The Price Point

Newsletter of the ABA Section of Antitrust Law Pricing Conduct Committee

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We are pleased to bring you this issue of the Pricing Conduct Committee's newsletter, which includes articles by Susan Ning on China's new Price Rules; by Brian J. Ellman and Evan Hoffman Schouten on the use of average wholesale prices by drug manufacturers and litigants, and by James J. Calder and Dean N. Razavi on the use of most favored nation clauses in the health care industry.

If you have comments or questions about **The Price Point**, or if you are interested in submitting an article or following a case, please contact the Editor, Mary Marks, at mary.marks@srz.com or David Gonen, at david.gonen@kattenlaw.com.

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New & Noteworthy

Bay Guardian Co. v. New Times Media LLC, 2010-2 Trade Cases P 77,193 (Cal. App. 2010), *cert. denied* (Cal. Nov. 23, 2010). The California Supreme Court has declined to review the long-fought predatory pricing case between two SF newspapers. The Bay Guardian, which alleged that rival publication SF Weekly sold advertising below its cost, won a $16 million jury verdict in 2008. The Court's disposition leaves in place a lower court decision from August, which clarified that California law (Cal. Bus. & Prof. Code § 17000 et seq.), in contrast to federal law, does not require proof of the defendant's ability to recoup its losses: "[R]ather than the actual or threatened harm to competition[, t]he intent or purpose of the below-cost sale is at the heart of the statute."

People of the State of California v. Bioelements, Inc., No. 10011659 (Cal. Sup. Ct. Jan. 11, 2011) (final judgment including permanent injunction). Cosmetics company Bioelements has settled a resale price maintenance action brought by the California Attorney General. The complaint alleged that Bioelements entered into contracts with third-party resellers that prohibited them from selling products online for less than the manufacturer's suggested retail price. The stipulated judgment does not constitute an admission by Bioelements, but requires the company to permanently refrain from fixing resale prices for its merchandise and to inform its resellers that it will not enforce existing contracts containing such provisions. In contrast to vertical minimum resale price maintenance claims brought under federal law, which as of the Supreme Court's decision in *Leegin Creative Leather Products, Inc. v. PSKS, Inc.*, 551 U.S. 877 (2007), are evaluated under the rule of reason, this case demonstrates that RPM remains per se illegal under California law.

New York v. Tempur-Pedic Int'l, Inc., No. 400837/10 (N.Y. Sup. Ct. Jan 14, 2011) (Decision, Order, & Judgment). Updating an article in our last edition, the NY Attorney General's action against foam mattress manufacturer Tempur-Pedic alleging resale price maintenance was dismissed. The OAG brought the suit under Executive Law § 63(12), which authorizes it to prosecute "persistent fraud or illegality in the carrying on, conducting or transaction of business." The OAG claimed that Tempur-Pedic, through its advertising and pricing policies, specifically violated Gen. Bus. Law §369-a, which sets forth: "[a]ny contract provision that purports to restrain a vendee of a commodity from reselling such commodity at less than the price stipulated by the vendor or producer shall not be enforceable or actionable at law." According to the court: (1) while §369-a renders RPM contracts unenforceable, it does not make them illegal; (2) Tempur-Pedic's price restraints were contained in a unilateral policy, not in contracts to which retailers agreed to adhere; and (3) there was no evidence showing that Tempur-Pedic misled retailers into believing they were bound by an enforceable contract to set retail prices.

Call for Articles. **The Price Point** is seeking submissions for its Spring 2011 issue. Consistent with the Pricing Conduct Committee's focus, articles on resale price maintenance, predatory pricing, bundled pricing, price squeezes, or other pricing-related topics are welcome, as of course are articles on price discrimination and Robinson-Patman Act issues. Articles should be approximately 3,000 words in length, excluding notes. Submissions are due by April 30, 2011.

The Price Point is published three times a year by the American Bar Association Section of Antitrust Law Pricing Conduct Committee. Members of the Section of Antitrust Law may access past issues through the Pricing Conduct Committee's website. The views expressed in this publication are the authors' only and not necessarily those of the American Bar Association, the Section of Antitrust Law or the Pricing Conduct Committee. If you wish to comment on the contents of **The Price Point**, please write to the American Bar Association, Section of Antitrust Law, 321 North Clark Street, Chicago, IL 60654-7598 or to the Editor, Mary Marks.

China Update: NDRC's Price Rules – A Commentary

By Susan Ning[1]

This article sets out and analyzes the salient provisions pursuant to the recently issued "Rules on Anti-Price Monopoly" ("Price Rules") by the National Development and Reform Commission ("NDRC"). The Price Rules elaborate on the substantive aspects of how price-related breaches of the Anti-Monopoly Law ("AML") will be interpreted and enforced.

Arguably the biggest "sins" in respect of competition law have to do with price: price-related cartel conduct (*e.g.*, price fixing, bid rigging, etc.) and price-related abuse of dominance conduct (*e.g.*, predatory pricing, excessive pricing, etc.). When competitors collude in respect of price or when a dominant entity unilaterally decides to manipulate prices, consumer interests suffer. Therefore, these rules are significant and it is important to look at these rules closely. Moreover, these rules are the only form of guidance that businesses have in relation to how the price-related prohibitions within the AML will be enforced and interpreted, especially since there has not been much jurisprudence or precedent on the matter (and this is in large part because the AML is a new law, having come into effect only in August 2008).

(I) Background

In fact, these Price Rules have not been issued in isolation. Recently, the NDRC and the State Administration of Industry and Commerce ("SAIC") (the antitrust authorities in charge of enforcing the price and non-price breaches of the AML respectively) issued a suite of five rules which elaborate on how the price and non-price prohibitions within the AML will be interpreted and enforced. Details to deal with these five rules are set out in the table below. Two years after the enactment of the AML,[1] it is timely that the antitrust authorities are publishing rules like these – it sends a signal that public enforcement efforts might be stepped up very soon.

