

THE PATENT
LITIGATION
LAW REVIEW

THIRD EDITION

Editor
Trevor Cook

THE LAWREVIEWS

THE PATENT
LITIGATION
LAW REVIEW

THIRD EDITION

Reproduced with permission from Law Business Research Ltd
This article was first published in November 2019
For further information please contact Nick.Barette@thelawreviews.co.uk

Editor
Trevor Cook

THE LAWREVIEWS

PUBLISHER

Tom Barnes

SENIOR BUSINESS DEVELOPMENT MANAGER

Nick Barette

BUSINESS DEVELOPMENT MANAGER

Joel Woods

SENIOR ACCOUNT MANAGERS

Pere Aspinall, Jack Bagnall

ACCOUNT MANAGERS

Olivia Budd, Katie Hodgetts, Reece Whelan

PRODUCT MARKETING EXECUTIVE

Rebecca Mogridge

RESEARCH LEAD

Kieran Hansen

EDITORIAL COORDINATOR

Gavin Jordan

HEAD OF PRODUCTION

Adam Myers

PRODUCTION EDITOR

Hilary Scott

SUBEDITOR

Helen Sou

CHIEF EXECUTIVE OFFICER

Nick Brailey

Published in the United Kingdom
by Law Business Research Ltd, London
Meridian House, 34-35 Farringdon Street, London, EC4A 4HL, UK
© 2019 Law Business Research Ltd
www.TheLawReviews.co.uk

No photocopying: copyright licences do not apply.

The information provided in this publication is general and may not apply in a specific situation, nor does it necessarily represent the views of authors' firms or their clients. Legal advice should always be sought before taking any legal action based on the information provided. The publishers accept no responsibility for any acts or omissions contained herein. Although the information provided was accurate as at October 2019, be advised that this is a developing area.

Enquiries concerning reproduction should be sent to Law Business Research, at the address above.

Enquiries concerning editorial content should be directed
to the Publisher – tom.barnes@lbresearch.com

ISBN 978-1-83862-071-4

Printed in Great Britain by
Encompass Print Solutions, Derbyshire
Tel: 0844 2480 112

ACKNOWLEDGEMENTS

The publisher acknowledges and thanks the following for their assistance throughout the preparation of this book:

ANAND AND ANAND

ANDERSON MÖRI & TOMOTSUNE

BOULT WADE TENNANT LLP

BRISTOWS LLP

CLIFFORD CHANCE

DEEP & FAR ATTORNEYS-AT-LAW

DERİŞ

GATTAL, MINOLI, AGOSTINELLI & PARTNERS

G ELIAS & CO

GOWLING WLG RUSSIA

HERBERT SMITH FREEHILLS

HOMBURGER AG

JADEK & PENSA

LINKLATERS LLP

LØJE IP

OLIVARES

PINHEIRO NETO ADVOGADOS

THE RADER GROUP PLLC

S HOROWITZ & CO

SMART & BIGGAR

TAYLOR WESSING NV

VIEIRA DE ALMEIDA

WILLIAM FRY

WILMER CUTLER PICKERING HALE AND DORR LLP

WINSTON & STRAWN LLP

CONTENTS

PREFACE.....	vii
<i>Trevor Cook</i>	
Chapter 1	OPPOSITIONS AND APPEALS BEFORE THE EUROPEAN PATENT OFFICE.... 1
<i>James Short and Roban Setna</i>	
Chapter 2	UNIFIED PATENT COURT..... 7
<i>Alan Johnson</i>	
Chapter 3	AUSTRALIA..... 18
<i>Sue Gilchrist and Steve Wong</i>	
Chapter 4	BELGIUM 29
<i>Christian Dekoninck</i>	
Chapter 5	BRAZIL..... 42
<i>Márcio Junqueira Leite and Victor Rawet Dotti</i>	
Chapter 6	CANADA..... 53
<i>Steven B Garland, Jeremy E Want and Daniel J Hnatchuk</i>	
Chapter 7	DENMARK..... 76
<i>Johan E Løje</i>	
Chapter 8	FRANCE..... 89
<i>Pauline Debré and Jean-François Merdrignac</i>	
Chapter 9	GERMANY..... 108
<i>Julia Schönbohm, Bolko Ehlgén and Natalie Ackermann-Blome</i>	
Chapter 10	INDIA..... 125
<i>Pravin Anand and Vidisha Garg</i>	

Contents

Chapter 11	IRELAND	137
	<i>Laura Scott, Charleen O’Keeffe and Erika O’Donnell</i>	
Chapter 12	ISRAEL.....	151
	<i>Tal Band and Dovev Apel</i>	
Chapter 13	ITALY	167
	<i>Licia Garotti</i>	
Chapter 14	JAPAN	183
	<i>Yasufumi Shiroyama</i>	
Chapter 15	MEXICO	192
	<i>Armando Arenas Reyes, Luz Elena Elías and Erwin Cruz</i>	
Chapter 16	NETHERLANDS.....	204
	<i>Wim Maas</i>	
Chapter 17	NIGERIA.....	215
	<i>Fred Onuobia, Solomon Ezike and Ayodele Kadiri</i>	
Chapter 18	PORTUGAL.....	226
	<i>António Andrade and Marta Alves Vieira</i>	
Chapter 19	RUSSIA.....	237
	<i>David Aylen and Vladislav Ugryumov</i>	
Chapter 20	SLOVENIA.....	252
	<i>Aleksandra Jemc Merc and Eva Gostiša</i>	
Chapter 21	SPAIN.....	262
	<i>Miquel Montañá Mora</i>	
Chapter 22	SWITZERLAND	275
	<i>Andri Hess</i>	
Chapter 23	TAIWAN.....	287
	<i>Yu-Li Tsai</i>	
Chapter 24	TURKEY.....	297
	<i>Mehmet Nazim Aydin Deriş, Okan Çan, Muazzez Korutürk and Oya Yalvaç</i>	

Contents

Chapter 25	UNITED KINGDOM.....	312
	<i>Trevor Cook</i>	
Chapter 26	UNITED STATES.....	322
	<i>Thomas L Jarvis, Cyrus T Frelinghuysen, Judge Randall R Rader and Benjamin Christoff</i>	
Appendix 1	ABOUT THE AUTHORS.....	343
Appendix 2	CONTRIBUTORS' CONTACT DETAILS.....	359

