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Indian Generic Companies, Affordability of Drugs and Local Production in Africa with Special Reference to Tanzania

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Abstract

Indian generic companies have played a major role in reducing the prices of HIV/AIDS drugs for the benefit of the people of Africa. However Indian companies in general display more interest in the larger and more lucrative markets of North America and Europe. Although the pharmaceutical industry has quite a long history in Tanzania, financial condition and growth have not been satisfactory, and, as in many other developing countries, Tanzanian industry suffers from some inherent cost disadvantages. However this paper argues that it is important for Tanzania to develop the industry further to take care of her drug needs, since there are problems with relying on foreign sources such as India. The government does provide some incentives to local manufacturers, but these are inadequate, and the paper argues for a proper industrial policy in Tanzania with both push and pull incentives. Abolishing product patents in pharmaceuticals operated as an important pull incentive in India, yet Tanzania has never abolished such patent protection. She can still do so: under TRIPS, Tanzania, as a least developed country is not required to introduce such protection in pharmaceuticals till 2016. Even if she chooses not to abolish product patents, there are other TRIPS flexibilities which Tanzania can use to develop her industry and enhance access to medicines.

I: Introduction

About half of the population in Africa lack regular access to essential medicines and about 90 per cent of the medicines are imported (WHO, 2005, p. 1). Promoting local production of pharmaceuticals figures prominently among the solutions being discussed to enhance medicine access. The African Union, for example, has launched an initiative for local production of pharmaceuticals.[i] India is often cited as an example of a developing country benefiting from the promotion of pharmaceutical industry. Taking advantage of the abolition of product patent protection in pharmaceuticals in 1972 and supported by other industrial policies, India has achieved enormous progress. Drug prices in India are among the lowest in the world and India has received world wide recognition as a low cost supplier of quality drugs. As is well known, the prices of antiretrovirals (ARVs) for HIV/AIDS have crashed after generic competition started from India. As a result the number of patients treated with ARVs has increased substantially.

However under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organization (WTO), formed in 1995, member countries are required to provide for minimum standards of intellectual property. Patents are required to be granted for all products including pharmaceuticals within the stipulated time frame. To implement TRIPS, India has re-introduced product patent protection in pharmaceuticals from 1 January, 2005. Indian generic companies will no longer be able to produce and market the new patented drugs. It is apprehended that as a result access to medicines will be adversely affected - African countries for example will not be able to import the new essential drugs from India.

But TRIPS provides some flexibilities. Under Article 66 of TRIPS, least developed countries (LDCs)[ii] may not introduce product patents till 2006. The transition period has been extended till 2016 for pharmaceutical products.[iii] These LDCs can produce the new patented drugs (and the older generic products) without violating any international law.

But what is the status of local production of pharmaceuticals in Africa? What are the problems of local production and what can be done to promote it? How can the other TRIPS flexibilities be utilized? What has been the role of Indian generic companies in Africa? Can African countries learn from India's experience? In this paper we will be concerned with such questions with particular reference to Tanzania. After a brief introduction to the African pharmaceutical market and industry and the role of the Indian generic companies in the continent in section II, we will undertake a more in-depth analysis of the situation in Tanzania in section III. We will see that though the pharmaceutical industry in the country has been in existence for quite some time, it suffers from various weaknesses. But questions which invariably crop up in any discussion of local production in developing countries are: is local production worth it?; isn't it better to import cheaper drugs from abroad rather than try to produce these locally? We will analyse the problems of relying on foreign sources such as India. Our case study of Tanzania suggests that local production can be and should be further developed. In the light of India's experience, we will discuss in section IV what industrial policy initiatives have been undertaken and what else can be done. Section V will be devoted to an analysis of the extent to which African countries

have taken advantage of the TRIPS flexibilities and what are the options still open to them. In the last section (VI), we will summarize the main conclusions.

II: African pharmaceutical market and industry and role of Indian generic companies

World pharmaceutical production and consumption of pharmaceutical products are highly concentrated in high income countries. In 1999, high income countries accounted for 92.9 per cent of world's production and 91.2 per cent of world's consumption. Low income countries, which include most of the African countries accounted for only 2.6 per cent and 2.9 per cent respectively (WHO 2004, pp. 5, 32).

Out of the global pharmaceutical market of $ 744,008 million in 2006, the entire Middle East and Africa accounted for only $ 14824 million (about 2 per cent) (Table 1). The largest pharmaceutical market in Africa is in South Africa with sales of $ 1761 million. This is quite small compared to markets in the larger developing countries such as China ($20800 million) and India ($ 9423 million).[iv] Most of the markets in Africa are much smaller than the South African market. In Tanzania, for example as we will discuss below, the market was only an estimated $ 110 million in 2004-05.

Imports are the pre-dominant source of supplies for drugs in Africa. But the total pharmaceutical imports by 53 African countries amounted to only $ 6.6 billion in 2006.[v] Imports exceeded $ 1 billion only in South Africa and Algeria. It was more than $ 100 million for 11 others (for example, Egypt, $ 465.4 million; Kenya, $ 225.2 million; Uganda, $ 119.7 million). Twenty four countries had imports less than $ 50 million (for example, Ghana, $ 30.7 million; Burundi, $ 20.8 million; Somalia, 7.6 million; Sao Tome Principe $ 0.3 million) and 16 countries between $ 50 and $ 100 million (for example, Burkino Faso, $ 99.9 million; Cameroon, $ 89.2 million; Tanzania, $ 87.3 million and Malawi, $ 57.5 million). The total pharmaceutical imports in 33 LDC countries in Africa amounted to only $ 1.6 billion in 2006.

Balance, Pogany and Forstner (1992, pp. 8-9) classified 190 countries into those:

- with sophisticated pharmaceutical industry and research base: 10 countries including USA, UK, Switzerland, Germany and France
- with innovative capabilities: 17 countries including Australia, Canada, Denmark, China and India
- producing both active pharmaceutical ingredients (APIs) and finished formulations: 14 countries including Brazil, Cuba, Indonesia, Romania and Turkey
- producing only finished formulations: 89 countries, for example Afghanistan, Bangladesh, Cambodia, Ethiopia, Kuwait and Morocco
- without any pharmaceutical industry: 60 countries, for example, Andorra, Bhutan,. Chad, Laos, Qatar, Suriname.

Out of the 52 African countries considered by Ballance, Pogany and Forstner, only one country (Egypt) had the capability to produce APIs (and formulations). Thirty two countries (for example Ghana, Kenya, Tanzania, South Africa, Uganda) could produce only finished formulations. Nineteen African countries did not have any pharmaceutical industry.

The situation has improved since then. Some of these countries have initiated some production including packaging of finished products or repackaging of bulk finished products. But there are still 8 countries - Botswana, Chad, Republic of Congo, Equatorial Guinea, Gambia, Guinea, Mauritania, Sao Tome and Principe – with no pharmaceutical manufacturing activity whatsoever (WHO, 2004, pp. 1-2).

Outside a few countries, notably South Africa and Kenya, MNCs are not involved in manufacturing in Africa in any significant way. Indian companies have set up some manufacturing plants in Africa primarily through joint ventures with local companies – Cipla in South Africa, Uganda and Morocco, Cadila in Ethiopia, Ajanta Pharma in Mauritius, and Ranbaxy in Nigeria and South Africa.[vi] Local manufacturing has been developing in Africa primarily due to the initiatives of local companies. Among the leading local companies are Aspen, Adcock Ingram, Enaleni Pharmaceuticals in South Africa (Avafia, Berger and Hartzenberg, 2006), Cosmos, Elys, Pharmaceutical Manufacturing Co (Kenya), Phillips Pharmaceuticals in Kenya (EPZA 2005), G.K.O. Medicines, Kisakye Pharmaceuticals, Uganda Pharmaceuticals in Uganda,[vii] Emzor, Fidson, Archy, Neros pharmaceuticals in Nigeria (BMI 2008), Shelys Pharmaceuticals, Tanzania Pharmaceutical Industries, Keko Pharmaceuticals in Tanzania (see below).[viii]

Africa constitutes a relatively small market for India's drugs and pharmaceuticals exports. Europe and America accounted for 57.8 per cent and Asia including the Middle East for another 26.9 per cent of India's total pharmaceutical exports of Rs 249421 million in 2006-07. Africa's share was only 14.1 per cent. But Africa is an expanding market for India. Its share has gone up from 10.7 per cent in 1994-95 to 14.1 per cent in 2006-07. The growth of the African Market has been faster than all other regions except America (Table 2). Just 6 countries (Nigeria, South Africa, Kenya, Ghana, Uganda and Tanzania) account for more than half and 15 countries for about three-fourths of India's drugs and pharmaceuticals exports to Africa in 2006-07. But India's exports now are more diversified than before. In 1994-95, just Nigeria and Kenya accounted for about 50 per cent of India's exports and the share of top 5 countries was nearly three-fourths (Table 3).[ix]

More than 90 per cent of India' pharmaceuticals exports are formulations, the remaining being APIs. Major importers of APIs from India are countries with more developed pharmaceutical industries in Africa, such as Egypt, South Africa, Nigeria, Kenya. [x]

India contributed to about 10 per cent of Africa's total formulations imports of $ 6617.1 million in 2006.[xi] But this underestimates India's contribution so far as the therapeutic value of the drugs supplied is concerned. The drug products exported by India are generic products and are priced much below that of the patented drugs imported by African countries from the MNCs. As we will mention below, African countries - even the LDCs which are not required under TRIPS to do so - have been providing product protection in pharmaceuticals. If these countries had not provided such patent protection and imported the drugs as generics from India or if the MNCs had practiced differential pricing and sold drugs to Africa at significantly lower prices, then India's contribution would have been much larger.[xii] Where drugs are purchased from multiple sources, as for example for ARVs, India has turned out to be the dominant supplier. WHO's Global Price Reporting Mechanism (GPRM) tracks ARV procurement by the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) and several other agencies. The data for 2006 show that India's supplies accounted for 69.6 per cent of the value of transactions (in terms of patient per year equivalents). The next largest source was South Africa (6.7 per cent) and UK (6.1 per cent). USA accounted for only 4.4 per cent of the value of transactions.[xiii]

But only seven Indian companies are involved in ARV manufacturing – Aurobindo, Cipla, Matrix, Strides Arcolab, Ranbaxy, Hetero and Emcure (Chaudhuri, 2007). While these companies have played a major role in reducing ARV prices and enhancing access to HIV/AIDS patients in developing countries including Africa, overall as we saw above, Africa still constitutes a small market for the Indian pharmaceutical manufacturers.

