UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

IN RE AGGRENOX ANTITRUST LITIGATION	No. 3:14-md-2516 (SRU)
THIS DOCUMENT RELATES TO: ALL ACTIONS	

MEMORANDUM OF DECISION AND ORDER

This large and complex multidistrict litigation, which was brought in the wake of the Supreme Court's seminal decision in *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013), aggregates cases challenging what the plaintiffs allege was a large and unjustified "reverse payment" settlement resolving patent litigation over the antiplatelet drug Aggrenox. Because it became clear that massive discovery and expensive litigation turned on questions related to market power and relevant market definition, I directed the parties to submit supplemental briefs and later issued an order for the defendants to show cause why I "should not enter an order restricting discovery and evidence in this case to the market in Aggrenox and any AB-rated bioequivalent substitute for Aggrenox" (doc. # 432), and setting a schedule for the plaintiffs to respond.[1]

For the reasons that follow, I hold that the relevant market in this case is determined by the nature of the challenged agreement, that the only relevant market in this litigation is therefore

[1] More specifically, the order to show cause directed the parties to address three questions: "(1) whether an antitrust plaintiff's proof of overcharges (which, by definition, is a proof of supracompetitive prices) necessarily proves market power, because the extraction of supracompetitive prices is itself an exercise of market power; (2) whether, in this case (and in any case brought under *FTC v. Actavis*), an allegation of supracompetitive prices can be proved or disproved directly with data on the allegedly supracompetitively priced product and its generic(s); and, if so, (3) whether, in such a case, an explicit articulation of (and discovery and argument on) market definition is necessary or relevant." (doc. # 432). The order also directed them to "address the so-called Cellophane fallacy, either as either as part of their responses to the questions above or separately, and whether they avoid or commit that fallacy in their positions on the questions above." *Id.*

the market of Aggrenox and its generic equivalents, and that no discovery or evidence relating to other drugs as potential substitutes is relevant.

I. *Actavis* and Market Power

This litigation was in significant part made possible by the Supreme Court's decision in *FTC v. Actavis, Inc.*[2] In short, the *Actavis* Court held that, in patent-invalidity litigation, large and unjustified reverse-payment settlements may violate antitrust law. The Court reasoned that such settlements can lead to the inference that the "payment's objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market—the very anticompetitive consequence that underlies the claim of antitrust unlawfulness." *Actavis*, 133 S. Ct. at 2236.

The *Actavis* Court rejected presumptive rules and "le[ft] to the lower courts the structuring of the present rule-of-reason antitrust litigation," *id.* at 2238, providing very limited guidance on that "structuring." It did, however, make at least two observations that begin to light the way. First, sketching the nature and limits of the flexibility left to the courts below, and providing a guiding principle for them, the Supreme Court noted that "trial courts can structure antitrust litigation so as to avoid, on the one hand, the use of antitrust theories too abbreviated to permit proper analysis, and, on the other, consideration of every possible fact or theory irrespective of the minimal light it may shed on the basic question—that of the presence of significant unjustified anticompetitive consequences." *Id.* Second, articulating more fully the contours of that "basic question," the Court wrote that "the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's

[2] *Actavis* is discussed at greater length in the Memorandum of Decision and Order on the first four motions to dismiss filed in this case, 94 F. Supp. 3d 224 (D. Conn. 2015) (doc. # 229), and in the opinion expanding upon and clarifying that one, and certifying it for interlocutory appeal, 2015 WL 4459607 (D. Conn. July 21, 2015) (doc. # 311).

anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of other convincing justification." *Id.* at 2237.

The *Actavis* Court did not expressly include market power in that list of factors, but it did, however briefly, allude to the concept. "[W]here a reverse payment threatens to work unjustified anticompetitive harm," the Court wrote, "the patentee likely possesses the power to bring that harm about in practice." *Id.* at 2236. Moreover, "the size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of . . . the power to charge prices higher than the competitive level." *Id.* (quotation marks removed). "An important patent itself helps to assure such power. Neither is a firm without that power likely to pay large sums to induce others to stay out of its market." *Id.* (quotation marks removed).