PREFACE

Although patent litigators should always be mindful that patent litigation has, with some justification, been called the ‘pathology of the patent system’, not so much as a criticism, but more in recognition of how remarkably little patent litigation there is, in fact, when seen in relation to the ever increasing number of patents in force at any one time, patent litigation is also the anvil on which patent law is forged. This is because the ‘black letter’ law of patents tends to be terse by comparison to most other areas of law, and it is only with experience of how courts and tribunals interpret such law and apply it that one can start to appreciate its true scope and effect. This, in part, explains how such similarly expressed statutory provisions as one finds in different patent laws can sometimes result in such different outcomes in different jurisdictions – disparities that are all the more evident when they concern the same product or process, and patents that, though in different jurisdictions, are all members of the same family, and are all intended to protect the same invention. As it becomes increasingly common for patent disputes to proceed in multiple jurisdictions these differences in outcome become ever more apparent.

Such disparities are not only a consequence of differing substantive laws, or differences in interpretation of similarly expressed laws. They can also be a consequence of the considerable procedural differences between jurisdictions, the nature of which is outlined in this Review. However, the Review does not only summarise patent litigation procedures. The respective contributors to it, as leading practitioners in each of their jurisdictions, also focus on recent developments in substantive patent law as demonstrated by the most important recent court decisions in their respective jurisdictions, meaning that this Review also provides insight into the current controversies that affect patent law generally.

On a global basis courts in multiple jurisdictions continue to be involved in controversies over standard-essential patents, one emerging aspect of which is the potential challenge that these present to the territorial nature of patents, as exemplified by the appeal, to be heard by the UK Supreme Court this autumn, against the imposition by the English courts of a global licence, on terms that they assess, as the price for exploiting standard-essential patents in the UK. Meanwhile, three appeals concerning standard-essential patents are pending before the German Federal Supreme Court, providing it with its first opportunity for a decade (since its *Orange Book Standard* decision) to revisit this area of the law. In the United States the most prominent controversy remains the question of excluded subject matter, which for want of clear judicial guidance has now attracted the interest of the legislature. In Europe, one apparent trend is towards greater flexibility as to injunctive relief, particularly in medicine – by for example, in the UK, tailored injunctions, or, in Germany, expedients such as compulsory licences, although in Germany there is also talk of legislation to address the issue. Again in Europe, the past year has seen no progress towards the entry into force of the

long-heralded Unified Patent Court Agreement. Although the pending challenge before the Federal German Constitutional Court to the consistency of the Agreement with the German Constitution is the only formal impediment to its entry into force, the imminent withdrawal of the UK from the EU as from 31 October 2019 presents a further problem, because the Agreement as drafted does not envisage participation by non-EU Member States. This raises the prospect, even if the German challenge is rejected, of having to amend the Agreement before it can enter into force to take account of such withdrawal; either to exclude the UK from its scope or, as the UK government has urged, expressly to provide for its inclusion, a course that, however, it is not at all clear would be compatible with the case law of the European Court of Justice, irrespective of any treaty language.

Trevor Cook

Wilmer Cutler Pickering Hale and Dorr LLP

New York

October 2019

ITALY

*Licia Garotti*¹

I OVERVIEW

With 22 civil courts specialised in intellectual property, Italy is one of the most active countries in Europe for patent litigation, including urgency proceedings.

The main legislation comprises the Italian Intellectual Property Code² (IPC), which provides a comprehensive regulation of intellectual property rights, and the general rules set out in the Italian Civil Code and Civil Procedure Code. Besides the several international treaties of which Italy is a member, the community legislation should also be taken into account.

II TYPES OF PATENT

Inventions that provide a technical contribution and that are new and inventive are protected in Italy by two kinds of patents: invention patents and utility models. Both are effective in Italy and San Marino, and can be validated in the Vatican City State.

As Italy is a member of the European Patent Convention, European Patents are also effective in Italy, provided that an Italian translation is filed with the Italian Patents and Trademarks Office (IPTO).

Invention patents can protect new products, new methods or processes, as well as new uses of an already known product.

Patents applications are filed with the IPTO and, specifically, before the chambers of commerce distributed through the Italian territory, which will then submit the application to the patent office in Rome.

Italian patents have gained a higher presumption of validity since starting from July 2008, the applications are forwarded by the IPTO to the European Patent Office (EPO) for a prior art search. Should the search opinion released by the EPO contain any objection, the applicant is entitled to submit arguments to support the patent validity or to provide potential amendments to the proposed claims.

Once the application is published (i.e., after 18 months from the filing), the IPTO decides on the granting of the requested invention patent, taking into account the EPO search report and the possible following arguments submitted by the applicant.

Italian patents last for a maximum of 20 years from the relevant filing date. The duration of patents protecting any medicinal product, an active pharmaceutical ingredient

1 Licia Garotti is partner at Gattai, Minoli, Agostinelli & Partners.

2 Legislative Decree No. 30 of 10 February 2005, and following amendments.

or an active ingredient of a plant may be extended by way of a supplementary protection certificate (SPC). The SPC can extend the life of the patent for a period not exceeding five years.³

As mentioned above, another way to protect innovation is through utility models. Utility model patents require a minor degree of inventive steps, and are aimed at protecting new models enhancing or improving the effectiveness, in terms of ease of application or use, of machines or parts thereof or products in general. Suitable for exclusively protecting new products, utility models have a shorter life cycle, lasting only 10 years.

The filing procedure provides for no prior art search either by the EPO or by the IPTO. According to the IPC, alternative filing is possible: the applicant for an invention patent is entitled to simultaneously file an application for utility model for the same invention, to be effective if the invention patent is not granted.

The IPTO can always invite the applicant to convert an invention patent into a utility model and vice versa.

Conversion of an invention patent into a utility model is also possible within a litigation, provided that, of course, the 10-year life of the utility model has not expired yet.