Among the major Indian companies which dominate both the domestic and the export market, Africa is a substantial foreign market only for Cipla. Africa accounted for 14.1 per cent of Cipla's sales in 2006-07. This is more than Europe's share in Cipla sales (10.6 per cent) and comparable to that of sales to Americas (16.6 per cent) (Table 4). But for Ranbaxy, USA constitutes 31 per cent and Europe 27 per cent of formulations sales in 2006. Africa's share is only 6.9 per cent. Similarly for Dr Reddys, North America constitutes 43.6 per cent and Europe 22.5 per cent of its total sales. Africa is included in the "others" category with only 12.8 per cent share. For Ipca, Africa constitutes 7.7 per cent of its total income compared to India, 46.7 per cent and Europe, 23.3 per cent. As can be seen from Table 4, for other major Indian companies, Africa is included in the residual category. Not only is the share of Africa small - only a few African countries are considered important by them, for example South Africa, Cameroon and Nigeria for Ranbaxy and South Africa for Dr Reddys, Sun and Glenmark. [xiv]

Lately Indian pharmaceutical companies have been acquiring companies abroad. As can be seen from Table 5, out of the 57 acquisitions between 2002 and 2008, only four were in Africa – all in South Africa. The target companies primarily belonged to developed countries – 14 in USA, 8 in UK, 4 each in France, Germany and Japan.

The reason why the larger Indian companies are more interested in the markets of North America and Europe is simple – these markets provide larger markets and higher price realizations. Price realizations are higher because regulatory requirements to enter these markets are stricter and entry is more difficult. USA has the toughest regulatory standard. Indian companies exporting to USA are required to file a Drug Master File (DMF) for APIs and Abbreviated New Drug Application (ANDA) for formulations and dedicated plants need to be set up. These are costly and time consuming, which most companies are unable to afford and hence they concentrate on the unregulated markets (Chaudhuri 2005, chapter 6).

The pharmaceuticals markets in most of the LDCs in Africa have basically been unregulated markets. It is only recently that some countries, for example Tanzania are trying to implement higher standards. As can be seen from Table 6, major Indian exporters to Tanzania include not only those who are also active in USA with ANDAs/DMFs filed (for example, Ranbaxy, Cipla, Aurobindo) but also those who are not yet present in USA. The later group includes companies such as Intas who is a significant player in India's retail formulations market, with sales of Rs 4888 million in 2006 (rank: 18). What is interesting to note is that some of the major exporters of formulations to Tanzania, for example Lincoln, Simrone and Aurochem are actually small players in the retail formulations market in India. Simrone does not find a place in the list of top 468 domestic retail formulators. Vital (rank 433), Medreich (rank 442) and Aurochem (rank 454) are insignificant players in the Indian market. Medo Pharma and Lincoln are slightly larger with sales of Rs 125 million (rank 161) and Rs 271 million (rank 111) respectively.[xv]

III: Pharmaceutical market and industry in Tanzania

The pharmaceutical market in 2004-05 was estimated at $ 110 million, of which $ 78 million (71 per cent) were supplied from imported sources and the remaining $ 32 million from local production (29 per cent).[xvi] All drugs marketed in Tanzania are required to be registered with the Tanzanian Food & Drugs Authority (TFDA). Out of the 3388 drugs registered for sale in Tanzania, only 269 products (about 8%) are from Tanzanian local manufacturers. Tanzania imports drugs from forty other countries which account for the remaining 92% of the products registered. Major countries supplying to Tanzania are India (1315 products registered), Kenya (307 products), Egypt (199 products), United Kingdom (165 products), Cyprus (137 products), Germany (131 products), Belgium (106 products) (Table 7).

There are 53 companies supplying drugs to Tanzania, each with 20 or more drugs registered. Of these, 41 are generic companies and 12 MNCs. The largest company in terms of products registered is the Indian generic company, Cipla with 165 products registered. The other generic companies with substantial number of products registered include Shelys of Tanzania (99 products), Elys of Kenya (81), Remedia of Cyprus (81), Ranbaxy of India (79), Interchem of Tanzania (70), IPCA of India (59), Medochemie of Cyprus (54). The largest MNC operating in Tanzania is GlaxoSmithKline with 130 products registered. The other major MNCs in Tanzania are Pfizer/Pharmacia (49), Sanofi (40), Bristol Myers-Squibb (37), Novartis (33). Interestingly, products are registered by the MNCs not only by the parent companies but also by their subsidiaries in different countries. In the case of GSK, for example, products have been registered also from countries such as Kenya, Egypt and India; For Pfizer, from Italy, South Africa, Belgium, Puerto Rico; Bristol Myers-Squibb from France, Italy, UK and Puerto Rico among others.[xvii]

Local production

There are eight pharmaceutical manufacturers in Tanzania.[xviii] The pharmaceutical industry was started in the country in 1962 with the setting up of a private sector company, Mansoor Daya Chemicals. The company still operates but has remained a small scale unit. It accounted for only 2 per cent of the value of pharmaceutical production in Tanzania in 2004-05 (Table 8). The next two units to be set up were public sector units during the socialistic phase of the country. Keko Pharmaceuticals was set up in 1968 as a unit under the Ministry of Health to supply tablets, capsules and large volume parenterals to the government procurement agency, Central Medical Stores (now Medical Stores Department) for distribution through public healthcare facilities. Tanzania Pharmaceutical Industries (TPI) was set up in 1978 by the government with assistance from the Finnish government. Both suffered from financial stress and were closed down in the early 1990s. Both were privatized (60 per cent of equity with private partners) in 1995 and are now operating. TPI and Keko are the second and fourth largest companies in Tanzania accounting for about 20 per cent and 11 per cent of the value of pharmaceutical production respectively in 2004-05. The largest pharmaceutical producer in Tanzania is Shelys Pharmaceuticals accounting for half the production (Table 8). It was established in 1979 and was acquired by the Sumaria group in 1984. Sumaria group is one of the largest private sector business groups in East Africa with interests in diverse sectors such as plastics, dairy, agro-processing. In 2008, Shelys has been taken over by Aspen of South Africa. The third largest company, Interchem Pharma was set up in 1989 and accounted for 15 per cent of the production in 2004-05. Out of the remaining three, A.A. Pharmaceuticals and Tanzansino United Pharmaceuticals are marginal producers (Table 8).[xix]

The latest entrant in the pharmaceutical industry in Tanzania is Zenufa Laboratories. It initially functioned as an importer and distributor of MNC products but has now diversified to manufacturing

with the setting up of a WHO Good Manufacturing Practice (GMP) compliant plant in 2007 through a strategic collaboration with the Belgian Investment Company for Developing Countries.[xx]

None of the older plants met GMP standards. In fact in 2000, after an inspection by the Pharmacy Board (TFDA's predecessor), 3 registered plants were asked to stop production (Center for Pharmaceutical Management 2003, p. 25). Since then production facilities have been upgraded. Substantial investments have been made by Shelys, TPI, Keko and Interchem to expand, diversify and attain TFDA GMP status (Ministry of Health & Social Welfare, 2006, pp. 7-8). Shelys has commissioned a new WHO GMP compliant plant which the company claims is the first of its kind in East Africa (Shelys Pharmaceuticals 2008, p. 6). But none of the Tanzanian manufacturers have yet applied for approval under the WHO Prequalification project. HIV/AIDS, malaria and tuberculosis medicines are evaluated in this project for quality, safety and efficacy to qualify for international procurement by United Nations organizations and others such as GFATM.

The production activities of Tanzanian manufacturers are relatively simple. They do not produce the APIs. The APIs required for formulation activities are entirely imported from countries such as India and China. In formulations too, they do not produce IV fluids, injectables, which are technologically more sophisticated. Only four companies – Shelys, TPI, Keko and Zenufa - produce antibiotics: the simpler ones such as amoxicillin, ampicillin, chloramphenecol, not the more advanced ones such as cepholosporins. The product range of the largest company, Shelys comprise mainly of simple antibiotics, cough and cold preparations, analgesics and antipyretics, sedatives, nutraceuticals, anthelmintics and antimalarials. Just six products of Shelys – Koflyn, Mucolyn and Coldril (all cold and cough preparations), Diclopar (fever and pain), Hemovit (iron tonic) and Malafin (anti malarial) account for 50 per cent of its sales. It does not yet produce antidiabetics, antihypertensives, ophthalmic preparations.[xxi] TPI has started producing fixed-dose combinations of three ARVs. With financial assistance from Action Medeor, a German NGO and technical assistance from Krisana Krasintu of Thailand, TPI is implementing a programme for production and quality assurance and setting up a GMP compliant plant for ARVs, including the second-line ARVs (Losse, Schneider and Spennemann, 2007, pp. 23-24). According to Shelys Pharmaceuticals (2008), it plans to diversify to ARVs, large volume perenterals and anti tuberculosis drugs. Roche has announced that it will provide technical expertise to Shelys Pharmaceuticals to produce the second-line ARV, saquinavir.[xxii]

Apart from TPI and Shelys, Tanzanian manufacturers sell only in the domestic market. TPI exported about 3 per cent of its production in 2004-05. But Shelys is a substantial exporter to neighbouring countries in East Africa. It exported about 18 per cent of its production in 2004-05. In 2003, it acquired Beta Health care a leading healthcare manufacturing company in Kenya. Shelys and Beta's products are available in about 22 countries in Sub-saharan Africa (Shelys Pharmaceuticals, 2008).

Although the pharmaceutical industry in Tanzania has been in existence for quite some time now, financial conditions and growth have not been satisfactory for most of the companies. TPI, the second largest company reported losses until 2002. Since then it has started earning profits but accumulated losses are yet to be wiped out (Losse, Schneider and Spennemann, 2007, p. 25). Shelys is believed to be a profitable concern but like the other manufacturers, suffers from gross under-utilization of capacity.[xxiii] Interchem used only 50 per cent of its overall production capacity in 2004-05.[xxiv] Shelys used in 2005, only 36 per cent of capacity in tablets, 30 per cent in capsules, 57 per cent in liquid orals and 30 per cent in dry syrups (including penicillin products). Similarly for Keko and Tanzansino, the capacity utilization has been very low (Ministry of Health & Social Welfare,

2006, annexures). According to the manufacturers, a major reason for underutilization of capacities is the stiff competition from imported products (Ministry of Health & Social Welfare, 2006, p. 9).

