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IN THE SUPREME COURT OF THE UNITED STATES

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FEDERAL TRADE COMMISSION, :

Petitioner : No. 12-416

v. :

ACTAVIS, INC., ET AL. :

- - - - - x

Washington, D.C.

Monday, March 25, 2013

The above-entitled matter came on for oral argument before the Supreme Court of the United States at 11:05 a.m.

APPEARANCES:

MALCOLM L. STEWART, ESQ., Deputy Solicitor General, Department of Justice, Washington, D.C.; on behalf of Petitioner.

JEFFREY I. WEINBERGER, ESQ., Los Angeles, California; on behalf of Respondents.

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P R O C E E D I N G S

(11:05 a.m.)

CHIEF JUSTICE ROBERTS: We'll hear argument next this morning in Case 12-416, the Federal Trade Commission v. Actavis.

Mr. Stewart.

ORAL ARGUMENT OF MALCOLM L. STEWART

ON BEHALF OF THE PETITIONER

MR. STEWART: Mr. Chief Justice, and may it please the Court:

As a general matter, a payment from one business to another in exchange for the recipient's agreement not to compete is an paradigmatic antitrust trust violation. The question presented here is whether such a payment should be treated as lawful when it is encompassed within the settlement of a patent infringement suit. The answer to that question is no.

Reverse payments to settle Hatch-Waxman suits are objectionable for the same reasons that payments not to compete are generally objectionable. They subvert the competitive process by giving generic manufacturers an incentive to accept a share of their rival's monopoly profits as a substitute for actual competition in the --

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
11 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.)

16 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.

22 If the infringement defendant won, it would
23 be able to sell wherever it wanted to.

24 Now, there may be some --

25 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 --

3 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.

13 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.

3 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
15 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.

18 That's all they mean. And if that were the
19 exclusive test, the defendants in *Masonite*, in *New*
20 *Wrinkle*, in *Line 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.

25 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.

10 Now, Respondents say, well, that's
11 consistent with their theory because the restriction
12 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.

15 But if that's the test for whether a
16 restriction is within the scope of the patent, then we
17 would say that it's not met here because there's nothing
18 in the Patent Act that says you can pay your competitor
19 not to engage in conduct that you believe to be
20 infringing.

21 And really that's the thrust of their
22 position, that if you have -- if a patentholder has a
23 non-sham allegation that a particular mode of
24 competition would be an infringement of its patent, the
25 patentholder can pay the competitor not to engage in

1 that competition.

2 Again, we are not talking about conduct in
3 which there has been any judicial determination that
4 infringement has occurred. We are just talking about
5 cases in which the patentholder has a non-sham
6 allegation that infringement would occur.

7 JUSTICE GINSBURG: Mr. Stewart, does this
8 represent a change in the government's position? I got
9 the idea from the briefs that at the time of this
10 Schering-Plough case, that was also before the Eleventh
11 Circuit, that the government was not taking that
12 position it is now taking.

13 MR. STEWART: Well, the FTC has consistently
14 taken this position. The Department of Justice, up
15 until 2009, we didn't endorse the scope of the patent
16 test. Indeed, in our invitation brief in Joblove we
17 specifically said that the scope-of-the-patent test
18 was -- didn't provide for enough scrutiny of these
19 settlements.

20 But what we advocated -- what the Department
21 of Justice advocated, instead was a test that would
22 focus on the strength and scope of the patent. That is,
23 the likelihood that the brand name would off --
24 ultimately have prevailed if the suit had been litigated
25 to judgment.

1 And in 2009, for the first time in an amicus
2 brief filed in the Second Circuit, we took essentially
3 the position that we're taking here, that is that
4 agreements of this sort should be treated as
5 presumptively unlawful with the presumption able to be
6 rebutted in various ways.

7 JUSTICE KENNEDY: And one way is to assess
8 the validity or the strength of the infringement case?

9 MR. STEWART: We would say that that's not a
10 way, that --

11 JUSTICE KENNEDY: That's -- that's my
12 concern, is your test is the same for a very weak patent
13 as a very strong patent. That doesn't make a lot of
14 sense.

15 MR. STEWART: Well, the test is whether
16 there has been a payment that would tend to skew the
17 parties' choice of an entry date, that would tend to
18 provide an incentive for the parties to -- for the
19 generic to agree to an entry date later than the one
20 that it would otherwise insist on.

21 Now, it probably is the case that our test
22 would have greater practical import in cases where the
23 parties perceive the patent to be --

24 JUSTICE KENNEDY: Why wouldn't that
25 determination itself reflect the strength or weakness of

1 the patent so that the market forces take that into
2 account?

3 MR. STEWART: Well, I think in the kind of
4 settlement that we would regard as legitimate, where the
5 parties simply agree to a compromise date of generic
6 entry, then the parties would certainly take into
7 account their own assessment of what would likely happen
8 at the end of the suit.

9 And so if the parties believe that the brand
10 name was likely to prevail, then if the brand name
11 agreed to early generic entry at all, it would
12 presumably be for a fairly small amount of time.

13 Conversely, if the parties collectively
14 believe that the generic -- that the brand name had a
15 weak case and the generic was likely to prevail, then
16 they would negotiate for an earlier date. And the
17 problem with the reverse payment is that it gives the
18 generic an incentive to accept something other than
19 competition as a means of earning money.

20 I mean, to take another --

21 JUSTICE SCALIA: This -- this was not a
22 problem, I gather, until the Hatch-Waxman amendments?

23 MR. STEWART: These suits -- these types of
24 payments appear to be essentially unknown in other
25 lawsuits and other patent infringement cases.

1 JUSTICE SCALIA: Yes, and so -- and so do
2 suits against this kind of payment. And I have -- I
3 have the feeling that what happened is that Hatch-Waxman
4 made a mistake. It did not foresee that it would
5 produce this kind of -- this kind of payment.

6 And in order to rectify the mistake, the FTC
7 comes in and brings in a new interpretation of antitrust
8 law that did not exist before, just to make up for the
9 mistake that Hatch-Waxman made, even though Congress has
10 tried to cover its tracks in later amendments, right,
11 which -- which deter these, these -- these payments.

12 MR. STEWART: Congress has tried to reduce
13 the incentives for these payments to be made. I mean --

14 JUSTICE SCALIA: So why should we overturn
15 understood antitrust laws just to -- just to patch up a
16 mistake that Hatch-Waxman made?

17 MR. STEWART: Well, a couple things I would
18 say. First, I don't think we're -- we're not asking you
19 to overturn established antitrust laws. To take along
20 analogy, for example, if Watson instead of developing a
21 generic equivalent to AndroGel, had developed an
22 entirely new drug that it believed would be better than
23 AndroGel for the same conditions and if Solvay had paid
24 Watson not to seek FDA approval and not to seek -- to
25 market the drug, I think everyone would agree that that

1 was a per se antitrust violation, even though Watson's
2 ultimate ability to market the new drug would depend on
3 FDA approval that might or might not be granted.

4 And so when we say it's unlawful to buy off
5 uncertain competition, it's unlawful to buy out
6 competition, even when the competition might have been
7 prevented by other means, we are just enforcing standard
8 antitrust principles.

