

TRADE MARKS ACT 1994

**IN THE MATTER OF APPLICATION NUMBER 2175192
IN THE NAME OF ML LABORATORIES PLC**

AND

**IN THE MATTER OF OPPOSITION THERETO
UNDER NUMBER 49925 BY ASTRA ZENECA UK LIMITED**

TRADE MARKS ACT 1994

**IN THE MATTER OF application number 2175192
in the name of ML Laboratories PLC**

AND

**IN THE MATTER OF opposition thereto
under number 49925 by Astra Zeneca UK Limited**

Background

On 18 August 1998, ML Laboratories PLC filed an application to register the trade mark ADEPT in Class 5 in respect of the following goods:

Pharmaceutical preparations for use in the field of human surgical laparoscopic procedures.

On 30 June 1999, Astra Zeneca UK Limited filed notice of opposition to this application. The grounds of opposition are in summary:

- 1. Under Section 3(1)(b)** because the mark is devoid of any distinctive character.
- 2. Under Section 3(1)(c)** because the mark consists exclusively of a sign or indication which may serve in the trade to designate characteristics of the goods, namely, the kind or intended purpose.
- 3. Under Section 3(1)(d)** because the mark consists exclusively of a sign or indication which has become customary in the current language or the bona fide and established practices of the trade to designate “antibody directed enzyme prodrug therapy”.
- 4. Under Section 3(3)(a)** because the registration of the mark would be contrary to public policy.
- 5. Under Section 3(3)(b)** because the mark is of such a nature as to deceive the public as to the nature of the goods.

The applicants filed a Counterstatement in which they refer to a number of registrations for the trade mark ADEPT, details of which are shown as an annex to this decision. They deny the grounds of opposition and request that the opposition be rejected and that they be awarded costs.

Both sides filed evidence in these proceedings. The matter came to be heard on 12 April 2001, when the applicants were represented by Mr Michael Edenborough of Counsel, instructed by Harrison Goodard Foote, their trade mark attorneys, the opponents were represented by Ms Jessica Jones of Counsel, instructed by Astra Zeneca PLC.

Opponent's evidence in chief

This consists of a Statutory Declaration dated 21 December 1999, and comes from Stephen John Bradley, a Trade Mark Adviser in Global Intellectual Property of Zeneca Limited (now Astra Zeneca UK Limited), a position he has held since 1994 having been involved with the trade marks of the opponents since 1985. Mr Bradley says that he has free access to the records of his company relating to the trade marks it owns and the use made of them, and that the facts contained in the Declaration come either from his own knowledge or the records of the company.

Mr Bradley gives details of the nature and extent of the opponent's business. He refers to the ground under Section 3(1)(b) of the Act, and to exhibit SJB1 which consists of an extract from the Shorter Oxford English Dictionary showing the word ADEPT to mean "thoroughly proficient, a person who is proficient in or at anything" which Mr Bradley says is inherently laudatory and consequently means that the word cannot, prima facie, serve to distinguish.

Mr Bradley refers to the trade mark registrations detailed in the Counterstatement saying that none have been registered in Class 5. The first example relating to a registration by Rhone-Poulenc Agro is registered in Class 5 and in respect of preparations for destroying vermin, fungicides and herbicides and this statement is clearly wrong. He says that it is practice for pharmaceutical companies to watch for trade mark infringements and attempts to register and monopolise generic names. He refers to exhibits SJB2 and SJB3 which includes details of two Community Trade Mark applications by Cortecs Limited who had applied to register ADEPT in respect of goods in Class 5, and correspondence between Cortecs Limited's trade mark attorneys, the opponents and the Cancer Research Campaign which resulted in the applications being withdrawn, Mr Bradley saying that this was because it was established that ADEPT was in use in the pharmaceutical industry.

Mr Bradley next goes to the grounds under Section 3(1)(c) and 3(1)(d), giving examples of how the word ADEPT could describe a characteristic of the goods, and refers to Chapter 6 of the Registry Work Manual (exhibit SJB4) saying that ADEPT is a description used, and that has become customary in the trade as a designation for ADEPT therapy (Antibody Directed Enzyme Prodrug Therapy) and should be refused registration.

Mr Bradley refers to exhibit SJB5 which consists of extracts from the October 1999 United Kingdom issues of the Monthly Index of Medical Specialities, the November 1999 edition of Chemist & Druggist Monthly Price List and the 1999/2000 edition of the Pharmaceutical Trade Marks Directory, noting that there is no product sold under the trade mark ADEPT. He goes on to refer to exhibit SJB6 which consists of the following papers:

Antibody Directed enzymes revive anti-cancer prodrugs concept published in Br J Cancer (British Journal Cancer?) by K.D. Bagshawe of the Cancer Research Campaign Laboratories in 1987.

Cephalosporin Nitrogen Mustard Carbamate Prodrugs for “ADEPT” published by two United Kingdom companies. The article is noted as being classified under the key word ADEPT and is annotated “Printed in Great Britain” and “Received in the UK April 1991”.

