

Biosimilars & Exclusive Dealing Antitrust Law: The Case of Pfizer Inc v Johnson & Johnson et al.

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Abstract

Following the [generally accepted theories](#) of the legal scholar Robert Bork and his Chicago School colleagues, vertical restraints such as exclusive dealing contracts are **presumptively** procompetitive and welfare-enhancing because it would be irrational for a buyer to exclude the lowest cost supplier.

On September 20, 2017, the drug manufacturer Pfizer filed a lawsuit [Pfizer Inc. v Johnson & Johnson et al](#) (link to the full court filing) claiming that Johnson & Johnson (J&J) violated Section 2 of the Sherman Antitrust Act by monopolizing the market for its incumbent biologic drug Remicade®.

We will present the case that Pfizer's antitrust case is weak because it was unlikely that Pfizer was the low cost supplier based on a view of lump sum rebate offers as [efficiency-enhancing "signals"](#) of expected consumer demand for a product.

Introduction

Johnson & Johnson's (J&J) biologic drug infliximab -- trade name Remicade® -- was approved by the FDA for use in August 1998. It was the first autoimmune drug to be approved in three different therapeutic classes and is used to treat patients with autoimmune diseases including rheumatoid arthritis, psoriatic arthritis, Crohn's disease, plaque psoriasis, and ulcerative colitis.

In 2016, Remicade was the 5th highest selling drug in the United States [with estimated sales of \\$5.3 Billion](#). Remicade was J&J's top selling drug, [representing 20%](#) of its total global drug sales.

Remicade consists of monoclonal antibodies bioengineered from mouse tumors. It is prescribed to patients with autoimmune diseases. Because it is infused at physician's offices or outpatient clinics, it is almost always covered by a medical benefit plan rather than a drug benefit plan. Remicade is a live, large molecule protein. It is impossible for other companies to manufacture perfect substitutes, only "biosimilars".

Remicade now faces competition from biosimilars due to the expiration of FDA exclusivity coupled with court judgements invalidating some of J&J's patents protecting its bio-engineering processes.

In November 2016, the FDA approved Pfizer's biosimilar drug Inflectra® followed by a June 2017 approval of Merck and Samsung's biosimilar drug Renflexis®.

Pfizer's Antitrust Lawsuit

On September 20, 2017, Pfizer filed a lawsuit [Pfizer Inc. v Johnson & Johnson et al](#) (link to the full court filing) in the U.S. District Court, Pennsylvania Eastern District Court, Philadelphia Office, No 17-04180.

Pfizer claimed that J&J violated Section 2 of the Sherman Act by monopolizing the infliximab market using a

“...web of exclusionary contracts on both health insurers and healthcare providers (e.g., hospitals and clinics) to maintain its stranglehold in respect of an

important biologic, brand named Remicade, also known by its generic name, infliximab.”

It is significant to note that the Pfizer chose Section 2 (monopolization) of the Sherman Act rather than Section 1 (restraint of trade) of the Sherman Act or Section 3 (exclusive dealing) of the Clayton Act.

Former FTC Commissioner J. Thomas Rosch [had noted in a 2007 article](#) that the one exception to the trend of courts ruling against plaintiffs in vertical restraint cases focused on Section 2 of the Sherman Act. He found that the 1978 case of Eli Lilly v SmithKline was often cited by plaintiffs who won their cases.

It is interesting to note that the SmithKline case involved bundled drug discounts. It was tried by the Third Circuit Court of Appeals which encompasses the District Court in which the Pfizer case is to be tried.

J&J’s exclusionary contracts were

“... designed to block both insurers from reimbursing, and hospitals and clinics from purchasing, Inflectra or other biosimilars of Remicade despite their lower pricing.”

The suit also claimed that J&J engaged in below cost predatory pricing:

“..when the total amount of discounts and rebates that J&J offers to insurers and providers under the contracts described herein, including multi-product bundle contracts, is attributed to the portion of Remicade sales that is contestable by a biosimilar like Inflectra, J&J is pricing Remicade below its own average variable cost.”