9 To focus on the distinction between
10 Hatch-Waxman and other patent litigation, Professor
11 Hovenkamp's conclusion is that the reason that you don't
12 see payments like this in the normal patent infringement
13 suit is that in the typical market if a patentholder
14 were known to have paid a large sum of money to a
15 competitor who had been making a challenge to the
16 patent, if other competitors knew that that had
17 happened, then they would perceive that to be a sign
18 that the patent was weak and that they would leap in.

19 But he says Hatch-Waxman makes it more
20 difficult for that to be done because Hatch-Waxman gives
21 unique incentives to the first paragraph 4 filer.

22 JUSTICE KENNEDY: Is that the 18 -- the
23 18-month rule primarily?

24 MR. STEWART: It's a 180-day period of
25 exclusivity.

1 JUSTICE KENNEDY: Right. I mean 180 days,
2 yes.

3 MR. STEWART: Yes, and the way it works is
4 that the exclusivity period is not good in and of itself
5 for consumers. That is, during the period when one
6 generic is on the market and the others are not yet
7 allowed to compete, you have essentially duopoly
8 conditions, the price of the -- the drug drops but only
9 by a little bit.

10 Congress granted the 180-day exclusivity
11 period because it wanted generics to have ample
12 incentives to challenge patents that were perceived to
13 be weak.

14 And if the first filer is able essentially
15 to be bought off, is able to set settle for something
16 other than early entry into the marketplace, then other
17 potential competitors face barriers to entry that
18 they -- similarly situated competitors wouldn't face in
19 other industries.

20 JUSTICE BREYER: Well, that doesn't mean
21 that -- that's rather thin. I don't know how -- I don't
22 have the ability to assess that, the significance of it,
23 empirically. The thing I wonder, therefore, you said
24 it's common in antitrust?

25 I'm -- I'm not up to everything in the

1 field, but I know there's an existence of something
2 called the per se rule, let's price fix it.

3 I know there's a rule of reason, and I know
4 there's a sort of vague area that sometimes in some
5 cases that Justice Souter mentioned in California
6 Dental, there is something slightly in between, which as
7 I saw those cases, they're very much like price fixing
8 or -- or agreements not to enter.

9 And what they seem to say is, Judge, pay
10 attention to the department when it says that these are
11 very often can be anticompetitive, and ask the defendant
12 why he's doing it.

13 I mean, is that what you want us to say? It
14 didn't seem in your briefs as if you were. If you were
15 asking us to produce some kind of structure -- I don't
16 mean to be pejorative, but it's rigid -- a whole set of
17 complex per se burden of proof rules that I have never
18 seen in other antitrust cases, I -- my question is, when
19 I say I've never seen anything like this before in terms
20 of procedure, I want you to refer me to a case that will
21 show, oh, no, I'm out of date.

22 MR. STEWART: Well, the -- the Court has
23 recognized such a thing as the quick look approach, but
24 I think even though the case didn't use the term "quick
25 look," I don't believe it did, NCAA v. Regents of

1 University of Oklahoma is probably the best example,
2 where the --

3 JUSTICE BREYER: And are there others?

4 MR. STEWART: Well, that's the -- that's the
5 one I'm most familiar with.

6 JUSTICE BREYER: Is there any other? Are
7 you familiar with any other? Because I want to be sure
8 I read all of them.

9 MR. STEWART: I'll need to look back and see
10 what --

11 JUSTICE BREYER: Well, if there are few or
12 none, then I would say, why isn't the government
13 satisfied with an opinion of this Court that says, yes,
14 there can be serious anticompetitive effects. Yes,
15 sometimes there are business justifications, so Judge,
16 keep that in mind. Ask him why he has this agreement,
17 ask him what his justification is, and see if there's a
18 less restrictive alternative.

19 In other words, it's up to the district
20 court, as in many complex cases, to structure their case
21 with advice from the attorneys.

22 MR. STEWART: I think that would leave
23 courts without guidance as to --

24 JUSTICE BREYER: It's got guidance?

25 MR. STEWART: -- without guidance as to what

1 factors would be appropriate --

2 JUSTICE BREYER: The same thing is
3 appropriate as is appropriate in any antitrust case.
4 Are there anticompetitive effects?

5 I have 32 briefs here that explain very
6 clearly what you said in a sentence. It may be that
7 they're simply dividing the monopoly profit. I
8 understand that -- you know, I can take that in and so
9 can every judge in the country. And what's complicated
10 about that.

11 And then I have some very nice dark green
12 briefs that clearly say, four instances, maybe five,
13 where there would be offsetting justifications. I think
14 they can get that, too.

15 MR. STEWART: Well, certainly our proposed
16 approach accounts for that. It provides -- it provides
17 really two different forms of rebuttal. First our
18 approach says, this is on its face an agreement not to
19 compete, the generic has agreed to stay out of the
20 market for a defined period of time, and the payment
21 gives rise to an inference that the agree -- that the
22 delay that the generic has agreed to is longer than the
23 period that would otherwise reflect its best assessment
24 of its likelihood of -- of success in the lawsuit.

25 But then we say, there are basically two

1 different types of ways in which the presumption could
2 be rebutted. First, the parties can show that the
3 payment was not in consideration for delay, that there
4 was some other commensurate value transferred, and the
5 payment -- and that arrangement would have been entered
6 into even without the larger settlement.

7 And then second, we're at least accepting
8 the possibility that brand names and generics could come
9 in and say, even though our payment was for delay, even
10 though we can't identify anything else that the payment
11 could have been consideration for, it's still, quote,
12 "competitive" under --

13 JUSTICE BREYER: And they mention at least
14 two others. The first one they mention is because the
15 person's already in the market thinks that the next year
16 or two or three years is worth \$100 million a year, and
17 the person who's suing thinks it's worth 30 million a
18 year. And so he says, hey, I have a great idea, I'll
19 give him the 30 million and keep the 70. And -- and
20 that, I don't see why that's anticompetitive if that's
21 what's going on.

22 And the second instance they bring up is
23 that it's very hard to break into a market. So for the
24 new generic to come in, he's thinking, giving me two
25 years isn't worth much because I'll spend a lot of

1 money, it's very hard for me to do it. But the
2 defendant -- the defendant who wants this patent kept
3 intact says, I will not only let -- I'll let you in a
4 year earlier and I'll give you enough money so that you
5 can start up a distribution system. The second seems
6 procompetitive, the first, neutral.

7 The problem of deciding whether other
8 matters are or are not really payments for something
9 else, a true nightmare when you start talking about five
10 drugs and different distribution systems and the matter
11 of whether you're paying for litigation costs, a matter
12 of great debate for the judge. Okay, that's the
13 arguments that they make. Go ahead.

14 MR. STEWART: Let me say a couple of things
15 about the administrative nightmare. The first is that
16 to the extent that these inquiries are difficult,
17 they're difficult only by -- because the brand names and
18 the generics have made them difficult by tacking on
19 additional transactions to their settlement proposal.

20 And to take an analogy, there are government
21 ethics rules that say that -- what are called prohibited
22 sources. Basically, people who have business before the
23 department can't give me gifts as a government employee.
24 Now, obviously, it would be absurd to have a rule that
25 said a prohibited source couldn't give me a Rolex watch,

1 but could sell me a Rolex watch for a dollar. And so
2 the ethics rules treat as a gift an exchange for value
3 in which fair market value is not paid.

