Questionnaire

The following questionnaire is addressed to the volunteers from each member country, who will ensure that the views expressed represent the collective view of each member country.

Country: Hungary

By Mónika Biacs, András Cserny, Gábor Faludi, Pálma Gróf, Bettina Kövecses, Zoltán Kovári, Daisy Machytka-Frank

In lack of recent case law, the below responses, especially with respect to experimental use exemption, are primarily based on educated guesses.

As a general introduction to our responses below, reference is made to the legal background of the experimental use exemption and Bolar type exemption, which is provided by Article 19 (6) of the Act XXXIII of 1995 on the Protection of Inventions by Patents (in the following: Patent Act),

"The exclusive right of exploitation shall not extend to:

[…]

(b) acts done for experimental purposes relating to the subject matter of the invention;

(c) tests, trials and consequentially required acts necessary for the marketing authorisation of the medicine in the territory of the European Economic Area or in a third country, including in particular production, use, selling or other marketing, offering for sale, stocking, importing or exporting, irrespective of whether these acts are performed by the person applying for the marketing authorisation or by another person having a business relation with the applicant for this purpose;

[…]."

The above wording of the Patent Act entered into force on 1 January 2022. In the former version of Article 19 (6) of the Patent Act experimental use exemption and Bolar type exemption were not separated, Bolar type exemption was a subcategory of the general experimental use exemption (in the following: old experimental use exemption). It is also worth mentioning that under the former text of the statute the Bolar type exemption (within the old experimental use exemption) was not limited to medicines. The explanatory memorandum for the former provisions expressly stated that …"the amendment of Section 19(6)(b) of the Act is also related to the TRIPS Agreement. The decision in the dispute settlement proceedings initiated by the EC against Canada in the World Trade Organization confirmed that this provision of our current law is in principle in compliance with the TRIPS Agreement (in particular, Article 30 of the TRIPS Agreement), but becomes unambiguous only, if, in accordance with Article 27(1) of the TRIPS Agreement, *it is drafted in a technologically neutral manner (i.e. not focusing solely on pharmaceuticals)*." As a result, earlier, the legislator was of the view that only a technology neutral exception is in conformity with the TRIPS requirements.

The current wording means that under the currently applicable provisions, the experiments and tests necessary for marketing authorization of the product seem to be not just an example

of the acts done for experimental purposes, but a specific and separate type of exemption applicable only for medicinal products. This approach of the legislator stems from Art 10 (6) of the Medicines Directive [DIRECTIVE 2001/83/EC].

1. Do member countries in their patent laws except acts done for experimental purposes from the rights of the patentee ("**experimental use**")?

   YES, see the above cited Article 19 (6) (b).

   As it can be seen from the above citation from the Patent Act, with respect to Bolar type exemption the Patent Act provides much more detailed guidance than with respect to experimental use exemption.

2. If so, please provide details of the relevant member country law on experimental use. Ensure to include in your answer:

   - Whether the "experimental use" law is considered a "right" or a "defence"?

     We think that it is both a "right", and a "defence", depending on the facts. If the beneficiary uses this exemption, it is a subjective right. If the use of the exception is challenged by the patentee, the exception is an effective defence. It is right to say, that it is an exemption of a right, closer to a "defence" than to a "right".

   - Whether courts interpret "experimental use" in a broad or narrow manner?

     As mentioned above, in the earlier version of Article 19 (6) of the Patent Act experimental use exemption and Bolar type exemption were not separated. After the recent amendment of said Article of the Patent Act, the above cited new experimental use exemption is understood to apply to scientific experiments, experimental tests, research, academic research work etc. How broad the application of this 're-worded' exemption will be is now a reoccurring topic for example for plant protection products. Unfortunately, we do not have any new case law yet that could guide us on interpreting the new experimental use exemption.

     However, there are certain aspects the courts considered in their former, albeit scarce case law under the old experimental use exemption which could still be relevant when relying on the new experimental use exemption.

     a) One of these aspects are the extent of the activities. This means that the extent of the activities – e.g. experiments, studies, tests, trials and investigations – should be undertaken to the extent necessary to achieve the scientific purpose.

     Based on former case-law, the amount and the source of the substance subject to the experiment could have relevance, i.e.,
     - if the amount is considered to be more than as reasonably required for experimental purposes then the exception is unlikely to apply.
     - when the substance is sourced from a country from where import/shipping/transport would seem unreasonable for solely testing (in particular from China) compared to available alternatives in closer proximity (e.g. in Europe) is a factor the court looks at and considers.

b) Another aspect is that the activities should be pursued for experimental purposes, e.g. academic, scientific or research purposes. Here the court assessed the party relying on exemption, i.e., if the party does not engage in experimental, research and development (R&D) activities in general (e.g., such activity is not listed in the company registry) the court may consider this as a factor advising against applying the exemption.

