

The Trips Regime of Patents and Test Data

4th Edition

By Nuno Pires de Carvalho



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The TRIPS Regime of Patents and Test Data

*For Ana
(for ever)*

*For André, Hugo & Carolina
For Theo, Felipe, Sofia, Pedro & Mateo*

Foreword

When it started, the implementation of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) gave rise to two sorts of reactions: enthusiasm and rejection. A significant number of TRIPS supporters believed that the new standards of TRIPS obligations would deliver on its promise of generating an unencumbered flow of patented goods and technology from developed to developing countries. At the other end, a likewise significant number of TRIPS adversaries feared that a considerable transfer of resources from developing to developed countries would follow as a consequence of increased prices of intellectual property protected articles and the abuses in the exercise of market power derived from the newly created rights. Such transfer would be, however, compensated by a significant flow of technology from developed to developing countries' World Trade Organization (WTO) Members that would enable the latter not only to replace imported patented articles with those of their own making but also to become sources of international trade of patented goods.

Almost twenty years later, the profound change in the international scenario of intellectual property protection is visible. The TRIPS Agreement has had a deep impact on the levels of protection of differentiating intangible assets – not only on those that concern creation and innovation, such as copyright and patents, but also on those that cover designs, reputation, quality, origin, such as trademarks, industrial designs and the repression of unfair competition. However, the implementation of the TRIPS Agreement, especially in the two areas covered by this book – patents and test data – by a large number of WTO Members has not been entirely achieved, which has to a large extent frustrated the expectations of developed WTO Members. Indeed, three fundamental provisions of the TRIPS Agreements have been ignored by a large part of the WTO Membership: the prohibition of imposing the local exploitation requirement; the prohibition to exclude inventions from patentability on morality or public order grounds, unless that exclusion is preceded from a prohibition of their commercial exploitation and only if that exclusion is necessary to ensure non-exploitation; and the obligation to accord substantive protection to test data (i.e., protection against unfair commercial use) in addition to adjective protection (i.e., protection against unjustified disclosure).

In the end, developing WTO Members do not miss an opportunity to express their disappointment that the TRIPS Agreement has not delivered on the promise to ensure a permanent and reasonably priced flow of technology. The high prices of new patented drugs is another reason for complaint against the TRIPS Agreement – whose main, if not only, initial justification was to put an end to the discriminatory treatment against pharmaceutical inventions.*

Some of those frustrations of developed WTO Members are being addressed by means of free trade agreements (FTAs). Using card playing as an illustration, things happen as if a number of players left the main table and took a seat at small tables, to replay the same game but under new rules, discussed on a case by case basis. By contrast, the frustrations of developing WTO Members cannot be addressed, because they result from a misunderstanding of the nature of the Agreement. The TRIPS Agreement was adopted with a fundamental objective of enhancing the protection of pharmaceutical inventions. For that objective to be achieved, those WTO Members that host research-based pharmaceutical companies agreed to pay in the form of granting market access to the exports of commodities originated in developing countries. In other words, one should not seek trade-offs within the TRIPS Agreement, in isolation, but rather by comparing TRIPS standards with concessions made in the other components of the WTO Agreement.

This fact has led to a profound change in the way intellectual property is seen in the multilateral setting. In the nineteenth century, intellectual property was presided by the perceived need to promote national industry. In the course of the twentieth century, under the aegis of the Paris and Berne Conventions, other considerations were accepted, such as the promotion of national development and the protection of human rights. In 1994, all this changed: intellectual property became a token of negotiations on market access.

It is this aspect that the adversaries (as well as the supporters) of the TRIPS Agreement tend to overlook. The only promise that came associated with the TRIPS Agreement was the increased flow of intellectual property protected articles in exchange for an increased flow of commodities (which, actually, can also be protected by intellectual property).

This fourth edition visits these controversial aspects of the implementation of the TRIPS Agreement. It comes, however, with a noticeable change in its title. Whereas the three previous editions were named *The TRIPS Regime of Patent Rights*, this one is entitled *The TRIPS Regime of Patents and Test Data*. The special mention to test data is caused by the fact that, although closely associated with the regime of patent rights, test data are a different mechanism and cover different subject matter. Because of that close association, the previous editions had already an extensive commentary to Article 39.3. But the fourth edition adds more depth and detail to that commentary.

