Controlling the Costs

People's Health Forum
Roundtable 2 on Sustainable Healthcare Financing in Malaysia
7 August 2019

National Medicine Policy (revised 2012)

- To promote equitable access to the use of safe, effective and affordable essential medicines of good quality to the population

5 core areas in the Policy:

- Good governance in medicines;
- Provision of safe, quality and efficacious medicines;
- Access to medicines in terms of availability and affordability;
- Quality use of medicines; and
- Collaboration with the private healthcare industry

Competition and medicines prices

- Malaysian Competition Commission: Market review of the pharmaceutical sector (2017)

https://www.mycc.gov.my/market-review

Objectives:

- Determine market structure & profile of pharma industry
- Determine competition level in industry
- Identify anti-competitive practices
- Identify rules and policies that promote or inhibit competition

- Market research, inquiries and investigations in the European Union, the United States, South Africa and India showed that although many important blockbuster drugs were coming off patent, authorities realised that there were delays in the entry of generics into the markets which should have taken place immediately.
- This was due to life-cycle management strategies such as evergreening of patents, patent “pay-to-delay” settlements, follow-on drugs, and other practices affecting generic entry.

Domestic Pharmaceutical Manufacturers in Malaysia (2014/15 data)

- Total market size RM 1.7 billion
- All manufacture only generics & mainly domestic market
- Small contract manufacturing very small - most cos. <5% of sales
- Larger ones seek export market

Importers

- 2 groups – foreign/MNCs and local importers – differentiated by size and type of products imported
- Foreign cos are large esp MNCs; Pfizer is biggest - sales of RM452 m
- 35 foreign cos with sales of RM 3.9 bn - 87% mkt share & 77% of net profit
- 19 local cos. Sales of RM 553 m acct for 13% mkt share & 23% net profit

Manufacturers

- Pharma market is competitive at manufacturers and importers levels
- Market is competitive because companies are producing generic drugs with low entry barriers (caveat: regulatory challenges)
- Price competition from India and other generic imports
- Moderate profit margin avg of 14.3% for top 6 companies and 12.0% for all manufacturers

Importers

- Importers: low market concentration, but high degree of market power concentrated among major MNC importers (price setting)
- Importing patented products grant MNCs pricing power
- Product life-cycle management extends market exclusivity
- Local importers of generic drugs are highly competitive; feel squeezed between MNC importers and local generic manufacturers

Pricing and Profitability

- Market power should translate into high profitability but this does not show up in MNC subsidiaries in Msia
- Avg net profit margin 2.5% for foreign importers
- Comparison of 5 MNC subsidiaries with parent companies show big divergence btw parent and subsidiaries profitability

Profit Margin of MNC parent vs subsidiaries in Malaysia, 2014/15

Company	Parent Company	Malaysian Subsidiary
Pfizer	29.4%	2.4%
Abbvie	27.0%	1.9%
Rocher	26.0%	3.4%
Norvatis	24.6%	2.6%
Merck	24.2%	1.6%
Average	26.2%	2.4%

Capital Investments – Foreign vs Local Importers

	Capital Investment (RM)	Capital Investment per company (RM)
Foreign Importers	69,449,479	2,104,530
Local Importers	128,296,926	5,831,678

Intellectual property and prices

- Prices of Medicines
  - vary across countries and within countries
  - How are prices set? Research and development? Production cost? Mark up? etc
- Intellectual property rights –after Trade- Related Aspects of Intellectual Property Rights (TRIPs) Agreement in 1995/2000 – all products and technologies can be patented with certain exceptions and limitations
- Local production usually limited in developing countries creating dependency on imported medicines
- Malaysia's domestic pharmaceutical sector has potential

- PhAMA 2009 study of 47 originator drugs in top 5 therapy areas – Malaysian prices lower by comparison to most of 10 countries chosen
- Hassali et al 2012 study of 10 most used drugs – Malaysian prices higher ranging from 30% to 148% with median difference 58% (compared to Australia)

- Free in MOH hospitals or subsidised
- Private sector prices can be unaffordable unless covered by health insurance
- Prices in private sector can be 30x higher mainly due to difference in price btw originator and generic medicines (Malaysian Competition Commission, 2017)
- When comparing originator medicines btw private and public sector, there is not much difference (noting that it is a small sample)

