

Dominance in the pharmaceutical sector

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Background

Invite

‘This event will look at recent trends in the pharmaceutical industry and how to advise pharma companies in today’s aggressive enforcement environment’.

Recent request for compliance advice for major pharma company

Basic rules for compliance

*Thou shall not coordinate
with competitors*

(Art. 101)

If your market share is above **40%** you will likely be regarded as dominant hence a number of practices (such as loyalty rebates) would likely be regarded as abuse

(Art. 102)

But – What do these rules mean for a pharma company? Particularly as regards ‘*dominance*’?

Art.102 Compliance – Dominance in Pharma



How does this rule translate in the pharmaceutical sector?

- **Step 1** – Define relevant market (at what level? For compliance purposes ‘conservative’ approach: molecule level)
- **Step 2** – Measure market share

Typical case

Pharma company has a **patent** over specific drugs: it has a **‘legal’ monopoly** for the duration of the patent which insulates it from competition

This is necessary given the economics of the pharma industry: guarantee recoupment of (large and uncertain) investments in R&D, clinical trials, launch costs, etc.

- Competition FOR the market. Rivalry at the initial stage
- Once patent is obtained ‘monopoly price’ to generate returns to compensate for initial costs

Dominance test in pharma

If we were to apply a dominance test it would inevitably be met. By definition a patent gives a monopoly...

There might be instances where there are potential substitutes, but often not very close, hence, easy conclusion of dominance

Does this mean that all companies with a drug under patent are dominant in that particular market? If so, given:

Art.102 application: still *form based* (despite decades of discussion of *effect based* approach!)

Therefore: *Thou shall be in trouble of potential [exclusionary or exploitative] abuse* if you adopt certain forms of conduct (e.g. loyalty rebates/bundling/refusal to supply/ 'excessive' prices)

Dominance: Hence abuse?

Test

- Generic entry normally results in sharp decline in price, and sharp decline in originator's profits, therefore, after generic entry: intense price competition
- If the price post generic entry is the 'competitive' price, the higher price during the life of the patent is the result of exploitation of market power

But

- If that is the legitimate exploitation of a 'legal' monopoly which compensates for the R&D competition for the market then is it not what it is intended to be, i.e., a monopoly?!
- Do we conclude that the profits made before the entry of generics are 'supra-normal' profits resulting from abuse of dominance?



Conclusion

- If monopoly prices are the legitimate reward for ex-ante competition, how is that competition accounted for in an ex-post assessment of dominance? Will dominance be an obvious conclusion of the test?
- Risk of overintervention given form based approach—even if action legitimate exercise of IP rights, it could be problematic if seen as potentially foreclosing or exploitative
- Need to resist temptation to use abuse of dominance to fill in regulatory/patent system gaps
- Good for consumers? Maximising consumer welfare in the short-term vs long-term
- Go back to my client: No bright lines to ensure compliance...



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