III PROCEDURE IN PATENT ENFORCEMENT AND INVALIDITY ACTIONS

i Competent courts

Since 2003, patent litigations are to be submitted to the exclusive jurisdiction of specialised divisions comprising judges skilled in intellectual property matters. Initially named ‘Specialised Divisions in Intellectual Property Matters’ and present in 12 Italian courts, they have been renamed as ‘Specialised Divisions in Enterprise Matters’ and the number has been increased to 22.⁴ However, only 11 of them have jurisdiction on cases involving a foreign defendant. Even if the specialised divisions are spread throughout the Italian territory, the most active – and most skilled – courts are in Milan and Turin, followed by Venice, Bologna and Rome.

Italian laws foresee no bifurcation of the process: in the same proceedings, both infringement and validity or invalidity of the patent can be discussed and decided.

The criteria for establishing the territorial venue of the specialised divisions are as follows:

- a* for infringement proceedings, the domicile or the registered office of the defendant or, alternatively, the place where the infringement took place; and
- b* for nullity actions, the place where the patentee has elected domicile for that patent. This rule does not apply if the invalidity of the patent is brought as a counterclaim in infringement proceedings pending before another court.

In case of plurality of defendants, it is also possible to file the action for patent infringement before the specialised division where one of them is domiciled. However, Italian judges are

3 The extended period must be equal to the period elapsed between the date on which the application for the patent was filed and the date of the first marketing authorisation.

4 Please note, however, that according to the main case law, the division between Specialised Divisions in Enterprise Matters and the Ordinary Division is a mere internal division and it does not entail a matter of the competence (see Court of Milan, decision No. 11175 of 8 November 2017).

more likely to declare the lack of territorial venue if the patentee involves a defendant that clearly has nothing to do with the case, just in order to bring the litigation before a certain court.⁵

ii Standing to sue

The standing to sue in proceedings aimed at obtaining patent revocation belongs to whoever has a commercial interest on the basis of competitive relationship in the sector where the patent will be effective.⁶ More often discussed is the standing to sue for patent infringement.

Article 131 of the IPC only quotes the owner of the enforced intellectual property right. In accordance with the main Italian case law, exclusive licensees are also acknowledged as being entitled to bring the infringement action, their rights considered equivalent to the patent owner rights. More debated is the potential entitlement of a non-exclusive licensee in the absence of the authorisation of the patent owner. With Decision No. 15350 of 4 July 2014, the Supreme Court stated that the standing to sue also belongs to other persons or entities, including a mere distributor of a patented product⁷, 'who has an interest of their own in the action since they suffered damages from the infringement'. The standing to sue for the negative ascertainment of a patent violation belongs to the accused infringer.

While infringement and invalidity actions are not subject to any time limit, damages compensation can be claimed within five years. However, some Italian case law outlines that the time limit for the restitution of the profits achieved by the infringer should be extended to 10 years, for requests that have no compensatory nature and are not linked to the ascertainment of wilful misconduct.⁸

iii Procedure in patent infringement and patent invalidity proceedings

As ordinary proceedings on the merits, patent infringements and patent invalidity actions are pending once the claimant serves the writ of summons to the defendant.⁹ The latter is entitled to file a defence statement with counterclaims and exceptions, including, *inter alia*, the invalidity of the enforced patent and, eventually, asking to extend the litigation to a third party allegedly involved in the matter at stake, within 20 days from the first hearing. Such hearing cannot take place before 90 days if the served defendant is based in Italy. The term is extended to 150 days for foreign defendants.

After the first hearing, the parties are allowed to exchange three defensive briefs as provided by the Civil Procedure Code, also formulating their pleadings on the basis of the adversary arguments (first brief) and bringing evidence means (documents) and evidence requests (witnesses examination) to support the formulated claims (second brief).¹⁰

Despite the high degree of specialisation in intellectual property matters¹¹ of the judges belonging to the specialised divisions, in almost all patent litigations the court appoints a

5 See Court of Turin, Decision of 31 July 2015.

6 See, among other things, the decision issued by the Court of Milan on 11 June 2014.

7 Please note that recent case-law has denied the standing of the mere distributor of the product infringed by the patent (refer to Section VIII.iii).

8 See the decision issued by the Court of Turin on 20 February 2009.

9 Within 10 days from the service of the writ of summons, the proceeding has to be registered with the Court, either by the plaintiff or the defendant. Otherwise, the proceeding becomes ineffective.

10 The third brief is the last chance to file a replica against the adversary evidence requests.

11 The specialisation is indeed a specialisation in law, with no specific skill in technical matters.

technical expert skilled in the specific field of the patent, referring the technical question to him or her. This is commonly aimed at evaluating the validity of the patent and the technical interference of the attacked good with the existing scope of protection of the enforced patent.

In the technical debate the parties are represented by their respective technical experts, who usually exchange two technical briefs.

Partially derogating to the general evidence rule quoted above, the IPC entitles the parties to submit to the court expert new documents, even if these were not filed by the deadline for the second evidence brief, provided that such documents pertain to the technical question.

After the technical debate, the court expert issues his or her report. Even if it is not binding for the judge, such opinion often provides a sort of anticipation of the outcome of the litigation.

The parties have the option to discuss the court technical expert's report before the judge, who will then invite the claimant and the defendant to exchange their final statement of defence and relevant replica. A final hearing to discuss the case takes place only upon the request of a party.

iv Patent's amendment in the course of the proceeding

Article 79.3 of the IPC entitles the patentee to submit, within a nullity action, and 'in each stage of the proceedings', a 'reformulation of the claims that remains within the content of the application as filed and which does not extend the protection it confers'.

Because there is no limit to the number of requests¹² to amend the patent, there have been several cases where this possibility has been exploited by the patent owner multiple times. This option joins the already available administrative procedure for the limitation of a patent before the IPTO.

With respect to the Italian part of a European patent, the Italian Supreme Court recently affirmed that the patent limitation approved by the EPO has retroactive effects starting from the filing date of the original patent application.¹³

v Processes for obtaining and presenting material to the court or tribunal

The burden to prove the nullity of a patent falls on whoever claims the patent revocation. The entity enforcing the patent has, on the contrary, the burden to prove the claimed infringement.

A court order for discovery can be obtained by the party that has provided serious indications to support its claims and has, in substantiating those claims, specified evidence that lies in the control of the opposing party.

Under the same conditions, for infringement committed on a commercial scale, the patentee can also obtain the disclosure of banking, financial or commercial documents under the control of the opposing party, subject to the protection of confidential information.

