QUESTIONNAIRE FOR POST-FILING DATA ISSUE

COMPLETED ON BEHALF OF THE HUNGARIAN GROUP OF AIPPI

by Zoltán KOVÁRI, Daisy MACHYTKA-FRANK and Imre MOLNÁR

Hypothetical 1:

The specification and claims are directed to novel compounds of genus A, which inhibit Enzyme 1, and are useful for treating various diseases, including diabetes.

A) The claims are rejected by the patent office on inventive step grounds over compounds of genus B. In response, can the applicant submit to the patent office, data developed after the filing date, which shows that the compounds are more potent in inhibiting Enzyme 1 than the compounds of genus B?

The answer depends on the statements or data in the specification, see below.

> Does the answer depend on the statements or data in the specification? If yes, please explain this in 200 words. Please restrict your response to only the issue of allowing such data to be filed.

Yes.

If in the original specification there is a teaching in form of a statement or data indicating that the inventive step is based on inhibition of Enzyme 1, the Hungarian Intellectual Property Office (HIPO) would accept comparative data developed after the filing date to prove that the novel compounds of genus A are inventive over the known compounds of genus B. However, these comparative data cannot be inserted into the description in view of the legal ban on introducing new matter but rather they will form part of the Official file.

> Would your answer be different if the patent was instead granted and later subject to post-grant opposition before the Patent Office under a similar fact pattern? If yes, please explain this in 200 words. Please restrict your response to only the issue of allowing such data to be filed.

There is no possibility for opposition in Hungary in patent cases.

> Would your answer be different if the patent was instead granted and later subject to an invalidity challenge in forums other than the patent office under a similar fact pattern? If yes, please explain this in 200 words. Please restrict your response to only the issue of allowing such data to be filed.

In Hungary invalidity procedure (which is called in Hungary as nullification procedure) starts at the HIPO. Comparative data can be filed with the HIPO also in a nullification procedure. For the acceptability of the additional data the considerations provided above for the exmination procedures apply.

The next forum in a nullification procedure is the Budapest-Capital Regional Court which is the only first instance court in Hungary entitled to bring decisions in patent nullification procedures. However, if the

compounds of genus B were brought up by the petitioner in the procedure before the HIPO and patentee failed to file data evidencing inventive step with the HIPO, the Budapest-Capital Regional Court is likely to consider their filing as belated and unacceptable. The Metropolitan Court of Appeal of Budapest, entitled to reconsider the decisions of the Budapest-Capital Regional Court, is also likely to consider the filing of comparative data as belated because theoretically the task of this court is to reconsider whether the decision of the Budapest-Capital Regional Court was rightful rather than to take into account new evidences. It is also to be mentioned that if compounds of genus B were not brought up by the petitioner in the procedure before the HIPO, they cannot be brought up by the petitioner in the court procedures either.

B) The claims are rejected by the patent office on inventive step grounds over compounds of genus B. In response, can the applicant submit to the patent office, data developed after the filing date, which shows that the compounds of genus A have other favorable properties (other than the inhibition of Enzyme 1) in comparison to the compounds of genus B?

The answer depends on the statements or data in the specification.

> Does the answer depend on the statements or data in the specification? If yes, please explain this in 200 words. Please restrict your response to only the issue of allowing such data to be filed.

Although no relevant case law is known, we are of the opinion that novel favorable properties of compounds of genus A that were not indicated in the specification as filed could not support inventive step. Namely, it is unlikely that for example the better crystallisation properties of compounds of genus A over those of compounds of genus B would support inventive step in case the same were not mentioned in the specification as filed.

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There is no possibility for opposition in Hungary in patent cases.

> Would your answer be different if the patent was instead granted and later subject to an invalidity challenge in forums other than the patent office under a similar fact pattern? If yes, please explain this in 200 words. Please restrict your response to only the issue of allowing such data to be filed.

No.

Hypothetical 2:

The specification and claims are directed to novel compounds of genus A , which inhibit Enzyme 1, and are useful for treating various diseases, including diabetes. The claims are rejected by the patent office

on lack of sufficiency. In response, can the applicant submit to the patent office, data developed after the filing date, which shows that the compounds are effective in treating diabetes?

