Patent Litigation + Competition Law
Two Different Worlds?

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Overview

- Matthew Hall – the ***Competition Law*** world
- Matthew Royle – the ***Patent Litigation*** world
- George Moore – the ***Real*** world....?

Overview

- Matthew Hall – the ***Competition Law*** world
  - Update on the leading competition law cases on settlements;
  - *Lundbeck* (citalopram); *Servier* (perindopril); *GSK* (paroxetine);
  - Newer cases
- Matthew Royle – the ***Patent Litigation*** world
  - The back story to the patent litigation settlements;
  - *Lundbeck v Lagap* (citalopram)
  - *Apotex v Servier* (perindopril)
  - Various v *GSK* (paroxetine)
- George Moore – the ***Real*** world....?
  - Reflections and Talking Points
  - How does patent litigation get settled now?

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The Story Continues: Patent Settlements and EU Competition Law

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How We Got Here

- Sector Inquiry Report (Preliminary Findings Nov. 2008; Final Report July 2009)
- Basic principles (and statistics) from the annual Patent Settlement Monitoring Reports
  - delineation according to type of agreement and nature of value transfer
  - case by case analysis required (no presumption of violation of the competition rules, even for “category B.II” settlements)
- Enforcement action via decisions
  - Lundbeck (citalopram) (June 2013) (EC), upheld Sep. 2016 by the EU General Court
  - Servier (perindopril) (July 2014) (EC)
  - GSK (paroxetine) (Feb. 2016) (UK CMA)
  - and now Actavis UK (hydrocortisone) (March 2017) (UK CMA) (preliminary)

How We Got Here: Monitoring

- *"The main objectives of the monitoring exercises are to better understand the use of this type of agreement in the [EU/EEA] and to identify those settlements that delay generic market entry to the detriment of the European consumer."*
- 7 reports covering the period mid-2008 to Dec. 2015
- Dec. 2016 report (covering 2015):

  - *"confirmed the continued use of patent settlements in the European pharmaceutical sector"*

  - shows that *"the Commission's announcement that it would continue scrutinizing B.II category settlements in the future has not hindered companies from concluding settlements in general"*

  - *"The number of B.II settlements…[has] stabilized at a low level"*

How We Got Here: Monitoring Statistics

"might attract competition law scrutiny"

Period	Total Number of Settlements	Type of Settlements		
		Category A (no limitation)	Category B.I (limitation/no value transfer)	Category B.II (limitation/value transfer)
Jan. 2000-June 2008 (Pharma Sector Inquiry)	207	108 (52%)	54 (26%)	45 (22%)
July 2008 – Dec. 2009	93	53 (57%)	31 (33%)	9 (10%)
Jan. 2010 – Dec. 2010	89	54 (61%)	32 (36%)	3 (3%)
Jan. 2011 – Dec. 2011	120	84 (70%)	23 (19%)	13 (11%)
Jan. 2012 – Dec. 2012	183	78 (43%)	93 (51%)	12 (7%)
Jan. 2013 – Dec. 2013	146	66 (45%)	69 (47%)	11 (8%)
Jan. 2014 – Dec. 2014	76	37 (49%)	30 (39%)	9 (12%)
Jan. 2015 – Dec. 2015	125	32 (26%)	80 (64%)	13 (10%)

What *Should Be* The Position?

- A naked agreement between two competitors whereby one agrees to delay launch is an "object" or automatic infringement of competition law (no need to show anti-competitive "effects" and no realistic possibility of exemption)
- In current context, "object" category only really appropriate where clear beyond doubt that:
    - generic would have been able to enter without infringing; or
    - patent(s) is/are invalid
- In other words, no actual or potential dispute to settle

But what do we have in practice?

The First One Has Now Been Upheld: Lundbeck (EC June 2013)

Press and Information

General Court of the European Union

PRESS RELEASE No 90/16

Luxembourg, 8 September 2016

Judgments in Case T-460/13 Sun Pharmaceutical Industries and Ranbaxy v Commission, T- 467/13 Arrow Group and Arrow Generics v Commission, T-469/13 Generics (UK) v Commission, T-470/13 Merck v Commission, T-471/13 Xellia Pharmaceuticals and Alpharma v Commission and T-472/13 Lundbeck v Commission

The General Court of the European Union confirms the fines of almost €150 million imposed on several undertakings in the context of an infringement intended to delay the marketing of generic versions of the antidepressant citalopram

Lundbeck is a Danish company specialising in researching and marketing new medicinal products, including for the treatment depression. From the late 1970s, Lundbeck developed and patented an antidepressant medicinal product containing the active ingredient 'citalopram'.

