PATENTS EXAMINATION BOARD

PRACTICAL LEGAL PROBLEMS

EXAMINATION: JULY 2021

PAPER 2

EXAMINERS: J WHITTAKER
D DOHMEN

MODERATOR: H. MOUBRAY

DURATION: READING TIME – 30 MINUTES
EXAMINATION TIME – 3 HRS
TOTAL: 3 HOURS 30 MINUTES

NOTES TO CANDIDATES:

1. Attached to the paper are copies of the following documents:
   (i) A copy of the Patents Act No. 57 of 1978;
   (ii) A copy of the Patent Regulations 1978; and
   (iii) 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 of Questions 1 to 4 (100 marks) (12 pages) and Annexure Q.2 (2 pages).
4. Where appropriate, reference should be made to case law.

QUESTION 1: **(30 marks)**

Your client, BetaX Pharmaceuticals (Pty) Limited ("BetaX"), is the patentee of South African Patent No. ZA 2002/0111. ZA 2002/0111 is due to expire at the end of October 2022. The patent covers a pharmaceutical composition which is extremely effective for the treatment of pneumonitis (inflammation of lung tissue) including pneumonia. BetaX markets and sell the composition of the patent in South Africa for the treatment of pneumonia under the trade name InflaGo.

BetaX advises you that it has become aware that a competitor, Multi Pharmaceuticals (Pty) Limited ("Multi"), has obtained registration or marketing approval at the South African Health Products Regulatory Authority (SAHPRA) for a pharmaceutical composition called NoMonia for the treatment of pneumonia.

BetaX has obtained a copy of a marketing pamphlet regarding the launch of NoMonia through one of BetaX's marketing representatives. From the pamphlet it is clear that NoMonia falls within the scope of claim 1 of ZA 2002/0111 (the only independent claim of the patent). The pamphlet states that NoMonia should be available at pharmaceutical wholesalers and pharmacies at the end of July 2021.

BetaX previously advised you that corresponding patents to ZA 2002/0111 were granted in Japan, the EPO and the USA, all of which were subjected to substantive examination. The claims that were allowed by the Examiners in Japan and the USA are identical to those which were granted in South Africa. However, the Examiner in the EPO objected to the validity of the same claims based on lack of inventive step argument. As a result of a strict application of the EPO's problem solution approach to inventive step enquiries the EPO Examiner could not be persuaded by the arguments submitted and, accordingly, in order to obtain grant of a patent in the EPO it became necessary to limit the scope of the pharmaceutical composition to a very specific dosage of between 10 mg and 15 mg of the active ingredient.

You have previously advised BetaX that in light of the prosecutions in Japan, the USA and the patent and in summary you were of the opinion that the claims appeared to be novel in light of the prior art of which you were aware at the time. However, there

was some doubt about whether or not the claims would withstand an attack on its validity based on lack of inventive step. You concluded at the time that claim 1 (which is not limited to the dosage of between 10 mg and 15 mg of the active ingredient) was arguably valid but this could probably only be resolved by a Court with the benefit of oral expert evidence, tested under cross-examination.

From the NoMonia's launch pamphlet it is apparent that NoMonia will be provided in a 5 mg dosage form.

BetaX's product InflaGo is sold in the private and public health sectors. In the state or public health sector, a first-generation product has been used for the treatment of pneumonia as a first line treatment for over 30 years and InflaGo is only used as a second line treatment when first line treatment is ineffective. A fixed term tender is awarded for a second line treatment of pneumonia in the public sector every three years. BetaX's was awarded the tender for the supply of InflaGo in the public sector a year and a half ago and the next tender award will only take place after the patent has expired.

BetaX's product is sold in the private sector at a price of R3 000,00 per treatment course (42 tablets taken 3 times a day over 14 days) and the agreed tender price in the public sector is R900,00 per treatment course.

Pneumonia falls in the category of conditions for which treatment falls under the regulatory declared prescribe minimum benefit conditions, and accordingly, almost all medical aid companies are required to reimburse in full for the prescription of InflaGo. Some medical aid companies require the patients to make a nominal 10% co-payment of R200,00 per month.

BetaX has been reliably informed that NoMonia will be sold at a price of approximately R1 400,00 per treatment course. BetaX's representative who deals with medical reimbursement schemes has advised that this will inevitably result in the medical aid schemes lowering the amount allowed for reimbursement to the price of NoMonia (as the new reference price) and any patient wishing to continue to use BetaX's product

InflaGo will be required to make a much larger co-payment (of R1 600,00) to address the difference in price.

Multi is a well-established company in South Africa with a significant annual turnover in excess of R800 million per year. Furthermore, an investigation into the assets of the company revealed that they are the owners of warehouse facilities in Port Elizabeth and Cape Town valued at at least R50 million each. There are no bonds registered over these properties.