Expectation for Price Competition Between Biologics and Biosimilars

The pattern of price competition in 2017 between Remicade and Inflectra represents the first “clean” case study of price competition in the United States between a newly introduced biosimilar and its original biologic.

A year and a half earlier in March 2015, Sandoz introduced a self-administered, injectable drug called Zarxio that was a biosimilar to Amgen’s biologic Neupogen used to stimulate white blood cell production after chemotherapy.

Zarxio’s ease at gaining exclusivity on drug benefit formularies turned out to be an anomaly. That is because Amgen decided not to compete with Sandoz on price. Instead, Amgen focused its marketing efforts on [converting existing Neupogen users](#) to Amgen’s newly introduced, long-lasting version of Neupogen called called Neulasta.

Before we turn to the lawsuit itself, we want to discuss the expectations that experts had for biosimilar competition in general. We also want point to signs indicating what Pfizer’s own expectations were.

The reason for this is to show that no one was expecting aggressive price competition from the incumbent. When Pfizer realized its strategy was a failure, it decided to sue, claiming it was J&J fault.

Instead, it should have renewed its efforts by devising a “winnable” strategy involving deeper discounts and rebate percentages on contracts that offered exclusive coverage for a subset of infliximab users.

[At the time of its launch, Pfizer list priced](#) Inflectra at \$946 a vial, only 15% below \$1,113 for a comparable vial of Remicade. The normal regimen for both drugs consists is [an IV infusion every 8 weeks](#) or 6.5 times a year. This translates to a yearly list price of \$6,149 for the biosimilar versus \$7,235 for Remicade.

Pfizer [stated in its antitrust lawsuit](#) that it

“... introduced Inflectra with a list price 15 percent lower than Remicade, and, in negotiations with insurers and providers, offered substantial additional pricing concessions in the form of discounts and/or rebates that in some instances were more than 40 percent below Inflectra’s list price. The goal and effect was to offer Inflectra for less than J&J was offering Remicade; indeed, for many customers, Pfizer committed to ensure that Inflectra would have a lower net per-unit price than Remicade”

Pfizer failed to mention in its lawsuit that, when Merck launched a second biosimilar called Renflexis in June 2017, Pfizer [reduced its list price from 15% to 35%](#) to match Merck. We view this downward revision as an acknowledgement by Pfizer that its pricing between November 2016 and July 2017 had not been competitive.

In September 2017, J&J's [CFO Dominic Caruso told Wall Street analysts](#) that Remicade sales had dropped only 5% year-over-year since the introduction of Pfizer's biosimilar. He attributed J&J's success to doing a "pretty good job of contracting for Remicade well in advance of the biosimilar entry from Pfizer." He also attributed J&J's success to natural barriers to biosimilar adoption in general.

The costs above do not include infusion costs, [running \\$3,000+ per visit](#) or \$19,500 a year, for administering the infusion at physicians offices or outpatient clinics. Insurance coverage for the combination of drug and infusion fall under a medical benefit plan

rather than a drug benefit plan, which limits coverage to self-administered drugs. In the case of Medicare, both drugs are covered under Medicare Part B as opposed the drug benefit plan Medicare Part D.

Pfizer's choices for discounts off list have been in line with general expectations for new biosimilars. [Experts had thought](#) that biosimilar competition would mirror the modest price competition that had been observed among branded, but therapeutically equivalent, small molecule drugs.

No one believed that the competition would mirror the vigorous price competition initiated by generic manufacturers once a brand drug lost its patent protection. In these cases, a number of generic manufacturers with offshore operations would enter the market within a year and offer perfect substitutes that pharmacists could switch to automatically. The vigorous competition caused generic prices to fall 80+% lower than the original brand.

These expectations for modest price competition seemed to be based only on the economics of the biosimilar manufacturer. The idea was that the willingness of a biosimilar manufacturer to compete on price was a lot less than a generic manufacturer. This stems from a need to cover amortized R&D expenses [estimated](#) at \$100 Million to \$250 Million for a biosimilar versus \$1 Million to \$4 million for a generic.

