

## Patent Exhaustion and International Trade Regulation

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# Patent Exhaustion and International Trade Regulation

*By*

Santanu Mukherjee



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# Foreword

International Trade Regulation, right from GATT 1947 Agreement to the present day has witnessed a sea change as modes of trading changed with time. The shift from GATT 1947 to GATT 1994 introduced Intellectual Property Rights (IPR) in an effective manner through long years of negotiations. The Agreement on Trade Related aspects of Intellectual Property Rights (TRIPS) became a pillar of the World Trade Organisation (WTO). Directly interfacing between GATT and IPR, TRIPS addressed number of issues and forcing many WTO members to change their laws, but one of the issues that remained open, was 'Exhaustion' of IPR.

This book addresses this issue of exhaustion most vividly, explaining the rationale of patents, managing ubiquity through patent exhaustion. The evolution of exhaustion principle in different jurisdictions is remarkable. Gradually bringing readers to WTO regulation, not only different modes of exhaustion and treatment of parallel trade is established, but the exegesis of exhaustion principle under TRIPS as well as GATT and GATS is unprecedented. The book's analyses of MFN and National Treatment and the exceptions to them, supported by detailed elaboration of GATT Panels and Appellate Body Reports is noteworthy. As the author moves to the negotiation history of TRIPS, the meticulous detail, literally takes one back to the negotiations. Interesting to note that the author does not stop at that but studies exhaustion in the plethora of regional trade blocs. Further, the link between Trade Regulations, IPR and Competition Policy which is often overlooked is also well captured. Finally, one of the most critical aspects of public policy, the interface between patents and international trade is captured in every aspect of international trade, leading to the TRIPS amendment.

I commend the author for his painstaking research, robust arguments and vast comparative analyses of different legal jurisdictions. The author's grasp over the subject speaks about his in-depth knowledge and experience, his ability to explain lucidly is indeed laudable. Such a comprehensive book that covers one of the most complicated issues of patent law, as well as TRIPS, GATT and GATS, undoubtedly makes an indispensable reading for those engaged in legal practice, academia and policy making on IPR and WTO. I congratulate the author for this valuable contribution to international trade law and IPR scholarship.

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Former India's lead negotiator at the GATT, later at the WTO

New Delhi, September 2022

## Preface

Parallel trade of products protected by intellectual property, in particular patents, has been a long-standing and unresolved issue in intellectual property law. International trade in original goods put lawfully on a market abroad and imported at lower prices to the benefit of consumers has been considered detrimental to intellectual property. Despite an overall commitment to open market and free trade, parallel trade is met with persistent resistance and often called grey imports, suggesting unlawfulness, or at least illegitimate trade impairing monopoly rights and rents. It challenges the tradition of nationally defined and protected intellectual property rights.

With the advent of the TRIPS Agreement and the incorporation of intellectual property standards and enforcement in the multilateral trading system of the World Trade Organization and in bilateral or plurilateral agreements, the problem of parallel trading was linked to the broader agenda and framework of international trade and the principles of WTO law. The present thesis explores the wider implications of provisions of the TRIPS Agreement beyond Article 6 and includes a detail assessment of the implications of GATT and the GATS Agreements. It links the problem not only to international trade regulation but also to regional trade agreements, in particular EU law, and disciplines of competition law and policy.

Since parallel trade goods relates to the geographical origin of the product, and not the nationality of the right holder, restrictions are subject to national treatment and the ban on quantitative restrictions, exceptions from which required detailed justification under Article XX GATT and Article XIV GATS. They have to meet the necessity test and thus call for the least restrictive manner in pursuit of a public policy goal. The thesis draws attention to this wider regulatory field and takes issue with the widespread opinion among intellectual property lawyers that Article 6 TRIPS exhaustively deals with the matter and leaves it to full discretion of Members of the WTO.

The thesis concludes that the doctrine of international exhaustion offers a convincing answer within the multilateral trading system, and that the doctrines both of national and regional exhaustion do not stand the legal test of international trade regulation. In light of persistent and long-standing insistence on national exhaustion and the territoriality of intellectual property rights in the patent field by industries affected, this is a challenging, but well-founded and well-argued proposition. The thesis succeeds to support the proposition with a multitude of legal and policy arguments. It doing so, it offers the

most comprehensive analysis of the subject of parallel trading and exhaustion of rights ever produced. It makes an important contribution to the debate.

Accompanying Dr Santanu Mukherjee over many years in the pursuit of his research has been most rewarding. The thesis was developed by the author next to a busy professional life as a practising lawyer in India, and upon completing the MILE programme at the World Trade Institute, University of Bern, Switzerland. Despite a busy schedule, he persistently pursued his academic work and sets an example to all those in comparable circumstances. I am particularly glad and happy to see this volume added to the World Trade Institute Advanced Series.

