

LEGISLATION

SUMMARY

Poor countries: attuning patents to lifesaving drug access

Communicable diseases disproportionately affect the resource-constrained countries. As patent system does generate incentive to new drug development in profitable markets only, it does not work for poor end user's treatment needs. Nonetheless, increasing

pressure is registered nowadays for strategies up to promoting pharmaceutical innovation in the sake of the worst-off. Analysis here will compare some models in their potential to attune patents to lifesaving drug access.

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REGIONAL FOCUS

Sub-Saharan migrations: Does Europe really want to stop them?

This article analyses the shift in migration routes from West Africa to North Africa during the last century, and shows how these have eventually moved towards Europe since the 90s, in spite of the tightening of migratory regulations both in the Maghreb and the European countries. Migration flows from sub-Saharan countries are doomed to increase in the future but solutions advocated by European states focus on security, while greater attention should be put on the development of African countries, which is believed to remove the need to migrate.

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CASE STUDY

Role and accountability of peacekeeping missions

Peacekeeping missions intervene in conflict and post-conflict situations to restore democracy, rule of law and human rights. Acts of personal misconduct and particularly of sexual misconduct committed by peacekeepers delegitimize the entire role of the UN. Since crimes of sexual abuse, sexual exploitation and human trafficking have been condemned as grave crimes, to certain extent as war crimes in international and non-international armed conflict and crimes against humanity, the possibility of international criminal responsibility of peacekeepers may arise when troop-contributing countries fail to effectively prosecute the perpetrators.

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INTERNATIONAL LAW

Responsibility to protect and Africa

The Responsibility to Protect doctrine recognizes each State's responsibility to protect its population from genocide, war crimes, ethnic cleansing and crimes against humanity and the complementary duty to protect bearing on the international community when the State is "manifestly failing" to perform the protection. The growing success of the doctrine suggests the need to avoid any misuse of its principles. To this end, a strong cooperation between UN and regional organizations, especially in Africa, is recommended at the institutional level.

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LEGISLATION

Poor countries: attuning patents to lifesaving drug access

(Dr. Daniele Dionisio)

Shaping needs

4.8 billion people live in the developing countries: 43% of them rely on less than US\$ 2 a day. Communicable diseases (including HIV/AIDS, malaria, tuberculosis-TB, schistosomiasis, river blindness, Chagas disease, sleeping sickness, and leishmaniasis) disproportionately affect these populations. Treatments for these illnesses may be very expensive, or toxic, or difficult to administer, or ineffective if microbial resistance spreads (as is the case for resistant TB). Therefore, appropriately formulated novel medicines that are safe, affordable and effective are needed.

As current patent system does generate incentive to new drug development in profitable markets only, it does not work for poor end users in resource-constrained countries. Nonetheless, increasing pressure is registered nowadays for strategies up to promoting pharmaceutical innovation in the sake of the worst-off.

According to the resolutions of WHO's 61st World Health Assembly in May 2008, an expert working group (EWG) was established straight afterwards to examine innovative sources of funding to stimulate research and development (R&D) related to diseases that disproportionately affect the developing world (<http://www.who.int/phi/ewg/en/index.html>). Actually, there is expectation that the EWG would be up to selecting proposals for their ability to both drive innovation and ensure long-term access, while paying attention that R&D costs be separated from product end prices.

Analysis here will compare key models, including Product development partnerships (PDPs), Prizes, Advance Market Commitments (AMCs), Patent buy-outs, Priority Review Vouchers (PRVs), and Health Impact Fund (HIF). Patent Pools were just analysed in 02-2009 CALLS Newsletter.

