LAW AND PRACTICE OF PATENTS

EXAMINATION PAPER 2018

Time Allowed: 3 Hours

Answer <u>SIX</u> questions only. Any additional answers will be disregarded and <u>NOT</u> marked.

Candidates <u>MUST</u> answer Question Number 1 and Question Number 2.

In the event of a Candidate failing to answer Question Number 1 and Question Number 2 the examination paper of that Candidate will <u>NOT</u> be considered valid.

1. Devos Pharmaceuticals Inc holds an Irish patent relating to Fixopide, a previously known compound that has been found to be effective in the treatment of persistent or recurring fungal infections. Claim 1 is for:

"Fixopide for use in a regimen of five oral administrations of a 10mg dose of Fixopide every twelve days with at least one day between each administration for use in treating a patient who is suffering from a persistent or recurring fungal infection."

Claim 2 of the patent is for:

"A medicament comprising Fixopide for use in treating a patient who is suffering from a persistent or recurring fungal infection."

Bonty Healthcare Limited manufactures and packages 10mg tablets containing Fixopide which are exported to Canada where they are prescribed and sold as a treatment for fungal nail infections. Bonty Healthcare Limited does not have a marketing authorisation to allow it to sell these tablets on the Irish market and they are produced for export only. It has received a letter from Devos Pharmaceuticals Inc warning that if it does not cease manufacturing and exporting the tablets it will be sued for infringement of the Irish patent.

Advise Bonty Healthcare Limited as to whether it has a potential liability for patent infringement. Your advice should be confined to the liability issue alone and you are not required to consider issues of validity in respect of the patent.

- 2. Analyse and discuss **EACH** of the following:
 - (a) The judgment of Barrett J rejecting the invalidity challenge to the patent in *Norton (Waterford) Ltd v. Boehringer Ingleheim Pharma GmbH and Co KG v.* [2017] IEHC 495 (High Court); and
 - (b) The judgment of McGovern J refusing to grant an interlocutory injunction in *Gilead Sciences Inc* v. Mylan SAS [2017] IEHC 666 (High Court).
- 3. Set out in detail the procedural steps that have to be taken in order to oppose the grant of a European patent and the appellate structure applicable to a determination made in respect of such an opposition.

- 4. Outline the procedure to be followed in securing the restoration of a lapsed patent and set out the circumstances in which this is possible.
- 5. Consider the approach adopted by the Court of Justice of the European Union to the interpretation of the requirement that *"the product is protected by a basic patent in force"* contained in Article 3(a) of European Parliament and Council Regulation 469/2009/EC of 6 May 2009 concerning the supplementary protection certificate for medicinal products.
- 6. Outline the concept of priority in the context of patent applications and set out the means by which priority is claimed.
- 7. Explain the purpose of a know-how licensing agreement, the circumstances in which one might find recourse being had to such an agreement and the provisions that one would expect to see in a properly drafted know-how licensing agreement.
- 8. You have been consulted by a client who has presented what he believes is a new means of filtering emissions from diesel engines in older cars so as to reduce the amount of nitrogen dioxide released. Outline the resources and techniques that you would use in conducting searches to determine whether there is a basis for seeking patent protection.
- 9. Write notes on **THREE** of the following:
 - (a) The concept of *"common general knowledge"* as applied in the context of obviousness.
 - (b) Divisional patents.
 - (c) A declaration as to non-infringement.
 - (d) Damages for patent infringement in respect of *"convoyed goods"*.
- 10. While making appropriate reference to relevant case law, discuss the principles to be applied when considering whether an innovation involving the use of a computer program is patentable.