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Bundled Discounts and Combination Products: Implications of *Norvir* for Drug Manufacturers

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Like other sellers of products and services, pharmaceutical manufacturers face significant uncertainty in the application of antitrust laws to ''bundled'' discounts—*i.e.,* discounts offered only when multiple products are purchased together. Equally unclear is the antitrust framework to be applied to combination products that consist of two or more goods that are packaged together, but that may also be sold separately. For both bundled discounts and combination products, antitrust issues typically arise when the manufacturer may be said to have market power in at least one of the products that is priced or packaged together with others.

Recently, the U.S. Court of Appeals for the Ninth Circuit issued an opinion bearing on these issues in *Doe v. Abbott Laboratories*, No. 08-17699, 2009 WL 1926322 (9th Cir. July 7, 2009) (*Norvir*). Practitioners viewed *Norvir* as an opportunity for the Ninth Circuit to address the extent to which its recently adopted standard for analyzing bundled discounts applies to combination products. Defying expectations, the court instead held that the case was controlled by the Supreme Court's February decision in *Pacific Bell Telephone Co. v. linkLine Communications Inc.*, 129 S. Ct. 1109 (2009), a case involving vertical integration in the telecommunications industry. In taking this route, the Ninth Circuit opened a new avenue of defense for manufacturers accused of improperly pricing combination products, while leaving unclear the proper analysis of bundled drug discounts.

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Background

Like other forms of discounting, bundled discounts generally are procompetitive and therefore permitted under the antitrust laws. In several recent decisions, however, courts have considered the circumstances in which bundled discounting by a monopolist may harm competition by making it more difficult for other sellers to compete with the monopolist on other products.

In 2007, the Ninth Circuit issued a leading decision on bundled discounting in *Cascade Health Solutions v. PeaceHealth*, 502 F.3d 895 (9th Cir. 2007), *as amended at* 515 F.3d 883 (9th Cir. 2008). The case involved Cascade Health's challenge to discounts offered by rival hospital PeaceHealth—the only provider of tertiary hospital services in the county—to managed care customers who made PeaceHealth the exclusive provider of all acute care services to their insureds. 515 F.3d at 891-93. In *PeaceHealth*, the Ninth Circuit held that ''[t]o prove that a bundled discount was exclusionary or predatory for the purposes of a monopolization or attempted monopolization claim under § 2 of the Sherman Act, the plaintiff must establish that, after allocating the discount given by the defendant on the entire bundle of products to the competitive product or products, the defendant sold the competitive product or products below its average variable cost of producing them.'' *Id.* at 910. In adopting this ''attribution test,'' the Ninth Circuit expressly rejected the Third Circuit's approach to bundled discounts articulated in *LePage's Inc. v. 3M*, 324 F.3d 141 (3d Cir. 2003) (en banc), which appears to permit a finding of Section 2 liability whenever a monopolist in

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one product offers a bundled discount that its competitors cannot match. *PeaceHealth*, 515 F.3d at 903; *see id.* at 898-903 (discussing problems with Third Circuit's approach).

Norvir appeared to present an opportunity for the Ninth Circuit to determine whether and how to apply *PeaceHealth*'s attribution test to the pharmaceutical industry generally and to combination products in particular. The case involved Norvir, a protease inhibitor that Abbott originally introduced as a stand-alone product to fight HIV. 2009 WL 1926322, at *1. Over time it became apparent that Norvir was more useful as a ''booster'' than as a standalone product—that is, taken at low doses, Norvir ''boosted'' the effectiveness of other protease inhibitors. *Id.* Abbott later introduced a ''boosted'' protease inhibitor, Kaletra, which consists of a compound of protease inhibitor lopinavir with a boosting dose of ritonavir (Norvir's chemical name) in a single pill. *Id.*

Subsequently, two of Abbott's competitors, Bristol-Meyers Squibb (BMS) and GlaxoSmithKline (GSK), introduced their own protease inhibitors (Reyataz and Lexiva, respectively). *Id.* BMS and GSK also obtained FDA approval to market their products for use with Norvir as a booster. Once these products came onto the market, Abbott's market share for Kaletra fell. Abbott then raised the price of Norvir from $1.71 to $8.57 per 100 mg, but kept the price of Kaletra the same. *Id.* The purpose, according to plaintiffs, was to make Kaletra cheaper than any of the competing protease inhibitors that depend upon Norvir for their effectiveness and thereby obtain a monopoly in the ''boosted market.''

