Institut der beim Europäischen Patentamt zugelassenen Vertreter
Institute of Professional Representatives before the European Patent Office
Institut des mandataires agréés près l'Office européen des brevets

European Patent Institute · Bayerstrasse 83 · 80335 Munich · Germany

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epi's comments on the European Commission's proposal dated 27.04.2023 for a Regulation on compulsory licensing for crisis management and amending Regulation (EC) 816/2006

epi, the Institute of Professional Representatives before the European Patent Office, welcomes the Commission's thoughts and efforts to strengthen intangible assets including inventions and patents by fostering EU's IP system and IP enforcement.

epi is the professional body representing all European Patent Attorneys. Currently the Institute has about 14,000 European Patent Attorneys as members coming from each of the 39 Contracting States of the European Patent Convention who work either in industry or in private practice. European Patent Attorneys help their clients and employers, which include international big corporations, SMEs and private inventors, to protect and create value from their inventive ideas, thus supporting an innovative ecosystem within as well as outside the Contracting States.

epi has been considering the above-mentioned proposal and wish to make the following comments:

1. The existing mechanisms for compulsory licenses

The proposal recognizes that there are already mechanisms in place to grant compulsory licenses in cases of emergency through the TRIPS Agreement, Regulation (EC) No. 816/2006 and national legislations of member states.

In fact, TRIPS under Article 31 gives a solution for allowing use of the subject matter of a patent without the authorization of the right holder in cases of emergency. Article 31bis of TRIPS gives a solution for supplying pharmaceutical products to least developed countries, having insufficient or no manufacturing capacities. This Article was implemented in the European Union by Regulation (EC) No. 816/2006 establishing a procedure for granting such compulsory licenses for the manufacture of pharmaceutical products for export purposes to countries with public health problems.

On the other hand, national legislation of member states already establishes provisions for compulsory licenses in cases of public interest in particular when the start, increase or generalization of the exploitation of an invention would be of capital importance for public health.

President • Peter R. Thomsen
epi Secretariat · Bayerstrasse 83 · 80335 Munich · Germany
Phone +49 89 242052-0 · Fax +49 89 242052-220
info@patentepi.org · www.patentepi.org

Direct Phone: : +41 79571 0076
president@patentepi.org

So, we already have in the EU mechanisms in place to establish compulsory licenses in situations of crisis management that are properly controlled.

These procedures have also fast-track mechanisms that, at the same time, have the necessary mechanism of control to ensure legal certainty for all parties involved.
It is also important to consider that in the EU there are no EU-wide patent rights, but national rights that can be obtained either individually or centrally through the European Patent Convention, which is not an EU treaty but an International Treaty incorporating more than 39 Contracting States.

Even the recently introduced European Patent with Unitary Effect does not provide a true EU-wide right. Firstly, not all of the EU states (17 at the moment) have ratified the Agreement on a Unified Patent Court. European Patents must be validated individually in the remaining EU states not party to the Agreement, meaning that EU-wide protection is likely to be a mix of national patents and the European Patent with Unitary Effect. Secondly, certain aspects of the European Patent with Unitary Effect, in particular inventorship, property rights, licenses and especially, compulsory licenses are continued to be governed by the national law of one member state.

Accordingly, it is not adequate to establish a European Union wide compulsory license, since the existing mechanisms already provide a solution to the problem and because there are not EU wide patent or utility model rights to which the EU compulsory license could be applied, but a bundle of national rights with different scope, nature and effects to which only national compulsory licenses could be applied.

2. Exceptional and sensitive nature of compulsory licenses

It must not be underestimated, on the other hand, the very exceptional nature of compulsory licenses and at the same time that compulsory licenses are a very sensitive issue for patent holders and inventors. In fact, a compulsory license can weaken the broadly recognized patent system of which the exclusive rights of patents are a fundamental pillar.

The patent system compensates the investments and efforts of those who invest in innovation by granting a temporary exclusive right. Obliging patentees to grant compulsory licenses is equal to depriving those patentees from their exclusive right.