After its basic patent for the citalopram molecule had expired, Lundbeck only held a number of patents which provided more limited protection. In particular, Lundbeck had filed a patent relating to a process for the production of citalopram (the salt crystallisation patent). Producers of cheaper, generic versions of citalopram could therefore envisage entering the market.

The First One Has Now Been Upheld: Lundbeck (EC June 2013)

- Fining decision concerning citalopram
- All appeals upheld Sep. 2016 by the EU General Court
- A real slam dunk for the European Commission
- Three key issues for an "object" infringement
    - (actual or) potential competitors following expiry of molecule patent; and
    - limitations on market entry; and
    - value transfer ("inducement")
- Also specific elements
    - level of value transfer
    - out of scope
    - litigation not sorted out

Key Quotes From The First One: Lundbeck appeal judgment (General Court Sep. 2016)

Certainty + inducement: *"(336)…the agreements at issue transformed the uncertainty in relation to the outcome of such litigation into the certainty that the generics would not enter the market, which may…constitute a restriction on competition by object when such limits do not result from an assessment, by the parties, of the merits of the exclusive right at issue, but rather from the size of the reverse payment which, in such a case, overshadows that assessment and induces the generic undertaking not to pursue its independent efforts to enter the market…"*

But do need to analyse all elements: *"(354)…the Commission did not find…that all patent settlement agreements containing reverse payments were [infringements of competition law]; it found only that the disproportionate nature of such payments, combined with several other factors — …correspond at least to the profit anticipated by the generic undertakings …absence of provisions allowing the generic undertakings to launch their product on the market upon the expiry of the agreement without having to fear infringement actions …restrictions going beyond the scope of Lundbeck's patents…"*

Buzzwords/phrases are underlined

A Development of Lundbeck: Servier (EC July 2014)

- Fining decision concerning perindopril
- EC also includes "effects" analysis and abuse of dominance
- "Object" infringement *Lundbeck*-esque
- Abuse of dominance by Servier (not *"competition on the merits"* but a *"single and continuous exclusionary strategy"*)
  - dominant in the supply of perindopril and API tech.
  - acquisition of technology
  - implementation of settlements
  - creation of a patent cluster
  - patent disputes/warning letters
  - buying out competitors
- Currently on appeal

"Object" infringement buzzwords are there:

- A strategy
- Secondary patents only
- Generics intensively preparing entry
- Several €10 millions
- Servier gained certainty

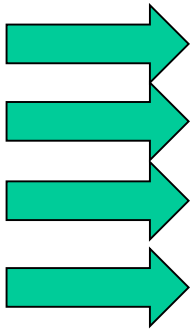
The UK Follows and Gets in on The Act: GSK (UK CMA Feb. 2016)

- Fining decision concerning paroxetine
- "Object" infringement again *Lundbeck*-esque
  - primary patent expired and steps to enter
  - cash payments/distribution agreements ("induce")
  - contractual promise not to enter
  - other characteristics
- "Effects" infringement as well
- Abuse of dominance
  - dominant in the supply of paroxetine in the UK
  - no legitimate commercial basis ("*induce*")
- Currently on appeal

Other characteristics:
- No resolution of disagreement
- Significant value transfers

The UK Goes Again: Actavis UK (UK CMA March 2017)

- "Statement of Objections" concerning hydrocortisone tablets
- Alleged anti-competitive agreement and abuse of dominance
- Presumably at least an underlying potential patent dispute
- All the *Lundbeck* buzzwords are in the press release:



"incentivised"/"inducing"