In the wake of Abbott's price change, several suits were filed alleging that Abbott had unlawfully ''leveraged'' its monopoly in the ''booster market'' for Norvir to monopolize or attempt to monopolize the ''boosted market'' in which Kaletra competes. The *Norvir* district court rejected Abbott's two successive motions for summary judgment. *See In re Abbott Labs. Norvir Anti-Trust Litigation*, 562 F. Supp. 2d 1080, 1091 (N.D. Cal. 2008); *In re Abbott Labs. Norvir Anti-Trust Litigation*, 442 F. Supp. 2d 800, 813 (N.D. Cal. 2006). In doing so, the district court concluded that the plaintiffs had a viable claim of ''monopoly leveraging'' as recognized by the Ninth Circuit in *Image Technical Services Inc. v. Eastman Kodak Co.*, 125 F.3d 1195, 1202 (9th Cir. 1997).

Significantly, the district court found that Abbott could not be held liable if *PeaceHealth*'s attribution test were to apply. 562 F. Supp. 2d at 1086 (incorporating by reference the court's decision rejecting this argument in parallel litigation, *Meijer Inc. v. Abbott Laboratories*, 544 F. Supp. 2d 995 (N.D. Cal. 2008)). The record reflected that Abbott charged $17.14 for 200 milligrams of Norvir, while it charged $18.78 for a dose of Kaletra containing the same amount of ritonavir. Applying the entire discount implicit in Kaletra to its litonavir component (*i.e.*, assuming no discount on ritonavir at $17.14), the imputed discounted price of litonavir would be the bundled price ($18.78) minus the full price of its ritonavir component ($17.14), or $1.64. Because the parties agreed that the average variable cost of producing litonavir was most likely pennies per unit and therefore well below $1.64, if *PeaceHealth* provided the decision rule, Abbott's pricing conduct would not have violated Section 2. *Meijer*, 544 F. Supp. 2d at 1003-04.

The district court, however, ruled that the *PeaceHealth* attribution test did not apply. Even assuming the case involved a bundled discount within the ''general purview'' of *PeaceHealth*, the court found that application of *PeaceHealth*'s attribution test would not serve its underlying goal of making ''unlawful only pricing that would exclude equally efficient competitors from the market.'' *Id.* at 1003. Rather, under the attribution test Abbott could price Norvir such that the imputed price of the litonavir component of Kaletra would be no more than the pennies it cost to manufacture. At that price, no prospective manufacturer of a competing protease inhibitor that required Norvir to be effective could ever hope to recoup its substantial sunk costs of researching, developing, and bringing the product to market. *Id.* at 1003. ''If the [*PeaceHealth*] rule were applied in this context, it would stifle competition; even a competitor who could produce an equally-effective drug for only $0.01 per pill would be excluded from the market.'' *Id.* at 1003-04.

According to the district court, the fundamental difference between the facts in *PeaceHealth* and those in *Norvir* resulted from the ''unique structural characteristics of the pharmaceutical industry, where fixed costs in the form of investment in research and development dwarf variable costs.'' *Id.* at 1004. As a result, while *PeaceHealth* asks whether the defendant's bundled discounts could exclude from the market an equally efficient *manufacturer*, the proper question in this case was whether Abbott's pricing practices could potentially exclude an equally effective *developer* of competing pharmaceutical products. *Id.* at 1004-05. The court articulated what it deemed to be the ''appropriate antitrust rule here'': Abbott should be found liable if, as a result of its pricing practices, ''a hypothetical equally efficient developer of an equally effective [protease inhibitor] would not be able to profit if it introduced that [protease inhibitor] to the market at a price of $1.64, the imputed price of lopinavir.'' *Id.* at 1004. In a footnote, the court expressed doubt that the *PeaceHealth* formula could be adapted for this purpose by incorporating the cost of developing lopinavir into the costs against which the imputed price of lopinavir would be analyzed. *Id.* at 1004 n.9. ''[A]sking if $1.64 would have been a profitable price for lopinavir when Abbott first introduced it to the market would require the development of complex economic models that depend on variables which may not be readily ascertainable.'' *Id.*

Following the district court's decision, the parties entered into a high/low settlement that conditioned the ultimate settlement amount on the Ninth Circuit's resolution of several issues Abbott would appeal, including whether *PeaceHealth* applied to this case. 2009 WL 1926322, at *1.

The Ninth Circuit's Decision

Framed by the parties' settlement, the *Norvir* appeal was expected to elicit a decision bearing on important issues concerning the application of *PeaceHealth*. However, the Ninth Circuit took a significantly different approach and expressly declined to address *PeaceHealth*'s ''impact on this case or others pending in the district court.'' 2009 WL 1926322, at *4. Rather, the Ninth Circuit held that the intervening decision by the Supreme Court in *Pacific Bell Telephone Co. v. linkLine Communications Inc.*, 129 S. Ct. 1109 (2009),

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''control[ed] the outcome here.'' 2009 WL 1926322, at *2.