That "power to charge prices higher than the competitive level" is market power, which is an essential element of antitrust cases. Courts have sometimes defined market power as the ability to control prices or exclude competition, though it has been noted that such a definition is needlessly confusing, not least because "the disjunctive 'or' implies erroneously that excluding rivals—whether by the defendant, the law, or market circumstances—itself brings substantial market power." IIB Areeda & Hovenkamp, Antitrust Law, ¶ 501, at 111 (3rd ed. 2007) ("Areeda"). On the contrary, there are circumstances in which the exclusion of rivals does not permit charging supracompetitive prices and may not reflect a meaningful power at all—for instance, a patent allows the lawful exclusion of rivals but it brings the patent-holder "no market power when consumers have little use for [the patented product] or can buy adequate substitutes from others." *Id.* The exclusion of rivals will typically go hand-in-hand with market power, but it is the ability to charge supracompetitive prices that is the *sine qua non* of market power. As the leading antitrust treatise puts it: "[M]arket power is the abilities (1) to price substantially above

the competitive level *and* (2) to persist in doing so for a significant period without erosion by new entry or expansion." *Id. See also, e.g.*, *Nat'l Collegiate Athletic Ass'n v. Bd. of Regents of Univ. of Oklahoma*, 468 U.S. 85, 109 (1984) ("Market power is the ability to raise prices above those that would be charged in a competitive market."); William M. Landes & Richard A. Posner, *Market Power in Antitrust Cases*, 94 HARV. L. REV. 937, 937 (1981) ("The term 'market power' refers to the ability of a firm (or a group of firms, acting jointly) to raise price above the competitive level without losing so many sales so rapidly that the price increase is unprofitable and must be rescinded.").

To be sure, as the defendants point out, the *Actavis* Court did not hold that a large reverse payment is dispositive of antitrust liability, nor that a patent guarantees market power. Indeed, reverse payments beg to be explained, and defendants will have the opportunity to proffer an explanation, perhaps to a jury. And some patents are worthless—consumers may have no interest in the patented product, or they may be equally satisfied by unpatented alternatives.[3] But patents are only valuable as a result of whatever market power they confer, and they are more or less valuable precisely in proportion to that market power. Indeed, it is the reward of lawful (albeit temporary) market power that creates the incentive for innovation that patent protection is intended to foster. And the size and circumstances of the reverse payment are suggestive of the market power conferred by the patent: the larger the reverse payment (and the greater its

[3] *See Illinois Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 45–46 (2006) ("Congress, the antitrust enforcement agencies, and most economists have all reached the conclusion that a patent does not necessarily confer market power upon the patentee. Today, we reach the same conclusion . . . ."). The defendants additionally cite *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965), and its progeny to argue that the existence of a patent does not create a presumption of market power or necessarily imply the definition of the relevant market. I agree with that proposition as far as it goes, but I do not believe it goes as far the defendants urge me to take it. *Walker Process* concerns fraudulently procured patents and requires an appraisal of "the exclusionary power of the illegal patent claim in terms of the relevant market for the product involved," *id.* at 177, because otherwise "there is no way to measure [the defendant's] ability to lessen or destroy competition." *Id.* That is consistent with the fact that some patents confer little or no market power (that is: relatively worthless patents). It does not follow, however, that the defendant's ability to harm competition is never measurable directly or that it cannot be manifest in direct evidence of the harm itself.

independence from other services for which it might represent compensation), the likelier that the challenged patent in fact confers a high degree of market power—and the stronger the inference that the reverse payment is intended "to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market." *Actavis*, 133 S. Ct. at 2236.

Evidence of market power (in addition to direct evidence of competitive harm in the form of supracompetitive prices) will therefore be available in cases like this one even without an express articulation of the relevant market definition. Moreover, as a practical matter, the only "relevant" market in this case, and in similar cases brought under *FTC v. Actavis*, will be the market in which the challenged settlement agreement allegedly acted as an anticompetitive restraint: that is, in this case, it will be implicitly defined by the scope of the disputed patent. It does not necessarily follow from the existence of that patent that the defendants have market power, because it is conceivable that the patented drug faced such fierce competition from therapeutically similar drugs that it could not be sold at supracompetitive prices—in other words, it is conceivable that the patent was worthless. It is vanishingly unlikely, however, that a large reverse payment would be made in such a case, which is why a large reverse payment is such a strong indicator of market power.

