

IN-DEPTH

# Patent Litigation

BULGARIA



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# Patent Litigation

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*In-Depth: Patent Litigation* (formerly The Patent Litigation Law Review) provides a perceptive overview of patent litigation procedures in major jurisdictions worldwide, while also examining the practical implications of the most important recent court decisions. In addition, it offers useful insights into the current controversies that affect patent law generally.

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# Bulgaria

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## Introduction

Bulgaria's patent system is bifurcated. Civil courts hear infringement disputes and invalidity proceedings are administrative. Pending invalidity proceedings constitute legal grounds for a stay of infringement proceedings.

Bulgarian patent case law is not very rich nor as well-developed compared to other European jurisdictions. There are no specialised patent courts and high-profile cases are scarce. More recently, however, a number of very interesting patent cases between original and generic pharmaceutical companies have been initiated in the pharmaceutical sector. They will certainly touch upon a number of issues that lack established national case law. More importantly, they are all related to analogous multi-jurisdictional disputes across and outside Europe that will contribute to building a better comparative picture.

## Year in review

The past 18 months in Bulgarian patent litigation, as noted above, are characterised by patent cases in the pharmaceutical sector concerning invalidity actions by generic companies against the national counterparts of classic European patents of original medicinal products, respective infringement cases, and related preliminary injunction measures undertaken by the original medicinal products' pharmaceutical companies. None of these cases have come to a definitive end.

## Types of patent

The types of patents that exist in Bulgaria are:

1. national patents under the Patents and Utility Models Registration Act (PUMRA);
2. European patents (including with unitary effect)<sup>[1]</sup> under the European Patent Convention; and
3. patents under the Patent Cooperation Treaty.

The term of protection of each of these patents is 20 years as of the date of application.

A national counterpart of a classic European patent, if validated in Bulgaria, confers the same rights as a national patent under PUMRA. Validation requires a request be filed with the Patent Office within three months of grant being mentioned in the European Patent Bulletin. The request, which must be translated into Bulgarian, must include the title of the invention, a description of it (including drawings, where necessary), and the patent claims.

Supplementary protection certificates under Regulation 469/2009 and paediatric extensions are also available.

Regarding patents under the Patent Cooperation Treaty, and in order to open a national phase, the applicant must file the international application with the Patent Office within 31

months from the date of priority, subject to the requirements of Article 35 of PUMRA (i.e., that a national patent application must be made in the Bulgarian language).

As evident from the title of the main piece of national patent legislation, PUMRA, utility models exist under Bulgarian law, which are known as 'small inventions'. The requirements for utility models are formally the same as for patents (i.e., novelty, an inventive step and industrial application) but their levels are lower, the registration procedure is more relaxed, and the term of protection is shorter. Novelty is only considered within the territory of Bulgaria, and the inventive step is considered from the viewpoint of a person of ordinary skill and knowledge in the field. The procedure for registration only involves an examination of formalities – novelty and inventive steps are not evaluated. Regarding industrial application, an assessment is only made for an obvious conflict with this requirement. Novelty and inventive step may be considered in the case of invalidity actions by third parties following registration. The term of validity of utility model registration is four years from the date of application. It may be extended for two consecutive periods of three years. The total term of protection cannot exceed 10 years from the date of the application.

## Procedure in patent enforcement and invalidity actions

The Bulgarian patent system is bifurcated. Infringement proceedings are civil and develop separately and independently from invalidity proceedings which are administrative. By imperative statutory law, the question of validity is always prejudicial to the question of infringement and the defendant may not challenge patent validity in infringement proceedings. Pursuant to Article 64 of PUMRA, pending invalidity proceedings constitute legal grounds to request a stay of infringement proceedings until a definitive resolution on validity is reached. By law, a civil court is not competent to assess the validity of a patent and may only formally consider if a patent is valid, expired or invalid. According to case law, only the party that has initiated pending invalidity proceedings may request the stay of infringement proceedings against itself (i.e., a defendant in infringement proceedings may not invoke invalidity proceedings initiated by a third party). However, if a patent is invalidated by a definitive decision in proceedings initiated by a third party, that decision affects vis-à-vis third parties. In any case, pursuant to Article 26(8) of PUMRA a declaration of invalidity of a patent does not affect patent infringement judgements that have entered into force, to the extent that they have been enforced, and licence agreements concluded and executed prior to declaration of invalidity, unless otherwise agreed.

