The economics of Pay for Delay cases

Brussels, May 2013

Dr. Matthew Bennett
Vice President, CRA

CRA Charles River Associates

Features of the pharma sector

Main players

- Pharmaceutical companies that are active in research for new compounds (**originators**) usually produce limited number of drugs, most with patent protection (patent owned or under license). They **invest heavily in R&D and promotion**.
- **Generic** producers specialise in production of drugs which are non-patent protected. Produce a broad range of drugs**. Little or no R&D and promotion.**

Sector Dynamics

- Originator introduces a new product into the market is granted an exclusivity period from patent in which it is only authorized producer of drug.
- After marketing authorization is granted, drug enters market at price set in accordance with maximum reimbursable price decided by national authorities.
- **Duration of exclusivity** period linked to period of validity of patent (**20 years from moment in which patent is granted**). On average, at moment in which drug reaches market there are around **8 years of exclusivity** are left.
- At the end of exclusivity period:
  - replicas of the drug can be introduced into the market
  - reimbursable price adjusted downwards to meet the new market conditions
  - Price competition introduced. **Empirical evidence** shows the **average price of a drug can drop up to 80% in first two years** after first generic enters the market

Features of the pharma sector (cont)

Originator producers' incentive:

- to **defer the loss of exclusivity** (LoE) of their successful drugs
- to **deter the introduction of generic** replicas of their drugs
- possibly, to introduce new version of their drugs – eg second generation products – before generics enter the market

Generic producers incentive:

- To **introduce replicas of high-selling drugs as swiftly as possible**. If they are successful, they can gain:
  - A six months period in which they are only authorized generic producers (US only – under Hatch-Waxman Act 1984 (more on this later))
  - **First mover advantage** (everywhere)
- In order to anticipate rivals, generic producers can:
  - **Challenge patents** protecting the drug of interest
  - **Enter before loss of exclusivity** (and therefore risk to be challenged

The **counteracting incentives** of originator and generic producers close to LoE can lead to patent litigation

Why may pay to delay be problematic?

Concern is that originator *always* has an incentive to pay to settle

- Assume V_u and V_a are the expected pay-off is case patent is upheld or annulled, respectively, for originator and generic. The one who loses the litigation pays the litigation costs. Assume probability of patent being upheld is 0.7.
- Originator: $V_u = 1000$; $V_a = 400$; litigation costs = 100
- Generic: $V_u = 0$; $V_a = 400$; litigation costs = 100
- $V_{u\text{-}gen} = 0.3 * 400 + 0.7*(0-100) = 50$
- $V_{u\text{-}orig} = 0.7 * 1000 + 0.3 * (400-100) = 790$
- Thus **originator has strong incentive to pay generic not to contest**, even though it is highly likely to win (1000-790>50).
- However **consumer *is always worse off*** because it loses out on the expected benefit of greater competition through generic entry.

Key is that **generic does not internalise the consumer benefit** that contesting the patent brings to society, and originator has incentive to pay generic to leave it a monopoly position (same incentive to allocate markets).

1. Framework for analysis

CRA Charles River Associates

Patents are probabilistic

Patents are **not a full-proof property** right.

- There is some **uncertainty** as to both its validity and its scope. Cannot simply assume that a patent's worth is its full certainty value

Patent holder obligation?

- Patent holders should act to **ensure that settlement** does not result in **lower consumer welfare** than if it was invalidated with some probability? Why only for settlements?

Incentives to challenge patents

- Higher cost of settling makes it less likely that generic firms will challenge patents in the first place.

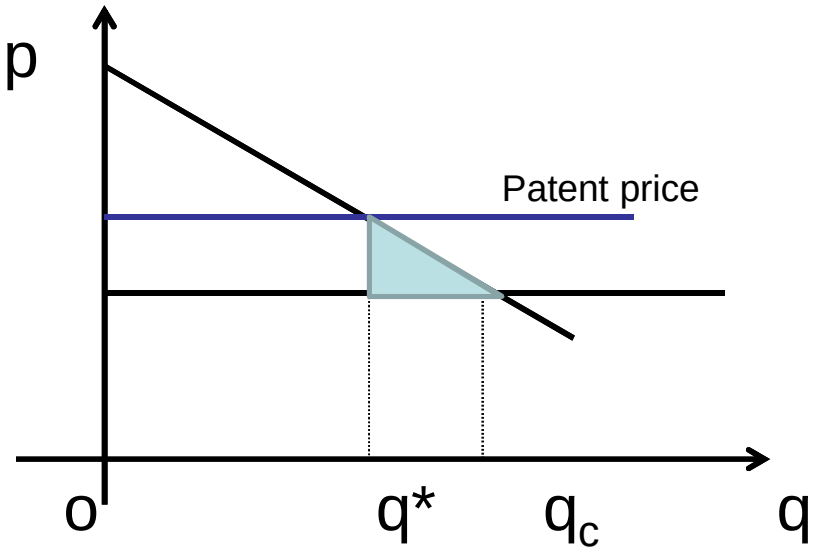
Optimal patent system may involve some payments for settlement