Moreover, market power exists in degrees. *See* Areeda, ¶ 501 ("Market power exists in degrees. Power is small when more than a slight increase in price would lead to an unacceptable loss of sales. It is large when a firm can profit by raising prices substantially without losing too many sales."). The patented drug could face some competition from imperfectly interchangeable drugs (which may or may not themselves be supracompetitively priced) yet still have a meaningful degree of market power, enabling it to be sold profitably at supracompetitive prices.

A large reverse payment is itself suggestive of market power, but the ability to profitably charge supracompetitive prices over a sustained period (which ability the reverse payment may be calculated to preserve) is conclusive of market power, by definition.

II. Supracompetitive Prices Despite Some Restraints on Price

The defendants assert that proof of the extraction of supracompetitive prices "emphatically" does not constitute proof of market power, Defs.' Mem. 8 (doc. ## 439/445 at 16), but it is not clear that they actually mean that; rather, they dispute what constitutes "supracompetitive" and assert that a mere price differential between brand and generic drugs (or a price above marginal cost) is insufficient. They make two principal arguments: first, that analysis of what constitutes "competitive" pricing must take into account certain fixed (or sunk) costs, like research and development; and second, that even if the challenged settlement delayed competition among different manufacturers of the same molecule, that molecule still faced fierce competition from other drugs in the same therapeutic class, and its pricing therefore cannot be deemed "supracompetitive."

A. The Need to Recoup Costs

The first argument, though presented as an economic one, is effectively a policy argument. The defendants argue (perhaps correctly) that brand manufacturers incur enormous fixed costs developing and marketing new drugs, and that they therefore *need* to charge higher prices in order to recoup those costs. Generic manufacturers are free-riders who do not undertake those investments, and this fact alone is sufficient to account for the price differential. That may be right, but it does not mean that the price of the brand drug is not supracompetitive. Rather, it is an argument that brand manufacturers *need* to exclude competition and charge supracompetitive prices, in order to be able to afford to bring new drugs to market and to have

the profit incentive to do so. Patents, of course, allow them to do that lawfully, so long as the drug in question remains under patent protection. Congress, however, has made the policy decision to create incentives for generic manufacturers to challenge drug patents they perceive to be vulnerable, thereby encouraging competition. The purported need for brand manufacturers to exclude those competitors in order to recoup costs is therefore an argument for Congress, and outside the scope of this antitrust litigation.

The defendants quote dicta from *United States v. Eastman Kodak Co.*, 63 F.3d 95, 109 (2d Cir. 1995), for the proposition that fixed costs, rather than market power, can explain "certain deviations between marginal cost and price," but that will generally be true only if those are ongoing rather than historical fixed costs (the latter of which are sunk costs). The competitive price may be somewhat theoretical in the absence of actual competition, but prices in a competitive market will tend (perhaps asymptotically) toward marginal cost, so prices substantially above that cost are supracompetitive by definition. The mere existence of some differential between price and marginal cost is not necessarily of concern to antitrust law (the ability to profitably charge a premium may be explained, for instance, by brand loyalty or something similarly innocuous), but that is largely a matter of degree and not an argument for including sunk costs in an analysis of what constitutes a competitive price.

There are generally accepted economic means of analyzing the probability that given prices are supracompetitive using price and marginal cost. *See, e.g.*, Areeda, ¶ 503b (discussing the Lerner Index). Moreover, in this case we have a history of actual market data because generics have already entered, and the effect of new competitors entering a market provides an additional direct basis to evaluate the question of supracompetitive pricing. We have data from a less competitive market of the molecule in question, and we have data from a more competitive

market of that molecule. The *extent* to which prices were supracompetitive can be litigated by way of summary judgment or trial, but if competitive prices were being charged before the patented drug had a generic competitor, then the entry of new competitors would not result in a substantial change in price. The more significant issue in an *Actavis* case like this one is not whether the patented drug was sold at a supracompetitive price but whether that price was *lawfully* supracompetitive because the drug was under the protection of a patent the expected life of which was not unlawfully extended by a large and unjustified reverse payment settlement.