Like so many other similar developing countries, Tanzania in fact suffers from some inherent cost disadvantages. An investigation by the Ministry of Health & Social Welfare, 2006) has found the major problems as:

- Finance: access to both working capital and long term credit has been limited. The cost of finance also has been very high. This has prevented most of the companies from undertaking improvements for operations and expansion.
- Utilities: The cost of electricity is very high – in fact it is the highest in the SADC (Southern African Development Community) region and water supply is erratic.
- Technical expertise: The country suffers from lack of local people with expertise in pharmaceutical manufacturing. There are only two pharmaceutical training institutes and the curriculum does not emphasize GMP and other regulatory issues (Ministry of Health & Social Welfare, 2006, pp. 15-16).

As officials of Shelys Pharmaceuticals explained to us, contrary to common belief, labour costs in Tanzania are actually not low. [xxv] The wage rate of unskilled workers is lower in Tanzania than in India. But the cost advantages are often not realized because of lower productivity. Technical and senior managerial manpower are imported mainly from India, for example by Shelys and Zenufa. To attract such people to come to Tanzania from India, higher salaries and perquisites are offered, which makes such costs actually higher than in India.

The situation in Tanzania's pharmaceutical industry seems to support those who are critical of local production in developing countries and argue that if enhancing access is the objective then rather than promoting local production, they should import drugs from other countries which can produce drugs more efficiently.[xxvi]

But there are problems of relying on foreign sources such as India, as we will elaborate below. We will argue that it is important for Tanzania to develop a pharmaceutical industry in the country to take care of her drug needs. And to do so an industrial policy is necessary. This will be discussed in the next section. A basic problem with much of the critical writing on local production is that it is static in nature. It does not consider the possibility that competencies can be created to produce drugs efficiently. We may add in this connection that the failure to reap the advantages of economies of scale due to small markets is often cited as an important reason for the higher cost of production in smaller developing countries. But economies of scale can be more of an issue for the production of APIs. In formulations, average fixed costs are often higher not because of technological reasons, but for the failure to utilize the capacities installed as in the case of Tanzania.

Pharmaceutical market in Tanzania and role of India[xxvii]

Drugs imported from India (and other countries) and those locally produced are distributed to the ultimate consumers through an elaborate network (see the Chart on the distribution structure of pharmaceuticals in Tanzania). The two broad channels are:

(i) The government's Medical Stores Department (MSD) and
(ii) Private importers/distributors/wholesalers.

MSD is the single largest distributor of drugs in Tanzania. In 2004-05, drug purchased by MSD ($ 43 million) accounted for about 40 per cent of the total market of $ 110 million.[xxviii] Currently its share is estimated to be about half.[xxix] It procures drugs through a process of competitive bidding from both local and foreign sources and distributes these primarily through public health facilities (dispensaries, health centres and hospitals). It also supplies drugs to not-for-profit organizations such as NGO/FBO health care facilities.

In 2004-05, MSD imports ($ 32 million) accounted for about 74 per cent of its drug purchases of $ 43 million (Ministry of Health & Social Welfare, 2006, pp. 9, 12). India accounts for about 60 per cent of MSD imports.[xxx]

The low share of local production in MSD supplies is explained by a number of factors. As we have mentioned above, the capacity of local manufacturers is limited: they do not produce a number of essential medicines such as IV fluids, injectables, higher antibiotics and many other types of drugs.

Drug procurement, particularly for HIV/AIDS, malaria, tuberculosis has significantly increased under international initiatives such as GFATM and United States President's Emergency Plan for AIDS Relief (PEPFAR). Tanzania is a beneficiary under both GFATM and PEPFAR. Tanzania is in fact one of the 15 focus countries under PEPFAR. But to be eligible to supply drugs, manufacturing must conform to required quality standards: USFDA standards under PEPFAR and WHO Prequalification project standard under GFATM. Tanzania manufactures anti-malarials and has also started production of ARVs for HIV/AIDS. But as we have mentioned above, none of the local manufacturers have yet applied for getting their plants approved and hence cannot supply the drugs purchased by MSD under these programmes.

Local manufacturers receive a price preference of 15 per cent in MSD tenders. This operates as follows: 15 per cent is added to the cost+freight price of international suppliers. This is compared with the price quoted by local manufacturers. The latter gets the order if its price is less than or equal to the international suppliers price+15 per cent. Previously another 8 per cent was added to the cost+freight price of international suppliers to account for the clearing and transport costs which MSD incurs for imported drugs. Now this has been stopped. Thus the effective protection for local manufacturers is now less because their prices are post-delivery, i.e., include the transport cost to MSD warehouses.

The 15 per cent price preference for the local manufacturers is also often negated because of the practice of marginal cost pricing by some large importers. As we have mentioned above, Africa is not the main market for the large Indian generic companies. To win the tenders, these companies can quote a price below their full cost of production. Given the capacities already installed, they still earn additional profits provided of course the variables costs are covered. Marginal cost pricing by major international manufacturers is a major issue for the local industry.[xxxi] There is no government machinery for investigating anti-dumping activities of importers and imposing countervailing duties wherever dumping is confirmed. Thus the international suppliers can very easily go on supplying at below production costs.

Such high dependence on imports is not desirable from the point of view of access to essential medicines by the people of Tanzania. Most of the procurement by MSD is done through one big tender annually. For unanticipated requirements, there are provisions for emergency purchases. For drugs locally produced, emergency procurement can be made without much delay. But for drugs not available locally, floating international tenders and arranging supplies from foreign manufacturers

can take substantial time. Particularly in cases of public health crises, this can be a big bottleneck to ensuring access. Shelys Pharmaceuticals consider manufacturing flexibility as an important advantage of the local industry. They can very quickly change their manufacturing schedule depending on demand conditions and supply the requirements.[xxxii]

Thus it is very important to promote local production. Local manufacturers must not only be protected particularly against unfair import competition. They also should be encouraged to take up production of items not currently produced. For this, as we will discuss below a proper industrial policy is necessary.

In the private sector, the drug import trade is dominated by few large organizations, for example, Salama, Phillips, Astra Pharma, Macmedics, Harsh, Heko, Samiro, J D Pharmacy, Metro. They combine the functions of importing, distributing and wholesaling. Some of them even have retail outlets in Dar-es-Salaam. They are the main source of supply of drugs for the private retail drug shops.

Previously Indian companies used to export to Africa through European companies such Missionpharma Helm, Troge etc. Now they export directly to the private market through local logistics partners, who usually are these local importers/distributors. Some companies have country managers who oversee the operations. Some Indian companies have medical representatives to promote their products. These and other marketing costs are borne in different ways: (i) incurred by the companies themselves (ii) incurred by the importers/distributors and reimbursed by the companies (iii) incurred by the importers/distributors and adjusted through higher sales commissions etc. The promotional literature is mailed from India. Some these distributors, for example Astra Pharma and Phillips have their own sales representatives in different parts of the country for collecting orders for supply to retail outlets.[xxxiii]

The pharmaceutical market in Tanzania can be classified as follows:

- Patented drugs
- Generics

The patented drugs are high priced and are mainly marketed in the branded segment in urban areas primarily Dar-es-Salaam. Precise estimates are not available about the share of patented drugs in the Tanzanian market, but it is considered to be quite small. As we have mentioned above, MNCs do not produce any drug in Tanzania. The MNCs manufacture patented drugs mainly in developed countries and supply these to Tanzania (and other countries). Developed countries accounted for about 15 per cent of Tanzania's imports of drugs of both patented and generic drugs in 2002. UK was the largest source (8 per cent of Tanzania's imports), followed by Switzerland and Germany, 2 per cent each, and USA, Denmark, and France 1 per cent each (Mhanwge, 2004, p. 58).[xxxiv]

The generics market can be further classified into:

- Branded generics
- Generic-generics

Like the patented drugs, the branded generics market is primarily located in urban areas. The rural market is primarily generic-generics. There is a perception that generics from Europe (and also from

Cyprus and Egypt) are of better quality and hence these products are sold at a premium in the branded generics segment.

The rural generic-generics market is highly competitive and price sensitive. A survey of the rural retail market in Tanzania by Mackintosh and Mujinja (2008) reveals that the market is dominated by supplies from Tanzania itself, India and Kenya and that there is hardly any significant price differential between the prices by country of origin.

Pharmaceutical companies supplying the generics market in Tanzania can be classified between (i) those who follow proper quality standards and (ii) those who don't. The larger and more reputed Indian companies with larger overheads and larger investments in GMP plants are finding it very difficult to compete in the generic-generics markets with suppliers including from India who are less quality conscious. In some of the products, these larger companies have become non-competitive. Zydus Cadila, an Indian company has decided to withdraw from Tanzania. The products registered have not been renewed. Inability of the Tanzanian drug control authorities to prevent the sale of sub-standard drugs by unscrupulous suppliers has been cited as one of the major reasons for their withdrawal.[xxxv] The other larger Indian companies such as Ranbaxy, Cipla, Sun, Glenmark have not withdrawn. They are trying to target the niche markets in urban areas where there are entry barriers and branding is possible.

It is no wonder, therefore, that the rural market survey cited above (Mackintosh and Mujinja, 2008) shows that the predominant suppliers from India are not these larger companies but smaller companies such as Simrone, Aurochem and Lincoln. An official of a local manufacturer pointed to us in an interview that they are not afraid of competition from quality conscious Indian companies. Their problem rather is with those Indian companies who sell substandard drugs at lower prices without incurring the necessary costs.[xxxvi] It is not difficult for unscrupulous manufacturers to enter the market – hardly any fixed investments are required. What they need to do is to tie up with some importers/distributors/wholesalers. The latter already have a marketing infrastructure in place. Together with the other products from more reputed companies, they can also push the sales of these sub-standard products. Profits can be shared between the manufacturer and the wholesaler at the cost of the consumers.