No.	Rule	Brief synopsis	Issued by	Date published	Date effective
1	Rules on anti-price monopoly	Elaborates on the substantive aspects of how price-related breaches of the AML will be interpreted and enforced.	NDRC	29 December, 2010	1 February, 2011
2	Procedural rules in relation to administrative enforcement of anti-price monopoly	Elaborates on the procedural aspects of how price-related breaches of the AML will be enforced by the NDRC.	NDRC	29 December, 2010	1 February, 2011
3	Rule in relation to conduct amounting to monopoly agreements	Elaborates on the substantive aspects of how non-price "monopoly agreements" breaches of the AML will be interpreted and enforced.	SAIC	7 January, 2011	1 February, 2011
4	Rules in relation to conduct amounting to abuse of dominance	Elaborates on the substantive aspects of how non-price abuse of dominance breaches of the AML will be interpreted and enforced.	SAIC	7 January, 2011	1 February, 2011
5	Rules in relation to conduct amounting to abuse of administrative powers	Elaborates on the substantive aspects of how the prohibition against an abuse of administrative powers will be interpreted and enforced.	SAIC	7 January, 2011	1 February, 2011

[1] The author would like to thank the following Antitrust & Competition Associates at King & Wood PRC Lawyers for their assistance with this article: Angie Ng, Shan Lining and Zheng Ziqing.

[2] To read more about the rule listed in row 2 of the table, please see: China Law Insight (King and Wood), "Procedural rules re Administrative Enforcement of Anti-Price Monopoly effective 1 February, 2011" published on 30 December, 2010 at http://www.chinalawinsight.com/2010/12/articles/corporate/antitrust-competition/procedural-rules-re-administrative-enforcement-of-antiprice-monopoly-effective-1-february-2011/. To read more about the rules listed in rows 3 to 5 of the table, please see: China Law Insight (King and Wood), "3 rules which shed light on non-price violations of the Anti-Monopoly Law effective 1 February 2011" published on 10 January 2011 at http://www.chinalawinsight.com/2011/01/articles/corporate/antitrust-competition/3-rules-which-shed-light-on-nonprice-violations-of-the-antimonopoly-law-effective-1-february-2011/.

(II) The Price Rules

The objective of the Price Rules is to "prevent and restrain price monopolistic conduct, in order to protect fair competition and to safeguard the interests of consumers and the interests of society as a whole". The term "price monopolistic conduct" refers to conduct amounting to price-related prohibitions within the AML. The main price-related prohibitions relate to the prohibition on anticompetitive agreements and the prohibition on abuse of dominance.

There are 29 provisions within the Price Rules. Articles 5 to 8 elaborate on how price-related breaches of the prohibition on anticompetitive agreements will be interpreted and enforced. Articles 11 to 19 elaborate on how price-related breaches of the prohibition on abuse of dominance will be interpreted and enforced.

This article will focus on what the Price Rules say about these two prohibitions (the prohibition on anticompetitive agreements and the prohibition on abuse of dominance).

(III) Prohibition on anticompetitive agreements

There are two provisions which prohibit anticompetitive agreements. Article 13 of the AML prohibits anticompetitive agreements, decisions and concerted practices between competitors. Article 14 of the AML prohibits anticompetitive agreements between businesses in a supply-chain relationship. The Price Rules elaborate on how price related breaches of these two prohibitions will be interpreted and enforced.

(a) Prohibition re anticompetitive agreements, decisions and concerted practices between competitors

As mentioned above, Article 13 of the AML prohibits anticompetitive agreements, decisions and concerted practices between competitors. Article 13 also lists examples of conduct which, may, in particular, breach this prohibition. Amongst all the examples of conduct, the only price-related example is price-fixing (see Article 13(1) of the AML).

The Price Rules address three main issues in relation to price-related agreements, decisions and concerted practices between competitors. First, the Price Rules emphasise what is meant by a "price monopolistic agreement". Second, the Price Rules elaborate on what is meant by the phase "concerted practice". Third, the Price Rules list examples of price fixing conduct which would be considered as strictly prohibited.

As mentioned above, first, the Price Rules re-emphasise that "price monopolistic agreements", referring to agreements, decisions and concerted practices which have a price element and which eliminate or restrict competition, are prohibited (Article 5, Price Rules).

Second, Article 6 of the Price Rules sets out what is meant by the term "concerted practices". Article 6 states that a number of factors will be taken into account when determining if conduct amounts to a concerted practice, including: the existence of "consistency" between business operators in relation to their pricing acts; whether there was a "communication of intentions" between business operators; and the structure of the relevant and changes within the relevant market.

The term "concerted practice" is also used in European Union ("EU") competition law. Since this is a "borrowed" term, it is likely (at least in this initial stage when the AML is still relatively new) that the NDRC will be partial as to how the term has been defined pursuant to EU law and jurisprudence. Pursuant to EU competition law, the term "concerted practice" is a complex concept which broadly refers to some form of coordination between businesses but not to the extent where these businesses have reached a formal agreement. A concerted practice may also be constituted by direct or indirect contact between businesses whose intention or effect is either to influence the conduct of the market or to disclose intended future behavior to competitors.

The factors listed out in the Price Rules do give some indication as to how the term "concerted practices" will be construed. However, terms used in the Price Rules such as "consistency" or "communication of intentions" would still need to be defined. Questions remain such as: What types of evidence would be required to prove that a "concerted practice" exists? How would the NDRC distinguish between the following concepts: "concerted practice"; conscious parallelism; and an unconscious raising of prices?

Third, the Price Rules also set out a list of seven examples of conduct which would be construed as "price monopolistic agreements" between competitors (see Articles 7(1) to 7(7),

Price Rules). Pursuant to the Price Rules, competitors are not to:

- fix or change the price levels of commodities or services;
- fix or change price margins;
- fix or change a commission, discount or other charges that have an influence on prices;
- apply an agreed price as the basis for transacting with a third party;
- agree to apply a standard formula as a basis to calculate prices;
- agree that a price shall not be changed without the consent of other business operators participating in the agreement; and
- apply other measures to fix or change the prices of commodities in a disguised form.

It is interesting that Article 7 of the Price Rules merely sets out the examples above but does not say that conduct which amount to those examples are subject to a competition test. This suggests that conducts listed in Article 7 of the Price Rules above are subject to a very strict, almost per se, type of rule. In other words, if competitors undertake conduct which amounts to any of the examples of conduct as listed in Article 7 of the Price Rules, such conduct will likely, by itself, breach the law – the NDRC may not subject such conduct to a competition test.

If the NDRC chooses to interpret Article 7 of the Price Rules as set out above, then businesses should be cautious when conduct that they wish to undertake could amount to any of the examples of conduct listed above. Of course, businesses may also wish to be reminded that if they wish to undertake conduct which could be construed as any of the forms of "price fixing" as listed in Article 7 of the Price Rules, there is a possibility that the exemption regime pursuant to Article 15 of the AML may apply (Article 15 lists examples of agreements which may not be construed as monopoly agreements such as agreements to raise efficiencies, etc.).