4 And everybody understands that once you go
5 down that route, occasionally, you will have hard cases
6 in which people could legitimately agree, was this a
7 legitimate arm's length exchange or was it a concealed
8 gift? But the prospect of those difficult cases doesn't
9 mean that we get rid of a gift ban altogether.

10 And certainly, Federal employees couldn't
11 bring the -- the ethics office to its knees by engaging
12 in such a proliferation of these side deals that the
13 ethics office decided it's not worth it.

14 The second thing is that Respondent's
15 approach would apply even when there are no hard
16 questions. Respondents would say that even if the
17 agreement provides for delayed generic entry until the
18 date the patent expires, and even if the only other term
19 of the agreement is the brand name pays the generic a
20 lot of money, that that would be a legitimate agreement
21 because the restriction would apply to arguably patented
22 drugs and it wouldn't extend beyond the date of patent
23 expiration.

24 I guess the -- the other thing I would say
25 about the way in which these payments can facilitate

1 settlement really shows their anticompetitive potential.
2 That is, suppose the parties were negotiating for a
3 compromise date of entry, but they couldn't agree.
4 The -- the brand name said beginning of 2017 is the
5 earliest we'll let you in and the generic said beginning
6 of 2015 is the latest date that we would accept.

7 Now, the Respondents use the term "bridge
8 the gap," but there's obviously no way that a payment
9 from the brand name to the generic could enable the
10 parties to agree on an entry date between 2015 and 2017.

11 The brand name is never going to say, well,
12 I would insist on holding out until 2017, but if I'm
13 going to pay you a whole lot of money, then I'll let you
14 earlier and accept a -- a diminution of your profits.
15 The brand name is going to say, if I pay you money, I'm
16 going to insist on deferring entry even later than the
17 2017 date that would otherwise be my preferred
18 compromise.

19 So the natural effect of these payments is
20 not to facilitate a -- a bridging the gap in the sense
21 of a picking of a point between the dates that the
22 parties would otherwise insist on. It is going -- it is
23 very likely to cause the parties to agree to an entry
24 date that's even later than the one the brand name would
25 otherwise find acceptable.

1 JUSTICE SOTOMAYOR: Mr. Stewart, can we go
2 back to Justice Breyer's question -- initial question.
3 It's rare that we find a per se antitrust violation.
4 Most situations we put it into rule of reason.

5 You seem to be arguing that this is price
6 fixing, a reverse payment like price fixing so that it
7 has to fall into something greater than the rule of
8 reason.

9 MR. STEWART: Not -- not price fixing, but
10 it's -- it's an agreement not to compete. That is, the
11 parties are not agreeing as to the prices they will
12 charge. The generic is agreeing to stay off the market
13 first. But that would be treated as per se --

14 JUSTICE SOTOMAYOR: But why is the rule of
15 reason so bad? As an -- and that's really my bottom
16 line because you're creating all -- I think that's what
17 Justice Breyer was saying. I mean, for -- for example,
18 I have difficulty under -- understanding why the mere
19 existence of a reverse payment is presumptively gives --
20 changes the burden from the Plaintiff.

21 It would seem to me that you have to bear
22 the burden -- the burden of proving that the payment for
23 services or the value given was too high. I don't know
24 why it has to shift to the other side.

25 MR. STEWART: Now, if you wanted to tweak

1 the theory in that way and to say that in cases where
2 there is not just a payment and an agreement on the date
3 of market entry, but there is additional consideration
4 exchanged beside, if you wanted to say that the
5 Plaintiff would bear the burden of showing that this was
6 not a fair exchange for value. That -- that's not
7 something we would agree with, but that would be a
8 fairly minor tweak to our theory.

9 JUSTICE SOTOMAYOR: So answer the more
10 fundamental question, why is the rule of reason so bad?

11 MR. STEWART: The rule -- I mean, it's bad
12 for reasons both of administrability and it's bad
13 conceptually. The reason it's bad for reasons of
14 administrability is that -- at least I take what you are
15 proposing to be that the antitrust court would consider
16 all the factors that might bear on the assessment of the
17 agreement, that those would include presumably a
18 strength of the patent claim, the subjective --

19 JUSTICE BREYER: No. No. I mean, Professor
20 Areeda, who is at least in my mind a minor deity in the
21 matter, in this area, if not major, he explains it. He
22 says don't try for more precision than you can give.
23 The quality of proof required should vary with the
24 circumstances.

25 Do you know how long it took -- I mean, and

1 I -- of course, I -- I know a little bit of antitrust.
2 But I mean, I think -- do you know how long it takes to
3 take in your basic argument that these sometimes can be
4 a division of profit, monopoly profit? It takes
5 probably 3 minutes or less. And judges can do that.

6 So you say to the judge, Judge, this is
7 what's relevant here. And there's a rule of evidence,
8 don't waste the jury's time.

9 So -- so you shape the case as -- and this
10 is what goes -- used to go on for 40 years. You shape
11 the case in light of the considerations that are
12 actually relevant, useful, and provable in respect to
13 that case. And district judges, that's their job.
14 So -- so what -- I'm not saying you'd lose the case.
15 They didn't side with the Eleventh Circuit. They said
16 there's no violation, okay?

17 I've got your point on that. But -- but I'm
18 worried about creating some kind of administrative
19 monster.

20 MR. STEWART: It's not atypical -- I mean --
21 and the Court did this in NCAA, for example, where it
22 said that the agreement it was looking at, which dealt
23 with the allegation of -- of -- allocation of rights to
24 televised football games was essentially a limitation on
25 output, and the Court said those are presumptively

1 unlawful. Long experience in the market has shown that
2 they are suspect.

3 The Court didn't say there was long
4 experience in the market for television rights to
5 football. It just said output limitations have been
6 established as disfavored.

7 Nevertheless, because competitive sports by
8 nature require a degree of cooperation between the
9 people who compete against each other -- to establish
10 the rules of the game and so forth -- we will look to
11 see whether the parties have identified -- whether the
12 defendants have identified anything about their specific
13 industry that would justify our decision not to apply
14 the usual presumption, and it concluded that there was
15 nothing there.

16 And we're really asking the Court to take
17 the same approach here. We're saying payments not to
18 compete are generally disfavored. The parties can --
19 when you have a Hatch-Waxman settlement, in which money
20 is passing from the brand name to the generic, it's an
21 unusual settlement to begin with because there's no way
22 that the suit could have culminated in the generic
23 receiving a money judgment.

24 And therefore, we'll -- we'll look upon this
25 with suspicion, but we'll give the parties adequate

1 opportunities to -- to rebut.

2 If I may, I'd like to reserve the balance of
3 my time.

4 CHIEF JUSTICE ROBERTS: Thank you,
5 Mr. Stewart.

6 Mr. Weinberger?

7 ORAL ARGUMENT OF JEFFREY I. WEINBERGER

8 ON BEHALF OF THE RESPONDENTS

9 MR. WEINBERGER: Mr. Chief Justice, and may
10 it please the Court:

11 I'd like to first respond to a question that
12 was asked of my friend by Justice Scalia a few minutes
13 ago. He was asked if there were any cases in which the
14 Court has ever found a restraint outside the scope of
15 the patent to be unlawful, and the answer to that
16 question is no.