The right of information under Article 121 *bis* of the IPC was introduced through the implementation of the Enforcement Directive,¹⁴ which entitles the patentee to obtain from the opponent precise information on the origin of the infringing goods or services, distribution channels and the identity of any third party involved in the infringement.

12 Provided, however, that the repeated amendments are not considered as gross abuse.

13 Decision of the Supreme Court No. 21402 of 14 August 2019.

14 Directive 2004/48/EC on the enforcement of intellectual property rights.

Judicial inspection is a very common type of proceeding used in Italy to collect evidence about a suspected patent infringement, especially if the enforced patent protects a certain process, and provided that the confirmation of the infringement cannot reasonably be obtained elsewhere. In particular, this proceeding is aimed at gathering evidence to confirm:

- a* the actual occurrence of the alleged infringement (typically the collection of technical information, seizure of technical documentation and samples of products where possible); and
- b* the scope of infringement (seizure of accounting documentation, pricing information, invoices, volumes of stocks, etc.).

Authorisation is granted by a court order upon specific application filed by the patentee, usually submitted (and granted) *ex parte*, being the ‘surprise’ effect essential for the most effective execution of the obtained order.

The operations generally last between half a day and a full day, and are performed by a bailiff, usually assisted by a technical expert appointed by the court. If the judge agrees, the technical operations can also be attended by the lawyers and the patent attorney of the patentee.

If not filed when the patent infringement case is already pending, the inspection is followed by the filing of the main proceeding by the deadline imposed by the court or, in its absence, within 20 working days or 31 calendar days (if the latter is a longer period) from the obtained order.

The judge also provides specific measures aimed at preserving the confidentiality of the seized documents and obtained information, which are customarily sealed in a closed envelope kept by the court. The relevant examination could be restricted to the lawyers and technical experts of the patentee, who would in such case be bound to confidentiality towards their client.

vi Challenge of patent validity in infringement proceedings

Stay of the infringement proceedings

As mentioned above, the challenge of the validity of the patent is the most common defence brought by the accused infringers against the patentee.

Very rarely is an infringement proceeding stayed, pending a revocation action.¹⁵

With the decision of 14 April 2016, the Italian Supreme Court¹⁶ stated, however, that infringement proceedings are necessarily suspended when, in separate proceedings between the same parties, the patent invalidity is claimed. The purpose is to avoid a decision acknowledging the patent infringement contrasting with a later decision revoking the same patent.

15 In the same way, in accordance with the main case law, infringement proceedings concerning the Italian portion of a European patent is not stayed even if an opposition is pending against the same European patent before the EPO.

16 Court of Cassation, which is the Court for third and last instance. See also, decision of the Supreme Court No. 9500 of 4 April 2019.

vii Timing and cost considerations for patent infringement and patent invalidity proceedings

A first instance decision is expected about two or three years from the first hearing. It could, however, take longer for matters that are technically very complex or that require analysis and experiments.

The proceeding will certainly last longer if the patent is amended in the course of the proceedings under Article 79.3 of the IPC (see Section III.iv).

Patent litigations in Italy are not excessively expensive, especially if compared to other European jurisdictions. The costs requested by the court for filing a patent infringement or patent invalidity proceedings on the merits amount to about €1,000, while the filing of urgency proceedings amounts to about €500.

Legal fees for the defence have to be added. However, the winning party can usually recover at least part of the sustained costs. The average sums quantified by the courts for the legal fees amount to €7,000 to €15,000 for preliminary injunction proceedings and to €20,000 to €35,000 for cases on the merits, significantly increasing in certain particularly complex cases.

viii Urgency proceedings and available preliminary relief

The usual way to claim patent infringement in Italy is through urgency proceedings. The right holder is entitled to claim the infringement against any imminent or already existing non-authorised use of the patented invention, as well as toward any contributory infringer (see Section IV.i).

In accordance with Article 132 of the IPC, the right owner is entitled to enforce the patent even if it is still pending as application, and also when it has not been published yet. In such case, the right holder can act upon prior notification of the patent application to the infringer. Once the application is filed, a hearing for the trial is scheduled and the judge usually invites the defendant to bring its defensive arguments a few days before the scheduled hearing. For the reasons outlined in Section III.iii, as with ordinary proceedings on the merits, in urgency proceedings the judge usually appoints a technical expert. These kinds of proceedings require, by definition, the urgency to obtain the requested measures (*periculum in mora*) together with the likelihood of both the validity of the enforced patent and the infringement thereof (*fumus boni iuris*).

In principle, interim measures can also be claimed *ex parte*. In patent cases, however, Italian courts are quite reluctant to grant them. Should this be the case, a hearing for the confirmation, modification or revocation of the granted measure shall take place.

In general, the potentially available remedies are:

- a* injunction to cease and desist from any infringing act and the prohibition to advertise, manufacture, commercialise and use the infringing goods or process;
- b* withdrawal of the infringing goods from the market;
- c* penalty for any potential further infringement or non-compliance with the decision or for each day of delay in the execution of the court's order;
- d* seizure of the infringing products; or
- e* publication of the decision.

The right of information under Article 121 *bis* of the IPC can be obtained, under the conditions outlined in Section III.v, in the course of preliminary injunction proceedings. The patentee can claim the discovery; however, this is rarely granted. No damages compensation can be claimed within urgency proceedings.

An injunction order does not require the following filing of ordinary proceedings on the merits, where the interim order is suitable to bring forward the effects of a decision on the merits. This applies, for instance, if the patent owner obtained the requested injunction and is not interested in pursuing the infringer for damages compensation and other remedies.

On the contrary, a granted seizure not followed by the filing of the case on the merits will lose its effectiveness.

A decision is commonly expected within two to four months, and could extend a further two to three months if the technical phase requires more time. This usually happens when the subject matter of the patented invention is particularly complex.

While preliminary injunction proceedings are managed by a single judge, the potential appeal against the first instance order will be managed by a panel of three judges of the same specialised division of the court.

The obtainment of a preliminary injunction or of a seizure is not necessarily subject to a security. It is, however, at the discretion of the judge to require the applicant to lodge an adequate security for possible damages compensation.