It is also important to note that Article 7(8) of the Price Rules states that price monopolistic agreements between competitors will also include "any other price monopolistic agreements as identified" by the NDRC. This "catch-all" provision suggests that the list of examples in relation to what constitutes price fixing pursuant to Article 7 of the Price Rules is not an exhaustive list.

(b) Prohibition re: anticompetitive agreements between businesses in a supply chain relationship

As mentioned above, Article 14 of the AML prohibits anticompetitive agreements between businesses in a supply-chain relationship. Specifically, Article 14 of the AML lists two forms of agreements between businesses in a supply-chain relationship which are prohibited, namely fixing the prices of commodities for resale to third parties and fixing the lowest prices for the resale of commodities to third parties (in other words, resale price maintenance and minimum resale price maintenance).

It is interesting that Article 8 of the Price Rules is simply a repeat of Article 14 of the AML. In other words, Article 8 of the Price Rules does not give any further guidance or elaboration of how Article 14 of the AML will be interpreted or enforced. This is not useful because many questions remain, such as, are all agreements to fix resale prices between vertical entities absolutely prohibited? What factors would the NDRC take into consideration when determining if an agreement to fix resale prices could breach Article 14 of the AML? To what extent would the exemptions pursuant to Article 15 of the AML apply to an agreement which fixes resale prices?

(IV) Prohibition on abuse of dominance

Article 17 of the AML prohibits dominant business operators from abusing their dominant position. Article 17 also lists examples of conduct, which, may, in particular, flout this prohibition, including: selling commodities at unfairly high prices or purchasing commodities at unfairly low prices; selling commodities at below-cost prices without a valid reason; and bundling sales of commodities without a valid reason or imposition of any other unreasonable terms of transaction during a transaction and implementing differential treatment in relation to transaction terms such as transaction price for similar trading counterparts without a valid reason.

The Price Rules provide further clarity on: the definition of the term dominant market position; the boundaries on the prohibitions in relation to unfairly

high/low prices; predatory pricing; and exclusive dealing.

Definition of the term dominant market position. Article 17 of the AML defines the phrase "dominant market position" to mean a position held by a business operator that has the ability to control the prices or quantities of commodities or other trading conditions in the relevant market or to block or affect the entry of other business operators into the relevant market. Article 17 of the Price Rules goes into further detail in respect of what the phrases "other trading conditions" and "to block or affect entry of other business operators into the relevant market" mean.

In relation to the former (*i.e.*, other trading conditions), the Price Rules say that this means factors other than prices of commodities and quantities which may substantially affect market transactions including the grade of commodities, terms of payment, method of delivery, after sale services, trading options and technical constraints, etc.

In relation to the latter (*i.e.*, to block or affect entry of other business operators into the relevant market), the Price Rules say this phrase refers to the act of excluding or delaying the entry of other business operators into the relevant market within a reasonable time period, or significantly increasing the cost of entry if business operators are able to enter the relevant market such that these business operators are not able to compete effectively with existing business operators.

While it is useful to understand what is meant by the two phrases mentioned above, there would be more clarity if the Price Rules went into some detail as to what a "reasonable time period" is in respect of the second phrase; and it would also be useful to know the boundaries of the phrase "significantly increasing the cost of entry".

Unfairly high prices/unfairly low prices. Article 17(1) of the AML prohibits dominant business operators from selling commodities at unfairly high prices or purchasing commodities at unfairly low prices. Article 11 of the Price Rules provides a list of factors that the NDRC will take into consideration when determining what is an "unfairly high price" and what is a "unfairly low price", including:

- whether the selling/buying price is obviously higher/lower than the selling /buying price of other business operators;
- whether the selling/buying price of a good or service increases/decreases beyond a normal margin when costs are basically stable; and
- whether the increase/decrease in selling/buying price is obviously larger than the increases/decrease in cost.

While it is useful to have some guidance as to what might constitute an unfairly high price or an unfairly low price, some questions remain, including how and to what extent the NDRC will benchmark the selling or buying prices of "other business operators", what constitutes a "normal margin" and what is meant by the phase "obviously larger than the increase / decrease in cost".

Predatory pricing. Article 17(2) of the AML prohibits dominant business operators from selling commodities at below-cost prices without a valid reason (in other words, predatory pricing). Article 12 of the Price Rules elaborates on what some possible "valid reasons" are in the context of Article 17(2) of the AML, including:

- reducing prices of fresh or live commodities, seasonal commodities and expiring commodities, or overstock;
- reducing commodity prices due to debt repayment, production switch, or discontinuation of business; and
- adopting sales promotions for the purpose of promoting new products.

The Price Rules, however, do not address some important issues in relation to this prohibition against predatory pricing. First, what is meant by the term "below cost prices" – would the NDRC take into account short run marginal costs or average variable cost or some other method of calculation? Second, to what extent is the dominant business' ability to recoup losses a factor to consider when determining a predatory pricing breach?

Exclusive dealing. Article 17(4) of the AML prohibits dominant business operators from restricting their trading counterparts to transact only with itself or only with designated business operators without a valid reason. Article 14 of the Price Rules outlines what some of these "valid reasons" could be:

- where conduct was undertaken for the purpose of ensuring product quality and safety;
- where conduct was undertaken for the purposes of maintaining brand image or improving service levels; and
- where conduct was undertaken to be able to reduce cost, enhance efficiency remarkably and enable consumers to share the benefits derived.

Other provisions that the Price Rules elaborate on. Article 13 of the Price Rules elaborates on the prohibition in relation to refusal to deal within the AML (see Article 17(3), AML) by listing some "valid reasons" for conduct which may amount to a refusal to deal, including the existence of serious credit records by the transacting parties or occurrence of continued deterioration of operations. In addition, Article 15 of the Price Rules states that dominant business operators may not impose unreasonable charges to transactions in addition to price; and Article 16 of the Price Rules states that dominant business operators may not apply discriminatory treatment on a transaction price to transacting parties with the same status without a valid reason. These two provisions shed some light and correspond to Article 17(5) (prohibition in relation to an imposition of unreasonable terms during a transaction) and Article 17(6) (prohibition in relation to implementing differential treatment) of the AML respectively.

