1	IN THE SUPREME COURT OF THE UNITED STATES
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3	FEDERAL TRADE COMMISSION, :
4	Petitioner : No. 12-416
5	v. :
6	ACTAVIS, INC., ET AL. :
7	x
8	Washington, D.C.
9	Monday, March 25, 2013
10	
11	The above-entitled matter came on for oral
12	argument before the Supreme Court of the United States
13	at 11:05 a.m.
14	APPEARANCES:
15	MALCOLM L. STEWART, ESQ., Deputy Solicitor General,
16	Department of Justice, Washington, D.C.; on behalf of
17	Petitioner.
18	JEFFREY I. WEINBERGER, ESQ., Los Angeles, California; or
19	behalf of Respondents.
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1	PROCEEDINGS
2	(11:05 a.m.)
3	CHIEF JUSTICE ROBERTS: We'll hear argument
4	next this morning in Case 12-416, the Federal Trade
5	Commission v. Actavis.
6	Mr. Stewart.
7	ORAL ARGUMENT OF MALCOLM L. STEWART
8	ON BEHALF OF THE PETITIONER
9	MR. STEWART: Mr. Chief Justice, and may it
LO	please the Court:
L1	As a general matter, a payment from one
L2	business to another in exchange for the recipient's
L3	agreement not to compete is an paradigmatic antitrust
L 4	trust violation. The question presented here is whether
L5	such a payment should be treated as lawful when it is
L6	encompassed within the settlement of a patent
L7	infringement suit. The answer to that question is no.
L8	Reverse payments to settle Hatch-Waxman
L9	suits are objectionable for the same reasons that
20	payments not to compete are generally objectionable.
21	They subvert the competitive process by giving generic
22	manufacturers an incentive to accept a share of their
23	rival's monopoly profits as a substitute for actual
24	competition in the
2.5	JUSTICE SCALIA: Why why are payments not

- 1 to compete different from, let's say, dividing a market?
- 2 I mean, suppose there's a lawsuit, somebody challenging
- 3 the validity of the patent, and the patentee agrees to
- 4 allow the person challenging the patent to have
- 5 exclusive -- exclusive rights to sell in a particular
- 6 area.
- 7 Does that violate the antitrust laws?
- 8 MR. STEWART: I mean, there are really two
- 9 differences between that -- that scenario and the one
- 10 presented here. The first is that an exclusive license
- is expressly authorized by the Patent Act, in Section
- 12 261 of Title 35, but -- but the second thing is --
- 13 JUSTICE SCALIA: That -- that doesn't
- 14 impress me. What else? What's your second point?
- 15 (Laughter.)
- MR. STEWART: The second thing is that an
- 17 exclusive license doesn't give the -- the infringement
- 18 defendant anything that it couldn't hope to achieve by
- 19 prevailing in the lawsuit. That is, if the -- at least
- 20 any right to compete that it wouldn't get by prevailing
- 21 in the lawsuit.
- If the infringement defendant won, it would
- 23 be able to sell wherever it wanted to.
- Now, there may be some --
- JUSTICE SCALIA: In order to make money. I

- 1 mean, that's -- that's what it wants is money.
- 2 MR. STEWART: But the point of --
- JUSTICE SCALIA: So instead of giving them a
- 4 license to compete -- you know, we'll short-circuit the
- 5 whole thing, here's the money. Go away.
- 6 MR. STEWART: But the point here is that the
- 7 money is being given as a substitute for earning profits
- 8 in a competitive marketplace. That is, in -- in the
- 9 Hatch-Waxman settlement context, by definition, we have
- 10 a disagreement by parties as to the relative merits of
- 11 the infringement and -- and/or invalidity questions as
- 12 to the patent infringement suit.
- The brand name is saying its patent is valid
- 14 and infringed. The generic is saying either that the
- 15 patent is invalid or that its own conduct won't be
- 16 infringing or both. And if the generic wins, it will be
- 17 able to enter the market immediately. If the brand name
- 18 wins, it will be able to keep the generic off until the
- 19 patent expires.
- 20 And so in that circumstance, a logical
- 21 subject of compromise would be to agree upon an entry
- 22 date in between those two end points, just as the
- 23 parties to a damages action would be expected to settle
- 24 the case by the defendant agreeing to pay a portion of
- 25 the money it would have to pay if it lost. That's an

- 1 actual subject of compromise and we don't have a problem
- 2 with that.
- JUSTICE SCALIA: Mr. Stewart, do you have a
- 4 case in which the patentee acting within the scope of
- 5 the patent has nonetheless been held liable under the
- 6 antitrust laws --
- 7 MR. STEWART: Yes.
- 8 JUSTICE SCALIA: -- for something that it's
- 9 done acting within the scope of the patent?
- 10 MR. STEWART: Yes, if you adopt Respondent's
- 11 conception of what it means to act within the scope of
- 12 the patent. And let me explain. When the Respondents
- 13 say that the restrictions at issue here are within the
- 14 scope of the patent, what they mean is that the goods
- that are being restricted are arguably encompassed by
- 16 the patent and the restriction doesn't extend past the
- 17 date when the patent expires.
- That's all they mean. And if that were the
- 19 exclusive test, the defendants in Masonite, in New
- 20 Wrinkle Inline Material, they would all have been off
- 21 the hook, because all of those cases involved
- 22 restrictions on trade in patented goods during the
- 23 period that the patent was in effect, and yet, the Court
- 24 found antitrust liability in each of these.
- Now, the way that Respondent tries to

- 1 explain Masonite, for example, Masonite involved a
- 2 resale price maintenance agreement in which the
- 3 patentholder sold goods and then attempted to control
- 4 the price at which they would be resold, and the Court
- 5 said that under the rule of patent exhaustion, the
- 6 patentholder didn't have the right to do that and
- 7 therefore the patent laws provided no shield and the
- 8 agreement was held to be a violation of the antitrust
- 9 laws.
- Now, Respondents say, well, that's
- 11 consistent with their theory because the restriction
- imposed went beyond the scope of the patent because the
- 13 right to control resale is not one of the rights that
- 14 the Patent Act confers. But if that's the test for
- 15 whether a restriction is within the scope of the patent,
- 16 then we would say that it's not met here, because
- 17 there's nothing in the Patent Act that says you can pay
- 18 your competitor not to engage in conduct that you
- 19 believe to be infringing.
- 20 And really that's the thrust of their
- 21 position, that if you have -- if a patentholder has a
- 22 non-sham allegation that a particular mode of
- 23 competition would be an infringement of its patent, the
- 24 patentholder can pay the competitor not to engage in
- 25 that competition.

Again, we are not talking about conduct in
Again, we are not talking about conduct is

- 2 which there has been any judicial determination that
- 3 infringement has occurred. We are just talking about
- 4 cases in which the patentholder has a non-sham
- 5 allegation that infringement would occur.
- 6 JUSTICE GINSBURG: Mr. Stewart, does this
- 7 represent a change in the government's position? I got
- 8 the idea from the briefs that at the time of this
- 9 Schering-Plough case, that was also before the Eleventh
- 10 Circuit, that the government was not taking that
- 11 position it's now taking.
- MR. STEWART: Well, the FTC has consistently
- 13 taken this position. The Department of Justice, up
- 14 until 2009, we didn't endorse the scope of the patent
- 15 test. Indeed, in our invitation brief in Joblove we
- 16 specifically said that the scope-of-the-patent test
- 17 was -- didn't provide for enough scrutiny of these
- 18 settlements.
- 19 But what we advocated, what the Department
- 20 of Justice advocated, instead was a test that would
- 21 focus on the strength and scope of the patent. That is,
- the likelihood that the brand name would ultimately have
- 23 prevailed if the suit had been litigated to judgment.
- 24 And in 2009 for the first time in an amicus brief filed
- 25 in the Second Circuit, we took essentially the position