While in Italy the filing of protective letters aimed at reducing the risk of suffering preliminary injunctions *ex parte* is not allowed. In 2010, the IPC implemented a specific rule entitling the accused infringer to also claim the non-infringement through urgency proceedings, substantially conforming the already existing main case law.

ix Potential liability for threatening infringement proceedings

The threatening of infringement proceedings addressed to the alleged infringer usually raises no liability. It is a different case if the patentee sends a cease-and-desist letter to dealers or clients of the alleged infringer, where the patent owner could be considered liable under unfair competition law.

The patentee is also exposed to liability if it files a claim for patent infringement, while being aware of the nullity or the ineffectiveness of the patent, or where the claim is found to be groundless. In such case of wilful misconduct, the patentee is usually condemned to reimburse the legal costs borne by the winning party. Furthermore, it could be condemned to a damages compensation if the action was filed on the basis of a non-existing patent.

IV SUBSTANTIVE LAW

i Infringement

Any unauthorised use of a patented invention depicts a patent infringement. In particular, the patentee has the following rights:

- a* if the patent covers a product, the patentee can prohibit to manufacture, use, put on the market, sell or import for sale the protected product;
- b* if the patent covers a process or method, the patentee can use the process, as well as use, put on the market, sell or import for sale the product directly obtained with such process; and
- c* the patentee can prohibit third parties from supplying or offering to supply to persons or entities that are not entitled to use the patent, any means concerning an essential element of the patented invention and that are necessary for the relevant realisation of such invention within the territory of a state in which the invention is protected, when the third party knows, or should have known using the ordinary care, that those means are suitable and intended for putting that invention into effect. This provision

does not apply if the means are staple products currently on the market, unless the third party induces the supplied entity to infringe the patent. It should also be outlined that persons and entities benefitting from the limitation of the effects of the patent (for instance for private use or experimental use) are not 'persons or entities entitled to use the patent' for the purposes of this rule.

The right under point (c) is provided for by Article 66.2 *bis* of the IPC, introduced by recent Law 214/2016, which implemented the case law already existing on this topic.¹⁷

Besides the actual non-authorised use of the patent, the right owner can also challenge an 'imminent' infringement.

As a general rule and under certain circumstances, Italian case law includes among the infringing acts the preparatory activity, recognising that activities performed by a third party in preparation of the potential future sale of the counterfeited good (including advertisement)¹⁸ can harm the right of the patent owner, even if, in the end, the infringing product is not sold.¹⁹

The potential challenge of preparatory activity is particularly debated in the pharmaceutical sector, when these are aimed at the commercialisation of the product. Reference is made to the beginning of the necessary administrative procedures, before the expiry of the patent or of the SPC.

The case law is also not consistent with reference to preparatory acts aimed at marketing the product after the expiry of the patent.²⁰ From a civil perspective, the company is liable for patent infringement as an entity, while its directors or commercial employees are not directly liable. The company directors could, however, be deemed liable under Law 231/2001 for patent infringement.

Patent claims interpretation in patent infringement actions

The scope of protection of the patent is defined by the claims, but the description and the drawings shall be used to interpret the claims. A patent infringement occurs if the patented invention is reproduced literally or by equivalence. While, in the former, all features contained

17 See, among other things, decision of the Supreme Court No. 22495 of 19 October 2006.

18 See Court of Milan, decision of 14 January 2015 and Court of Turin, first instance order of 29 June 2018 (confirmed by the Court of Turin, appeal decision of 14 December 2018).

19 Supreme Court, decision No. 5112 of 3 April 2003.

20 With decisions of 4 November 2010 and of 8 November 2012, the Court of Milan ruled that such preparatory activity is lawful. Of the opposite opinion are the Court of Rome (decision of 11 November 2011) and the Court of Turin (decision of 11 February 2011). Recently the new EU Regulation No. 2019/33 (amending Regulation No. 469/2009 concerning the supplementary protection certificate for medicinal products), entered into force on 1 July 2019, provides that manufacturers of generic and biosimilar products established in the European Union shall, during the term of validity of the SPC, manufacture said products for the purpose of export to third-country markets where the protection does not exist or has expired. The waiver of the Reg. No. 2019/933 applies also to the stockpiling of the product in European Union territory during the last six months of the term of the SPC to allow the launch of the generic or biosimilar products on the European Union market as soon as the SPC expires.

in the patent claims are literally reproduced, in infringement by equivalence (Article 52.3 *bis* of the IPC),²¹ the liability is held where the challenged device or process is equivalent to the claimed invention.

Infringement by equivalence is usually assessed by applying the triple identity test: same function, same effect and same way.

Recent Decision No. 24568, issued by the Supreme Court on 2 December 2016, faced once again the debated issue of the infringement by equivalence of a pharmaceutical patent. In that case, the Court stated:

[I]n order to assess whether the disputed embodiment can be considered equivalent to the patented one, so as to constitute an infringement thereof, it is necessary to ascertain whether, in the event of reaching the same final result, this is provided with originality, offering a non-trivial or repetitive solution to the previous one.... That is to say, in order to exclude infringement by equivalence, it does not matter the variation, albeit original, of a single element of the patented invention, if the variation does not exclude the use, even partial, of the earlier patent.

The infringement is also not excluded when the solution adopted by the third party modifies the earlier invention so that it constitutes an improvement (evolutionary infringement) or implies the implementation of a former patented invention, in that case being a dependent invention.²²

A matter that is currently debated is the possibility to challenge the infringement by equivalence if the scope of the patent has been limited through amendments of the relevant claims, making reference to the file wrapper estoppel theory.²³ This happens particularly when, applying Article 79.3 of the IPC, the patent is modified several times within proceedings when the relevant validity is challenged. In this respect, a recent decision of the Court of Milan²⁴ affirmed that if the patent has been expressly limited within the granting process or within a proceeding, the scope of protection of the same cannot be extended by means of an interpretation by equivalence in order to cover also the cases excluded by the previous limitation.

ii Invalidation and other defences

Patent validity attacks

A patent is regarded as null for the following reasons: lack of novelty, lack of inventive step, insufficient disclosure, if it cannot be industrially implemented,²⁵ for absence of lawfulness and if the subject matter extends beyond the content of the application as filed or the protection it confers has been extended. The most discussed invalidity arguments are as follows.