(V) Concluding comments

Overall, the Price Rules shed light and provide some transparency in terms of how the NDRC will enforce the price-related breaches of the AML. This should assist businesses in their compliance efforts in relation to the price-related provisions of the AML. Though we note that some important questions still remain unanswered in relation to how the price-related prohibitions of the AML will be interpreted and enforced (as outlined above), it is anticipated that those issues will be gradually elaborated upon as the enforcement experience of the NDRC develops and accumulates.

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Average Wholesale Price: Efficient Benchmark or Conspiratorial Instrument?

By Brian J. Ellman and Evan Hoffman Schouten

I. Introduction

Over the past few years, plaintiffs in multiple litigations throughout the country have alleged that Average Wholesale Price ("AWP") is an instrument of conspiracy used by drug manufacturers to defraud and inflate prices to third-party payers. Defendants in such cases have argued that AWP has been well known by all parties to be a metric that is divorced from the actual net prices charged to pharmacy providers by the industry. Defendants have also argued that AWP is an efficient starting point for payers to determine reimbursement levels to pharmacy providers, and for drug manufacturers to negotiate discount and rebate policies to pharmacy providers, third-party payers, and pharmaceutical benefit managers. To assess whether AWP is a likely instrument for a conspiracy among drug manufacturers, it is important to understand how AWPs are set and the context in which they are used.

In this article, we provide a description of the drug payment system and the role of third-party payers. We then provide an overview of the different uses of AWP and show that it has served (and continues to serve) a useful purpose as a benchmark for reimbursement. However, for reasons explained here, AWP is an inefficient and unreliable basis for drug manufacturers to illegally increase their profits. It is therefore an improbable and ineffective instrument upon which to base a price-fixing conspiracy among drug manufacturers.

II. Brief Overview of Drug Payment System

The prescription drug industry is unusual in that the beneficiary of its products (the patient) often pays no more than a preset fraction of the price of the product (in the case of coinsurance) or a fixed amount (in the case of copays), while intermediaries and third-party payers pay varying prices determined through market transactions, complex contracting agreements that may cover multiple products, or formulaically determined amounts based on a series of pricing benchmarks.

Most prescription drugs are sold by drug manufacturers to wholesalers. Prices to wholesalers tend to be based on list prices that are set by manufacturers, or wholesale acquisition costs ("WACs"). Companies set prices of their drugs at levels that account for multiple competitive factors, including the relative safety and efficacy profiles and prices of available treatment alternatives, the type of drug (for instance, brand or generic), and the total cost to the manufacturer of research and development for the drug entering the market and those that fail to make it to the market.[1] Wholesalers negotiate discounts and rebates with manufacturers, often depending on purchase quantities. Wholesalers then resell the drugs to retail pharmacies and nonretail providers (for instance, hospitals and nursing homes) at a marked-up price. In turn, these providers dispense the drugs to consumers with a prescription for a specific drug.

Embedded within this chain of distribution are numerous negotiations and payments among the various parties. Buyer power and the competitive landscape for a particular prescription drug can significantly affect sales of that drug as well as the prices paid to pharmaceutical manufacturers. Different buyers in the distribution chain will pay different amounts for different drugs, depending on the type of drug (brand versus generic), the number of alternative therapies (single-source versus multisource), and the class of trade (for example, chain pharmacy versus independent pharmacy), among other factors. The net cost of a drug to the provider is known as the actual acquisition cost ("AAC").

For patients with prescription benefit coverage, the pharmacy provider is reimbursed from two sources: the copayments or coinsurance paid by patients, and the amount reimbursed by a third-party payer (for example, a commercial insurance company, Medicaid, or other public-sector payer). The amounts paid by the third-party payer are

[1] See, e.g., Berndt, Ernst R., "Pharmaceuticals In U.S. Healthcare: Determinants of Quantity and Price," *Journal of Economic Perspectives*, Fall 2002, 16(4), pp. 45 – 66.

based on negotiated contracts with providers or, in the case of Medicare and Medicaid, pre-defined reimbursement amounts expressed in terms of a series of price benchmarks.

The difference between the amount reimbursed to providers by the third-party insurer and the AAC (the "spread") helps cover the providers' administrative and distribution costs.[2] Because providers are often reimbursed different amounts by different third-party payers, and pay different amounts for different drugs, they receive a different spread on virtually every transaction they complete.

III. The Role of Third-Party Payers

Third-party payers include commercial insurance companies and government payers (Medicare and Medicaid programs). Each payer has its own objectives; while some seek to maximize their profits, others operate with specific public policy goals and seek to maximize access to health care. No matter their ultimate objectives, however, third-party payers must contract with providers to have any role in the industry.

In general, payers cover numerous drugs and seek to contract with multiple providers to increase their presence in the marketplace and provide adequate access to their members. While a large market presence can help payers achieve their objectives it also produces significant administrative and logistical complexities. In particular, the payer has to determine the appropriate reimbursement amounts to pay providers with different cost structures for numerous drugs with different acquisition costs across different geographies and classes of trade. These reimbursement amounts must be sufficient to ensure that providers will continue to contract with the payer. They must also be cost-effective and recognize the reality of budget constraints.

It is not feasible for a payer to know the AAC for each drug dispensed by a provider to a payer's beneficiary, nor is that information publicly available. Further, the establishment of individualized reimbursements — for example, pharmacy by pharmacy — to account for differences in acquisition costs and other factors would be costly to administer, excessively burdensome, and have a high potential for error. As a result, payers seek to reasonably estimate providers' acquisition costs and other dispensing (and occasionally administrative) costs using all available information.[3] They also rely on formulas incorporating price benchmarks to administer reimbursement for a broad set of drugs and providers.

The use of price benchmarks to calculate and communicate reimbursement payments reflects an efficient method by which to maintain the system's flexibility, minimize uncertainty through predictable costs, maximize coverage in a cost-effective manner, and provide a mechanism for competition among payers. Third-party payers are free to establish their own reimbursement policies and procedures, bounded primarily by the availability of data and competitive pressures. Payers' reimbursement formulas will often include a series of price benchmarks and payment caps.[4, 5] The price benchmarks used in payers' formulas are commonly adjusted by a percentage that is contractually set (for commercial payers) or established through regulatory procedures (for public payers). For example, reimbursement could be determined based on the lower of the drug's (i) AWP – *x*%, (ii) WAC + *y*%, and (iii) payment cap.

