

# FEDERAL PATENT COURT

## Guiding principles

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Reference Date of ruling:	3 Li 1/16 (EP)
Judicial review admissible:	November 21, 2017 no
Standards:	Sect. 24, para. 6 of the German patent law PatG

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### "Isentress II

1. Where, in a compulsory licence proceeding by way of an interim order pursuant to sect. 85 PatG, an authorisation of use is granted on a preliminary basis while reserving the decision pertaining to assessment of the licence fee and invoicing are reserved for the principal case proceedings, any revocation of the patent effected in the course of the compulsory licence principle case proceedings pertaining to the decision to be issued with respect to the licence fees and invoicing does not entail the settlement of the dispute. Jurisdiction of the Federal Patent Court shall be maintained even for the ruling to be issued.

2. Where the applicant for a compulsory licence makes use of an authorisation of use granted on a preliminary basis by way of an interim court ruling, he / she shall be liable to pay compensation as determined by law for the duration of such (interim) licence granted even if the patent is revoked in the course of the compulsory licence (principal case) proceedings wherein the decision as to the amount of the licence fees is still outstanding.

3. A) As it would be reasonable for the assessment of such licence fees for a compulsory licence to base such fees upon such licence fees that would be agreed under the conditions of the respective individual case in a licence agreement (cf. BGH landmark ruling GRUR 2017, 1017, marginal note Rn. 28), circumstances such as a specific threat potential of the patent given in individual cases as well as other factors such as the contribution of the active substance content having accounted for the development of the pharmaceutical active substance falling under the compulsory licence or any co-use of any industrial property rights owned by the licence holder himself, can also be taken into account in such a fictitious agreement, apart from any licence fee scale customary to the product sector.

These will - as the case may be - entail a rise or a drop of such licence fee amount.

b) When evaluating the contribution to be made potentially in the context of assessing the licence amount and added by the patent with respect to the development of the distribution of an active substance of a drug authorised under a compulsory licence, the question must be which developments based upon the content of the (fictitious) patent disclosure shall still be required to achieve the active substance under licence. In this context, any potential further state of art as well as any potential developments made by the licence holder himself / herself shall not be taken into account.

c) The factors that might entail any rise of the licence fees in the event of a compulsory licence could include, among others, any persistent vulnerability of the patent and compulsory assistance for the benefit of a competing company, and, to a smaller extent, though, the absence of typical implied terms in contractual licence agreements or the opportunity pursuant sect. 24, para. 6 PatG providing for any modification or withdrawal or adjustment of the compulsory licence.

4. Licence fee amounts payable for a compulsory licence can be assessed by way of an evaluation (sect. 287, para. 1 and 2 of the German Code of Civil Procedure ZPO, combined with sect. 99, para. 1 PatG) taking into account the principles developed to assess any licence amount as well as the points of reference brought forward by the parties to this effect.