21 This rule was introduced in the IPC in 2010 and corresponds to Article 69 of the European Patent Convention. The previous case law did, however, already apply the principle contained therein.

22 See Court of Milan, decision of 24 January 2017.

23 The scope of protection of a patent cannot extend to features that the patentee eliminated or surrendered by limiting the patent.

24 Decision of 12 September 2017.

25 This option rarely applies.

Lack of novelty

The validity of a patent requires ‘absolute novelty’, in other words, the patented invention shall not be comprised in the prior state of the art (Article 46 of the IPC).²⁶ Italian courts²⁷ have stressed that, for the ascertainment of the novelty requirement, it must be assessed whether the invention, as defined in the patents claims, was already described at the priority date in a single prior art document, known or disclosed, so that it can be considered to fall within the definition of state of the art. Thus, the invention meets the requirement of novelty unless it was described directly and non-ambiguously in a single prior art document. The combination of two or more prior art documents, or different parts of each of them, cannot be used for novelty attacks.

Lack of inventive step

A patent is inventive if it is not obvious to a person skilled in the art in respect to the prior art.

To assess the inventive step of a patent, Italian courts²⁸ customarily apply the ‘problem-and-solution approach’ criterion. For such purpose, the ‘closest prior art’ has to be determined first. This identifies the most promising starting point to obtain the claimed invention, and normally has the highest number of characteristics in common with the patent (or allows at least the minimum number of modifications to obtain the claimed solution). Then, the ‘distinctive features’ have to be selected. It is also necessary to determine:

- a the ‘objective technical problem’ solved by the distinctive characteristics of the claimed solution (selecting them from that or those characteristics that are not described or suggested by the closest prior art); and
- b the expertise of the skilled person in the patent field, in order to understand whether the same, starting with the closest prior art, would (not could) solve the objective technical problem in an obvious way, possibly combining the teaching of the closest prior art with another different prior art document or with the general common knowledge of the technical sector of the patented invention.

Sufficient disclosure

The requirement of sufficient disclosure is met when, for the mid-level person skilled in the art of the patent field, the implementation of the invention requires no further complex investigations and experiments, but only routine activities²⁹.

Moreover, the exclusive rights conferred by a patent do not extend to:

- a private or non-commercial activities and activities having an experimental purpose;

26 Under Article 47 of the IPC, the prior state of the art does not, however, include: (a) any disclosure of the invention occurred within six months before the filing of the patent application and resulting directly or indirectly from an evident abuse to the detriment of the applicant or his legal predecessor; (b) potential disclosures of the patented invention in an official or officially recognised exhibition as defined pursuant to the Paris convention of 22 November 1928.

27 See, in particular, Court of Milan, decision of 17 January 2017, Court of Milan, decision of 24 January 2017 and Court of Milan, decision of 31 October 2018.

28 See, in particular, Court of Milan, decision of 17 January 2017, Court of Milan, decision of 24 January 2017, Court of Milan, decision of 31 October 2018, Court of Milan, first instance order of 14 January 2019 and Court of Milan, first instance order of 4 March 2019.

29 See, in particular, Court of Milan decision of 7 March 2019.

- b studies and experimental uses aimed at obtaining a marketing authorisation for a drug or medicine, comprising the 'preparation and the use of the raw materials strictly necessary for this purpose' (*Bolar* exemption);³⁰ and
- c extemporaneous preparation of single units of medicine upon medical prescription in a pharmacy, provided that no industrially manufactured active principles are used (galenic exception).

Other defences to infringement claims

Other defences to infringement claims are detailed below.

Licence

Besides the licence that the attacked infringer can prove on the basis of an effective agreement,³¹ the licence in respect to standard-essential patents (SEPs) deserves a specific mention. The implementation of an SEP is necessary in order to comply with a certain industrial standards set by the relevant standard-setting organisations.³² There are many interests that need to be balanced: on one side, the owner of a patent is interested in obtaining the highest royalty for its patent; on the other side, any interested market player is entitled to have access to the patent at fair, reasonable and not discriminatory (FRAND) conditions.

The filing of court proceedings aimed at obtaining an injunction against any non-authorised (i.e., non-licensed) entity has been often used in order to 'convince' the attacked infringer to pay for play. With Decision C-170/13, the European Court of Justice stated that the holder of a SEP cannot start a legal action against the infringer before a prior notice.

The attacked infringer shall declare if it is interested in taking licence of the specific SEP at FRAND conditions. If this is the case, the patentee shall make a specific and written offer that must be accepted within a reasonable period of time.

Standardisation often raises issues under antitrust law – in particular, whether the filing of an infringement action against a non-licensed entity depicts an abuse of a dominant market position.

Exhaustion of rights

Under Article 5 of the IPC, the patentee's rights on a given product are exhausted if such product has been marketed by the patent owner or with its consent within the European Economic Area. The exhaustion does not apply if the patentee can oppose reasonable grounds, in particular where the marketed product has been modified or altered.

Prior use

In accordance with Article 68.3 of the IPC:

30 As outlined in Section IV.i, such use is, however, not considered as authorised use for the purposes of the exclusion of the contributory infringement under Article 66.2 *bis* of the IPC.

31 According to the most recent case-law, the existence of a licence agreement can be proved by means of simple presumptions, based on the conduct of the patent owner (Court of Milan decision No. 10965 of 31 October 2017).

32 Reference is made, for instance, in the Information and Communications Technologies (ICT) field, to the GSM and UMTS standard.

[A]nyone who, during the twelve months before the filing or priority date of the patent application, has made use of the invention within their business enterprise, can continue to use it within the limits of their prior use. Said right can only be transferred together with the business where the invention is used. The burden to prove prior use and its extension belongs to the prior user.

The ‘internal business use’ excludes any public use of the invention, which would deprive the patent of the novelty requirement (see Section V.ii).

Lack of knowledge

The lack of knowledge cannot be opposed as a defence by the infringer. This can, however, be evaluated by the judge in the quantification of the damages compensation.

