



Patent practices in the pharmaceutical sector – the aftermath of the Commission’s Preliminary Report

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“We are finding facts, not commenting on them”

- “The effects [on generic entry] are clearly shocking”
 - Dr H Ungerer (Deputy DG, DG Comp)
- “[W]hen we put it on paper, what is wrong, what is absolutely to be changed, then the players in the game so to say are already changing their behaviour so I sincerely hope that our clear language is reason for the industry and certain companies to change their attitude already.”
 - Commissioner Kroes

The core accusation

- A series of measures (the “toolbox”) delay or block generic entry.
- “Several of the most damaging are”
 - Patent “clusters”
 - “A large number of litigation cases over patents”
 - Settlement agreements
 - Interventions before regulatory authorities
 - Introducing improved products towards end of patent life
- Period of delay between loss of exclusivity and generic entry
 - Wide variation between MS
 - Average 12 months (whole sample of 219 INNs)
 - 7 months weighted
 - 4 months for blockbusters
- “Savings could have been €3 billion [in 17 countries]...if generic entry had taken place without delay”
- “The findings suggest that the practices under investigation contribute to this”

How the media saw it

- Drug maker delay on generics cost €3 billion EU says
 - Bloomberg
- EU antitrust chief criticizes major pharmaceutical firms
 - Wall St Journal Europe
- Drug companies trigger European ire for holding back supplies of cheap medicine
 - The Times
- EU “has declared war on pharma” expert warns
 - Pharma Times

Litigation - three apparent concerns

- “A high number of cases”
- Delays in generic entry caused by litigation
- Outcome of litigation (including oppositions) is evidence of too many “weak” patents

Number of litigation cases

- > 26,600 patents for 219 top-selling INNs
- No litigation in relation to 151 INNs or > 26,000 patents
- 700 litigations concerning 478 patents started in relation to 68 INNS – nearly 50% related to 6 INNs
- 320 cases started by generics
- 149 final decisions
- Concern about parallel cases, sometimes in different countries
 - inevitable
 - multiple generics might launch in same country
 - generics might launch products in different countries
 - multiple generics might launch revocation/declaration cases in different countries
- Assume an average of 20 Member States in the period surveyed
 - = 0.5 cases initiated per litigated INN per MS
 - = 0.11 cases fought to trial per litigated INN per MS
- Is this “a “large number of litigation cases over patents”?”

The evidence for delays created by litigation

- Litigation can only cause delay to entry if
 - Post trial injunction
 - Pre trial injunction (“PI”)
- If PI is followed by patentee success at trial, no cause for concern.
- What if PI is followed by patentee failure at trial?
 - Report talks of “very serious effects” that PI can have on generic
 - Report does not mention effect of absence of PI on innovator market)
 - Report notes 255 requests for PIs of which 112 granted
 - Report does not say in how many cases PI granted and patentee lost at trial
- So there is no evidence of any delay caused by litigation

Outcomes of litigations and oppositions

- Litigation (149 cases) – overall patentee loses 62%
 - Patentee loses 75% of cases started by generic (note the selection bias)
 - Patentee wins 51% of cases it starts
 - No comparative data with other sectors
 - And note that approx 50 cases which patentees brought and won at trial but then settled appear to be excluded from the dataset
- Oppositions (data set of 52 final decisions)
 - 31 revoked
 - Upheld unamended in 13
 - 8 upheld in amended form (described as generic success by DG Comp)
- 75% of all decisions in Oppositions are upheld in whole or in part - generics “very successful”
- 74% of all Commission cartel decisions which are appealed are successfully appealed in whole or in part

“A consequence flowing from filing numerous patent applications in order to create patent clusters can also be an increase of weak patents”

- “Many generic companies complained that novelty and inventive step requirement for secondary patent applications were too easily considered to be met by the EPO. This seems to be confirmed by the fact that in the patent litigation cases between originator and generic companies reaching a final judgement, the majority of patents were revoked”
- Percentage of patents revoked at trial
 - Cases brought by generics – 40%
 - “Secondary” – 36%
 - Overall – 29.5%