17 That -- all of the cases that have found
18 violations of the antitrust laws based on a patent-based
19 restraint do so because the object of the agreement, the
20 restraint that's being achieved in the agreement, is
21 beyond the scope that could be legitimately achieved
22 with a patent.

23 For example, it's an attempt to control
24 downstream the resale prices of -- of products that you
25 cannot do simply by exercising your patent. Or it's an

1 attempt to control the sale of unpatented products that
2 go beyond what a patent can protect.

3 Every -- every case in which --

4 JUSTICE SOTOMAYOR: Why isn't this then?

5 Meaning there is no presumption of infringement.

6 There's no presumption that the item that someone else
7 is going to sell necessarily infringes.

8 MR. WEINBERGER: That's correct.

9 JUSTICE SOTOMAYOR: And so what you're
10 arguing is that in fact a settlement of an infringement
11 action is now creating that presumption.

12 MR. WEINBERGER: No, Justice Sotomayor, I'm
13 not arguing that. But -- but I do want to say that I
14 think our patent system depends upon the notion that you
15 don't evaluate from the anti -- the perspective of the
16 antitrust laws a patent restraint based upon whether you
17 could have proved in a litigation that that patent --
18 that the patent was infringed.

19 JUSTICE SOTOMAYOR: I don't know, but I
20 don't know why we would be required to accept that there
21 has or would be infringement by the product that has
22 voluntarily decided not to pursue its rights.

23 MR. WEINBERGER: I think you're
24 not -- you're not accepting infringement. What you're
25 doing is recognizing there's a reasonable basis to

1 assert the patent, a bona fide, reasonable dispute, and
2 the parties have the ability to settle the dispute.

3 Just as if the party -- if someone was
4 entering into a license agreement with -- with someone
5 who had a product that they claimed did not infringe the
6 patent, they sat down, negotiated a license and resolved
7 it --

8 JUSTICE SOTOMAYOR: But there, you'd know
9 that they're not sharing the profits.

10 MR. WEINBERGER: Yes.

11 JUSTICE SOTOMAYOR: Meaning there you know
12 that a -- a product's been licensed and the -- that's
13 normal. The infringer is now paying the other side
14 money to sell that product.

15 MR. WEINBERGER: But, Justice Sotomayor,
16 many other --

17 JUSTICE SOTOMAYOR: A reverse payment
18 suggests something different, that they're sharing
19 profits.

20 I don't know what else you can conclude.

21 MR. WEINBERGER: Many license -- I don't
22 think that's correct, and that's because many license
23 disputes are, in fact, resolved by the -- the alleged
24 infringer exiting the market for a period of time, or
25 agreeing to stay off until a certain time.

1 And then the license --

2 JUSTICE SOTOMAYOR: But not many for reverse
3 payments.

4 MR. WEINBERGER: Yes, they are because --
5 because, for example, it could be a license agreement
6 where the infringer agrees to stay off the market for X
7 number of years, and when it comes on it pays a certain
8 royalty.

9 Now, anybody could argue that that royalty,
10 if it were higher, could result in an earlier entry.
11 There's always an argument to be made with any delayed
12 entry situation that monopoly profits are shared.
13 That's just -- just inherent in the nature of it.

14 And if you take the FTC's argument to its
15 full force, it would mean that any situation where
16 anyone is agreeing to a delayed entry, and there's any
17 other value that's being exchanged in that situation,
18 that in effect in economic terms is a payment for
19 delayed entry. There's no difference.

20 JUSTICE BREYER: Yes. But there, it's
21 not -- their point is not it's per se unlawful. What
22 they want is they want to cut some kind of line between
23 a per se rule and the kitchen sink. And if you look at
24 the brief supporting you, it is the kitchen sink. You
25 have economists attacking the patent system or praising

1 it, da, da, da, and here and there and the other. They
2 don't want the kitchen sink.

3 Now, suppose I don't want the kitchen sink,
4 but I have a hard time saying what the per se rule is.
5 So what's your idea?

6 MR. WEINBERGER: I -- I've obviously given a
7 lot of thought to whether there is any kind of an
8 intermediary test that works and I don't believe there
9 is. Let me explain why.

10 First, you can't really measure whether
11 there were any anticompetitive effects from such a
12 settlement agreement without determining what would have
13 happened if the case hadn't settled and it would have
14 been litigated. And if the patentee had won the
15 litigation, then there would be no anticompetitive
16 effects.

17 That's what the Second Circuit and the
18 Federal Circuit concluded in applying the rule of reason
19 test, and saying the first condition of such a test has
20 not been met because there's no demonstration of
21 anticompetitive effects.

22 And the cases -- both of those cases are
23 very good illustrations of what I'm talking about.
24 Those were the Tamoxifen and Cipro cases, where the
25 parties agreed to so-called reverse payment settlements

1 that FTC would say are basically per se lawful.

2 JUSTICE KENNEDY: Would it -- would it help
3 if you were -- were thinking about rules and caps, to
4 consider not what the branded company would have --
5 would have made, but what the generic company would have
6 lost? And -- and use the latter as the limit?

7 MR. WEINBERGER: Well, you really don't know
8 unless you can assume when they could have entered --

9 JUSTICE KENNEDY: Well, you -- you have to
10 make an extrapolation, yes.

11 MR. WEINBERGER: Well, because it all
12 depends on what would have happened in the patent
13 litigation. So that you can't really tell whether
14 there's any anticompetitive effect.

15 I should also say with respect to the
16 generic losing, there's really no risk to the generic
17 here, which is one of the reasons you see these
18 settlements, that in this industry --

19 JUSTICE KENNEDY: Well, if the generic wins,
20 though, its -- everybody's profits are lower. And you
21 can gear it to just what the -- what the generic would
22 have made.

23 MR. WEINBERGER: They're -- they're lower
24 than they would be under some other situation, but --
25 but the patent gave the patentholder the legal right to

1 exclude. So unless there's a reason, there's some
2 reason to believe that it couldn't reasonably assert
3 that patent, it's entitled to monopoly profits for the
4 whole duration of the patent.

5 JUSTICE KAGAN: Mr. Weinberger, can I just
6 understand what you're saying, and maybe do it through a
7 hypothetical.

8 MR. WEINBERGER: Certainly.

9 JUSTICE KAGAN: Suppose you had a -- a
10 lawsuit and the generic sends the brand name
11 manufacturer an e-mail and the e-mail says, we have this
12 lawsuit, I think I have about a 50 percent chance of
13 winning.

14 If I win, I take your -- your monopoly
15 profits down from 100 million to \$10 million. Wouldn't
16 it be a good thing if you just gave me 25 million? All
17 right? And then the brand name sends an e-mail back,
18 says -- you know, that seems like a pretty good idea, so
19 I'll give you 25 million.