V FINAL REMEDIES FOR INFRINGEMENT

Besides the final remedies available in urgency proceedings (see Section III.viii), the patentee is entitled to obtain:

- a* definitive recall of the infringing goods from the market against the owner or anyone in possession of the infringing goods;
- b* destruction of the infringing goods; or
- c* transfer of the property of both the infringing products, as well as of the specific means univocally destined to manufacture the infringing goods, or to implement the patented method or process (contributory infringement); and
- d* compensation for damages suffered because of the patent infringement.

With specific reference to damages compensation, Article 125 of the IPC³³ provides certain criteria for the relevant quantification, namely:

- a* loss of profits and other arising damages;
- b* profits achieved by the infringer (which can be claimed alternatively to the compensation of the loss of profit or to the extent exceeding such amount); or
- c* the reasonable royalty that the infringer should have paid having obtained a patent licence.

The burden of proof is on the patentee, who – under certain circumstances – is entitled to obtain disclosure of the adversary accounting information.

Italian courts³⁴ often take into account elements such as:

- a* loss of value of the infringed patent;
- b* costs for the registration and maintenance of the patent;
- c* research and development costs directly relating to the patented invention; and
- d* costs for the promotion of the product incorporating the patented invention.

The loss of profit is often reflected in the loss of sales of the products lawfully incorporating the patent in connection with the sales made by the infringer.

When the proof is not met, the judge tends to apply the criteria set out in the second paragraph of Article 125 of the IPC, quantifying the loss of profit in a sum corresponding

33 Which implements the criteria set forth by European Directive 2004/48.

34 See, among the others, the decisions of the Court of Milan of 5 April 2016 and of 14 June 2016.

to the royalties the infringer would have paid to the owner of the infringed right had he or she obtained a licence from the patentee. Such amount is usually determined with regards to conditions set out in agreements in force with third-party licensees and industry best practice.

Lastly, upon request, in accordance with Paragraph 3 of Article 125 of the IPC, the court can provide for the restitution of the profits obtained by the infringer, which, contrarily to damage compensation, does not imply the assessment of any subjective element (fault). The infringer's profits are often identified with 'gross profit' obtained by subtracting incremental costs from total revenues. On the other hand, fixed costs are usually not taken into account, as they are borne regardless of the specific production.³⁵

Italian law does not provide for punitive damages. However, a very recent decision of the Supreme Court³⁶ ruled in favour of enforcing in Italy foreign judgments granting the payment of punitive damages.

VI OTHER TYPES OF PATENT PROCEEDINGS

i Ownership challenge

The ownership of a patent is assumed. Article 118 of the IPC, however, entitles whoever has obtained a final decision ascertaining that the rights to the patents belongs to a different person or entity to obtain the transfer of the patent application, if still pending, or of the patent if already granted.

ii Compulsory licences

In certain cases (i.e., in case of lack of implementation of the patented invention within three years from the date of granting of the patent or for dependent patents), the interested entity is entitled to file administrative proceedings before the IPTO claiming a compulsory licence, provided that it proves:

- a* to have previously unsuccessfully asked the patentee for a licence;
- b* to be ready to pay an equitable royalty; and
- c* to be able to implement the patented invention in a 'satisfactory way'.

The duration of the compulsory licence cannot exceed the life of the patent and can be transferred only with the business activity where the licensed patent is exploited. The licensee is not prevented from seeking the patent invalidity or from challenging the width of the rights deriving therefrom.

iii Customs seizure

The patentee is entitled to seek protection against its rights infringement through the Customs Authority in accordance with EU Regulation No. 608/2013. In particular, upon the filing of an application outlining the reasons of the claim, the patentee can obtain the 'suspension of the release or detention' of the alleged infringing goods.

If the request is granted, the Customs Authority invites all customs offices to block the goods identified by the patentee. The order becomes ineffective (and, where already seized, the infringing products are automatically released) if the patent holder does not file

³⁵ See, in particular, Court of Appeal of Bologna, decision of 8 May 2017.

³⁶ Supreme Court, Decision No. 16601 of 5 July 2017.

proceedings (which can consist of both a civil or a criminal action) aimed at ascertaining the infringement. As for common practice, during this 10-day period the order is not amended and the seized goods are not released.

iv Criminal proceeding

Criminal proceedings are less exploited for IP matters. However, there are many cases where the criminal action has been started in order to maintain the block of the alleged infringing goods before the Customs Authority.

VII APPEAL

A first-instance decision can be appealed for factual or legal grounds before the local court of appeals 30 days from the service of the decision or, lacking that, six months from the relevant publication.

In the appeal proceedings, the parties are not allowed to file new claims, and usually submit new evidence, unless the interested party proves that such evidence could not be filed before for independent reasons. Also, a new technical phase is very rare, unless any lack of motivation or error in the technical report of the expert appointed by the court in the first-instance proceedings is proven. Appeal proceedings are filed by serving a writ of summons on the counterpart, which is entitled to file a statement of defence, formulating a possible counter-appeal if it was only partially winning, within 20 days before the hearing scheduled by the court. If the statement of defence is filed at the hearing, no counter-appeal is admissible.

At the first hearing, the court usually schedules the hearing for the final formulation of the respective pleadings. The decision is issued after the exchange of two briefs (i.e., final statement of defence and replica) and to the possible final hearing when required by at least one of the parties. Appeal proceedings usually last between two and three years.

VIII THE YEAR IN REVIEW

Besides the recent case law quoted (see, in particular, Section V with reference to damages compensation), the following decisions deserve a dedicated comment.

i Amendment of patent claims within a proceeding: Court of Milan, Decision of 24 January 2017

Since it was introduced in 2010, the possibility to amend the patent during invalidity proceedings in accordance with Article 79.3 of the IPC has given rise to heated debates about, *inter alia*, methods of modifying claims. In this respect, the judge clarified that the amendment is not limited to a ‘unification of the claims, but can consist of additions and specifications that draw on the content of the patent, provided that they do not extend the scope of protection and the original application’. The court added that potential additions can be drawn from the patent description, but not from an *ex post* perspective, ‘treating the description as a pot’.³⁷

³⁷ This position has been recently confirmed by the decision of the Court of Milan No. 11910 of 27 November 2017.