Product development partnerships

These provide a framework for cooperation between the public (governments, academic and research institutions) and the private sector (companies, NGOs, and philanthropic organizations like the Bill & Melinda Gates Foundation). This is a working model, which enables both industry and government to do what they could not alone. Several PDPs have been established: amongst them, DNDi (Drugs

for Neglected Diseases Initiative)-Sanofi Aventis, and DNDi- Brazilian Farman-guinhos/Fiocruz, which have resulted in artesunate-amodiaquine (ASAQ) and artesunate-mefloquine (ASMQ) antimalarial fixed-dose combination production, respectively; TB Alliance-Tibotec, to expedite development of new TB drug TMC207; and DNDi-Merck partnership, to develop medicines for leishmaniasis and Chagas. Sustainability of PDPs might be enhanced if governments decided to effectively support them.

Prizes

Rewards to boost R&D may be in the prize form, that is a large enough cash bonus (lump sum) once a product (including vaccines and antibiotics) has been registered for marketing. Prize funds for TB and Chagas diagnostic tools have been proposed by the governments of Bolivia and Barbados. If coupled with openings to generic copy production, prizes would actually create good economic incentives and dominate prices when implemented as part of schemes that disconnect the cost of R&D from the price of medicines. Notably, prize amount to make it attractive to industry would be critical, along with risks of exceeding (or insufficient) payments than would be the case, or, even, of product withdrawn from the market after rewarding, due to adverse effects.

Advance Market Commitments

They guarantee future purchase of specified volumes of a product to be developed at an agreed price, provided it meets targeted standards and there is demand by countries. An AMC program for pneumococcal vaccines was launched in February 2007 by Canada, Italy, Norway, Russia and United Kingdom governments, along with the Bill & Melinda Gates Foundation. This is a working model, though critics deem firms selling medicines for the same disease may have no incentives to undertake AMC vaccine programs: vaccine discovery, indeed, while leading to progressive epidemic disappearance, would shrink market and prices for related medicines.

Patent buy-outs

This would be the case if governments, "tout-court" or through a partner organization (such as WHO) pledged to purchase future patent on a research product, aiming to make it available at low

or no cost. Patents would be sold to the highest bidder. This model would avoid monopoly price distortions, but shortcomings do exist, like collusion risks and hard patent value determination.

Priority Review Vouchers

This U.S. FDA program gives the producer of a "tropical" drug (not registered yet in the U.S.) a "voucher" entitling the company to fast FDA review (6 months or less) of a new application for any unrelated medicine it makes. Shortcomings were evidenced: no obligations to affordable prices; no openings to generic suppliers competition; no incentive to "tropical" therapy implementation; health risks bound with accelerated product review; litigation risks (Novartis is currently under fire due to PRV approved for its ten-year old, not yet registered in U.S., artemether/lumefantrine malarial combination). Anyway, PRVs could benefit high-tech, broad product portfolios generic firms from India, Thailand, Brazil, China, and South Africa, as they would be up to new drug development either for under-served or wealthy markets.

Health Impact Fund

It would offer firms a share of a fixed fund for each of ten years, in proportion to the share of health impact of their registered product out of all registered products. To exemplify, if all registered products saved twenty million "Quality-Adjusted Life Years" (QALYs), a registered product that had saved two million of these QALYs would receive ten percent of the fund. In exchange, the firm would offer royalty-free open license for generic copies following the reward period. While pushing medicine development for the poor, HIF is hard bet with regard to: 1) high level starting financing by partners (at least \$6 billion per year); 2) QALYs estimating complexity; 3) partner countries commitment to financial support for at least twelve years to secure innovators payments they could wait for.

Conclusions

None of the models above is likely to be enough solution, and a combination of two or more may be needed to ensure that outputs of R&D are available without restrictions. To this aim, all models should complement current intellectual property regimens and channel open source schemes. Meanwhile, EWG should continue discussion on a R&D treaty bound up with needs-driven health R&D and sustainable financing mechanisms.



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REGIONAL FOCUS

Sub-Saharan migrations: does Europe really want to stop them?