Invalidity actions are filed before the Patent Office. Appeals are then generally possible through two court instances: the Sofia City Administrative Court and then the Supreme Administrative Court. Proceedings before the Patent Office are governed by a special ordinance for hearing disputes under PUMRA (a sub-normative act adopted on the basis of PUMRA). Court proceedings follow the general procedure under the Administrative Procedure Code.

Pursuant to Article 55(2) of PUMRA, invalidity actions are admissible during the entire term of validity of the patent. The law is not very clear what would happen if, as a defence in view

of pending infringement proceedings initiated after the expiry of the patent, an invalidity action is also filed after the expiry of the patent. We are not aware of any case law on this matter yet. A formalistic interpretation of Article 55(2) of PUMRA suggests that such an invalidity action would be inadmissible. On the other hand, a civil court is not competent to assess patent validity in infringement proceedings by itself. All reason indicates that in such a scenario, invalidity actions should be admissible, otherwise the defendant would be unjustly deprived of this defence.

It is admissible to make auxiliary requests in order to amend a patent in the course of invalidity proceedings, but the claims may not be amended to extend the scope of protection.

As regards to infringement proceedings, the first instance court is always the Sofia City Court. Appeals are generally possible before the Sofia Court of Appeal and, subject to special selection criteria, before the Supreme Court of Cassation. The proceedings develop following general rules under the Civil Procedure Code. The general statute of limitations is five years.

Evidence in both invalidity and infringement proceedings is collected under general evidentiary rules. Basically, each party bears the burden to prove its own statements. As an exception, Article 29 of PUMRA provides that in the case of infringement of the patent rights to a method, if the product is new, the burden of proof to show that the product was not obtained by the patented method is on the alleged infringer.

Expert opinions in both invalidity and infringement proceedings, including in the administrative phase before the Patent Office, are only admissible if prepared within the particular proceedings by experts appointed by the court or the Patent Office. By law, civil and administrative courts do not possess expert knowledge, as opposed to the Patent Office. However, the Patent Office may use experts at its own discretion.

By law, private expert opinions are not admissible, including expert opinions from other courts or administrative proceedings. Experts are appointed at the request of a party, or ex officio by the court or the Patent Office, from special official expert lists held by the respective court, wherein experts are included by area of expertise and wherefrom they are subsequently selected to be appointed. If the required area of expertise is not present in the list or no expert is listed in it, the court or Patent Office may address enquiries to official institutions or organisations in order to find an expert. In such rare cases, the court may ask the parties for help in directing it to an institution or expert.<sup>[2]</sup>

Time-wise, invalidity proceedings in Bulgaria are slow. It can take several years before a definitive resolution of the dispute is achieved. Infringement proceedings can be even more time-consuming, as they may remain stayed for the duration of invalidity proceedings.

The costs for state fees are not substantial in invalidity proceedings. State fees for infringement claims are 4 per cent of the price of the claim, and upon appeal 2 per cent of the appealed material interest. Remunerations of experts in both invalidity and infringement proceedings are not substantial, and are determined by the court or the Patent Office based on the complexity of the questions asked.

Preliminary injunctions are possible in infringement cases. Preliminary injunction proceedings follow the general procedure under the Civil Procedure Code. The first phase is ex parte until the request is granted by the court. If the request is granted the preliminary

injunction is imposed, as of which moment the future defendant has the right to appeal. If the request is dismissed the future claimant may appeal in ex parte proceedings. If an appeal is dismissed, the counterparty will not formally learn about the request. Further injunction requests following an unsuccessful appeal are possible in theory, but in practice the court ex officio will have information about the previous outcome. Each party to preliminary injunction proceedings may only appeal once.