IP system trades off **scope of patent with length of patent.**

- Return on patent increases with scope and length of patent. **Uncertainty is equivalent to scope** (average probability of being able to enforce).
- Ayres and Klemperer (1999) may be **optimal to make patents *less certain***, if one can increase protection along another dimension (length, geographic coverage) to preserve innovation incentives.

Pay for delay is equivalent to increasing the **length** of the patent – allows one to reduce the scope of the settlement, and will reduce deadweight loss.

Note: not necessarily always legal, but that there is a rationale for society to allow some scope for settlement.



- Increasing scope of patent allows a higher price mark-up and increases proportion of deadweight loss to price.
- Increasing patent length minimises proportion of deadweight loss. **(Gilbert and Shapiro 1990**)

But in some instances it can be efficient (i) High probability of patent winning

Note that litigation to end is not always desirable for society

- As probability of generic winning litigation becomes small, and **litigation costs become large**, expected **consumer welfare gain may be outweighed by loss to society in litigation costs**. Assume probability of patent uphold is 0.9.
- Originator: $V_u = 1000$; $V_a = 400$; litigation costs = 100
- Generic: $V_u = 0$; $V_a = 400$; litigation costs = 100
- $V_{u\text{-}gen} = 0.1 * 400 + 0.9*(0-100) = -50$
- $V_{u\text{-}orig} = 0.9 * 1000 + 0.1 * (400-100) = 930$
- Generic no longer has incentive to litigate to conclusion.
- Note that **consumer's still better off if litigation goes on – but society as a whole may be worse off** if expected consumer benefit is less than litigation costs incurred.

Question: why would generic ever start litigation in the first place?

- If new information becomes present resulting in generic **updating belief** of generic in winning, generic may have an incentive to settle.
- Forcing generics to always continue litigation once started may reduce their incentives to start in first place.

In some instances it can be efficient (ii) Asymmetric costs or benefits

Second**, litigation costs may be asymmetric** between generic and originator due to knock-on damage to businesses costs.

- If originator litigation costs are much higher then generic, generic may have an incentive to litigate which is inefficient for society.
- Originator: $V_u = 1000$; $V_a = 400$; litigation costs = 150
- Generic: $V_u = 0$; $V_a = 400$; litigation costs = 40
- $V_{u\text{-}gen} = 0.1 * 400 + 0.9*(0-40) = 4$
- $V_{u\text{-}orig} = 0.9 * 1000 + 0.1 * (400-150) = 925$
- Thus generic still has (marginal) incentive to litigate to conclusion.
- Consumer's better off if litigation goes on.
- But **society as a whole may be worse off** if expected consumer benefit is less than litigation costs incurred. (Suppose expected consumer welfare was is 50, and expected litigation cost is -51)

Note assumes that litigation costs are higher because of damage to originators' business rather than actual litigation costs per-se.

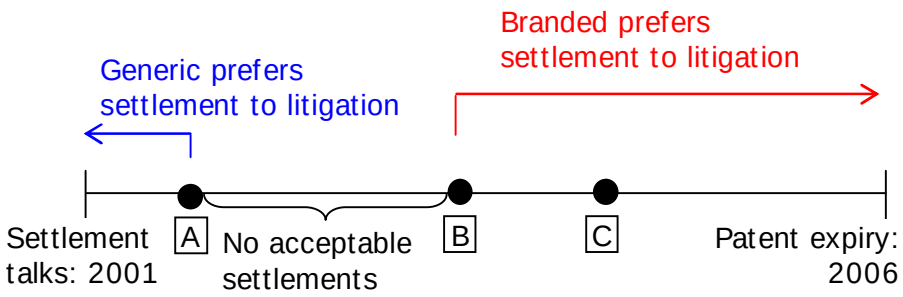
- **Brand value versus generic value.**

In some instances it can be efficient (iii) Inability for generic to wait until litigation

Generic may have high discount rate and **only willing to accept early entry dates**, although believes its chances of winning litigation imply later entry.

- Settlement between 'B' and 'C' could be efficient and benefit consumers if it **allows for earlier entry** than if litigation continued.
- Relies on Originator being **less confident of patent strength** than Generic, and Generic being cash-strapped so requiring a payment to postpone entry beyond 'A'.

