## Towards a new Spanish Patent Act

C L I F F O R D C H A N C E Content

### Main New Aspects of the Patent Bill

One single procedure for the grant of patents: the prior examination procedure.

50% reduction in application fees, preparation of the report on the state of the art and performance of the substantive examination, and in the first 3 yearly payments for certain entrepreneurs and SMEs.

Express inclusion of supplementary protection certificates for drugs and plant protection products.

Separate regulating of the exceptions of "experimental use" and the "bolar provision".

New aspects in the regulating of actions against patent right infringement.

New aspects in matters of patent invalidity.

New procedure for the revocation or limitation of the patent before the SPTO.

New aspects in matters of patent expiry.

New aspects in matters of obligatory licences.

More precise system of employment-related inventions.

Explicit mention of the doctrine of equivalents.

Amendments of procedural rules.

Amendments in the regulating of conciliation before the SPTO on matters of employmentrelated inventions.

Express reference to arbitration.

Strengthening of the utility model.

Introduction of the rules of application of International Conventions.

The Spanish regulatory framework on patent matters is undergoing a process of change. After having been in force for almost three decades, the 1986 Spanish Patent Act is to be replaced by a new Patent Act, the bill for which is currently before the Spanish Parliament.

Specifically, on 14 November 2014, the Spanish Cabinet approved the referral of this Patent Bill to the Parliament, where it will continue to be processed with the Congress and Senate until it is finally passed.

The 1986 Patent Act has to date been subject to sporadic amendments in order to adapt it to new aspects that have been introduced by the Community and international legislation. However, in recent years the significant changes that have taken place in patent law on a Community and international level, as well as the new national legislative aspects affecting patent law that have been approved have led to the need for a general modernisation of this Act.

The object of this newsletter is to underline the main new aspects of the Patent Bill (the "Bill") currently before the Parliament, in order to anticipate the possible changes which are to be introduced by the new Spanish Patent Act.

### One single procedure for the grant of patents: the prior examination procedure (Title V, Chapter II and Chapter III)

At present in Spain it is possible to choose between a grant procedure for the patent with a prior examination analysing whether, in the patent requested, the requisites of novelty, inventive step and disclosure sufficiency exist, and the general grant procedure for patents with no prior examination, in which the existence of these requisites is not analysed.

The Bill only contemplates the prior examination procedure and introduces certain changes into it.

## *Ex officio* actions of the SPTO: Search stage together with the initial technical examination (articles 35 and 36)

This grant procedure with prior examination commences with the submission of the patent application. The Spanish Patent and Trademark Office ("SPTO") then performs an *ex officio* action: the search of the state of the art existing at the time and an initial technical examination of the patent application. These actions will result in the report on the state of the art and an initial preliminary non-binding opinion and on the patent application.

The purpose of this initial SPTO *ex officio* examination is for the applicant to be aware from an early stage of the procedure of the possibilities of the patentability of their invention and, based on this, to be able to decide whether to maintain the application as filed, amend it, and/or extent it to other States within the priority year.

#### Substantive examination at the request of the applicant and grant of the patent (articles 39 to 42)

This initial SPTO *ex officio* examination may be followed by a substantive examination at the request of the patent applicant, already existing in the prevailing procedure at present. This examination consists of the analysis of the application and of the invention to see whether they meet the formal, technical and patentability requisites established in the Bill. Once this second examination is passed, the patent will be granted.

### Post-grant opposition stage of the patent (article 43)

The opposition stage will take place after the grant of the patent, similar to the grant procedure of European patents with the European Patent Office, and in contrast to the provisions of the current Patent Act were this occurs after its grant.

## Appeals only against the decision on the opposition and by those who have been opponents (article 44)

On the establishment of this new post-opposition stage, the appeal system against the acts of grant of the patent is also amended so that an appeal may only be lodged against the act of the decision of the opposition (instead of the act of grant) and by those who have been parties to the opposition procedure.

These reforms to the procedure for the grant of patents warrant a positive evaluation as they should speed up this procedure and increase the quality of those patents granted by the SPTO and, as a result, make patent applications in Spain more attractive for foreign applicants.