The use of a formula results in pharmacy providers earning different spreads on sales of

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[2] The spread earned by a provider on the sale of a drug can be conceptualized as a gross profit (revenue minus the cost of goods). As such, a spread helps to cover other provider operating costs, such as labor and overhead.

[3] Different levels of data on drug sales are available through numerous resources. For example, IMS offers data on revenues and prescription quantities for each drug through different classes of trade. Additionally, numerous surveys have been conducted to estimate average costs to providers for different drugs. See, e.g., "Medicaid Pharmacy – Actual Acquisition Cost of Brand Name Prescription Drug Products," Department of Health and Human Services: Office of Inspector General, A-06-00-00023, August 10, 2001, available at http://oig.hhs.gov/oas/reports/region6/60000023.pdf.

[4] Examples of payment caps include Maximum Allowable Costs ("MACs") set by state Medicaid agencies or by commercial insurance companies for individual drugs (most commonly, multiple-source drugs), and Federal Upper Limits ("FULs") set by the Centers for Medicare & Medicaid Services ("CMS").

[5] See, e.g., Kaiser Family Foundation, "Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain," March 2005, available at http://www.kff.org/rxdrugs/upload/Follow-The-Pill-Understanding-the-U-S-Commercial-Pharmaceutical-Supply-Chain-Report.pdf; and Mullen, Patrick, "The Arrival of Average Sales Price," Biotechnology Healthcare, June 2007, pp. 48 – 53.

different drugs, depending on each provider's AAC for each drug and the prevailing reimbursement level determined through the payer's formula.

Notably, as sophisticated entities with the ability to affect sales of drugs, third-party payers are able to use mechanisms to reduce their net costs. Specifically, payers develop formularies – lists of covered drugs – that specify which drugs are approved for payment under a particular contract and the copayment levels or coinsurance percentages that must be paid by their beneficiaries, and whether there are other requirements for coverage (for example, prior approval or step therapy requirements). Formularies can affect demand for (and sales of) individual drugs and, therefore, provide payers with buyer power in their negotiations with drug manufacturers. As such, payers are often able to negotiate discounts, rebates, and chargeback policies with drug manufacturers as part of the competitive process to attain favorable formulary placement and meet sales targets.[6] The reduction to a payer's net costs (for instance, in the form of rebates) are often calculated using price benchmarks, such as AWP or, in the case of Medicare and Medicaid, the drug's reported average manufacturer price ("AMP"), taking best price requirements into consideration.[7]

IV. AWP as a Benchmark Price

Despite multiple modifications to third-party payers' reimbursement policies over time, the most commonly and continuously used set of reference prices in reimbursement and provider payment calculations and negotiations remains AWP.[8]

Of note, there is no precise legal or regulatory definition of AWP.[9] AWP is an amount that is calculated and published by compendia — such as the *Blue Book* (First DataBank) and the *Red Book* (Medical Economics). The compendia have calculated a drug's AWP by applying a relatively fixed estimated markup to the WAC (list price) reported by the drug manufacturer. AWPs are widely recognized as wholly fictitious prices among industry observers and participants. Indeed, AWP has long been facetiously referred to as "Ain't What's Paid."[10]

Why then do payers continue to use AWP as one of the price benchmarks in reimbursement formulas? In addition to being one of the few publicly available price benchmarks, AWP is the only metric that is focused on the pharmacy provider, the target recipient of payers' reimbursement. From an administrative perspective, AWP provides a logical starting point for the calculation and communication of reimbursement to various pharmacy providers for various drugs. Moreover, given the historical use of AWP by all industry participants, one cannot discount the significance of AWP's entrenchment in the complex and highly automated payment system. As such, it is widely used as a competitive benchmark and to estimate costs and revenues.

This is not to suggest that AWP reflects the ideal price benchmark, but its continued use as *one of* the price benchmarks used by industry participants is understandable.[11]

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6 Cohen, Laurie P., and Elyse Tanouye, "Bitter Pill: Drug Makers Set to Pay $600 Million to Settle Lawsuit by Pharmacies", Wall Street Journal, 18 January 1996, p. A1, A8.

7 Statutorily defined basic rebates from drug manufacturers are generally calculated as the greater of: (1) AMP times 15.1% or (2) AMP minus the best price. In concept, the AMP is the average unit price paid to the manufacturer for the drug in the U.S. by wholesalers for drugs distributed to the retail pharmacy class of trade. The best price is the lowest manufacturer price paid for a drug by any purchaser, including all discounts, rebates, and other pricing adjustments.

8 See, e.g., Kolassa, Mick, "Guidance for Clinicians in Discerning and Comparing the Price of Pharmaceutical Agents," Journal of Pain and Symptom Management, 9(4), May 1994, pp. 235 – 243. See also, "Use of Average Wholesale Prices in Reimbursing Pharmacies Participating in Medicaid and the Medicare Prescription Drug Program," Department of Health and Human Services: Office of Inspector General, A-06-89-00037, October 3, 1989, available at http://oig.hhs.gov/oas/reports/region6/A-06-89-00037.pdf; "Medicaid Pharmacy – Actual Acquisition Cost of Prescription Drug Products for Brand Name Drugs," Department of Health and Human Services: Office of Inspector General, A-06-96-00030, April 10, 1997, available at http://oig.hhs.gov/oas/reports/region6/60100053.pdf; and "Medicaid Pharmacy – Actual Acquisition Cost of Brand Name Prescription Drug Products," Department of Health and Human Services: Office of Inspector General, A-06-00-00023, August 10, 2001, available at http://oig.hhs.gov/oas/reports/region6/60000023.pdf.

9 Scanlon, William J., "Medicare Part B Drugs: Program Payments Should Reflect Market Prices," United States General Accounting Office, September 21, 2001, GAO-01-1142T, p. 4.

10 See, e.g., Alpert, Bill, "Hooked on Drugs: Why do insurers pay such outrageous prices for pharmaceuticals?," Barrons, June 10, 1996, p. 3.

11 For additional discussion of the role of AWP as a pricing benchmark, see, e.g., Gencarelli, Dawn M., "Average Wholesale Price for Prescription Drugs: Is There a More Appropriate Pricing Mechanism?" NHPF Issue Brief No.

