IP, LOCAL MANUFACTURING, INDUSTRIAL AND ACCESS POLICIES

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SOUTH AFRICA'S LOCAL PRODUCTION ENVIRONMENT

- Each country has particular industrial policy and public health characteristics so that local production priorities will differ
- Among developing countries, South Africa has comparatively strong infrastructure and science base, experience with relevant production processes, good regulatory framework, well-established legal infrastructure, financial services capacity
  - Entry into force of WTO TRIPS Agreement was largely coincident with decline in local pharmaceutical manufacturing; potentially encouraged reliance on imports, but one of several factors and difficult to isolate causal relationship
  - 37 pharmaceutical plants were closed in South Africa between 1999 and 2003, resulting in the loss of 40% of manufacturing capacity and a similar proportion of jobs

IMPORT-EXPORT DATA 2015

South African imports of pharmaceuticals (Customs Tariff Chapter 30) in 2015 were R 27.6 billion of which R 5.7 billion came from India, R 3.8 billion from the USA, R 3.2 billion from Germany

South African exports (including re-exports) of pharmaceuticals (Customs Tariff Chapter 30) in 2015 were R 5.1 billion of which the top three destinations were:

- Namibia (R 1.4 billion), Botswana (R 675.5 million) and the USA (R 360 million - the bulk of that coming from Aspen-Pharmacare)

South African imports of ARV APIs (TH 29.34) in 2015 were R 1.3 billion of which R 642.3 million came from India and R 469.8 million came from China. From the total imports of subtract SA "exports" (i.e. re-exports) which were worth R 102.8 million.

South Africa's net imports of ARV APIs in 2015 were Rand 1.2 billion

Source: DTI

PROJECTS IN SA PHARMACEUTICAL INDUSTRY INCLUDED IN GOVERNMENT'S INDUSTRIAL POLICY (IPAP)

- Key action plan:

  - "Designation" of pharmaceutical tenders - terms & conditions of government tenders favouring domestic manufacturers (*designated tenders : the 2012 OSD and 2013 family planning*)

  - Pharmaceutical projects enjoy preferential access to Government's investment incentives.

- Strategic projects:

- "Project Ketlaphela" a US$ 185 million / R 1.4 billion ARV APIs project in Pelindaba, taking advantage of South Africa's expertise in fluorine technology (*status: Lonza withdrew – new RfP advertized*) [update: currently in version 3, targeted APIs]
- "Biovac" – R 250 million vaccine manufacturing project, a 48%-52% jv SA Govt - private consortium, pursued since 2003,
- Various private sector project in pharmaceutical formulation, capital investment totaling R 4.5 billion, 2008-2013.

DTI: 2014

IPAP - ENVIRONMENT FOR PHARMACEUTICAL MANUFACTURERS IN SOUTH AFRICA

Level of protection for domestic manufacturers in SA:

Zero customs duties on pharmaceuticals – across Chapter 30 (customs tariff headings TH 30.01, 30.02, 30.03 30.04 and 30.06); Only a few duties on APIs (paracetamol, codeine phosphate).

Preference in Government tenders: new preferential procurement rules (effective Dec. 2011), "*empowered importers"* eligible for 10 preference points, while most SA manufacturers (level 5 and 4 BEE contributors) max 4 or 5 points.

► Provision for "designation" of strategic sectors / products exclusively for SA manufacturers. 1st pharmaceutical tender (Oral Solid Dosage - OSD) designated by Minister Davies in April 2012 (70% of the tender).

NB: South Africa is not a signatory of the 1994 WTO Agreement on Government Procurement (GPA). The only requirement: transparency of the tender rules and process.

Key areas of investors' concern:

① Price control of medicines;

② Delayed registration of new products by the MCC (average waiting time: 4 to 5 years; loss of income for the "1st to the market" generics);

③ No advantage for trade with African countries – so far, futile efforts to harmonize regulatory affairs in Africa (SEAMRAC).

DTI: 2014

MPP AND TAF LICENSE

- In June 2014, MPP obtains license from Gilead to manufacture TAF (tenofovir alafenamide) that is extended to South Africa
  - TAF may be sold under license in 112 countries, with compulsory license option for others open
- This ARV has potential for substantially reduced dosage as compared to TDF (tenofovir disoproxil fumarate)
- Manufacturing active pharmaceutical ingredient (API) requires significantly lower quantities of basic and intermediate chemicals, and substantially reduces environmental concerns
  - See Fortunak et al 2010

LOCAL PRODUCTION POLICY

- Local production of pharmaceuticals involves a mix of public health and industrial policy issues, of which IP is one
- Addressing IP policy in isolation is unlikely to create a successful manufacturing platform, though in some cases it might!
- Governments, including of South Africa, have been reluctant to use IP flexibilities because of pressure from originator-base countries
- Reluctance is not based on public health considerations, since national interest (including industrial policy) would almost certainly favor more extensive use of flexibilities, including as negotiating tools