### 50% reduction in application fees, preparation of the report on the state of the art and performance of the substantive examination, and in the first 3 yearly payments for certain entrepreneurs and SMEs (Title XVI, article 186)

Individual entrepreneurs or SMEs wishing to obtain the protection of an invention through a patent or utility model may request a 50% reduction in the application fees. preparation of the report on the state of the art and performance of the substantive examination, and also in the first three yearly payments, evidencing, with the documentation required under a future regulation, that they are in line with the definition of entrepreneur of Act 14/2013, of 27 September, supporting entrepreneurs and their internationalisation and the definition of small- and mediumsized enterprise (SME) adopted by Recommendation 2003/361/EC, of the European Commission, of 6 May, concerning the definition of micro, small and medium-sized enterprises or that which, in the event of the amendment or substitution of the same, is applicable on submitting the application.

### Explicit inclusion of supplementary protection certificates for drugs and plant protection products (Title V, Chapter IV)

The Bill expressly includes among the titles of protection the supplementary protection certificates for drugs and plant protection products regulated under Community Regulation (EC) n<sup>o</sup> 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, and Regulation (EC) n<sup>o</sup> 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products.

These industrial property titles extend for a maximum period of 5 years the protection afforded to a patent protecting a medicinal or plant protection product to compensate for the time during which it is not possible to exploit the patent by marketing such drug or plant protection product as the application and grant of their corresponding marketing authorisations are being processed.

Their regulation continues to be that established in European Union regulations, with the Bill limiting itself to including certain general guidelines on the administrative procedures for their application and grant.

# Separate regulating of the exceptions of "experimental use" and of the "bolar provision" (Title VI)

"Experimental use" and the "bolar provision" are two circumstances excepted from the protection of patent law. Article 52.1 b) of the current Patent Act, in its wording amended by the Drug Act, included the "bolar provision" together with the exception of "experimental use" already contained in the original wording, although these are two exceptions of a different origin and purpose. The Bill separates these exceptions on stating in two different sections of article 61.1 that the rights conferred by the patent do not extent:

- On the one hand, "To acts performed for experimental purposes referring to the object of the invention patented." (exception of experimental use) (article 61.1. a)) and;
- On the other hand, " To the performing of the studies and trials necessary for obtaining marketing authorisation for drugs, including the preparation,

obtaining and use of the active ingredient for these purposes" ("bolar provision") (article 61.1 b)).

# New aspects in the regulating of actions against patent right infringement (Title VII)

### Explicit reference to actions for prohibition (article 71.1 a))

An action for prohibition is explicitly included for the first time in the list of actions which may be brought against acts infringing patent rights. The intention of this action is to obtain a decision from the corresponding Court prohibiting the committing of an infringing act before it occurs. The current Patent Act only covered these actions in interim injunction proceedings although in practice they had also been brought in main proceedings.

#### Improvements in the regulating of actions for the compensation of damage (articles 73 and 74)

### Amendments to the criteria for establishing the compensation of damage

 Alternative criteria: the profit not obtained by the holder of the patent or the profit obtained by the infringer (article 74.2 a))

The Bill clarifies a question which had been the object of significant dispute in the Spanish Courts: whether the holder of the patent is entitled to claim the profit it would presumably have obtained from the exploitation of the invention (lost profit) and, cumulatively or alternatively, the profit obtained by the infringer from the unlawful exploitation of the invention (profit through interference). The wording of the current Patent Act leads to the interpretation that it is possible to claim both, but the interpretation of some Courts is that it is only possible to claim one or the other.

The Bill brings an end to this dispute as it establishes that the holder of the patent can request the profit presumably not obtained from the exploitation of the invention "*or alternatively*" the profit obtained by the infringer of the exploitation carried out of the invention in infringement of their patent.

 A hypothetical royalty of at least the price of the licence (article 74.2 b))

The Bill also clarifies whether the holder of the patent opting for the criterion of the hypothetical royalty, i.e. opting for claiming the price the infringer would have had to pay for the grant of a licence, can claim at "least" or at "most" such price on specifying that they may claim " at least the amount the infringer would have had to pay to the holder of the patent for the grant of a licence enabling it to carry out its exploitation pursuant to law ".

In this way, legal coverage is provided to a practice which had already been accepted by case law based on the holder of the patent warranting as compensation of damage for the infringement of their patent a greater amount than the price that would be paid by a party which had carried out a consented use of the same.