Otherwise, this edition updates the comments to the TRIPS provisions that relate to patent protection, thereby reflecting the current status of old debates in the TRIPS Council as well as describing new discussions and topics. The fourth edition also brings new perspectives on the debate concerning the relation between TRIPS and the Convention on Biological Diversity (CBD). The proposal to amend the TRIPS Agreement so as to include the requirement to disclose the origin of genetic resources in

patent applications, albeit supported by a vast majority of the WTO Membership, continues lingering, and its extremely slim chances of soliciting consensus seem to have faded away. Therefore, the corresponding comments have been shortened.

One topic, by contrast, has gained more attention – the interface between intellectual property and competition. The reason for that is the significant rise in the scrutiny of the enforcement of patent rights in the context of antitrust law. This may be basically due to the fact that in the last years an increasing number of WTO Members have enacted anti-monopoly statutes and set national competition authorities. Those statutes tend to include provisions that directly or indirectly impinge on intellectual property. Moreover, under the Agenda for Development, the World Intellectual Property Organization (WIPO) has adopted a work program on intellectual property and competition policy, aimed at raising the level of understanding of that interface and permitting the sharing of experiences among its Member States in its regard. Accordingly, comments to Articles 8.2 and 40 have been extended and included, respectively.

Because of its origins and main purpose – to prohibit free riding in pharmaceutical inventions – the TRIPS Agreement has been, is, and will be a controversial Agreement, and the right measure of its correct implementation will never solicit consensus. The fourth edition, like the previous editions, does not avoid the controversies – and, actually, proposes a few new ones. But no commentator can analyse the TRIPS Agreement without stumbling into difficult and controversial matters. At this point, I am therefore under the obligation to emphasize that all opinions expressed in this book are exclusively my responsibility, and that they do not necessarily reflect the views of the Secretariat of the WIPO, which I serve, or its Member States.

Belo Horizonte, MG, Brazil,
15 November 2013

Table of Contents

Foreword	xvii
Introductory Note: The TRIPS Agreement Twenty Years After	1
I The Origins	1
II Awakening to Reality	5
III Finding the Evidence: The TRIPS Agreement Is about Trade	8
IV A New Piece of the Puzzle: TRIPS "Flexibilities"	10
[A] The Concept of "Flexibilities"	10
[B] Four Clusters of Flexibilities	12
[1] The First Cluster: Transition Periods	12
[2] The Second Cluster: Flexibilities Regarding Implementation of International Obligations	12
[3] The Third Cluster: Flexibilities As to Standards of Protection; Upward (TRIPS Plus) and Downward (Exceptions and Limitations) Flexibilities; Modalities of Exceptions and Limitations: Internal and External Examples	13
[4] The Fourth Cluster: Flexibilities in the Field of Enforcement; Injunctions and the Principle of Equity	15
[C] Another Approach to Flexibilities: Three Sequential Moments in the Life of Rights and Corresponding Flexibilities	15
[D] General Principles That Apply to Flexibilities and Conclusion	17
V The TRIPS Agreement As Unfinished Business and the Need to Move Forward	20
Preamble Agreement on Trade-Related Aspects of Intellectual Property Rights	31
1 The Scope, the Nature and the Function of the TRIPS Agreement	32
(a) The scope of the TRIPS Agreement	32

Table of Contents

	(b) The dynamic dimension of the TRIPS Agreement	35
	(c) The nature and the function of the Agreement	37
	(i) The first objective of the TRIPS Agreement: to reduce distortions and impediments to international trade	40
	(ii) The second objective of the TRIPS Agreement: to protect private property rights	44
2	Intellectual Property and Trade	46
	(a) TRIPS and the GATT	51
	(b) The WTO and WIPO	57
3	Patent Protection and Economic Development	62
PART I		
	General Provisions and Basic Principles	71
Article 1	Nature and Scope of Obligations	71
1	The TRIPS Agreement: A Minimum Standards Agreement (in Part)	72
2	Method of Implementing the Provisions of the TRIPS Agreement	77
3	Implementation	81
4	The Scope of TRIPS Obligations	86
Article 2	Intellectual Property Conventions	89
1	The Objective of the Paris Convention in the Field of Patents: The Articulation of National Patent Systems	89
2	The National Treatment Principle under the Paris Convention	92
3	Priority	93
4	The Principle of Independence	96
5	Article 5 of the Paris Convention and Trade Protectionism	98
6	From the Paris Convention to the TRIPS Agreement	99
7	The Relationship between the TRIPS Agreement and the Paris Convention	102
Article 3	National Treatment	109
1	The "No Less Favourable" Treatment Standard of the TRIPS Agreement As Opposed to the "Same" Treatment Standard of the Paris Convention	109
2	The Concept of "Necessity" in the TRIPS Agreement	113
3	Two GATT Panel Reports on the National Treatment Principle and Article XX(d) of the GATT 1947	117
4	The Principle of National Treatment in the <i>European Communities</i> Cases	120
5	Scope and Reach of Footnote 3	123
Article 4	Most-Favoured-Nation Treatment	127
1	The MFN Treatment Principle	127
2	The MFN Principle and the National Treatment Principle: A Rule of Thumb	128