Quality has been a major issue in Tanzania. Products meant for sale in Tanzania whether locally produced or imported are required to be registered. But the registration system was quite weak particularly before 1999 and there was hardly any quality control of drugs (Center for Pharmaceutical Management, 2003, p. 18). Some manufacturers including some from India are believed to have taken advantage of the lax quality control administration and supplied substandard dugs to the market.

A new law, Tanzania Food, Drugs & Cosmetics Act, 2003 was enacted and TFDA came into being in 2003. TFDA approves products on the basis of (i) product dossiers submitted by the manufacturers; (ii) plant inspection and (iii) laboratory tests, to ensure that the manufacturing plants follow GMP safeguards and procedures. Registration is given for 5 years and after that products need to be re-registered. [xxxvii]

After TFDA strengthened the registration system based on plant inspection, things have improved. Some of the international traders who used to get products manufactured from India on contract basis, disappeared. Both local and foreign manufacturers have been forced to upgrade. Some Indian companies initially failed to satisfy the inspectors. But they too have improved and now have

products registered with TFDA. But the problem persists, as Bate, *et al*, 2008, for example found for anti-malarial drugs procured from private pharmacies in major urban and peri-urban areas in major cities of six African countries including Tanzania. Newspapers continue to carry reports of widespread sales of fake drugs.[xxxviii]

TFDA's GMP standards are not as elaborate as in many regulated markets in the United States and Europe. Unlike USFDA, TDFA inspections are plant specific not product specific. TFDA has much less resources than USFDA. It primarily checks whether the procedures mentioned in the product dossiers submitted by the manufacturers are followed by them. It does not carry out checks separately for each product manufactured in the formulation plant. It also does not check the raw materials sources. In fact unlike as in USA, manufacturers catering to the Tanzanian market can change the manufacturers of APIs without seeking the permission of TFDA. TFDA does not insist in any bio-equivalence testing.

But ultimately what matters is not just specification of standards. What is critical is to monitor whether the manufacturers are following the procedures and abiding by the safeguards to produce drugs which are safe and effective and if not to take corrective action. This is where Tanzania lags behind like so many countries including India. There are manufacturers in both the countries, who knowingly or unknowingly produce drugs which do not satisfy the quality requirements and the drug control authorities in both the countries have not yet been able to take appropriate action to ensure it. Only about 400 retail drug shops are supervised by trained pharmacists (Part I drug shops). The remaining more than 6000 are non-prescription shops (Part II drug shops).[xxxix] About one-third of the population rely on these drug shops for their drug supplies, but the state of affairs is far from satisfactory. Among the problems are: poor dispensing practice and indiscriminate sale of drugs especially antibiotics, inadequate and/or poor storage condition for medicines, sale of sub-standard, unregistered or expired medicines Steps have been initiated in some districts to replace the current drug shops with Accredited Drug Dispensing Outlets (ADDOs) which would be better regulated and can sell some prescription drugs also.[xl] In Tanzania, the selling of expired products is not the responsibility of manufacturers but that of sellers. Since it is more difficult to regulate large number of sellers, the sale of expired products may be undetected. This provides an incentive to unscrupulous manufacturers and traders to indulge in such practices.

TFDA checks in the ports whether the drugs imported are registered or not. But so far as quality control is concerned, TFDA takes samples for testing only for tuberculosis, malaria and HIV/AIDS drugs. For other products, testing is done only when something is suspected. It does not carry out systematic and regular tests. In fact it lacks some sophisticated equipments to test some procedures for quality checking. In case of any complaint for a locally manufactured product, TFDA officials can go to the plant and investigate. This is not done for imported products. All that is being done is to communicate the complaint to the manufacturer. When registering an imported product, TFDA officials go to the country for plant inspection. But the current system does not ensure that products are actually manufactured in the plants approved by TFDA.

Imports in fact are more difficult to regulate and this is a major reason for promoting local production.

IV: Industrial policy for promotion of local production

Much of the traditional arguments in favour of local production for enhancing access to medicines are relevant in Tanzania. In the context of our discussion above, two major advantages are worth

reiterating: (i) local production will make the country less dependant on foreign sources and make supplies more reliable and (ii) local production will make it easier for drug control administration to ensure quality.

Tanzania's National Drug Policy of 1991, which continues to remain in force accords high priority to local production. The objective is to make the country self reliant in formulations. It also speaks of the long term policy " to support the gradual development of self-sufficiency in the production of intermediary and raw materials on such chemical entities, where Tanzania has a comparative advantage in production." It further states "the promotion and development of the national pharmaceutical industries will become a multi-sectoral activity, both encouraging national and international investment and transfer of technology. It will provide the necessary protection, until the industries have matured to full competitiveness (Ministry of Health, 1993, p. 12).

However the pharmaceutical industry in Tanzania has not developed as charted out in the National Drug Policy. The Policy spoke about protecting the local industries, but it is only recently that a 10 per cent import duty has been imposed on pharmaceuticals formulations (except on ARVs, anti-malarials, anti-TB drugs and MSD imports). Among the other official steps which provide some benefit to the local formulators, are no import duty on raw materials, components and machinery and no value added tax or excise for domestic formulations. Another policy is the 15 per cent price advantage given to local manufacturers for MSD procurement as mentioned above.

Like the 15 per cent price preference for local manufacturers in MSD tenders discussed above, the advantage of the 10 per cent is often negated by the practice of marginal cost pricing by some large importers. If such tariff protection is to have any effect, then as the manufacturers demand, a proper anti-dumping system must be put in place.

If the country is to develop a vibrant pharmaceutical industry, then a proper industrial strategy is required which goes much beyond the simple steps mentioned above. As India's experience shows, various types of incentives are required.

Pharmaceutical industrial policy in India[xli]

All the developing countries including India and Tanzania as colonial countries basically duplicated the patent system of their imperial masters. But the patent system inherited can be changed and used as an important element of the industrial policy to promote industries.

The net benefits of product patent system particularly in developing countries have long been questioned. The principal economic rationale for granting patents is that it will stimulate investment for research for innovation. Incentives for R&D for innovation are classified into two categories: "push" and "pull." Push programmes are designed to stimulate R&D by providing funds and inputs and reducing the costs. Pull mechanisms are essentially market enhancing. These create a market or increase the certainty of a market. The patent system has been the most important pull incentive. Product patents by granting market exclusivity permits the innovators to charge higher prices. This helps them to recoup the R&D costs and earn higher returns on their investments. MNCs consider product patent protection as fundamental for their research efforts for development of new drugs.

Pull mechanisms offer a better return for the output of R&D. It presupposes that the countries have the capacity and capability to undertake R&D. If they do not have this, if they cannot generate an output in the first place, then obviously the question of benefiting from the higher value of the output promised does not arise. In fact they lose out because they suffer from higher prices resulting from patent monopolies, but do not benefit from technological progress that is supposed to follow from patent protection.

Historically, pharmaceutical product patents have been recognized in most of the developing countries, such as India and Tanzania not because they wanted to do so but because it was thrust upon them by their imperial masters.

After independence some of the countries amended their patent laws and benefited. India is one such country. The product patent protection in India before 1972 did not have any positive effect because the MNCs, who held the patents were not keen on manufacturing (and R&D) activities in India and prevented the Indian companies from doing so by using their patent rights. It was not product patent protection but its abolition which operated as a pull mechanism in India by providing the Indian companies with the space of operations and the opportunity to develop and innovate. What Indian companies innovated are processes for manufacturing. And it is this capability which has permitted India to have an international presence and be a global source of drugs.

Tanzania never abolished product patent protection in pharmaceuticals. Tanzania can still do so as an LDC and we will discuss in the next section how some of the TRIPS flexibilities can be taken advantage of.

The success of the indigenous pharmaceutical sector was not due only to the revision of the patents act. India also had the entrepreneurial and technological skills to take advantage of the absence of product patent protection. The entrepreneurial spirit of the indigenous private sector was actively supported through public investments in R&D and manufacturing. These acted as push incentives. The laboratories set up by the government helped the development of the technological skills necessary for pharmaceutical industry. In fact a distinctive feature of the pharmaceutical industry in India has been the close collaboration between the government laboratories and the private sector. The setting up of the two public sector companies – Hindusthan Antibiotics Ltd (HAL) and Indian Drugs & Pharmaceuticals Ltd (IDPL) - was another important factor for the development of the industry. Though both the companies are now in financial trouble, they gave a tremendous boost to indigenous efforts in the private sector and contributed to its success. IDPL and HAL created a new climate and confidence that India could also manufacture APIs in a big way. Indian universities, like their counterparts in Tanzania did not provide the type of specialized training required by pharmaceutical companies By creating the demand for and helping the supply of inputs in the form of skilled labour, specialized capital, and other relevant services, both IDPL and HAL sparked industrial development in up and downstream businesses

The situation in Tanzania

Tanzania had none of these advantages. When Tanganyika and Zanzibar (which united in 1964 to form Tanzania) became independent in 1961, they had a small industrial sector. Even British investments were meagre as they preferred the neighbouring country of Kenya and made much of their investments there (Costello, 1994). Initially Tanzania followed a private sector led import substituting industrial strategy. But from 1967 to 1985, Tanzania followed a state-led industrialization programme under socialism. Private industries were nationalized and the growth of the private

entrepreneurs was stunted. By the time market reforms were initiated in Tanzania in the mid-1980s, the country therefore had a weak entrepreneurial class. The market reforms dislocated and discarded some of the useful capacities that were created during the socialistic phase (Wangwe, 2003, pp. 6-7).

The two pharmaceutical public sector companies, Keko and TPI were privatized. The government still holds 40 per cent equity in both the companies but has stopped providing any funds to these companies – a factor which makes the growth of these units quite difficult. Three industrial R&D institutions were set up in the early 1980s – Tanzania Industrial Research and Development Organization (TIRDO), Centre for Agricultural Mechanisation and Rural Technology (CARMATEC) and Tanzania Engineering and Manufacturing Design Organisation (TEMDO). But much of the R&D output was underutilized due to poor links with actual users, the industrial units, unlike in India. After the reforms the government has practically stopped funding these institutions and that has made them even more ineffective. Tanzania has an S&T policymaking body, Tanzania Commission for Science & Technology (COSTECH). But it is also suffering from lack of funds (Diyamett and Wangwe, 2001, pp. 9-10).