(Jacopo Marcomeni)

The extreme diversity in the ethnic composition of the people living in the Maghreb area, who are characterized by sub-Saharan, Berber, Arab and Hebraic influences, testifies of a long tradition of high mobility in North and West Africa. During the colonial period, West African migrations basically went from the Sahel countries, such as Mali, Burkina Faso, Niger and Chad, which do not have coastal borders, towards the coastal countries' cities in Cote d'Ivoire, Liberia, Ghana, Nigeria, Senegal and Gambia. During the 50s and 60s, these movements were particularly directed towards Ghana and Cote d'Ivoire. Ghana was hit by an economic crisis in 1969, provoking the expulsion of nearly two million immigrants, who then moved towards Cote d'Ivoire and oil-rich Nigeria. Similar crisis happened in Nigeria (80s), due to high levels of political corruption, and in Cote d'Ivoire (from 1993 to the beginning of the civil war in 2002), the last migratory pole in West Africa. No country emerged as new attraction pole for migrants in the region and an increasing number of people then started to move towards South Africa (after 1994) and Libya.

The embargo imposed on Libya by the UN Security Council between 1992 and 2000 played a decisive role in the increase in trans-Saharan migration. Disappointed by the perceived lack of support from fellow Arab countries during the embargo, Libyan leader al-Qadhafi embarked upon a radical reorientation of Libyan foreign policy. To counteract the effects of the embargo and the subsequent international isolation, al-Qadhafi started to particularly welcome sub-Saharan Africans to work in Libya in the spirit of pan-African solidarity. Traditionally a destination for North African migrants, in the early 90s most migrants came from Libya's neighbours Sudan, Chad and Niger, which subsequently developed into transit countries for migrants from a much wider array of sub-Saharan countries. Increasing sub-Saharan immigration was also part of a more general trend due to a restructuration and segmentation of the Libyan labour market, which further increased the demand for abundant and cheap African migrant labour. In September 2000, however, violent clashes between Libyans and African workers led to the deaths of 130 sub-Saharan migrants. The Libyan authorities instituted a number of repressive measures, including detention in prisons and camps, more restrictive immigration regulation and expulsions (which continue nowadays).

However, the Libyan state would soon manipulate this crackdown for foreign policy goals by presenting it as Libya's contribution to the fight against illegal migration vis-à-vis European countries as part of Libya's general efforts to become reintegrated into the international community. Migration from sub-Saharan Africa has continued because of the persistent need for cheap immigrant labour in Libya, although this migration became increasingly irregular. Nevertheless, it is likely that increasing repression in Libya has contributed to a partial diversion of the migration routes away from Libya and in the direction of Algeria, Morocco and Tunisia.

The increasing number of sub-Saharan migrants flowing to the Maghreb countries led Moroccan and Tunisian governments to harden their immigration laws. As for Morocco, the 02-03 law of 2003 has reunified the old regulation texts that went back to the French protectorate. The law is composed by 58 articles and focuses its interest on sanctions, both administrative and penal, against irregular migrants entering, but also leaving, the Moroccan state. The stay in the country is permitted only for immigrants in possession of a *carte de séjour* (when residing for more than 3 months) or a *carte d'immatriculation* (when residing continually for 4 years), while the law does not pronounce on family reunifications. The law has been criticized for its lack of protection towards the numerous refugees and asylum seekers present within the migrants. In this sense, even if the law has extended the international protection to minors and pregnant women, the principle of non refoulement defended by the Geneva Convention on refugees is not always respected, having the practice of mass expulsions in countries that don't guarantee the rights and freedoms of people continued, also after 2003. Morocco signed the Geneva Convention in 1957 but has stipulated an agreement with the UNHCR only in 2007. Before that date, the UN organization was able to confer protection to refugees but the Moroccan government didn't use to give the national document to all of them (necessary to live and work in the accepting state), fearing an invasion of refugees from everywhere in Africa. With this new agreement there is strong conviction that the situation will slowly get better. However, African migrants nowadays travel in mixed flows of people with different status, causing high confusion in the arrival states between the migrants that should be sent back and the ones who need

