This document is not intended to be definitive. If you would like more detailed guidance, please contact a member of Bristows' Competition & EU team.

Different types of value transfer in 'reverse payment' settlement agreements

In recent years, competition authorities and courts in the EU and the US have paid significant attention to patent settlement and similar agreements in the pharmaceutical sector – and particularly those in which the originator company makes a 'reverse payment' to the generic company in return for the generic's promise to stay off the market for a period of time. Agreements of this kind are often referred to (rather pejoratively) as 'pay-for-delay' settlements.

Not all of these cases involve cash payments. In many cases of this kind, careful consideration has been given to whether there is 'transfer of value' from the originator to the generic that induces the generic to cease or defer its efforts to enter the market independently. Recent cases have shown that other forms of consideration are not immune from competition law scrutiny. We summarise below the different forms of value transfer that competition authorities and courts in the EU and the US have considered in a 'pay-for-delay' context.

A. Competition authority investigations and decided cases – EU and UK

Competition authority / Court	Companies	Drug	Forms of value transfer from originator to generic	Was the value transfer made as part of a patent litigation settlement?
European Commission Case 39226 Decision 19 June 2013 Press Release ECJ – General Court *Lundbeck v Commission* T-472/13 Judgment 8 September 2016 Press Release Appealed to CJEU C-591/16	Lundbeck Generics UK Arrow Alpharma Ranbaxy	Citalopram	Purchase of generic company's drugs stocks for purpose of destroying them (values between £3m and $11m). Distribution agreement with net profit guarantee (value £5m) Additional cash payments (values between $1m and $5m). Generic permitted to sell up to 10% of Lundbeck's sales in the previous month having bought stock below factory price (value of stock $1.5m).	Yes – Lundbeck had issued infringement proceedings in multiple jurisdictions. The agreements reached with the generic companies suspended or terminated those litigations.
European Commission Case 39612 Decision 9 July 2014 Press Release	Servier Niche/Unichem Matrix	Perindopril	Lump sum cash payments (values between £5m and £11.8m). An agreement for supply/purchase of perindopril for three years that included a liquidated damages clause for non-	Yes – litigation was settled with each of the generic companies between 2005 and 2007. (Litigation with

Competition authority / Court	Companies	Drug	Forms of value transfer from originator to generic	Was the value transfer made as part of a patent litigation settlement?
ECJ - General Court T-691/14 *Servier v Commission* Appeal heard summer 2017 Judgment pending	Teva Krka Lupin		supply. This was triggered creating a further payment (value £5.5m). Purchase of technology and patent applications relating to perindopril (values between €30m and €40m). This technology was never used but simply used as a defensive strategy. Grant of an exclusive licence in seven Member States after agreeing to a non-compete elsewhere.	other challengers was not settled.)
European Commission Case 39685 Decision 10 December 2013 Press Release	Johnson & Johnson Sandoz	Fentanyl	Johnson & Johnson paid Sandoz for a co-promotion agreement but Sandoz subsequently engaged in very limited or no actual co-promotion activities. The agreed monthly payment under this agreement exceeded the profits that Sandoz expected to obtain from selling its generic product.	No – Sandoz was about to launch the generic competitor when the co-promotion agreement was implemented.
European Commission Case 39686 Statement of Objections, 17 July 2017 Press Release	Cephalon Teva	Modafinil	The Statement of Objections provides only a preliminary view. The press release refers to a 'series of cash payments and various other agreements'.	Yes – infringement proceedings had been issued in the UK and the US
UK Competition and Markets Authority (**CMA**) Case CE/9531-11 Decision 12 February 2016 Press Release	GSK Generics UK Alpharma	Paroxetine	Purchase of drug stocks (value of $12.5m). Grant of a distribution agreement with an annual marketing allowance/payment of launch costs and profit guarantee (value of between £3m and £4.5m). Payment of legal costs (value of £500,000).	Yes – GSK had issued infringement proceedings that were settled before trial.

Competition authority / Court	Companies	Drug	Forms of value transfer from originator to generic	Was the value transfer made as part of a patent litigation settlement?
Competition Appeals Tribunal GSK v CMA Case 1252/1/12/16 Case Page Appeal heard March 2017			First refusal on divested products (value estimated at £500,000)	
CMA Statement of Objections, 3 March 2017 Press Release	Actavis Concordia	Hydrocortisone	Actavis provided Concordia with a fixed supply of 10mg tablets for a "*very low price*", which Concordia could resell to customers. Actavis was the sole supplier of hydrocortisone and the cost to the NHS rose from £49 to £88 per pack.	No

B. Competition authority investigations and decided cases – United States (selection of key cases)

Competition authority / Court	Companies	Drug	Form of value transfer from originator to generic	Was the value transfer made as part of a patent litigation settlement?
US Federal Trade Commission (**FTC**) Case 071 0060 Case Page Supreme Court *FTC v Actavis*, 570 US 756 Judgment 17 June 2013	Solvay Actavis	Testosterone	Solvay made cash payments to Actavis and granted a licence to market and promote AndroGel, Solvay's branded testosterone cream, to doctors. The Supreme Court held that this practice was sharing in monopoly profits. The Court was split 5-3 in this first ruling that reverse payments could amount to antitrust violations.	Yes – Solvay had issued patent infringement proceedings against Actavis
3rd US Circuit Court of Appeals *King Drug v SmithKline Beecham* Case 14-1243	GSK Teva	Lamotrigine	Dispute over a no authorised generic (no-AG clause) agreement – Under US law, a generic company that successfully challenges a patent has a statutory 180-day	Yes – Teva had challenged the validity and enforceability of GSK's patents. The judge had