- 1 that we're taking here, that is that agreements of this
- 2 sort should be treated as presumptively unlawful with
- 3 the presumption able to be rebutted in various ways.
- 4 JUSTICE KENNEDY: And one way is to assess
- 5 the validity or the strength of the infringement case?
- 6 MR. STEWART: We would say that that's not a
- 7 way, that --
- JUSTICE KENNEDY: That's my concern, is your
- 9 test is the same for a very weak patent as a very strong
- 10 patent. That doesn't make a lot of sense.
- 11 MR. STEWART: Well, the test is whether
- 12 there has been a payment that would tend to skew the
- 13 parties' choice of an entry date, that would tend to
- 14 provide an incentive for the parties to -- for the
- 15 generic to agree to an entry date later than the one
- 16 that it would otherwise insist on. Now, it probably is
- 17 the case that our test would have greater practical
- 18 import in cases where the parties perceive the patent to
- 19 be --
- JUSTICE KENNEDY: Why wouldn't that
- 21 determination itself reflect the strength or weakness of
- 22 the patent so that the market forces take that into
- 23 account?
- MR. STEWART: Well, I think in the kind of
- 25 settlement that we would regard as legitimate, where the

- 1 parties simply agree to a compromise date of generic
- 2 entry, then the parties would certainly take into
- 3 account their own assessment of what would likely happen
- 4 at the end of the suit. And so if the parties believe
- 5 that the brand name was likely to prevail, then if the
- 6 brand name agreed to early generic entry at all, it
- 7 would presumably be for a fairly small amount of time.
- 8 Conversely, if the parties collectively
- 9 believe that the generic -- that the brand name had a
- 10 weak case and the generic was likely to prevail, then
- 11 they would negotiate for an earlier date. And the
- 12 problem with the reverse payment is that it gives the
- 13 generic an incentive to accept something other than
- 14 competition as a means of earning money. I mean, to
- 15 take another --
- 16 JUSTICE SCALIA: This -- this was not a
- 17 problem, I gather, until the Hatch-Waxman amendments?
- 18 MR. STEWART: These suits -- these types of
- 19 payments appear to be essentially unknown in other
- 20 lawsuits and other patent infringement cases.
- 21 JUSTICE SCALIA: Yes, and so -- and so do
- 22 suits against this kind of payment. And I have -- I
- 23 have the feeling that what happened is that Hatch-Waxman
- 24 made a mistake. It did not foresee that it would
- 25 produce this kind of -- this kind of payment. And in

- order to rectify the mistake the FTC comes in and brings
- 2 in a new interpretation of antitrust law that did not
- 3 exist before, just to make up for the mistake that
- 4 Hatch-Waxman made, even though Congress has tried to
- 5 cover its tracks in later amendments, right, which --
- 6 which deter these, these -- these payments?
- 7 MR. STEWART: Congress has tried to reduce
- 8 the incentives for these payments to be made.
- 9 JUSTICE SCALIA: So, why should we overturn
- 10 understood antitrust laws just to -- just to patch up a
- 11 mistake that Hatch-Waxman made?
- MR. STEWART: Well, a couple things I would
- 13 say. First, I don't think we're -- we're not asking you
- 14 to overturn established antitrust laws. To take along
- 15 analogy, for example, if Watson instead of developing a
- 16 generic equivalent to AndroGel, had developed an
- 17 entirely new drug that it believed would be better than
- 18 AndroGel for the same conditions and if Solvay had paid
- 19 Watson not to seek FDA approval and not to seek to
- 20 market the drug, I think everyone would agree that that
- 21 was a per se antitrust violation, even though Watson's
- 22 ultimate ability to market the new drug would depend on
- 23 FDA approval that might or might not be granted.
- And so when we say it's unlawful to buy off
- 25 uncertain competition, it's unlawful to buy out

- 1 competition even when the competition might have been
- 2 prevented by other means, we are just enforcing standard
- 3 antitrust principles. To focus on the distinction
- 4 between Hatch-Waxman and other patent litigation,
- 5 Professor Hovenkamp's conclusion is that the reason that
- 6 you don't see payments like this in the normal patent
- 7 infringement suit is that in the typical market if a
- 8 patentholder were known to have paid a large sum of
- 9 money to a competitor who had been making a challenge to
- 10 the patent, if other competitors knew that that had
- 11 happened, then they would perceive that to be a sign
- 12 that the patent was weak and that they would leap in.
- But he says Hatch-Waxman makes it more
- 14 difficult for that to be done, because Hatch-Waxman
- 15 gives unique incentives to the first paragraph 4 filer.
- JUSTICE KENNEDY: Is that the 18 -- the
- 17 18-month rule primarily?
- 18 MR. STEWART: It's a 180-day period of
- 19 exclusivity.
- JUSTICE KENNEDY: Right. I mean 180 days,
- 21 yes.
- MR. STEWART: Yes, and the way it works is
- 23 that the exclusivity period is not good in and of itself
- 24 for consumers. That is, during the period when one
- 25 generic is on the market and the others are not yet

- 1 allowed to compete, you have essentially duopoly
- 2 conditions, the price of the drug drops but only by a
- 3 little bit. Congress granted the 180-day exclusivity
- 4 period because it wanted generics to have ample
- 5 incentives to challenge patents that were perceived to
- 6 be weak.
- 7 And if the first filer is able essentially
- 8 to be bought off, is able to set settle for something
- 9 other than early entry into the marketplace, then other
- 10 potential competitors face barriers to entry that
- 11 they -- similarly situated competitors wouldn't face in
- 12 other industries.
- JUSTICE BREYER: Well, that doesn't mean
- 14 that -- that's rather thin. I don't know how -- I don't
- 15 have the ability to assess that, the significance of it,
- 16 empirically. The thing I wonder, therefore, you said
- 17 it's common in antitrust? I'm -- I'm not up to
- 18 everything in the field, but I know there's an existence
- 19 of something called the per se rule, let's price fix it.
- I know there's a rule of reason, and I know
- 21 there's a sort of vaque area that sometimes in some
- 22 cases that Justice Souter mentioned in California
- 23 Dental, there is something slightly in between, which as
- 24 I saw those cases, they're very much like price fixing
- or -- or agreements not to enter. And what they seem to

- 1 say is, Judge, pay attention to the department when it
- 2 says that these are very often can be anticompetitive,
- 3 and ask the defendant why he's doing it.
- I mean, is that what you want us to say? It
- 5 didn't seem in your briefs as if you were. If you were
- 6 asking us to produce some kind of structure -- I don't
- 7 mean to be pejorative, but it's rigid -- a whole set of
- 8 complex per se burden of proof rules that I have never
- 9 seen in other antitrust cases, I -- my question is, when
- 10 I say I've never seen anything like this before in terms
- 11 of procedure, I want you to refer me to a case that will
- 12 show, oh, no, I'm out of date.
- MR. STEWART: Well, the -- the Court has
- 14 recognized such a thing as the quick look approach, but
- 15 I think even though the case didn't use the term "quick
- 16 look, " I don't believe it did, NCAA v. Regents of
- 17 University of Oklahoma is probably the best example,
- 18 where the --
- 19 JUSTICE BREYER: And are there others?
- MR. STEWART: Well, that's the -- that's the
- 21 one I'm most familiar with.
- JUSTICE BREYER: Is there any other? Are
- 23 you familiar with any other? Because I want to be sure
- 24 I read all of them.
- 25 MR. STEWART: I'll need to look back and see

- 1 what --
- JUSTICE BREYER: Well, if there are few or
- 3 none, then I would say why isn't the government
- 4 satisfied with an opinion of this Court that says, yes,
- 5 there can be serious anticompetitive effects; yes,
- 6 sometimes there are business justifications; so, Judge,
- 7 keep that in mind. Ask him why he has this agreement;
- 8 ask him what his justification is, and see if there's a
- 9 less restrictive alternative.
- In other words, it's up to the district
- 11 court, as in many complex cases, to structure their case
- 12 with advice from the attorneys.
- 13 MR. STEWART: I think that would leave
- 14 courts without quidance as to --
- JUSTICE BREYER: It's got guidance.
- 16 MR. STEWART: -- without guidance as to what
- 17 factors would be appropriate --
- 18 JUSTICE BREYER: The same thing is
- 19 appropriate as is appropriate in any antitrust case.
- 20 Are there anticompetitive effects? I have 32 briefs
- 21 here that explain very clearly what you said in a
- 22 sentence. It may be that they're simply dividing the
- 23 monopoly profit. I understand that -- you know, I can
- 24 take that in and so can every judge in the country. And
- 25 what's complicated about that?