BetaX is predominantly a South African company and it conducts all of its research and development through a research centre in South Africa. BetaX has incurred costs of approximately R400 million developing the pharmaceutical composition that is the subject matter of ZA2009/0111 and to bring InflaGo to market. It took approximately 15 years to develop InflaGo and because of delays as a result of the time required to conduct the required clinical trial and in regulatory approval, InflaGo has only been on the market since 2014.

Your client incurred a significant amount of these costs and time in isolating and testing approximately 20 candidate compositions. However, once the testing was completed only one composition (the patented composition) was considered suitable.

BetaX Pharmaceuticals is a niche pharmaceutical company i.e. it does not produce and sell a broad range of pharmaceutical products. It specialises in the treatment of inflammation disorders, such as pneumonia. As a result, it only has three important products which it sells, and the patented product makes up approximately 70% of its sales annually in South Africa.

Multi sells pharmaceutical products across a large number of therapeutic areas and its market share for treating pneumonia is approximately 10% of its total market share in Rand value.

Although InflaGo is one of the preferred treatments for pneumonia, the pharmaceutical composition is classified into a group which contains eight other "therapeutic equivalents" which are already on the market. Two of these are used as first line

treatment in the public sector and InflaGo together with the other five products are used as second line treatment in the public sector. In the private sector, each of these products are interchangeably prescribed by doctors depending on a number of factors.

BetaX's marketing director explains to you that if NoMonia was brought onto the market it would not be easy to determine whether or not BetaX's losses would be entirely attributed to the introduction of NoMonia or other factors such as the marketing efforts and/or price changes that could occur in relation to the other seven substitutable products.

Furthermore, BetaX would be faced with a difficult situation were Multi to launch NoMonia at the expected lower price in that BetaX would need to consider whether or not to reduce its price to mitigate any loss in the market while any proceedings were being decided.

A further complication is that as a result of the Covid-pandemic the demand for InflaGo has increased dramatically as doctors are now prescribing InflaGo to patients as a prophylactic against lung inflammation as soon as a patient is diagnosed with Covid. Anecdotal evidence seems to suggest that the treatment is working in a large percentage of cases. As a result, the production of InflaGo can hardly keep up with demand. BetaX has in response been increasing their manufacturing capacity and expect that any possible shortages in the market of InflaGo will be addressed within the next month or two.

In light of the above circumstances, please advise BetaX comprehensively on the approach that should be followed in this matter. In doing so, please deal with the relevant legal requirements and provide BetaX with an overview of the prospects of success and all the options available to it in light of the facts set out above.

QUESTION 2: **(25 marks)**

You receive the below letter from your client.

Your client, a UK renewals agency, informs you that patent no. 2018/02222, which belongs to one of their major clients, lapsed owing to the non-payment of renewal fees. You obtain a copy of an extract of the Patent Register and confirm that this is indeed the case. A copy of the form P2 obtained from the patent register is **attached** marked "**Annexure Q.2**"

Your client provides you with the following explanation.

> *"We are an annuity agency and attend to the renewal of patents on behalf of patentees globally. The patentee is responsible for all aspects of the filing and prosecution of the patent. Once the application is filed and/or granted the patentee will provide us with the biographic details of the patent which we capture into our records.*
>
> *Our annuities programme then generates renewal reminders and requests for instructions which are sent to the patentee at various intervals prior to the renewal due date as well as a final lapse reminder on the actual renewal due date if no prior instructions were received. If and when we receive renewal instructions from a patentee, we instruct in-country firms like yours to attend to the renewal payment on our behalf.*
>
> *Often patentees instruct us to automatically renew their more important patents in which case we will automatically attend to the renewal of the patent at about one month prior to the annual renewal due date. We will then simply report to the patentee that the renewal was paid and invoice the patentee accordingly.*
>
> *The patentee (Global Cement Inc.) of South African Patent No. 2018/02222 contacted us earlier today regarding the non-renewal and lapse of the patent. The patentee is highly upset as they learnt of the lapse yesterday during pre-litigation preparations in South Africa. A South African competitor has apparently*

built a productions plant in South African and has commenced production of cement and the sale of cement in South Africa using the protected process of the patent. Apparently, the cement which is being sold by the competitor also falls within a number of product claims of the patent.

On investigation we found that the biographic information which the patentee sent to us did not include the PCT or priority information and simply indicated that the patent was applied for on 1 September 2018. The patent was entered into our annuity records as a South African Convention patent application with a filing date of 1 September 2018. As we now understand the patent did have an earlier priority claim and was in fact a national phase patent application in South Africa based on an earlier international (PCT) patent application.

In this case we hold instructions from the patentee to automatically renew the patent but since our annuity programme calculated the first annual renewal to be due on 1 September 2021, we did not take any action in respect of the first renewal fee.