Price in Ringgit	MOH	Average price of 3 private hospitals	Difference between MOH and private hospitals	Private hospitals price range
Cardiovascular				
Atorvastatin (40mg/tablet)	0.20 (GM)	6.50 (OM)	32.5x	4.90 - 7.60
Perindopril *	0.08 (GM)	3.00 (OM)	37.5x	3.0 - 3.1
Clorpidogrel (75mg/tablet)	0.30(GM)	9.43 (OM)	31.4x	9.00 - 10.30
Cancer				
Trastuzumab (440 mg per vial)	6170 (OM)	8658 (OM)	1.4x	8,000 - 9,426
Imatinib (400 mg/tablet)	276	272	0.98x	153 - 352
Treatment for 30 days **	8280 (OM)	8183 (OM)		4,600-10,560

Implementing TRIPS flexibilities in Patents Act

- Need for Malaysian Patents Act to be reformed

- Scope and patentability criteria of what is “new”, “inventive step” and “industrial applicability” – criteria for medicines, medical devices

- Second indication/second use of existing medicines, salts, polymers, crystalline forms, dosages, formulations, combinations etc can be patented (**secondary patents**)

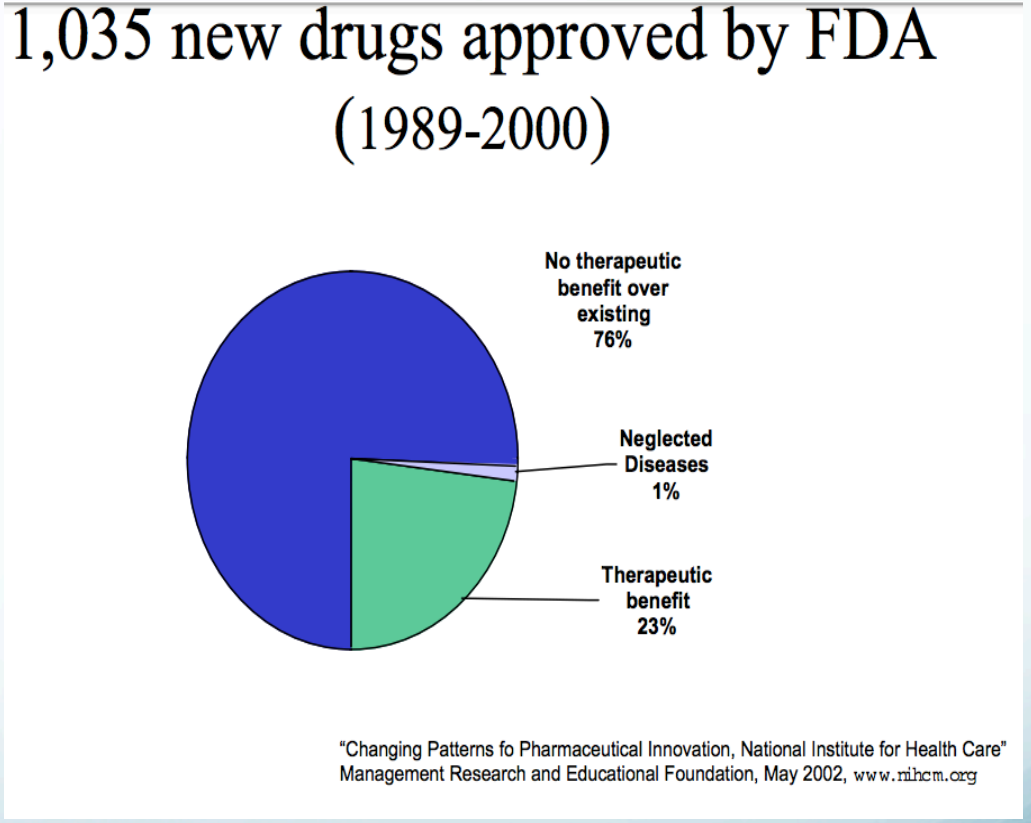
- Result: exclusivity/monopoly extended after expiry of primary patent (**compound**) with these secondary/”evergreening” patents – impact on competition level, affordability and accessibility

Patents Act remedies for anti-competitive conduct

- Consistent with WTO TRIPS
- 3rd party compulsory licence (option for generic companies to obtain licence from originator company)
- Rights of Government – a form of compulsory licence for "public non-commercial use"
- Control of anti-competitive practices in contractual licences: "invalid clauses" in Patents Act

"Evergreening" of patents?

