PHARMACEUTICALS AND INTELLECTUAL PROPERTY TRAINING SEMINAR

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THE INTERFACE BETWEEN IP AND COMPETITION LAW

COMPETITION LAW PERSPECTIVE

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Maintenance and Promotion of Competition Act, 1979 – Intellectual Property (IP) excluded from competition law.

- Possible anti competitive abuses dealt with in IP legislation.

Competition Act No 89 of 1998 – applies to all economic activity having an effect within the Republic and therefore applies to IP.

Jurisdictional tension exists where:

- Specific competition law provisions provided in IP legislation;
- IP abuse dependent upon the validity of IP and exclusive jurisdiction provisions in IP legislation.
Referral to the Commission – 1 year to investigate (extendable) and then must either refer to the Competition Tribunal or decline resulting in the possibility to self refer. Where to with an IP validity issue?

In court proceedings, invoke Section 65(2) for referral to Competition Tribunal, provided not vexatious and necessary to determine final outcome.
Competition Act (Section 4) applies to agreements (very broadly defined) between competitors (actual or potential).

“Potential competitor”: does the entity have or will it incur the necessary investment to enter the market in a relatively short period?

**EXAMPLES**: IP License Agreements; Joint R&D Agreements; Partial Function Joint Ventures; Co-marketing/branding agreements.
Certain agreements may out rightly be anti competitive even if the effect is pro competitive.

**EXAMPLE:** A patent license agreement, between competitors, which provides for a division of markets (pharmaceuticals: public v private market; general: use of new developments in one market v other markets).

**EXAMPLE:** Agreements that envision the co marketing of products, between competitors, cross licensing of IP wherein trading conditions are fixed.
HORIZONTAL RELATIONSHIPS

☐ Result: A chilling effect.

☐ Remedy: Consider a “characterising approach” (Case No 554/03, Supreme Court of Appeal) with respect to the Agreement or alternate clauses.

☐ Certain agreements may be anti competitive if they result in a substantial lessening and prevention of competition and for which there are no pro competitive aspects outweighing the negative effects.

  ☐ EG: exclusivity v non exclusivity;

  ☐ EG: rebate structures and discounts.
Competition Act (Section 5) applies to relationships between a firm, its suppliers, customers or both.

Few IP specific examples – aside from franchising issues and IP license agreements, vertical agreements wherein IP is not the primary object take the form of run of the mill distribution / supply agreements.

No guidelines in South Africa but EU Technology Transfer Block Exemption Regulations and guidelines instructive.
Breather

"I'll show you what's in mine if you'll show me what's in yours."
Establishment of dominance complicated by exclusivity offered by IP.

In pharmaceutical sector:

- Just because there is a patent for the active pharmaceutical ingredient (or process, formulation, crystal form) does not mean dominance.

- South African Competition Tribunal (merger cases): ATC3 level.

- Treatment Action Campaign complaint against GSK / BI: ATC4.
Market Analysis

- Demand and supply side substitutability. Look across disease groups to see what actually competes with the product.
  - Constructed Market / Market Shares / Market Power.

- Look at competitive constraints:
  - The varying degrees of efficiency between products, *e.g.* the number of treatment days it would take for differing products to heal a patient with the same condition.
  - The indispensability of a specific product to some patients.
• Whether the modes of action of different products give rise to different uses.

• The prescribing practices of healthcare professionals and the momentum in prescribing.

• Whether a product is available over-the-counter, as against those that are only available on a prescription basis.

• Whether there is medical evidence to support a higher pricing strategy and, consequently, a lack of substitutability with lower priced products.
CONCLUSION: general aspersions of abuse of dominance by originator pharmaceutical companies cannot be made. Detailed case by case market analysis required. In any event, being dominant is not anti-competitive.

“The conclusion to be reached is that competition law in SA has degenerated. It has become an arbitrary political playground, a legal minefield creating huge levels of uncertainty”

Economic Development Minister Ebrahim Patel (Bus Day 8/11/11)
EXCESSIVE PRICING

- No reasonable relation to the economic value.
- Difficult concepts.
- Competition Authority – reticent to be a price regulator.
- Pot calling the kettle black? Are the prices of generics excessive?
EXCLUSIONARY CONDUCT

- Catch all – must be substantial / significant in foreclosing parties or preventing them from expanding.

Potential issue – enforcement of patents (validity / ever greenening)

- Need to show some form of bad faith.
- Validity issues will raise jurisdictional issues.
There are no other burning issues on abuse right?
The issue of authorised generics is that an originator may, prior to patent expiry, reserve for itself first mover status by launching an authorised generic.

Why? Competitors taking calculated risks against patent rights and “jump the gun” in order to be “first to market”.

From a patent law perspective, patentee can launch as many of its patented products under different brands as it wants.
Abuse of Dominace

- To deny a patentee of this right in a general sense, through competition law, is to use the latter to legislate over the Patents Act 57 of 1978.

STOP

Shouldn’t be jurisdictionally possible, may be unconstitutional.

- Therefore, the assessment of whether the introduction of an authorised generic is anti-competitive or not requires a case by case analysis.
Abuse of Dominance

Factors to be considered having regard to the relevant market:

- Is there room to compete on price?
- Does the second / third / fourth etc mover have access to the market through its own distribution / retail levels?
- Does the second / third / fourth etc mover have a plan to be in a market segment from a strategic point of view?
- From a temporal market definition point of view, is there potential for market shares to grow?
Abuse of Dominance

- Solutions – is the Competition Act the way to go?
- Solutions – what about benchmarking provisions, when in effect?
- Solutions – legislative reforms?
THANK YOU FOR YOUR TIME