The Decision also deserves to be mentioned for the quantification of damages compensation. Indeed, the court added that the damages compensation had to be calculated from the date of the provided amendment as it is not admissible to place a disproportionate burden on the market players. It should, however, be stressed that in the case at stake, the patentee formulated several requests for amendments, picking many features from the description.

ii Software patent eligibility: Court of Appeals of Turin, Decision of 3 January 2017

The litigation concerned the validity and infringement of patents relating to the Electronic Program Guide for digital television and satellite. The attacked infringer claimed that the invention was, in reality, software and thus not eligible to gain patent protection.

At the end of a very complex litigation, the court decided that the patent was valid, outlining that a computer program is eligible for patent protection whenever there is 'a technical effect that goes beyond the normal physical interaction generated by a program running on a computer'.

iii Counterfeiting claim against the mere distributor: Court of Milan, Decision of 18 January 2018

The litigation concerned the negative assessment of the infringement of a pharmaceutical patent.

The Court of Milan affirmed that, in such case, the proceeding cannot be brought against the mere distributor of the products covered by the patent. In fact, the quality of mere distributor does not entail the right to participate in a proceeding regarding the infringement of a patent, neither as defendant in an action aimed at the negative ascertainment of a patent violation, nor as claimant for the ascertainment of the patent infringement.

iv Coexistence between a partially void Italian patent and the Italian portion of a valid European patent having the same scope: Court of Venice, Decision of 23 May 2018

The litigation concerned the request for injunction from the manufacture of certain products infringing the Italian portion of a European Patent corresponding to an Italian patent, which had been previously declared partially null.

The judge clarified that the decision that declared the partial nullity of the Italian patent does not have any effect on the following proceedings, which are brought on the basis of the correspondent European Patent. In fact, the declaration of nullity of the Italian patent does not entail the nullity of the European Patent, which, in the meantime, has been granted.

v The retroactive effects of the patent limitation requested in the course of a proceeding also concern the calculation of compensation for damages: Court of Milan, Decision of 5 October 2018

The litigation concerned the validity and infringement of an Italian patents relating to an innovative electronic turnstile for managing the access of passengers to public transport vehicles.

The Court set the principle according to which the retroactive effects of the patent limitation requested in the course of the proceeding also concern the quantification of the damages suffered because of the patent infringement. In this way, a previous and more

restrictive case law – which excluded that the damages were due for the conduct prior to the presentation of the limitation request (see, among others, Court of Milan, Decision 24 January 2017) – was overcome.

vi The patent limitation approved by the European Patent Office has retroactive effects starting from the filing date of the original patent application: Italian Supreme Court, Decision of 14 August 2019

The Court affirmed that, according to Article 69, Paragraph 2, of the European Patent Convention, a European patent as amended in limitation proceedings shall determine retroactively the protection conferred by the application, as long as such protection is not thereby extended.

Article 56, Paragraph 1, of the IPC, stating that the scope of protection determined by the limitation is confirmed as of the date of publication of the limitation decision, shall be interpreted in accordance with Article 69, Paragraph 2. This interpretation respects the need of legal certainty and the protection of third parties. Indeed, third parties' interests are respected by the fact that the patent as limited does not extend beyond the scope of the original patent application.

IX OUTLOOK

With Law No. 214 of 3 November 2016,³⁸ Italy ratified the Unified Patent Court (UPC) Agreement, which shall have jurisdiction on infringement and validity of both Unitary Patents and European patents. Milan will be one of the local divisions of the UPC, and is competing to become the seat of the UPC central division for pharmaceuticals and life sciences, overtaking London as a consequence of Brexit.

Milan is also a candidate for hosting the European Medicines Agency.

38 On 12 March 2019 the Legislative Decree n. 18/2019 (implementing the delegation pursuant to Article 4 of Law No. 163/2017 concerning the connection between the national legislation both with the provisions of the Reg. No. 1257/2012 - regarding the implementation of an enhanced cooperation on the unitary patent protection – and with the provisions of the Agreement on the Unified Patent Court, ratified and enforced with Law No. 214/2016) has been published on the Italian Official Journal. The Legislative Decree (1) modifies Article 56 of the IPC introducing the so-called unitary patent protection, which means that 'the European patent issued for Italy and the European patent with unitary effect provide the owner with the rights referred to in articles 25 (right to prevent the direct use of the invention) and 26 (right to prevent the indirect use of the invention) of the Agreement on a unified patent court, and is subject to the limits referred to in Article 27 of the same Agreement (limitations of the effects of a patent)' and (2) introduces the new Article 245 *bis*, which provides that proceedings concerning the European patent issued for Italy and pending until the Agreement on the Unified Patent Court enters into force as well as those proceedings promoted in Italy before the Italian Court in the following seven years from the entry into force of the said Agreement will be decided according to the Italian law.

ABOUT THE AUTHORS

LICIA GAROTTI

Gattai, Minoli, Agostinelli & Partners

Licia Garotti has been head of the department of intellectual property and information technology law in Gattai, Minoli, Agostinelli & Partners since 2015. She focuses her activity on intellectual property, copyright and ICT (Information Communication Technology) matters, assisting and representing Italian and foreign clients both in transactions as well as in complex litigations concerning patents, software, trademarks, design and unfair competition, often coordinating multi-jurisdictional cases. She assists clients from different industries, including electronics, telecommunications, chemical, pharmaceutical and biotechnology, mechanical as well as the banking and finance, fashion, luxury and food sectors. Panellist and speaker at several Intellectual Property and ICT Seminars, Ms Garotti has authored various publications in the field of patents, design and trademarks law, 3D printing and disruptive technologies, for both Italian and European legal magazines. She is a member of the International Association for the Protection of Intellectual Property and of the Licensing Executives Society. She graduated in law from the University of Bologna and was admitted to the Italian Bar Association in 2001. She was named Lawyer of the Year in the Trademarks and Patents category at the Legal Community IP & TMT 2018 Awards. Licia has also been recognised by the Legal Community IP&TMT report 2017 as having ‘a deep knowledge of software and connected technical issues’ and for being ‘skilled, capable, headstrong’.

GATTAI, MINOLI, AGOSTINELLI & PARTNERS

Via Principe Amedeo, 5
20121 Milan
Italy
Tel: +39 02 3032 3232
Fax: +39 02 3032 3242
lgarotti@gattai.it
www.gattai.it

an LBR business

ISBN 978-1-83862-071-4