#### Establishing of coercive compensation per day elapsed until the cessation of the infringing action (article 74.4)

In those cases in which the defendant is ordered to cease the acts of patent infringement but continues infringing, coercive compensation is established in favour of the claimant per day elapsed until the effective cessation of the infringement. The final amount of this compensation and the day as from which the obligation to compensate will arise will be established on the enforcement of the judgment.

### Referral of the calculation and liquidation of the compensation to the enforcement stage of the decision observing the existence of infringement (article 74.5)

In legal proceedings on patent right infringement, great difficulties exist for determining and quantifying the damage suffered as a result of the infringement. For this reason the services of expert accountants and the corresponding expert accounting evidence are required, with the corresponding investment in time, money and other resources this involves. Furthermore, this investment takes place when it is still not known whether the action for compensation of damage will be upheld, so that, in the event it is dismissed, it might have been pointless.

The Bill refers the calculation and liquidation of the compensation of damage to the enforcement stage of the judgment, which will prevent this investment from being made before knowing whether the action for compensation of damage will be upheld.

## Safeguarding of the legitimate interests of the defendants in respect of their trade secrets or of acts of unfair competition (article 73.2)

The holder of the patent may ask the defendant for the discovery of documents to obtain the information necessary in order to calculate and establish the amount of the compensation. The Bill ensures the interests of the defendants in respect of their trade secrets or of acts of

unfair competition on establishing that " in the enforcement of this measure, consideration will be taken of the legitimate interests of the defendant in the protection of its trade manufacturing and business secrets " and it intends to guarantee that this does not hinder access to such information on foreseeing that this is carried out "notwithstanding the right of the patent holder to possess the information necessary in order to be able to specify the scope of the compensation in its favour when the investigation to these effects is carried out in the enforcement stage of the decision on the merits which has observed the existence of infringement."

## New aspects in matters of patent invalidity (Title X, Chapter I)

#### Partial annulment of a claim

The Bill removes the prohibition existing under the current Patent Act of partially annulling a claim, which will facilitate the limitation of patents through the amendment of its claims (limitation constituting another of the new aspects foreseen in the Bill, which we describe below).

### Judicial limitation of the patent (articles 102.2 and 103.4)

- In judicial proceedings judging the validity of a patent where the holder of the patent defends:
  - Principally, the validity of the claims as granted, and
  - Subsidiarily, in the event the Court understands that such claims are invalid, the validity of a new set of claims remedying the grounds for invalidity alleged,

the Court may maintain the patent, through its limitation, with such new set of claims (article 102.2).

In judicial proceedings judging the validity of a patent, the holder of the same may request its limitation to overcome an objection of invalidity and, if agreed, the patent thus limited will serve as a basis in such proceedings (article 103.4).

## Possibility of the general public challenging the validity of a patent (article 103.1)

With the new Bill, active standing for bringing an action for challenging the validity of a patent is held not only by "*those deeming themselves injured*", as under the current Patent Act, but also by the general public.

## Extension of the effects of the invalidity to supplementary protection certificates (article 104.2)

The effects of the invalidity of the patent will be extended to supplementary protection certificates insofar as they affect the right over the product protected by the basic patent grounding the grant of such certificates.

# Revocation or limitation of the patent through administrative means (Title X, Chapter II)

The holder of a patent may request its revocation or limitation at any time during its legal lifespan including, where applicable, the validity period of the supplementary protection certificates, through an administrative procedure carried out with the SPTO, with the effects of such revocation or limitation (articles 105 and 107) being retroactive.

### New aspects in matters of patent expiry (Title X, Chapter III)

### Re-establishment of rights in the event of expired patents

In the new Bill:

- The re-establishment of rights currently set out in the Trademark Act and that applies to patents by virtue of the Seventh Additional Provision thereof has been included, and it will also apply to the priority period (article 53 of the Bill).
- The possibility to restore patents that expired due to a failure to pay the annual fee in cases of *force majeure*, established under article 117 of the current Patent Act, has disappeared. Nevertheless, in such cases it is possible to resort to the procedure for the reestablishment of rights.

## Expiry due to the lack of payment of the yearly fee only after the elapsing of delay periods (article 108.3)

The expiry due to the lack of payment of yearly fees will not take place until the six-month delay periods established in the Bill have elapsed.

