

# DEPOSITS OF BIOLOGICAL MATERIAL AND THEIR AVAILABILITY UNDER THE EPC

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## INTRODUCTION

- Biological material = any material containing genetic information and capable of reproducing itself or being reproduced in a biological system ([Rule 26\(3\) EPC](#))
- Sometimes not publicly available and cannot be described in the application in an enabling manner for purposes of reproduction by a person skilled in the art
- The EPO allows the deposit of a sample of the biological material for disclosure purposes ([Article 83 EPC](#), [Rule 31 EPC](#))

## EPO: LEGAL BASIS / RELEVANT SOURCES

- [Budapest Treaty](#) on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, and [Regulations](#) under the Budapest Treaty
- [Guide to the Deposit of Microorganisms](#) under the Budapest Treaty
- [Article 83 EPC](#) and [Rules 31](#) to [34 EPC](#)
- [Rule 13bis PCT](#) and EPO notification to IB
- [EU Biotechnology Directive](#) – Article 13
- EPO notice dated 7 July 2010 ([OJ EPO 2010, 498](#))
- Decision of the President of the EPO dated 10 July 2017 ([OJ EPO 2017, A60](#))
- EPO notice dated 10 July 2017 ([OJ EPO 2017, A61](#))
- Guidelines for Examination in the EPO, [A-IV, 4](#) and [F-III, 6](#)

## WHEN IS A DEPOSIT REQUIRED?

- If biological material is required to carry out the invention but is not publicly available and cannot be described in an enabling manner in the description ([Article 83 EPC](#) and [Rule 31\(1\)\(a\) EPC](#))
  - the deposit must be made not later than the date of filing
- Deposit in a priority application: if a deposit was made at a national institution not recognised under the Budapest Treaty, the deposit must be converted into a deposit under the Budapest Treaty no later than on the date of filing of the subsequent application

## REFERRING TO THE DEPOSIT

- Reference to the deposit ([Rule 31\(1\) EPC](#)) must include:
  - date of deposit with a recognised IDA under the Budapest Treaty
  - relevant information on the characteristics of the biological material (to the extent available to the applicant)
  - name and address of depository institution
  - accession number
  - name and address as well as statement by depositor (if depositor is not the applicant)
- By complying with these requirements, the applicant gives their unreserved and irrevocable consent to the deposited biological material being made available to the public ([Rule 31\(2\) EPC](#))

## DEPOSIT BY A PERSON OTHER THAN THE APPLICANT

- If the depositor is not the applicant (or one of the applicants), the following additional particulars must be furnished ([Rule 31\(1\)\(d\) EPC](#)):
  - name and address of the depositor
  - declaration of authorisation and consent
  
- The declaration must establish that, from the date of filing, the depositor has authorised the applicant to refer to the deposit and has consented to make the biological material available to the public

## TIME LIMIT FOR FURNISHING PARTICULARS ABOUT THE DEPOSIT

- [Rule 31\(2\) EPC](#)
- The particulars under Rule 31(1)(c) and 31(1)(d) EPC must be furnished **within 16 months of filing or of the priority date**
  - The time limit is deemed to be met if information provided before the end of the technical preparations for publication of the application
  - No remedy available
- If the time limit is not met, the **biological material cannot be considered as having been disclosed** and, as a consequence, the application may be **refused** during examination proceedings



## AVAILABILITY OF DEPOSITED BIOLOGICAL MATERIAL

- After publication, the deposited biological material is publicly available and may be furnished to any person upon request for the issuance of a sample
- The request must be made via the EPO by means of a specific form ([Rule 33\(4\) EPC](#), [Rule 11.3 Budapest Treaty](#))
- The requester must declare that the biological material furnished is for experimental use only and will not be passed on to third parties ([Rule 33\(2\) EPC](#)) (until such time as the patent application is refused or withdrawn or deemed to be withdrawn or before the European patent has lapsed in all the designated States)
- The EPO checks and certifies that the request fulfils the formal requirements
- The EPO forwards the request to the IDA where the biological material is deposited
- The IDA issues the sample and forwards it to the requester

## EXPERT SOLUTION ([RULE 32 EPC](#))

- The applicant may request that a **sample** of the deposited biological material **be issued only to an independent expert nominated by the requester**
- The request must be filed in written form before the technical preparations for publication of the European patent application are completed
- The restriction to issue a sample only to the independent expert is valid
  - until the publication of the mention of the grant of the European patent ([Rule 32\(1\)\(a\) EPC](#)) or, where applicable,
  - for 20 years from the date of filing if the application has been refused or withdrawn or deemed to be withdrawn ([Rule 32\(1\)\(b\) EPC](#))



**THANK YOU**

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