Identity problem for authority, how do you know this setting exists?



A – latest acceptable entry date for cash-strapped generic.

B – entry date based on Originator's beliefs about patent strength.

C – entry date based on Generic's beliefs about patent strength.

Originators incentives?

Will **originator ever have an incentive** to engage in a sham settlement?

- Suppose the patent is weak, and a generic challenges it.
- Originator can offer a 'sham' settlement of ½ monopoly profit to generic that ensures both are better off.
- Generic goes away – but **next generic** comes along.
- Originator can't offer ½ monopoly profit because it doesn't have it anymore! ¼ monopoly profit may **not be sufficient to prevent entry**.

If there are weak barriers to entry then a sham settlement is never optimal.

- Hatch-Waxman Act 1984 actually relaxes this problem for originator
- Provides six months period in which only authorized generic can enter – therefore creates barrier to entry for subsequent generics.

So the issue is an identity problem

Some **potential efficiencies** from settling, however originator may have incentive to settle independent of level of efficiency and **consumers suffer the harm** (depending on barriers to entry).

Very difficult for Competition Authorities to **distinguish anti-competitive settlements** from potentially pro-competitive ones.

In practice:

- Assessing **patent strength** is very difficult for Competition Authorities (for example it has generally not been accepted by US courts.
- Very difficult to assess **side payments** and **potential efficiencies**.

How can economics help?

Probability as an identifier:

- **High probability** of being upheld, settlements are more likely to be **pro-competitive** in order to save litigation costs.
- **Low probability** of being upheld, implies more likely to be problematic as a potentially **'sham' settlement** not to challenge.

SO…

- If we know the transfer fee, and the expected profit levels of both the generic and originator and litigation costs, we can **back out the probability** under the assumption that both firms have a common understanding of the probability of patent being upheld.
- A low probability of not being upheld is associated with a high transfer fee, holding all else constant.

Are we starting to solve the problem?

Summary of the Commission's reports on monitoring of pharmaceutical patent settlements

Period	Total settlements	Settlements, by type		
		No limit on generic entry (A type)	Generic entry restricted, but no value transfer from originator to generic (B.I type)	Generic entry restricted, value transfer from originator to generic (B.II type)
Jan 2000 to Jun 2008 (Inquiry)	**207**	**104** (50%)	**54** (26%)	**46** (22%)
Jul 2008 to Dec 2009	**93**	**53** (57%)	**31*** (33%)	**9** (10%)
Jan 2010 to Dec 2010	**89**	**54** (61%)	**32*** (36%)	**3** (3%)
Jan 2011 to Dec 2011	**120**	**84** (70%)	**23*** (19%)	**13** (11%)

* "*In these agreements the generic company agreed to enter only after the patent(s) at issue had expired*" – paragraph 31 in the 1st report; paragraph 30 in the 2nd report; and paragraph 39 in the 3rd report.

2. Policy suggestions?

CRA Charles River Associates

Possible policy suggestion – **the stick**

A possible solution would be to include pay-to-delay agreements among **hardcore restrictions** according to the following equation:

- No generic entry + value transfer = object infringement under Art. 101(1) – query whether could satisfy exemption criteria – seems doubtful

However it could **still be difficult to establish** that:

- the generic is a **real potential entrant**.
- there is a **value transfer**, as settlements could be very complex deals (including exclusive licensing, distribution and production agreements, patent transfer, etc.) and it could be difficult the determine the direction of the payment and its amount.
- A given amount of **payment could be justifiable**.

Patent settlement which does not include payment in favour of challenger should not be assumed as object.

Possible policy suggestion – **the carrot**

Exemption from 101(1) for patent settlements **without reverse payments**?

- Could provide guidance for pharmaceutical companies concerning agreements generally seen as legal by competition authorities.

In practice:

- Exemption could be granted to agreement which **include non-assertion** and non-compete clauses **only if no reverse payment**
- Could also include value transfers – but may be difficult to differentiate between anti-competitive value transfer and pro-competitive (for example license for entry).

Too early to give exemption?

- The issue is novel to EU and US although several cases have been brought to court, waiting judgement for pay-to-delay case issued in the EU.
- One case in pipeline at OFT and two at DG Comp too early to provide comprehensive guidance (TTBERs)?

London
Tel +44 (0)20 7664 3700
Fax +44 (0)20 7664 3998
99 Bishopsgate
London EC2M 3XD
United Kingdom

Brussels
Tel +32 (0)2 627 1400
81 Avenue Louise
Brussels B-1050
Belgium

Paris
Tel +33 (0)1 70 38 52 78
27 Avenue de l'Opéra
75001 Paris
France

www.crai.com/ecp

CRA Charles River Associates