The government in Tanzania will have to play a more active role if the pharmaceutical industry in Tanzania is to develop. It cannot afford to withdraw from the economy as it has been doing under market reforms. The private sector in Tanzania is too small and weak to be left alone. The task of developing the pharmaceutical industry in Tanzania is actually much more difficult than what it was in India. Tanzania today faces an intense competition from the Indian generic companies – and as we have discussed above, not always fairly. When India started developing her industry in the 1970s, she had the advantage that she did not face any competition from generic producers from any other developing countries. India's competitors were mainly the MNCs who were not keen on producing drugs in developing countries. They preferred developed country locations despite the high labour costs.

As discussed above, tariff protection of 10 per cent or the 15 per cent price preference for MSD procurement may not be adequate particularly due to the practice of dumping. The government may announce a "negative list" of drug products. For the drugs so listed, imports may be banned. This is being practised in some countries such as Ghana and Nigeria. In Nigeria, the "import prohibition list" comprises of 18 types of products including paracetamol tablets and syrups, metronidazole tablets and syrups, haematinic formulations, multivitamin tablets and capsules.[xlii] In Tanzania, the Ministry of Health & Social Welfare (2006, pp. 19-20) has similarly recommended that the government may introduce such a list and include in it technologically simple products where substantial local capacities have been created but are not adequately utilized. It also provides an illustrative list of 16 products - a number of these common with the Nigerian list. Such a measure is unlikely to increase the price – rather, international competition will be replaced by local competition. The competition among the local manufacturers is intense enough to keep the prices low.

There can be and must be close collaboration between the government and the private sector. If India's experience is any guide then a big "push" is required for the development of the industry. Even if large investments by the government are not feasible or not advisable under the current circumstances in Tanzania, the government can provide a big push by coordinating drug production and procurement.

Government may announce a list of products to be exclusively procured by MSD from local units. This list may be larger than the negative list mentioned above. It may also include additional drugs

which are not currently produced or not adequately produced but which can be produced by Tanzanian manufacturers competitively within a reasonable period of time. The target may be not only development of new formulations but also the development of the capacity and capability to produce APIs. In India, close collaboration between government laboratories and private industry contributed to development of efficient processes for manufacturing many drugs. The same model can be attempted in Tanzania. The government may assure the market through MSD procurement, the public R&D institutions may develop laboratory scale processes and manufacturers may scale up these processes and manufacture the drugs. The Ministry of Health and Social Welfare may coordinate such efforts.

Such drugs to be produced and procured by MSD may include patented drugs. As we will see below, even under the current product patent regime in Tanzania, the law permits “government use” of patents - the government can empower local manufacturers to produce the drugs (on payment of royalty to the patentees). The fact that these drugs would be procured by MSD for distribution through public health facilities will satisfy the conditions that such government use is for “public interest” or “health or the development of vital sectors of the public-economy ..” (Section 61 of the Patents Act, 1987).[xliii]

The volume of production is more important for API production than for formulation production. Where economies of scale are considered to be particularly important, exports may be considered, at least to the regional markets.[xliv] Certain restrictions on the export of drugs in the patent regime under TRIPS have been removed for regional markets, as we will discuss below. Coordination among the government procurement agencies of the countries in the East African Community, for example may make it possible for each country to develop capacities for different drugs.

The government may provide assistance to the local units to improve drug quality. TFDA may not only regulate the products marketed in the country. The technical resources of TFDA built up over the years may also be used to help the local units to upgrade. If the Tanzanian companies can get their plants approved under the WHO prequalification project or by the USFDA, then they will be eligible to bid for MSD procurement of drugs such as HIV/AIDS, malaria and tuberculosis funded by GFATM, PEPFAR and others.

V: Patent reforms and TRIPS flexibilities

So far as patent protection is concerned, most of the African countries are members of either the African Organization for Intellectual Property (OAPI in French) for the French speaking African countries such as Benin, the Central African Republic, Niger, Senegal or the African Regional Industrial Property Organization (ARIPO) for the English speaking African countries such as Malawi, Uganda, Zimbabwe, Tanzania. Pharmaceutical product patent protection is provided in each of the OAPI countries. Patents are actually issued by OAPI and then regulated by the respective states. For the English speaking African countries, patents may be obtained either through a national procedure or through ARIPO. Under the Harare Protocol adopted in 1982, ARIPO Office can receive and process patent applications and also grant patents subject to the consent of the member countries. ARIPO countries too recognize pharmaceutical product patents except Somalia which did not sign the Harare protocol. (Ghana signed the Protocol but did not accept pharmaceutical patents in the past). Among the non-OAPI/ARIPO African countries, Angola did not and still does not provide for product patents in pharmaceuticals (but it

recognizes pharmaceutical process patents). Djibouti did not have any patent law. No patent applications are accepted pending the introduction of a patent law. Eritrea is another African country with no patent law. But she is not yet a member of WTO.[xlv]

It seems that Angola, Djibouti, Eritrea and Somalia are the only African countries which still do not recognize product patents in pharmaceuticals. All the other African countries including the LDCs provide product patent protection in pharmaceuticals, though under TRIPS they are exempted from doing so till 2016.

Tanzania Patents Act

Before the Patents Act, 1987 (which came into effect in 1994), Tanzania did not have an independent patent system. Under the Patent (Registration) Ordinance (chapter 217) of 1962 enacted soon after her independence, patents granted in UK were automatically eligible for registration in the country with all the patent rights of the UK patent (Mwalimu, 2003).

Before WTO came into being in 1995, individual countries were free to have their own patent regime. When a new law was enacted in Tanzania in 1987, she could have abolished pharmaceutical product patents as India did in 1970 by replacing the British Act of 1911. But she chose not to do so. Under the Act of 1987, which is currently in force, both pharmaceutical products and processes can be patented in Tanzania.

The negative impact of product patents in products such as pharmaceuticals in developing countries in particular are now much more widely understood and discussed than before. African and other developing countries recognizing product patents had to pay exorbitant prices for the ARVs for HIV/AIDS. The lowest price from the MNCs for the three-drug combination (stavudine+lamivudine+nevirapine), which dramatically reduced AIDS deaths in developed countries, exceeded $ 10,000 per person per year in June 2000. Intense competition following generic supplies from India has drastically reduced the price. Now it is available at less than $ 100 (MSF, 2008, p. 6).

When South Africa and Brazil wanted to take some TRIPS complaint measures to make medicines more affordable and accessible, MNCs and some developed country governments resisted such efforts. A law suit was filed in South Africa and a complaint was lodged against Brazil in the WTO panel. In both the cases, ultimately the MNCs did not have their way. But apprehensions were increasingly being expressed whether access to medicines can improve under TRIPS. The WTO Ministerial Conference at Doha adopted a special declaration on issues related to TRIPS and public health in November 2001. The Doha Declaration clarified and confirmed the rights, which member countries have in taking appropriate measures to protect public health. For the LDCs, a significant step that was taken was that they were exempted from providing product patent protection in pharmaceuticals until 1 January 2016 (para 7).

However international concerns about product patents did not have much impact in Tanzania, though it is among the worst sufferers. Tanzania continued with the old 1987 Act which is in

fact much more extensive than the minimum standards required to be followed under TRIPS, except perhaps the term of patent. Unlike the minimum term of 20 years required under TRIPS, in Tanzania, the term of a patent is only 10 years, though it can be extended for further periods of 5 years each (Section 38(2)(a and b) of Patents Act, 1987).

Even if Tanzania chooses not to abolish product patents in pharmaceuticals, it could have amended the law to take advantage of some flexibilities permitted under TRIPS and to minimize the effects of product patents.

TRIPS flexibilities

Within the scope of TRIPS, the following are the main flexibilities which developing countries can use:

1. Provide exemptions from grant of patents in certain cases
2. Provide exceptions to product patent rights in certain cases
3. Provide for government use and
4. Provide compulsory licenses to non-patentees[xlvi]

Exemptions from grant of patents

Under Article 27(1) of TRIPS, patents will have to be provided for inventions, which are "new, involve an inventive step and are capable of industrial application" The agreement however does not define these terms. This provides some flexibility. India has taken advantage of this flexibility. Under Section 3(d) of the Patents Amendment Act, 2005, derivates of known substances such as salts, esters, polymorphs, particle size, combinations, cannot be patented "unless they differ significantly in properties with regard to efficacy". In other words, secondary patents would not be permitted unless these are therapeutically significant. Using this flexibility, India has been able to deny Novartis the patent for Gleevec, an anti-cancer drug. The Patent office rejected the patent application of Novartis on the ground that its patent relates to a new form (beta crystal form) of a chemical entity, imatinib mesylate patented before WTO came into being in 1995. It was not a significant improvement in terms of efficacy and hence not patentable under section 3(d). Unless Tanzania makes corresponding changes in her patent law, she cannot import from India (or develop herself) such products.

Exceptions to exclusive rights

Patents basically confer on the patentee the right to prevent others from using the invention. But such rights are not absolute. All patent laws usually provide some qualifications to such exclusive rights. Article 30 of TRIPS permits member countries to "provide limited exceptions to the exclusive rights conferred by a patent … " This article does not list the specific acts for which exceptions can be provided. But the following three are the most significant and common exceptions which the national laws in many countries provided when TRIPS came into effect and which are considered to satisfy the conditions imposed in the Article:

1. Early working
2. Parallel imports and
3. Research and experimental use.

Early working

The “early working” provision is popularly referred to as the “Bolar” provision or exception, as it is known in USA. The Bolar provision is very important for generic entry. It permits generic entry soon after the patents expire and hence allows the consumers to benefit from competition and lower prices without delay. In the absence of it, generic companies will have to wait till the patents actually expire before they can start the tests necessary for getting regulatory approval. During the several months or even years it may take to get such approvals, the patentee will effectively enjoy monopoly status even though there are no legal barriers to entry.

