

ASTRAZENECA PLC  
Form 6-K  
September 16, 2003

**FORM 6-K**

SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

Report of Foreign Issuer

Pursuant to Rule 13a-16 or 15d-16 of  
the Securities Exchange Act of 1934

For August 2003

Commission File Number: 001-11960

**AstraZeneca PLC**

15 Stanhope Gate, London W1K 1LN, England

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F  Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): \_\_\_\_\_

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): \_\_\_\_\_

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes  No

If Yes is marked, indicate below the file number assigned to the Registrant in connection with Rule 12g3-2(b): 82- \_\_\_\_\_

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**AstraZeneca PLC**

INDEX TO EXHIBITS

1. Press release entitled, "AstraZeneca to seek triple damages in patent infringement lawsuit against Mylan Pharmaceuticals", dated 8 August 2003.

2. Press release entitled, "Crestor® receives FDA approval", dated 12 August 2003.
  3. Press release entitled, "Disclosure of interest in voting shares in public companies", dated 27 August 2003.
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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AstraZeneca PLC

Date: 16 September 2003

By: /s/ A C N Kemp

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Name: A C N Kemp

Title: Assistant Secretary

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Item 1

**ASTRAZENECA TO SEEK TRIPLE DAMAGES IN PATENT  
INFRINGEMENT LAWSUIT AGAINST MYLAN PHARMACEUTICALS**

AstraZeneca announced today that it will amend its lawsuit against Mylan Pharmaceuticals to seek triple damages for the wilful and intentional infringement of AstraZeneca's Prilosec® (omeprazole) formulation patents. In addition, AstraZeneca is filing suit to recover wilful infringement damages against Esteve Quimica, S.A. and Laboratorios Dr. Esteve, S.A., which are formulators of the Mylan omeprazole product. AstraZeneca reaffirms its commitment to vigorously defend its right to patent protection both in the remaining omeprazole patent infringement cases now pending in New York federal court, and in relation to the Schwarz/KUDCo formulation case now under appeal. The company will continue to monitor the situation closely and retains recourse to further legal action.

On August 4, 2003 Mylan Pharmaceuticals announced it had begun sale of the 10mg and 20mg dosages of omeprazole delayed release-capsules.

Mylan is one of the five defendants in the second wave of cases currently in the discovery phase. A trial date has not been set. Mylan has decided to launch at risk its generic omeprazole product even though AstraZeneca's two formulation patents were found valid following a trial in 2002, involving four other generic

manufacturers. In a 275-page opinion, Federal District Court Judge Barbara S. Jones found that three of four generic manufacturers infringed AstraZeneca's formulation patents. Judge Jones ruled that Schwarz' formulation did not infringe the patents and Schwarz/KUDCo launched its version of generic omeprazole in December 2002.

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- 2 -

AstraZeneca is a major international healthcare business engaged in the research, development, manufacture and marketing of prescription pharmaceuticals and the supply of healthcare services. It is one of the top five pharmaceutical companies in the world with healthcare sales of over \$17.8 billion and leading positions in sales of gastrointestinal, oncology, cardiovascular, neuroscience and respiratory products. AstraZeneca is listed in the Dow Jones Sustainability Index (Global and European) as well as the FTSE4Good Index.

- Ends -

August 8, 2003

Media Enquiries:

Emily Denney, Tel: +44 (0) 207 304 5034

Steve Brown, Tel: +44 (0) 207 304 5033

Rachel Bloom-Baglin, Tel: +1 302-886-7858

Investor Relations:

Jonathan Hunt, Tel: +44 (0) 207 304 5087

Jorgen Winroth: +1 212-581-8720

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Item 2

**CRESTOR® RECEIVES FDA APPROVAL**

*CRESTOR Significantly Lowers LDL Cholesterol by As Much As 63%*

AstraZeneca announced today that its new cholesterol-lowering medication, CRESTOR® (rosuvastatin calcium), which has been shown to lower LDL-cholesterol by up to 63 percent, has received approval from the U.S. Food and Drug Administration (FDA) as an adjunct to diet for the treatment of various lipid disorders including primary hypercholesterolemia, mixed dyslipidemia and isolated hypertriglyceridemia. This follows the successful Advisory Committee Meeting held in the US on 9th July 2003 where the Committee voted unanimously to recommend the approval of CRESTOR.

CRESTOR is the newest member of the cholesterol-lowering statin (HMG-CoA reductase inhibitors) class of drug therapy. In addition to its LDL (low-density lipoprotein) or "bad" cholesterol lowering effects, CRESTOR has been shown to provide a significant increase in HDL (high-density lipoprotein) or "good" cholesterol.