20 Now, as I understand it, your argument is, I
21 mean, that's just fine. That's hunky dory.

22 MR. WEINBERGER: Well, what I'm saying is
23 that in -- in any given situation --

24 JUSTICE KAGAN: Is that fine?

25 MR. WEINBERGER: I -- I think that if the --

1 if it's a single situation and the evidence is that
2 there's a reasonable basis to assert that patent and in
3 truth, the patent has, which you say, has a 50/50 chance
4 of prevailing, then I think that there could be a
5 settlement like that, if it's in good faith.

6 JUSTICE KAGAN: Even though -- but what if
7 it isn't in good faith? It's clear what's going on here
8 is that they're splitting monopoly profits and the
9 person who's going to be injured are all the consumers
10 out there.

11 MR. WEINBERGER: Any -- any situation in
12 which there's any -- in any patent dispute in which
13 there's a tradeoff, like the examples I mentioned
14 before, time for value, could -- that argument could be
15 made.

16 And, in fact, if that was true, if it was
17 true that the natural inference and the motivations of
18 the people were simply to divide these profits with no
19 other consideration, then what you'd expect to see is
20 that every single patent dispute, would, especially in
21 Hatch-Waxman, would result in a settlement that just
22 pays the generic until the end of the patent because
23 after all, the market would be --

24 JUSTICE KAGAN: Well, Mr. Weinberger, I
25 think if we give you the rule that you're suggesting we

1 give you, that is going to be the outcome because this
2 is going to be the incentive of both the generic and the
3 brand name manufacturer in every single case is to split
4 monopoly profits in this way to the detriment of all
5 consumers.

6 MR. WEINBERGER: Let me address that, Your
7 Honor. I don't think that's realistic at all because --
8 and let's take this industry specifically, that the
9 ability to challenge a patent in this industry is lower
10 than any industry that I can think of, and that's
11 because a generic is given the right to certify against
12 the patent and then basically challenge the patent
13 without having actually developed the product, gotten a
14 marketing force, gotten a factory, putting the product
15 on sale and taking the risk that everyone else who
16 challenges a patent has to take.

17 All they have to do is -- is file an ANDA,
18 which is roughly 300,000 to \$1 million for these size
19 drugs, that's not a lot, and certify it. And the FTC's
20 own studies have shown that it takes a very small chance
21 of winning, something like 4 percent for a drug over
22 \$130 billion to justify a generic suing a brand name
23 company.

24 And what happens -- so what happens in these
25 cases --

1 JUSTICE SOTOMAYOR: Is that in all cases or
2 just Hatch-Waxman cases?

3 MR. WEINBERGER: It's Hatch-Waxman cases.
4 It's because of --

5 JUSTICE SOTOMAYOR: Because it does skew the
6 dynamics a lot.

7 MR. WEINBERGER: Yes.

8 JUSTICE SOTOMAYOR: You know, the Second
9 Circuit recognized, even though it accepted your scope
10 of the patent, that there was a troubling dynamic in
11 what you're arguing, which is that the less sound the
12 patent, the more you're going to hurt consumers because
13 those are the cases where the payoff, the sharing of
14 profits is the greatest inducement for the patentholder.

15 MR. WEINBERGER: The Second Circuit
16 recognized that, but then they said further -- upon
17 further reflection, further consideration of this, we
18 are not troubled by it.

19 One of the reasons they were not troubled,
20 it's what I was trying to answer Justice Kagan about, is
21 because the reality of the situation is with so many
22 potential challengers to the patent, all they have to do
23 is file an ANDA, there are 200 generic companies in this
24 industry, that if you try to adopt that strategy of
25 paying the profits of a generic, there's going to be a

1 long line of --

2 JUSTICE BREYER: Okay. Suppose --

3 JUSTICE KAGAN: Well, I don't think that
4 that's true, Mr. Weinberger, and it's because of
5 something that Justice Scalia suggested, that there's a
6 kind of glitch in Hatch-Waxman. And the glitch is that
7 the 180 days goes to the first filer.

8 And once the 180-day first filer is bought
9 off, nobody else has the incentive to do this.

10 MR. WEINBERGER: That's clearly not correct
11 either by logic or by reference to actual experience.
12 It's true that the first filer is given a greater
13 incentive, but these products can last for 20 or
14 25 years.

15 JUSTICE KAGAN: But the -- the huge
16 percentage of the profits is done in the exclusivity
17 period. I mean, it's true that it can go on for a long
18 time, but you're making dribs and drabs of money for a
19 long time. Where you're really making your money is in
20 the 180 days.

21 MR. WEINBERGER: Experience doesn't show
22 that because if you look at Hatch-Waxman litigation,
23 we've cited in -- in the red brief and it's been
24 discussed by the antitrust economists and the Generic
25 Pharmaceutical Association in their amicus brief, that

1 many of these Hatch-Waxman cases involve multiple
2 filers.

3 You have 5, 10, as many as 16 companies
4 challenging these patents, all of -- one of whom are not
5 the first filer. So there -- there must be an incentive
6 for them to do this, and -- and they are. So I think
7 experience says that that kind of extreme view of
8 incentives is not really true.

9 JUSTICE KENNEDY: What -- what do we look at
10 to verify what you say? Is that -- is that all in the
11 briefs?

12 MR. WEINBERGER: Yes, it's in the -- in the
13 Solvay brief. I don't have the page --

14 JUSTICE KENNEDY: Because I had thought, as
15 Justice Kagan's question might indicate, that the
16 180 days is crucial, it allows you to go to the doctors,
17 to give them the name of your generic equivalent, et
18 cetera, and that that's a big advantage.

19 MR. WEINBERGER: It's a big advantage --

20 JUSTICE KENNEDY: And now, you're -- now,
21 you're indicating that it isn't.

22 MR. WEINBERGER: It's a big advantage. It's
23 an incentive for the first six months, I don't debate
24 that, but after that, the market opens up.

25 JUSTICE BREYER: Okay. Suppose -- this

1 sounds like an argument, a discussion that you have in
2 the district court, so -- so why -- what's your reaction
3 to this. Say A, sometimes these settlements can be very
4 anticompetitive, dividing monopoly profit. In deciding
5 whether anticompetitive outweighs business practices
6 without less restrictive alternatives, judge, you may
7 take that into account. Two, do not take into account
8 the strength of a patent. Three, do not try to
9 relitigate the patent.

10 Four, there are several possible
11 justifications, ones I listed before out of the briefs,
12 litigation costs -- the other products, different
13 assessments of -- of value. Five, there could be, in
14 fact, no anticompetitive effect here because of what you
15 just said now in response to Justice Kennedy and Justice
16 Kagan, but there could be. We don't know. Okay?

17 So start with where we were. Could be
18 anticompetitive. Give the defense a chance to go
19 through five, one through five, and if they convince you
20 there is a six, we're not saying there isn't, but we
21 can't think of one on the briefs, let them have the
22 sixth, too. Okay? Now, judge, weigh and decide.
23 That's what we do. So we've structured it somewhat to
24 keep the kitchen sink out on the basis of the briefs
25 given to us. What's wrong with that?

1 MR. WEINBERGER: Well, I think the first
2 problem with it is that it's -- it's very unpredictable.
3 It's really hard to figure out how that all gets sorted
4 out, and the parties who are sitting down to do a
5 settlement need, I feel, much clearer guidance --

6 JUSTICE SCALIA: You can't -- you can't
7 possibly figure it out, can you, without assessing the
8 strength of the patent?

