Major Intellectual Property issues faced from a contracting/research partnership perspective in Africa other regions

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1. Introduction: Relevance of Intellectual Property in the research contracting/partnership context

Relevant legislation usually recognizes that intellectual property rights (IPRS) are owned by the person who has created the work in question. Consequently, collaborating firms often enter into contracts in order to transfer the rights to themselves. Research contracts are popular among researchers because evidence shows that researchers who contract with industry have superior productivity.[1] Uneven playing fields however exist between researchers in the low and middle income countries (LMICs) and their high income country counterparts. This disparity can be attributed to the fact that institutions and researchers in LMICs have a broader teaching and skills-development mandate while the high income countries that usually partner with them face competitive pressures and financial incentives, which can prevent them from being good partners.[2]

Another factor that leads to uneven playing field is lack of legal frameworks to effectively manage IPRS. It has therefore been noted "that poorly developed IPR management hinders equal research partnerships between the South and the North."[3] This is the case because IPRS have both enabling and limiting characteristics.

[1] World Intellectual Property Organization, *World Intellectual Property Report: the Changing Face of Innovation,* WIPO Economics & Statistics Series 2011, p.164 (hereinafter WIPO Report).
[2] D McCoy, C Mwansambo, A Costello & A Khan, Academic partnerships between rich and poor countries. *Lancet* (2008) 371:1055-6.
[3] W van Genugten et al., *Harnessing Intellectual Property Rights for Development Objectives: The Double Role of IPRs in the Context of Facilitating MDGs Nos. 1 and 6.* Wolf Legal Publishers, Nijmegen, 2011, p.v

Uneven playing fields can hamper development of competitors in LMICs and can make collaborating institutions appear as potential adversaries rather than partners.[4] Inequality in bargaining power among collaborators can also lead to wastage of valuable resources and time and detract from focusing on research. Research partnerships in such situations can be very difficult to manage.[5]

Unfavorable intellectual property arrangements affect not only developing countries in Africa[6] but other regions as well. It follows that without proper management of IPRS, the parties are likely to be embroiled in protracted disputes.[7] Trust and contracts have been identified in literature as critical success factors particularly for asymmetric research and development (R&D) partnerships.[8] In health research, managing IPR ownership through contracts is vital because it is an area, which is highly sensitive and affected by struggles over who controls and benefits from the scientific and technological changes that are underway.[9] Health research therefore requires strategic management of access to proprietary knowledge.[10]

2. Specific IP issues

Increased focus on knowledge and the rise of new innovating countries, coupled with the desire to protect inventions abroad have prompted a growing demand for IP protection.[11] This situation has led to increased complexity of legal arrangements without the corresponding increase in legal resources and capacities of research institutions in LMICs.[12] Scientists and researchers however seem to focus more on research protocols without considering the fact that legal aspects are equally important

[4] D Sack, V Brooks, M Behan, A Cravioto, A Kennedy, C IJsselmuiden & N Sewankambo, "Improving international research contracting", *Bull World Health Organ* (2009) 87:000–000 doi:10.2471/BLT.08.058099
[5] McCoy et al, *op cit* at 1055.
[6] P Andanda 'Health-Related Biotechnology in Africa: Managing the Legislative and Regulatory Issues' *African Journal of Medicine & Medical Sciences* (2007) 36 Suppl. 55-61.
[7] K Blomqvist, P Hurmelinna & R Seppa¨nen, 'Playing the collaboration game right-balancing trust and contracting' *Technovation* (2005) 25: 497-504 at 498.
[8] *Ibid* p.498.
[9] G Tansey, "Introduction: Legal Fictions and Public health", in: P Roffe, G Tansey & Vivas- Eugui (eds.), "Negotiating Health: intellectual property and access to medicines" p.2 (Earthscan, London 2006).
[10] Organisation for Economic Co-operation and Development (OECD), "The Bioeconomy to 2030: designing a policy agenda," 152 (OECD Publishing, 2009).
[11] WIPO Report, p.171.
[12] Sack *et al, op cit.*

for a successful partnership.[13] Such limited focus can miss the emerging trend where collaborators are increasingly innovative when collaborating with universities; while fostering cooperation they also ensure control by insisting on royalty-free licence on any university patent emerging from research that they have funded.[14]

The specific IP-related issues in the research contracting/partnership context are: exclusive ownership of intellectual property, exclusive data ownership, specimen ownership and disagreements over dispute settlement procedures to be followed. These are explained below.