### Payment of the yearly fee by the holders of registered rights (article 109)

Payment of any pending yearly fee may be made, apart from by holder of the patent, by those holders of rights registered over such patent which might be affected by the expiry of the same, notwithstanding their right to pass on any amounts paid to the patent holder.

### New aspects in matters of obligatory licences (Title IX)

When the Patent Act was drafted and the prevailing system of obligatory licences configured, the patent holder was required to manufacture the products protected by patents in Spain, with the intention of avoiding these being imported instead of being manufactured in the country.

After the application of TRIPS<sup>1</sup> in Spain, this requisite was removed, it sufficing for the manufacture to take place in Spain or in any member state of the WTO<sup>2</sup>. However, the system of obligatory licences was not adapted and was kept based on this requisite of manufacturing in Spain. This is why one of the purposes of Title IX of the Bill has been to rearrange and simplify the system of obligatory licences and eliminate numerous articles connected to the requisite of "national manufacture".

### Change of the cases for the grant of obligatory licences (article 91)

### 2 new cases are included for the grant of obligatory licences:

- When a final administrative decision of national or Community scope, or a judgment, have declared that the holder of the patent has committed acts contrary to competition defence legislation. In such cases, the grant of obligatory licences will be admissible in order to bring an end to such anti-competition practices (articles 91 c) and 94).
- In the case of patents relating to the manufacture of drugs for export to countries with public health problems established under Regulation (EC) nº 816/2006, of the European Parliament and of the Council of 17 May 2006, regulating them (articles 91 e) and 95).

<sup>&</sup>lt;sup>1</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1C of the Agreement establishing the World Trade Organization.

<sup>&</sup>lt;sup>2</sup> World Trade Organization.

The case of insufficiency of production of the object of the patent will now fall within the case of the grant of obligatory licences for reasons of public interest (articles 91 d) and 95).

The grant of obligatory licences due to an insufficiency of production of the object of a patent for meeting the export needs such production insufficiency does not allow to be met is removed as a separate case.

This case will fall within the cases of the grant of obligatory licences for reasons of public interest (articles 91 d) and 95).

### 1 year of interruption of legitimate exploitation for requesting an obligatory licence (article 92.1)

In the event of a lack or insufficiency of exploitation of the patent, the possibility is established of requesting the obligatory licence when exploitation has been interrupted for 1 year, instead of the 3 years established under the current Patent Act.

#### The requisite of having previously tried to obtain a contractual licence is established in general (article 97)

Whereas the current Patent Act only requires this requisite in one of the cases of obligatory licences, the Bill generalises it to all, except for the following cases:

- National emergency or in any other circumstances of extreme urgency;
- Non-commercial public use; and
- Need to bring an end to practices that a Court or administrative decision have declared contrary to competition defence legislation.

#### Simplification of the processing and resolution of the grant procedure for the obligatory licences (Chapter II, articles 97 to 99)

The processing and resolution of the procedure to grant obligatory licences is simplified and a procedure is regulated in which the application for the obligatory licence and reply of the holder of the patent must attach the appropriate evidence and in which the parties may agree the licence conditions through a mediator appointed by them or, failing this, by a committee of experts, one appointed by each of the parties and a third appointed by the SPTO.

## Extension of the obligatory licence to supplementary protection certificates (article 100.5)

The obligatory licence granted over a patent will be extended to any supplementary protection certificates which, on the granted of the licence or subsequently, might fall over the object of the patent.

### More precise system of employment related inventions (Title IV)

### Specification of the conditions for exercising the rights of the worker and of the employer (articles 18 and 19)

The Bill specifies the conditions for the exercise of the rights of each of the parties to the employment or service relationship, seeking a better balance between the duty of information of the employee and that of response and enforcement of the undertaking assumed, where applicable, by the employer.

- The worker will have a period of 1 month from the date on which they conclude an invention belonging to or assumable by the employer in order for them to inform the latter of the making of the invention (article 18.1).
- The employer will have a period of 3 months from the day following receipt of such notification to assess the invention and notify the employee in writing of its intention to maintain its rights over the invention, requesting the corresponding patent or reserving a right of use over the same, whether exclusive or not. Should the employer fail to make this notification in these terms and within this period, its right will expire, and the employee may then submit the patent application (article 18.2).