Τ.	And then I have some very little dark green
2	briefs that clearly say, four instances, maybe five,
3	where there would be offsetting justifications. I think
4	they can get that, too.
5	MR. STEWART: Well, certainly our proposed
6	approach accounts for that. It provides it provides
7	really two different forms of rebuttal. First our
8	approach says, this is on its face an agreement not to
9	compete, the generic has agreed to stay out of the
L 0	market for a defined period of time, and the payment
L1	gives rise to an inference that the agree that the
L2	delay that the generic has agreed to is longer than the
L3	period that would otherwise reflect its best assessment
L 4	of its likelihood of of success in the lawsuit.
L5	But then we say, there are basically two
L6	different types of ways in which the presumption could
L7	be rebutted. First, the parties can show that the
L8	payment was not in consideration for delay, that there
L9	was some other commensurate value transferred, and the
20	payment and that arrangement would have been entered
21	into even without the larger settlement.
22	And then second, we're at least accepting
23	the possibility that brand names and generics could come
24	in and say, even though our payment was for delay, even
25	though we can't identify anything else that the payment

- 1 could have been consideration for, it's still, quote,
- 2 "competitive" under --
- JUSTICE BREYER: And they mention at least
- 4 two others. The first one they mention is because the
- 5 person's already in the market thinks that the next year
- 6 or two or three years is worth \$100 million a year, and
- 7 the person who's suing thinks it's worth 30 million a
- 8 year. And so he says, hey, I have a great idea, I'll
- 9 give him the 30 million and keep the 70. And -- and
- 10 that, I don't see why that's anticompetitive if that's
- 11 what's going on.
- 12 And the second instance they bring up is
- 13 that it's very hard to break into a market. So for the
- 14 new generic to come in, he's thinking, giving me two
- 15 years isn't worth much, because I'll spend a lot of
- 16 money, it's very hard for me to do it. But the
- 17 defendant -- the defendant who wants this patent kept
- 18 intact says, I will not only let -- I'll let you in a
- 19 year earlier and I'll give you enough money so that you
- 20 can start up a distribution system. The second seems
- 21 procompetitive; the first, neutral.
- The problem of deciding whether other
- 23 matters are or are not really payments for something
- 24 else, a true nightmare when you start talking about five
- 25 drugs and different distribution systems, and the matter

- of whether you're paying for litigation costs, a matter
- of great debate for the judge. Okay. That's the
- 3 arguments that they make. Go ahead.
- 4 MR. STEWART: Let me say a couple of things
- 5 about the administrative nightmare. The first is that
- 6 to the extent that these inquiries are difficult,
- 7 they're difficult only by -- because the brand names and
- 8 the generics have made them difficult by tacking on
- 9 additional transactions to their settlement proposal.
- 10 And to take an analogy, there are government
- 11 ethics rules that say that -- what are called prohibited
- 12 sources. Basically, people who have business before the
- department can't give me gifts as a government employee.
- 14 Now, obviously, it would be absurd to have a rule that
- 15 said a prohibited source couldn't give me a Rolex watch,
- 16 but could sell me a Rolex watch for a dollar. And so
- 17 the ethics rules treat as a gift an exchange for value
- 18 in which fair market value is not paid.
- 19 And everybody understands that once you go
- 20 down that route, occasionally, you will have hard cases
- 21 in which people could legitimately agree, was this a
- 22 legitimate arm's length exchange or was it a concealed
- 23 gift? But the prospect of those difficult cases doesn't
- 24 mean that we get rid of a gift ban altogether. And
- 25 certainly, Federal employees couldn't bring the -- the

- 1 ethics office to its knees by engaging in such a
- 2 proliferation of these side deals that the ethics office
- 3 decided it's not worth it.
- 4 The second thing is that Respondent's
- 5 approach would apply even when there are no hard
- 6 questions. Respondents would say that even if the
- 7 agreement provides for delayed generic entry until the
- 8 date the patent expires, and even if the only other term
- 9 of the agreement is the brand name pays the generic a
- 10 lot of money, that that would be a legitimate agreement,
- 11 because the restriction would apply to arguably patented
- 12 drugs and it wouldn't extend beyond the date of patent
- 13 expiration.
- I guess the -- the other thing I would say
- 15 about the way in which these payments can facilitate
- 16 settlement really shows their anticompetitive potential.
- 17 That is, suppose the parties were negotiating for a
- 18 compromise date of entry, but they couldn't agree;
- 19 the -- the brand name said beginning of 2017 is the
- 20 earliest we'll let you in and the generic said beginning
- 21 of 2015 is the latest date that we would accept.
- Now, the Respondents use the term "bridge
- the gap, "but there's obviously no way that a payment
- 24 from the brand name to the generic could enable the
- 25 parties to agree on an entry date between 2015 and 2017.

- 1 The brand name is never going to say, well, I would
- 2 insist on holding out until 2017, but if I'm going to
- 3 pay you a whole lot of money, then I'll let you earlier
- 4 and accept a -- a diminution of your profits. The brand
- 5 name is going to say, if I pay you money, I'm going to
- 6 insist on deferring entry even later than the 2017 date
- 7 that would otherwise be my preferred compromise.
- 8 So the natural effect of these payments is
- 9 not to facilitate a -- a bridging the gap in the sense
- 10 of a picking of a point between the dates that the
- 11 parties would otherwise insist on. It is going -- it is
- 12 very likely to cause the parties to agree to an entry
- 13 date that's even later than the one the brand name would
- 14 otherwise find acceptable.
- JUSTICE SOTOMAYOR: Mr. Stewart, can we go
- 16 back to Justice Breyer's question, initial question.
- 17 It's rare that we find a per se antitrust violation.
- 18 Most situations we put it into rule of reason.
- 19 You seem to be arguing that this is price
- 20 fixing, a reverse payment like price fixing so that it
- 21 has to fall into something greater than the rule of
- 22 reason.
- 23 MR. STEWART: Not -- not price fixing, but
- 24 it's -- it's an agreement not to compete. That is, the
- 25 parties are not agreeing as to the prices they will

- 1 charge. The generic is agreeing to stay off the market
- 2 first. But that would be treated as per se --
- JUSTICE SOTOMAYOR: But why is the rule of
- 4 reason so bad? As an -- and that's really my bottom
- 5 line, because you're creating all -- I think that's what
- 6 Justice Breyer was saying. I mean, for -- for example,
- 7 I have difficulty understanding why the mere existence
- 8 of a reverse payment is presumptively gives -- changes
- 9 the burden from the Plaintiff.
- 10 It would seem to me that you have to bear
- 11 the burden -- the burden of proving that the payment for
- 12 services or the value given was too high. I don't know
- 13 why it has to shift to the other side.
- MR. STEWART: Now, if you wanted to tweak
- 15 the theory in that way and to say that in cases where
- 16 there is not just a payment and an agreement on the date
- of market entry, but there is additional consideration
- 18 exchanged beside, if you wanted to say that the
- 19 Plaintiff would bear the burden of showing that this was
- 20 not a fair exchange for value, that -- that's not
- 21 something we would agree with, but that would be a
- 22 fairly minor tweak to our theory.
- 23 JUSTICE SOTOMAYOR: So answer the more
- 24 fundamental question: Why is the rule of reason so bad?
- 25 MR. STEWART: The rule -- I mean, it's bad

- 1 for reasons both of administrability and it's bad
- 2 conceptually. The reason it's bad for reasons of
- 3 administrability is that -- at least I take what you are
- 4 proposing to be that the antitrust court would consider
- 5 all the factors that might bear on the assessment of the
- 6 agreement, that those would include presumably a
- 7 strength of the patent claim, the subjective --
- JUSTICE BREYER: No. No. I mean, Professor
- 9 Areeda, who is at least in my mind a minor deity in the
- 10 matter, in this area, if not major, he explains it. He
- 11 says don't try for more precision than you can give.
- 12 The quality of proof required should vary with the
- 13 circumstances.
- Do you know how long it took -- I mean, and
- 15 I -- of course, I -- I know a little bit of antitrust.
- 16 But I mean, I think -- do you know how long it takes to
- 17 take in your basic argument that these sometimes can be
- 18 a division of profit, monopoly profit? It takes
- 19 probably 3 minutes or less. And judges can do that.
- 20 So you say to the judge: Judge, this is
- 21 what's relevant here. And there's a rule of evidence:
- 22 Don't waste the jury's time.
- 23 So -- so you shape the case as -- and this
- 24 is what goes -- used to go on for 40 years. You shape
- 25 the case in light of the considerations that are