Targeting enzymes for cancer therapy: old enzymes in new roles published by the Tumour Targeting Laboratory of Hammersmith Hospital in Br J. Cancer in 1994 referring to, inter alia, Antibody-directed enzyme prodrug therapy (ADEPT).

A Monoclonal Antibody against Human β -Glucuronidase for Application in Antibody-Directed Enzyme Prodrug Therapy referring to Antibody-directed enzyme prodrug therapy (ADEPT). The article is shown as having been received October 1994 and accepted February 1995. It is not clear whether the article was published in the United Kingdom.

Prodrugs of anthracycline antibiotics suited for tumour-specific activation published by Oxford University Press in 1995, referring to “the antibody-directed enzyme prodrug therapy (ADEPT) (Bagshawe, 1987; Bagshawe et al., 1988; Senter et al., 1988) In this two-step approach, which has been recently reviewed (Bagshawe, 1994; Heunneken, 1994.”. In the references is an entry “Bagshawe, K.D. (1994). Antibody-directed enzyme prodrug therapy (ADEPT). Journal of Controlled Release, 28, 187”.

Development of Humanized Disulfide-stabilized Anti-p185her2 Fv- β -Lactamase Fusion Protein for activation of a Cephalosporin Doxorubicin Prodrug published by Cancer Research January 1 1995, with a footnote saying that “the abbreviations used are: ADEPT, antibody dependant enzyme-mediated prodrug therapy...”. The references refer, inter alia, to Bagshawe, K.D. Antibody-directed enzyme prodrug therapy (ADEPT) ...Chapman and Hall Medical 1991.

β -Glucuronyl Carbamate Based Pro-moieties Designed for Prodrugs in ADEPT noted as published in Great Britain in 1995.

Activation of methotrexate-phenylalanine by monoclonal antibody-carboxypeptidase A conjugate for the specific treatment of ovarian cancer in vitro, published in the British Journal of cancer 1996, referring to “In 1987 Bagshawe et al. Introduced a new concept called ADEPT (antibody-directed enzyme prodrug therapy).

A novel nitro-substituted seco-CI: Application as a reductively activated ADEPT prodrug published in the Biorganic & Medical Chemistry letters in 1996, noted as Copyright 1996 and published in Great Britain, referring to “Antibody-directed enzyme prodrug therapy (ADEPT) as a new technique...”.

Mr Bradshaw goes to the grounds founded under Section 3(3)(a) and Section 3(3)(b), saying that ADEPT is accepted in the pharmaceutical industry and in pharmaceutical research to mean Antibody-directed enzyme prodrug therapy (ADEPT), and that the name should remain freely available for use. He asserts that general use of the term could cause confusion in the industry and deceive the public as to the nature of the goods. He refers to unsworn Declarations by Dr

Caroline Joy Springer, Mr Shaun Fountain and Professor Norman Maitland (see below), stating that these do not comply with the Act and Rules and should be disregarded.

Mr Bradshaw goes on to say that cancer patients who are treated with ADEPT therapy may also require surgery, inter alia, to remove cancerous tissues, and could lead to confusion and the possibility of medical errors. He refers to exhibit SJB7 which consists of reports of medical errors stated to have been caused by confusion over names. Mr Bradshaw outlines what he sees as the consequences for the pharmaceutical industry should the application be registered. He refers to exhibit SJB8 which consists of an extract from an Internet web site taken on 8 December 1999. The print is headed Hierarchical Index Category Pharmaceuticals and contains the entries “Antibody directed enzyme prodrug therapy, and ADEPT therapy. The exhibit is dated after the relevant date and there is nothing to establish its availability in the United Kingdom. Mr Bradshaw comments on the consequences of an exclusion of the specification in respect of Antibody-directed enzyme prodrug therapy.

Applicant’s evidence

This consists of a Statutory Declaration dated 14 April 2000, and comes from Mary Spears, technical assistant at Harrison Goddard Foote, the applicant’s representatives. Ms Spears says that the facts within her Declaration come from the applicant’s records or from her own knowledge, and are true and correct to the best of her knowledge. In her Declaration Ms Spears refers to Declarations by Dr Caroline Joy Springer (exhibit CJS1), Mr Sean Fountain (exhibit SF1) and Professor Norman Maitland (exhibit NM1). I have summarised these before turning to Ms Spear’s Declaration to enable her comments to be taken in context.

The Statutory Declaration from Caroline Joy Springer is dated 14 October 1999. Ms Springer says that she has a background in chemistry, holds a Doctorate in Biochemistry obtained in 1984 and has experience in cancer research having spent her post-doctoral years to 1992 in research at the Royal Postgraduate Medical School at Charing Cross Hospital.

Ms Springer says that she is currently a Team Leader funded by the Cancer Research Campaign at the Institute for Cancer Research. She says that she has several years experience in research in cancer treatments, and has published, either alone or in conjunction with others, a large number of papers in the area of cancer drug treatments. By way of example Ms Springer refers to “Antibody directed enzymes prodrug therapy (ADEPT)” published in 1991 with, inter alia Bagshawe KD, and “Ablation of human choriocarcinoma xenografts in nude mice by antibody-directed enzyme prodrug therapy (ADEPT) with three novel compounds.” in the European Journal of cancer. Ms Springer says that having been involved in research since 1987 she is not only familiar with Antibody Directed Enzyme Prodrug Therapy (The therapy), but is also aware that there is no treatment based on the therapy available on the market.

