Competition Section podcast: CJEU Judgment in the GSK paroxetine case: Reverse patent settlements

The Law Society

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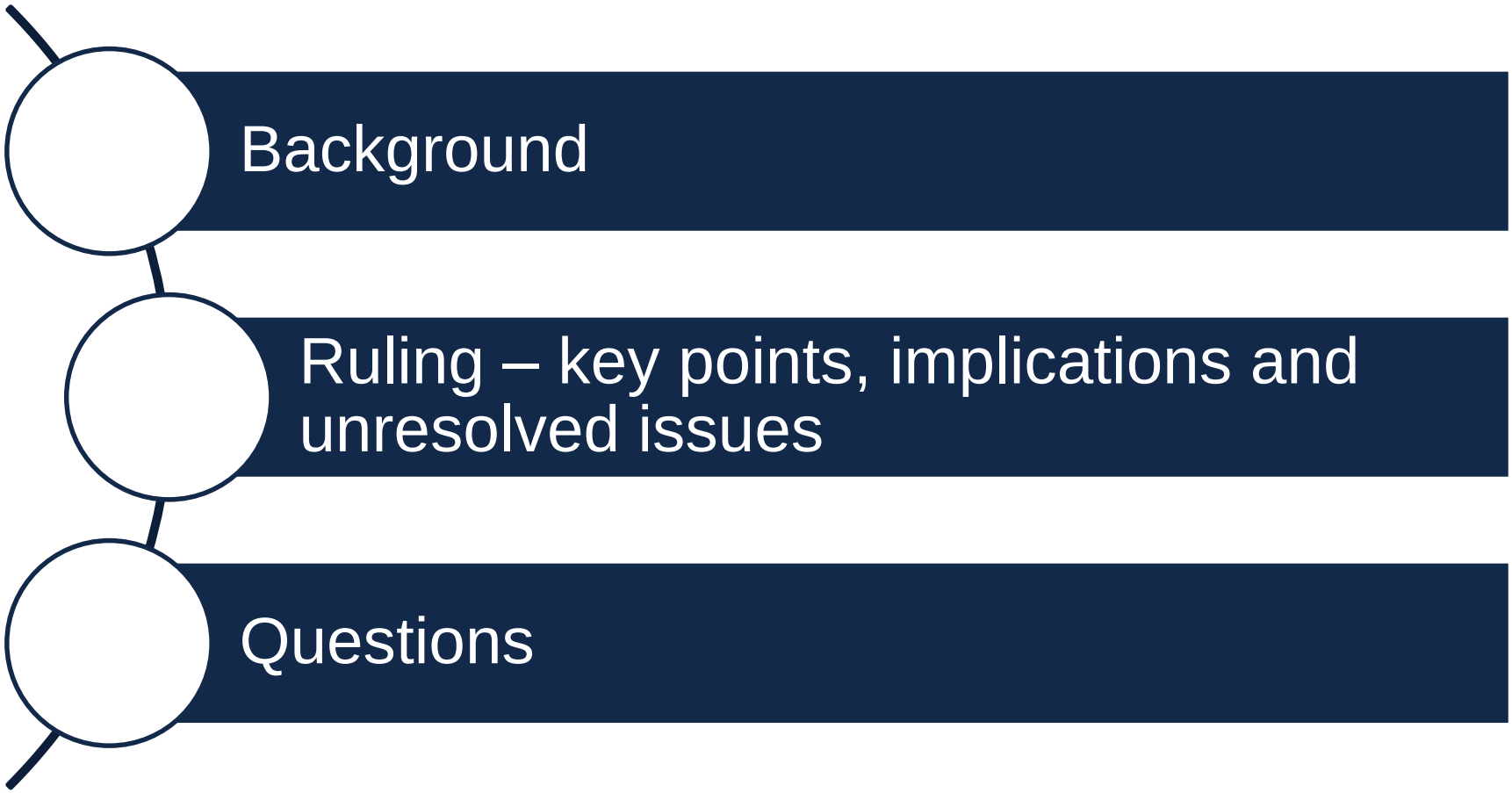
Plan