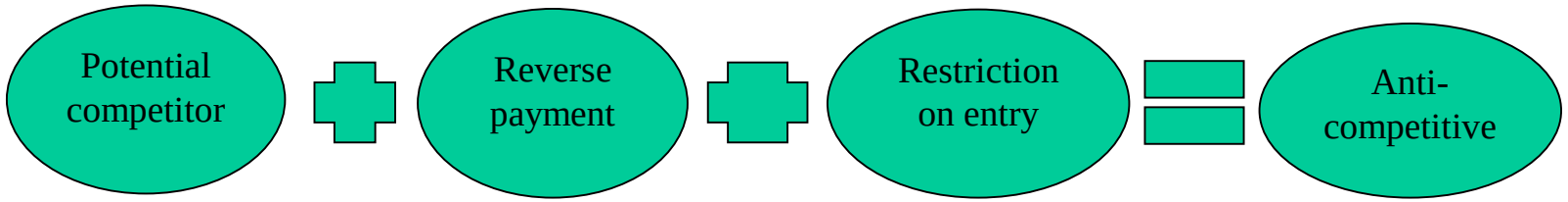
"delay its independent entry"

"fixed supply" under a distribution agreement

"potential competitor"

Concordia/Actavis UK (UK CMA March 2017)

All the main elements of regulatory concern are there:



Need "*real concrete possibilities*" of entry, but this can arise even when a (presumptively) valid patent if there is a possibility of entry (whether at risk or not)

But value transfer *"can take different forms"*

"Can be limited in several ways"

But the aggravating factors are important too

Lundbeck - citalopram

- More than 30 process patents filed as market formation date approached
- This included the so-called "crystallisation patent"
  - difficult to work around because of breadth of claim
- Litigation against Lagap Pharmaceuticals – ultimately settled
- Settlements with four companies under investigation

GSK – paroxetine

- Introduced concept of clearing the way
  - Initially in 2001 against Generics UK
  - Confirmed by the Court of Appeal in 2003
- Litigation was in relation to the anhydrate patent
- Settlements with three companies under investigation
- Apotex continued with litigation and was found not to infringe by the Court of Appeal

GSK – paroxetine (2)

- Apotex was successful – rewarded with damages under the cross-undertaking?
- Two Canadian Apotex companies not included on the cross-undertaking
- Further litigation about adding them to the cross-undertaking
- Court of Appeal decision not to allow them to be joined
  - not fully compensated

Servier – perindopril

- Servier had a large number of patents – many with "zero inventive step"
- Again, only a small number were relevant to generic launches
  - alpha crystalline form
  - alternative manufacturing processes
- Apotex launched its product – sold for a week and was then injuncted
- Settlements with five companies under investigation

Servier – perindopril (2)

- Apotex proceeded to trial
  - conducted experiments to reproduce prior art production process
- Patent was revoked – it was described as *"the type of patent that gives the patent system a bad name"*
- Apotex awarded £17.5m in damages on the cross-undertaking, **but…**
- …this has since been repaid as a result of the "but for" manufacture infringing a CA patent

Why settle?

- Risk of damages if launching "at risk"
- Preliminary injunctions preventing launch likely
- Barriers to market entry significant:
  - Cost
  - Uncertainty
- Claim on the cross-undertaking?

Reflections and Talking Points - I

- It was all so long ago...
  - Relevant litigation was 10-15 years ago
  - Before the EU Commission Pharma report (2008)
- Patents on polymorphs and purification methods
  - Are similar patents granted by EPO these days? Enforced?
  - Arguably, EPO has tightened up on polymorphs?
- Before EU Enforcement Directive (2005)
  - Preliminary injunctions easier to be granted now?
  - ....damages mechanism for Gx now more well established?
- Examples
  - 2008 – *Apotex v Servier* – perindopril – UK – 17.5m GBP;
  - 2014 – *Krka v AZ* – esomeprazole – UK – 27m GBP;
  - 2016 – *Hexal v Sanofi* – irbesartan + HCTZ – DE – €5.1m;
  - 2017 – *Teva v AZ* – quetiapine XR – DK – 100m DKK (€13,4m),

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Reflections and Talking Points - II

- No More Reverse Payment Settlements?
  - Number of “BII” settlements is small (and growing smaller)?
  - No more annual patent litigation settlement surveys?
  - Impact of Lundbeck / Servier / GSK decisions?
- More Patent Litigation?
  - Probably, Gx market even more competitive (as between Gx)
  - More patent challenges, more launches at risk, more injunctions
  - ...more damages cases
- Less Settlements?
  - Probably not – cases can settle for wide variety of reasons
  - Reasons for settlement not reflected in EU survey
- The Future?
  - More 3rd party damages cases?
  - Impact of UPC?

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