Parallel Imports

Under Article 28 of TRIPS, the patent owner has the exclusive right to prevent others not only from making, using or selling the invented product or process in the country, but also from importing from other countries. This is however subject to Article 6 on "exhaustion." What it basically means is that the patent holder in a country cannot legally stop imports of patented products offered for sale in another country. Such imports of patented products without the consent of the patent holder in the importing country are known as parallel imports. This is very important in the pharmaceutical industry because the same patented medicine is often sold at different prices in different countries and hence parallel imports permit a country to shop around for the lowest price. The underlying justification of allowing parallel imports is that since the innovator has been rewarded through the first sale of the product, its patent rights have been "exhausted" and hence it should have no say over the subsequent re-sale. Under Article 6 of TRIPS as clarified by the Doha Declaration (paragraph 5(d)), each country is "free to establish its own regime for such exhaustion without challenge."

In the Tanzanian Patents Act, 1987, there is no explicit reference to any early working exception and parallel imports are also not permitted (Losse, Schneider and Spennemann, 2007, pp. 10-12).

Research and experimental use

Tanzania's Patent Act, 1987 does provide for this exception. According to Section 37(1), "The rights under the patent shall extend to only acts done for industrial or commercial purposes and in particular not to acts done for scientific research." But the exception can be not only for scientific research with no commercial intent. It is also possible to exempt acts of experimentation even if made with commercial purposes. This has not been done in the Tanzanian Patent Act.

Compulsory licensing

As different studies and reports have highlighted, in a product patent regime, a proper compulsory licensing system is of vital importance to deal with the negative implications of product patent protection on prices. If generic companies are given licenses to produce a patented drug on payment of royalty, then competition among manufacturers would drive down prices, but the royalty paid to the innovators would continue to provide funds and the incentive for R&D.

In Section 52(1), the Tanzanian Patent Act, 1987 lists the grounds for granting compulsory licences. These basically reduce to two grounds:

1. Failure to exploit or insufficiently working the patent in the country
2. Refusal to grant voluntary licence.[xlvii]

It is noteworthy that Patents Act, 1987 states that a compulsory licence can be granted on the ground "that the working of the patented invention in the United Republic is being hindered or prevented by the importation of the patented product …". According to Losse, Schneider and Spennemann (2007, p. 14) such a local working requirement is not TRIPS compliant. But Musungu and Oh (2007, pp. 30-31) argue that this can be a valid ground for granting a compulsory licence under TRIPS.

There is significant scope for Tanzania to improve her compulsory licensing regime. The list of grounds for granting such licences can been enlarged by incorporating grounds which are quite standard in many other countries, for example excessive pricing due to anti-competitive behaviour of the patentees. The procedure for the grant of compulsory licences also can be improved. In Tanzania, compulsory licences can be granted only by a court and that too after four years from the filing of an application or three years from the grant of a patent, whichever is later. This is not mandatory under TRIPS. Applicants are required to negotiate with the patentees for a voluntary licence before applying for a compulsory licence. The qualification in TRIPS that in national emergencies or other situations of extreme urgency this requirement may be waived is not there in the Tanzanian law (Losse, Schneider and Spennemann, 2007, p. 14).

As a follow up to the Paragraph 6 (of the Doha Declaration) problem of using the provision of compulsory licences by countries with insufficient or no manufacturing capacities, the member countries decided to waive some requirements of Article 31 of the TRIPS agreement on 30 August, 2003. It was decided on 6 December, 2005 to amend the TRIPS agreement to incorporate the waiver with a new Article 31*bis*).[xlviii] Under the new provision, Tanzania can import drugs for which it has insufficient or no manufacturing capacities under compulsory licensing from another country, say India. In that case royalties are payable in India, not in Tanzania. Another important change introduced is that if a developing country or an LDC is a member of a regional trade agreement with 50 per cent membership from LDC countries, then any member country can export without any restriction to the other member countries of the agreement, drug products produced or imported under compulsory licenses. This has been done to utilize the advantages of economies of scale.[xlix] And Tanzania, for example, which is a member of the East African Community can take advantage of it (Losse, Schneider and Spennemann, 2007, p. 14). The majority of EAC are LDCs - Tanzania, Uganda, Burundi, and Rwanda. Kenya is the only non-LDC in the group. The Patents Act of 1987 has not yet been amended to benefit from such provisions. Not only Tanzania. Other African countries too with underdeveloped pharmaceutical industry have not been able to use such TRIPS flexibilities (Avafia, Berger and Hartzenberg, 2006).

Government Use

As we have already mentioned above, Section 61 of Patents Act, 1987 permits "government use" of patents. The TRIPS (Article 31) requirement that such uses are limited to "public, non-commercial purposes" is not qualified in the Act. But Tanzania has never used this positive aspect of its patent law.

Patent reforms in Tanzania

Tanzania has initiated the process of amending the Patents Act, 1987. A task force has been set up with membership of different stakeholders. But this is a part of an elaborate exercise to revise and consolidate the entire intellectual property system including other laws such as Trade and Service Marks Act, 1986.[l] This reflects a lack of urgency on the part of the government in Tanzania to use the LDC flexibility available till 2016. Tanzania could have simply suspended pharmaceutical product patenting without going for other changes which take time. As we have mentioned above, initially in the TRIPS agreement, the transition period was 1 January, 2006. It was extended to 2016 for pharmaceutical products and to 2013 for other products. It is important to note that for other products, the legal changes already made as on the beginning the additional transition period, i.e., 1 January, 2006 are not permitted to be rolled back. For pharmaceuticals no such restrictions apply. Any existing laws and regulations can be amended or suspended.[li]

VI: Conclusions

Promotion of local production of pharmaceuticals figures prominently among the solutions being discussed to enhance medicine access in developing countries. India is often cited as an example of a developing country benefiting from the development of pharmaceutical industry. Taking advantage of the abolition of product patent protection in pharmaceuticals in 1972 and supported by other industrial policies, India has achieved enormous progress and has received world wide recognition as a low cost supplier of quality drugs. To implement TRIPS, India has re-introduced product patent protection in pharmaceuticals from 1 January, 2005. It is apprehended that as a result access to medicines will be adversely affected - African countries for example will not be able to import the new essential drugs from India.

Local production has been developing in Africa but the countries are still primarily dependent on imports and there are some countries with no manufacturing capacity, not even for packaging of imported products. India has played a major role in reducing the prices of HIV/AIDS drugs. But in general, Africa constitutes only a small market for India generic exporters. They are more interested in the larger and more lucrative North American and European markets.

There are 8 manufacturers of pharmaceuticals in Tanzania supplying nearly a third of the market. But the production activities are relatively simple. They do not produce the active pharmaceutical ingredients (APIs). They also do not produce more technologically sophisticated products such as IV fluids, injectables, higher antibiotics and many other essential drugs. The financial condition and the growth have not been satisfactory. Like so many other developing countries, Tanzania suffers from some inherent cost disadvantages.

The situation in Tanzania's pharmaceutical industry seems to support those who are critical of local production in developing countries and argue that if enhancing access is the objective then they should import cheaper drugs from other countries rather than promote local production. But there are problems of relying on foreign sources such as India. If Tanzania is to take care of her drug needs, it is important to develop local production of pharmaceuticals. And it is possible to do so with the help of a proper industrial strategy. A basic problem with much of the critical writing on local production is that these are static in nature. These do not consider the possibility that competencies can be created to produce drugs efficiently.

The government does provide some facilities to local manufacturers, for example, a 10 per cent import duty on pharmaceuticals formulations (except on HIV/AIDS, malaria and tuberculosis drugs and on government imports), no import duty on raw materials, components and machinery, no value added tax or excise for domestic formulations, a 15 per cent price advantage for local manufacturers in government procurement. But these are not enough. The country lacks a proper industrial policy to develop a vibrant pharmaceutical industry.

India has been able to develop a pharmaceutical industry through the pull incentive of abolishing product patent protection in pharmaceuticals aided by the push incentives of public investments in manufacturing and R&D. Tanzania lacks some of the advantages which India enjoyed. Still there is significant scope for government intervention. The government in Tanzania cannot afford to withdraw from the economy the way it has been doing under market reforms. It can provide a big

push by coordinating drug production and procurement even if direct public investments in a significant scale are not considered feasible.

Even before TRIPS, Tanzania never abolished product patent protection in pharmaceuticals. But the negative impact of product patents in developing countries in particular is now much more widely understood and discussed. Even now she can abolish product patent protection. Under TRIPS, Tanzania, as a least developing country is not required to introduce such protection in pharmaceuticals till 2016. Even if she chooses not to abolish product patents, there are other TRIPS flexibilities which Tanzania can use to develop her industry and enhance access to medicines.

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Table 1: World Pharmaceutical Market, 2006

	Market ($ million)	Market (per cent)
Americas	372,624	50.1
Western Europe	208,262	28.0
Asia	128,339	17.2
Eastern Europe	19,961	2.7
Middle East/Africa	14,824	2.0
TOTAL	744,008	100.0

Source: Espicom World Pharmaceutical Market Fact Book, 2006

Table 2: India's Pharmaceutical Exports

	1994-95 (Rs million)	1994-95 (per cent)	2006-07 (Rs million)	2006-07 (per cent)
Europe	10663	42.4	76661	30.7
America	3661	14.6	67573	27.1
Asia	6476	25.8	50553	20.3
Africa	2676	10.7	35237	14.1
Middle East	1465	5.8	16539	6.6
Oceania	182	0.7	2799	1.1
Others	0	0.0	59	Neg.
Total	25123	100.0	249421	100.0

Source: India's Directorate General of Commercial Intelligence and Statistics (DGCI&S) trade data accessed from the "India Trades" data base of the Centre for Monitoring Indian Economy.

Table 3: India's Pharmaceutical Exports to Major African Countries

	1994-95 (Rs million)	1994-95 (per cent)	2006-07 (Rs million)	2006-07 (per cent)
Nigeria	888	33.2	5908	16.8
South Africa	169	6.3	4413	12.5
Kenya	433	16.2	2929	8.3
Ghana	92	3.4	2050	5.8
Uganda	241	9.0	1528	4.3
Tanzania	132	4.9	1522	4.3
Congo, D.R.	0	0.0	1438	4.1
Egypt	87	3.3	1398	4.0
Sudan	30	1.1	1159	3.3
Ethiopia	82	3.1	958	2.7
Cameroon	7	0.3	943	2.7
Zambia	58	2.2	917	2.6
Angola	2	0.1	912	2.6
Guinea	9	0.3	826	2.3
Benin	1	0.0	819	2.3
Algeria	2	0.1	737	2.1
Zimbabwe	24	0.9	683	1.9
Mozambique	16	0.6	656	1.9
Mauritius	39	1.5	428	1.2
Malawi	21	0.8	413	1.2
Morocco	3	0.1	409	1.2

Source: India's Directorate General of Commercial Intelligence and Statistics (DGCI&S) trade data accessed from the "India Trades" data base of the Centre for Monitoring Indian Economy.