- 1 actually relevant, useful and provable in respect to
- 2 that case. And district judges, that's their job.
- 3 So -- so what -- I'm not saying you'd lose the case.
- 4 They didn't side with the Eleventh Circuit. They said
- 5 there's no violation, okay?
- 6 I've got your point on that. But -- but I'm
- 7 worried about creating some kind of administrative
- 8 monster.
- 9 MR. STEWART: It's not atypical -- I mean --
- 10 and the Court did this in NCAA, for example, where it
- 11 said that the agreement it was looking at, which dealt
- 12 with the allocation of -- of -- allocation of rights to
- 13 televised football games -- was essentially a limitation
- 14 on output, and the Court said those are presumptively
- 15 unlawful. Long experience in the market has shown that
- 16 they are suspect.
- 17 The Court didn't say there was long
- 18 experience in the market for television rights to
- 19 football. It just said output limitations have been
- 20 established as disfavored.
- Nevertheless, because competitive sports by
- 22 nature require a degree of cooperation between the
- 23 people who compete against each other -- to establish
- 24 the rules of the game and so forth -- we will look to
- 25 see whether the parties have identified -- whether the

- 1 defendants have identified anything about their specific
- 2 industry that would justify our decision not to apply
- 3 the usual presumption, and it concluded that there was
- 4 nothing there.
- 5 And we're really asking the Court to take
- 6 the same approach here. We're saying payments not to
- 7 compete are generally disfavored. The parties can --
- 8 when you have a Hatch-Waxman settlement in which money
- 9 is passing from the brand name to the generic, it's an
- 10 unusual settlement to begin with, because there's no way
- 11 that the suit could have culminated in the generic
- 12 receiving a money judgment.
- And therefore, we'll -- we'll look upon this
- 14 with suspicion, be we'll give the parties adequate
- 15 opportunities to -- to rebut.
- 16 If I may, I'd like to reserve the balance of
- 17 my time.
- 18 CHIEF JUSTICE ROBERTS: Thank you,
- 19 Mr. Stewart.
- Mr. Weinberger?
- 21 ORAL ARGUMENT OF JEFFREY I. WEINBERGER
- ON BEHALF OF THE RESPONDENTS
- 23 MR. WEINBERGER: Mr. Chief Justice, and may
- 24 it please the Court:
- 25 I'd like to first respond to a question that

- 1 was asked of my friend by Justice Scalia a few minutes
- 2 ago. He was asked if there were any cases in which the
- 3 Court has ever found a restraint outside the scope of
- 4 the patent to be unlawful, and the answer to that
- 5 question is no, that -- all of the cases that have found
- 6 violations of the antitrust laws based on a patent-based
- 7 restraint do so because the object of the agreement, the
- 8 restraint that's being achieved in the agreement, is
- 9 beyond the scope that could be legitimately achieved
- 10 with a patent.
- 11 For example, it's an attempt to control
- 12 downstream the resale prices of -- of products that you
- 13 cannot do simply by exercising your patent. Or it's an
- 14 attempt to control the sale of unpatented products that
- 15 go beyond what a patent can protect.
- 16 Every -- every case in which --
- 17 JUSTICE SOTOMAYOR: Why isn't this then?
- 18 Meaning there is no presumption of infringement.
- 19 There's no presumption that the item that someone else
- 20 is going to sell necessarily infringes.
- 21 MR. WEINBERGER: That's correct.
- JUSTICE SOTOMAYOR: So what you're arguing
- 23 is that in fact a settlement of an infringement action
- 24 is now creating that presumption.
- MR. WEINBERGER: No, Justice Sotomayor, I'm

- 1 not arguing that. But -- but I do want to say that I
- 2 think our patent system depends upon the notion that you
- 3 don't evaluate from the perspective of the antitrust
- 4 laws a patent restraint based upon whether you could
- 5 have proved in a litigation that that patent -- that the
- 6 patent was infringed.
- JUSTICE SOTOMAYOR: I don't know, but I
- 8 don't know why we would be required to accept that there
- 9 has or would be infringement by the product that has
- 10 voluntarily decided not to pursue its rights.
- 11 MR. WEINBERGER: I think you're not --
- 12 you're not accepting infringement. What you're doing is
- 13 recognizing there's a reasonable basis to assert the
- 14 patent, a bona fide reasonable dispute, and the parties
- 15 have the ability to settle the dispute. Just as if the
- 16 party -- if someone was entering into a license
- 17 agreement with -- with someone who had a product that
- 18 they claimed did not infringe the patent, they sat down,
- 19 negotiated a license and resolved it --
- JUSTICE SOTOMAYOR: But there, you'd know
- 21 that they're not sharing the profits.
- MR. WEINBERGER: Yes.
- JUSTICE SOTOMAYOR: Meaning there you know
- 24 that a -- a product's been licensed and the -- that's
- 25 normal. The infringer is now paying the other side

- 1 money to sell that product.
- 2 MR. WEINBERGER: But Justice Sotomayor, many
- 3 other --
- 4 JUSTICE SOTOMAYOR: A reverse payment
- 5 suggests something different, that they're sharing
- 6 profits.
- 7 I don't know what else you can conclude.
- 8 MR. WEINBERGER: Many license -- I don't
- 9 think that's correct, and that's because many license
- 10 disputes are in fact resolved by the -- the alleged
- 11 infringer exiting the market for a period of time, or
- 12 agreeing to stay off until a certain time. And then the
- 13 license --
- JUSTICE SOTOMAYOR: But not many for reverse
- 15 payments.
- 16 MR. WEINBERGER: Yes, they are, because --
- 17 because, for example, it could be a license agreement
- 18 where the infringer agrees to stay off the market for X
- 19 number of years, and when it comes on it pays a certain
- 20 royalty. Now, anybody could argue that that royalty, if
- 21 it were higher, could result in an earlier entry.
- 22 There's always an argument to be made with any delayed
- 23 entry situation that monopoly profits are shared.
- 24 That's just -- just inherent in the nature of it.
- 25 And if you take the FTC's argument to its

- 1 full force, it would mean that any situation where
- 2 anyone is agreeing to a delayed entry, and there's any
- 3 other value that's being exchanged in that situation,
- 4 that in effect in economic terms is a payment for
- 5 delayed entry. There's no difference.
- 6 JUSTICE BREYER: Yes. But there, it's
- 7 not -- their point is not it's per se unlawful. What
- 8 they want is they want to cut some kind of line between
- 9 a per se rule and the kitchen sink. And if you look at
- 10 the brief supporting you, it is the kitchen sink. You
- 11 have economists attacking the patent system or praising
- 12 it, da, da, da, and here and there and the other. They
- 13 don't want the kitchen sink.
- 14 Now, suppose I don't want the kitchen sink,
- 15 but I have a hard time saying what the per se rule is.
- 16 So what's your argument?
- 17 MR. WEINBERGER: I -- I've obviously given a
- 18 lot of thought to whether there is any kind of an
- 19 intermediary test that works, and I don't believe there
- 20 is. Let me explain why.
- 21 First, you can't really measure whether
- 22 there were any anticompetitive effects from such a
- 23 settlement agreement without determining what would have
- 24 happened if the case hadn't settled and it would have
- 25 been litigated. And if the patentee had won the

- 1 litigation, then there would be no anticompetitive
- 2 effects.
- 3 That's what the Second Circuit and the
- 4 Federal Circuit concluded in applying the rule of reason
- 5 test, and saying the first condition of such a test has
- 6 not been met, because there's no demonstration of
- 7 anticompetitive effects.
- 8 And the cases -- both of those cases are
- 9 very good illustrations of what I'm talking about.
- 10 Those were the Tamoxifen and Cipro cases, where the
- 11 parties agreed to so-called reverse payment settlements
- 12 that FTC would say are basically per se lawful.
- 13 JUSTICE KENNEDY: Would it -- would it help
- 14 if you were -- were thinking about rules and caps, to
- 15 consider not what the branding company would have --
- 16 would have made, but what the generic company would have
- 17 lost, and -- and use the latter as the limit?
- MR. WEINBERGER: Well, you really don't know
- 19 unless you can assume when they could have entered --
- JUSTICE KENNEDY: Well, you -- you have to
- 21 make an extrapolation, yes.
- MR. WEINBERGER: Well, because it all
- 23 depends on what would have happened in the patent
- 24 litigation. So that you can't really tell whether
- 25 there's any anticompetitive effect.

