

Impact case study (REF3)

Institution: University of Central Lancashire		
Unit of Assessment: UoA 18 Law		
Title of case study: <u><i>Improving Accessibility and Affordability of Medicines Through the Use of Intellectual Property (IP) Flexibilities</i></u>		
Period when the underpinning research was undertaken: 2006- ongoing		
Details of staff conducting the underpinning research from the submitting unit:		
Name(s):	Role(s) (e.g. job title):	Period(s) employed by submitting HEI:
Mohammed El Said	Professor in International Trade and Intellectual Property Law	2006 - Present
Period when the claimed impact occurred: 2014-2020		
Is this case study continued from a case study submitted in 2014? N		
<p>1. Summary of the impact (indicative maximum 100 words)</p> <p>Accessibility and affordability of medicines is a global challenge. El Said's research has had a significant impact by mapping the current global standards of intellectual property (IP) protection and by making recommendations about adopting strategies which resulted in creating IP regimes incorporating the necessary legal tools needed to improve access to medicines. As a result, policy debate (internationally and nationally) has been stimulated and informed by the research evidence, leading to policy decisions and changes to patent legislations, such as in the case of [text removed for publication] and [text removed for publication] patent laws. The research has impacted on the policy approaches of international organisations such as the World Intellectual Property Organisation (WIPO) and Unitaid and upon debates in several developing countries. This has resulted in legislative change in individual jurisdictions, including [text removed for publication] and [text removed for publication]. It has informed current debate in other countries such as [text removed for publication] and [text removed for publication], where the research has been utilised to both advance a set of rationales for legal intervention and to promote legislative changes. These changes make medicines more affordable and accessible, which in turn improves the health of citizens.</p>		
<p>2. Underpinning research (indicative maximum 500 words)</p> <p>Accessibility and affordability of medicines and new health technologies has attracted considerable attention from governments, international organisations, civil society groups, and specialised United Nations (UN) agencies. As such, accessibility and affordability of medicines is viewed as a global challenge. Statistics indicate that one third of the global population lacks reliable access to medicines. More than 13% of Americans, about 34 million people, say a friend or family member recently passed away in the last five years after being unable to afford treatment for a condition, according to a recent poll from Gallup and West Health. A recent study in the UK found that total NHS spending on medicines in England has grown from GBP13,000,000,000 in 2010/11 to GBP17,400,000,000 in 2016/17 – an average growth of around 5% a year. The situation is even worse in the poorest countries of Africa and Asia, where as much as 50% of the population lacks such access. While some 10 million lives a year could be saved by improving access to essential medicines and vaccines, 4 million in Africa and South-East Asia alone, a major obstacle to achieving this has been the price. In 2016, the United Nations Secretary-General's High-Level Panel on Access to Medicines highlighted the negative impact arising from strengthened levels of IP on access to medicines and medical health technologies. The current global outbreak of the COVID-19 pandemic has also raised considerable challenges at the global level, giving El Said's work higher recognition and relevance. El Said's research addresses these issues within the context of the United Nations Sustainable Development Goals (SDG) with a focus on SDG3, Good Health and Well Being and SDG10, Reduced Inequalities.</p>		

Research undertaken by El Said has informed research, policy makers and international agencies on the relationship between IP and patent laws and access to medicines through focusing on raising awareness and proposing solutions to improve access to medicines nationally, regionally and globally [3]. In 2010, El Said solely authored a policy guide for the World Health Organisation (WHO) on the impact of IP and free trade agreements on access to medicines. This was the first publication of its type in the Eastern Mediterranean Regional office of the WHO (EMRO) targeting policy makers and government officials [5]. El Said was also the legal lead for the REWARD project (2014-2019) which is funded by the European Research Council (ERC). The objective of REWARD was to create an ethically and legally sound performance-based reward tool for pharmaceutical innovation, which complements the existing patent regime, yet mitigates its considerable disadvantages for the global poor [2].

El Said has been the sole author of publications and policy documents for the WHO [5] and co-author of United Nations Development Programme publications (UNDP) [6] in both English and Arabic languages. The research was initiated in 2005. There has been continuing international impact with important developments within the current REF period, impacting on legislatures, policy makers, international organisations, civil society groups and researchers in countries where reform of the patent regime has taken place or is being considered. The global COVID-19 pandemic has further highlighted the importance of access to medicines. El Said's research has become increasingly relevant as Lower Middle-Income Countries (LMIC) struggle to deal with the impacts of the pandemic [1].

El Said's involvement in international high-level policy research with international organisations has contributed to international debate. He has advised policy makers in several countries on the reform of their patent legislation, with the aim of improving access to medicines and public health.

Since the publication of the Policy Guide by WHO in 2010 [5], El Said continued to be actively involved in the global debate on IP and access to medicines. In 2011 he co-authored (with one other international expert) a working paper on the role of IP Law and Policy on Access to Medicines for the Global Commission on HIV and the Law which was published by the United Nations Development Programme (UNDP) [4]. El Said's contribution in the working paper was significant in terms of analysing current global IP norms and in making recommendations about reforming the global IP regime [A].