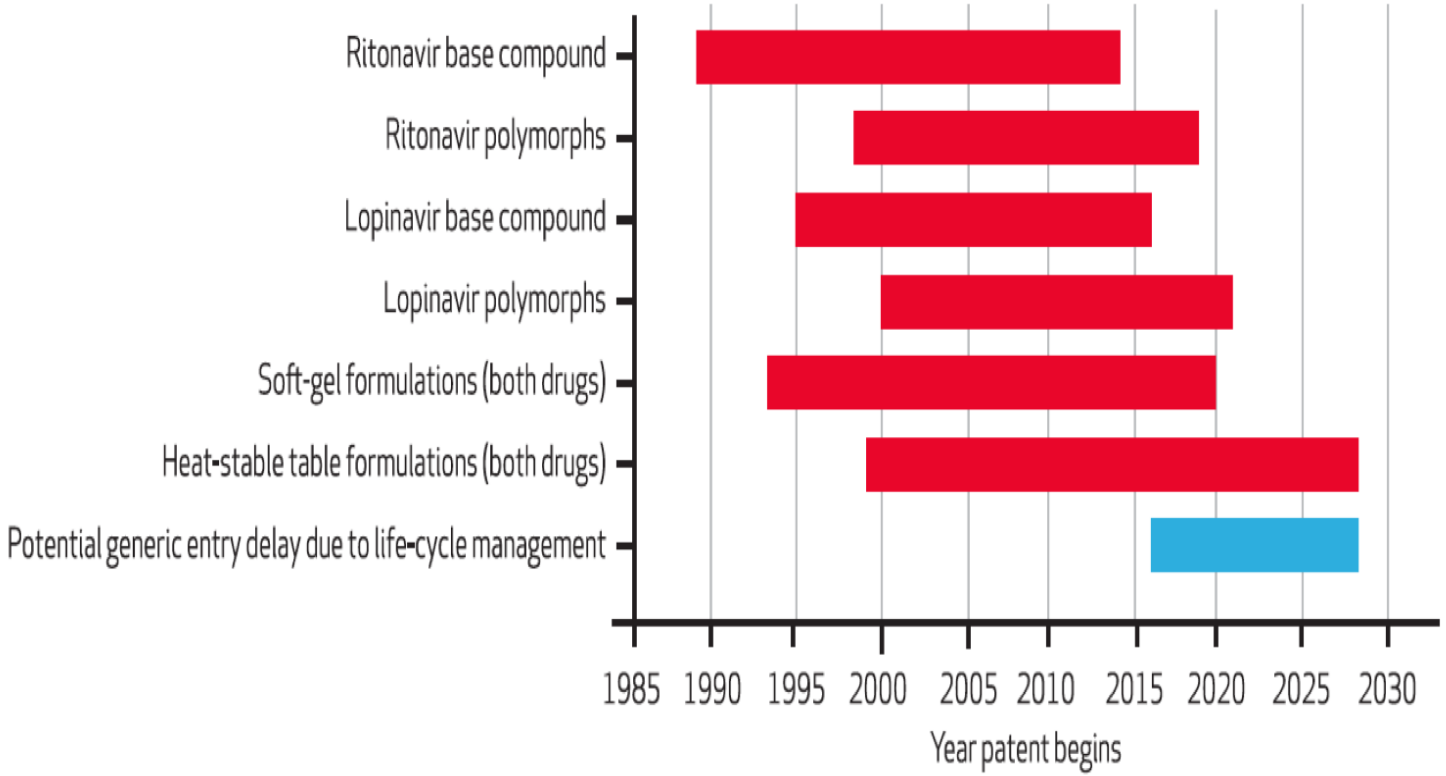
- Primary patents on molecule/basic compound
- Secondary patents on most drugs introduced are for new forms, new uses, different dosages or combinations of existing drugs
- This is known as 'evergreening' – practice that extends market exclusivity beyond 20 years of primary patent