- 1 I should also say with respect to the
- 2 generic losing, there's really no risk to the generic
- 3 here, which is one of the reasons you see these
- 4 settlements, that in this industry --
- 5 JUSTICE KENNEDY: Well, if the generic wins,
- 6 though, its -- everybody's profits are lower. And you
- 7 can gear it to just what the -- what the generic would
- 8 have made.
- 9 MR. WEINBERGER: They're -- they're lower
- 10 than they would be under some other situation, but --
- 11 but the patent gave the patentholder the legal right to
- 12 exclude. So unless there's a reason, there's some
- 13 reason to believe that it couldn't reasonably assert
- 14 that patent, it's entitled to monopoly profits for the
- 15 whole duration of the patent.
- 16 JUSTICE KAGAN: Mr. Weinberger, can I just
- 17 understand what you're saying, and maybe do it through a
- 18 hypothetical.
- 19 MR. WEINBERGER: Certainly.
- JUSTICE KAGAN: Suppose you had a -- a
- 21 lawsuit and the generic sends the brand name
- 22 manufacturer an e-mail and the e-mail says, we have this
- 23 lawsuit, I think I have about a 50 percent chance of
- 24 winning.
- 25 If I win, I take your -- your monopoly

- 1 profits down from 100 million to \$10 million. Wouldn't
- 2 it be a good thing if you just gave me 25 million? All
- 3 right? And then the brand name sends an e-mail back,
- 4 says -- you know, that seems like a pretty good idea, so
- 5 I'll give you 25 million.
- Now, as I understand it, your argument is, I
- 7 mean, that's just fine. That's hunky dory.
- 8 MR. WEINBERGER: Well, what I'm saying is
- 9 that in -- in any given situation --
- 10 JUSTICE KAGAN: Is that fine?
- 11 MR. WEINBERGER: I -- I think that if the --
- 12 if it's a single situation and the evidence is that
- 13 there's a reasonable basis to assert that patent and in
- 14 truth, the patent has, which you say, has a 50/50 chance
- 15 of prevailing, then I think that there could be a
- 16 settlement like that, if it's in good faith.
- 17 JUSTICE KAGAN: Even though -- but what if
- 18 it isn't in good faith? It's clear what's going on here
- 19 is that they're splitting monopoly profits and the
- 20 person who's going to be injured are all the consumers
- 21 out there.
- MR. WEINBERGER: Any -- any situation in
- 23 which there's any -- in any patent dispute in which
- there's a tradeoff, like the examples I mentioned
- 25 before, time for value, could -- that argument could be

- 1 made. And, in fact, if that was true, if it was true
- 2 that the natural inference and the motivations of the
- 3 people were simply to divide these profits with no other
- 4 consideration, then what you'd expect to see is that
- 5 every single patent dispute, especially in Hatch-Waxman
- 6 would result in a settlement that just pays the generic
- 7 until the end of the patent, because after all, the
- 8 market would be --
- JUSTICE KAGAN: Well, Mr. Weinberger, I
- 10 think if we give you the rule that you're suggesting we
- 11 give you, that is going to be the outcome, because this
- 12 is going to be the incentive of both the generic and the
- 13 brand name manufacturer in every single case is to split
- 14 monopoly profits in this way to the detriment of all
- 15 consumers.
- MR. WEINBERGER: Let me address that, Your
- 17 Honor. I don't think that's realistic at all,
- 18 because -- and let's take this industry specifically.
- 19 That the ability to challenge a patent in this industry
- 20 is lower than any industry that I can think of, and
- 21 that's because a generic is given the right to certify
- 22 against the patent and then basically challenge the
- 23 patent without having actually developed the product,
- 24 gotten a marketing force, gotten a factory, putting the
- 25 product on sale and taking the risk that everyone else

- 1 who challenges a patent has to take. All they have to
- 2 do is -- is file an NDA, which is roughly 300,000 to
- 3 \$1 million for these size drugs, that's not a lot, and
- 4 certify it.
- 5 And the FTC's own studies have shown that it
- 6 takes a very small chance of winning, something like
- 7 4 percent for a drug over \$130 billion to justify a
- 8 generic suing a brand name company. And what -- so what
- 9 happens in these cases --
- 10 JUSTICE SOTOMAYOR: Is that in all cases or
- 11 just Hatch-Waxman cases?
- 12 MR. WEINBERGER: It's Hatch-Waxman cases.
- 13 It's because of --
- 14 JUSTICE SOTOMAYOR: Because it does skew the
- 15 dynamics a lot.
- MR. WEINBERGER: Yes.
- 17 JUSTICE SOTOMAYOR: You know, the Second
- 18 Circuit recognized, even though it accepted your scope
- 19 of the patent, that there was a troubling dynamic in
- 20 what you're arguing, which is that the less sound the
- 21 patent, the more you're going to hurt consumers, because
- 22 those are the cases where the payoff, the sharing of
- 23 profits is the greatest inducement for the patentholder.
- MR. WEINBERGER: The Second Circuit
- 25 recognized that, but then they said further -- upon

- 1 further reflection, further consideration of this, we
- 2 are not troubled by it. One of the reasons they were
- 3 not troubled, it's what I was trying to answer Justice
- 4 Kagan about, is because the reality of the situation is
- 5 with so many potential challengers to the patent, all
- 6 they have to do is file an NDA, there are 200 generic
- 7 companies in this industry, that if you try to adopt
- 8 that strategy of paying the profits of a generic,
- 9 there's going to be a long line of --
- 10 JUSTICE BREYER: Okay. Suppose --
- 11 JUSTICE KAGAN: Well, I don't think that
- 12 that's true, Mr. Weinberger, and it's because of
- 13 something that Justice Scalia suggested, that there's a
- 14 kind of glitch in Hatch-Waxman, and the glitch is that
- 15 the 180 days goes to the first filer. And once the
- 16 180-day first filer is bought off, nobody else has the
- 17 incentive to do this.
- MR. WEINBERGER: That's clearly not correct
- 19 either by logic or by reference to actual experience.
- 20 It's true that the first filer is given a greater
- 21 incentive, but these products can last for 20 or
- 22 25 years.
- 23 JUSTICE KAGAN: But the -- the huge
- 24 percentage of the profits is done in the exclusivity
- 25 period. I mean, it's true that it can go on for a long

- 1 time, but you're making dribs and drabs of money for a
- 2 long time. Where you're really making your money is in
- 3 the 180 days.
- 4 MR. WEINBERGER: Experience doesn't show
- 5 that, because if you look at Hatch-Waxman litigation,
- 6 we've cited in -- in the red brief and it's been
- 7 discussed by the antitrust economists and the Generic
- 8 Pharmaceutical Association in their amicus brief, that
- 9 many of these Hatch-Waxman cases involve multiple
- 10 filers.
- 11 You have five, 10, as many as 16 companies
- 12 challenging these patents, all of -- one of whom are not
- 13 the first filer. So there -- there must be an incentive
- 14 for them to do this, and -- and they are. So I think
- 15 experience says that that kind of extreme view of
- 16 incentives is not really true.
- JUSTICE KENNEDY: What -- what do we look at
- 18 to verify what you say? Is that -- is that all in the
- 19 briefs?
- MR. WEINBERGER: Yes, it's in the -- in the
- 21 Solvay brief and other briefs.
- JUSTICE KENNEDY: Because I had thought, as
- 23 Justice Kagan's question might indicate, that the
- 24 180 days is crucial, it allows you to go to the doctors,
- 25 to give them the name of your generic equivalent, et