Background
Ruling – key points, implications and unresolved issues
Questions

(A) Background

The major European patent settlement cases: GSK is the only reference to the Court

Originator	Drug	Authority	Status
Lundbeck	citalopram	EC	• Decision June 2013 • GC judgments September 2016 • AG expected 4 June 2020
Servier	perindopril	EC	• Decision July 2014 • GC judgments Dec 2018 • On appeal to CJEU
GSK	paroxetine	CMA	• Decision Feb 2016 • 5 week trial Feb-March 17 • Initial judgment March 2018, reference to CJEU • CJEU AG and judgment January 2020
Cephalon	modafinil	EC	• SO 2017

Paroxetine: the agreements

- 3 settlement agreements – IVAX, GUK, Alpharma
- In all cases generic threatening to enter
- In GUK and Alpharma (not IVAX):
  - Existing litigation afoot
  - GSK sought and had obtained interim injunctions preventing entry pending trial
- Settlement agreements centrally involved supply agreements in all 3 cases (IVAX as master-exclusive distributor). Majority of alleged "value" transferred was margin on those, so key feature

Procedure

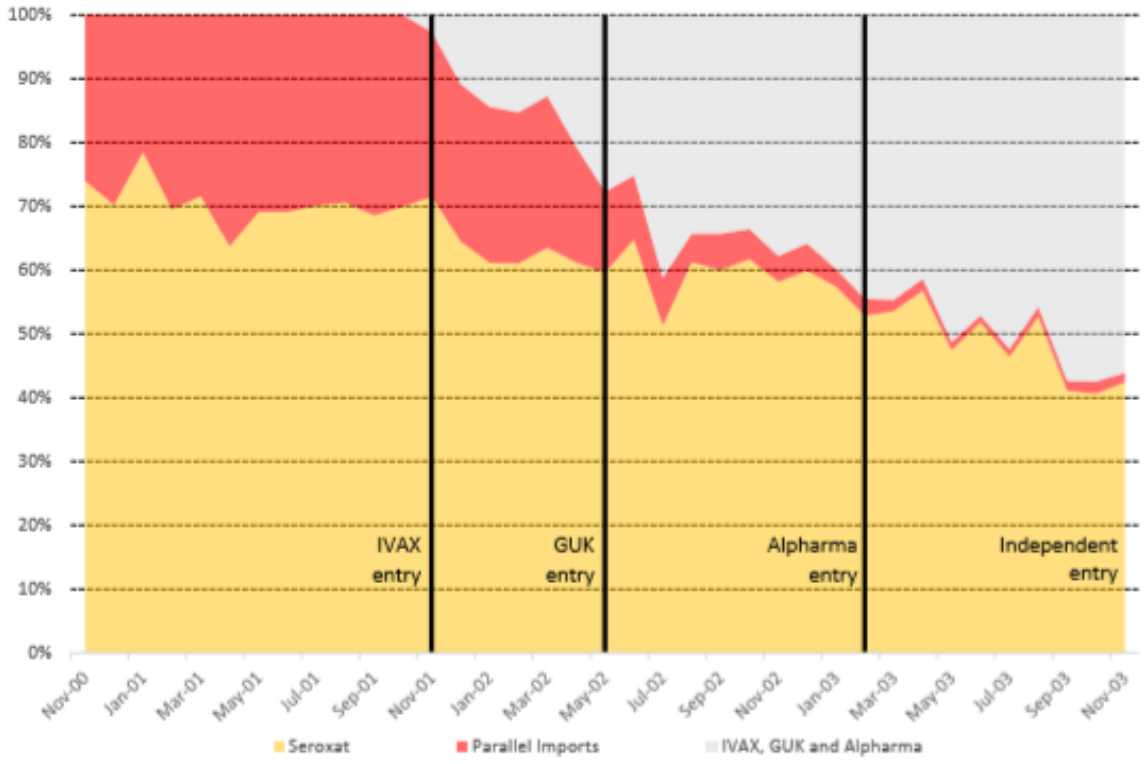
- CMA investigation 2011 to 2016, infringement finding Chapter One (anti-competitive agreements) and Chapter Two (abuse of dominance), February 2016
- CAT interim judgment March 2018
  - Findings of fact
  - Inclinations
  - Reference to CJEU (first time ever) on object, effect, market definition, abuse
- AG 21 January 2020, CJEU 30 January 2020, Exit Day 31 January…
- Now back to CAT