3	The Scope of the MFN Principle	129
4	Exemptions from the MFN Principle	131
Article 5	Multilateral Agreements on Acquisition or Maintenance of Protection	135
1	The Scope of the Exemption under Article 5	135
2	An Example of an Admissible Exemption: Discriminatory Reduction of Fees	138
Article 6	Exhaustion	139
1	Exhaustion	139
2	The Meaning of Article 6	148
3	The Legal Implications of International Exhaustion	151
4	Using Exhaustion As a Tool to Address Anticompetitive Practices	159
5	Other Modalities of Exhaustion	160
Article 7	Objectives	164
1	The Origins of Article 7 and the Notion of Intellectual Property	164
2	Patents, Trade Secrets and Patronage: Alternative Mechanisms to Promote Invention and Innovation	171
3	Article 7 Is Not about the Objectives of the TRIPS Agreement	178
4	Patents, Innovation, and Transfer and Dissemination of Technology	179
	(a) Patents and invention	182
	(b) Transfer and dissemination of technology	184
5	The Meaning of the Second Part of Article 7	191
Article 8	Principles	193
Paragraph 1		193
1	Article 8 Is Not about Principles of the Agreement but Rather about Principles of Implementation of the Agreement	193
2	The Origins of Article 8	194
3	The Conditions of the Application of Article 8.1	194
4	Article 8.1 and Non-violation Complaints	197
5	The TRIPS Agreement and Public Health	198
6	The Doha Declaration on the TRIPS Agreement and Public Health	205
	(a) Introduction	205
	(b) Commentary	206
Paragraph 2		213
1	The Meaning and the Reach of Article 8.2	213
2	The Interface between Patent and Competition Law	215
	(a) Patents and monopolies	215
	(b) The interface between intellectual property and competition law	228
	(i) The three levels of the interface	229
	(ii) Examples	231
	- Intellectual property in the wrong dosage (too much and too less intellectual property)	231
	- Abuses of patent rights	232

Table of Contents

	- (Rare) cases of anticompetitive intellectual property rights (even if in the correct dosage and not abused)	234
3	The Interface between Patent and Competition Law: A List of Issues	236
4	The Interface between Intellectual Property and Competition in the TRIPS Agreement	238
PART II		
	Standards Concerning the Availability, Scope and Use of Intellectual Property Rights	245
	Section 5: Patents	245
	Article 27 Patentable Subject Matter	245
	Paragraph 1	245
1	The History of Article 27	245
2	Prohibition of Discrimination	248
3	Article 27.1 and Article 1	252
4	The Scope of Article 27.1: Superjacent and Subjacent TRIPS Conditions of Patentability	252
	(a) The superjacent TRIPS conditions of patentability	254
	(i) Novelty	254
	(ii) Inventive step (non-obviousness)	257
	(iii) Capability of industrial application (usefulness)	261
	(b) The subjacent conditions of patentability	264
	(i) Artificiality	264
	(ii) Non-communicability	265
	(iii) Alternativeness	266
	(iv) Materiality	269
	(c) The conditions of patentability and the differentiating function of patents	272
	(i) Computer software	273
	(ii) Business methods	274
	(iii) Second uses	278
5	Substantive Examination	284
6	Conditions of Patentability: A Minimum or a Maximum?	288
7	Discrimination As to the Place of Invention	290
8	Discrimination As to the Field of Technology	290
9	Discrimination As to the Local of Production: The Local Working Requirement	292
	(a) The working requirement under the Paris Convention	292
	(b) The meaning of the last sentence of Article 27.1	294
	(c) The interface between international exhaustion and the local working requirement	296
	(d) A persuasive precedent of the GATT jurisprudence: The United States Manufacturing Clause	297