Example of HIV medicine

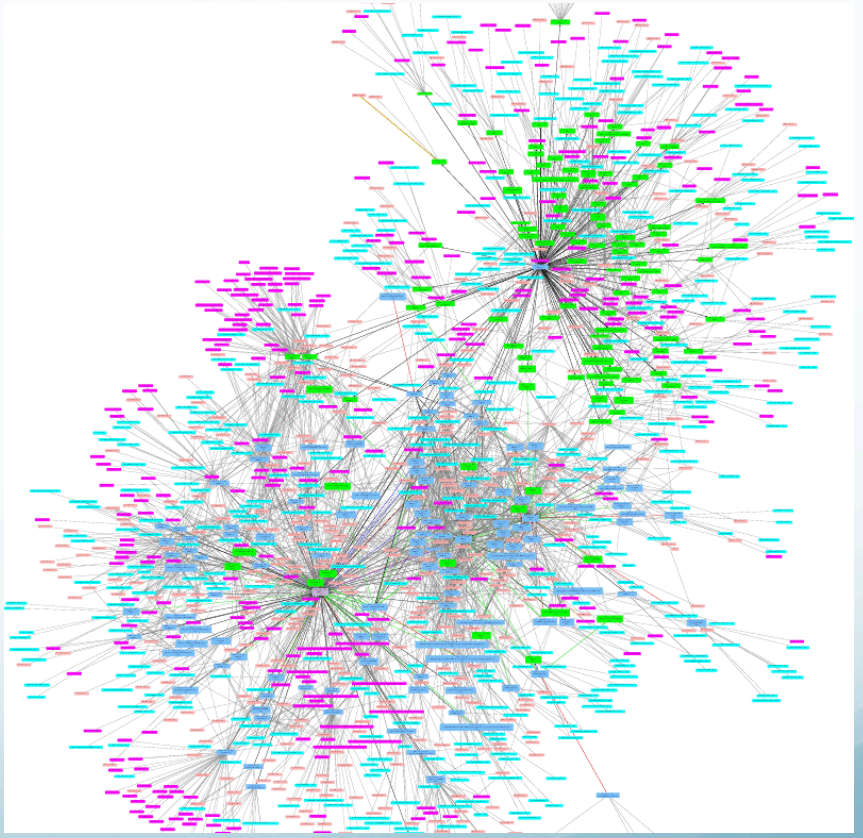
Lopinavir/Ritonavir

Duration Of Patents Covering Ritonavir And Lopinavir/Ritonavir



Patent Thickets: The Ritonavir Patent Landscape

- Original compound (primary) patent filing: 1995
- 805 patent families
- Generic entry for lopinavir/ ritonavir likely to be delayed 13 to 14 years after original primary patent expiry



https://www.keionline.org/21711

Malaysia – granted patents

Formulation/Dosage	Description	Status	Application No.	Expected Expiry Date
Lopinavir/Ritonavir 100/25 mg tablet	Ritonavir crystalline polymorph	Granted	MYPI9903007	28/02/2021
Lopinavir/Ritonavir 100/25 mg tablet	Lopinavir/Ritonavir heat-stable formulations	Granted	MYPI20060745	22/02/2026
Lopinavir/Ritonavir 100/25 mg tablet	Ritonavir crystalline polymorph	Granted	MYPI0402546	13/01/2027
Lopinavir/Ritonavir 200/50 mg tablet	Ritonavir crystalline polymorph	Granted	MYPI9903007	28/02/2021
Lopinavir/Ritonavir 200/50 mg tablet	Lopinavir/Ritonavir heat-stable formulations	Granted	MYPI20060745	22/02/2026
Lopinavir/Ritonavir 200/50 mg tablet	Ritonavir crystalline polymorph	Granted	MYPI0402546	13/01/2027
Lopinavir/Ritonavir 80/20 mg (per ml) oral solution	Lopinavir/Ritonavir liquid compositions & capsules	Granted	MY199902107	27/05/2019
Lopinavir/Ritonavir 80/20 mg (per ml) oral solution	Ritonavir crystalline polymorph	Granted	MYPI9903007	28/02/2021
Lopinavir/Ritonavir 80/20 mg (per ml) oral solution	Ritonavir crystalline polymorph	Granted	MYPI0402546	13/01/2027