9 MR. WEINBERGER: That's right.

10 JUSTICE SCALIA: Isn't that crucial to -- to
11 the conclusion?

12 MR. WEINBERGER: I -- I believe that the
13 only thing that brought --

14 JUSTICE SCALIA: And to say you can consider
15 every other factor other than the strength of the patent
16 is -- is to leave -- leave out the -- the elephant in
17 the room.

18 MR. WEINBERGER: I agree with that,
19 Justice Scalia. I don't think that an alternative
20 test -- the only alternative test that could be
21 fashioned that would -- that would make sense is one
22 based on strength of the patent.

23 But there are so many reasons that that is
24 an undesirable result that I -- I don't think it's the
25 way this Court should go.

1 JUSTICE SOTOMAYOR: For whom? And -- and --
2 you know, the government is basically saying, we really
3 don't want reverse payments, period. We want people to
4 settle this the way they should settle it, which is on
5 the strength of the patent. And that means settling it
6 simply by either paying a royalty for use or settling as
7 most cases do, on an early entry alone, so there's no
8 sharing of -- of -- of profits. What's so bad about
9 that?

10 I mean, it doesn't deprive either side of
11 the ability to finish the litigation if they want to.

12 MR. WEINBERGER: Let's say -- I wouldn't
13 concede that most cases settle like that. But let's --
14 let's accept that and take the case of a -- of a strong
15 patent or a patent with a long term. Let's say
16 it has -- you evaluate the strength of the patent and
17 you conclude that it has 10 or 15 good years remaining.

18 Now, you have a generic who is -- or many
19 generics who have sued with no risk or minimal risk in
20 Hatch-Waxman, and their response is, why would I -- why
21 would I drop this lawsuit to get an entry date in 2025
22 or 2028? That doesn't meet my business needs, I have
23 shareholders, I have investors, I have to run a
24 business, and I'm going to keep on litigating unless you
25 give me something of value.

1 So that's what these agreements are about.
2 They're saying, well, what other -- remember, this is
3 not just a cash payment. There are all --

4 JUSTICE SOTOMAYOR: Well, in the normal
5 course, if the patent's really strong, if you get a year
6 or two earlier entry, that has an inherent value, and
7 that's what you'll pay for is what the government is
8 saying. That will be the determination the two parties
9 will make, which is at what point is earlier entry worth
10 it --

11 MR. KATZ: Well, first of all --

12 JUSTICE SOTOMAYOR: -- for the very strong
13 patentholder.

14 MR. WEINBERGER: First of all, parties often
15 don't agree on the merits. Parties tend to be
16 overconfident. They both think they are going to win.
17 So it's sometimes very hard to come to a consensus where
18 entry date is the only bargaining chip available.

19 JUSTICE SOTOMAYOR: Well, they pointed to
20 most settlements and say that is the vast majority.

21 MR. WEINBERGER: I don't know where the
22 evidence would be for that. I don't think --

23 JUSTICE SOTOMAYOR: Well, we do know that
24 these reverse payments, except for recent times when
25 people figured out they were so valuable, were the

1 exception, not the rule.

2 MR. WEINBERGER: Actually, we have ten years
3 of experience since the circuit courts first began
4 applying scope-of-the-patent tests to these settlements
5 since 2003. So we have a pretty good window as to what
6 would happen.

7 JUSTICE SOTOMAYOR: They have been
8 increasing in number, not decreasing.

9 MR. WEINBERGER: No, I think they have been
10 actually very steady. They are roughly between 25 and
11 30 percent, pretty much constant and you don't really
12 see any huge blips depending on what a particular court
13 is ruling.

14 If the FTC's kind of
15 the-sky-is-going-to-fall approach is right, that
16 everybody's going to run out and do this, you would have
17 thought that after the first Eleventh Circuit ruling,
18 after the Federal Circuit ruling, after the Second
19 Circuit ruling, after second Eleventh Circuit ruling,
20 that there would be huge increases in this, but we
21 haven't seen that.

22 Some of the numbers increased last year, but
23 as a percentage of the total settlements they are very
24 steady. They are pretty much the same.

25 JUSTICE GINSBURG: What about the

1 consideration that seems to be driving the government?
2 That is, the generic is getting an offer that they would
3 never get on the street. I mean, they have been paid
4 much more than they would get if they won the patent
5 infringement suit.

6 If they won the patent infringement suit,
7 then they can sell their generic in competition with the
8 brand. But under this agreement they get more than they
9 would get by winning the lawsuit.

10 MR. WEINBERGER: Justice Ginsburg, first of
11 all, every settlement agreement involving one of these
12 cases must be filed with the FTC. They have hundreds of
13 them. And they haven't pointed to a single example
14 where that's the case.

15 JUSTICE KAGAN: But it's just an economic --

16 JUSTICE KENNEDY: Well, suppose -- suppose
17 that hypothetical is correct. That's was my concerns,
18 too. What the brand company can lose is much greater
19 than what the generic can make. So why don't you just
20 put a cap on what the generic can make and then we won't
21 have a real concern with the restraint of trade, or
22 we'll have a lesser concern. I think that's the thrust
23 of Justice Ginsburg's question and it's my concern as
24 well.

25 MR. WEINBERGER: Yes, and I want to make

1 clear that I don't think that could happen because if a
2 brand name company adopted that as a strategy to protect
3 its patent, it would -- it would be held up. It would
4 be held up by the many generic companies that could
5 easily challenge these patents without actually having a
6 manufactured product, without putting it on sale, et
7 cetera.

8 So I think that the antitrust rule should
9 not be fashioned to deal with a case on the extreme,
10 which hasn't been shown to happen, which logically from
11 an economic point of view is highly unlikely to happen.
12 And if for some reason that starts happening
13 empirically, then Congress -- and it is a loophole in
14 Hatch-Waxman that is causing that, and there is really
15 no evidence that that extreme example has happened --
16 then Congress can deal with it, just as it dealt with
17 the exclusivity provision.

18 JUSTICE GINSBURG: I thought the government
19 was telling us that that's this case, that the -- what
20 the generic is being offered in the way of sharing the
21 monopoly profits is more than it could ever make if it
22 wanted to and sold its drug.

23 MR. WEINBERGER: Well, I don't see any
24 examples of that cited in their brief. It's a theory,
25 it's a hypothetical theory, but there is no data. We

1 have had years of experience with this case.

2 JUSTICE KENNEDY: Well, but it's not
3 hypothetical that if the generic wins everybody -- the
4 brand companies profits are going to go way, way down
5 right away and generic profits are not going to be that
6 great.

7 MR. WEINBERGER: Of course. I think that's
8 true in many -- many patent litigations.

9 JUSTICE KENNEDY: Well, but so then the
10 question still holds. If you -- if you key your payment
11 to what the brand company will make, it's just a much
12 higher figure, and a greater danger of unreasonable
13 restraint.