Since 2010, El Said has been approached by a number of leading global organisations to share his research insights on policy approaches and agendas. For example, El Said's research **'contributed to setting the ground for the implementation work that has been undertaken'** by the World Intellectual Property Organisation (WIPO) [G]. El Said's research was sought by Unitaid (of which the UK is a founding member). Unitaid is a global health initiative that works with partners to develop innovation in the prevention, diagnosis and treatment of major diseases in LMICs. The initiative states the importance of El Said's contributions as: **"his inputs and suggestions have helped shape Unitaid's approach to intellectual property rights and access to medicines"** [H]. In addition, the work of El Said has been recognised by other organisations such as the South Centre, an intergovernmental organisation of developing nations that undertakes research and analysis on various international policy areas which are considered key to the protection and promotion of the interests of developing countries. The South Centre recognised El Said's research as: **"useful for policy makers to address those issues at the national and regional level, notably with relation to process of reform of patent laws"** [I].

In January 2017, El Said was invited by the UNDP to edit the Arabic language version of the UN High-Panel Report [J]. The impact of the translation for the Arabic speaking countries is vital in assisting these countries in keeping up with international developments and in taking a more active role in policy debates nationally and internationally. As stated by UNDP: **"the**

significance of the report's availability for the Arabic speaking countries was highlighted to us through the positive feedback we continue to receive from officials in these" [J].

El Said's research has led to national training, policy decisions, proposals and amendments to legislations in [text removed for publication]. It has been used to advance a set of rationales for legal intervention and legislative reform through national workshops with policy makers and led to policy recommendations. This has already led to legislative reform in [text removed for publication] and [text removed for publication] [I, J].

3. References to the research (indicative maximum of six references)

1. El Said M, 2020. 'Radical Approaches During Unusual Circumstances: Intellectual Property Regulation and the COVID-19 Dilemma', *Development*.
<https://doi.org/10.1057/s41301-020-00257-x>
2. El Said M, (2016). 'TRIPS-Plus, Public Health and Performance-Based Rewards Schemes Options and Supplements for Policy Formation in Developing and Least Developed Countries'. *American University International Law Review*: Vol. 31: Issue. 3, Article 2, pp 374-444.
3. El Said M, (2014). 'The Accession of Arab Countries to the TRIPS Agreement: The Past, the Present and the Future'. *Manchester Journal of International Economic Law*, Vol 11, Issue. 1, pp 60-78.
4. El Said M and Kapczynski A. (2011). Co-authored Background paper on 'Access to Medicines: the Role of Intellectual property Law and Policy', The Global Commission on HIV and the Law, the United Nations Development Programme (UNDP). Paper co-authored with Publication available from the following link:
<https://hivlawcommission.org/wp-content/uploads/2017/06/ACCESS-TO-MEDICINES-THE-ROLE-OF-INTELLECTUAL-PROPERTY-LAW-AND-POLICY.pdf>
5. El Said, (2010). 'Public Health Related TRIPS-Plus Provisions in Bilateral Trade Agreements: A Policy Guide for Negotiations and Implementers in the Eastern Mediterranean Region', The World Health Organization (WHO) and the International Centre for Trade and Sustainable Development (ICTSD), 2010. Publication available from the following link: <http://applications.emro.who.int/dsaf/dsa1081.pdf>
6. Co-author (2010), UNDP, *Good Practice Guide: Improving Access to Treatment by Utilizing Public Health Flexibilities in the WTO TRIPS Agreement*, 2010.

* All publications are peer reviewed.

All outputs can be supplied by the HEI on request

4. Details of the impact (indicative maximum 750 words)

El Said's legal research and policy publications have stimulated and informed national policy and public debate in several countries. Moreover, El Said's research was adopted by international agencies and organisations in addition to making a significant contribution to national and international policy debate. This has led to policy decisions and changes and amendments to legislation in individual jurisdictions in the field of IP and access to medicines. El Said's research has contributed to raising awareness, stimulating national and international debate on the issue of access to medicines [G, H, I, J] and prompted legislative reform [I, J]. It has also facilitated the uptake of tools that drive innovation [G, H].

Stimulating and informing international and national policy debates

El Said's 2010 policy guide for the WHO [5] was the first ever publication of its type directed to the EMRO region. WHO's Eastern Mediterranean Region comprises 21 Member States and Palestine (West Bank and Gaza Strip), with a population of nearly 583 million people. It presently remains the leading document for policy makers and stakeholders concerned with public health and access to medicines in the region. The document was distributed officially to all concerned member states and has been widely cited beyond the region.