Note: Only those African countries which individually have an export share of more than 1 per cent of India's total pharmaceutical exports (2006-07) have been included in this table.

Table 4: Geographical area-wise sales of Indian generic companies, 2006-07

Indian company	Major markets
Ranbaxy	• USA: 31% of total formulation sales of $ 1223 million • Europe: 27.1% • India: 21.3% • Latin America: 3.9% • Africa: 6.9% ($ 85 million), of which South Africa $ 24 million
Dr Reddys	• North America: 43.6% of total sales of Rs 65125.7 million • Europe 22.5% • India: 13.6% • Russia/CIS: 7.5% • Others: 12.8%
Cipla	• India: 49.6% of total gross sales of Rs 35331.7 million • North/Central/South America: 16.6% • Africa: 14.1% • Europe 10.6% • Australasia: 5.5% • Middle-east: 3.5%
Sun Pharmaceuticals	• India: 67.4% of total formulation sales of Rs 19017 million • US generics: 27.1% • Others: 10.6%
Wockhardt	• Europe: 54% of total revenue of $ 673 million • India: 29% • US: 10% • Rest of world: 7%
Lupin	• India: 53% of total sales of Rs 20716.5 million • Advanced markets: 22% • Emerging markets: 25%
Ipca	• India: 46.7% of total income of $ 227 million • Europe: 23.3% • CIS: 7.9% • Asia: 7.5% • Africa: 7.5% • Americas: 5.7% • Australasia: 1.3

(Contd)

Table 4 (Contd)

Indian company	Major markets
Zydus Cadila	• India: 67% of total revenue of $ 415 million • US/Europe: 23% • Emerging markets: 10%
Glenmark Pharmaceuticals	• India: 43.8% of total formulations sales of $ 222.06 million • USA: 22.5% • Latin America: 14.5% • Semi-regulated markets: 19.2%
Torrent Pharmaceuticals	• India: 52.6% of total sales of Rs 12633.3 million • Brazil: 13.2% • Europe: 24.3% • Rest of World: 9.9%

Sources: Compiled from company Annual Reports and websites

Table 5 Overseas acquisitions by Indian pharmaceutical companies, 2002-06

Country	No of acquisitions
USA	14
UK	8
Germany	4
Japan	4
South Africa	4
France	4
Belgium	3
Brazil	3
China	2
Spain	2
Netherlands	2
Rep of Ireland	1
Romania	1
Mexico	1
Australia	1
Bulgaria	1
Czech Republic	1
Israel	1
TOTAL	57

Source: Mergers & Acquisitions database of the Centre for Monitoring Indian Economy, Mumbai, accessed 4 August, 2008

Table 6 India companies with products registered in Tanzania

Company	No of products	Regulatory approvals in USA
Cipla	165	ANDA; DMF
Ranbaxy Laboratories	79	ANDA; DMF
IPCA Laboratories	59	ANDA; DMF
Aurochem Pharmaceuticals (India)	44	Neither
Panacea Biotec	41	Neither
Dr. Reddy's Laboratories	40	ANDA; DMF
Unichem Laboratories	40	ANDA; DMF
Aurobindo Pharma	37	ANDA; DMF
Intas Pharmaceuticals	37	Neither
Sun Pharmaceutical Industries	36	ANDA; DMF
Lincoln Pharmaceuticals	36	Neither
Cadila Pharmaceuticals	36	DMF
Glenmark Pharmaceuticals	36	ANDA; DMF
Wockhardt	34	ANDA; DMF
Medopharm	31	Neither
Alembic	28	DMF
Emcure Pharmaceuticals	24	DMF
Vital Healthcare	24	Neither
Unique Pharmaceutical Laboratories	21	ANDA; DMF
Cadila Healthcare	21	ANDA; DMF
Medreich Sterilab	20	Neither
Simrone Pharmaceutical Industries	20	Neither

Sources: (i) Col (2) - calculated from data on human drug products registered, obtained from the TFDA website (www.tfda.or.tz, accessed 1 October, 2007); (ii) Col (3) – obtained from the USFDA website, http://www.fda.gov/cder/dmf/ (for DMF) and http://www.fda.gov/cder/ob/ (for ANDA), accessed 8 August, 2008.

Note: Only those companies with 20 or more products registered in Tanzania have been listed in this table.

Table 7 Drug products registered in Tanzania, 2007

Country	No of products registered
India	1315
Kenya	307
Tanzania	269
Egypt	199
United Kingdom	165
Cyprus	137
Germany	131
Belgium	106
Switzerland	82
France	77
South Africa	65
Italy	59
Korea	58
Malaysia	52
Rep. of Yemen	35
Spain	31
Greece	31
China	24
Jordan	23
USA	23
Zimbabwe	22
Malta	21
Denmark	20
Netherlands	16
Republic Of Ireland	16
Portugal	14
Pakistan	13
Canada	12
Sweden	10

(Contd)

Table 7 (Contd)

Country	No of products registered
Puerto Rico	10
Hungary	8
Uganda	8
Thailand	8
Mexico	7
Japan	4
Senegal	2
Syria	2
Finland	2
Mauritius	2
Morocco	1
Austria	1
Total	3388

Source: Calculated from data on human drug products registered, obtained from the TFDA website, www.tfda.or.tz, accessed 19 September, 2007

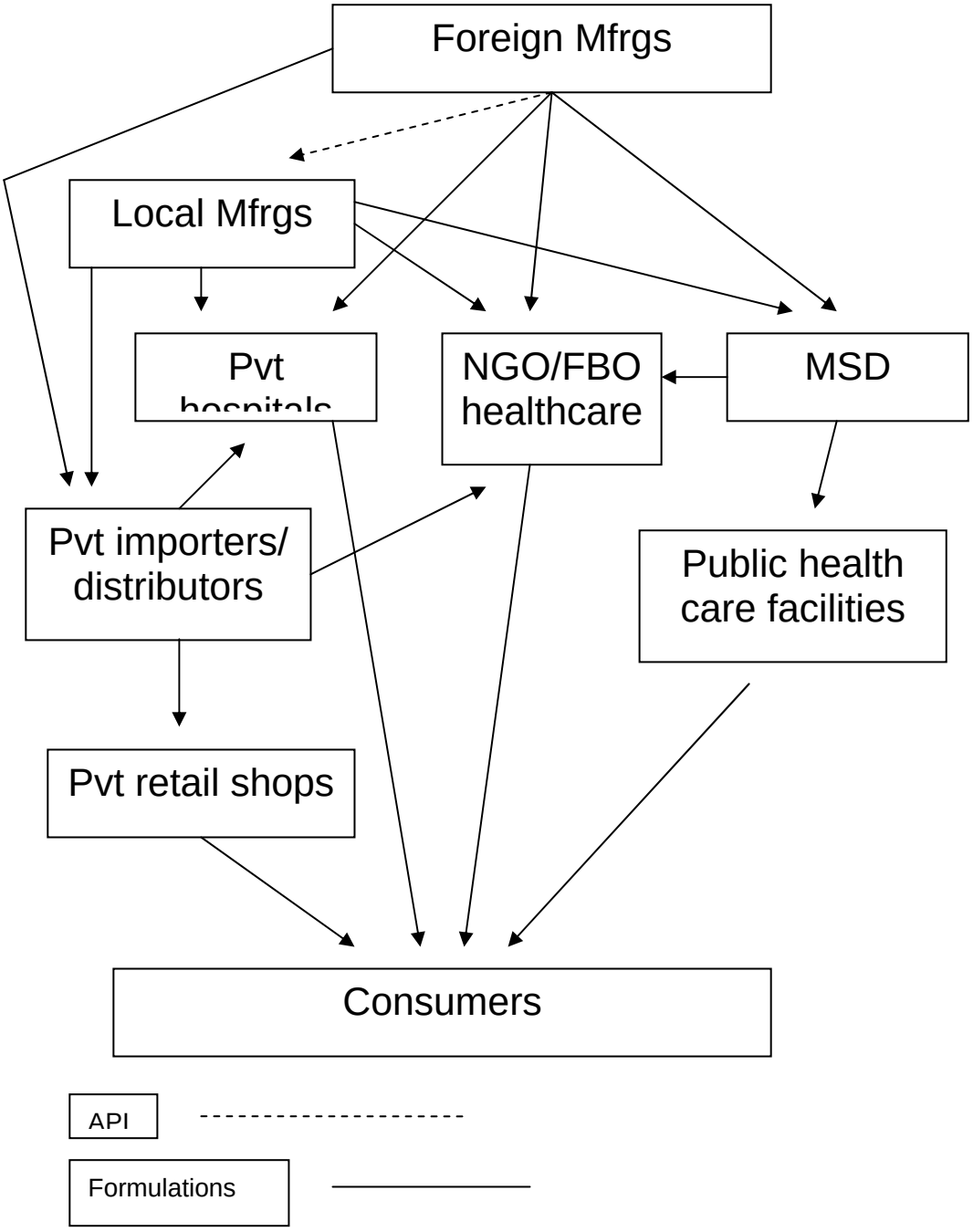
Table 8: Pharmaceutical Production and Imports in Tanzania, 2004-05

Company	Value of Production ($ million)	Value of Production (Per cent)	Sales to MSD ($ million)	Sales to private retail market ($ million)	Exports ($ million)
Shelys Pharmaceuticals	16023	49.2	5689	7441	2893
Tanzania Pharmaceutical Ind	6650	20.4	3990	2470	190
Interchem Pharma	4893	15.0	151	4742	0
Keko Pharmaceuticals (1997)	3686	11.3	1045	2641	0
Mansoor Daya Chemicals	669	2.1	47	622	0
Tanzinsino United Pharm	513	1.6	162	351	0
A.A. Pharmaceuticals	137	0.4	0	137	0
Total	32570	100	11084	18403	3083

Source: Ministry of Health & Social Welfare, 2006, pp. 9, 12. Figures in Tanzanian shillings (TShs) were converted to US $ by using the average exchange rate of 0.00095 for the year July 2004 to June 2005 obtained from www.oanda.com.

