

Intellectual property, competition law, and access to medicines: opportunities for litigation



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**Regional health litigation training
Johannesburg, South Africa
27 – 29 June 2016**

Overview of presentation

- **How can litigation be used to increase access?**
- **Why consider competition law?**
- **What are the relevant competition “rules” under TRIPs?**
- **How the rules can be used**
- **Using competition law in South Africa**

How can litigation be used?

- **By relying on current laws to increase access**
 - Reliant on existence of such laws
 - Potentially a broad range of actors
- **To develop the existing legislative framework**
 - Dependent on nature of broader rights framework
 - Particularly useful where framework is relatively new
- **To put an access-friendly framework in place**
 - Dependent on nature of the Constitution
 - Most difficult use of the law

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Why consider competition law?

- **Standing to bring a complaint**
 - Standing provisions likely to be broad
 - Likely to be no need to show a legal interest
- **Existence of competition law framework**
 - Unlike in patent law, TRIPs flexibilities may often exist
 - Existence of specialised (resourced) authorities
- **Limited jurisprudence on the topic**
 - Relatively new laws
 - Limited jurisprudence globally

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The relevant TRIPs “rules” (1 of 4)

- **Article 1.1: freedom to determine “*appropriate method of implementing the provisions of ... [TRIPs] within ... own legal system and practice*”**
 - form of legislation
 - Single IP statute, including dealing with anti-competitive practices
 - Separate legislation for patents, copyright, competition law
 - Abuse of exclusive rights in patent and/or competition law
 - institutional framework
 - Specialist regulatory authority
 - Utilise ordinary court system
 - Hybrid system
 - extent/nature of state involvement
 - Forum/mechanism for third party dispute settlement
 - Active enforcement of competition law and policy

The relevant TRIPs “rules” (2 of 4)

- **Article 8.1: recognises that there may be a need to adopt certain measures in the public interest**
 - regardless of conduct of exclusive rights holder
 - may include, for example, strengthening of domestic manufacturing capacity to ensure sustainability of supply
- **Article 8.2: recognises that there may be a need to prevent abuse of rights in IP and/or to address other forms of problematic conduct**
 - abuse of exclusive rights
 - unreasonable restraint of trade
 - adversely affect international transfer of technology

The relevant TRIPs “rules” (3 of 4)

- **Articles 31(c) and (k)**

- expressly recognise the egregious nature of anti-competitive practices

- 31(c): limits use of compulsory licensing with regard to semiconductor technology to *“public non-commercial use”* or to remedy an anti-competitive practice

- 31(k): exemption from certain requirements (that ordinarily apply to compulsory licences) if issued to remedy an anti-competitive practice

- no prior negotiations

- no limitations on exports

- no possibility of termination of licences

- but no definition of *“anti-competitive”*?

The relevant TRIPs “rules” (4 of 4)

- **Article 40**

- Recognises that rights holders free to determine
 - whom to license, and
 - under what conditions and subject to what terms to license
- But provided
 - none of the terms and conditions of the licences, or the manner of their implementation
 - constitutes an abuse of rights
 - having an “*adverse effect on competition*”
- Law can be used to address such abuses when they –
 - have adverse effects on trade, or
 - impede the transfer and dissemination of technology.

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How the rules can be used

- **Relationship between IP and competition law**
 - When can competition law be used?
- **Excessive pricing**
 - Focus on context
 - Value of pricing inquiry
- **Refusals to license**
 - Is a mere refusal to license abusive?
 - Is there any consensus on the issue?
 - How could a case be framed?

Relationship between IP and competition law

- **On its own, exercise of rights doesn't provide a basis for using competition law tools**
 - freedom to determine grounds for licensing is not enough for a broad definition of “anti-competitive”
 - when no abusive or problematic conduct, better to invoke government-use and other standard instruments
- **Patents do not necessarily confer dominance**
- **Focus on unfair advantage of dominance**
 - it is not enough that prices of patented medicines are higher than those of (potential) generic competitors
 - simple refusals to license are not enough

Excessive pricing

- **Context specific**

- may vary from country to country
 - human development index
 - constitutional context
- taking unfair advantage of market exclusivity
 - to extract unjustifiable benefit
 - not necessary for creating or maintaining incentives to innovate

- **Value of pricing inquiry**

- openness and accountability
- justification of pricing models
- easy to tap into public sentiment
- strengthen hand in negotiations for licences

Refusals to license

- **Refusal to license is not necessarily abusive**
 - essence of the right to exclude
 - needs a case-by-case analysis
- **No developed country consensus**
 - EU: unlawful where it prevents market entry of innovative product for which there is consumer demand if –
 - not objectively justifiable
 - excludes competition in a “secondary market”
 - US: freedom to choose whether to license
- **How to frame?**
 - essential facilities doctrine vs. exclusionary conduct
 - refusal to deal not objectively justifiable

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Tau v GSK and Boehringer Ingelheim

- **GSK and BI alleged to have**
 - “engaged in excessive pricing of ARVs to the detriment of consumers”
- **Conduct was alleged to be –**
 - directly responsible for the premature, predictable and avoidable death of adults and children with HIV
- **In contravention of –**
 - section 8(a) of the Competition Act, 89 of 1998
 - part of chapter on abuse of dominance
 - as interpreted in light of the Constitution
 - definition of excessive price: no “*reasonable relation*” between the price charged and the “*economic value*” of the product

Resolution by settlement

- **Matter settled in December 2003**
 - avoided potentially embarrassing public hearing
 - separate settlement agreements
 - Tau et al and two groups of companies
 - Competition Commission and companies (later declared invalid)
 - complex legal issues remained unresolved
- **Implementation of settlement**
 - excessive pricing complaint, but licensing solution
 - reasonable terms and conditions
 - public and private sectors
 - imports and/or local production of products (including FDCs), with exports of latter to all of sub-Saharan Africa
 - 5% royalty maximum (including for FDCs)

TAC v MSD and Merck

- **Began discussions with MSD in May 2002**
 - no licences had been issued at this point
 - simultaneously began discussions with other companies
- **Discussions and correspondence through 2007**
- **MSD's history of inching along**
 - first licence granted in November 2004
 - company never brought products to market
 - Aspen Pharmacare became sole licensee in July 2005
 - Adcock Ingram became second licensee in August 2007
 - price of patented medicine reduced as and when generic prices dropped

Essence of legal argument

- **Refusal to license *per se* is not anti-competitive**
- **Approach to abuse of dominance provisions**
 - interpret within context of Act, constitutional rights recognised in South Africa, and international law
 - balance between effect of, and reason for, exclusion
- **Is there a sufficient reason, *in the circumstances*, to compel MSD to license?**
 - prevented market entry of cheaper and new combinations (FDCs and co-packs) of existing drugs
 - placed sustainability of supply at risk

Outcome of the complaint

- **Additional licences granted**
 - Cipla-Medpro, Aurobindo and Sonke (Ranbaxy JV)
- **Terms of all licensing agreements amended**
 - permission for FDCs and co-packs not to be withheld unreasonably
 - contribution in lieu of royalty no longer required
- **State procurement of generic efavirenz**
 - as was the case with the GSK settlement, resolution of complaint focusing on private sector had significant impact on public sector and state's ability to procure

Conclusion on the use of competition law

- **Successes of complaints**
 - practical outcomes (price and sustainability of supply)
 - confirmed approach to private sector (mere litigation threat insufficient; rational response to strong complaint)
- **Challenges**
 - unsustainable (case-by-case; capacity to investigate)
 - unlikely to result in jurisprudence as parties may settle
- **Other possibilities for competition law**
 - merger control
 - horizontal and vertical constraints