Competition authority / Court	Companies	Drug	Form of value transfer from originator to generic	Was the value transfer made as part of a patent litigation settlement?
Judgment 26 June 2015 (Appeal to Supreme Court denied)			exclusivity period, in which it only competes against the originator. – No-AG agreements are where the originator agrees not to compete during that 180 day period. The Court held that a no-AG clause can constitute a value transfer from patentee to alleged infringer and be subject to antitrust scrutiny.	ruled the patent's main claim was invalid just before settlement.
1st US Circuit Court of Appeals *Re Nexium (Esomperazole) Antitrust Litigation* Case 12-md02409-WGY Judgment 7 August 2015 News report	AstraZeneca Ranbaxy	Esomeprazole	AstraZeneca had made $700m of lump-sum payments to Ranbaxy. At first instance the jury found that a large and unjustified payment had been made but awarded no damages as plaintiffs had not proved they had been harmed.	Yes – Ranbaxy had challenged the validity of AstraZeneca's patents
FTC Was due to be heard in the District Court for the Eastern District of Pennsylvania Case settled with the FTC in May 2015 Press Release	Cephalon (now owned by Teva) Teva (pre purchase of Cephalon) Ranbaxy Mylan Barr	Provigil	Lump sum payments (value in excess of £200m) FTC launched its suit in 2008 and settled in 2015. As part of the settlement Teva agreed to a prohibition on anti-competitive reverse payment agreements and Teva also made available $1.2 billion to compensate drug purchasers.	Yes – the generic companies had challenged the patent related to the size of particles used in the product
FTC v Boehringer Ingelheim Federal Court, District of Columbia	Boehringer Ingelheim Barr	Acetylsalicylic acid/ dipyridamole Pramipexole	The companies entered a co-promotion agreement with substantial compensation paid as part of that agreement.	Yes – Boehringer had filed infringement proceedings

Competition authority / Court	Companies	Drug	Form of value transfer from originator to generic	Was the value transfer made as part of a patent litigation settlement?
Case Timeline Outcome pending				
United States Court of Appeal for the Third Circuit *In re Lipitor Antitrust Litigation* Final outcome pending	Pfizer Ranbaxy	Atorvastatin	Pfizer granted Ranbaxy licences to sell in seven important markets before patent expiry, in return for a delay to Ranbaxy's launch in the USA. Both companies we emphasise that no payments were made in the settlement.	Yes – Pfizer sued Ranbaxy for patent infringement

C. Guidance from authorities

Competition Authority	Guidance as to what constitutes a value transfer
European Commission Technology Transfer Guidelines	Section 4.3 (Paragraphs 234 to 243) comments on settlement agreements. The Commission recognises that settlement agreements in technology disputes are a legitimate way to find a compromise, but also states that it is in the public interest for invalid intellectual property rights to be removed. If the parties to the settlement agreement are actual or potential competitors and there is a significant value transfer from the licensor to the licensee, the Commission will be particularly attentive to the risk of market allocation and market sharing. Similarly, non-challenge clauses do not necessarily give rise to competition concerns (as they are an integral part of settlement agreements), but they can be problematic if a financial inducement is involved.
European Commission 7th Report on Monitoring of Patent Settlements - 2015 (Previous reports cover similar ground)	Following its Pharmaceutical Sector Enquiry, the Commission has monitored patent settlement agreements and collated its findings in annual reports. The reports identify problematic agreements as those that have a value transfer from the originator to the generic company and a limitation on generic entry. The 2015 Report provides examples of value transfers in paragraph 12: • Direct monetary transfer – often nominally has the purpose of purchasing an asset but can also have the purpose – explicitly or implicitly – of paying for delay or discontinuing a patent challenge. Can be problematic even if the stock is purchased at market price.

Competition Authority	Guidance as to what constitutes a value transfer
	• Distribution/licensing agreements – allowing market entry with the contested product or another product marketed by the originator company. • Non-assert clause – allowing generic to enter the market before patent expiry.
US FTC Report on Authorized Generic Drugs – 2011 Press Release, Report	"*There is strong evidence that agreements not to compete using authorized generics have become a way that some branded firms compensate generic firms for delaying entry to the market*." (page vi of Report) The FTC found between 2004 and 2010 that 25% of patent settlements involved explicit agreements by the originator not to launch an authorised generic, in return for the deferred market entry from the generics company.
US FTC Overview of Agreements Filed in Fiscal Year 2014: A Report by the Bureau of Competition Press Release, Report	The report identified 21 potential pay-for-delay agreements containing the following forms of value transfer: • Cash payments (mostly purportedly covering litigation fees) with values of $35,000 to $5 million. • Side business deal between the companies • Promise from the originator not to market an authorised generic for a defined period
US FTC Blog post – 'Is *FTC v. Actavis* Causing Pharma Companies to Change Their Behavior?' (13 January 2016)	"*Using a no-AG commitment as a reverse payment can harm consumers twice: first, by delaying entry of a generic product which keeps branded prices from falling during the period of delay, and then by reducing the number of generic competitors that ultimately enter, resulting in higher generic prices*." (Emphasis in the original)

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