Ms Springer says that she is familiar with the concept of post-operative adhesions which occur as a result of tissue damage during surgery, and that a product called ADEPT to prevent such adhesions is in clinical trial. She says that such a product would, in her view, be used by an surgeon, that she does not believe it likely that it would be in competition or be complementary to a product used for anti-cancer treatments which would be used by an oncologist. She concludes that the different users would go some way to ensuring confusion would not arise.

Ms Springer goes on to say that only cancer patients would need treatment by the therapy, whereas all surgical patients would be treated by the anti-adhesions product ADEPT. She says that she thought it unlikely that confusion between the ADEPT product and ADEPT therapy would arise because surgeons, physicians, pharmacists and nurses would normally have enough medical background not to confuse a general term like therapy with a product, especially when the product has such a specific and unrelated purpose. Ms Springer says that the public would not be confused because they do not prescribe for themselves, and in any case, the ADEPT product would not be available to them as it is solely for use in an operating theatre.

Ms Springer says that she would not assume that ADEPT would come from the same company or type of company involved in antibody-directed enzyme prodrug therapy, and that she thinks ADEPT is a good trading name for a product because it probably stands for adhesion prevention, or similar. She says that ADEPT is a good trading name for the therapy because it stands for Antibody-Directed Enzyme Prodrug Therapy, a description of the therapy.

The next Statutory Declaration is dated 14 October 1999, and comes from Shaun Fountain, a Consultant Obstetrician and Gynaecologist in the department of Obstetrics and Gynaecology at Salisbury District Hospital, a post he has held since 1996. Mr Fountain says that in 1990 he was the registrar of Hammersmith Hospital, in 1991 he became a Research Fellow of Reproductive Medicine and a Senior registrar in 1994.

Mr Fountain says that through his background in the field of obstetrics and gynaecology he is familiar with the concept of post-operative adhesions. He says that he knows the applicant's ADEPT product works by coating the operative surface of the wound site aiming to reduce adhesion formation by preventing direct contact of other organs to the wound site. Mr Fountain goes on to say that he is familiar with the concept of antibody-directed enzyme prodrug therapy in which specific antibodies linked to an enzyme which converts an inactive prodrug into an active drug are injected, the antibodies attach to the tumour and the prodrug administered. He says that he knows there is no treatment or set of treatments based on the therapy on the market.

Mr Fountain goes on to say that he does not think it likely that the product used for anti-cancer treatments, which would be used by oncologists, and those for preventing the formation of post-operative adhesions, which would be used by surgeons, would ever be in competition. He continues saying that he was asked whether he thought the products were complementary, his answer being that he did not believe this to be the case.

Mr Fountain says that he would not assume that ADEPT anti-adhesion products would come from the same company or type of company involved in the manufacture or sale of products related to Antibody-Directed Enzyme Prodrug Therapy. He gives his views that ADEPT is not a good trading name for products sold in relation to the therapy because it is an acronym for a type of therapy, not a specific therapy, and that because a different antibody and a different prodrug would be needed to treat different cancers, calling them by the same name would be confusing and dangerous. He also says that he did not think ADEPT is a particularly good trading name for the anti-adhesions product because it does not naturally imply an anti-adhesion product.

The third Declaration from Norman Maitland is dated 12 October 1999. Mr Maitland says that he is a Professor of Molecular Biology and Director of the YCR Cancer research Unit at the

Department of Biology at the University of York. He says that he has been a Senior Lecturer in Molecular Pathology and has published, either alone or in conjunction with others, over 100 papers on cancer and/or virology.

Professor Maitland says that through his background in the field of cancer research he is familiar with the concept of Antibody-Directed Enzyme Prodrug Therapy (the therapy). He says that his laboratory has an interest in gene-based therapies and that he has heard the therapy described at meetings and that he knows that as yet there is no treatment or set of treatments based on the therapy available on the market. Professor Maitland confirms that he is familiar with the concept of the formation of post-operative adhesions, which, he says occur as a result of tissue damage during surgery. He says that he has been told by Dr Susan Conroy that a product to prevent the formation of adhesions is currently in clinical trials, and that this product is called ADEPT.

Professor Maitland goes on to say that he believed it unlikely that products used for anti-cancer treatments, which would be used by oncologists, and those used for preventing the formation of post-operative adhesions, which would be used by surgeons, would be in competition. He also says that he has been asked whether he thought that such products would be complementary, his response being that he considered this would only happen in cases where surgery was possible, the therapy being targeted against metastatic inoperable cancers making it difficult to see how they could be complementary. Professor Maitland continues saying that only cancer patients would need treatment by the therapy, whereas all surgical patients at risk of post operative adhesions would be treated by the anti-adhesion product ADEPT.

Professor Maitland says that he does not consider it likely that there would be confusion between the acronym for the therapy and the name of the product, ADEPT being a generic term for a particular type of treatment whereas in relation to the product it is the name of a single unrelated anti-adhesion product. He goes on to say that the volumes and method of delivery of the treatments would be different for the therapy and the anti-adhesion product, and even in the unlikely event of confusion arising and the therapy administered instead of the anti-adhesion product there would be no adverse activity.