It was also felt that biosimilar manufacturers would hold back from aggressive pricing because substantial gross profits would be needed to cover large sales expenses for consumer advertising and "physician detailing." This non-price competition followed from the expectation that physicians would be reluctant to switch existing patients to another drug that was not a perfect substitute.

No one in general, and not Pfizer specifically, expected that the manufacturer of the biologic would become the driver of vigorous price competition upon entry of a biosimilar. After enjoying 16 years of monopoly profits with fully amortized R&D, the incumbent could afford to undercut any biosimilar “burdened” by the yearly amortization of \$100 - \$250 Million in R&D expenditures.

Also, no one considered the possibility that payers -- insurance companies and plan sponsors -- would be the drivers of biosimilar price competition. This is surprising because there there [has been considerable evidence since 2010](#) that payers and contracted specialists called pharmacy benefit managers (PBMs), have been driving price competition among small molecule brand drugs via exclusive formulary rebate contracts.

The Chicago School on Exclusive Dealing

Following the now [generally accepted theories](#) of the legal scholar Robert Bork and his University of Chicago colleagues, vertical restraints such as exclusive dealing contracts are **presumptive** welfare-enhancing and procompetitive because it would not be rational for a buyer to exclude the lowest cost supplier.

Beginning in the 1980s, Federal courts have ruled that most cases involving various vertical restraints -- exclusive dealing, tying arrangements, slotting arrangements, rebate bundling, etc -- are procompetitive and do not violate antitrust laws.

The Chicago School argued persuasively that antitrust cases involving vertical restraints should be decided on the basis of prices and costs. The Chicago School has rendered the industrial organization paradigm of structure-performance-conduct and related data, which Pfizer offered as evidence in its lawsuit, as irrelevant to vertical restraint antitrust cases.

We believe that Pfizer's antitrust lawsuit is weak. Following the Chicago School, we believe that the exclusive dealing contracts between J&J and insurance companies are procompetitive as it is highly unlikely that Pfizer's biosimilar had a lower price after rebates than Remicade.

Pfizer Inc v Johnson & Johnson et al is no different that the 2014 case of [Eisai Inc. v. Sanofi-Aventis U.S., LLC](#), No. 08-4168 (MLC) (D.N.J. Mar. 28, 2014) tried in The United States District Court for the District of New Jersey. The court ruled that contracts between a drug company and hospital groups offering "loyalty discounts" if buyers met market share targets were procompetitive as long as the net prices exceeded costs.

Predatory Pricing

Pfizer alleged in its lawsuit that "J&J is pricing Remicade below its own average variable cost."

Predatory pricing is a form of vertical restraint initiated from the sell-side. The Chicago School [argued that predatory pricing is unlikely](#) to occur as it would be irrational for a seller operating under a normal profit-maximizing business model to so.

Pfizer's claim of predatory pricing is weak. The bioengineering costs to manufacture infliximab have to be about the same for the two companies. Where the two firms' cost structures differ is in the area of amortized R&D expenditures.

J&J has been amortizing Remicade's R&D costs for the past 18 years. By now J&J's R&D expenditures on its balance sheet have been fully amortized. No longer is J&J required by GAAP to "burden" its cost of goods sold.

On the other hand, Pfizer introduced Inflectra a year ago and has to “burden” its cost of goods sold with a yearly amortization of the total R&D for its biosimilar in range of \$100 Million to \$250 Million.

Unburdened by amortization, J&J could easily underprice Pfizer without going below its costs of goods sold. In other words, J&J would not have to engage in predatory pricing to outbid Pfizer for exclusive dealing contracts. It would be irrational for them to do so.

Business Model Misalignment

One factor that might have bolstered Pfizer’s case would have been a misalignment of the business model of the buyers. But, we rule that out here.

The buyers in this case are the largest national health insurance companies in the United States and a slew of regional Blue Cross Blue Shield companies. Below is the list of these companies and how they chose to cover Pfizer's biosimilar.

- UnitedHealthcare - only after Remicade failed first
- Anthem -- outright exclusion
- Aetna -- complex indication list before approval
- Cigna -- only after Remicade failed first

In its lawsuit Pfizer estimated that “70% of medical drug benefits of commercially insured patients in US” are managed by the companies named in its lawsuit.