- Generic available since 2016
- Lopinavir 200mg/ritonavir 50mg tablet: MOH buy the originator product at **US$1,489.20 per patient per year**
- Generic product from Cipla at **US$268 per patient per year**
- Potential savings of up to **82%.**

- In Malaysia's ARV treatment guidelines
- But high costs prevent inclusion for free treatment
- Originator DTG only in Malaysia; compound patent expires October 2027
- Pending patent application on Lamivudine/Abacavir/ Dolutegravir combination
- RM 9,264 pppy in private sector Internationally generic DTG can be as low as RM 244 ppy

LAWS/POLICIES

- **Guided by national policy objectives**
  - Affordable access
  - Increasing competition
  - Promoting development of generic industry

- **Modernising Patents Act**
  - Maximis use of TRIPS flexibilities: review Patents Act and Patent Examination Guidelines (MDTCA/MyIPO and MOH working group)
  - Rigorous patentability criteria and thorough patent application examination (enhance scientific/technical capacity of MyIPO)
  - Strengthen examination of pharmaceutical patents to exclude “trivial” or “evergreening” patents
  - Patent transparency: (i) Patent applications to include information in other jurisdictions, e.g. rejection or withdrawal of patent applications or invalidation of granted patents; and (ii) Such information to be available on MyIPO website. E.g. Indian patent office website discloses communications with patent applicant

- Safeguard policy and regulatory space when negotiating trade agreements
- Cooperation among MyCC, MDTCA/MyIPO, MOH on synergy between intellectual property and competition law

UNCTAD TRADE AND DEVELOPMENT REPORT 2017

There is evidence in evolving IPR frameworks of a growing bias towards the excessive protection of private investor interests, often at the expense of wider public interests. The use (and abuse) of IPRs (patents, copyrights and trademarks) has become one of the main means of enhancing market power, and thereby generating and appropriating more and higher rents. The practices, policies and regulations relating to the granting of IPRs have become the subject of intense scrutiny and debate in recent years (Standing, 2016; Patterson, 2012). This debate touches upon the fundamental question of whether, in the context of the growing importance of knowledge- and information- intensive production and exchange, "the knowledge factor" continues to provide the basis for the granting of IPRs, particularly patents.

Reduction and stabilisation of drug prices can only be done through:

- Competition in the market
- Local production
- Rethinking medicines production
- Appropriate use of medicines
- Fair price mechanism (WHO/MDTCA)

All require transparency of R&D cost and price setting. World Health Assembly debate and resolution adopted in May 2019

WHO and price transparency

- 72nd World Health Assembly (WHA) of health ministers on 28 May 2019 adopted the resolution on “Improving the transparency of markets for medicines, vaccines, and other health products”
- First step to improve the transparency on medicine pricing and other factors impacting prices such as clinical trial costs
- Initiative of Italy co-sponsored by 10 countries including Malaysia

WHO Member States urged to:

- Take appropriate measures to publicly share information on the net prices* health products
- Take the necessary steps, as appropriate, to support dissemination of and enhanced availability of and access to aggregated results data and, if already publicly-available or voluntarily-provided, costs from human subject clinical trials regardless of outcomes or whether the results will support an application for marketing approval, while ensuring patient confidentiality
- Work collaboratively to improve the reporting of information by suppliers on registered health products, such as reports on sales revenues, prices, units sold, marketing costs, and subsidies and incentives
- Facilitate improved public reporting of patent status information and marketing approval status of health products.
- Improve national capacities, including through international cooperation, open and collaborative research for development and production of health products, especially in developing countries and low- and middle-income countries (LMICs), including for diseases that primarily affect them

* amount received by manufacturers after subtraction of all rebates, discounts, and other incentives