Pursuant to general civil procure rules, preliminary injunctions may only be based on convincing written evidence (i.e., oral evidence is excluded). Under Bulgarian law, expert opinion is considered oral evidence, hence is not admissible at this stage. In the absence of convincing written evidence, the court may decide to grant the request if the future claimant expresses willingness to pay a monetary security, the purpose of which is to serve as (partial) indemnification for the defendant in case the future claim turns out to be unsuccessful. As a rule of thumb, the amount of the monetary security will be up to 10 per cent of the price of the future claim. If the request is granted the future claimant must file the claim within a term determined by the court, no later than one month of measure being granted. If the future claimant fails to file the claim within that term or to pay the security, the granted measure is automatically invalidated.

The types of preliminary injunction measures are not fixed by law but they must bear relevance to the type of claim and infringement (e.g., prohibition of making, sale, offering for sale, marketing, distribution, etc). From a practical perspective, the effectiveness of such measures is very doubtful, given the lack of serious statutory legal consequences for non-compliance and established case law in this respect.

There is not much case law on preliminary injunction measures in patent cases. Earlier and recent case law, to the extent it exists, appear to take different approaches. Due to the fact that patent cases in Bulgaria are heavily dependent on expert opinions, which are by law inadmissible at this stage, earlier case law seemed unwilling to grant preliminary injunction measures so early in the dispute. Recent case law, however, seems to demonstrate willingness of courts to grant preliminary injunction measures against generic pharmaceutical companies, including where there are pending national invalidity proceedings, and even where there are one or more judgments from other European jurisdictions invalidating the respective national counterpart of a European patent, thus creating reasonable doubt as to the validity of the Bulgarian counterpart.

Costs for state fees for preliminary injunction proceedings are not substantial, save for the monetary security which is determined as a percentage of the price of the claim.

Protective letters are not available under Bulgarian law.

Lastly, pursuant to Article 26(7) of PUMRA, the bad-faith holder of a patent that is declared invalid will owe indemnification for damages. We are not aware of any case law in this respect.

## Substantive law

Article 6(1) of PUMRA provides the general requirements for patentability, namely that 'inventions from all technical fields that are new, have an inventive step and are industrially applicable are patentable'.

## Novelty

Regarding novelty, Article 8 of PUMRA provides that:

- (1) An invention is new if it is not part of the state of the art.
- (2) The state of the art includes everything that has become generally available through written or oral description, use or disclosure in any other way anywhere in the world before the filing date, respectively the priority date, of the patent application.
- (3) The state of the art also includes the content of national patent applications, European and international patent applications, for which the Republic of Bulgaria is a designated party and which have a filing date, respectively, a priority date earlier than the date according to paragraph. 2, if subsequently published in the official bulletin of the Patent Office.
- (4) The state of the art also includes the content of the national applications for the registration of utility models that have a filing date, respectively a priority date, earlier than the date under paragraph 2, if a publication is subsequently made about their registration.
- (5) Substances or compositions included in the state of the art according to paragraphs 2 and 3, which are used in the methods under Article 7, paragraph 1, item 2, are considered new if their use is not included in the state of the art.

## Inventive step

Article 9 of PUMRA provides that an 'invention has an inventive step when for the skilled person it does not derive in an obvious way from the state of the art according to Article 8, paragraph 2 as of the application date, respectively the priority date'.

## Industrial application

Article 10 of PUMRA provides that '[i]ndustrially applicable are inventions which subject matter can be produced or repeatedly used in any branch of industry and agriculture'.

Article 7a of PUMRA also contains special provisions regarding patentability of biotechnological inventions.

## Exclusive rights

The scope of the patent holder's exclusive right to an invention is provided for in Article 19 of PUMRA:

(1) The exclusive right to the invention includes the right to use the invention, the prohibition of third parties from using it without the consent of the patent holder and the right to dispose of the patent.

[...]

(3) The right to use the invention includes the making, offering for sale, trade with the subject of the invention, including import, the use of the subject matter of the invention, as well as the application of the patented method.

(4) When the subject matter of the patent is a product (article, device, machine, facility, substance, etc), the patent holder has the right to prohibit third parties from performing the following actions:

1. making of the product;
2. offering for sale, trading with the product, including importing, using or keeping the product in stock for offering, selling or using it.