EVERY SINGLE ONE of the national health insurance companies either excluded Inflectra outright or required Remicade to “fail first” before covering Inflectra. It is presumed that **EVERY SINGLE ONE** of these big insurance companies signed these

exclusive coverage contracts only after a thorough investigation of competing bids leading to the conclusion that J&J was the low cost supplier.

In the lawsuit, Pfizer did make the persuasive argument that “fail first” coverage for Inflectra amounted to ***de facto*** exclusion. They argued that if one infliximab drug -- Remicade -- did not work, a physician would then turn to a non-infliximab drug, not to another biosimilar infliximab drug like Inflectra. This is because years of clinical trials submitted to the FDA proved that there was no meaningful difference in outcome between Remicade and Inflectra.

The question is are there other circumstances under which a large insurance company would intentionally exclude coverage for a biosimilar with lower costs?

We have been the [first to raise the possibility](#) that a buyer with a misaligned business model could be an exception to the Chicago School dictum about vertical restraints.

This is because their conclusion depends on the assumption that the buyer has a rational business model in the economic sense of maximizing revenue minus costs. But, we rule the possibility of irrational business model out as the insurance companies in this case operate under normal economic business models.

One is an insurance model based on revenue from fixed premiums offset by provider reimbursement costs. The other is a self-insured model where the insurance company operates as a fee-for-service contractor offering medical benefits management with 100% pass through of provider reimbursements to plan sponsors.

While mistakes can occur without affecting profits in the short run, it is in the best interest of an insurance company to produce a cost-effective medical benefit as plans will compare results at contract renewal time.

Unlike cases involving insurance companies as buyers, [we have pointed out](#) that the Chicago School's assumption of a rational buyer business model is problematic in instances involving exclusionary formulary contracts between drug companies and PBMs as buyers.

PBMs have a reseller business model where their gross profits on brand Rx are derived only from opaque retained rebate percentages. The PBM business model setups up a possible misalignment of interests between plan sponsor preferences for the lowest net cost drug in a therapeutic class and PBM preferences for the drug with the highest rebate retention **dollars**.

Lump Sum Rebates

The question is how do you determine the low cost supplier in cases where the defendant uses market share or lump sum rebates in return for exclusive deals?

Pfizer alleged that its rebates offers would have make Inflectra the lower cost drug on a "unit-for-unit" basis. While Pfizer's specific descriptions of the form of J&J rebates is somewhat vague in the lawsuit, it appeared that J&J's payments to insurance companies were in the form of a contractual commitments of multimillion dollar lump sums contingent upon meeting near 100% market share targets for Remicade.

Below, we present a "stylized facts" comparison of rebates offers where our estimate for the total annual lump payment paid by J&J reasonably could have been as much as \$2 BILLION, or 28% off Remicade's list price.

Who is The Low Cost Supplier?				
Manufacturer	J&J	Pfizer		
Drug Name	Remicade	Inflectra		
	Original Biologic	Biosimilar	%	Notes
WAC List Price	\$ 1,173	\$ 997	15%	% reduction from Remicade
Exclusivity Rebate	\$ 2,000,000,000	\$ -		
Unit Volume Rebate	\$ -	\$ 400	40%	Pfizer's Rebate as a % Off List
Vials Sold -- Year	6,000,000	275,000	4%	Inflectra's % of Market - Units
Effective Unit Rebate	\$ 333	\$ 400		
Effective Unit Net Price	\$ 840	\$ 597		
"Unit to Unit Comparison"		\$ (243)		
Dollars Off List Price	0	\$ (48,386,250)		
Dollars In Additional Rebates	\$ (2,000,000,000)	\$ (110,000,000)		
Total Dollars Off List	\$ (2,000,000,000)	\$ (158,386,250)		
"Dollars to Dollars Comparison"	\$ (1,841,613,750)			
What if? -- Pfizer Rebate at Remicade Volume		\$ 2,400,000,000		

We show that on “unit for unit” basis, Pfizer is the low cost supplier. However, on a “dollar for dollar” basis, J&J is the low cost supplier given our estimated 25:1 volume advantage for Remicade coupled with our estimated \$2 Billion lump sum rebate.

