The TRIPS Regime of Antitrust and Undisclosed Information

Nuno Pires de Carvalho
# TABLE OF CONTENTS

**Foreword** xiii

**INTRODUCTORY NOTE**

**THE LEGAL STRUCTURE AND THE ECONOMIC NATURE OF INTELLECTUAL PROPERTY** 1

1. The legal structure of intellectual property 2
   (a) Intellectual property: The branch of law that protects business differentiating intangible assets 2
   (b) The intrinsically exclusive nature of intellectual property 12

2. The economic nature of intellectual property 13
   (a) The economic function of intellectual property: To promote the creation and the preservation of business differentiation 13
   (b) Intellectual property and the reduction of transaction costs 18

3. Intellectual property: a spontaneous legal tool that has embedded the structural fabric of every organized society since the dawn of civilization 22

**THE TRIPS REGIME OF ANTITRUST**

**INTRODUCTION** 31

1. Industrial property, an integral element of competition policy 31
   (a) The first level of interoperability: Industrial property needs antitrust law 31
   (b) The second level of interoperability: Antitrust law needs industrial property 32
   (c) A special note on the interface between patent and competition law 33
      (i) Patents and monopolies 34
      (ii) Abuses of patent rights 42
   (d) Patents and trademarks at a crossroads 45
   (e) Industrial property, competition law and repression of unfair competition 47
### PART I
**GENERAL PROVISIONS AND BASIC PRINCIPLES**

**Article 6**  
*Exhaustion*  
1. The meaning of Article 6  
2. Exhaustion  
3. The legal implications of international exhaustion  
4. A third modality of exhaustion: controlled international exhaustion

**Article 7**  
*Objectives*  
1. The scope and the meaning of Article 7  
2. Transfer and dissemination of technology  
3. The meaning of the expression ‘balance of rights and obligations’

**Article 8**  
*Principles*  
*Paragraph 2*

### PART II
**STANDARDS CONCERNING THE AVAILABILITY, SCOPE AND USE OF INTELLECTUAL PROPERTY RIGHTS**

**Section 2: Trademarks**

**Article 21**  
*Licensing and Assignment*  
1. The scope of Article 21  
2. Quality control  
3. Compulsory licenses of trademarks  
4. Compulsory assignments of trademarks  
5. Alternative solutions to trademark compulsory licensing  
   (a) Prohibitions of use and cancellation of registration  
   (b) Limitations on injunctions  
6. The implementation of Article 21
### Section 5: Patents

**Article 31**  
*Other Use Without Authorization of the Right Holder*  
*Paragraph (k)*  
1. The legislative history of Article 31(k)  
2. Compulsory licenses and antitrust law  
3. Remuneration  
4. Adjudication  

*Paragraph (l)*  

**Article 32**  
*Revocation/Forfeiture*  
1. The meaning and the scope of Article 32  
2. Revocation or forfeiture of patents to remedy antitrust violations. Divestiture and the fruits doctrine  

### Section 8: Control of Anti-Competitive Practices in Contractual Licences

**Article 40**  
1. The meaning and scope of Article 40  
2. Legislative history of Article 40  
3. An exhaustive or indicative list of antitrust practices? The different approaches to this matter and the impact of the language of article 40.2 on the freedom of members to address it  
4. International cooperation in the field of antitrust violations in licensing agreements  
5. Work in the WTO on the interface between intellectual property and antitrust  

### THE TRIPS REGIME OF UNDISCLOSED INFORMATION

**Section 7: Protection of Undisclosed Information**

**Article 39**  
*Paragraph 1*  
1. Introduction  
2. The legislative history of Article 10 *bis* of the Paris Convention  
   (a) Legislative history
The TRIPS Regime of Antitrust and Undisclosed Information

(b) Does Article 10 bis of the Paris Convention provide for mandatory protection of trade secrets? 200
(c) Conclusions 204

3. Do paragraphs 1 and 2 cover different subject matter? 206

Paragraph 2

1. The legislative history of Article 39.2 of the TRIPS agreement 207
2. Protection of trade secrets under Article 39.2 224
3. Protection of confidential information in court procedures 237

Paragraph 3

1. The legislative history of Article 39.3 240
   (a) The origins of the protection of test data 240
   (b) The legislative history of Article 39.3 243
      (i) Proposals on test data in the first round of discussions (1987–1990) 243
      (ii) Proposals on test data in the second (and last) round of negotiations 250
   2. Economic and social constraints over protection of test data 259
   3. The scope, the reach and the application of Article 39.3 263
      (a) Test data protection under Article 39.3 of the TRIPS Agreement: a sui generis mechanism 263
      (b) Protection of undisclosed test data against unfair commercial use is mandatory as regards pharmaceutical and agricultural chemical products only 267
      (c) Protection against unfair commercial use 270
         (i) The meaning of ‘unfair commercial use’ 270
         (ii) The first possible modality of protection: data exclusivity 272
         (iii) The second possible mechanism of protection: Right-to-remuneration 281
      (d) Exclusivity of data does not mean either exclusivity of information or product or market exclusivity 284
      (e) Requirements 286
         (i) Submission must be mandatory 286
         (ii) The nature of the product 287
         (iii) Novelty 288
         (iv) Secrecy of the data 292
(v) Considerable efforts required for obtaining the data 295
(vi) Approval of the relevant chemical entity 296
(vii) Opportunity 297
(f) Protection against disclosure 298
(g) Term of protection 299
(h) The relationship between test data protection and patent rights 301
(i) Exceptions and limitations to rights conferred 307
   (i) Fair use of test data 307
   (ii) Non-commercial use 313
   (iii) International exhaustion 314
(j) A few additional issues 315
   (i) Restoration of terms of protection 315
   (ii) Core dossier registrations and the protection of supplementary data 317
   (iii) Biological products 317
(k) Transition periods for least-developed country WTO Members (LDCs) 318

4. Recent developments concerning protection of test data. ‘TRIPS plus’ standards in the context of bilateral free trade agreements 319

5. The dispute settlement mechanism in the context of undisclosed information 323
   (a) First lesson: Good intentions do not count 325
   (b) Second lesson: More (protection) is always better than less 325
   (c) Third lesson: International trade has reasons that the Reason does not know 325

Annex 329
Agreement on Trade-related Aspects of Intellectual Property Rights 329
Paris Convention for the Protection of Industrial Property 367
Declaration on the TRIPS Agreement and Public Health 381
Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products 383
Extension of the Transition Period Under Article 66.1 for Least-Developed Country Members 384
## Reference

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jurisprudence</td>
<td>392</td>
</tr>
<tr>
<td>WIPO Documents</td>
<td>394</td>
</tr>
<tr>
<td>GATT Documents</td>
<td>394</td>
</tr>
<tr>
<td>WTO Documents</td>
<td>395</td>
</tr>
</tbody>
</table>

## Index

399