- Whether the exception is limited for acts done for "academic purposes" having "no commercial value"?

  NO.

- Does the burden of proof of an experimental use exception lie on the party alleged of patent infringement who raises the defence in member countries?

  YES.

- The types of activities covered by the law.

  The types of activities covered are not specified in the Patent Act. However, the Patent Act has a closed list of activities that are deemed to be infringing. This being said and based on case law predating the recent amendment to the Patent Act, the court took the view when assessing infringement that if no activity that appears on said closed list took place, patent infringement cannot be established. As to what specific activities were so far considered exempted, unfortunately, no specific case law exists.

3. Would contribution to the experiments by third persons other than the persons conducting the experiments constitute patent infringement?

   We think that in case of economic, e.g. commercial interest of the third persons the answer is YES, the above cited Article 19 (6) (b) the Patent Act does not encourage a contrary view. It should be noted that third party contributions usually do not serve experimental purposes from said third party's perspective but are typically provided for remuneration, which is highly likely to be regarded as pure commercial interest.

4. Would supply of the patented invention for experimental use in another jurisdiction amount to infringement?

   YES, if there is a commercial interest on the side of the third person. As mentioned earlier, supplying the patented invention to the experimenting party is typically for remuneration, which is highly likely to be regarded as a commercial interest.

5. Would importation of the patented invention for experimental use from another jurisdiction amount to infringement?

   NO.

6. Do member countries include in their laws exceptions which allow exploitations of patented inventions as research tools?

   NO.

Bolar type exemption

7. Do member countries in their patent laws except use by a third-party during patent life for the purpose of obtaining regulatory approval to sell after patent expiry (**Bolar type exemption**)?

   YES.

   If so, please provide details of the relevant member country law.

   See Article 19 (6) (c) the Patent Act cited above.

8. Is the Bolar type exemption limited in time (with respect to the life of the patent).

   NO.

9. Is the activity of seeking pricing and reimbursement listing (i.e. negotiating a price between manufacturer and payer that allows the manufacturer access to that market) during the patent term covered by the Bolar type exemption in your country?

   NO, but it still may be considered as non-infringement, however, not because of the Bolar type exemption. As mentioned already above in point 2, the Patent Act in Article 19 defines a closed list of activities that are deemed to be infringing and according to the case law, pricing and reimbursement listing is an administrative procedure that is usually not considered as an activity falling under said closed list, nor as a preparation for any activities of the closed list.

10. Are clinical trials exempted?

    YES.

    If so, is there a difference between clinical trials phase 1, 2, 3, 4?

    NO.

~~11. Can one perform clinical trials without applying for regulatory approval?~~

~~12.~~11. Is stock-piling permitted in your jurisdiction? i.e. manufacturing a drug during the patented period, not for clinical trials, but with the express purpose of sale after the patented period?

    YES, under certain circumstances in accordance with the SPC waiver, thus not because of the Bolar type exemption. Otherwise stock-piling and manufacturing are covered by the definition of exploitation of the Patent Act, so it is an exclusive right of the proprietor under patent protection.

~~13.~~12. Is there a difference in the scope of the experimental use defence and/or Bolar type exemption between the period of the original patent term and the period of a patent term extension or an equivalent, e.g. SPC?

    NO.

HealthTech considerations

~~14.~~13. Should any Bolar type exemption be applicable to pharmaceutical/biological patents only, or also medical devices, diagnostic devices, MedTech devices, MedTech software?

We think that the Bolar type exemption should be applicable not only to pharmaceutical/biological patents, but also to medical devices, diagnostic devices, MedTech devices, MedTech software.

~~15.~~14. Should any experimental use exception and/or bolar type exception permit data obtained during experiment and/or clinical trials to be used in the creation and advancement of new health technologies?

YES.

~~16.~~15. Should any Bolar type exemption permit activities solely directed to obtaining data for seeking regulatory approval outside of your jurisdiction?

YES. In Hungary the Bolar type exemption already applies to such scenario.

Amendment of the experimental use exception and/or Bolar type exemption in your jurisdiction

~~17.~~16. Should the experimental use exception and/or the Bolar type exemption in your jurisdiction be modified?

We think that the experimental use exemption should not, but Bolar exemption should be modified.

~~18.~~17. If so, in what way?

The Bolar type exemption is limited to medicines. We think, however, that Bolar type exemption should cover all products which require a marketing authorization and, thus, lengthy trials, such as e.g. pesticides. We refer also to our response provided above in point 13.