- 1 cetera, and that that's a big advantage.
- 2 MR. WEINBERGER: It's a big advantage --
- JUSTICE KENNEDY: And now, you're -- now,
- 4 you're indicating that it isn't.
- 5 MR. WEINBERGER: It's a big advantage. It's
- 6 an incentive for the first six months, I don't debate
- 7 that, but after that, the market opens up.
- 8 JUSTICE BREYER: Okay. Suppose -- this
- 9 sounds like an argument, a discussion that you have in
- 10 the district court, so -- so why -- what's your reaction
- 11 to this: Say A, sometimes these settlements can be very
- 12 anticompetitive, dividing monopoly profit. In deciding
- whether anticompetitive outweighs business practices
- 14 without less restrictive alternatives, judge, you may
- 15 take that into account; 2, do not take into account the
- 16 strength of a patent; 3, do not try to relitigate the
- 17 patent.
- 18 4, there are several possible
- 19 justifications, ones I listed before out of the briefs,
- 20 litigation costs -- the other products, different
- 21 assessments of -- of value. 5, there could be, in fact,
- 22 no anticompetitive effect here because of what you just
- 23 said now in response to Justice Kennedy and Justice
- 24 Kagan, but there could be. We don't know. Okay?
- 25 So, start with where we were. Could be

- 1 anticompetitive. Give the defense a chance to go
- 2 through five, 1 through 5, and if they convince you
- 3 there is a 6, we're not saying there isn't, but we can't
- 4 think of one on the briefs, let them have the 6th, too.
- 5 Okay? Now, judge, weigh and decide. That's what we do.
- 6 So we've structured it somewhat to keep the kitchen sink
- 7 out on the basis of the briefs given to us. What's
- 8 wrong with that?
- 9 MR. WEINBERGER: Well, I think the first
- 10 problem with it is that it's -- it's very unpredictable.
- 11 It's really hard to figure out how that all gets sorted
- 12 out, and the parties who are sitting down to do a
- 13 settlement need, I feel, much clearer guidance.
- JUSTICE SCALIA: You can't -- you can't
- 15 possibly figure it out, can you, without assessing the
- 16 strength of the patent?
- 17 MR. WEINBERGER: That's right.
- JUSTICE SCALIA: Isn't that crucial to -- to
- 19 the conclusion?
- 20 MR. WEINBERGER: I -- I believe that the
- 21 only thing that brought --
- JUSTICE SCALIA: And to say you can consider
- 23 every other factor other than the strength of the patent
- 24 is -- is to leave -- leave out the -- the elephant in
- 25 the room.

Т	MR. WEINBERGER. I agree with that,
2	Justice Scalia. I don't think that an alternative
3	test the only alternative test that could be
4	fashioned that would that would make sense is one
5	based on strength of the patent. But there are so many
6	reasons that that is an undesirable result that I I
7	don't think it's the way this Court should go.
8	JUSTICE SOTOMAYOR: For whom? And and
9	you know, the government is basically saying, we really
LO	don't want reverse payments, period. We want people to
L1	settle this the way they should settle it, which is on
L2	the strength of the patent. And that means settling it
L3	simply by either paying a royalty for use or settling as
L 4	most cases do, on an early entry alone, so there's no
L5	sharing of of of profits. What's so bad about
L6	that? I mean, it doesn't deprive either side of the
L7	ability to finish the litigation if they want to.
L8	MR. WEINBERGER: Let's say I wouldn't
L9	concede that most cases settle like that. But let's
20	let's accept that and take the case of a of a strong
21	patent or a patent with a long term. Let's say
22	it has you evaluate the strength of the patent and
23	you conclude that it has 10 or 15 good years remaining.
24	Now, you have a generic who is or many
25	generics who have sued with no risk or minimal risk in

- 1 Hatch-Waxman, and their response is, why would I -- why
- 2 would I drop this lawsuit to get an entry date in 2025
- 3 or 2028? That doesn't meet my business needs, I have
- 4 shareholders, I have investors, I have to run a
- 5 business, and I'm going to keep on litigating unless you
- 6 give me something of value. So that's what these
- 7 agreements are about. They're saying, well, what
- 8 other -- remember, this is not just a cash payment.
- 9 There are all --
- JUSTICE SOTOMAYOR: Well, in the normal
- 11 course, if the patent's really strong, if you get a year
- 12 or two earlier entry, that has an inherent value, and
- that's what you'll pay for is what the government is
- 14 saying. That will be the determination the two parties
- 15 will make, which is at what point is earlier entry worth
- 16 it --
- 17 MR. KATZ: Well, first of all --
- 18 JUSTICE SOTOMAYOR: -- for the very strong
- 19 patentholder.
- MR. WEINBERGER: First of all, parties often
- 21 don't agree on the merits. Parties tend to be
- 22 overconfident. They both think they are going to win.
- 23 So it's sometimes very hard to come to a consensus where
- 24 entry date is the only bargaining chip available.
- JUSTICE SOTOMAYOR: Well, they pointed to

- 1 most settlements and say that is the vast majority.
- 2 MR. WEINBERGER: I don't know where the
- 3 evidence would be for that. I don't think --
- 4 JUSTICE SOTOMAYOR: Well, we do know that
- 5 these reverse payments, except for recent times when
- 6 people figured out they were so valuable, were the
- 7 exception, not the rule.
- 8 MR. WEINBERGER: Actually, we have ten years
- 9 of experience since the circuit courts first began
- 10 applying scope-of-the-patent tests to these settlements
- 11 since 2003. So we have a pretty good window as to what
- 12 would happen.
- JUSTICE SOTOMAYOR: They have been
- increasing in number, not decreasing.
- MR. WEINBERGER: No, I think they have been
- 16 actually very steady. They are roughly between 25 and
- 17 30 percent, pretty much constant and you don't really
- 18 see any huge blips depending on what a particular court
- 19 is ruling.
- 20 If the FTC's kind of
- 21 the-sky-is-going-to-fall approach is right, that
- 22 everybody's going to run out and do this, you would have
- 23 thought that after the first Eleventh Circuit ruling,
- 24 after the Federal Circuit ruling, after the Second
- 25 Circuit ruling, after second Eleventh Circuit ruling,

- 1 that there would be huge increases in this, but we
- 2 haven't seen that.
- 3 Some of the numbers increased last year, but
- 4 as a percentage of the total settlements they are very
- 5 steady. They are pretty much the same.
- 6 JUSTICE GINSBURG: What about the
- 7 consideration that seems to be driving the government?
- 8 That is, the generic is getting an offer that they would
- 9 never get on the street. I mean, they have been paid
- 10 much more than they would get if they won the patent
- 11 infringement suit. If they won the patent infringement
- 12 suit then they can sell their generic in competition
- 13 with the brand, but under this agreement they get more
- 14 than they would get by winning the lawsuit.
- 15 MR. WEINBERGER: Justice Ginsburg, first of
- 16 all, every settlement agreement involving one of these
- 17 cases must be filed with the FTC. They have hundreds of
- 18 them. And they haven't pointed to a single example
- 19 where that's the case.
- JUSTICE KAGAN: But it's just an economic --
- JUSTICE KENNEDY: Well, suppose -- suppose
- 22 that hypothetical is correct. That's was my concerns,
- 23 too. What the brand company can lose is much greater
- 24 than what the generic can make. So why don't you just
- 25 put a cap on what the generic can make and then we won't

- 1 have a real concern with the restraint of trade, or
- 2 we'll have a lesser concern. I think that's the thrust
- 3 of Justice Ginsburg's question and it's my concern as
- 4 well.
- 5 MR. WEINBERGER: Yes, and I want to make
- 6 clear that I don't think that could happen, because if a
- 7 brand name company adopted that as a strategy to protect
- 8 its patent, it would --it would be held up. It would be
- 9 held up by the many generic companies that could easily
- 10 challenge these patents without actually having a
- 11 manufactured product, without putting it on sale,
- 12 etcetera.
- 13 So I think that the antitrust rule should
- 14 not be fashioned to deal with a case on the extreme,
- 15 which hasn't been shown to happen, which logically from
- 16 an economic point of view is highly unlikely to happen.
- 17 And if for some reason that starts happening
- 18 empirically, then Congress -- and it is a loophole in
- 19 Hatch-Waxman that is causing that, and there is really
- 20 no evidence that that extreme example has happened --
- 21 then Congress can deal with it, just as it dealt with
- 22 the exclusivity provision.
- JUSTICE GINSBURG: I thought the government
- 24 was telling us that that's this case, that the -- what
- 25 the generic is being offered in the way of sharing the

