Patent dispute settlement agreements – an economist's perspective

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Questions for today

- Are these like cartel agreements?
- Effects-damages:
 - Absent the agreement, when would generic entry have occurred?
 - Absent the agreement, what would prices/volumes have been?

Patent dispute settlement agreements, involving payments from originators to generics – are these like cartel agreements?

Agreements between actual or potential competitors	 Should be no surprise that competition authorities pay attention – clear scope for restriction of competition if (actual/potential) competitors enter into agreements 'Competitors cannot agree to share markets or market rents instead of competing, even when these agreements are in the form of patent settlements.' (Servier EC press release 9 July 2014)
Settlement of litigation	 But, avoiding or settling litigation out of Court is generally desirable (saves time and costs) – cartels have no such potentially redeeming feature 'Patent dispute settlement agreements are, in principle, a generally accepted, legitimate way of ending private disagreements. They can also save courts or competent administrative bodies, such as patent offices, time and effort and can therefore be in the public interest.' (Lundbeck EC Decision Summary ¶5). But don't like reverse payments
On balance?	 Effects/Damages: Each case will turn on its facts, such as the nature of the patent(s) involved, the agreement as a whole (payment terms, duration, other terms), and what would otherwise have happened?

Absent the agreement or anti-competitive conduct, when would generic entry have occurred?

- Two word summary of economics? (It depends)
- Does the agreement prevent entry beyond the time period of the relevant patent, or permit early entry? Not the end of the matter.
- Strength of the patent(s) at issue may be difficult to judge
 - Servier EC Provisional Decision references 'blocking patents' or 'zero inventive activity' (¶¶ 115-123) and the controversial '947 patent which "most constrained" the development of generics (¶126) and which was annulled by the Court of Appeal in 2008 (¶125):
 - The '947 patent is one of Servier's most controversial patents. In its annulment decision the Court of Appeal ruled the '947 patent "is invalid. And very plainly so. It is the sort of patent which can give the patent system a bad name".
- Beliefs and actions How close are generics to (non-infringing) entry? Are they bluffing? What would a generic do, if anything, if expecting a payment? What happened after patent expiry?

Absent the agreement, what would customers have paid after generic entry?

- Consumers are generally health authorities/tax payers (plus consumers/patients in co-payment situations)
- Counterfactuals: what happened after generic entry/generic entry of similar drugs?
- How quickly would (branded and generic) prices have fallen? Depends on:
 - Timing and number of generic entrants
 - Pricing/reimbursement arrangements in the country in question
- How quickly would volumes have switched from branded to generic drugs?
 Depends on:
 - Incentives and ability of prescribers and/or pharmacists to substitute cheaper drugs
 - Degree of generic or open prescribing (in the UK)
- What would have happened to overall <u>volumes</u> of the drug/molecule in question?
 - Depends on degree of substitution from similar drugs (harm can extend beyond drugs in question), changes in prescribing guidelines and behaviour

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