V. AWP as an Alleged Instrument of Conspiracy

It has been alleged that prevailing AWPs are the result of a conspiracy among drug manufacturers to defraud and inflate prices paid by third-party payers.[12]

The purpose of a conspiracy is to inflate market prices and, ultimately, to enhance conspirators' profits. In practice, establishing and maintaining a successful conspiracy is difficult. Firms' ability to set and sustain supracompetitive prices is conditional on numerous factors.[13]

At its most basic level, the instrument of conspiracy (such as the production output, or the sales prices) must ultimately affect participants' profits or otherwise provide an incentive for firms to illegally conspire. In forming a collusive agreement, firms must consider and balance the incentives of all participants to determine the optimal degree by which to affect the instrument of conspiracy (for instance, the joint profit-maximizing price or each participant's output level). Typically, many, if not all, cartel members will have the incentive to "cheat" – that is, to deviate from the collusive agreement to sell more than their pro rata share of output. To prevent such cheating, the cartel must monitor each firm's actual sales and punish cheaters. Detecting cheaters and punishing them can be a difficult task, especially when the cartel cannot turn to the legal system for enforcement. Rather, cartel members must establish their own mechanisms for minimizing firms' incentives to cheat and punishing those that do cheat.[14]

Firms' ability to fix prices above competitive levels is also contingent on many factors, including the number of colluding firms and their combined share of the market; the size and sophistication of buyers; the homogeneity of products sold by and relative cost structures of colluding firms; and the characteristics of demand for the firms' products.[15] To the extent that the industry characteristics are not "ideal" for collusion, the ability of firms to maintain a successful conspiracy can be significantly hindered.

Within the context of economic theory, AWP is not an effective instrument for a conspiracy among drug manufacturers. In particular, AWP reflects the basis of amounts paid to pharmacy providers. Drug manufacturers do not directly reap the benefits of an inflated AWP because, as explained above, there are other factors that influence payments to manufacturers and providers that do not depend on AWP. Therefore, an increase to AWP would not necessarily reflect an increase in the prices received or profits achieved by drug manufacturers. In fact, as AWP is sometimes used as a benchmark for the determination of drug manufacturers' rebate payments to payers, an inflation of AWP might serve to *decrease* their profits. Therefore, as AWP levels do not correlate with drug manufacturers' profits, it would not be possible to coordinate manufacturers' incentives based on AWP.

Drug sales are driven by prescriptions. For self-administered drugs (such as those dispensed through a pharmacy), the person writing the prescription receives no marginal payments for writing a script for a certain drug. Therefore, a modification to AWP would not serve as an incentive to increase prescriptions (sales) of a given drug. More important, any action that seeks to increase sales of one manufacturer's drug at the expense of another manufacturer's drug signals a competitive market, not a conspiracy.

775, Washington, D.C.: National Health Policy Forum, June 7, 2002. For a discussion of other potential benchmarks, see, e.g., Curtiss, Frederic R., et al., "What is the Price Benchmark to Replace Average Wholesale Price (AWP)?" Journal of Managed Care Pharmacy, 16(7), September 2010, pp. 492 – 501.

12 See, e.g., Commonwealth of Pennsylvania v. TAP Pharmaceutical Products, Inc. et al., No. 212 M.D. 2004, Pa. Commonwealth. A more complex conspiracy among drug manufacturers was alleged in In re Pharmaceutical Industry Average Wholesale Price Litigation, MDL No. 1456, D. Mass.

13 See, e.g., George Stigler, "A Theory of Oligopoly," Journal of Political Economy, 1964, Vol. 72, pp. 44-61; Hay, George A. and Daniel Kelley, "An Empirical Survey of Price Fixing Conspiracies," Journal of Law & Economics, 1974, 17(1), pp. 13 – 38; and Carlton, Dennis W. and Jeffrey M. Perloff, Modern Industrial Organization, 4th edition, Pearson/Addison Wesley, 2005.

14 See, e.g., Kaplow, Louis and Carl Shapiro, "Antitrust," in A. Mitchell Polinsky and Steven Shavell (eds.), Handbook of Law and Economics, Volume 2, Elsevier, 2007, pp. 1073 – 1226, 1103.

15 See, e.g., Motta, Massimo, Competition Policy: Theory and Practice, Cambridge University Press, 2004; Ivaldi, Marc, Bruno Jullien, Patrick Rey, Paul Seabright, and Jean Tirole, "The Economics of Tacit Collusion," European Commission, March 2003; Levenstein, Margaret C. and Valerie Y. Suslow, "What Determines Cartel Success?," Journal of Economic Literature, Vol. XLIV, March 2006; and Posner, Richard, Antitrust Law, University of Chicago Press, Chicago, 2nd ed. 2001.

Further, as highly sophisticated entities with significant buyer power, payers would be able to use formularies and other tools to control costs and drive choice of pharmaceutical agents, including the use of other price benchmarks to establish reimbursement levels. Because they can avoid paying based off of AWP, and can affect sales through formulary placement and other policies, payers would be able to circumvent a collusive agreement on AWP.

Moreover, the effect on payers of an increase in a drug's AWP could vary based on the competitive landscape of each market (for instance, brand versus brand, brand versus generic). For example, if payers require generic substitution when possible and a generic version is available, an increase in the AWP for a branded drug would have no effect. Such variations across multiple drug markets would complicate, if not wholly invalidate, any attempt to coordinate incentives of drug manufacturers with different product mixes that compete in different markets.

VI. Conclusion

The prescription drug industry operates under a highly complex distribution and payment system. The inherent administrative and logistical obstacles associated with third-party payment in such a system are alleviated through the use of price benchmarks that can be applied across numerous drugs. As part of comprehensive programs to manage costs, payers have developed formulas to calculate reimbursement amounts to providers that include a series of price benchmarks and payment caps and have modified the adjustments (such as the percentage discount applied to AWP) used in those formulas. Ultimately, the specific price set for a given benchmark has little effect on the reimbursement amounts paid by payers to providers. Rather, AWP can be thought of as a "language" in which pricing negotiations are communicated between payers and manufacturers.

AWP is but one of the potential benchmarks commonly used in payers' reimbursement formulas. While it is well-known in the industry that AWP does not reflect the actual price paid by pharmacy providers for drugs, it also does not reflect or have any direct effect on the amounts received by drug manufacturers. A drug's AWP provides no information on the manufacturer's profits earned on sales of that drug, nor does it inform the level of sales that could be achieved by the drug. As such, AWP is an inefficient and unreliable basis upon which to seek to increase drug manufacturers' profits. It is therefore an improbable instrument for the effective operation of a conspiracy.