- 1 monopoly profits is more than it could ever make if it
- 2 wanted to and sold its drug.
- MR. WEINBERGER: Well, I don't see any
- 4 examples of that cited in their brief. It's a theory,
- 5 it's a hypothetical theory, but there is no data. We
- 6 have had years of experience with this case.
- JUSTICE KENNEDY: Well, but it's not
- 8 hypothetical that if the generic wins everybody -- the
- 9 brand companies profits are going to go way, way down
- 10 right away and generic profits are not going to be that
- 11 great.
- 12 MR. WEINBERGER: Of course. I think that's
- 13 true in many -- many patent litigations.
- 14 JUSTICE KENNEDY: Well, but so then the
- 15 question still holds. If you -- if you key your payment
- 16 to what the brand company will make, it's just a much
- 17 higher figure, and a greater danger of unreasonable
- 18 restraint.
- 19 MR. WEINBERGER: There is that hypothetical
- 20 risk. What I'm -- I am trying to make the point that
- 21 it's not -- with the number of challenges you have here,
- 22 which is basically unlimited, that if you put a sign
- 23 around your neck that says, paying off all generic
- 24 companies their profits, whoever wants to challenge my
- 25 patent come do it, there is going to be a long line of

- 1 people, of companies, doing it.
- JUSTICE KENNEDY: Okay, I will grant you
- 3 that point that the 180 days is not that big a
- 4 difference, and that there are many generics out there.
- 5 But isn't that true in every industry? You said at the
- 6 outset: Oh, well, now in the drug industry there are a
- 7 lot of people ready to pounce in. Isn't that true in
- 8 any industry?
- 9 MR. WEINBERGER: It is true and that's why
- 10 it doesn't happen. It's -- it's more true here because
- 11 it's much easier to challenge a patent. So in any other
- 12 industry a potential challenger has to make a major
- 13 investment in a product, has to get it manufactured, has
- 14 to put it on sale, and then litigate. And if they lose,
- they are going to be liable for enormous damages.
- 16 That's not the case under Hatch-Waxman. All
- 17 they need to do is file an ANDA. They have nothing at
- 18 risk. If they lose, they haven't lost any damages.
- 19 They just walk away. So there is an enormous difference
- 20 in the risks between Hatch-Waxman and other cases that
- 21 explains the particular form of some of these
- 22 settlements and why they happen.
- 23 JUSTICE SOTOMAYOR: I see that as an
- 24 argument that there is an economic reality in
- 25 Hatch-Waxman that would require us not to apply any rule

- 1 we choose or accept here to other situations; only here.
- 2 That's the argument that you're creating for me, that
- 3 there's a different economic reality here that requires
- 4 a different rule.
- 5 MR. WEINBERGER: Justice Sotomayor, I think
- 6 the economic reality cuts the other way. It doesn't cut
- 7 in favor of making a rule that makes these more
- 8 difficult. What I'm saying is that --
- JUSTICE SOTOMAYOR: Oh, but it does, because
- 10 in Hatch-Waxman Congress decided that there was a
- 11 benefit for generics entering without suffering a
- 12 potential loss to enter the market more quickly.
- 13 MR. WEINBERGER: Justice Sotomayor, I don't
- 14 think the legislation --
- 15 JUSTICE SOTOMAYOR: And any settlement in
- 16 these cases deprives consumers of the potential of
- 17 having the benefit of an earlier entry.
- MR. WEINBERGER: I don't think there is
- 19 anything in Hatch-Waxman that supports the idea that the
- 20 purpose was to provide for generic entry prior to patent
- 21 expiration. What the structure is designed to do is
- 22 encourage challenges --
- 23 JUSTICE SOTOMAYOR: Exactly, and what you
- 24 are doing with permitting settlements of this kind is
- 25 not permitting the process to go to conclusion.

- 1 MR. WEINBERGER: I don't think there is
- 2 anything in Hatch-Waxman that suggests in any way that
- 3 settlements or -- should be discouraged or that cases
- 4 should be mandated to proceed to judgment or that all
- 5 have to be litigated.
- JUSTICE SOTOMAYOR: It's encouraging
- 7 infringement suits.
- 8 MR. WEINBERGER: It's encouraging challenges
- 9 and it has produced many challenges. And can I say that
- 10 with 10 years of the application of the
- 11 scope-of-the-patent rule, there is no particular problem
- 12 with Hatch-Waxman. It's working very well. The
- 13 amount -- the number of drugs that have now gone generic
- 14 from just 10 years ago to today has increased
- 15 enormously.
- 16 JUSTICE BREYER: So why does it help you to
- 17 say, if the Court says or the FTC says when you get one
- 18 of these suits you can settle it by letting them in, but
- 19 you can't pay them money, that that will help to stop
- 20 strike suits. It costs them nothing to get in. They
- 21 have to really want to enter or they won't bring
- 22 lawsuits. So why does that hurt you?
- 23 MR. WEINBERGER: Well, I actually think that
- 24 you raise a point that the generic -- in some of the
- 25 amicus briefs, some of the generic parties have talked

- 1 about, which is that their ability to challenge these
- 2 cases depends on their not having to litigate every one
- 3 of them to conclusion. And that's not bad, because most
- 4 patent cases settle. Most -- most of these disputes
- 5 settle. And if our system was one in which every case
- 6 had to be litigated fully to judgment, we would be
- 7 unable to cope with that.
- 8 So -- so what I think the statute mandates
- 9 or contemplates is that generics should be able to
- 10 challenge, and should have strong incentive to
- 11 challenge, but that doesn't mean that they should be
- 12 required to litigate to conclusion. And if settlement
- is made more difficult so that different perceptions or
- 14 different business objectives can't be bridged with some
- 15 kind of a business settlement, that is going to mean
- 16 that fewer generics are going to challenge these patents
- 17 and that is contrary to the purpose of the Hatch-Waxman
- 18 Act.
- 19 JUSTICE KENNEDY: I think it's correct that
- 20 to develop a new drug sometimes you need not just
- 21 scientists and attorneys, you need investment bankers.
- 22 And you then need marketers, because the cost of these
- 23 drugs can be hundreds of millions. Is there anything in
- 24 the record that shows the development cost of this drug?
- 25 MR. WEINBERGER: This particular drug, I

- 1 don't know. I mean, there are lots of studies of how
- 2 much average drugs cost, and that figure is over a
- 3 billion dollars.
- 4 JUSTICE KENNEDY: It can be a billion.
- 5 MR. WEINBERGER: Easily a billion dollars.
- 6 JUSTICE KENNEDY: Anything in this case?
- 7 MR. WEINBERGER: This particular drug --
- 8 JUSTICE KENNEDY: Anything in the record?
- 9 MR. WEINBERGER: No, because we are on a
- 10 12(b)(6) motion on a motion to dismiss, so none of that
- 11 was ever developed, but --
- 12 JUSTICE KAGAN: I'm sorry, go ahead.
- MR. WEINBERGER: But I was just going to say
- 14 that the -- of course, any given drug development cost
- 15 doesn't even begin to tell the picture, because for
- 16 every drug that succeeds, there are at least 10 that
- 17 fail, and all the costs that are involved in the drugs
- 18 that fail have to be covered with the one drug that
- 19 succeeds.
- JUSTICE KAGAN: Could I just make sure I
- 21 understand the way the 180-day period worked? The first
- 22 filer gets it, if I buy off -- if I'm a brand name
- 23 manufacturer and I buy off the first filer with one of
- these reverse payments, you're suggesting that that's
- 25 not going to do me much good because they're all going

- 1 to be -- there's going to be a long line. And that long
- line of people, it's not just that they don't get the
- 3 180-day period, it's like even if one of those people
- 4 wins, the person whom I've paid off is going to get the
- 5 180-day exclusivity period; isn't that right?
- 6 MR. WEINBERGER: Not completely. First of
- 7 all, it depends on the -- the agreement. For example,
- 8 in this case, that 180-day exclusivity was waived.
- 9 JUSTICE KAGAN: But if it's not waived by
- 10 the parties, in other words, it's just like I don't get
- 11 it so my incentives go down. It's that my competitor
- 12 gets it. So why in the world am I standing in line
- 13 to -- to challenge this if my competitor is going to get
- 14 the exclusive period?
- MR. WEINBERGER: This was the exact problem
- 16 that Congress addressed in 2003, when it amended
- 17 Hatch-Waxman and changed the exclusivity requirements.
- 18 So the way the law now reads is that subsequent
- 19 generics, subsequent filers can trigger that 180-day
- 20 exclusivity by continuing to litigate. So, if the first
- 21 filer settles and these other folks are in line and
- 22 they're litigating, they can force that period to start
- 23 running and then they can come in right after. So, it
- 24 is not correct that you can tie up the first filer in
- 25 settlement and prevent everybody else from entering.

