

The Wellcome Trust
Ethics of Biomedical Research in Developing Countries
Research Summary

Title: Intellectual Property Rights and the Promotion of Biomedical Research for the Prevention and Treatment of Diseases Prevalent in Developing Countries: The Case of Malawi.

Investigator: Chikosa Moses Ulendo Banda.

Supervisors: Professor Lionel Bently and Dr Kathy Liddell.

Institution: Centre for Intellectual Property and Information Law, Faculty of Law, University of Cambridge. Field research to be conducted primarily in Malawi and to be supervised by Dr Garton Kamchedzera, Faculty of Law, University of Malawi: Chancellor College.

Type of Grant: PhD Studentship

Time Period: 36 Months.

Start Date: 1 October 2005.

Background:

This study considers the role of intellectual property rights (IPRs) in the promotion of biomedical research for the prevention and treatment of diseases that disproportionately affect impoverished countries using Malawi as a case study. I intend to examine global and domestic factors that contribute to the inequitable distribution of research resources/benefits between the developed world and poor countries. I will employ legal, economic and political theory to explain the failure of current regulatory mechanisms to stimulate biomedical research catering for health needs unique to the poor. I will also review literature and conduct field research to assess the validity of the assumption that stronger intellectual property rights stimulate research that is of universal benefit. Specifically, I will focus on how patents fail to stimulate research for the poor because of lack of viable markets.

I will further explore how IP law can be used as a regulatory tool for promoting biomedical research benefiting the poor by means of public policy incentives aimed at addressing market failure. Recent proposals requiring fuller analysis include transferable patent extensions and advance purchase commitments under global trust funds. Finally, I will propose reforms to the IPR legal framework in order to stimulate ethical biomedical research into neglected diseases.

Aims:

- To examine the extent to which intellectual property rights (IPRs) may be used as a regulatory strategy for the promotion of biomedical research into neglected diseases.
- To examine the impact of expanded patent protection to pharmaceutical products/processes under the TRIPS agreement on biomedical research and development of essential medicine for the benefit of the poor in Least Developed Countries including Malawi.
- To ascertain the willingness and ability of researchers (in public and private sectors) to take advantage of IP incentives in order to achieve human rights and public health objectives.
- To examine the extent to which the legal and policy framework guarantees that products of research and development reach those who need them, namely the poorer sections of the Malawian society.
- To assess the extent to which IPRS may be modified to better accommodate the changing nature of biomedical research and the health needs of the developing world.

Main Research Questions:

- 1) What incentives does the current IPR legal framework provide for conducting biomedical research into neglected diseases?
- 2) In what ways does the current IPR legal framework hinder access to new medical treatments?
- 3) To what extent do laws and policies external to the IPR legal framework form incentives and barriers to biomedical research into neglected diseases?
- 4) Could the IPR legal framework be modified so that biomedical research into neglected diseases is stimulated more thoroughly and in a balanced and effective way?
- 5) What additional incentives could the IPR legal framework provide to stimulate biomedical research into neglected diseases?
- 6) What potential advantages and disadvantages surround the idea of transferable patent extensions?
 - What alternative approaches might be adopted?
 - How could the barriers that the IPR legal framework creates for the development and access to new medical treatments be reduced?
 - How can conflicts between the two objectives – covering R&D costs and minimising consumer costs- be resolved.
 - What potential advantages and disadvantages do the alternatives have?
- 7) How could the legislative framework guarantee equitable post-trial access to research benefits?
- 8) What structural, economic, social, cultural and political factors depress effective demand for products of biomedical research?

Methodology:

The study is intended to detail the conceptual and practical issues regarding the implications of intellectual property rights for stimulating research into diseases affecting poor countries. Consequently, it will involve literature research combined with qualitative field research. The literature research will involve analysing legal and policy instruments that are relevant to biomedical research. These will include intellectual property, human rights, drug regulation and research regulation instruments. Reference will also be made to case law to determine how the legal instruments have been applied in practice. I will also consult literature and reports of institutions having a direct bearing on biomedical research and examine surveys conducted by NGOs and developmental bodies in this area. The normative analysis will involve reviewing existing scholarly work in the area. The interdisciplinary nature of the study will require an identification of leading contemporary authors in legal, moral and economic theory; particularly those who have attempted to apply the regulatory theory and progressive theories of justice to global inequalities in biomedical research. Human rights theories will also be analysed. I will also focus on authors who have critically analysed the role of patents as a negotiating tool for innovation. The literature survey will help me develop tools that I will utilize during field research. Field research will be conducted primarily in Malawi. I will also visit Geneva because of the concentration of the pharmaceutical industry, policy makers and NGOs therein. This will provide a more balanced analysis. I will interview key stakeholders in the area using a semi-structured interview approach. These include researchers, research regulators, policy makers, service providers and the civil society.

Application of Research Results:

The significant contribution of this study will be an in-depth scholarly analysis of recently proposed patent-based incentives for biomedical research in order to give policy makers an informed basis for action. This work will naturally feed into the global community's efforts to find a sustainable solution to the disease burden facing the developing world. The suggested reforms to the IPR legal framework will address the health needs of countries with insufficient drug research and development capacity. Additionally, this study has a natural connection with some of Wellcome Trust's recent and ongoing studies on the promotion of biomedical research. The legal reforms that I will recommend will also directly benefit biomedical researchers in the developing world since they will facilitate the creation of a more conducive environment for the conducting of biomedical research.

Further Information:

Further information relating to this study can be obtained from: Chikosa Banda, Wolfson College, Cambridge, CB3 9BB. E-mail: cmub2@cam.ac.uk.