
EXPLANATORY NOTE

(This note does not form part of the Regulations)

These Regulations implement Article 12 of Directive [98/44/EC](#) of the European Parliament and of the Council on the legal protection of biotechnological inventions (OJNo. L 213, 30.7.98, p. 13). Articles 1 to 11 of that Directive have been implemented by the Patents Regulations 2000 (S.I.2000/2037) and Articles 13 and 14 by the Patents (Amendment) Rules 2001 (S.I. 2001/1412).

These Regulations enable the Comptroller General of Patents, Designs and Trade Marks and the Controller of Plant Variety Rights, acting jointly, to grant non-exclusive compulsory licences and cross licences where the exploitation of a patent would infringe a plant variety right and vice versa (regulations 6 and 13).

In these circumstances an applicant for a compulsory patent or plant variety licence must show that he has applied unsuccessfully to the respective patent or plant variety right holder to obtain a licence (regulations 3(2)(b) and 11(2)(b)).

In the case of an application for a compulsory patent licence, the applicant must also show that the new plant variety, in which he wishes to acquire or exploit the plant breeders' rights or a Community plant variety right, constitutes significant technical progress of considerable economic interest in relation to the invention protected by a prior patent (regulation 3(2)(c)).

In the case of an application for a compulsory plant variety licence, the proprietor of a patent for a biotechnological invention must also show that his invention constitutes significant technical progress of considerable economic interest in relation to the existing plant variety protected by prior plant breeders' rights (regulation 11(2)(c)).

Where a compulsory licence has been granted, the holder of plant breeders' rights or proprietor of a patent for a biotechnological invention, in respect of whose rights the compulsory licence has been granted, is entitled to payment of an appropriate royalty and the grant of a cross licence on reasonable terms (regulations 7 and 14).

Where the Community Plant Variety Office has granted a compulsory exploitation right in respect of a Community plant variety right to a proprietor of a patent for a biotechnological invention who could not otherwise exploit his invention in the UK without infringing the prior Community plant variety right, the holder of the Community plant variety right concerned may apply to the Comptroller General of Patents, Designs and Trade Marks for a cross licence to use the biotechnological invention protected by the patent (regulation 15).

Part IV of these Regulations makes provisions for appeals (regulations 17 to 19). The route of appeal depends upon the nature of the main compulsory licence which forms the subject matter of the controllers' decision appealed from.

If the decision appealed from relates to the grant of a compulsory patent licence, the appeal is to the Patents Court of the High Court. An appeal lies also to the Patents Court of the High Court in respect of a cross licence granted under regulation 7(2) or 7(3) as a condition of the grant of the compulsory patent licence.

If the decision appealed from relates to the grant of a compulsory plant variety licence or cross licence of a patent for a biotechnological invention (granted under regulation 14(2) as a result of the grant of the compulsory plant variety licence), the appeal is to the Plant Variety and Seeds Tribunal (regulations 17 to 19) and subsequently, on points of law only, to the High Court.

Status: This is the original version (as it was originally made).

The respective powers of the Secretary of State and Ministers to make rules and regulations under the relevant primary legislation have been extended so as to permit them to make rules and regulations governing applications and proceedings under these Regulations (regulations 20 and 21).

Subject to the exercise of extended powers, existing procedures and fees for applications and proceedings in the relevant primary and subordinate legislation relating to compulsory licences apply to applications for compulsory licences under these Regulations as if these applications were made under section 48(1) of the Patents Act 1977 and section 17(1) of the Plant Varieties Act 1997 respectively (regulations 22 to 25).

The provisions of primary legislation extend and apply to matters provided for in these Regulations with any necessary modifications (regulations 26 and 27).

A regulatory impact assessment and transposition note are available, copies of which have been placed in the libraries of both Houses of Parliament. Copies of the assessment and transposition note are also available from the Intellectual Property Policy Directorate of the Patent Office, Room 3B38, Concept House, Cardiff Road, Newport NP10 8QQ.