

PATENT EXAMINATION BOARD

PRACTICAL LEGAL PROBLEMS

EXAMINATION: JUNE/JULY 2026

PAPER 1

EXAMINERS: A LEWIS

T BALL

MODERATOR: J WHITTAKER

DURATION: READING TIME – 1 HOUR

EXAMINATION TIME – 4 HOURS

TOTAL: 5 HOURS

NOTES TO CANDIDATES:

1. Attached to the paper are copies of the following documents:
 - (i) An Annexe Bundle;
 - (ii) A copy of the Patents Act No. 57 of 1978;
 - (iii) A copy of the Patent Regulations 1978; and

- (iv) A copy of the Uniform Rules of the High Court under the Superior Courts Act 10 of 2013 (Rules 6, 14, 17, 18, 19, 21, 22, 23, 24, 25, 30, 35, 36, 37 and 63).
- 2. Each candidate is also allowed access to (1) one dictionary during the exam.
- 3. This paper comprises 4 pages in total, made up of Questions 1 to 4 (100 marks), and an Annexe bundle comprising 45 pages in total.
- 4. Where appropriate, reference should be made to case law.

FACTUAL BACKGROUND FOR ALL QUESTIONS:

ONE PHARM (Pty) Limited (“ONE PHARM”) wishes to import and market a generic medicine in South Africa containing the active pharmaceutical ingredient, Nintedanib, for use in the treatment of idiopathic pulmonary fibrosis.

Searches conducted for ONE PHARM have identified patent 2010/03601 in the name of GLOBAL PHARMA INNOVATIONS GMBH (“GPI”), entitled “MEDICAMENTS FOR THE TREATMENT OF FIBROTIC DISEASES”.

Copies of the following documents obtained from the CIPC file for patent 2010/03601 are attached:

- A register extract – **Annexe A – Bundle pp 1-3;**
- The specification – **Annexe B – Bundle pp 4-11;**
- The Form P3 filed in support of the application – **Annexe C – Bundle pp 12-13;**
- Claims as filed – **Annexe D – Bundle pp 14 – 18;**
- A first application for amendment on Form P12 (there was a subsequent application for amendment on Form P13 that was not included in the file as provided by the CIPC) – **Annexe E – Bundle pp 19 – 22;** and
- The International Preliminary Report on Patentability in relation to parent International Application No. PCT/EP2008/057002 – **Annexe F – Bundle pp 23 – 30.**

A copy of WO 2004/017948, cited in the IPRP, is attached as – **Annexe G – Bundle pp 31 – 38.**

ONE PHARM has obtained an opinion from an expert regarding the disclosure of patent 2010/03601 and the significance of WO 2004/017948, a copy of which is attached as – **Annexe H – Bundle pp 39 – 45.**

NOTES:

- (1) YOU ARE NOT BEING TESTED ON YOUR KNOWLEDGE OF CHEMISTRY OR MEDICINE. ACCORDINGLY, INsofar AS IS NECESSARY FOR PURPOSES OF ANSWERING THIS PAPER, YOU MAY ACCEPT THAT:**
- a. **THE CONTENTS OF THE OPINION (ANNEXE H) ARE CORRECT; AND**
 - b. **ALL TECHNICAL INFORMATION REQUIRED FOR UNDERSTANDING THE SPECIFICATION OF PATENT 2010/03601 AND WO 2004/017948 IS SET OUT IN THIS OPINION; and**
- (2) RENEWAL INFORMATION PREDATING THE CURRENT ELECTRONIC REGISTER, AND INTO THE MID-2010s, WAS NOT RELIABLY CAPTURED ON THE ELECTRONIC REGISTER. SEE FURTHER NOTES IN THIS REGARD IN RELATION TO QUESTIONS 2 AND 3.**

QUESTION 1:

(10 marks)

Discuss whether, and on what basis, the supply of ONE PHARM's proposed Nintedanib product in South Africa would infringe patent 2010/03601.

NOTE: Do not address validity in your answer to this question.

QUESTION 2:

(45 marks)

Putting yourself in the position of ONE PHARM's patent attorney, draft an application for revocation of patent 2010/03601, based on no more than 3 grounds of revocation.

NOTES:

(1) You will not be marked on more than 3 grounds.

(2) You may consider grounds based on different provisions of section 25 to be separate grounds of revocation.

(3) Do not include the potential lapsing of the patent due to non-payment of renewal fees as one of your grounds in your answer to this question.

QUESTION 3:

(25 marks)

Discuss the potential grounds of revocation that you chose not to include in your answer to question 2, including a brief assessment of whether you would have included such grounds in your revocation application if you were not limited to 3 grounds, and why.

NOTE: You may include a discussion of the renewal status of the patent, and its implications, in your answer to this question.

QUESTION 4:

(20 marks)

Now place yourself in the position of GPI's patent attorney, having received the revocation application you drafted in question 2. Draft a counterstatement to the revocation application.