Sales and pricing data about other drugs would at best be redundant, because any substitution effect constraining the price of Aggrenox will already be "priced in" to this analysis. Worse, the inclusion of evidence or argument about other drugs could cause confusion as a result of the Cellophane Fallacy—that is, by obscuring the fact that cross-elasticity of demand among those drugs "may . . . be the product of monopoly power rather than a belief on the part of consumers that the products are good substitutes for one another," *United States v. Eastman Kodak Co.*, 63 F.3d 95, 105 (2d Cir. 1995), because "[a]t a high enough price, even poor substitutes look good to the consumer." *Id. See also Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 471 (1992) (noting that competition imposing restraints on price can coexist with market power) (citing Areeda, ¶ 340(b) ("[T]he existence of significant substitution in the event of *further* price increases or even at the *current* price does not tell us whether the defendant *already* exercises significant market power.")). That risk of confusion may be worth taking in some cases, but there is no need to take it in this one, where plaintiffs elect to undertake the burden of directly proving anticompetitive effect and where such evidence is (at least potentially) so readily available.

B. Competition Coexisting with Market Power

The defendants' second argument is addressed by the above discussion of market power and relevant market. It may be true, as the defendants argue, that Aggrenox meaningfully competes in a broad market of antiplatelet drugs—insofar as Aggrenox and other antiplatelet drugs are at least roughly substitutable—and that Aggrenox is a relatively small player in that market. But, as discussed above, *limited* competition can impose a *limited* constraint on prices and can therefore coexist with *some degree* of market power and supracompetitive prices. Substitutability with other drugs shows a lack of market power only if it "effectively limit[s] the price . . . to the competitive level or something slightly above," Areeda, ¶ 507, and if that is the case, then entry of new competitors should not have a substantial effect on average price and the plaintiffs will not be able to prove supracompetitive prices or anticompetitive effect.

Limited competition that is consistent with a degree of market power does not result in antitrust immunity, but rather acts *to limit the degree* of supracompetitiveness of price and therefore *to limit provable damages*. If there is robust competition between Aggrenox and perfectly interchangeable substitutes, then charging supracompetitive prices will not be profitable and prices will be driven toward marginal cost. If there is no competition with substitutes whatsoever, then prices may be extremely supracompetitive, limited only by the willingness and ability of consumers to pay for or to forgo the drug. And if Aggrenox competes against imperfectly interchangeable substitutes, prices may be somewhat supracompetitive within limits determined by the degree of effective interchangeability. In that case, damages will be constrained proportionally to actual competition; but it would not be correct to conclude, as the defendants suggest, that there would be no market power and no supracompetitive price.

This case is very different from the typical Sherman Act case where proving competitive harm can be difficult and relies on a showing of ability to harm through market power in the

relevant market; in a post-*Actavis* case, especially in one in which we have actual market data reflecting the impact of the introduction of a generic on the price of the patented drug, we do not need to do economic gymnastics to determine whether the defendant had market power or, indeed, whether it was actually charging supracompetitive prices. Aggrenox was protected by a patent, which granted the legal right to exclude generic competition and the practical ability to profitably charge higher prices than generic competitors would charge. There is nothing wrong with exercising that ability during the valid life of the patent, but wrongly extending that ability through a large reverse payment would violate the antitrust laws. Thus, the critical question in this case, indeed the only real question affecting liability, is whether the defendants acted wrongfully to extend the patent monopoly beyond its expected life. The existence of a broader market that imposed some price constraints on Aggrenox—but without approximating the more competitive market that developed after generic entry—has no bearing on any issue in the case.

It must be remembered that articulating a relevant market definition is not an end in itself, but is in the service of answering the question of market power, which in turn "is but a surrogate for detrimental effects." *FTC v. Indiana Fed'n of Dentists*, 476 U.S. 447, 460–61 (1986). "Since the purpose of the inquiries into market definition and market power is to determine whether an arrangement has the potential for genuine adverse effects on competition, proof of actual detrimental effects . . . can obviate the need for an inquiry into market power . . . ." *Id.* And a "finding of actual, sustained adverse effects on competition . . . is legally sufficient to support a finding that the challenged restraint was unreasonable even in the absence of elaborate market analysis." *Id.*[4] The explicit articulation and analysis of relevant market and market power,