	(e) The cross-disputes between the United States and Brazil	298
	(f) The local exploitation requirement and Article XX(j) of the GATT 1947: an admissible exception to Article 27.1?	304
10	The Local Exploitation Requirement As Distinguished from the Working Requirement	305
11	Prohibition to Discriminate As to the Enjoyment of Rights	307
	Paragraph 2	308
1	Exclusions from Patentability on Ethical Grounds	308
2	Morality and " <i>Ordre Public</i> "	311
3	The Two-Step Necessity Test	313
4	Exclusions from Commercial Exploitation as Opposed to Other Forms of Exploitation	317
5	Article 27.2 and Article 4 <i>quater</i> of the Paris Convention	317
6	Other Remarks on Article 27.2	319
	Paragraph 3(a)	319
	Paragraph 3(b)	322
1	Plant Variety Protection: The UPOV	324
	(a) The farmers' exemption	327
	(b) The breeders' exemption	329
2	The Relationship between the TRIPS Agreement and the CBD	331
	(a) The negotiations in the TRIPS Council	331
	(b) The intersection of the TRIPS Agreement with the CBD	337
	(i) The precautionary principle and the TRIPS Agreement	338
	(ii) Article 8(j) of the CBD and the TRIPS Agreement	339
	(iii) Article 15 of the CBD and Articles 27 and 28 of the TRIPS Agreement	342
	(iv) Article 16 of the CBD and the TRIPS Agreement	345
	(v) Article 18 of the CBD and the TRIPS Agreement	348
	(vi) In a nutshell, there is no necessary conflict between the CBD and the TRIPS Agreement	348
3	The Relationship between the TRIPS Agreement and the FAO International Treaty on Plant Genetic Resources for Food and Agriculture	352
	Article 28 Rights Conferred	355
	Paragraph 1	355
1	The Meaning and Scope of Article 28	356
2	Administrative Enforcement of Patent Rights by Regulatory Authorities: The Patent Linkage, a New Trend?	359
	Paragraph 2	361
	Article 29 Conditions on Patent Applicants	364
1	Enabling Disclosure	364
2	Elements for Assessing the Sufficiency of the Disclosure	365
3	Best Mode Disclosure	368

Table of Contents

4	Information Concerning Foreign Applications	370
5	The Requirement to Disclose the Origin of Genetic Resources and Prior Informed Consent of the Use of Traditional Knowledge in Patent Applications	371
Article 30	Exceptions to Rights Conferred	375
1	The Three Conditions for the Application of Article 30	378
2	Article 30 and Article 27.1	383
3	Examples of Exceptions to Rights Conferred; the Problems with Exhaustion, Manual Handling of Pharmaceutical Preparations and the Prior User Exceptions	383
4	Article 30 and the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health	386
Article 31	Other Use without Authorization of the Right Holder	387
Paragraph		387
Subparagraph (a)		399
Subparagraph (b)		400
Subparagraph (c)		410
Subparagraph (d)		413
Subparagraph (e)		414
Subparagraph (f)		415
1	The Meaning and Scope of Article 31(f)	415
2	Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health	418
3	The Decision of the WTO General Council of 30 August 2003, on the Implementation of Paragraph 6 of the Doha Declaration of the TRIPS Agreement and Public Health	420
(a)	Introduction	420
(b)	Commentary	427
Subparagraph (g)		456
Subparagraph (h)		458
Subparagraph (i)		459
Subparagraph (j)		460
Subparagraph (k)		460
1	The Legislative History of Subparagraph (k)	460
2	Compulsory Licenses and Antitrust Law	462
3	Remuneration	467
4	Adjudication	468
5	Other Issues	469
Subparagraph (l)		470
Article 32	Revocation/Forfeiture	476
1	The Meaning and the Scope of Article 32	476
2	Revocation or Forfeiture of Patents to Remedy Antitrust Violations: Divestiture and the <i>FRUITS Doctrine</i>	482
Article 33	Term of Protection	485

