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Patentamt**

**Europäische
Eignungsprüfung**

Prüfungssekretariat

**European
Patent Office**

**European
qualifying examination**

Examination Secretariat

**Office européen
des brevets**

**Examen européen de
qualification**

Secrétariat d'examen

EUROPEAN QUALIFYING EXAMINATION 2000

PAPER D - PART II

THIS PAPER COMPRISES:

- * LEGAL ADVICE 2000/DII/E/1-6
- * ANNEX - CALENDAR FOR 2000 WITH INDICATION
OF THE DAYS ON WHICH AT LEAST ONE OF THE
EPO FILING OFFICES IS NOT OPEN FOR THE
RECEIPT OF DOCUMENTS 2000/DII/E/7

45% OF THE MARKS AVAILABLE FOR PAPER D ARE AWARDED FOR PART I, 55%
FOR PART II.

You are a European patent attorney, working in the Legal Department of your employer, the Irish company Gobbleup Pharmaceuticals plc. Yesterday you were called to a meeting with the managing director.

Gobbleup has recently taken over Sadly-Resources Limited and needs to determine whether that company's products and processes are adequately protected by patent rights, and whether there are any patents that might prevent them marketing their products. You are responsible for the future handling of all the pending applications, which will remain in the name of Sadly-Resources Limited. You have full authorisation to act for Sadly-Resources Limited.

Sadly-Resources Limited is a British company and has had little money to deal with its patent applications. It has provided you with the files for each of its patent applications; the files contain a copy of the specification, all known prior art, and all correspondence between the patent offices and Sadly-Resources Limited.

Following the meeting you reviewed the files, and the following are the facts and questions you need to consider. You must now prepare a memorandum for the follow-up meeting where you give comprehensive advice to the managing director.

SAD-FORM

SAD-FORM is a pharmaceutical formulation for administering therapeutic amounts of any pharmaceutical to human beings and animals. The production of this formulation involves encapsulating a few molecules of the pharmaceutical in a minute soap bubble. The formulation is applied by spraying the soap bubbles into, for example, the lungs, from where the pharmaceutical is absorbed.

A national patent application, FORM-UK1, describing SAD-FORM, its production and its use in great detail, was filed at the UK Patent Office on 24 July 1998.

The inventors given for FORM-UK1 are Dr Fairy, the research director of Sadly-Resources Limited, and Professor Blowit from London University. The file contains a copy of a research agreement between Sadly-Resources Limited and Professor Blowit, assigning all rights in his inventions to Sadly-Resources Limited. The agreement indicates that Professor Blowit may not disclose any information on the research until after a patent application is filed.

A European patent application, FORM-EU2, claiming priority of FORM-UK1 was filed at the UK Patent Office on 26 July 1999. FORM-EU2 also includes a further embodiment of the invention called SAD-FORM/2. However, SAD-FORM/2 is not disclosed in FORM-UK1. SAD-FORM/2 is commercially very important. No other applications were filed.

Very recent work at Gobbleup indicates that the soap bubbles, particularly those used in the embodiment SAD-FORM/2, can unexpectedly be made more stable and effective if the pharmaceutical they contain is mixed with an oil. Clearly, if this is correct, the inventions, particularly the embodiment SAD-FORM/2, will be very valuable. The inventions need to be protected as widely as possible but bearing in mind that it will take about 18 months to assess the commercial value of the inventions.

The published search report for FORM-EU2 includes, as the sole citation, an article dated 1 April 1999 naming Professor Blowit as author, in the Journal of Soap Chemistry. The article corresponds exactly to the description of FORM-UK1.

1. **Will it be possible in view of the citation to get a valid patent in Europe for the subject matter of FORM-EU2?**
2. **In view of the citation and the uncertainty about the commercial value of the inventions, what actions would you take to give your employer the best chance of securing patent protection in Europe, Japan and the USA, and in as many other countries as possible?**

SAD-PROT

Sadly-Resources Limited had a research programme on ways of purifying proteins. The research was carried out on a mixture of proteins obtained from brewer's yeast. A special process was developed by which each of the proteins in the mixture was isolated. The isolated proteins were shown to be pure and to have activity as a fermentation promoter. Sadly-Resources Limited are not aware of any prior art related to the isolated proteins.

A European patent application PROT-EU1 was filed on 14 January 1997 disclosing the results of the research and having a single claim. The claim is directed to the isolation process per se. It is not limited to any specific mixture of proteins. Because the search report revealed large amounts of prior art related to the process, designation fees were paid for the UK, France and Germany only. No applications were filed claiming priority from PROT-EU1.

A communication from the Examining Division dated 4 September 1999, and giving four months to respond, indicated that it intended to refuse the application. Sadly-Resources Limited requested a two-month extension, but did not file a response because it felt that the process as claimed did not have sufficient value to warrant the expense of continuing.

In an article from the American Air Force published last week and describing research work carried out in 1999, details are given of a protein which reduces the symptoms of jet lag. This protein is one of those isolated in the Sadly-Resources Limited work and is described in PROT-EU1, in which it is called SAD-PROT. A patent for SAD-PROT and its method of isolation would clearly be commercially very valuable.