asylum but are often considered as illegal. For these reasons, the tightening of the regulation on immigration in Morocco has been considered as the result of the pressure exerted by the European states and Union so that North African countries would contribute to clamp down on irregular migration, in a perceived effort to "externalise" the EU border controls. Tightening of European visa policies with the institution of the Schengen agreements (effective since 1995) and the intensification of migration controls at official ports of entry, prompted an increasing number of West African migrants to avoid official air and maritime links and to cross the Mediterranean illegally from North Africa, joining the already established flow of Maghrebis, after crossing the Sahara overland. This is why the anti-immigrant riots in Libya have set a turning point in West African migration to North Africa and Europe after year 2000. Today, trans-Saharan migration routes are further diversified, with migrants moving to Algeria, Morocco and Tunisia, not only from Libya, but increasingly directly. As a consequence, departure points for Europe have remarkably increased and European countries (mainly Italy and Spain) have started to make bilateral agreements with North African counterparts, providing them of technical and financial aid and of a greater number of yearly migrant entries in change of higher standards of border controls. These agreements include the readmission of irregular sub-Saharan migrants from Europe and their deportation to their national territories. The increasing control of maritime routes going to the Canary islands, in the Strait of Gibraltar between Morocco and Spain and from Tunisia to Italy in these recent years have therefore been seen as the result of these agreements and have caused two main consequences. First, traditional migrant routes are becoming more risky and have pushed an increasing number of migrants, if not yet expelled, to try to cross the Mediterranean back from Libya; second, the 2008 readmission agreement between Italy and Libya, which still has not signed the Geneva Convention on refugees, has caused the concern of different international organization on the adhesion of this agreement, likely as the others, to the refugees' rights for better life conditions.

Sub-Saharan migrants will increasingly continue to reach North African countries, not only for reaching Europe but also as a destination point, but the latter will not be able to afford an invasion and will continue to tighten migratory regulations. Irregular migration in Europe has increasingly been defined as a security problem associated with international crime and terrorism and dominant discourses obscure that African migration to Europe is fuelled by a structural demand for cheap migrant labour in informal sectors. This explains why restrictive immigration policies have invariably failed to stop migration.



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INTERNATIONAL LAW

Responsibility to protect and Africa

(Ludovica Poli)



The concept of "Responsibility to Protect" (R2P) has been first presented by the International Commission on Intervention and State Sovereignty (ICISS) in December 2001 in response to Kofi Annan's call to define whether - and under which conditions - the international community should intervene within a State for human protection purposes.

The initial timing of the ICISS Report was not favourable (September 11 attacks had shifted the international debate on different issues); this notwithstanding, since 2004 various UN documents mentioned the R2P and the attention for the concept has grown among international institutions, regional organizations, scholars and the civil society itself. The R2P doctrine implies that each State has the responsibility to protect its population from genocide, war crimes, ethnic cleansing and crimes against humanity. The international community, mainly through the UN, should assist States in exercising that responsibility and in building their protection capacities; moreover, whenever a State is "manifestly failing" to protect its own population, the duty to protect shifts to the international community.

The protection has a threefold dimension:

- prevention,
- reaction,
- and rebuilding.

A debate on the legal nature of R2P (is it an emerging norm or just a successful rephrasing of well-known concepts?), is still going on.

Since the adoption of the ICISS Report, the relevant role played by regional organizations in preventing and responding to internal crises has been underlined; the Report itself envisages the opportunity of prompt interventions by regional organizations (with subsequent, ex post facto, approval) in case of Security Council's failure to act. On the other side, the R2P seems to have been even anticipated in the 2000 African Union Constitutive Act, which states at Article 4(h) the "right of the Union to intervene in a Member State pursuant

to a decision of the Assembly in respect of grave circumstances, namely war crimes, genocide and crimes against humanity."