Professor Maitland concludes his Declaration saying that he considers it unlikely that anyone would assume that ADEPT came from the same company or type of company involved in Antibody-Directed Enzyme Prodrug Therapy because the prodrug would need to be requested with the targeting compound mixture for use in relation to the therapy, neither being called ADEPT.

Returning to the Statutory Declaration by Ms Spears. She goes first to the Declaration by Stephen John Bradley, denying that the word ADEPT is laudatory (saying that this is evidenced by the trade mark registrations referred to in the Counterstatement) or that the word describes a characteristic of the goods. Ms Spears refers to exhibit MS1 which consists of information taken from the Internet in March 2000, and which shows the word ADEPT being used in connection with various goods and services.

Ms Spears correctly notes that one of the registrations for ADEPT detailed in the Counterstatement is for goods found in Class 5, and refers to exhibit MS2 which consists of a letter from the proprietor of that trade mark giving consent to the applicant's mark.

Ms Spears says that pre-filing searches did not find any registrations for ADEPT for pharmaceutical preparations. She denies that the word is generic, giving the definition of generic taken from the Concise Oxford Dictionary, saying that the public, whether inside or outside of the pharmaceutical industry will have no knowledge of antibody-directed enzyme drug therapy, but would in any case, not be confused.

Ms Spears refers to exhibit SF1 which consists of the Statutory Declaration of Shaun Fountain summarised earlier. She refers to Mr Fountain's statement that through his experience he is familiar with the concept of the formation of post-operative adhesions, that he knows of the applicant's product ADEPT, that he is familiar with the concept and methodology of antibody-directed enzyme prodrug therapy, and to his being aware that there is as yet no treatment based on this therapy on the market. Ms Spears draws from this the conclusion that there is no likelihood of there being confusion between the anti-cancer therapy and the anti-adhesion product.

Ms Spears gives her reasons why the withdrawal of the Community Trade Mark application is not persuasive, saying that such an event cannot determine the outcome of any other application.

Ms Spears returns to the Declaration of Stephen Bradley, in particular, exhibit SJB3 saying that it will be seen from the exhibit that the Cancer Research Campaign were asked not to use ADEPT in connection with an actual pharmaceutical product or course of treatment. Ms Spears says that the Antibody-Directed Enzyme Prodrug Therapy is as yet unproven and not available on the market. She refers to exhibit MS3 which consists of an extract from a publication dating from 15 December 1999 relating to the development of a cancer treatment by Astra Zeneca in conjunction with the Cancer Research Campaign, referring to ADEPT (Antibody-Directed Enzyme Prodrug Therapy) as an oncology project that has been discontinued. Ms Spears says that this is in contradiction to the impression given by the opponents that their intention in preventing the adoption of ADEPT as a trade mark is to protect the pharmaceutical industry.

Ms Spears comments on the statement in paragraph 4.1 in which Mr Bradley says that the application is not for the goods anti-adhesion pharmaceutical preparations, but is a description of the ADEPT therapy, noting that the applicant had offered to exclude antibody-directed enzyme prodrug therapies, and goes on to offer a limitation of the specification to:

Pharmaceutical preparations for use in the field of human or surgical laparoscopic procedures; none being for the treatment of cancer.

Ms Spears denies that antibody-directed enzyme prodrug therapy is a term used in the trade, saying that the evidence provided by the opponents shows it to be a term used in relation to the research and development of an enzyme-directed cancer therapy, and there is therefore no trade involved, but in any event, a product resulting from the research would not be called ADEPT because this would refer to the therapy, and not any associated product. Ms Spears goes on to say that there are so few individuals involved in antibody directed prodrug therapy research that it cannot be said that ADEPT consists exclusively of a sign or indication which has become customary in the pharmaceuticals trade.

Ms Spears refers to exhibit SJB5 which consists of an extract from the United Kingdom issue of the November 1999 edition of Chemist & Druggist Monthly Price List in which Mr Bradley had

highlighted that there is no entry for ADEPT, Ms Spears saying this is exactly why the applicants adopted the term. She goes on to say that it is not surprising that the Pharmaceutical Trade Marks Directory does not show ADEPT in use, suggesting that this may be because of the policing activities of the opponent.

Ms Spears does not deny that patients treated with the antibody-directed enzyme prodrug therapy may also require surgery, but refers to the Declarations by Dr Caroline Joy Springer (exhibit CJS1), Mr Sean Fountain (exhibit SF1) and Professor Norman Maitland (exhibit NM1) which she says shows that medical professionals who know of the ADEPT therapy and ADEPT product are not, and would not be confused because of differences in the physical nature of the therapy and products.

Ms Spears refers to exhibit MS4 which consists of a press release issued by the applicants on 1 November 1999, announcing that approval had been granted to market their ADEPT product throughout Europe, which Ms Spears says shows that the regulatory authority had perceived no likelihood of confusion. She goes on to say that the instances of confusion cited in exhibit SJB7 are different because they are concerned with products of similar names whereas any product resulting from antibody-directed enzyme prodrug therapy, or ADEPT would not be called by that name.