Many investments in innovations do not end up with a useful result and even when results are achieved, then inventors have to go through a complex and difficult procedure to prove that the innovation fulfills the patentability requirements that are examined by patent offices. Therefore, innovation is a costly and difficult procedure.

It is, accordingly, very important that a balance of interests is maintained and any attempt to change this balance might end up discouraging innovators to invest in innovation, or worse promoting that innovators move away from the EU to other regions that would offer a more innovation friendly environment.

It has been SMEs like BioNTech or Moderna that have proven in the times of the COVID-19 crisis to be highly innovative and to develop an effective vaccine in less than a year. It didn't need a compulsory licensee to make the results of their innovative work available to the public.

Due to all the considerations above, **epi** is of the opinion that the current status-quo on compulsory licensing should be maintained, since what the EU needs is to increase innovation and create an environment in which creativity thrives and innovations will pay off for those who invested.

The EU as a group of countries that strives for becoming an innovation leader in all important technologies should strengthen the patent system and not give in to the temptation to lower the bar in the conditions to grant compulsory licenses as an alleged solution to make "critical IP in times of crisis" available.

3. Detailed comments on the draft Regulation

Despite the fact that **epi** is of the opinion that the proposed draft Regulation should not be pursued, we wish to make the following specific remarks to some of the articles of the draft Regulation.

a. Article 6 Advisory body

The evaluation of a compulsory license requires an expertise in patent matters to assess the scope of protection of a patent and the need to obtain a compulsory license under a particular patent to manufacture a particular product. Therefore, experts on patents need to be involved in the process of these evaluations. We believe that **epi**, as the European body that incorporates and represents the European patent professionals, should be involved in that process.

b. Article 9 Remuneration

Article 9.2, Article 31 (h) of TRIPS, to which the EU and EU member states belong, requires that the licensee shall pay an adequate remuneration to the right holder, taking into account the economic value of the patent. Imposing the limit of maximum 4% of the total gross revenue generated by the

licensee in all cases is not consistent with TRIPS. Depending on the circumstances, market players may regard a 4% royalty as inadequately low based on current experiences from voluntary licenses (see for instance the market royalty range of 2-15% as recited for pharmaceutical patents in Compulsory Licensing decision of the German Federal Patent Court, 3 Li 1/16 "Isentress II", wherein certain circumstances could have led to a higher royalty than the finally decided 4%). The mechanism that would in our view serve this aim best is determining the compulsory licence royalty as the remuneration to be paid to the patent holder for a contractual licence. For this purpose, earlier licence contracts executed for similar products or derived income or royalties payable for the same patent in different markets should be used as a basis.

c. Article 9.3 (b)

The fact that the right-holder has received public support to develop the invention should be treated independently of compulsory licenses. The conditions for providing public support to inventors must find a balance in a free competition system as the one in the EU in general terms. For example, member states will receive a return from the new taxes that the right-holder will pay due to the income generated by the success in the exploitation of an invention. Accordingly, no particular treatment should be given in the establishment of the remuneration for compulsory licenses. We would therefore suggest deleting this factor from the list in Article 9.3.

d. Article 9.4

The general principles of patent law and of contractual licenses should also apply to compulsory licenses.

Compulsory licenses, like any contractual license agreed on commercial terms, benefit from the advantages of a degree of exclusivity, since only the patent owner and its licensees (compulsory or otherwise) are able to make and sell the products without the threat of patent infringement. This factual effect of exclusivity from which any licensee may have benefitted should be taken into account, in cases where a pending patent application is finally not granted.

Accordingly, no refund of paid royalties should be made when the patent application is finally not granted or even when having been granted, is later limited or revoked. The refund should only be required when the licensor acted in bad faith.

According to Article 8 1. (d) a compulsory license will be granted only for a certain period of time which (see Article 4) depends on the duration of the crisis mode. In most cases, especially pharmaceuticals, crisis periods may be too short to attract investors because the time to amortize

e.g. the production line for a vaccine will be short and often unforeseeable. No business plan can be based on such imponderability.

Yours sincerely,

Peter R. Thomsen
President