14 MR. WEINBERGER: There is that hypothetical
15 risk. What I'm -- I am trying to make the point that
16 it's not -- with the number of challenges you have here,
17 which is basically unlimited, that if you put a sign
18 around your neck that says, paying off all generic
19 companies their profits, whoever wants to challenge my
20 patent come do it, there is going to be a long line of
21 people, of companies doing it.

22 JUSTICE KENNEDY: Okay, I will grant you
23 that point that the 180 days is not that big a
24 difference, and that there are many generics out there.
25 But isn't that true in every industry? You said at the

1 outset, oh, well, now in the drug industry there are a
2 lot of people ready to pounce in. Isn't that true in
3 any industry?

4 MR. WEINBERGER: It is true and that's why
5 it doesn't happen. It's -- it's more true here because
6 it's much easier to challenge a patent. So in any other
7 industry a potential challenger has to make a major
8 investment in a product, has to get it manufactured, has
9 to put it on sale, and then litigate. And if they lose,
10 they are going to be liable for enormous damages.

11 That's not the case under Hatch-Waxman. All
12 they need to do is file an ANDA. They have nothing at
13 risk. If they lose, they haven't lost any damages.
14 They just walk away. So there is an enormous difference
15 in the risks between Hatch-Waxman and other cases that
16 explains the particular form of some of these
17 settlements and why they happen.

18 JUSTICE SOTOMAYOR: I see that as an
19 argument that there is an economic reality in
20 Hatch-Waxman that would require us not to apply any rule
21 we choose or accept here to other situations, only here.
22 That's the argument that you're creating for me, that
23 there's a different economic reality here that requires
24 a different rule.

25 MR. WEINBERGER: Justice Sotomayor, I think

1 the economic reality cuts the other way. It doesn't cut
2 in favor of making a rule that makes these more
3 difficult. What I'm saying is that --

4 JUSTICE SOTOMAYOR: Oh, but it does because
5 in Hatch-Waxman Congress decided that there was a
6 benefit for generics entering without suffering a
7 potential loss to enter the market more quickly.

8 MR. WEINBERGER: Justice Sotomayor, I don't
9 think the legislation --

10 JUSTICE SOTOMAYOR: And any settlement in
11 these cases deprives consumers of the potential of
12 having the benefit of an earlier entry.

13 MR. WEINBERGER: I don't believe there is
14 anything in Hatch-Waxman that supports the idea that the
15 purpose was to provide for generic entry prior to patent
16 expiration. What the structure is designed to do is
17 encourage challenges because --

18 JUSTICE SOTOMAYOR: Exactly, and what you
19 are doing with permitting settlements of this kind is
20 not permitting the process to go to conclusion.

21 MR. WEINBERGER: I don't think there is
22 anything in Hatch-Waxman that suggests, in any way, that
23 settlements or -- should be discouraged or that cases
24 should be mandated to proceed to judgment or that all
25 have to be litigated.

1 JUSTICE SOTOMAYOR: It's encouraging
2 infringement suits.

3 MR. WEINBERGER: It's encouraging challenges
4 and it has produced many challenges. And I can say --
5 can say that with 10 years of the application of the
6 scope-of-the-patent rule, there is no particular problem
7 with Hatch-Waxman. It's working very well. The
8 amount -- the number of drugs that have now gone generic
9 from just ten years ago to today has increased
10 enormously.

11 JUSTICE BREYER: So why does it help you to
12 say, if the Court says or the FTC says when you get one
13 of these suits you can settle it by letting them in, but
14 you can't pay them money. That that will help to stop
15 strike suits. It costs them nothing to get in. They
16 have to really want to enter or they won't bring
17 lawsuits. So why does that hurt you?

18 MR. WEINBERGER: Well, I actually think that
19 you raise a point that the generic -- in some of the
20 amicus briefs, some of the generic parties have talked
21 about, which is that their ability to challenge these
22 cases depends on their not having to litigate every one
23 of them to conclusion. And that's not bad because most
24 patent cases settle. Most -- most of these disputes
25 settle. And if our system was one in which every case

1 had to be litigated fully to judgment, it -- we would be
2 unable to cope with that.

3 So -- so what I think the statute mandates
4 or contemplates is that generics should be able to
5 challenge, and should have strong incentive to
6 challenge, but that doesn't mean that they should be
7 required to litigate to conclusion. And if settlement
8 is made more difficult, so that different perceptions or
9 different business objectives can't be bridged with some
10 kind of a business settlement, that is going to mean
11 that fewer generics are going to challenge these patents
12 and that is contrary to the purpose of the Hatch-Waxman
13 Act.

14 JUSTICE KENNEDY: I think it's correct that
15 to develop a new drug sometimes you need not just
16 scientists and attorneys, you need investment bankers.
17 And you then need marketers because the cost of these
18 drugs can be hundreds of millions. Is there anything in
19 the record that shows the development cost of this drug?

20 MR. WEINBERGER: This particular drug, I
21 don't know. I mean, there are lots of studies of how
22 much average drugs cost, and that figure is over a
23 billion dollars.

24 JUSTICE KENNEDY: It can be a billion.

25 MR. WEINBERGER: Easily a billion dollars.

1 JUSTICE KENNEDY: Anything in this case?

2 MR. WEINBERGER: This particular drug --

3 JUSTICE KENNEDY: Anything in the record?

4 MR. WEINBERGER: No, because we are on a
5 12(b)(6) motion on a motion to dismiss, so none of that
6 was really developed, but --

7 JUSTICE KAGAN: I'm sorry, go ahead.

8 MR. WEINBERGER: But I was just going to say
9 that the -- of course, any given drug development cost
10 doesn't even begin to tell the picture because for every
11 drug that succeeds, there are at least 10 that fail, and
12 all the costs that are involved in the drugs that fail
13 have to be covered with the one drug that succeeds.

14 JUSTICE KAGAN: Could I just make sure I
15 understand the way the 180-day period worked? The first
16 filer gets it, if I buy off -- if I'm a brand name
17 manufacturer and I buy off the first filer with one of
18 these reverse payments, you're suggesting that that's
19 not going to do me much good because they're all going
20 to be -- there's going to be a long line. And that long
21 line of people, it's not just that they don't get the
22 180-day period, it's like even if one of those people
23 wins, the person whom I've paid off is going to get the
24 180-day exclusivity period, isn't that right?

25 MR. WEINBERGER: Not completely. First of

1 all, it depends on the -- the agreement. For example,
2 in this case, that 180-day exclusivity was waived.

3 JUSTICE KAGAN: But if it's not waived by
4 the parties, in other words, it's just like I don't get
5 it so my incentives go down. It's that my competitor
6 gets it. So why in the world am I standing in line
7 to -- to challenge this if my competitor is going to get
8 the exclusive period?

9 MR. WEINBERGER: This was the exact problem
10 that Congress addressed in 2003, when it amended
11 Hatch-Waxman and changed the exclusivity requirements.
12 So the way the law now reads is that subsequent
13 generics, subsequent filers can trigger that 180-day
14 exclusivity by continuing to litigate. So if the first
15 filer settles and these other folks are in line and
16 they're litigating, they can force that period to start
17 running and then they can come in right after. So it is
18 not correct that you can tie up the first filer in
19 settlement and prevent everybody else from entering.