Ms Spears comments on the extent of the protection afforded by registration and the effect of any exclusion. She denies that there will be any confusion when searches for ADEPT are carried out, be it by patent searchers or otherwise. She refers to exhibit MS5 which consists of a leaflet giving instructions on the use of ADEPT, saying that it is intended for use as an intra peritoneal instillate for reduction of adhesions following abdominal surgery, and that it is provided in 1 litre bags. Ms Spears says the product will only be available to hospitals for use in operating theatres, and any surgeon reading the instructions will be completely aware of the product and will not be confused.

Ms Spears says that regardless of whether the application is registered the opponents will not be able to prevent the applicants using the trade mark in respect of goods for use in respect of its anti-adhesions product. She comments on the registration of ADEPT by Rhone-Poulenc for, inter alia, fungicides. She says that it is well known that such goods are used within the pharmaceutical industry to treat fungal disorders in cancer patients, and yet there was no objection to the registration, Ms Spears concluding that this is because no connection would be made between such goods and a therapy of the same name even though both may be for treating cancer patients.

Opponent's evidence in reply

This consists of a Statutory Declaration dated 7 July 2000 and is a second declaration by Stephen John Bradley

Mr Bradley goes to the Declaration of Mary Spears in which she refutes the assertion that ADEPT is laudatory, and refers to exhibit SJB1 which consists of an extract from Collins Shorter Dictionary and Thesaurus showing the word ADEPT to mean "skilled" or "expert", Mr Bradley listing the alternatives in the Thesaurus. He questions the reasons given for the adoption of ADEPT given by Ms Spears and gives his views as to why the internet sites shown in exhibit MS1 adopted the word ADEPT, and that in his view the evidence shows ADEPT to be generic.

Mr Bradley refers to exhibit SJB2 which consists of a collection of articles published in the United Kingdom and internationally, relating, inter alia, to research carried out into antibody-directed enzyme prodrug therapy (ADEPT), a number of which were published by Caroline Springer (and others) a Declarant in support of the application. The articles contain many references to ADEPT as an anti cancer treatment. Although all published after the relevant date, the papers contain references to earlier papers on antibody-directed enzyme prodrug therapy ADEPT, one credited to Bagshawe K et al, BJ Cancer 1988.

Mr Bradley introduces exhibit DCB1 which consists of a Statutory Declaration by David Charles Blakey (summarised later) which, he says establishes that the opponents have a continuing interest in antibody-directed enzyme prodrug therapy, and that whilst he admits that the resulting product of this therapy would not be called ADEPT, the word will be used as a reference to the class of that product. By analogy he refers to exhibit SJB3 which is an article on the class of compounds known angiotensin converting enzyme ACE inhibitors which he says has become an important classes of drugs in less than 15 years. The article refers to seven brand names for ACE inhibitors, albeit marketed in the United States. Further examples of such usage can be found in exhibit SJB4 which consists of an extract from MIMS Monthly Index of Medical Specialities which refers to ACE inhibitors as a class of goods, and lists various brand names describing them as ACE inhibitors. Mr Bradley says that this shows how the name of a class of compounds is used when the goods come to the market, and that the compound name ADEPT is used in the pharmaceutical industry in the same way.

Mr Bradley makes a number of comments on the applicant's claims that there is no likelihood of confusion, noting that exhibit NM1 admits to there being a possibility of confusion. He goes to refer to exhibit AJMC1 which consists of a Statutory Declaration by Anthony John Martin Coombs (summarised later) which he says confirms that the ADEPT therapy and anti-adhesion product have the same customer base, and that both would be administered in the form of infusions, both factors which Mr Bradley cites in his views on how confusion could arise.

Referring to exhibit JHP1, which consists of a Statutory Declaration by Jacqueline Heather Provan (summarised later), Mr Bradley says that the opponents have not been able to find evidence of regulatory approval by European authorities of the applicants' ADEPT anti-adhesion product. He continues saying that in any event, not all authorities examine for possible confusion and even if they had done in this case, there is no evidence of the references or sources used. He says that even if they had considered possible confusion, ADEPT when used in respect of antibody-directed enzyme prodrug therapy is not the name of a trade mark or been included in any submission for product approval. Mr Bradley concludes his Declaration by explaining why no opposition had been filed against the Rhone-Poulenc ADEPT mark, referring to exhibit SJB5 which he says shows that the mark is not going to be used in the human field of pharmaceuticals.

Summary of exhibits DCB1, JHP1 and AJMC1

These consists of three Statutory Declarations. The first is dated 4 July 2000, and comes from David Charles Blakey. Mr Blakey outlines his academic achievements and employment history prior to becoming a Senior Scientist and Project Manager in Cancer and Bioscience Department of Astra Zeneca. Mr Blakey confirms that he is project manager responsible for ADEPT within Cancer and Infection Discovery at Astra Zeneca. He says that he is the chief point of contact for

ADEPT collaborative studies with the Cancer Research Campaign and confirms that Astra Zeneca has an ongoing interest in ADEPT, and that the article referred to by Mary Spears related to the discontinuation of two specific ADEPT products and not to the research as a whole.