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United States and the State of Michigan vs. Blue Cross Blue Shield of Michigan
New Justice Department Attack on Most Favored Nations Clauses

By James J. Calder
Dean N. Razavi

I. Background

In October of last year the Department of Justice and the State of Michigan attacked a series of most favored nation agreements ("MFNs") that Blue Cross Blue Shield of Michigan ("BCBSM") had with various hospitals. The case may represent renewed DOJ concern over the use of MFNs, at least in the health care industry.

In the complaint, which DOJ and Michigan's Attorney General filed jointly, the plaintiffs allege that BCBSM's MFN agreements violate Section 1 of the Sherman Act and Section 2 of Michigan's Antitrust Reform Act.[1] According to plaintiffs, the effect of the MFNs is to impair competition in the sale of health insurance throughout Michigan.[2]

DOJ and the Michigan Attorney General attack two different types of MFN agreements: "Equal-to MFNs" and "MFN–plus" agreements. The Equal-to MFNs are traditional MFN provisions. They require hospitals that participate in the BCBSM network to give their best rates to BCBSM patients. According to the complaint, BCBSM entered into Equal-to MFNs with approximately 48 community hospitals across the state in exchange for increased reimbursement rates.[3]

The second category of MFN attacked is less traditional. These provisions – so-called "MFN-plus" arrangements – do not require hospitals to give BCBSM the same rates they give to other health insurers. Rather, they require the hospitals to charge BCBSM *lower* rates than they charge other insurers. As characterized in the complaint, the "MFN-plus" provisions require the hospital to charge other health insurers a fixed percentage *more* than what they charge BCBSM.[4] According to the complaint, the percentage difference is, in some cases, as high as 25%.[5] The plaintiffs charge that MFN-plus arrangements were entered into with 22 tertiary care hospitals across the state – representing 45% of Michigan's tertiary hospital beds.[6]

The Complaint goes on to define three product markets: fully insured group health insurance, self-insured group health insurance, and individual health insurance.[7] It then identifies 16 separate relevant geographic markets, and makes specific allegations concerning five of them: (1) the Upper Peninsula (including the City of Marquette); (2) the City of Lansing; (3) the City of Alpena; (4) the City of Traverse; and (5) the Thumb Counties (including Huron, Sanilac, and Tuscola counties). The plaintiffs allege that BCBSM offered increased rates to all major or important hospitals in the area in exchange for MFNs.[8] The plaintiffs assert that, had the various hospitals not consented to the MFNs, BCBSM would have paid them lower rates.[9] In essence, the complaint charges that BCBSM paid the hospitals significantly higher rates in exchange for the MFNs.

The plaintiffs identify a number of separate anticompetitive effects from these arrangements. According to the Complaint, the MFNs:

a) Maintain a significant differential between the hospital costs paid by BCBSM and competing health insurers, preventing those insurers from competing more aggressively against BCBSM;

b) Raise hospital costs to BCBSM competitors;

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1 Compl. at ¶¶ 85, 90.

2 *Id.* at ¶ 3.

3 *Id.* at ¶ 4.

4 *Id.* at ¶ 4(A).

5 *Id.* at ¶ 39(e).

6 *Id.* at ¶4(a).

7 *Id.* at ¶¶ 13-18.

8 *Id.* at ¶¶ 49-79.

9 *Id.* at ¶ 44.

c) Establish a price floor below which "important hospitals would not be willing to sell hospital services. . . thereby deterring cost competition among commercial health insurers;"[10]

d) Raise the price floor for hospital services to all commercial health insurers -- "likely raising the prices for commercial health insurance;"[11] and

e) Limit the ability of other health insurers to compete with BCBSM "by raising barriers to entry and expansion."[12]

The plaintiffs seek injunctive relief barring enforcement of the MFNs and reformation of the BCBSM/Hospital Agreements striking the MFNs.[13]

II. Blue Cross' Motion to Dismiss

Blue Cross filed an omnibus motion to dismiss. A central theme of its motion is that the case is an attack on efforts to obtain price discounts. BCBSM emphasizes that theme by opening its brief with Judge Posner's language from *Blue Cross & Blue Shield of Wis. v.. Marshfield Clinic*, that "[m]ost favored nations clauses are standard devices by which buyers try to bargain for low prices . . . [I]t is the sort of conduct that the antitrust laws seek to encourage."[14] After noting that "[c]ourts are nearly unanimous in holding that MFNs do not violate the antitrust laws" [15] BCBSM advances three major arguments in favor of dismissal or abstention on the federal antitrust claims.

First, BCBSM argues that the conduct challenged is immune from Sherman Act attack under the State Action Doctrine.[16] According to BCBSM, Michigan established a comprehensive state policy displacing unfettered competition in health care and health care financing in favor of state regulation. The State created BCBSM as part of that scheme to act as an insurer of last resort and gave it the power and obligation to enter into reimbursement contracts with hospitals to assure subscribers reasonable access to quality health care.[17] Given these facts, BCBSM argues that, as a state created entity, it is entitled to State Action immunity solely because it satisfies the first prong of the state action immunity test set forth in *California Retail Liquor Dealers Ass'n v. Midcal Aluminum, Inc.*[18] The first prong of the *Midcal* test requires that the challenged restraint be "one clearly articulated and affirmatively expressed as state policy."[19]

As to the "active supervision" prong of *Midcal*'s state action immunity test, BCBSM argues that, even though it need not satisfy that element, it in fact does so because its conduct and its plans with health care providers are actively supervised by Michigan's Commissioner of the Office of Financial and Insurance Regulation.

Second, BCBSM argues that the court should abstain, on the basis of *Burford v. Sun Oil, Co.,*[20] from hearing the federal antitrust claims at all. According to BCBSM, the exercise of *Burford* abstention is necessary and appropriate because the application of federal antitrust principles to BCBSM's actions will upset the state's regulatory scheme and supervisory regime. In addition, BCBSM argues that application of federal competition law policies – which are based solely on maintaining competition in the market – would disrupt Michigan's broader "efforts to establish coherent health care policy." BCBSM contends that Michigan's health care policy is driven by public concerns beyond competition, such as ensuring broad access to the health care system.[21]

Third, BCBSM attacks the complaint under *Bell Atlantic Corp v. Twombly*[22] and *Ashcroft v. Iqbal*[23] on a number of grounds. With respect to the definition of the product markets alleged, BCBSM asserts that the individualized allegations necessary to establish their existence are never

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10 *Id.* at ¶ 41(c).