*Thomas Cottier*

Bern, September 2022

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This book is the culmination of my doctoral research at the University of Bern, Switzerland. I am deeply indebted to my doctoral supervisor Prof Dr Thomas Cottier, my guru, for his academic guidance and continuous moral support, without which I would have never reached the closure of my research. I thank him from the bottom of my heart for being a pillar of support right from conceptualising the research and going through challenging periods until the end. Thanks for all the discussions on the topic and especially when I was preparing the foundation of my arguments. His encouragement to think more deeply on the subject from different perspectives and not narrowly on TRIPS, has opened my thought process and changed my outlook.

I would like to thank the Max Planck Institute for Intellectual Property and Competition Law (MPI) in Munich for their support to undertake the initial research. Special thanks to Dr Christopher Heath, for all the enriched discussions while at the Institute (now with the Board of Appeals, European Patent Office). Thanks to Professors Dr. Joseph Straus, Dr. Ansgar Ohly, Dr Reto Hilty and Dr Josef Drexel for their guidance and also thanks to, Ms. Elfride Stangl at the MPI administration office for her kind help and assistance. Thanks also to the National Law University, New Delhi (NLU) for allowing me to use their library facilities. My friends, Prof. Yogesh Pai at NLU, Delhi and Prof. Arul George Scaria, now with NLSU, Bangalore for all the discussions and debates about my research.

I dedicate this book to my parents, wife, sister, aunt and maternal cousin for their constant support and inspiration and my young son for coping with shortened play time. I wish my father who had been a constant inspiration was there with us today to share my joy. I am thankful to each one of them for helping me balance family responsibilities, professional work and the doctoral research that emanated in this book. Thanks to all my friends who had helped me always with their positivity and support.

*Santanu Mukherjee*

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# Abbreviations and Acronyms

AB	Appellate Body
AIDS	Acquired Immune Deficiency Syndrome
AIIPI	International Association for the Protection of Industrial Property
AP	Andean Pact
ASEAN	Association of South East Asian Nations
CACM	Central American Common Market
CET	Common External Tariff
CGC	Gulf Co-operation Council
CL	Compulsory License
CU	Customs Union
CUSFTA	Canada-US Free Trade Agreement
DABMP	Dutch Assessment Board for Medicinal Products
DIAC	Draft International Antitrust Code
DSB	Dispute Settlement Body
EC	European Community
ECJ	European Court of Justice
ECOWAS	Economic Community of West African States
ECSC	European Coal and Steel Community
EEA	European Economic Area
EEC	European Economic Community
EFTA	European Free Trade Association
EMR	Exclusive Marketing Rights
EPC	European Patent Convention
EU	European Union
FTA	Free Trade Agreements
GATT	General Agreement on Trade Tariffs
GATS	General Agreement on Trade in Services
GSP	Generalised System of Preferences
HIV	Human Immunodeficiency Virus
ICC	International Chamber of Commerce
IMF	International Monetary Fund
INTA	International Trademark Association
IP	Intellectual Property
IPC	Intellectual Property Rights Committee
IPRS	Intellectual Property Rights
ITO	International Trade Organisation
LAFTA	Latin American Free Trade Area

LAIA	Latin American Integration Agreement
LDC	Least Developing countries
MNC	Multinational Corporations
MFN	Most Favoured Nation
NAFTA	North American Free Trade Agreement
NT	National Treatment
NTB	Non-Tariff Barrier
PAFTA	Pacific Free Trade Area
PMASA	Pharmaceutical Manufacturers' Association of South Africa
PTA	Preferential Trade Area
QC	Queen's Counsel
QR	Quantitative Restrictions
RTA	Regional Trade Agreements
R&D	Research and Development
SAARC	South Asian Association for Regional Cooperation
SADCC	Southern African Development Coordination Conference
SAFTA	South Asian Free Trade Agreement
SKF	Smith Kline & French Laboratories Ltd.
S & DT	Special and Differential Treatment
TRIPS	Trade Related aspects of Intellectual Property Rights
UK	United Kingdom
UN	United Nations
UNCTAD	United Nations Conference on Trade and Development
UNESCO	United Nations Educational, Scientific and Cultural Organisation
UNHCR	United Nations Commission on Human Rights
US	United States
USPTO	United States Patent and Trademark Office
USTR	United States Trade Representatives
WHO	World Health Organisation
WIPO	World Intellectual Property Organisation
WTO	World Trade Organisation