The compliance of both mechanisms with international law is in doubt: art. 53 of the UN Charter clearly states that "no enforcement action shall be taken under regional arrangements or by regional agencies without the authorization of the Security Council", even if the states practice have revealed some exceptions to the rule (ECOWAS intervention in Liberia e Sierra Leone in the '90).

In the UN context, however, it is widely recognized the need of a strong cooperation with regional organizations. According to Annan, these institutions give "important contributions to the stability and prosperity of their members, as well as of the broader international system" and, for this reason, "the UN and regional organizations should play complementary roles in facing the challenges to international peace and security". The intention to improve cooperation and coordination between UN and regional organizations - in particular in the African continent - has been confirmed and developed by Secretary-General Ban Ki-moon with the "Report on the relationship between the United Nations and regional organizations, in particular the African Union, in the maintenance of international peace and security".

An African Union-United Nations Panel has been established in September 2008 to consider in-depth the modalities of how to support peacekeeping operations. Regional organizations in Africa, for their part, have improved the efforts for maintenance of peace and security, adopting formal mechanisms with wide-ranging peace and security responsibilities. Both the AU and ECOWAS are developing standby-force concepts and increasing their headquarters capacity. Moreover, R2P has been embraced by the AU on various occasions, such as in the common position expressed by member states and known as "Ezulwini Consensus", adopted in 2005.

The undeniable large consent ac-

corded to the concept of R2P reveals the need to exclude any kind of abuse: if a correct achievement of R2P principles may improve quality and value of peace operations, (increasing efforts on early warning and prevention, enhancing humanitarian law and human rights compliance in reaction, and reinforcing rebuilding instruments), it is urgent to discourage States or groups of States (regional organizations included) from misuse R2P for inappropriate purposes.

The implementation of R2P represents an important challenge for the UN and regional organizations involved in peace and security maintenance; the African continent represents a testing ground for their joint institutional efforts.

The International Commission on Intervention and State Sovereignty (ICISS)

The International Commission on Intervention and State Sovereignty (ICISS) was an ad hoc commission of participants which in 2001 worked to popularize the concept of humanitarian intervention and democracy-restoring intervention under the name of "Responsibility to protect."

The Commission was founded by Gareth Evans and Mohammed Sahnoun under the authority of the Canadian Government and consisted of members from the UN General Assembly. The purpose of the Committee was to arrive at an answer to the following question posed by Kofi Annan:

"if humanitarian intervention is, indeed, an unacceptable assault on sovereignty, how should we respond to a Rwanda, to a Srebrenica - to gross and systematic violations of human rights that affect every precept of our common humanity?"

Fonti: <http://www.iciss-ciise.gc.ca> e <http://wikipedia.org>



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CASE STUDY

Role and accountability of peacekeeping missions (Daria Storia)

As of July 2009, 8 out of 17 United Nations (UN) peacekeeping operations are deployed in African countries, with the task of managing and monitoring intrastate conflicts and crisis and promoting reconciliation. Notwithstanding the institutional mandate, in the last few years numerous cases of personal misconduct of peacekeepers have been denounced to the UN, with a high incidence of cases of sexual as well as gender-related crimes.

In 2001, the UN Office of Internal Oversight Services (OIOS) was asked by the UN High Commissioner for Refugees (UNHCR) to review allegations of sexual exploitation of female refugees by UN and NGO staff and peacekeepers in Guinea, Liberia and Sierra Leone. The final report acknowledged that the refugees are vulnerable to sexual and other forms of exploitation, although the allegation of widespread sexual exploitation had not been confirmed by sufficient evidence. A few years later, following 150 allegations from Congolese women of sexual misconduct by MONUC peacekeepers, including rape, underage prostitution, pornographic videotaping and torture, the same Office was requested to investigate in Bunia, the capital of Ituri Province in the northeast area of the Democratic Republic of the Congo (DRC). In 2005, two reports acknowledged sexual abuses, compiling 20 individual case reports, 19 of which involved military personnel. During the investigation, sexual activities between the military and the local population apparently continued, indicating a lack of concern by peacekeepers about the possible repercussions of the investigation findings. In January 2006, investigators deployed once again in Bunia received 217 allegations of sexual abuse and exploitation against a total of 75 peacekeepers. Only one allegation was substantiated because the girls who had initially made the allegations either refused to participate further or failed to identify the alleged perpetrators during line-up of the peacekeepers. The report states that girls and young women remain at high risk of sexual exploitation and abuse