Evidence is accepted to undermine the presumption existing that inventions for which a patent application or other title for exclusive protection is submitted within the year following the termination of the employment or service relationship were made while the employment relationship was in force (article 19.1). Adaptation of the regulating of inventions made by research staff working for Public Universities and Public Research Bodies to the rules applicable in matters of research (article 21)

- The forms and amount of the participation of research staff of universities and the participation of the university, where applicable, in the profits of the inventor will be determined by the University Governing Council based on applicable regulations in university matters (article 21.6).
- The forms and amount of the participation of research staff of public bodies in the profits obtained from the exploitation of the invention will be determined by the Government, although the Autonomous Regions may establish through regulations specific profit-sharing schemes for research staff of the public research bodies of their competence (article 21.7).

This is a matter in respect of which there will inevitably exist a certain divergence in regulations given the referral of Bill to university governing bodies and the optional regulations of the Government or Autonomous Regions.

Further specification of the conditions of the exercise of the rights of each of the parties in the regulating of inventions made by research staff working for Public Universities and Public Research Bodies:

- The investigator will have a period of 1 month from the date they conclude an invention to notify the Public Authority they work for that this has been made, losing any rights over the same should they fail to do so (article 21.2).
- The Public Authority will have a period of 3 months from the day following receipt of such notification to provide the author of the invention with written notification of its intention to maintain its rights over the invention, applying for the corresponding patent or, if it is considered a trade secret, reserving the exclusive right of use over the same. The invention may not be published until such 3-month period has elapsed.

If the Public Authority fails to make such notification in these terms and within this period, the author may submit the patent application as established in the case of inventions within the framework of an employment relationship (article 21.3).

## Explicit mention of the doctrine of equivalents (article 68.3)

The scope of the protection of a patent is determined by its claims interpreted according to its description and drawings. Furthermore, account should also be taken of those elements equivalent to an element included in such claims. This is what has become known as "protection by equivalence" widely recognised by Spanish Courts but which is not expressly provided for under the current Patent Act.

The Bill explicitly includes this protection by equivalence on establishing that in order to determine the scope of protection of a patent, "due account should be taken of any element equivalent to an element indicated in the claims."

### Amendments of procedural rules (Title XII)

#### General provisions (Title XII, Chapter I)

- Recognition of active standing for bringing actions for infringement of those evidencing they have requested the registration of the legal transaction or act (for example, a licence), providing such registration is actually granted (article 117.1)
- Period of 2 months in which to reply to the complaint, counterclaim and the request for limitation of the patent (article 119.1).
- The submission of opinions subsequent to the complaint and the reply will occur exceptionally, only in the event that the defendant or counterclaim defendant duly justifies the impossibility of submitting the expert report(s) it intends to use when replying to the complaint or counterclaim (article 119.2).
- The request that the invalidity raised through an exception be treated as a counterclaim should be made within a period of 8 days from receipt of the reply to the complaint (article 120.2)
- The request for limitation of the patent, principally or subsidiarily, in the reply to the invalidity complaint, in the reply to the counterclaim or on replying to the invalidity exception (article 120.3).
- If the patent is amended in other proceedings, it may be requested that this amended version serve as a basis in the proceedings in progress, providing the opposing party with the opportunity to present allegations (article 120.4). This provision has been designed so that the patent might be amended, for example, in the opposition stage before the European Patent Office.

- The request for limitation of the patent will be sent to the SPTO for it to make a preventive registration.
  Subsequently, when a final decision is obtained, it will be notified to the SPTO for it to record the registration and, where applicable, amendment of the patent (article 120.6).
- The Judge or Court may, when thus requested by one of the parties, agree on the issuance of an expert written report of the SPTO dealing with specific points in which the expert reports submitted by the parties are contradictory, with the author of the report also possibly being called on to declare (article 120.7).

### Specifications in the procedures for the verification of facts (diligencias de comprobación de hechos) (Title XII, Chapter II)

- The need is stated clearly and unmistakably for procedures for the verification of facts to be carried out "Without any prior notification under any circumstances of their performance to the subject of such procedures" so as not to thwart the successful outcome of the same (article 124.1).
- A period is established of 30 days, instead of 2 months under the current Patent Act, to submit the corresponding complaint once the procedures have been carried out, period which will start to elapse as from the day of the delivery to the applicant of the certificate of the procedures (article 125.2).