Patent / litigation situation

- Compound patent expired 1999
- Data exclusivity expired 2000
- Extant product/process patents, expiring in 2006 and 2016
- Generics started preparations for entry, threatened to enter
- GSK sued GUK and Alpharma. Both injuncted pending trial
- Reached agreements that avoided (IVAX) and settled (GUK and Alpharma) litigation. Supply agreements central part
- Complex issues re patent validity and infringement arose, and subsequently litigated with other parties

Some points from the CAT (fact and argument) - (1)

Paroxetine 20mg tablets monthly volume market share: November 2000 to November 2003



Some points from the CAT (fact and argument) – (2)

- Volumes under supply agreements v substantial (became 60% of paroxetine prior to independent generic entry)
- On a transfer price at half the level of reimbursement price
- CAT found several benefits due to Agreements:
  - 15% NHS cost saving due to Drug Tariff reimbursement classification change (but 12% of it due to IVAX where no anti-competitive agreements finding due to UK technical exemption)
  - Modest price drop to pharmacies
  - Improvement in “quality” (non-over-stickered pack)
- But CAT found Agreements did not give rise to any meaningful competitive constraint on GSK and benefits were “dwarfed” by benefits of later independent generic entry
- On the facts, impossible to tell who would have won the litigation or whether alternative settlement possible

(B) Ruling: key points, implications and unresolved issues

Ruling – overriding points

- Theme running through ruling and incorporated as part of individual answers to questions: dealing with situation where
  - Compound patent has expired
  - What is left are patents covering process for manufacture of an active ingredient in the public domain
- Background, reasons and implications

Ruling (1): “Potential Competition”

Summary question(s) referred	Answer

• What is needed to qualify a generic company a “potential competitor” where there are extant patents	• *Twofold test:*
	  • *“Firm intention and inherent ability”* to *enter*
	  • Whether *“insurmountable”* barriers to entry
	• First limb focuses on **preparatory steps** e.g. source of bulk product, steps towards obtaining a licence (marketing authorisation), actual marketing etc – were these “*sufficient “to enable it to enter the market within such period of time as would impose competitive pressure on the* [originator]”
	• Second limb
	  • Court focuses on what is not sufficient - manufacturing process patent in itself, presumption of patent validity genuine uncertainty of dispute in itself, interim injunctions
	  • Left to National Court to determine

Ruling (1): “Potential Competition” – unanswered questions / why this matters

- Unanswered questions
  - Series of factors observed about pharma industry – to be taken into account in National Court’s assessment, e.g. existence of “at risk” launch, patent validity challenge actions
  - Additional overall factor - intention (to make VTs in exchange for entry restriction) – size of VT indicating strength of intention
  - What is NC meant to do with these factors?
- Why this matters
  - Meant to be a jurisdictional criterion
  - But Commission / CMA have placed it at centre of their overall case
    - The lower the threshold on object and effect the more invested this criterion becomes

Ruling (2): “Restrictive Object”

Summary question(s) referred	Answer

• Does settlement with (i) entry restriction + (ii) value transfer (**VT**) substantially > avoided litigation costs+time/disruption = object restriction?
 	