(5) When the subject matter of the patent is a method, the patent holder has the right to prohibit third parties from performing the following actions:

1. application of the method;
2. performance of all actions listed in paragraph. 4, item 2, in relation to the product directly obtained using the method.

## Infringement

Pursuant to Article 27(1) of PUMRA, patent infringement is any use of an invention that falls within the scope of patent protection and is carried out without the consent of the patent holder.

Pursuant to Article 27(2) a person who offers for sale products (subject matter of a patent, manufactured by others in infringement of the patent), or trades, stores for use, or uses such infringing products, is only liable for the infringement if they acts intentionally.

Liability for civil<sup>[3]</sup> infringements is borne by the person or entity committing the infringement, and individuals acting as statutory representatives (e.g., managing or executive directors of companies, etc) may not be held liable.<sup>[4]</sup>

## Patent protection

The scope of patent protection is determined in Article 17 of PUMRA, which adopts the doctrine of equivalence, as follows:

(1) The scope of legal protection is determined by the claims. The description and drawings serve to interpret the claims.

(2) The claims cover not only the features as expressed, but also their equivalents. A feature is considered equivalent to a feature as expressed in the claims where:

1. it performs substantially the same function in the same manner and achieves substantially the same result;
2. it is obvious to a skilled person that, at the date of priority, the result achieved by the feature expressed in the claims can be achieved by the equivalent feature.
- (3) When determining the scope of legal protection, the limitation of the claims made by the applicant or the patent holder in the process of examination for the grant of the patent or requests for declaration of its invalidity shall be taken into account.
- (4) The interpretation of the claims is not limited by the examples of specific implementation included in the description.
- (5) The abstract is not taken into account when determining the scope of legal protection granted by the patent.

## Invalidity and other defences

As discussed above, under Bulgarian law the question of patent validity, if challenged, is always prejudicial to the question of infringement.

The legal grounds for challenging patent validity are provided for under Article 26(3) of PUMRA, pursuant to which:

[T]he patent is declared invalid where:

1. the invention is unpatentable;
2. the essence of the invention has not been disclosed sufficiently clearly and completely;
3. the patent holder did not have a right to a patent, which was established by an effective court decision;
4. the subject matter of the patent goes beyond the content of the application as filed, or when the patent is granted under a divided application - beyond the content of the earlier application as filed.

## Exceptions to patentability

PUMRA contains provisions describing what constitutes excluded subject matter and exceptions to patentability.

Pursuant to Article 6 of PUMRA:

(2) The following are not considered inventions [i.e., excluded subject matter]:

1. discoveries, scientific theories and mathematical methods;

2. results of artistic creativity;
3. plans, rules and methods for intellectual activity, for games or for business activity and computer programs;
4. presentation of information.

(3) Paragraph 2 applies to the specified objects, insofar as legal protection is requested for them as such.

(4) The human body at the various stages of its formation and development, as well as the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable invention. An element isolated from the human body or otherwise obtained by a technical process, including a sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

Pursuant to Article 7 of PUMRA:

(1) Patents shall not be granted for [i.e., exceptions to patentability]:

1. inventions, the commercial use of which would violate public order and good morals, including those relating to:

- (a) human cloning methods;
- (b) methods for changing the genetic identity of a human embryo;
- (c) use of human embryos for industrial or commercial purposes;
- (d) methods of modifying the genetic identity of animals, where there is a risk that this will cause them suffering without having any substantial benefit from a medical point of view for humans or animals, as well as animals obtained by such methods;

2. methods of treating humans or animals through therapy or surgery, as well as diagnostic methods applied to humans or animals, and this does not apply to products, in particular substances or compositions, used in these methods;

3. varieties of plants and breeds of animals;

4. essentially biological methods of producing plants and animals, as well as plants and animals produced by such methods.

(2) The violation under paragraph 1, item 1 cannot result only from the fact that the use of the invention is prohibited by law.

As a limitation to patent protection, Article 20 of PUMRA provides that:

[T]he effect of the patent does not extend to:

1. use of the patented invention for non-commercial purposes in view of personal needs, if it does not cause significant material damage to the patent holder;
2. use of the invention for experimental or scientific research purposes related to the subject of the patented invention;
3. one-time immediate preparation of medicine in a pharmacy according to a doctor's prescription;
- [...]
6. use of the patented invention in foreign land, sea and air vehicles that temporarily or accidentally enter the land, sea or air territory of the country, provided that the patented invention is used exclusively for the needs of these vehicles.