IP POLICY

- Very few countries "profit" from strong IP protection with respect to pharmaceuticals
  - Few countries have combination of capital and science base necessary to take medicines from conception through clinical trial
  - Strong IP protection for new medicines essentially a transfer payment that will not be offset by "domestic invention"
  - Issue is what constitutes a "fair" transfer payment, which would better be assessed by royalty than by patent-owner pricing decisions
  - Royalties can be based on objective formulas and scaled

CHINA AND LOCAL PRODUCTION

- China developed local production capacity while economy isolated and domestic self-sufficiency necessary
- Provided (and provides) infrastructure (e.g., subsidized electricity, low cost land) and financial support (e.g., through tax incentives), often within special economic zones (SEZ's)
- China views local production as key part of achieving universal health care (UHC), and host of new policies and programs intended to integrate elements
- Strong commitment by President Xi to UHC and improvements to healthcare system

CHINA AND LOCAL PRODUCTION

- Strengthening of regulatory framework, including hiring and training of additional personnel
- Transition from using pharmaceutical sales to fund hospitals toward fee for services system
  - Intended to remove incentive for prescribing, and to reduce costs
- Limit price controls to permit investment in upgrading facilities

CHINA POLICY MEASURES

- Aggressive price-cutting negotiations with patent-owning pharmaceutical suppliers
- Improving transparency of procurement processes
- Promoting industry consolidation
- Reducing API production environmental impact
- Initiation of competition inquiry in pharmaceutical sector

CHINA R&D

- Promoting R&D, particularly in biotechnology
- Educating large number of PhD scientists
- Creating subsidized biotechnology parks
- Introducing new mechanisms for allowing SMEs to profit from early-stage invention
- Partnering with foreign companies
- Biosimilars market the near-term target

CHINA AND IP

- "On the ground", Chinese companies continue to manufacture local copies of products patented outside and within China
  - Chinese API manufacturers offer complete range of originator products
- China granting large number of patents, though quality is questionable
- Government objective is to create domestic originator industry with higher value exports
  - Medium to longer term prospect
  - Traditional Chinese medicines (TCM) major export focus
- China, unlike most developing countries, has vast resource base to allocate to preferred policy objectives
  - China identifies pharmaceutical industry as priority

INDIA

- In early stages, government established public manufacturing and research facilities (1950s) which provided technological base
- World-class generics industry developed during period when government had eliminated pharmaceutical product patent protection (1970-2005)
- Industry undergoing major shifts as domestic producers acquired by foreign multinationals, and as policy space shrinks
- Commodified API production has largely shifted to China

INDIA INDUSTRIAL POLICY

- India has used industrial parks to promote pharmaceutical industry, though somewhat less aggressively than China
  - Principally tax incentives
- Proposals under consideration for re-invigorating commodified API industry, including industrial parks with shared facilities (e.g., for chemical inputs and environmental controls)
  - High value specialty APIs still produced in India
- "Major" generics producers for international markets conform with highest FDA/EMA GMP standards, with little reliance on domestic regulatory framework

INDIA AND PUBLIC HEALTH

- Producers for local market pose regulatory problems, and government increasing regulatory capacity
- India has acted as pharmaceutical supplier to developing world, with generic products otherwise on patent in originator countries
- This is issue principally of central government allocation of resources
- India has paid less attention to addressing needs of local population, with purchases largely out of pocket, even among poorer segments of population

INDIA IP POLICY

- Patent law revised to provide pharmaceutical product patent protection in 2005
- Section 3(d) establishes enhanced efficacy standard for new forms of known compounds
  - Intended to limit evergreening patents
- Leads to well-known Gleevec challenge
- Supreme Court determines that Novartis fails to provide evidence of enhanced therapeutic efficacy, rejects challenge to Section 3(d)
- Subsequently, patent office and courts approve compulsory licensing of Bayer anti-cancer drug, Nexavar

INDIA AND IP

- Despite originator/home country complaints regarding India's patent policies, India remains major destination of foreign investment and joint R&D ventures in pharmaceuticals
- Indian companies have substantial interest in biosimilars market
- India has large number of individuals trained in pharmaceutical sciences, including those returning from USA industry
- Corporate investments in R&D have increased, but percentage remain substantially below those of multinational originators

SOUTH AFRICA AND THE WORLD

- South Africa's local pharmaceutical manufacturers will compete with Chinese, Indian, Israeli, etc. generic producers, including multinational originators increasing focus on generics market
- Realistically, this cannot be done without government support in terms of industrial policy
- Concept of pan-African integrated market intuitively appealing to take advantage of economies of scale, regulatory integration, potential preferences for regional producers. To date, this concept has been difficult to realize

IP, LOCAL PRODUCTION AND PRICING

- From a national interest standpoint, South Africa should probably focus on implementing IP flexibilities to allow local producers to take better advantage of externally-developed technologies
- Cost burden of industrial policy should not be placed on health system procurement through higher than world market prices
- The challenge is reconciling the objectives of industrial and scientific development, on one side, and public access to medicines on the other
- China model provides suggestions for how this can be done, and also for the depth of government commitment needed to do it