Some more fundamental issues

The concept of Loss of Exclusivity

- Key concept as alleged delays calculated from date of LOE
- Preliminary Report
 - “where a product no longer benefits from an exclusive right e.g. because of expiry of patent, SPC and data exclusivity)”
 - apparently as reported by innovators (or where they didn’t as reported by IMS Health) –
 - presumably in answer to request for the “*date when the product went off patent*” - which product (several formulations) and which patent?
- Unless all innovators interpreted the question in exactly the same way, and unless IMS got it right, the data is inherently flawed

The use of averages for delays in LOE

- How do outliers in the range impact averages?
 - Range of delay for top-selling 20% INNs is 0 – 50 months. If 3 were at the 50 month level, the rest would be at 0
- Cases of pre-LOE generic entry, treated as at date of LOE
 - Biases the average upwards
 - Every case where generic launched and lost at trial is early entry
- 195 pre-litigation interventions with marketing authorisation authorities relating to 43 INNS – 3.9 months delay
 - average delay for a blockbuster is 4 months
 - So where there is a regulatory intervention, other uses of the “toolbox” do not delay generic entries on blockbusters?

Other factors suggesting patent and patent litigation are not issues in post-LOE delay

- LOE is the date when “where a product no longer benefits from an exclusive right e.g. because of expiry of patent, SPC and data exclusivity”
 - if LOE is the start date for delay and is when the product no longer had patent protection, how can patent protection cause a post-LOE delay
- No apparent correlation between number of litigations/time to trial in a country and the average length of post-LOE delay in generic entry in that country
- The elements of the “toolbox” are most commonly used in relation to blockbusters
 - And yet generic versions of blockbusters come to the market more quickly (4 months) than either the average (12 months) or the weighted average (7 months) of delays

The biggest flaw – the failure to analyse causation

- “Although there may be other reasons for delays to generic entry, the successful implementation of these strategies [the “toolbox”] may have the effect of delaying or blocking generic entry to contribute to unnecessary cost of €3 billion in 17 countries over 8 years”
- “The findings suggest that the practices under investigation contribute to this”
- No analysis whatsoever of whether, when and the extent to which they cause delay
- No analysis whatsoever of whether, when and the extent to which other factors cause delay

What factors might cause delay

- Commercial and technical factors
 - Market size, manufacturing issues, likelihood of generic competition
- Old data exclusivity rules meant generics could not not apply for authorisation until after 6/10 year period
 - delay of “ a further 1 to 3 years” (EGA)
- Lack of Bolar under old rules
 - “Costing European patients and healthcare systems as much as €100 million per medicine per year” (EGA)
- Pricing and reimbursement delays
 - “Immediate generic competition on patent expiration ...No...Pricing and reimbursement decisions create delays in most Member States” – up to 14 months (EGA)

The elephant in the room

- Entry into the pharmaceutical market is conditioned by a range of hugely significant legal and regulatory factors
- In the highly regulated pharmaceutical market, it is unreasonable to expect generic entry on day 1 after LOE
- Where average delays are 4, 7 or 12 months, the failure to assess the causative relationship of the various factors is a significant omission



Conclusions

- The “toolbox” comprises nothing but a list of perfectly legal and wholly justified measures
- Any attempt to characterise use of the “tools” as unlawful or unjustified must be supported by strong evidence and analysis
- Much of the evidence and comment in the Preliminary Report is open to serious question
- There is no evidence to support the proposition that litigation unjustifiably delays generic entry
- The failure to analyse causation in this highly regulated market is a significant flaw which seriously undermines the value of the report and renders its judgmental nature unjustified

Thank you



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Back ups

The failure to address the generic market

- Concern is cost to payors of “toolbox”
- But no analysis of impact of other issues on cost
- Use of toolbox alleged to contribute to unnecessary cost of €3 billion in 17 countries over 8 years = approx. €0.9 per head of population in 27 countries per year
- Netherlands saved > €20 per citizen by promoting price competition between generics on 33 medicines in 2008
- Generics brought approx 20 cases to challenge new Dutch system and failed in most