• Does it make difference if
  • (iii) within scope of patent or
  • (iv) VT < counterfactual profit for generic company on entry?
	• Yes if
	  1. the “***net gain*** *from the transfers of value by* [the originator] *in favour of* [the generic] *can have no other explanation than the commercial interest of the parties to the agreement not to engage in competition on the merits”;*
	  2. unless settlement is “*accompanied by* ***proven pro-competitive effects*** *giving rise to reasonable doubt that it causes a sufficient degree of harm to competition*”
	• (iii) and (iv) don’t make a difference
	• Payment for goods/services may be explanation as might be discharge of cross-undertaking in damages
	• Fact that genuine dispute (which CAT found and CJEU took as read) not in itself sufficient justification

Ruling (2): Object – implications and unanswered questions

- All settlements by definition will involve entry "restrictions", so this is about **value**
- "Net gains" test is new i.e., **net gain to generic**
  - Can surely only include assessment of gain in the counterfactual – set off to determine "net" gain
  - Finding a net gain is not the end of the analysis – then need to see if justified by legitimate explanation – including valuing **savings to originator** (Court discusses discharge of cross-undertaking in damages here)
- Relevance of proven pro-competitive effects in knocking case out of the object box
  - Manifestation of requirement that restriction shows in itself a sufficient degree of harm - ambivalence requires effects analysis: *Cartes Bancaires*

Ruling (3): “Restrictive Effect”

Summary question(s) referred	Answer
• To show a restriction by effect, does [regulator/court] need to show generic company had **>50% chance of winning the litigation?** (UK Tribunal’s inclination was yes)	• No • Need show i. “realistic possibility”; and ii. how market will probably operate if agreement not concluded (number of factors, including chances of success and chances of less restrictive agreement, but only as “*some factors among many*” – not elaborated upon)

Ruling (3): Effect –unanswered questions

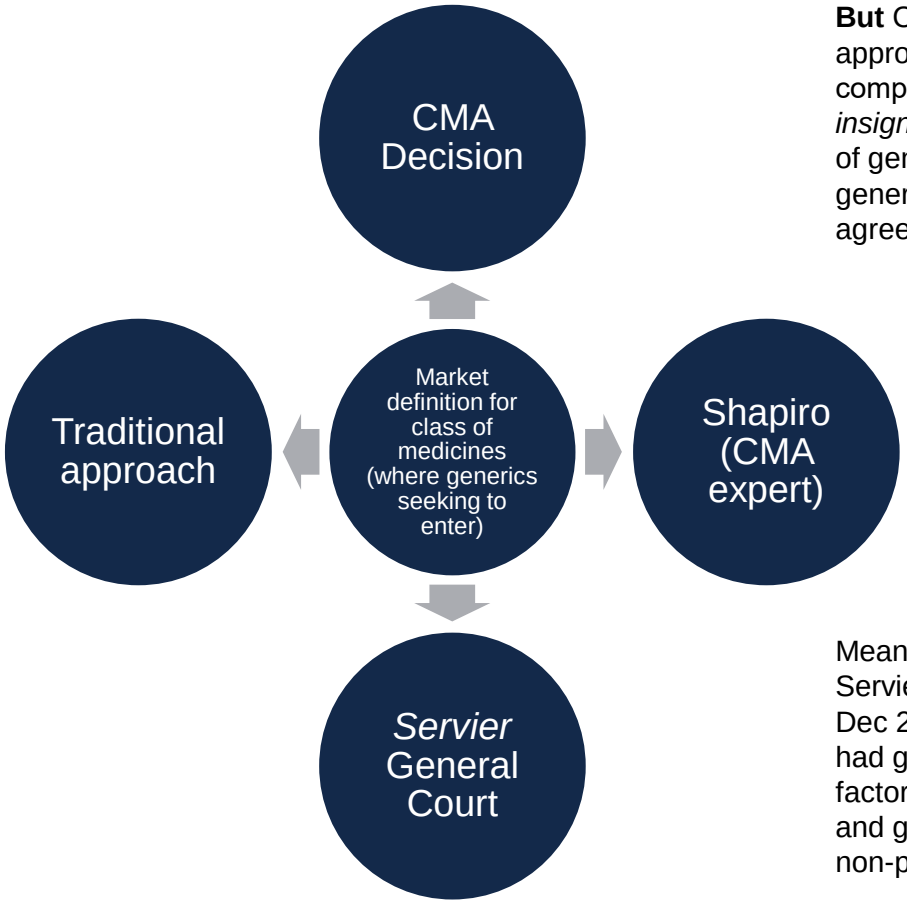
- Nothing answered other than what is not necessary to show (because of way question phrased)
- Key question: what is the distinction between object and effect
  - Court does not endorse AG's view that no distinction
  - Logic of Court's approach to Object dictates that more must be required
  - Suggestion that governing test is "*how the market will probably operate and be structured if the agreement concerned is not concluded*" while at same time suggesting no requirement to show generic would have entered does not get us very far