The final report of the Global Commission on HIV and the Law referenced and cited El Said's co-authored publication [A, 6]. The Global Commission is an independent body convened by the United Nations Development Programme to interrogate the relationships between legal responses, human rights and HIV. The UN High-Level Panel Report aims to address the role of

intellectual property law and policy in access to medicines. In November 2015, the former UN Secretary General Ban Ki-Moon, convened the High-Level Panel on Access to Medicines with the aim “to review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies”. El Said acted, in February 2016, as an adviser to a member of the High-Level Panel on Access to Medicines (H.E Awn Al Khasawneh, an ex-prime minister of Jordan and former Judge at the International Court of Justice ‘ICJ’) and was invited to participate at the High-Level Panel’s hearing which was held in London in March 2016 [J]. The published UN High-Level Panel Report [B] included reference to and citations of El Said’s published work, which highlights the development of the global IP regime in recent years by referencing the case of Jordan which El Said had extensively examined. The UN High-Level Panel Report is in many ways a milestone achievement since it calls upon governments, international organizations, the private sector, the science community, research institutions and civil society to adopt new approaches to the way in which innovation and access are addressed within and beyond the intellectual property protection regime. In addition, in January 2017, El Said was requested by the UNDP to edit the Arabic language version of the UN High-Level Panel Report [J].

Since 2010, El Said has been approached by a number of leading global organisations to share his research insights on policy approaches and agendas. For example, El Said’s research contributed to **‘setting the ground for the implementation work’** that has been undertaken by the World Intellectual Property Organisation (WIPO) [G]. Since 2017, El Said’s research was sought by Unitaid, in formulating and drafting its IP policy on access to medicines [H]. El Said’s research was also recognised by the South Centre to be **‘useful for policy makers to address those issues at the national and regional level, notably with relation to process of reform of patent laws’** [I].

At the national level, El Said has also been involved in providing national training workshops for policy makers in [text removed for publication] at the request of the UNDP on the protection of IP and the internet in April 2020. The training is part of the country’s IP implementation strategy. Beneficiaries include the Ministry of Justice, the Supreme Court, the Academy of Justice; the General Prosecutor Office, the High Judicial Council and the Ministry of Internal Affairs.

El Said’s research has also been widely cited in many official documents and policy publications by leading UN and other global organisations such as WIPO, WHO, WTO, UNDP, UNAIDS & the South Centre [A, B, C, D, E, F, G, H, I, J].

Improving public health in LMICs through legislative change

El Said’s research has had an impact on national legal debates within [text removed for publication] and [text removed for publication] [I, J]. El Said was invited to a series of national stakeholder meetings and seminars organised by official authorities and international organisations (such as WHO, WIPO, UNDP, Unitaid, the South Centre, Max Plank Institute for Competition) [G, H, I, J] to share the findings of his research. These meetings included representatives of civil society, patient groups, parliamentarians; policy makers, lawyers, academics, and researchers. More importantly, El Said provided technical reports and legal analysis and advice for patent law reform for several countries (including [text removed for publication]) [I, J]. The objective of amending these legislations was to incorporate greater flexibilities into the IP and patent regimes. There is recognition from both [text removed for publication] and [text removed for publication] of the impacts of El Said’s research on the legislative change of the patent laws [I, J]. The implementation of these provisions enables the introduction and supply of cheaper medicines to the domestic market and contributes substantially to improving the public health of the population.

El Said’s research has led to legislative change and this represents an important milestone in improving access to medicines. This has resulted in an increase in the number of patients having access to medicines and on public providers’ ability to cater for the needs for more

patients. The stakeholders benefiting from the impact are multiple including patients, NGOs, public health providers, practitioners, academics and politicians.

5. Sources to corroborate the impact (indicative maximum of 10 references)

- A. The Global Commission on HIV and the Law, the United Nations Development Programme (UNDP). <https://hivlawcommission.org/wp-content/uploads/2017/06/FinalReport-RisksRightsHealth-EN.pdf> Co-wrote Chapter 6. Cited on pages; 141, 143, 144 and 145
- B. 2016: The Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines, https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/596fed6d914e6b24d15ece26/1500507506991/50923+-+HLP+Report+-+ENGLISH+-+web_v3.pdf Cited page 41
- C. UNAIDS 2016 | REFERENCE, Intellectual property and access to health technologies, 2016, at http://www.unaids.org/sites/default/files/media_asset/JC2820_en.pdf Cited page 12
- D. WIPO, Standing Committee on the Law of Patents, Thirtieth Session, Geneva, June 24 to 27, 2019, DRAFT REFERENCE DOCUMENT ON THE EXCEPTION REGARDING COMPULSORY LICENSING, Document prepared by the Secretariat (Geneva, May 2019). https://www.wipo.int/edocs/mdocs/scp/en/scp_30/scp_30_3-main1.pdf Cited pages; 46, 48, 49 and 50
- E. World Trade Organization, World Health Organization and World Intellectual Property Organization, *Promoting Access to Medical Technologies and Innovation, Intersections between public health, intellectual property and trade*, 2020, Cited page 261
- F. South Centre (Germán Velásquez, Carlos M. Correa and Vitor Ido), *INTELLECTUAL PROPERTY, HUMAN RIGHTS AND ACCESS TO MEDICINES: A SELECTED AND ANNOTATED BIBLIOGRAPHY*, 2020, Geneva, THIRD EDITION, <https://www.southcentre.int/book-by-the-south-centre-2020/> Cited page 168 and 169
- G. (WIPO), Testimonial Letter.
- H. (Unitaid), Testimonial Letter.
- I. (South Centre), Testimonial letter.
- J. (UNDP), Testimonial letter.