"We are delighted with the approval of CRESTOR in the United States," said Sir Tom McKillop, Chief Executive Officer of AstraZeneca. "We believe that CRESTOR offers an important new treatment option for patients who are either untreated or not at target cholesterol levels."

The FDA has approved the recommended usual starting dose of CRESTOR to be 10 mg once daily with a dose range of 5 to 40 mg available. Therapy with CRESTOR should be individualised according to goal of therapy and response. For patients with marked hypercholesterolemia (LDL-C >190 mg/dL) and aggressive lipid targets, a 20 mg start dose may be considered, and for special populations a 5mg dose is also available.

The clinical development program for CRESTOR is the largest program ever submitted to initially evaluate a statin. In multiple clinical studies, CRESTOR has been shown to be more effective in lowering LDL-cholesterol (LDL-C or 'bad cholesterol') than currently prescribed statins. CRESTOR 10mg gets significantly more patients to their LDL-C goal (both NCEP ATP III (US) and European) than atorvastatin 10mg and, in addition to the dramatic reductions seen in LDL-C, CRESTOR produces a significant increase in HDL-C ('good cholesterol'), as well as reducing total cholesterol and triglycerides. Evidence collected from over 24,000 patients who have taken CRESTOR demonstrates that it is well tolerated with a safety profile comparable to that of other statins.

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Guidelines issued by the National Cholesterol Education Program's Adult Treatment Panel III have substantially increased the number of patients eligible for cholesterol-lowering drug therapy from approximately 13 million to 36 million. Currently, it is estimated that more than 20 million Americans have an LDL goal of <100 mg/dL, and it is estimated that only about one third of treated patients reach their LDL goal. Cardiovascular disease is the leading cause of death in the United States. According to the American Heart Association, more than 2,600 Americans die from cardiovascular diseases every day – an average of one death every 33 seconds.

The global statin market is estimated to be worth approximately \$20 billion and growing at a rate of around 13 per cent annually. CRESTOR was first approved in the Netherlands in 2002 and has since been approved in 23 other countries. Launches have occurred in a number of countries, including Canada, the Netherlands and the United Kingdom.

12 August 2003

Media Enquiries:

Emily Denney, Tel: +44 (0) 207 304 5034

Chris Major, Tel: +44 (0) 207 304 5028

Investor Relations:

Jonathan Hunt, Tel: +44 (0) 207 304 5087

Jorgen Winroth, Tel: +1 212 581 8720

NOTES TO EDITORS

\*National Cholesterol Education Program's Adult Treatment Panel III

- Full US prescribing information for CRESTOR is available at [www.astrazeneca-us.com](http://www.astrazeneca-us.com)
- AstraZeneca licensed worldwide rights to CRESTOR from the Japanese pharmaceutical company Shionogi & Co Ltd, the pharmaceutical company that discovered the drug, in April 1998.
- CRESTOR is indicated as an adjunct to diet to reduce elevated total-C, LDL-C, ApoB, nonHDL-C, and TG levels and to increase HDL-C in patients with primary hypercholesterolemia (heterozygous familial and nonfamilial) and mixed dyslipidemia (Fredrickson Type IIa and IIb); as an adjunct to diet

for the treatment of patients with elevated serum TG levels (Fredrickson Type IV); and to reduce LDL-C and total-C in patients with homozygous familial hypercholesterolemia as an adjunct to other lipid-lowering treatments (eg, LDL apheresis) or if such treatments are unavailable.

- CVD is estimated to account for a third of all deaths globally and is the leading cause of mortality in Europe and the US. Over 16.6 million deaths each year are due to CVD (more than 45,000 deaths

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every day, and almost 32 deaths each minute) In Europe, about half of all deaths from CVD are from CHD and nearly one-third are from stroke.

- For further information please see [www.astrazenecapressoffice.com](http://www.astrazenecapressoffice.com)

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Item 3

COMPANIES ACT 1985 SECTION 198  
DISCLOSURE OF INTEREST IN VOTING SHARES IN PUBLIC COMPANIES

ON 26 AUGUST 2003 WE WERE INFORMED BY THE CAPITAL GROUP COMPANIES, INC., A REGISTERED INVESTMENT MANAGER IN THE U.S., THAT ON 21 AUGUST 2003 ITS INTEREST IN THE USD0.25 ORDINARY SHARES OF ASTRAZENECA PLC HAD INCREASED TO 240,060,302 SHARES (14.03 PER CENT OF THE CURRENT ISSUED ORDINARY CAPITAL) FROM THE PREVIOUSLY NOTIFIED LEVEL OF 222,868,165 SHARES (13.00 PER CENT).

G H R MUSKER  
COMPANY SECRETARY  
27 AUGUST 2003