Ruling (4): “Market Definition”

Summary question(s) referred	Answer
• Where drug is therapeutically substitutable within a class, and alleged abuse is conduct that effectively excludes generic co.s, do you take the generic co.s into account in defining market • Sub-text and back story (next slide)	• Court takes as starting point where only “process patent” remains • Market definition is “dynamic” – can change over time • Must take them into account if generic co.s pass “potential competition” thresholds • Can in principle narrow to molecule

Market definition – back story in CAT and argument

– *"We see considerable force in GSK's criticism of the Decision. Even on its own terms, the…Decision does not establish real therapeutic distinction between paroxetine and the other SSRIs. [ ] This is the position...now conclusively demonstrated by [GSK's psychiatric expert]…much effort seems to be devoted in the Decision to showing the obvious: that there was little effective price constraint from other SSRIs compared to the effect once independent generic paroxetine entered the market….If that simple approach was sufficient… then almost every valuable medicine subject to patent protection…would constitute a distinct market…we agree with [GSK] that this would constitute a material change to the IP bargain"* – CAT, Interim judgment, 2018



But CAT preferred Shapiro approach on basis that SSRI competition "*pales into insignificance*" compared to effect of generic paroxetine, and effect of generic entry is what motivated the agreements

Meanwhile General Court in Servier overturned Commission in Dec 2018 on basis Commission had given too had allowed price factors to overwhelm the analysis and given insufficient attention to non-price factors

Market definition - implications

- Judgment confused in this section but direction is apparent
- Perils of ends-driven approach: implications beyond patent settlements
- Taken literally, would emasculate market definition as an analytical step in end-of-patent life conduct cases
- US economist
- “Potential competition” again …
- *Servier* CJEU – what will happen?

Ruling (5): “Abuse”

- Further technical questions referred on “abuse”
- High level takeaway is an overall strategy (“*contract-oriented strategy*” – CJEU) can be abusive if anti-competitive effect over and above that of each agreement

(C) Questions from the committee

Questions from the committee

1. When reviewing this by object, what is the test? Is there a clear concept of “value transfer”? Are there ever circumstances where some form of payment from originator to generic is justified? Will authorised generic supply agreements always be prohibited?

2. Are there any kinds of settlement that do not infringe the rules?

3. In what circumstances, if any, is a no challenge clause acceptable in a patent settlement agreement?

4. What practical steps do you think that parties need to build an evidence base to enable and support an assessment that a settlement agreement with a reverse payment is competition law compliant?

Final remarks

- Application in CAT awaited
- Lundbeck AG on 4 June, judgments to follow
- GSK *paroxetine* CJEU is our *Actavis* but it will not be the last word…

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  - Davina Garrod – head of EU/UK Competition, Akin Gump Strauss Hauer and Feld LLP

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