20 And even before that amendment, the Eleventh
21 Circuit, Federal circuit in the Second, applying the
22 scope of the patent rule recognized that if the
23 agreement creates a bottleneck to other filers that goes
24 beyond what the statutory exclusivity provides, where
25 they agree not to give up their exclusivity or agree to

1 retain it, then that's beyond the scope of the patent.
2 Because you can't achieve that kind of a restraint
3 simply -- with a patent, you -- you're using the
4 agreement to expand upon your patent rights to block
5 other filers.

6 So I think that problem's been addressed by
7 Congress. And if somebody feels that solution's not
8 perfect and they want to make it even easier for
9 subsequent filers to come in, then I submit that
10 Congress can do that. That they --

11 JUSTICE GINSBURG: Well, what was the change
12 that was made?

13 MR. WEINBERGER: The change that was made,
14 Justice Ginsburg, is that -- there were a number of
15 changes, but the one that's relevant here is that if
16 a -- if a subsequent filer -- strike that.

17 You can trigger the exclusivity beginning to
18 run by getting the judgment. So in the past, if a first
19 filer settled and they just didn't do anything -- may I
20 finish the --

21 CHIEF JUSTICE ROBERTS: Yes, certainly.

22 MR. WEINBERGER: And they just didn't do
23 anything, that would prevent other generics from coming
24 to market. But now anybody else who's litigating the
25 patent, if they go ahead and win their case, then

1 that -- that triggers the first filer's rights and if
2 they don't exercise that -- those rights within 75 days,
3 they're gone, they're forfeited. So that's the change.

4 CHIEF JUSTICE ROBERTS: Thank you, counsel.

5 MR. WEINBERGER: Thank you.

6 CHIEF JUSTICE ROBERTS: Mr. Stewart, you
7 have five minutes remaining.

8 MR. WEINBERGER: Thank you, Your Honor.

9 REBUTTAL ARGUMENT OF MALCOLM L. STEWART

10 ON BEHALF OF THE PETITIONER

11 MR. STEWART: Thank you.

12 Mr. Weinberger argued that in order to
13 determine whether a settlement of this sort has
14 anticompetitive effects, we would have to know how the
15 lawsuit would have turned out, but it's perhaps the most
16 fundamental principle of antitrust law that particular
17 conduct can be legal or illegal, depending on the
18 deliberative process that led up to it.

19 And to put that in concrete terms, if a
20 business charges a particular price for a particular
21 product because it's made the assessment that this will
22 maximize profits in a competitive environment, that
23 decision is almost immune from antitrust scrutiny. But
24 if the business charges the same price for the same
25 product in the same market because it's agreed with its

1 competitor that it will charge that price, that's a per
2 se antitrust violation.

3 So it's not at all anomalous to say that
4 this type of agreement can be deemed anticompetitive,
5 even though the same result, namely, exclusion of the
6 generic from the market might have been able to be
7 obtained by other means.

8 The second thing is, Mr. Weinberger said
9 there are instances in which second and successive
10 filers will attempt to challenge the brand name even
11 after the first filer has been bought off. I think
12 we -- we disagree that it's as easy as he would say it
13 is, but we'll concede it happens occasionally. But the
14 fact that particular anticompetitive conduct doesn't
15 always work doesn't make it lawful.

16 It could often happen that two firms were
17 thinking about entering into a price-fixing agreement,
18 for instance, but thought to themselves, if we do that,
19 there's a third competitor in the market who will be
20 able to undersell us, and this would make our agreement
21 unprofitable. And it might happen sometimes that two
22 firms try to proceed with a price-fixing conspiracy, but
23 they're thwarted because of the unexpected competition
24 from a third firm.

25 CHIEF JUSTICE ROBERTS: Well, I thought that

1 Mr. Weinberger's point was that this is always going to
2 happen because it's very easy -- as he said, you put a
3 sign on your neck saying, generics line up to get your
4 payment. That seems quite different than saying there's
5 another firm out there in the abstract that -- that
6 might want to enter into a similar market sharing
7 arrangement. This is a very different system.

8 MR. STEWART: I mean, first, there certainly
9 is no evidence suggesting that it has happened often,
10 although there is evidence that it has happened. But if
11 the brand name perceived on a systemic basis that the
12 likely result of paying off one competitor was that
13 another competitor would step in and couldn't be bought
14 off would litigate the suit to judgment, there would be
15 no incentive to make the reverse payment in the first
16 place.

17 That is, in making the reverse payment, what
18 the -- the brand name is attempting to purchase is
19 protection from the possibility that it will have its
20 patent invalidated, and it will suffer a large
21 competitive advantage. If a brand name thinks in a
22 particular instance there is somebody else who's going
23 to expose it to -- me to that risk, the -- the payment
24 wouldn't be expected to be made. So at least --

25 JUSTICE KAGAN: And what's your

1 understanding of why there would not be a long line in
2 some cases or in many cases?

3 MR. STEWART: I think for the reasons
4 that -- that your question suggested, that there is the
5 180-day exclusivity period and leaving aside the cases
6 in which that is waived, subsequent manufacturers would
7 realize not only that they wouldn't get that period of
8 heightened profits themselves, but they would have to
9 wait in line for others, and they might focus their
10 attention on other patents that were perceived to be
11 weak as to which they could hope to -- to get the
12 180-day exclusivity contract.

13 JUSTICE KAGAN: And is there anything to
14 show what I think Justice Kennedy asked -- you know, how
15 much of one's profits comes from the 180-day period as
16 opposed to what happens after that?

17 MR. STEWART: I know it is the great
18 majority, I don't have a percentage figure. And the
19 reason, as I indicated earlier, was that during the
20 180-day exclusivity period, you have only two
21 competitors. Basically, a biopoly arrangement. And my
22 understanding is that the generics would usually charge
23 around 80 to 85 percent of the brand name's price during
24 that period. And after there is full competition, the
25 price would drop to a fraction of that.

1 The next thing I would say is that our
2 system encourages settlement, but not to the nth degree.
3 And so for instance, if you had two -- two firms
4 fighting over a million dollars and each firm decided
5 internally, 600,000 is the least I will accept. If they
6 stuck to their guns, the case couldn't be settled.

7 Now, if the public could be made to kick in
8 an additional 200,000, then each of the firms could get
9 its 600,000 and walk away content. But we don't pursue
10 the policy in favor of settlement to that degree. But
11 that's essentially what's happening here. The -- the
12 way these payments facilitate settlement is by inducing
13 the generics to agree to a later entry date by
14 increasing the total pool of profits that are available
15 to the two firms combined and thereby maximizing the
16 likelihood that each firm will find its own share of the
17 profit satisfactory.

18 And the last thing I would say is I think
19 everyone who comes to this issue recognized that there
20 is a conundrum. Our natural instinct is to compare the
21 settlement to the expected outcome of litigation. But
22 everyone also recognizes that it just isn't feasible to
23 try the patent suit.

24 And, therefore, our approach focuses on
25 whether the competitive process has been preserved.

1 CHIEF JUSTICE ROBERTS: Thank you, counsel,
2 counsel.

3 The case is submitted.

4 (Whereupon, at 12:06 p.m., the case in the
5 above-entitled matter was submitted.)

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