Since the accession of Bulgaria to the European Union in 2007, PUMRA Article 20a(1) has provided that '[t]he exclusive right to the invention granted by a patent does not extend to actions with the product protected by the patent, which has been placed on the market in the territory of the European Economic Area by the holder or with his consent'.

### Compulsory licences

PUMRA provides for compulsory licences and compulsory cross-licences.

### *Bolar*-type defence

A *Bolar*-type defence is provided for under Bulgarian law. Until 2006 it was contained in PUMRA, but since then it has been moved to Article 33 of the Medicinal Products in the Human Medicine Act which provides that:

[C]onducting the necessary studies and tests for the purpose of preparing the documentation for marketing authorisation and the consequential practical requirements in connection with the authorisation to market medicinal products according to Article 28 and Article 29 shall not be regarded as an infringement of the patent or of the supplementary protection certificate for a medicinal product.

We are not aware of any established Bulgaria case law on the *Bolar*-type defence, in particular what may be considered to be 'consequential practical requirements'.

In terms of possible defences, we are not aware of any Bulgarian case law on the interrelation between competition and patent law.

## Final remedies for infringement

Under Article 28 of PUMRA:

(1) Claims for infringement of patent rights may be:

1. a declaratory claim for the fact of the infringement;
2. a claim for indemnification of damages and loss of profit;
3. a claim for the infringer to cease actions infringing the patent rights.

(2) When awarding an infringement claim under the preceding paragraph, the court may, at the claimant's request, rule:

1. publication in two daily newspapers of the judgement at the expense of the infringer;
2. processing or destroying the object of the infringement, and in case of intent – also the means by which the violation was committed.

Under Bulgarian law only immediate and direct damages are subject to indemnification. We are not aware of any established case law what that would include in cases of patent infringements. Generally speaking, and based on case law in other intellectual property cases (e.g., copyright and trademarks), it should include the price the infringer should have paid in order to avoid the infringement (i.e., to legitimately undertake the actions constituting the infringement). That would usually include the respective licence to have been paid by the infringer to the right (patent) holder for the particular actions constituting the infringement. The particular amount of such licences would normally be subject to evaluation by expert opinions appointed in the proceedings in view of the particular market conditions during the time of the particular infringing actions (e.g., a licence to make and sell a particular number of products on the Bulgarian market for a particular period, etc).

As a general rule, injunction measures may be requested at any stage of the pending infringement proceedings, including prior to the filing of the claim (i.e., preliminary injunction measures) and even while infringement proceedings are stayed. If an injunction is granted and the infringement claim is unsuccessful, the liability of the claimant for damages resulting from the granted measure under national law is strict. Regarding damages, the same understanding applies that only immediate and direct damages are subject to indemnification in those cases too. We are not aware of any Bulgarian case law in this respect, including in light of the more recent preliminary ruling on C-473/22.<sup>[5]</sup>

As noted above, currently there are several cases pending in the pharmaceutical sector in Bulgaria concerning both invalidity and infringement actions but none of them has come to an end.

## Other types of patent proceeding

There are other types of proceedings that may develop under PUMRA.

Proceedings for the grant and termination of compulsory licences are administrative and develop initially before the Patent Office. Appeals are possible through two instances before the Sofia City Administrative Court and the Supreme Administrative Court.

Disputes regarding the establishment of actual inventor, the official nature<sup>[6]</sup> of the invention, the right to application, the right of pre-use and post-use and the amount of remuneration in cases of compulsory licences are decided by the Sofia City Court as a first instance. A general appeal is possible before the Sofia Court of Appeal and a further limited cassation appeal before the Supreme Court of Cassation. The disputes for the right to application may also be heard in arbitration.

Disputes regarding the fact of integration follow general civil procedure rules.

Pursuant to Article 83a of PUMRA, customs authorities apply measures against goods under customs supervision or customs control, which are suspected of infringing a patent under the conditions and under the procedures of Regulation 608/2013.