11 *Id.* at ¶ 6.

12 *Id.* at ¶ 43.

13 *Id.* at ¶ 90.

14 65 F.3d 1406, 1415 (7th Cir. 1995) quoted in Memorandum in Support of Defendant's Motion to Dismiss ("Def. Mem") at 1.

15 *Id.* at 8.

16 S. Motor Carriers v. U.S., 471 U.S. 48 (1985).

17 *Id.* at 13.

18 445 U.S. 97 (1980).

19 Town of Hallile v. City of Eau Claire. 471 U.S. 34, 41 – 41 (1985), Def. Mem at 9.

20 319 U.S. 315 (1943).

21 Def. Mem at 29.

22 550 U.S. 544 (2007).

23 129 S. Ct. 1937 (2009).

made.[24] In addition, it argues that the market in which the alleged misconduct is said to have occurred – the market for buying hospital services – is not the relevant market pled in the complaint.[25] As for the relevant geographic markets, BCBSM attacks the pleading for failing to allege specific facts supporting the boundaries of the markets posited in the complaint. It argues that plaintiffs have simply made conclusory allegations that certain SMSAs or counties constitute geographic markets.[26]

Lastly, BCBSM attacks the complaint for failing to plead facts that show a plausible likelihood of anticompetitive effects arising from the MFNs. BCBSM makes a number of arguments here. First, it asserts that if the plaintiffs are claiming that the MFNs have the effect of predatory bidding by inflating the prices that other health insurers must pay for hospital services, they must plead facts showing that BCBSM will be able to recoup its losses once the competitors are driven from the market, under the Supreme Court's reasoning in *Weyerhaeuser Co. v. Ross-Simmons Hardwood Lumber Co.*[27] BCBSM asserts that the complaint contains no such allegations.[28] BCBSM also asserts that the complaint is deficient because, to the extent it alleges that the MFNs effectively foreclose other health insurers from the market, it pleads no facts showing such foreclosure.[29]

III. Plaintiffs' Opposition

In their opposition to the motion to dismiss,[30] plaintiffs note that MFNs are to be judged under the rule of reason. They also note that at least one court has recognized that MFNs may "effectively prevent discounting to other insurers."[31] Plaintiffs go on to argue that no court has ever held that all MFNs are procompetitive as a matter of law and that no court has ever ruled that MFN-plus arrangements are permissible under the rule of reason.[32]

Plaintiffs then respond to BCBSM's *Twombly* arguments. With respect to the product market allegations, plaintiffs argue that two separate markets are pled in the complaint – a market for commercial group health insurance and a market for commercial individual health insurance. Plaintiffs assert that the complaint alleges facts showing that there are no other reasonably interchangeable products for these two types of insurance and those facts are all that *Twombly* requires as far as product market definition is concerned.[33] As for geographic markets, plaintiffs assert that BCBSM does not challenge the plausibility of those markets, it merely demands more detail – a matter to be resolved after discovery.[34]

With respect to the challenge to the sufficiency of the allegations of anticompetitive effects, plaintiffs rely on the detailed allegations in the complaint concerning the terms of the specific MFNs that BCBSM has entered into with the hospitals identified in the complaint. Plaintiffs contend that those facts are more than sufficient to establish that the MFNs plausibly lead to the anticompetitive effects described in the complaint. Plaintiffs contend that this is especially the case in a rule of reason situation where the ultimate issue for trial is a balancing of the MFNs' anticompetitive and procompetitive effects. As for BCBSM's assertions that the complaint is defective because it fails to allege facts showing either recoupment under a predatory bidding theory or competitive foreclosure, plaintiffs dismiss both arguments saying that they do not rely on and do not need to rely on either theory to establish anticompetitive effects in this case. According to the plaintiffs, the fact that the MFNs make it more expensive for other insurers to compete against BCBSM is enough.[35]

Plaintiffs next address the State Action defense. As an initial matter, they cite to cases in

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24 Def. Mem at 34-38.

25 *Id.* at 35 – 37.

26 *Id.* at 38 – 41.

27 549 U.S. 312, 319 (2007).

28 Def. Mem at 44 – 45.

29 *Id.* at 46 – 47.

30 DOJ filed a memorandum on the federal antitrust claims. The State of Michigan filed a separate memorandum on the state law claim. It appears that the arguments made in the DOJ memorandum are advanced on behalf of both claims.

31 Quoting Reazin v. Blue Cross and Blue Sheild of Kansas, 663, F. Supp. 1360, 1418 (D. Kan. 1987), aff'd, 899 F.2d 951 (10th Cir. 1990). United States Memorandum in Opposition to Defendant's Motion to Dismiss ("DOJ Opp. Mem.") at 4-5.

32 *Id.*

33 *Id.* at 10-11.

34 *Id.* at 11-13.

35 *Id.* at 18 – 19.

which BCBSM takes the position that it is not a public entity and is not an agent of the state. As a result, plaintiffs contend that BCBSM must satisfy both elements of the *Midcal* test to qualify for State Action immunity.[36] With respect to the clear articulation requirement, plaintiffs assert that this element of the test cannot be satisfied because the MFNs are not the logical or foreseeable result of any state legislative enactment and because it is Michigan's policy to promote, not displace, competition.[37] As for the active supervision prong, plaintiffs assert that BCBSM cites to no facts showing Michigan review of the MFN-plus provisions and only general, rather than specific, review of the Equal-to MFNs.[38] Plaintiffs conclude that this is insufficient to satisfy the second prong of the *Midcal* test.

Finally, on the *Burford* abstention defense, plaintiffs contend that it would be "unprecedented" to abstain "from hearing a federal antitrust claim brought by the federal government in federal court."[39] Plaintiffs contend that "[f]ederal courts' exclusive jurisdiction over federal antitrust claims . . . has been recognized repeatedly as precluding *Burford* abstention."[40]

IV. Conclusion

In sum, *BSBCM* is an interesting and potentially important case. If plaintiffs succeed, the case may have significant implications for the use of MFNs, at least in the health care industry. If plaintiffs fail, the case may reaffirm Judge Posner's view that MFNs are "the sort of conduct that the antitrust laws seek to encourage." In either event, the case is worth watching.

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[36] *Id.* at 21.

[37] *Id.* at 26-29.

[38] *Id.* at 29-33.

[39] *Id* at 35.

[40] *Id.* at 36.