- 1 And even before that amendment, the Eleventh
- 2 Circuit, Federal circuit in the Second, applying the
- 3 scope of the patent rule recognized that if the
- 4 agreement creates a bottleneck to other filers that goes
- 5 beyond what the statutory exclusivity provides, where
- 6 they agree not to give up their exclusivity or agree to
- 7 retain it, then that's beyond the scope of the patent,
- 8 because you can't achieve that kind of a restraint
- 9 simply -- with a patent, you -- you're using the
- 10 agreement to expand upon your patent rights to block
- 11 other filers.
- So I think that problem's been addressed by
- 13 Congress. And if somebody feels that solution's not
- 14 perfect and they want to make it even easier for
- 15 subsequent filers to come in, then I submit that
- 16 Congress can do that. That they --
- 17 JUSTICE GINSBURG: Well, what was the change
- 18 that was made?
- 19 MR. WEINBERGER: The change that was made,
- 20 Justice Ginsburg, is that -- there were a number of
- 21 changes, but the one that's relevant here is that if
- 22 a -- if a subsequent filer -- strike that.
- 23 You can trigger the exclusivity beginning to
- 24 run by getting the judgment. So, in the past, if a
- 25 first filer settled and they just didn't do anything --

1	may I finish the
2	CHIEF JUSTICE ROBERTS: Yes, certainly.
3	MR. WEINBERGER: And they just didn't do
4	anything, that would prevent other generics from coming
5	to market. But now anybody else who's litigating the
6	patent, if they go ahead and win their case, then
7	that that triggers the first filer's rights and if
8	they don't exercise that those rights within 75 days
9	they're gone, they're forfeited. So that's the change.
10	CHIEF JUSTICE ROBERTS: Thank you, counsel.
11	MR. WEINBERGER: Thank you.
12	CHIEF JUSTICE ROBERTS: Mr. Stewart, you
13	have five minutes remaining.
14	MR. WEINBERGER: Thank you, Your Honor.
15	REBUTTAL ARGUMENT OF MALCOLM L. STEWART
16	ON BEHALF OF THE PETITIONER
17	MR. STEWART: Thank you.
18	Mr. Weinberger argued that in order to
19	determine whether a settlement of this sort has
20	anticompetitive effects, we would have to know how the
21	lawsuit would have turned out, but it's perhaps the most
22	fundamental principle of antitrust law that particular
23	conduct can be legal or illegal, depending on the
24	deliberative process that led up to it.
25	And to put that in concrete terms, if a

- 1 business charges a particular price for a particular
- 2 product, because it's made the assessment that this will
- 3 maximize profits in a competitive environment, that
- 4 decision is almost immune from antitrust scrutiny. But
- 5 if the business charges the same price for the same
- 6 product in the same market because it's agreed with its
- 7 competitor that it will charge that price, that's a per
- 8 se antitrust violation.
- 9 So it's not at all anomalous to say that
- 10 this type of agreement can be deemed anticompetitive,
- 11 even though the same result, namely, exclusion of the
- 12 generic from the market might have been able to be
- 13 obtained by other means.
- 14 The second thing is, Mr. Weinberger said
- 15 there are instances in which second and successive
- 16 filers will attempt to challenge the brand name even
- 17 after the first filer has been bought off. I think
- 18 we -- we disagree that it's as easy as he would say it
- 19 is, but we'll concede it happens occasionally. But the
- 20 fact that particular anticompetitive conduct doesn't
- 21 always work doesn't make it lawful.
- It could often happen that two firms were
- 23 thinking about entering into a price-fixing agreement,
- 24 for instance, but thought to themselves, if we do that,
- 25 there's a third competitor in the market who will be

- 1 able to undersell us, and this would make our agreement
- 2 unprofitable. And it might happen sometimes that two
- 3 firms try to proceed with a price-fixing conspiracy, but
- 4 they're thwarted because of the unexpected competition
- 5 from a third firm.
- 6 CHIEF JUSTICE ROBERTS: Well, I thought that
- 7 Mr. Weinberger's point was that this is always going to
- 8 happen, because it's very easy -- as he said, you put a
- 9 sign on your neck saying, generics line up to get your
- 10 payment. That seems quite different than saying there's
- 11 another firm out there in the abstract that -- that
- 12 might want to enter into a similar market sharing
- 13 arrangement. This is a very different system.
- 14 MR. STEWART: I mean, first, there certainly
- is no evidence suggesting that it has happened often,
- 16 although there is evidence that it has happened. But if
- 17 the brand name perceived on a systemic basis that the
- 18 likely result of paying off one competitor was that
- 19 another competitor would step in and couldn't be bought
- off would litigate the suit to judgment, there would be
- 21 no incentive to make the reverse payment in the first
- 22 place.
- 23 That is, in making the reverse payment, what
- 24 the -- the brand name is attempting to purchase is
- 25 protection from the possibility that it will have its

- 1 patent invalidated, and it will suffer a large
- 2 competitive advantage. If a brand name thinks in a
- 3 particular instance there is somebody else who's going
- 4 to expose it to -- me to that risk, the -- the payment
- 5 wouldn't be expected to be made. So at least --
- 6 JUSTICE KAGAN: And what's your
- 7 understanding of why there would not be a long line in
- 8 some cases or in many cases?
- 9 MR. STEWART: I think for the reasons
- 10 that -- that your question suggested, that there is the
- 11 180-day exclusivity period and leaving aside the cases
- in which that is waived, subsequent manufacturers would
- 13 realize not only that they wouldn't get that period of
- 14 heightened profits themselves, but they would have to
- 15 wait in line for others, and they might focus their
- 16 attention on other patents that were perceived to be
- 17 weak as to which they could hope to -- to get the
- 18 180-day exclusivity contract.
- 19 JUSTICE KAGAN: And is there anything to
- 20 show what I think Justice Kennedy asked -- you know, how
- 21 much of one's profits comes from the 180-day period as
- 22 opposed to what happens after that?
- 23 MR. STEWART: I know it is the great
- 24 majority, I don't have a percentage figure. And the
- 25 reason, as I indicated earlier, was that during the

- 1 180-day exclusivity period, you have only two
- 2 competitors. Basically, a biopoly arrangement. And my
- 3 understanding is that the generics would usually charge
- 4 around 80 to 85 percent of the brand name's price during
- 5 that period. And after there is full competition, the
- 6 price would drop to a fraction of that.
- 7 The next thing I would say is that our
- 8 system encourages settlement, but not to the nth degree.
- 9 And so, for instance, if you had two -- two firms
- 10 fighting over a million dollars and each firm decided
- 11 internally, 600,000 is the least I will accept. If they
- 12 stuck to their guns, the case couldn't be settled.
- Now, if the public could be made to kick in
- 14 an additional 200,000, then each of the firms could get
- its 600,000 and walk away content. But we don't pursue
- 16 the policy in favor of settlement to that degree. But
- 17 that's essentially what's happening here. The -- the
- 18 way these payments facilitate settlement is by inducing
- 19 the generics to agree to a later entry date by
- 20 increasing the total pool of profits that are available
- 21 to the two firms combined and thereby maximizing the
- 22 likelihood that each firm will find its own share of the
- 23 profit satisfactory.
- 24 And the last thing I would say is I think
- 25 everyone who comes to this issue recognized that there

1	is a conundrum. Our natural instinct is to compare the
2	settlement to the expected outcome of litigation. But
3	everyone also recognizes that it just isn't feasible to
4	try the patent suit. And, therefore, our approach
5	focuses on whether the competitive process has been
6	preserved.
7	CHIEF JUSTICE ROBERTS: Thank you, counsel,
8	counsel.
9	The case is submitted.
10	(Whereupon, at 12:06 p.m., the case in the
11	above-entitled matter was submitted.)
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