Last but not least, Article 172b of the Criminal Code provides for criminal liability for anyone who, without the consent of the holder of the exclusive right, uses in their commercial activity, inter alia, an invention without a legitimate ground. Criminal liability under Bulgarian law is only applied to a natural person (i.e., non-natural persons, such as companies, are not criminally liable).

## Appeal

The decision of the Patent Office in invalidity (and other types of) proceedings is subject to a general appeal before the Sofia City Administrative Court within three months as of the ruling's receipt. There is no restriction to evidence. A judgment of the Sofia City Administrative Court is subject to a general appeal before the Supreme Administrative Court filed within 14 days. Only written evidence related to the cassation grounds is admissible. State fees are not substantial.

In infringement (and other types of civil) proceedings, the decision of the Sofia City Court (or the first instance court) is subject to a general appeal before the Sofia Court of Appeal (or the respective court of appeal) within two weeks as the ruling's receipt. The grounds for a cassation appeal before the Supreme Court of Cassation are limited and an appeal must meet specific selection criteria. The term to file a cassation appeal is one month as of receipt of the second instance judgment. In each court instance there are preclusive evidentiary rules and certain exceptions which are not specific to patent cases, but are generally applicable to civil proceedings. The state fees for appeal and cassation appeal currently are 2 per cent (at each instance) of the appealed material interest.

In both types of proceedings, the remuneration of expert witnesses is determined by the court, based on the complexity of the questions to be answered, but is not substantial.

All legal terms for the appealing party are strict. All legal terms for the court are merely instructive, and in practice it takes (much) longer than prescribed by law for a judgment to be rendered, especially by the Supreme Courts.

There are no procedure rules, including in appeals, specific to patent cases in both types of proceedings. Appeals in invalidity cases follow the general order under the Administrative Procedure Code and appeals in infringement cases follow the general order under the Civil Procedure Code.

## Special considerations

A particular question that remains to be answered by the civil courts, specifically with regard to medicinal products, is to what extent the undertaking and completion of certain specific national regulatory and administrative procedures following and related to the obtaining of the marketing authorisation may, if at all, constitute patent infringement; and if that is the case, to what extent the *Bolar*-type of defence may apply. For instance, after obtaining a market authorisation Bulgarian law requires certain mandatory procedures related to the price of the medicinal product and its reimbursement which are strictly documentary. The law contains express mandatory provisions that the medicinal product may not be put on the market if those procedures are not completed. On the other hand, if those procedures are to be undertaken and completed after the expiry of the patent, that would take months, and in case of generic medicinal products, would result in the de facto extension of the patent protection of the original product. This and other questions related to the interrelation between patent law and pure specific national regulatory and administrative procedures remain to be answered by the civil court in infringement proceedings.

## Outlook and conclusions

Bulgarian patent case law is still developing, having its own national specificities as opposed to a number of other European jurisdictions. Those include a bifurcated system, certain specific national rules and concepts related, for instance, to expert opinions, damages subject to indemnification, (preliminary) injunction measures, etc.

Both invalidity and infringement proceedings may, in practice, take a long time. As discussed, above, there are currently a number pending invalidity and infringement cases related to national counterparts of European patents in the pharmaceutical sector which will inevitably serve as a base to shape the case law in the years to come.

*\* The information in this chapter was accurate as at October 2024.*

## Endnotes

- 1 Bulgaria has signed the Agreement on a Unified Patent Court. [^ Back to section](#)
- 2 However, if a party directs the court to or requests the appointment of a particular expert, that may raise doubts about the expert's independence. [^ Back to section](#)
- 3 Criminal liability under Bulgarian law is briefly discussed in Section VII below. [^ Back to section](#)
- 4 As an exception, civil liability may also be borne by shareholders jointly and severally with the legal entity where the legal entity is of the type in which shareholders are by statutory law jointly and severally liable therewith. [^ Back to section](#)

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<https://curia.europa.eu/juris/liste.jsf?lgrec=fr&td=%3BALL&language=en&num=C-473/22&jur=C>.

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6

i.e., invention under labour contract or commissioned invention. [^ Back to section](#)

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