Note: Zenufa Laboratories is not listed in the table. It started production after 2004-05.

Structure of Distribution of Pharmaceuticals in Tanzania



NOTES

[i] See the Resolution taken in the Assembly of the African Union, Fourth Ordinary Session, Abuja, 30-31, January, 2005, accessed from www.african-union.org.

[ii] Currently 49 countries are designated as LDCs by the United Nations (33 in Africa, 15 in Asia and the Pacific and 1 in Latin America) - http://www.unohrlls.org/, accessed 27 August, 2008. Earlier the list of LDCs included 50 countries - Cape Verde has graduated from the list in 2007.

[iii] See "Frequently Asked Questions About TRIPS", accessed from www.wto.org. Currently 32 LDCs are members of WTO.

[iv] *Espicom World Pharmaceutical Market Fact Book, 2006*

[v] Data on chapter 30 pharmaceutical imports of countries have been obtained from the website of the International Trade Centre (http://www.intracen.org/appli1/TradeCom/TP_IP_CI_HS4.aspx?IN=30&RP=834&YR=2006&TY=I), accessed, June, 2008.

[vi] Company Annual Reports and websites.

[vii] See the "List of Pharmaceutical Manufacturers in Uganda", in the website of the National Drug Authority in Uganda (http://www.nda.or.ug), accessed 28 August, 2008.

[viii] See Guimer, Lee and Grupper 2004, annex 2 for an illustrative list of pharmaceutical manufacturers in different sub-Saharan African countries.

[ix] Unlike in the past, Indian companies increasingly export drugs to Africa directly rather than through European traders. It is possible that in 1994-95 in particular, some exports to some African countries may have been routed through Europe and hence the trade data used in the text are underestimates.

[x] We have considered chapter 30 pharmaceutical exports as formulations exports and the difference between total pharmaceuticals exports and chapter 30 exports as exports of APIs.

[xi] India's exports of chapter 30 formulations exports of Rs 32362.3 million to Africa in 2006-07 (= $ 714.6 million at the average exchange rate of 45.2849, accessed from the Reserve Bank of India website, www.rbi.org.in) is on fob basis. The import share on cif basis will be marginally higher.

[xii] WHO 2004, pp. 3-4 has highlighted the problem of production, consumption and trade measures using monetary values in the face of wide price differentials between prices of patented products and other prices.

[xiii] Calculated from data obtained from the GPRM website, http://www.who.int/hiv/amds/gprm/en/.

[xiv] Company Annual Reports and websites.

[xv] The information on the retail formulations market in India has been obtained from ORG-IMS, "Stockist Secondary Audit", December 2006.

[xvi] No government or private organization publishes regular data on the Tanzanian pharmaceutical industry and market. Import data are available with the Tanzania Food & Drugs Authority (TFDA). As explained in the text, all products marketed in the country are required to be registered with TFDA. In ports and airports, TFDA checks whether the drugs imported are registered or not. But TFDA does not process the import data on a regular and systematic basis. Ministry of Health & Social Welfare conducted a survey in 2006 while preparing a document on "Strategies for Promotion of Local Production of Pharmaceuticals in Tanzania." The report (Ministry of Health & Social Welfare, 2006) contains some useful data on the industry for the year 2004-05. The production and import figures for 2004-05 are from this report (p. 9). (The figures in Tanzanian shilling (TShs) have been converted to US $ by using the average exchange rate of 0.00095 for the year July 2004 to June 2005 obtained from www.oanda.com). Industry sources suggest that the proportion of local production has remained broadly the same out of the estimated market of $ 140 million in 2007.

[xvii] Company-wise product registration data have been obtained from the website of TFDA (www.tfda.or.tz), accessed 19 September, 2007.

[xviii] TFDA website (accessed on 29 August, 2008) mentions only 7 companies in the list of registered manufacturers. It has not been updated to include Zenufa Laboratories.

[xix] The account of the pharmaceutical manufacturers of Tanzania in this paragraph is based on Ministry of Health & Social Welfare, 2006, pp. 6-9.

[xx] Company website, www.zenufa.com, accessed 11 June, 2008; interview with a company official, 11 June, 2008, Dar-es-Salaam.

[xxi] Interview with an official of Shelys Pharmaceuticals, 9 June, 2008, Dar-es-Salaam; Shelys Pharmaceuticals, 2008.

[xxii] "Roche Engages in Four Additional AIDS Technology Transfers to Strengthen Local Manufacturing", January 9, 2008 (www.reuters.com).

[xxiii] Shelys Pharmaceuticals is a private limited company and information on its financial performance is not available publicly.

[xxiv] This has been calculated as the value of production of TShs 5150 million as a percentage of value of production of TShs 10500 million possible at full capacity.

[xxv] Interview, Dar-es-Salaam, 9 June, 2008.

[xxvi] See, for example, Kaplan and Laing, 2005 and Bates, 2008. See also Guimer, Lee and 2004, pp. 12-14; Rovira 2006, for a review of the issues.

[xxvii] This section relies to a great extent on the insights and information obtained from a number of officials of Tanzanian manufacturers/importers/distributoirs and Indian exporters - Shelys Pharmaceuticals, 27 September, 2006, Dar-es-Salaam; TPI, 3 October, 2006, Arusha; Harsh Pharmaceuticals, 29 September, 2006, Dar-es-Salaam; Astra Pharma, 28 September, 2006, Dar-es-Salaam; Phillips Distributors, 28 September, 2006, Dar-es-Salaam; Generics & Specialities, 5 October, 2006, Dar-es-Salaam; Intas Pharmaceuticals, 21 August, 2006, Ahmedabad; Torrent Pharmaceuticals, 21 August, 2006, Ahmedabad; Zydus Cadila, 22 August, 2006, Ahmedabad; USV, 6 May, 2008, Mumbai; Bluecross Laboratories, 7 May, 2008, Mumbai and personal communication, 23 May, 2008; Shelys Pharmaceuticals, 9 and 13 June, 2008, Dar-es-Salaam; Zenufa Laboratories, 11 June, 2008, Dar-es-Salaam; Dar-es-Salaam; TPI, 10 June, 2008, Dar-es-Salaam.

[xxviii] Ministry of Health & Social Welfare, 2006, pp. 9, 12 – values in TShs have been converted to US $ as mentioned above.

[xxix] Industry sources. In 2004-05, MSD did not handle about $ 6.6 million worth of donated drugs imported. Now most of the drugs donated are routed through MSD (interview with an official of the Ministry of Health & Social Welfare, 12 June, 2008, Dar-es-Salaam).

[xxx] Interview of MSD officials by Maureen Mackintosh and Phares Mujinja, 8 September, 2006, Dar-es-Salaam.

[xxxi] Interviews with an official of Shelys Pharmaceuticals, 9 and 13 June, 2008, Dar-es-Salaam.

[xxxii] Interview with an official of Shelys Pharmaceuticals, 9 June, 2008,Dar-es-Salaam.

[xxxiii] Interviews with officials of Astra Pharma and Phillips, 28 September, 2006 and 28 September, 2006 respectively, Dar-es-Salaam.

[xxxiv] GSK has 42 products registered through its subsidiary in Kenya. But these are mainly generics such as salbutamol, paracetamol, caffeine, sulphamethoxazole, chlorpheniramine, albendazole (see the list of products registered, TFDA website).

[xxxv] Interview with an official of the company, 22 August, 2006, Ahmedabad.

[xxxvi] Interview, 27 September, 2006, Dar-es-Salaam.

[xxxvii] For the discussion on the TFDA regulatory procedure and the difficulties of controlling quality in Tanzania, we have relied to a great extent on interviews with TFDA officials on 29 September, 2006, 10 and 13, June, 2008.

[xxxviii] See, for example, Dailynewsonline, 8 June, 2008 (http://dailynews.habarileo.co.tz).

[xxxix] Presentation of Sikubwabo S. Ngendabanka, Director, Business Support, TFDA on "Accredited Drug Dispensing Outlets: Tanzania Experience", at the MMV Access Symposium Getting Antimalarials to Patients, Kampala, 9 May 2007.

[xl] See, "ADDO Program at Glance", http://www.tfda.or.tz/Addopage1.html, accessed, 5 August, 2008.

[xli] This account of the pharmaceutical industrial policy in India is based on Chaudhuri, 2005, chapter 2.

[xlii] See the website of the National Agency for Food and Drug Administration and Control (NAFDAC) (http://www.nafdacnigeria.org), accessed 31 August, 2008.

[xliii] A copy of the Patents Act, 1987 was obtained, courtesy Sandy Harnisch, then of UNCTAD, Geneva.

[xliv] For a discussion of the prospect of Tanzania in the East African Community, see Losse, Schneider and Spennemann, 2007, pp. 32-42.

[xlv] See Boulet, 2000, Boulet and Forte, 2000 and Thorper, 2001. The African IP Law Guide (in http://www.adamsadams.com/index.php/african-ip-law) was consulted to check the current pharmaceutical patent status in Angola, Somalia and Djibouti.

[xlvi] This account on TRIPS flexibilities is based on Chaudhuri, 2005, chapter 3 – see the references in the chapter. See also Musungu and Oh, 2005. We have not considered here data protection.

[xlvii] See Musungu and Oh, 2005, pp. 28-31 for a list of grounds under which compulsory licences are granted around the world.

[xlviii] The amendment will formally come into effect after two-thirds of the members ratify it by 31 December, 2009 (initially the deadline was 1 December, 2007 (http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm, accessed 2 September, 2008). Till the TRIPS agreement is formally amended, the waiver will continue as per the 30 September, 2003 decision.

[xlix] See "Amendment of the TRIPS Agreement", http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm, accessed 2 September, 2008.

[l] Interview with an official of Business Registrations and Licensing Agency (BRELA), Ministry of Industry, Trade and Marketing, 13 June, 2008, Dar-es-Salaam.

[li] Draft UNCTAD document, ("Reference Guide to Intellectual Property and Pharmaceutical Production in Developing Countries") discussed in the informal peer review meeting, Geneva, 11October, 2007.