a) Exclusive ownership of intellectual property

The emergence of knowledge markets based on IPRS has led to more frequent licensing as well as emergence of intermediaries that match buyers and sellers such as technology transfer offices (TTOs) at universities and public organisations.[15] IP is therefore viewed in the knowledge market as a vehicle for knowledge transfer and protection.[16] International differences in the protection of IPRS are factors that most companies consider when engaging in international R&D partnerships.[17]

Insistence on stronger IP protection, especially in many developing countries that "justify stronger IPRS by claiming that this policy will result in greater inward flows of technology, a flowering of local innovation and cultural development, and faster ability to close the gap in technological sophistication between themselves and rich countries"[18] is equally problematic. Maskus' observation of the effects of this approach is very instructive:

> "But improved IPRS by themselves are highly unlikely to engender such salutary effects. One need only think of the differences between countries in Sub-Saharan Africa, with long-standing and relatively strong laws (though limited ability to enforce them), and countries in East Asia, many of which reformed their regimes

[13] *Ibid.*
[14] WIPO Report, p.122.
[15] WIPO Report, p.9.
[16] *Ibid,* p.52.
[17] J Hagedoorn, D Cloodt & H van Kranenburg, Intellectual property rights and the governance of international R&D partnerships, *Journal of International Business Studies* (2005) 36: 175-186 at 184.
[18] K E Maskus, *intellectual property rights and global economy,* the institute for international economics, Washington DC, 2000, p.199.

only in the 1990s. The first group attracts little FDI and registers few patents at home or abroad. The latter group attracts the bulk of FDI in the developing world and is experiencing rising intellectual property protection."[19]

Insistence on stronger IP protection coupled with limited ability to enforce IPRS can be some of the factors that lead to exclusive ownership of IPRS. The negative effects of sluggish process of registering IPRS, which is prevalent in most LMICs can also not be underestimated.

An illustration of stronger IP protection can be gleaned by considering the enactment of the 2008 South African Intellectual Property Rights from Publicly Financed R&D Act (hereinafter IPR Act), which requires that intellectual property emanating from publicly financed R&D be identified, protected, utilized and commercialized for the benefit of the people of South Africa. Some provisions of the Act could interfere with research contracts and partnerships. For instance, the Act has unintentionally introduced a two-edged sword in the regulation of research particularly in section 4(2) (a) and (b), which provide as follows:

> "A recipient that prefers not to retain ownership in its intellectual property or not to obtain statutory protection for the intellectual property must:
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> (a) make the choice in accordance with the regulations and any guidelines published by [the National Intellectual Property Management Office] NIPMO by notice in the Gazette; and
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> (b) within the period set out in section 5(1) (e), notify NIPMO of the decision and the reasons therefore."

I have argued elsewhere that the "provision could conceivably be invoked in order to interfere with a properly negotiated consortium agreement on data sharing and protection of IPRs that accrue from a project."[20] This effect becomes evident when the subsection is read together with subsection 3, which provides that:

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[19] *Ibid,* p.199.

[20] P Andanda 'The impact of intellectual property rights protection by publicly-financed research institutions on clinical research: Lessons from South Africa.' The World Intellectual Property Organization (WIPO) and World Trade organization (WTO) *colloquium paper series for 2011* (published in 2012) pp.89-103 at 100 Available at

> "NIPMO may, within the prescribed period, after considering the reasons provided by the recipient in terms of subsection (2) (b), and any prejudice that may be suffered by the State if no statutory protection for the intellectual property is obtained, acquire ownership in the intellectual property and, where applicable, obtain statutory protection for the intellectual property.

My conclusion is that "the two subsections can be viewed to be a two-edged sword, facilitating research while at the same time contradicting and negating the current exception for experimental/noncommercial use protected under South African law. This essentially means that PFRIs [Publicly-Financed Research Institutions] will require licences for follow-on research."[21]

Other critics have also argued that section 15 of the Act, which lays down conditions for ownership of IPRS emanating from collaboration with private entities or institutions will "likely to lead to a decrease in private sector partnering with local R&D institutions, less contract research undertakings and fewer knowledge and technology transfer opportunities."[22]

An example of ineffective IP protection is the case of Uganda where available literature shows that low internal patenting causes local scientists to "miss out on country specific knowledge that may be in existence but not recorded or systematized in any way. As a result, much-needed data that can assist the development of the country is not shared and disseminated."[23]

b) Exclusive data ownership

Insistence on exclusive data ownership is a complex issue not only for LMICs but in high income countries as well. Pugatch has for instance noted that the issue of data exclusivity "seems to mark a shift from the conventional debates over patent protection and drug prices… [as it] involves both developed and developing countries, is characterized by political and economic interests, as well as by safety issues that guarantee to make it one of the more interesting as well as heated subjects in the IPR

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http://www.wipo.int/export/sites/www/academy/en/teaching/teaching_research/wipo_wto_colloq/pdf/wipo_wto_papers_2011.pdf

[21] *Ibid*.