The answer depends on the content of the specification as filed.

> Does the answer depend on the statements or data in the specification? If yes, please explain this in 200 words. Please restrict your response to only the issue of allowing such data to be filed.

Yes.

According to the Patent Act (Act XXXIII Of 1995 On The Protection Of Inventions By Patents, hereinafter: PA) Art. 60(1) : *"A patent application shall disclose the invention in a manner sufficiently clear and detailed for it to be carried out by a person skilled in the art on the basis of the description and the drawings".*

For pharmaceutical inventions the requirement of sufficient disclosure includes also the requirement that the effect of the compounds claimed has to be rendered probable by the specification as filed. Accordingly, the specification as filed shall include at least (respective) preliminary data.

Additional data included into the description after the filing date would qualify as new matter. The above referenced provision clearly requires the sufficient disclosure be present in the description (and not only in the file of the Office).

Experimental data present in the specification are not likely to be challenged by the Office. If the Office still challenges the at least preliminary data, then additional data can be filed. If, however, no data/evidence is present in the original disclosure at all, then the additional data if filed are likely not to be accepted.

> Would your answer be different if the patent was instead granted and later subject to post-grant opposition before the Patent Office under a similar fact pattern? If yes, please explain this in 200 words. Please restrict your response to only the issue of allowing such data to be filed.

There is no possibility for opposition in Hungary.

> Would your answer be different if the patent was instead granted and later subject to an invalidity challenge in forums other than the patent office under a similar fact pattern? If yes, please explain this in 200 words. Please restrict your response to only the issue of allowing such data to be filed.

The answer for the case of invalidity challenge filed with the HIPO for a granted patent would be similar to that provided for the examination procedure. Restrictions for filing new data in court procedures are indicated above in point Hypothetical 1 A).

Hypothetical 3:

The specification and claims are directed to novel compounds of genus A , which inhibit Enzyme 1, and are useful for treating various diseases, including diabetes. The claims are rejected by the patent office on lack of utility. In response, can the applicant submit to the patent office, data developed after the filing date, which shows that the compounds are effective in treating diabetes?

There is no utility requirement as such in Hungary.

Does the answer depend on the statements or data in the specification? If yes, please explain this in 200 words. Please restrict your response to only the issue of allowing such data to be filed.

Would your answer be different if the patent was instead granted and later subject to post-grant opposition before the Patent Office under a similar fact pattern? If yes, please explain this in 200 words. Please restrict your response to only the issue of allowing such data to be filed.

Would your answer be different if the patent was instead granted and later subject to an invalidity challenge in forums other than the patent office under a similar fact pattern? If yes, please explain this in 200 words. Please restrict your response to only the issue of allowing such data to be filed.

Hypothetical 4:

The specification and claims are directed to novel compounds of genus A, which inhibit Enzyme 1, and are useful for treating various diseases, including diabetes. The specification contains some data on the fact that the claimed compounds have better properties and are more potent in inhibiting Enzyme 1 as compared to compounds of genus B. The claims are rejected by the patent office on inventive step grounds, rejecting that the data is not convincing enough. The Applicant goes on appeal before the appellate forum. In the appeal proceedings, can the applicant submit additional data developed after the filing date, which corroborate the conclusions already in the specification?

> Does the answer depend on any particular conditions or circumstances? If yes, please explain this in 300 words. Please restrict your response to only the issue of allowing such data to be filed.

Yes.

In the examination procedure the Office shall indicate to the Applicant that the data provided are not convincing enough. Then Applicant must file an argumentation or further data with the Office as a response. As long as the Applicant is filing new data/arguments, the Office, if not satisfied, should issue further Office Actions. If in a response no new data/arguments are filed, the application may be refused by the Office. After such a careful examination and warning no new data can be filed with the courts. Instead, in such a scenario the Applicant will have to convince the courts that the data already provided with the HIPO are satisfactory.

If, however, the Office rejects the application without a proper prior warning that the data provided are not convincing enough, then it is possible to file convincing data in an appeal.