and reproduces the recommendation already made in the 2005 report.

The main problem in case of sexual abuse and exploitation committed by peacekeepers is that effective prosecution is not ensured. As general rule, UN peacekeepers remain under the exclusive criminal jurisdiction of their own national authorities and therefore are immune from local prosecution. Each UN mission sets specific terms for the conduct, privileges, immunities and jurisdictions of its military and civilian employees, usually included in the Status of Forces Agreements (SOFA), signed between the hosting country and the troop-contributing country. Moreover, the UN and each troop-contributing country sign a mission-specific memorandum of understanding (MoU), which includes prohibitions against sexual exploitation and abuse established by the 2003 Secretary-General's bulletin on protection from sexual exploitation and abuse, although these are considered mere guidelines and not binding rules. In March 2005, the so-called Zeid Report on "Sexual Exploitation and Abuse by UN Peacekeeping Personnel" provided a comprehensive analysis of the situation and innovative package of recommendations addressed to both the UN Secretariat and Member States, advising to obtain a formal assurance by the troop-contributing country that it would exercise jurisdiction with respect to crimes that might be committed by its forces in the mission area. In November 2005, the Conduct and Discipline Units in DPKO were established as part of a package of reforms in UN peacekeeping to strengthen accountability and uphold standards of conduct in the UN. The DPKO also adopted a comprehensive strategy on sexual exploitation and abuse, including measures aimed at preventing misconduct, such as pre-deployment training on standards of conduct and zero-tolerance policy, and at providing assistance and support to victims of sexual exploitation and abuse.

Notwithstanding the numerous ef-

orts, none of the provisions adopted so far put obligations on troop-contributing countries: a decision whether or not to prosecute remains an act of sovereignty. In 2007, the NGO Save the Children conducted fieldwork visits in Southern Sudan, Cote d'Ivoire and Haiti and found out that abuse of boys and girls continues in emergencies, with much of it going unreported. Provision of immunity cannot justify a situation of widespread –if not complete– impunity. Furthermore, an agreement establishing exclusive jurisdiction of troop-contributing state for crimes committed by peacekeepers does not exclude the jurisdiction of an international tribunal like the International Criminal Court (ICC). Nowadays the ICC Statute explicitly recognizes rape, sexual slavery, enforced prostitution, forced pregnancy, enforced sterilization and other grave forms of sexual violence as war crimes in international and non-international armed conflict, as well as crimes against humanity. The Statute also includes trafficking as a crime against humanity as among the crimes of enslavement. Consequently, international criminal responsibility can be relevant to international peacekeepers, and the situation might be heard by the ICC, in case a State is unwilling or unable genuinely to carry out investigation or prosecution. Such a possibility is confirmed by the fact that the U.S. has repeatedly attempted to avoid the jurisdiction of the Court over its peacekeepers through different mechanisms, including obtaining a one-year immunity for its peacekeepers and, recently, the so-called "Bilateral impunity Agreements - BIAs", to prevent US nationals from being investigated and prosecuted by the ICC.

When committed by peacekeepers, sexual exploitation and abuse damage the credibility and impartiality of an operation in the eyes of both the local population and the international opinion: a peacekeeping operation cannot legitimately advise a Government on adherence to international human rights standards and legal and judicial reform if its own peacekeeping personnel are engaging in acts of sexual exploitation and abuse, including such crimes as rape.



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