[4] *See also In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 388 n.19 (D. Mass. 2013) ("The relevant market serves merely as a proxy for market power when direct evidence of market power is unavailable. Where direct evidence of market power is available, however, a plaintiff need not attempt to define the relevant market." (citations omitted)).

therefore, may often be useful or necessary—as a surrogate for detrimental effects—primarily as a sword for plaintiffs when the nature of a claim or factual circumstances of a case impede the use of direct evidence of competitive harm.[5] That surrogate is not, however, a shield for defendants to deflect the significance of competitive harm that can be proved directly. It may be that plaintiffs can rarely prove competitive harms directly, but they are entitled to undertake that burden if they choose to do so. They may succeed or fail, but if they succeed, a showing by defendants of competition in a broader market (which may limit damages, to the extent that that competition restrains prices and therefore limits overcharges) does not eliminate the competitive harm and therefore provides no defense to liability.

III. Pending Discovery Motions

The defendants have sought expansive discovery of data relating to various other drugs in the broader market of antiplatelet treatments, and they have filed several discovery motions principally related to those requests (doc. ## 348/354, 363, 411). As explained above, those drugs—to the extent that Aggrenox actually competes against them—will have acted as a pricing constraint limiting the supracompetitiveness of the price that could profitably be charged for Aggrenox both before and after generic entry. That effect will be "priced in"—that is, reflected in the price actually charged for Aggrenox over time—and therefore requires no evidence not already possessed by the defendants. Such discovery is therefore irrelevant. In light of the reasoning explained above, those motions are substantively denied.

It may be that some aspects of those motions (for instance, regarding downstream discovery and duplicative damages, or on appropriate search terms for electronic discovery) have

[5] *See, e.g.*, *United States v. Brown*, 5 F.3d 658, 668 (3d Cir. 1993) ("[P]roof [of anticompetitive effect] is often impossible to make, however, due to the difficulty of isolating the market effects of challenged conduct. Accordingly, courts typically allow proof of the defendant's 'market power' instead." (citation omitted)).

not been resolved. The parties shall meet and confer on the effect of this ruling on any unresolved discovery disputes to determine whether those disputes can be resolved by the parties, or whether I should take them up at the next semimonthly telephone conference.

IV. Section 1292(b) Certification

As I discussed above, and in other rulings in this case, the Supreme Court in *Actavis* "le[ft] to the lower courts the structuring of the present rule-of-reason antitrust litigation," 133 S. Ct. at 2238, and offered very little guidance on that "structuring." *See also id.* at 2245 (Roberts, C.J., dissenting) ("Good luck to the district courts . . . ."). Various district courts have struggled to fill the gaps that *Actavis* left open, and not always with consistent results. This is an important case in the relatively new landscape of *Actavis* actions, and this opinion is an effort to provide some of the missing structure. It will have a significant impact on this case and perhaps in other cases, and the stakes are high for both the litigants and the court. If this ruling is reversed after final judgment, the litigation will effectively start anew, requiring extensive discovery beginning years from now. Moreover, the economic issues discussed above are relatively technical, and their application to antitrust law is not without debate, nor is the caselaw touching on them uniform.

For those reasons, I exercise my discretion under 28 U.S.C. § 1292(b) to certify the discretionary interlocutory appeal of this order. As that statute requires, I believe that this order (1) "involves a controlling question of law," (2) "as to which there is substantial ground for difference of opinion," and (3) "that an immediate appeal may materially advance the ultimate termination of the litigation." If any party wishes to pursue interlocutory appeal, it has ten days from the date this order to apply to the Court of Appeals. 28 U.S.C. § 1292(b); Fed. R. App. P. 5(a)(3). Any party seeking review "still has the burden of persuading the court of appeals" to

take the appeal, *Coopers & Lybrand v. Livesay*, 437 U.S. 463, 474–75 (1978) (quotation marks omitted), and "[t]he appellate court may deny the appeal for any reason, including docket congestion." *Id.*

So ordered.

Dated at Bridgeport, Connecticut, this 8th day of August 2016.

/s/ STEFAN R. UNDERHILL
Stefan R. Underhill
United States District Judge