The second Statutory Declaration comes from Jacqueline Heather Provan, an employee of Astra Zeneca since 1972, her current post being Director of European Regulatory Affairs and EMEA Liaison within the department of World Regulatory Affairs. Ms Provan describes her responsibilities as providing specialist expertise to Global Project Teams regarding European regulatory matters, to develop regulatory product strategies, interfacing with, and making and marketing authorisation applications to European Regulatory Authorities.

Ms Provan details the results of her investigations with the European Agency for the Evaluation of Medicinal Products (EMA), and the European Products Index , which she says revealed that the applicants have not received a centralised product approval for a post-operative adhesions solution called ADEPT, and that the applicants do not appear on either the EMA database or the list of medicines approved in the European Union. Ms Provan says that her investigations would suggest that the applicant's ADEPT product has approval in no more than one EU country and that further investigations with the Medicines Control Agency (UK) and the London Gazette where all approvals of new medicines are published proved negative.

Ms Provan concludes her Declaration by commenting on the instruction leaflet in exhibit MS5, which she says is not in the format required within the EU, and that the press release suggests that the ADEPT anti-adhesions product is in pre-clinical testing.

The final Statutory Declaration is dated 4 July 2000 and comes from Anthony John Martin Coombs, Global Marketing Director, Oncology, in the Product Strategy and Licensing Department of Astra Zeneca. He says that he has been involved with the ADEPT project since 1998 as a senior commercial member of the global team working on the project. Mr Coombs says that based on his involvement with the ADEPT therapy he can confirm that his company believes that there will be confusion if the term ADEPT is used as a trade mark for the goods covered by the application in suit, because they would share the same customer base and both be administered in the form of infusions.

Applicant's further evidence Rule 31(11)

This consists of a Statutory Declaration dated 11 December 2000, which comes from Lorna Margaret Clisby, Director of Regulatory Affairs for ML Laboratories Plc, a post she has held since March 1990. She confirms that the facts declared are from her own knowledge or taken from the relevant records of the applicant.

Ms Clisby refers to the Declaration of Stephen John Bradley and Jacqueline Heather Provan filed as part of the opponent's evidence, and in particular, to the statements that they had been unable to locate any authorisation having been granted by a competent European authority to the applicants in relation to the trade mark ADEPT. Ms Clisby explains that ADEPT is a Class III device and is regulated as medical device and not as a medicinal product and consequently the searches conducted by the opponents are incorrect. She says the device has been granted a Design Examination Certificate and Quality Assurance Certificate (exhibit LMC1) by the British

Standards Institute. Ms Clisby also says that her company's product ICODIAL has received marketing authorisation as a medicinal product throughout the EC, referring to exhibit LMC2 which consists of a schedule showing dates of approval. Ms Clisby concludes her Declaration by stating that the instruction leaflet for the product sold under ADEPT meets the requirements of the medical devices directive.

That concludes my review of the evidence in so far as it is relevant to these proceedings.

Decision

Turning first to the grounds under Section 3(1)(b), (c) and (d) of the Act. Those sections read as follows:

3.(1) The following shall not be registered -

- (a)
- (b) trade marks which are devoid of any distinctive character,
- (c) trade marks which consist exclusively of signs or indications which may serve, in trade, to designate the kind, quality, quantity, intended purpose, value, geographical origin, the time of production of goods or rendering of services, or other characteristics of goods or services,
- (d) trade marks which consist exclusively of signs or indications which have become customary in the current language or in the bona fide and established practices of the trade:

Provided that, a trade mark shall not be refused registration by virtue of paragraph (b), (c) or (d) above if, before the date of application for registration, it has in fact acquired a distinctive character as a result of the use made of it.

Ms Jones advanced two lines of argument; that ADEPT is an ordinary English word with a meaning apt for use in relation to any goods including those covered by the application, and secondly, that it is an acronym for a type of cancer treatment **Antibody-Directed Enzyme Prodrug Therapy**.

I begin by looking at how the law stands. In the Court of Appeal decision in the case of Phillips Electronics NV v Remington Consumer Products Ltd (1999 23 RPC 809), Aldous LJ considered the scope of Section 3(1)(b), saying:

“The requirement under section (Article) 3(1)(b) is that a mark must have a distinctive character to be registrable. Thus it must have a character which enables it to be distinctive of one trader's goods in the sense that it has a meaning denoting the origin of the goods.”

In the British Sugar Plc v James Robertson & Sons Ltd (TREAT) trade mark case, (1996) RPC 9, Mr Justice Jacob said:

“Next is “Treat” within Section 3(1)(b). What does *devoid of any distinctive character* mean? I think the phrase requires consideration of the mark on its own, assuming no use. Is it the sort of word (or other sign) which cannot do the job of distinguishing without first educating the public that it is a trade mark? A meaningless word or a word inappropriate for the goods concerned (“North Pole” for bananas) can clearly do. But a common laudatory word such as “Treat” is, absent from use and recognition as a trade mark, in itself (I hesitate to borrow the word *inherently* from the old Act but the idea is much the same) devoid of any distinctive character.”