[22] van Genugten *et al., op cit,* p.405.

[23] *Ibid,* p. 407.

field."[24] Insistence on exclusive data ownership emerges from viewing data as having proprietary value and misinterpreting of Article 39 of the TRIPS Agreement, which provides as follows:

> "Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use."

The protection, which Article 39 provides for is an intellectual property right since Article 1 (2) of the TRIPS Agreement defines the term 'intellectual property' to include all categories of IP that are the subject of Subsections 1 through to 7 of Part II and Article 39 falls within this range. The scope and the interpretation of Article 39.3 are however, rather contested. Correa, for instance, argues that the protection of test data does not confer exclusive rights in terms of Article 39.1, read together with Article 10bis of the Paris Convention for the protection of industrial property but only confers "the right to take legal action against whoever has obtained commercial advantage by means of dishonest practice."[25]

Article 39.1 requires member states to protect undisclosed information against unfair competition as provided in Article 10bis of the Paris Convention[26] if the information satisfies the requirements of paragraph 2 of the Article. This interpretation is in accordance with Articles 31 and 32 of the Vienna Convention on the Law of Treaties.[27] Consequently, the Article does not require data exclusivity. This position has been confirmed by the World Health Organization's (WHO) Commission on Intellectual

[24] MP Pugatch, "Intellectual Property, Data Exclusivity, Innovation and Market Access", in: Roffe *et al*., (eds.), 2006, p.129.
[25] MC Correa, "Protecting Test Data for Pharmaceutical and Agrochemical Products under Free Trade Agreements", in: Roffe *et al*., (eds.) 2006, p.84.
[26] The Article prohibits any acts of competition that 'are contrary to honest practices in industrial or commercial matters…'
[27] Article 31 of the treaty is a customary rule of interpretation of public international law, available at http://untreaty.un.org/ilc/texts/instruments/english/conventions/1_1_1969.pdf.

Property Rights, Innovation and Public Health. The Commission has stated that Article 39.3 "… does not create property rights, nor a right to prevent others from relying on the data for the marketing approval of the same product by a third party, or from using the data except where unfair (dishonest) commercial practices are involved."[28]

The above position notwithstanding, there is a tendency to resort to TRIPS-Plus standard, particularly in Free Trade Agreements (FTAs) that are signed between countries, by requiring countries to grant *sui generis* protection to test data. Collaborating researchers find themselves bound by such FTAs, more often than not without having negotiated their research contracts appropriately. The problem that is caused by insisting on this TRIPS-Plus standard is compounded by the fragmentation of mandate and power within institutions in countries that deal with health research. This results in for instance, departments of trade and industry committing a country to TRIPS-Plus terms in a FTA that the same country's department of health is not party to, which can negatively impact on collaborative health research.

c) Specimen/sample ownership

Insistence on sample ownership may be attributed to the value of human tissue/sample-related inventions, which eventually have intellectual property value. In research partnerships, parties rarely view this as an issue that is related to intellectual property because there is a clear distinction between ownership of the samples and ownership of IPRS that may arise from inventions that are derived from the samples.[29] Besides, ownership of samples is rarely accorded adequate attention, particularly in developing countries.[30]

Legal frameworks that govern ownership of samples are beset by lack of harmonization and lack of focus. Consequently, appropriate management of issues related to ownership of samples falls within the domain of research ethics committees.[31]

[28] "Public health, innovation and intellectual property rights, Report of the Commission on Intellectual Property Rights, Innovation and Public Health", p.124 (World Health Organization, Geneva 2006).
[29] See P Andanda 'Human Tissue Related Inventions: Ownership and Intellectual Property Rights in International Collaborative Research in Developing Countries' *Journal of Medical Ethics* (2008) 34(3): 171-179.
[30] Ibid, p.173.
[31] Ibid, p.176.