3. **Will it be possible to get valid patents in all the EPC contracting states for the isolation process in general and for SAD-PROT itself, and if so, what actions should be taken in the next six months?**
4. **What would be the consequences if the American Air Force have filed patent applications for their work - could they get a European patent and could they stop your employer selling SAD-PROT?**

SAD-ENZ

SAD-ENZ is an enzyme which was discovered as a result of collaboration between Sadly-Resources Limited and the Fat-Cat Research Institute in Munich. Fat-Cat carried out the preparation and testing of enzymes at the request of Sadly-Resources Limited. SAD-ENZ has been found to inhibit the deposit and accumulation of fat cells in mammals. Thus there is a potentially huge market for it as a slimming aid for humans and their pets.

The collaboration agreement between Fat-Cat and Sadly-Resources Limited allows both parties to file patent applications for inventions made by their employees without reference to the other party.

The Sadly-Resources attorney filed a European patent application ENZ-EU with the UK Patent Office on 12 April 1999 without claiming priority. Dr Plump, an employee, is named as inventor and Sadly-Resources as applicant. The filing fee and search fee were paid by deposit account debit order enclosed with the application documents. ENZ-EU discloses the enzyme structure and its activity, together with details of how to administer it to humans and animals. ENZ-EU does not include any information on how to prepare SAD-ENZ.

An attorney acting for Fat-Cat also filed a European application FAT-EU, in his case directly with the EPO in Munich on 7 April 1999, but he has paid no fees on the application. The application claims a novel and inventive high-yield process for the preparation of the enzyme. It describes the enzyme's structure, but not its activity. The application names Mr Puss, director of the Institute, as inventor and Fat-Cat as applicant.

Fat-Cat have written to say that they do not wish to continue with their application and would be happy to assign to Sadly-Resources Limited all rights in and derivable from the patent application FAT-EU; all they would like in consideration of the assignment is a single payment of one million euros.

The search report produced by the EPO for ENZ-EU includes two citations. One is a newspaper report dated 9 April 1999 of an interview the previous day with Mr Puss in which he discusses the preparation and structure of the enzyme but does not disclose its activity. The second citation is a PCT application in the name of Gene-Genie Inc. The PCT application had been filed in the USA in 1996 without claiming priority, designating all PCT member states. The application includes the structures of a huge number of enzymes and their preparation and isolation using a low-yield process. One of the enzymes described in the PCT application is now known to be SAD-ENZ. No use or any activity is described for any of the enzymes and we have been told by Gene-Genie that neither the European regional phase nor the US national phase was entered.

Clearly there is some risk that SAD-ENZ will not be as successful as hoped, and therefore costs should be kept to a minimum for the next two years until the results of clinical trials are available. The activity of SAD-ENZ has not yet been disclosed to the public.

- 5. What actions must be taken in the next two years to ensure your employer has the best chance of getting valid patents in Europe for SAD-ENZ itself, its preparation, and use as a slimming aid:**
- (a) assuming that your employer is willing to pay Fat-Cat one million euros, and alternatively**
 - (b) assuming that your employer is not willing to pay Fat-Cat any money?**

Annex

**INFORMATION FROM THE
EUROPEAN PATENT OFFICE**

**Notice from the President of the
European Patent Office dated
30 September 1999 concerning
the days on which EPO filing
offices are closed in 2000**

1. Under Rule 85(1) EPC time limits expiring on a day on which at least one of the filing offices of the EPO is not open for receipt of documents (closing days) are extended until the first day thereafter on which all the filing offices are open for receipt of documents and on which ordinary mail is delivered.

2. The EPO's filing offices in Munich, The Hague and Berlin will be closed for the receipt of documents on every Saturday and Sunday. The other closing days in 2000 are listed below.

2000

JANUARY

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30	31					

FEBRUARY

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APRIL

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JUNE

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JULY

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SEPTEMBER

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OCTOBER

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NOVEMBER

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DECEMBER

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Tage/Days/Jours		München Munich	Den Haag The Hague La Haye	Berlin
EPA geschlossen - EPO closed - OEB fermé	03.01.00	x	x	x
EPA geschlossen - EPO closed - OEB fermé	04.01.00	x	x	x
Heilige Drei Könige - Epiphany - Epiphanie	06.01.00	x		
Karfreitag - Good Friday - Vendredi Saint	21.04.00	x	x	x
Ostermontag - Easter Monday - Lundi de Pâques	24.04.00	x	x	x
Maifeiertag - May Day - Fête du travail	01.05.00	x	x	x
Tag der Befreiung - Liberation Day - Journée de la Libération	05.05.00		x	
Christi Himmelfahrt - Ascension Day - Ascension	01.06.00	x	x	x
Pfingstmontag - Whit Monday - Lundi de Pentecôte	12.06.00	x	x	x
Fronleichnam - Corpus Christi - Fête-Dieu	22.06.00	x		
Mariä Himmelfahrt - Assumption Day - Assomption	15.08.00	x		
Tag der Deutschen Einheit - Day of German Unity - Fête Nationale	03.10.00	x		x
Allerheiligen - All Saints' Day - Toussaint	01.11.00	x		
1. Weihnachtstag - Christmas Day - Noël	25.12.00	x	x	x
2. Weihnachtstag - Boxing Day - Lendemain de Noël	26.12.00	x	x	x