The meaning of “devoid of any distinctive character” was addressed by Lord Justice Robert Walker in a recent appeal by Proctor & Gamble Limited in relation to their bottle marks ([1999] RPC 673) who commented as follows:

Despite the fairly strong language of s.3(1)(b), “devoid of any distinctive character” - and Mr Morcom emphasised the word “any” - that provision must in my judgement be directed to a visible sign or combination of signs which can by itself readily distinguish one trader’s product - in this case an ordinary, inexpensive household product - from that of another competing trader”.

In the Home Shopping case (unreported) Mr Simon Thorley sitting as the Appointed Person cited with approval the decision in the Proctor & Gamble case went on to say:

In my judgement, Mr McCall is placing too light a restriction upon Section 3(1)(b) when he suggests that a mere spark of distinctiveness is enough.

I am bound, and with respect, agree with the reasoning of Robert Walker LJ. One must have regard to the mark as a whole, and ask whether the combination of signs contained in the trade mark can by itself readily distinguish the products or services of one trader from those of another.

This approach is in accord with the European Court of Justice’s judgement in Windsurfing Chiemsee [1999] ETMR 585.

I will deal first with the assertion that ADEPT is a word apt to describe the goods, the objection as I see it being that it is laudatory. The entry in Collins English Dictionary gives the meaning of ADEPT as:

“1. Very proficient in something requiring skill or manual dexterity. 2. skilful; expert. 3. a person who is skilled or proficient in something.”

The entry in The New Shorter Oxford English Dictionary on historical principles shown as exhibit SJB1 gives a meaning for ADEPT of:

“Thoroughly proficient; A person who is proficient in or at something.”

It seems reasonably clear from these definitions that the word ADEPT is apt for use in relation to a person who has acquired a proficiency or skill, but not so in describing a product that can perform a particular function effectively. I can see no merit in this line of argument and it is dismissed.

The second strand to the opponent's case, and quite clearly the most serious objection is that the word ADEPT is nothing more than an acronym for a particular medical treatment. On my reading, the evidence shows that ADEPT is an acronym for a type of cancer treatment known as **Antibody-Directed Enzyme Prodrug Therapy** and has been in use for many years. Mr Edenborough did not dispute this meaning, relying on the argument that ADEPT is no more than a term used in research and is not *customary* in the trade, and that it is not a term which is descriptive of the goods of the application.

Looking first at whether ADEPT is a sign or indication which may serve in the trade to designate characteristics of the goods, or that has become customary in the current language or bona fide and established practices of the trade. The wording of subsection (c) makes it clear that the enquiry is directed at the goods covered by the application. Although subsection (d) does not explicitly say so, the position must be the same under that subsection, for if this is not the case any term used in a trade would be barred from acceptance even if it had no relevance whatsoever for the goods. The question, therefore, is whether the evidence establishes that ADEPT (or antibody directed enzyme prodrug therapy) describes a characteristic of the goods applied for, or that is customarily used in the trade in relation to such goods.

The evidence describes antibody directed enzyme prodrug therapy as a therapy for targeting enzymes to tumour cells which catalyse the precursor drug conversion into an active drug at the site of the tumour. The earliest mention of the therapy dates from 1987 and although appearing to have been the subject of a significant amount of research, and reviews in medical and scientific journals, does not appear to have matured into a product by the relevant date, but does that matter? From the evidence it is clear that ADEPT is a term widely used in medical research to describe a specific type of cancer therapy, and I would say likely to be understood by persons working in that field although it is uncertain whether this awareness would extend to medical practitioners. Either way, the evidence shows longstanding and widespread use of ADEPT in relation to a cancer therapy, and that it is a term customarily used in the current language of the trade in respect of such a therapy.

This leads us to the next question, which is whether ADEPT has any connection with the goods covered by the application. Should the research be successful the result will be that ADEPT will become the generic name for a range of products utilising the therapy. As in the Jeryl Lynn trade mark case (1999 FSR 7 at 491) to which I was referred, it will not become a trade mark for any of these goods because it will not be capable of such. As indicated by Mr Edenborough, there is no evidence that by the relevant date in these proceedings, antibody directed enzyme prodrug therapy (ADEPT) had passed from the research phase to become a name in use in respect of a class of pharmaceutical products. That said, I do not see that the application only covers preparations which have become a reality in the marketplace, so assuming that ADEPT describes a class of pharmaceutical preparation, albeit in the developmental stage, an application for pharmaceutical preparations at large would in my view cover antibody directed enzyme prodrug therapy and be open to objection.

Exhibit MS4 describes the product that the applicant's intend to use under the ADEPT name as a preparation for use during and after surgery to reduce adhesions which in my view clearly places it outside of the description of antibody directed enzyme prodrug therapy. However, the application has not been made for such a description of goods, but in respect of pharmaceutical preparations qualified as being for use in the field of human surgical laparoscopic procedures. In my view that has the effect of restricting the pharmaceutical preparations to being for use in surgical procedures involving a laparoscope (an instrument for viewing internal organs) which is confirmed by exhibit MS5 which consists of an instruction leaflet for the applicant's ADEPT product describing it in the terms of a bag of sterile solution for connection to a laparoscope. It may well be that a laparoscope, and thereby, the applicant's preparations, could be used prior to, during and after antibody directed enzyme prodrug therapy, but I do not consider that this means that it would be taken to be part of the therapy any more than a scalpel or dressing.