d) Dispute resolution procedures

Disagreements on dispute resolution procedures can be linked to two possible factors that are IP- related: First Sponsors from more developed countries may prefer to use their own substantive laws and their institutions, which they find more effective in resolving disputes, particularly if they consider their LMIC counterparts' institutions that deal with dispute resolution to be weak or ineffective. Zhao has established that much as firms have been advised to keep their knowledge intensive activities away from weak IPR countries, i.e. where laws that protect IPR are either weak or ineffectual, yet evidence shows a contrary trend where R&D intensive firms from developed countries tend to utilize low-cost access to quality human capital in these countries if such firms possess alternative mechanisms for IPR protection.[32] The second factor, which is closely linked to insistence on data ownership, is that developed country collaborators may insist on the partnership being governed by the laws of their countries of origin rather than those of the LMICs where the research is being conducted as a strategic way of ensuring that the substantive IPR laws and institutions in the developed country are used in the event of a dispute. Once such a term is included in the research contract, it may indirectly impose TRIPS-plus standards on data ownership, if such standards are already included in the developed country partner's laws or a FTA with the collaborating LMIC.

R&D firms from developed countries are strategic enough in overcoming adverse consequences of weak IP protection such as unauthorized imitation. Such firms ensure that the type of the technology that is developed is dependent on the proprietary firm's internal resources that are crucial for commercialization. Zhao correctly concludes that "innovating firms can discourage imitation by developing technologies that require complementary knowledge and resources not readily available to potential imitators."[33]

Data exclusivity can be classified within the category of complementary internal resources that imitators may require for regulatory authorities to grant marketing approval for their products. Zhao argues that a competitor in a weak IP protection environment will need to overcome the hurdle of high costs of obtaining complementary

[32] M Zhao, "Conducting R&D in Countries with Weak Intellectual Property Rights Protection", *Management Science* (2006) 52(8): 1185-1199.
[33] *Ibid*, p. 1186.

knowledge and resources that are often located across national boundaries and guarded by effective IPR laws.[34]

3. The way forward in addressing the issues

One of the recommended principles for research partnerships with developing countries is that the collaborators should share profits equitably. The rights of all collaborating parties to patents and copyright in the published work should be discussed in advance and agreed on before research starts.[35] Knowledge sharing, in order to promote scientific progress, is one of the principles that is contained in the proposals, which were submitted to the WHO working group with a request that a treaty be created that can support, *inter alia*, incentives to invest in needs-driven R&D that is consistent with human rights and with the goal of ensuring that everyone shares in the benefits of scientific advancement.[36]

The working group's report views the proposal, not as a replacement of the existing IPR system "but as a supplementary instrument where the current system does not function to meet the R&D needs of developing countries."[37] The report also notes that IPRS are not an effective incentive in circumstances where there is little investment in R&D on diseases that mainly affect developing countries.[38] This essentially requires research collaborators to reckon with Maskus' suggestion of striking "a balance between the needs of information developers and users, with due regard for market externalities that may not be well managed, and could be exacerbated, in a framework of strong IPRS."[39] As mentioned earlier, such strong IPRS often lack effective enforcement and can contribute to collaborators from developed countries with more effective IP protection insisting on using their legal frameworks for dispute resolution.

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[34] *Ibid.*
[35] Swiss Commission for Research Partnership with Developing Countries, *Guidelines for Research in Partnership with Developing Countries*, 1998, see principle 9.
[36] World Health Organization, *Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination*, (Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination, April 2012), p. 143.
[37] *Ibid* at 53.
[38] *Ibid* at 1.
[39] *Op cit*, p.200.

A possible solution to insistence on exclusive data ownership would be to shift the default position from data confidentiality to one of disclosure.[40] Removal of data exclusivity can address IP management issues by eradicating one form of exclusivity and promoting earlier generic competition thereby playing a complimentary role with other existing incentives and mechanisms.[41] This solution highlights the need to empower research institutes and research governance bodies in LMICs. Empowerment initiatives should be emphasized because it has been established that LMICs' TTOs staff lack skills and experience related to IP and commercialization. The sluggish process of patenting at national patent offices and high costs have also been noted as great concerns.[42]

[40] For a detailed discussion of this strategy see P Andanda, "Managing intellectual property rights over clinical trial data to promote access and benefit sharing in public health" *International Review of Intellectual Property and Competition Law* (forthcoming).
[41] World Health Organization (April 2012), *op cit*, p.54.
[42] WIPO Report, p.171.