Article 34	Process Patents: Burden of Proof	494
Section 7	Protection of Undisclosed Information	499
Article 39		499
Paragraph 1		499
1	Introduction	499
2	The Legislative History of Article 10 <i>bis</i> of the Paris Convention	501
	(a) Legislative history	501
	(b) Does Article 10 <i>bis</i> of the Paris Convention provide for mandatory protection of trade secrets?	509
	(c) Conclusions	513
3	Do Paragraphs 1 and 2 Cover Different Subject Matters?	516
Paragraph 2		517
1	The Legislative History of Article 39.2 of the TRIPS Agreement	520
2	Protection of Trade Secrets under Article 39.2	534
3	Protection of Confidential Information in Court Procedures	547
Paragraph 3		550
1	The Legislative History of Article 39.3	550
	(a) The origins of the protection of test data	550
	(b) The legislative history of Article 39.3	552
	(i) Proposals on test data in the second cycle of TRIPS negotiations (1989-1990)	553
	(ii) Proposals on test data in the third (and last) round of TRIPS negotiations (1990-1991)	559
2	Economic and Social Constraints over Protection of Test Data	568
3	The Scope, the Reach and the Application of Article 39.3	572
	(a) Test data protection under Article 39.3 of the TRIPS Agreement: a <i>sui generis</i> mechanism	572
	(b) Substantive protection of undisclosed test data (i.e., against unfair commercial use) is mandatory as regards pharmaceutical and agricultural chemical products only	578
	(c) Test data protection: substantive and adjective protection	581
	(i) The meaning of "unfair commercial use" – the obligation to ensure substantive protection	582
	(ii) The first possible modality of substantive protection: data exclusivity	586
	(iii) The second possible mechanism of substantive protection: right-to-remuneration	593
	(d) Exclusivity of data does not mean either exclusivity of information or product or market exclusivity	598
	(e) Requirements	601
	(i) Submission must be mandatory	601
	(ii) The nature of the product	602
	(iii) Novelty	604
	(iv) Secrecy of the data	608

Table of Contents

	(v) Considerable efforts required for obtaining the data	611
	(vi) Approval of the relevant chemical entity	612
(f)	Protection against disclosure	613
(g)	Term of protection	617
(h)	The relationship between test data protection and patent rights – the “patent linkage”	619
(i)	Exceptions and limitations to rights conferred	623
	(i) Fair use of test data	623
	(ii) Non-commercial use	629
	(iii) International exhaustion	631
(j)	A few additional issues	632
	(i) Restoration of terms of protection	632
	(ii) Core dossier registrations and the protection of supplementary data	633
	(iii) Biological products	634
4	Recent Developments Concerning Protection of Test Data: “TRIPS Plus” Standards in the Context of Bilateral FTAs	635
Section 8:	Control of Anticompetitive Practices in Contractual Licences	640
Article 40		640
1	The Meaning and the Scope of Article 40	641
2	Legislative History of Article 40	642
3	An Exhaustive or Indicative List? The Impact of the Language of Article 40.2 on the Freedom of WTO Members to Address Anticompetitive Practices in Contractual Licenses	644
4	Article 40.2 and Non-violation Complaints	657
5	International Cooperation in the Field of Antitrust Violations in Licensing Agreements	658
6	Work in the WTO on the Interface between Intellectual Property and Antitrust	662
PART IV		
	Acquisition and Maintenance of Intellectual Property Rights and Related <i>Inter Partes</i> Procedures	667
	Article 62	667
	Paragraph 1	667
	Paragraph 2	671
	Paragraph 4	674
PART V		
	Dispute Prevention and Settlement	675
Article 64	Dispute Settlement	675
1	Objectives and Nature of the DSM	675
2	The New Features of the DSM	677

3	Conciliatory Steps	678
4	The Outcome of the DSM	679
5	Specific Issues Concerning the Withdrawal of Concessions in the TRIPS Agreement: The Problem of Cross-Retaliation Sanctions	681
6	Non-violation and Situation Complaints	684
7	The Special (and Overlooked) Interest of LDCs in Non-violation Complaints	691
8	Disputes	693
	(a) Patent-related disputes	693
	(b) Test data-related disputes	697
9	Lessons from the DSM	697
	(a) First lesson: Good intentions do not count	697
	(b) Second lesson: More (Protection) is always better than less	698
	(c) Third lesson: International Trade has reasons that the reason does not know	698
PART VI		
	Transitional Arrangements	701
Article 65	Transitional Arrangements	701
Paragraph 5		701
1	Standstill	701
2	Standstill and LDCs	702
Article 66	Least-Developed Country Members	708
Paragraph 1		708
Paragraph 2		715
Article 70	Protection of Existing Subject Matter	718
Paragraph 1		718
Paragraph 2		721
Paragraph 3		724
Paragraph 4		724
[...]		725
Paragraph 6		725
Paragraph 7		726
Paragraph 8		727
Paragraph 9		729
Jurisprudence		737
APPENDICES		
Appendix I	Agreement on Trade-Related Aspects of Intellectual Property Rights	743
Appendix II	Paris Convention for the Protection of Industrial Property	781
Index		821