In *linkLine*, the Supreme Court refused to recognize a ''price squeeze'' claim as a valid Section 2 claim. In a price squeeze, a company that is a monopolist in the market for an input to production and also sells the final goods or services at retail charges a high price for the input in the wholesale market to its retail competitors while keeping its own retail price low, thus compressing its competitors' profit margins. The *linkLine* court held that a ''price squeeze'' claim could only prevail if the defendant had an antitrust duty to deal with plaintiffs in the wholesale market or had priced its products below cost in the retail market. 129 S. Ct. at 1123. Having concluded that plaintiffs' claims failed at both the wholesale and retail levels, *linkLine* rejected the plaintiffs attempt, in the court's words, to ''alchemize'' them into a new form of antitrust liability for ''price-squeezing.'' *Id.* ''If there is no duty to deal at the wholesale level and no predatory pricing at the retail level, then a firm is certainly not required to price *both* of these services in a manner that preserves its rivals' profit margins.'' *Id.* at 1120 (emphasis original). ''Two wrong claims do not make one that is right.'' *Id.* at 1123.

In *Norvir*, the Ninth Circuit held that the plaintiffs' ''monopoly leveraging'' claim was the functional equivalent of the ''price squeeze'' claim rejected by the Supreme Court. 2009 WL 1926322, at *3. The court rejected plaintiffs' attempt to distinguish *linkLine* on the facts. The court noted that Abbott offered ritonavir to consumers both as a standalone inhibitor (Norvir) and as part of a boosted inhibitor (Kaletra) rather than sell ritonavir wholesale to its competitors at a high price for use with their inhibitors while setting a low price for Kaletra. *Id.* However, the court concluded that the ultimate ''vice'' is the same in either case. Abbott allegedly uses ''its monopoly position in the booster market to raise the price of Norvir while selling its own boosted inhibitor at too low a price,'' which ''puts the squeeze on competing producers of protease inhibitors that depend on Norvir for their boosted effectiveness and consumer acceptance.'' *Id.*

Adapting *linkLine*'s holding, the Ninth Circuit concluded that allegations of ''monopoly leveraging through pricing conduct in two markets'' do not state a claim under Section 2 ''absent an antitrust refusal to deal (or some other exclusionary practice) in the monopoly market or below-cost pricing in the second market.'' *Id.* at *1. The court distinguished on its facts its prior ''monopoly leveraging'' decision in *Image Technical* on the ground that that case, unlike this one, involved a defendant's absolute ''refusal to deal.'' *Id.* at *4. Explaining that plaintiffs had ''allege[d] no refusal to deal at the booster level, and no below cost pricing at the boosted level,'' the court held that plaintiffs failed to state a Section 2 claim against Abbott.

Having resolved the case based on *linkLine*, the court found it unnecessary to discuss the district court's determination that *PeaceHealth*'s attribution test did not apply to the pharmaceutical industry. *See* 2009 WL 1926322, at *4.

Potential Impact on Pricing Practices

Having taken a markedly different approach than anticipated, the Ninth Circuit's decision in *Norvir* raises many more questions than it answers. First, because the parties' settlement precluded remand, the Ninth Circuit expressly did not address the question whether plaintiffs could amend their complaint to allege facts sufficient to allege either an antitrust duty to deal in the booster market or below-cost pricing in the boosted market. 2009 WL 1926322, at *3 & n.4. In particular, *Norvir* did not address the district court's determination that average variable cost was not an appropriate measure of cost for determining whether Abbott had engaged in predatory pricing.

Second, by its terms *Norvir* did not address whether *PeaceHealth* applies to the pharmaceutical industry and, if so, whether its test must be modified (as suggested by the district court) to reflect differences between the health care services market at issue in *PeaceHealth* and the pharmaceutical market. These determinations must await further litigation.

One could argue that, after *Norvir*, plaintiffs challenging bundled discounts must show either that the defendant had an antitrust duty to deal in one or more products or that the defendant priced below cost. Indeed, there is no functional difference between Abbott's decision to produce a combination ritonavir/litonavir pill and the alternative approach of selling each drug separately with a discount to purchasers of both. But the reach of the decision is not clear.

More litigation will be needed to determine when *PeaceHealth* applies, when *Norvir* applies, and whether other circuits will follow either case. In the meantime, manufacturers are well advised to proceed cautiously, and with advice of antitrust counsel, in establishing bundled or combination prices involving products that may be viewed as having market power.