The applicant's evidence includes declarations from Dr Caroline Joy Springer (exhibit CJS1), Mr Sean Fountain (exhibit SF1) and Professor Norman Maitland (exhibit NM1) who are put forward as expert witnesses. In *The European Ltd v The Economist Newspaper Ltd*, Millett LJ said:

“The function of an expert witness is to instruct the judge of those matters which he would not otherwise know but which it is material for him to know in order to give an informed decision on the question which he is called upon to determine. It is legitimate to call evidence from persons skilled in a particular market to explain any special features of that market of which the judge would otherwise be ignorant and which may be relevant to the likelihood of confusion.”

In *Guccio Gucci SpA v Paolo Gucci* (1991 FSR 89) Sir Nicholas Browne-Wilkinson, The Vice Chancellor said:

“..If on the other hand you are in an area which requires specialist knowledge, it is the function of the expert to instruct and inform the court as to those things which the court would not otherwise know, and in the process of so doing the expert is frequently asked the very question which the court has to answer. In my judgement where you have a specific area of the market of which the judge is ignorant (such as I am in this case of the designer label market) it is legitimate to produce evidence from those who are skilled in that market and know of it, and likelihood of confusion amongst customers in the same market...”

From their qualifications and experience all three seem to be well qualified to inform and provide instruction in respect of the market, in this case, the medical profession, and specifically in relation to antibody directed enzyme prodrug therapy and the applicant's ADEPT preparation. All confirm that they do not consider antibody directed enzyme prodrug therapy and the applicant's anti-adhesion product to be in competition or complementary. They state that the products would be used by different medical specialists, the therapy by oncologists, the anti-adhesion product by surgeons, and give cogent reasons why they do not consider there to be a likelihood of them being confused.

Taking all factors into account, in particular, the evidence provided by Dr Springer, Mr Fountain and Professor Maitland, I come to the view that the term ADEPT is a term that customarily used

in the trade to describe antibody directed enzyme prodrug therapy, but not the goods covered by the application, and consequently, the grounds under Section 3(1)(b)(c) & (d) fail.

Turning to the grounds under Section 3(3)(a) and (b). Those sections read as follows:

(3) A trade mark shall not be registered if it is-

(a) contrary to public policy or accepted principles of morality, or

(b) of such a nature as to deceive the public (for instance as to the nature, quality or geographical origin of the goods or services).

On the ground under subsection (a) Ms Jones again had two strands to her arguments. Firstly that a patient who received treatment with the applicant's ADEPT product may be misinformed by a nurse familiar with the antibody directed enzyme prodrug therapy that they have cancer, thereby causing distress to the patient, and secondly, should there be problems with the applicant's product the adverse publicity would deter volunteers to assist in the research into the therapy, the consequence being that this would inhibit the development. Under Section 3(3)(b) Ms Jones submitted that to the informed and reasonably observant average consumer, ADEPT meant a cancer research therapy and therefore it is incapable of being a trade mark for the applicant's product. Mr Edenborough did not dissent from the view that ADEPT is incapable of being a trade mark for antibody directed enzyme prodrug therapy, but in respect of the goods of the application was capable of performing the function of a trade mark without leading to deception.

Much has been made in the evidence to establish that the preparations would be used by persons in separate and distinct areas of medicine/surgery. This is a position supported in the declarations of the three "expert witnesses" referred to above, but this is not reflected in the specification of the application and notionally the users would be the same. However, this is an area in which staff are highly trained and where diligence is of utmost importance. There is also the fact that antibody directed enzyme prodrug therapy is still in the research phase and likely to be known only to well informed medical practitioners, primarily in fields related to cancer treatment, who are also just as likely to know that the research had not as yet resulted in an end product.

The "expert witnesses" all confirm that they would not be confused by ADEPT being used in respect of the therapy and the applicant's anti-adhesion preparation. They also gave cogent reasons as to why they considered there to be no realistic proposition of others being confused, Professor Maitland going so far as to consider, and discount what he thought to be the likely circumstances where confusion could arise. Little can or need be said in respect of the assertion relating to the potential for adverse consequences should the applicant's product encounter problems. That is a possibility for any product, but I would say less so in the area of medicines where stringent testing is a prerequisite to a product reaching the market.

For the reasons given above, and in particular, relying on the facts advanced by the three experts, I find the scenarios cited in support of these grounds to be somewhat unlikely and the objections under Section 3(3)(a) and (b) are dismissed accordingly.

The opposition having failed on all grounds, I order that the opponents pay the applicants the sum of £635 as a contribution towards their costs. This sum to be paid within seven days of the expiry of the appeal period or within seven days of the final determination of this case if any appeal against this decision is unsuccessful.

Dated this 15th day of August 2001

**Mike Foley
for the Registrar
The Comptroller General**