### Specifications in the regulating of interim injunctions (Title XII, Chapter III)

- The setting of the bond, if any, will be made by the jurisdictional body hearing the parties in the same interim injunction proceedings, with no need to open new proceedings, as has been the case to date (article 129).
- A period of 1 month is established so that, once the interim injunctions have been lifted, the defendant might request compensation for the damage caused by the adoption of such measures. Should it fail to do so, the bonds provided shall be returned to the applicant of the interim injunctions (article 131.3).
- In those cases in which the existing bond is not sufficient for covering all the damage caused to the defendant by the adoption of the interim injunctions, it will not be necessary to bring a new liability action for claiming the remaining amount as established under the current Patent Act, but rather the claim will be heard directly through collection proceedings (article 131.4).

 Preventive writs are introduced as a procedural instrument for defence against the possibility of interim injunctions *inaudita parte* by a party which fears being subjected to the same, so it might appear before the competent jurisdictional body and preventively justify its position (article 132).

### Amendments in conciliation before the SPTO in matters of employment-related inventions (Title XII, Chapter IV)

- Conciliation becomes voluntary (article 133).
- The procedure to appoint the experts of the Conciliation Committee is left for subsequent regulatory development (article 134). The Preamble of the Bill states that the intention is to ensure a greater degree of parity of such Committee.
- Agreement with the proposed resolution of the Conciliation Committee must be declared by the parties expressly, and in case of silence it will be understood no agreement has been reached (article 135.1).
- The certificate of the conciliation resolution will be executed pursuant to the rules applicable to judgments and legally approved conventions (article 135.3).

## Express reference to arbitration (article 136)

- The Bill expressly states that any disputes arising between the interested parties due to the exercise of rights recognised under the future Patent Act may be submitted to mediation or arbitration.
- Excepted from being submitted to mediation or arbitration are "those issues relating to grant, opposition or appeal procedures referring to titles regulated under this act when the object of the dispute is the fulfilment of the requisites required for their grant, maintaining or validity."
- The role of the SPTO as mediating and arbitral body is reinforced (First Final Provision).

### Strengthening of the utility model (Title XIII, Chapters I, II and III)

#### Comparison of the state of the art to that of patents of invention (articles 139.1 and 6.2)

The state of the art in accordance with which the novelty and inventive step of inventions protected as utility models should be judged becomes the same as that of patents of invention. Thus, such state of the art will consist of everything which, prior to the date of submission of the application for the utility model, has been made available to the public in Spain or abroad through a written or verbal description or through any other means. Under the current Patent Act, the state of the art only consists of anything "*disclosed*" "*in Spain*".

#### Extension of the protection through utility models to inventions from virtually all technical fields (article 137)

In contrast to the current Patent Act, where the utility model is basically designed to protect small inventions in the field of mechanics, the Bill establishes that inventions from virtually all technical fields may be protected as utility models, including chemistry, with the exception of substances and compositions used as drugs in human or veterinarian medicine.

#### Obligatory nature of a report on the state of the art for bringing actions of infringement of utility models (article 148)

- In order to be able to bring actions for infringement of utility models, it will be necessary to have obtained or requested beforehand a report on the state of the art referring to such utility model.
- If the complaint is filed before submitting such report, the defendant may request the suspension of the period for replying to the complaint until such report is submitted.
- Once the report on the state of the art has been submitted, and even if it has not been submitted to the proceedings, the adoption may be requested of provisional and interim measures, providing these do not consist of the stoppage or cessation of the industrial or commercial activity of the defendant in relation to the invention protected.

### Introduction of the rules of application of International Conventions (Title XIV, Chapters I and II)

The Bill contains a new Title, XIV, Chapters I and II of which include, respectively, rules aimed at facilitating the application in Spain of (i) the Convention on the Grant of European Patents (basically containing the text of the regulation set forth in Royal Decree 2424/1986, of 10 October, relating to the application of the Convention on the Grant of European Patents) and (ii) the Patent Cooperation Treaty (incorporating the main provisions set forth in Royal Decree 1123/1995, of 3 July, on the Application of the Patent Cooperation Treaty).

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