasingly issued in a hermetically sealed US ATS system with less and less recourse to international law as the rest of the world sees it. I don’t know how else one takes a magisterial declaration by Judge Weinstein that it would simply be against public policy not to have corporate liability in a US court, irrespective of the authority for the proposition, or not, in actual international law. Maybe that is just me seeing what I want, to be sure; I think it is a correct concern, in any case.

Ironically, then, for those who would argue that the Cabranes opinion undermined “international law,” I would say that a view held more widely than one might guess (looking only to the sympathies that often lie with these claims) among international law experts outside the United States is that ATS jurisprudence actually undermines international law by contributing to its fragmentation among “communities of authority and interpretation,” as I’ve sometimes called it. International law is fracturing into churches and sects that increasingly do not recognize the existence or validity of others. The existence of more and more courts and tribunal systems contributes greatly to this fragmentation, I believe, because unlike the traditional ways of seeing international law as a pragmatic fusion of diplomacy, politics, and law in a loose sense—with the implied ability to see other points of view and accept them in a pluralist way—tribunals thrive in large part by asserting their own authority, on their internal grounds, in ways that achieve maximum authority inside their own systems precisely by denying the validity of other views. After all, if you’re going to lock up some defendant at the ICC, you have maximum claims to legitimacy for the holding if you take zero account of any other community of interpretation that thinks there is no ground to do so. The authority of courts, by contrast to the authority of Ministries of Foreign Affairs, is very much one that maximizes legitimacy by going “inside.” I’ve talked about this a lot in my own work—the fractious question of “Who owns international law?”

I do not want to try and characterize Judge Leval’s eloquent and passionate opinion; I don’t understand it as well at this point, and being less sympathetic to its point of view, I fear that without more careful study, I would characterize it unfairly. But I would note that the disputes between his opinion and that of the majority over experts and professors might best be settled by getting rid of us professors pretty much in toto. I am pleased to say that I said so in my own expert declaration in the Agent Orange case;
I thought it incumbent on me to tell Judge Weinstein that I didn’t think that professors’ opinions merited much weight if any, including my own.

And now a final thought, one that reaches far outside the case. It seems to me that this Second Circuit opinion is moving toward a much more confined ATS. There were other ways in which the court reserved on ways in which it might be curtailed still further—in passing, the court noted but declined to take a view on whether the ATS might have no extraterritorial application, limiting it to conduct within the United States. Once corporations were understood as targets, once everyone understood that neither plaintiff nor defendant required any traditional connection to the United States, as parties, in conduct, nothing, and once the plaintiffs bar saw opportunities to join forces with the NGOs and activists, the trend of the ATS has been to turn into a kind of de facto tort forum for the world. Whatever else it might be legally, politically this is a role suited for a hegemonic actor able to make claims against corporations stick on a worldwide basis. What happens if the hegemon goes into decline?

What happens, that is, when plaintiffs in Africa decide to start using the ATS to sue Chinese multinationals engaged in very, very bad labor or environmental practices in some poor and far away place? Does anyone believe that China would not react—in ways that others in the world might like to, but can’t? Does anyone believe that the current State Department would not have concerns—or more precisely, the Treasury Department? So let me end by asking whether a possible long run effect of this Second Circuit opinion, if followed in other circuits, and by SCOTUS, and perhaps other things that confine the ATS, is not over the long run an ATS for a post-hegemonic America?

Update: An international lawyer friend in Europe sent me an email commenting on this. This lawyer, who preferred not to be identified, said that despite agreeing with the opinion on corporate liability, both majority and concurrence once again exhibited that peculiarly American tendency to rely too much on Nuremberg cases. Even if a Nuremberg panel had held that some German firm could be held liable, international lawyers generally would not take that as very weighty evidence of the content of customary international law today. Rather, one should look to the way in which things had evolved over a long period of time to see what states did as a customary practice from a sense of legal obligation. A finding that a court long ago had ruled this or that was a peculiarly American way of re-configuring an inquiry into the content of customary international law into a common law inquiry.

Americans thought that was okay; not very many international lawyers outside the US agreed with that, said my friend, as a method of inquiry into customary international law. And they thought that American lawyers almost always overemphasized Nuremberg cases, treated them as hallowed ground—rather than looking to the path of treaties and state practice in the sixty years since. Even if a Nuremberg case had held there was corporate liability, nothing else since then supported the idea, and far more relevant, this lawyer friend concluded, was the affirmative consideration and rejection of the proposition in the ICC negotiations.