Who is the low cost supplier here?

J&J is the low cost supplier based on a view of lump sum rebate offers as [efficiency-enhancing "signals"](#) of expected consumer demand for a product.

Lump sum rebates can be viewed as the product of a unit rebate times a manufacturer's expected demand for their product. They provide a “signal” to buyers of which product among a group of therapeutic equivalents might offer buyers the single best opportunity for satisfying downstream consumer demand.

The intermediate market buyer is looking to maximize expected profits. This can be cast at the product of unit margin (unit resale price - unit cost) times expected

downstream demand. It would be irrational for an intermediate market buyer to enter into exclusive dealing contracts only on the basis of unit costs after rebates without considering expected demand as well.

What buyers are doing by comparing rebates on a lump sum basis and not on a unit basis is similar to the [AdWord algorithm](#) Google came up with for “slotting” search ads based on keyword bids on a unit basis.

Slotting ads based only on cost per click (CPC) bids most likely would have resulted in the top slots going to bidders advertising products that few viewers were interested in, resulting in few clickthroughs. Slotting ads only on the basis of CPC bids would be far from revenue-maximizing as measured by the product of CPC times clickthroughs.

Instead, Google looked at past data on bidders, their ad relevancy to viewers, and calculated something called an expected clickthrough rate (eCTR), a measure of expected demand. Google then sold the top slots to bidders with the highest "AdRank", a rating index that is a blend of CPC bid and expected demand as measured eCTR.

Consider insurance company in a situation similar Google selling a single slot for insurance coverage of supplying infliximab vials to patents. The insurance companies received two rebate bids -- \$333 per vial from J&J vs \$400 per vial from Pfizer. Who should they choose for the slot?

Unfortunately, insurance companies did not have a genius like Larry Page to come up with a "AdRank" for the two bids -- a measure combining unit bid with expected consumer demand. But, insurance companies were provided with a "signal" of expected demand in the form of a J&J's market share or lump sum rebate offer.

Pfizer could have chosen to outbid J&J's on a market share or lump sum basis. But, this would have required Pfizer to have the confidence that it could deliver a 25x increase in patient demand for its biosimilar if given exclusive coverage. But Pfizer did not have such confidence.

Bundling or Tying Arrangements

Pfizer's anticipated the "signaling" defense of lump sum rebates by arguing that J&J's rebates covering the entire market for infliximab were exclusionary bundling or tying arrangements. In its lawsuit, Pfizer viewed the "contestable" market for its biosimilar as consisting only of new patients. It viewed as "uncontestable" current users of Remicade.

Pfizer argued that J&J's offer should be viewed as tying a lump sum payment for supplying existing patients with a lump sum payment for supplying new patients. Pfizer argued that its rebate offer should be compared with J&J's lump sum, but only after it had been prorated over the "contestable" market. In effect, pro-rating amounts to an "unbundling" of J&J lump sum rebate offer turning it into a "unit-for-unit" offer. As we have shown above, Pfizer would be the low cost supplier on a "unit-for-unit" basis.

Again, the Chicago School argued that it is presumptive to expect that rational buyers would accept bundling or tying arrangements if they involved excluding the low cost supplier.

We recommend that in the future Pfizer asks insurance companies to create two types of contracts: (1) one contract offering exclusive coverage of patients already using Remicade; and (2) another contract offering exclusive coverage for new infliximab patients. Give this division, Pfizer has a chance to outcompete J&J on price by bidding only on (2).

Conclusion

We believe that Pfizer's case is weak. Pfizer did compete, but only moderately so. Pfizer never expected existing users of Remicade to switch to its biosimilar. Being excluded from that market was not a shock.

Pfizer really thought it had a chance to win over physicians looking to prescribe an infliximab for new patients. But, Pfizer was not smart enough to devise a "winnable" contract specifying rebates in return for coverage only in its "contestable" market.

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I have received no remuneration for these articles. I have no financial relation with any company written about in these articles.

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