For obvious reasons the patentee is extremely concerned. Please advise what, if anything, can be done to salvage the situation and re-instate the patent. If something can be done, please explain in detail what can be done and how, and also whether the lapse of the patent will have any effect on the patentee's intended infringement proceedings against the South African infringer.

We await your urgent response."

Please advise your client fully.

QUESTION 3: **(25 marks)**

Please draft the necessary affidavit(s) for filing in support of a restoration application based on the facts in Question 2. Please also include the appropriate heading to the affidavit(s).

QUESTION 4: **(20 marks)**

You received the following letter from your client:

"Dear Patent Attorney

I refer to our previous correspondence regarding our plastics container manufacturing division and our continued research in and development of sealable plastics container and lid combination products used for household storage of food.

As I previously explained we run a large plastics injection moulding and assembly operation and our products are distributed worldwide. In addition, we have two other divisions, the one dealing with plastics furniture and the other with plastics components for the automotive sector.

The previous managing director of the plastics container manufacturing division, Mr John Sly resigned in mid-2020 and subsequently started a competing business.

We are in the process of appointing a new managing director for the plastics container manufacturing division, Ms Susan Slick. Ms Slick has extensive management experience and has worked in the plastics products business in Europe and the USA. In the early years of her career, she was also involved with research into and development of a range of plastics products which are currently in use in the USA and Europe. Ms Slick comes highly recommended.

However, we are concerned that our standard employment conditions do not provide us with adequate protection in the case where Ms Slick contributes to or develops improvements to our existing products or new products. In addition, we would like to avoid a repeat of our experience with Mr Sly and need to ensure that she keeps all our information relating to our suppliers, clients, business plans, products, designs, manufacturing plants, suppliers, trade secrets etc confidential and does not use same if she leaves our company.

Since we are focussing in expanding our business in Africa and other developing countries, we also need to ensure that she does not use that which she will learn from us in competition against us in these markets.

Can you please assist and provide us with appropriate clauses to cover the above aspects for insertion in our existing employment agreement?

Yours faithfully
Mrs P Tshabalala
Chief Executive Officer
SA Plastics (Pty) Ltd."

Please provide your client with the requested contractual clauses.

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TOTAL: 100 marks

"Annexure Q.2"

FORM P.2

REPUBLIC OF SOUTH AFRICA			*REGISTER OF PATENTS*			*PATENTS ACT, 1978*	
OFFICIAL APPLICATION NO.			*LODGING DATE: PROVISIONAL*			*ACCEPTANCE DATE*	
22	*01*	2018/02222	*22*			*47*	*4 MAY 2019*
INTERNATIONAL CLASSIFICATION			*LODGING DATE: National Entry Date*			*GRANTED DATE*	
	C04B			1 September 2018			*27 JULY 2019*
FULL NAME(S) OF APPLICANT(S)/PATENTEE(S)							
71							
GLOBAL CEMENT INC.							
APPLICANTS SUBSTITUTED:						*DATE REGISTERED*	
71							
ASSIGNEE(S)						*DATE REGISTERED*	
71							
FULL NAME(S) OF INVENTOR(S)							
72							
JOHN C. STANKUS and JOHN G. OLDSEN							
PRIORITY CLAIMED AND PCT INTERNATIONAL APPLICATION		*COUNTRY*		*NUMBER*		*DATE*	
N.B. *Use International Abbreviation for country (See Schedule 4)*	*33*	PCT US	*31*	PCT/US2017/016543 10/687,960	*32*	24 FEBRUARY 2017 25 FEBRUARY 2016	
TITLE OF INVENTION							
54	CEMENTITIOUS PRODUCT AND MANUFACTURING PROCESS						
ADDRESS OF APPLICANT(S)/PATENTEE(S)			PITTSBURGH, PA, US				
ADDRESS FOR SERVICE				A & A REF:		PA0000ZA00	
74	SA PATENT INC., Pretoria						
PATENT OF ADDITION TO NO.			DATE OF ANY CHANGE				
61							
FRESH APPLICATION BASED ON			DATE OF ANY CHANGE				

FORM P.2
(continued)

AMENDMENTS AND RECTIFICATIONS, ETC.					
Document	*Date of Application*	*Advertisement Date*	*Opposition Date*	*Allowance or refusal*	*Date of latter*

PROCEEDINGS BEFORE THE COMMISSIONER OF PATENTS					*Appeals to Supreme Court TPD/AD*	*Date Withdrawn*
Nature	*Taken by:*	*Against*	*Date commenced*	*Date of order*		

LICENCES, ATTACHMENTS AND HYPOTHECATIONS			
Nature	*In favour of:*	*Date registered*	*Date cancelled*

RENEWALS				*RESTORATIONS*				
Year	*Date paid*	*Receipt*	*Penalty*	*Date Applied For*	*Advertised*	*Opposed*	*Restored by*	*Date of restoration*
				REMARKS: (FOR OFFICE USE ONLY)				