

**25 POST-RETIREMENT BENEFITS CONTINUED****Fair value of scheme assets**

	2007			2006		
	UK \$m	Rest of Group \$m	Total \$m	UK \$m	Rest of Group \$m	Total \$m
At beginning of year	6,078	2,493	<b>8,571</b>	5,314	2,284	7,598
Expected return on plan assets	402	171	<b>573</b>	364	154	518
Expenses	(9)	–	<b>(9)</b>	(9)	–	(9)
Actuarial (loss)/gain	(185)	(24)	<b>(209)</b>	(259)	55	(204)
Exchange	90	2	<b>92</b>	760	126	886
Contributions	245	101	<b>346</b>	204	157	361
Benefits paid	(311)	(99)	<b>(410)</b>	(296)	(97)	(393)
Settlements	–	–	<b>–</b>	–	(186)	(186)
At end of year	6,310	2,644	<b>8,954</b>	6,078	2,493	8,571

It is expected that the contributions to the scheme during the year ended 31 December 2008 will be \$236m.

Included in total assets and obligations for the UK scheme is £166m in respect of members defined contribution sections. Costs in respect of defined contribution schemes during the year were \$105m (2006 \$62m, 2005 \$71m).

**Reserves**

Included within the retained earnings reserve is the actuarial reserve. Movements on this reserve are as follows:

	2007 \$m	2006 \$m	2005 \$m
At 1 January	<b>(401)</b>	(328)	(303)
Actuarial losses	<b>(113)</b>	(108)	(35)
Deferred tax	<b>35</b>	35	10
At 31 December	<b>(479)</b>	(401)	(328)

The cumulative amount of actuarial losses before deferred tax recognised in the statement of recognised income and expense is \$635m (2006 \$522m).

**26 EMPLOYEE COSTS AND SHARE OPTION PLANS FOR EMPLOYEES****Employee costs**

The average number of people employed by the Group is set out in the table below. In accordance with the Companies Act 1985, this includes part-time employees:

<b>Employees</b>	2007	2006	2005
Average number of people employed by the Group in:			
UK	<b>11,800</b>	11,800	11,600
Continental Europe	<b>25,600</b>	26,600	26,200
The Americas	<b>20,200</b>	18,200	17,900
Asia, Africa & Australasia	<b>10,300</b>	10,000	9,200
Continuing operations	<b>67,900</b>	66,600	64,900

The number of people employed by the Group at the end of 2007 was 67,400 (2006 66,800, 2004 65,300).

The costs incurred during the year in respect of these employees were:

	2007 \$m	2006 \$m	2005 \$m
Salaries	<b>5,217</b>	4,580	4,270
Social security costs	<b>858</b>	832	670
Pension costs	<b>449</b>	390	339
Other employment costs	<b>584</b>	553	482
	<b>7,108</b>	6,355	5,761

Severance costs of \$724m are not included above (2006 \$66m, 2005 \$29m).

## NOTES TO THE FINANCIAL STATEMENTS CONTINUED

**26 EMPLOYEE COSTS AND SHARE OPTION PLANS FOR EMPLOYEES CONTINUED**

The Directors believe that, together with the basic salary system, the Group's employee incentive schemes provide competitive and market-related packages to motivate employees. They should also align the interests of employees with those of shareholders, as a whole, through long-term share ownership in the Company. The Group's current UK, Swedish and US schemes are described below; other arrangements apply elsewhere.

**Bonus plans****The AstraZeneca UK Performance Bonus Plan**

Employees of participating AstraZeneca UK companies are invited to participate in this bonus plan, which rewards strong individual performance. Bonuses are paid partly in the form of Ordinary Shares in the Company (under the Inland Revenue-approved AstraZeneca All-Employee Share Plan and up to a maximum annual value of £3,000) and partly in cash. A tax-efficient share retention scheme, under which employees leave their bonus shares in trust for three to five years, forms part of the All-Employee Share Plan. The Company also offers UK employees the opportunity to buy Partnership Shares (Ordinary Shares) under the All-Employee Share Plan. Employees may invest up to £1,500 over a 12 month accumulation period and purchase Partnership Shares in the Company with the total proceeds at the end of the period. The purchase price for the shares is the lower of the price at the beginning or the end of the 12 month period. A tax-efficient share retention scheme is also available in respect of Partnership Shares. At the Company's AGM in 2002, shareholders approved the issue of new shares for the purposes of the All-Employee Share Plan.

**The AstraZeneca Executive Annual Bonus Scheme**

This scheme is a performance bonus scheme for Directors and senior employees who do not participate in the AstraZeneca UK Performance Bonus Plan. Annual bonuses are paid in cash and reflect both corporate and individual performance measures. The Remuneration Committee has discretion to reduce or withhold bonuses if business performance falls sufficiently short of expectations in any year such as to make the payment of bonuses inappropriate.

**The AstraZeneca Deferred Bonus Plan**

This plan was introduced in 2006 and is used to defer a portion of the bonus earned under the AstraZeneca Executive Annual Bonus Scheme into Ordinary Shares in the Company for a period of three years. The plan currently operates only in respect of Executive Directors and members of the Senior Executive Team (SET). Awards of shares under this plan are typically made in February each year, the first award having been made in February 2006.

**The AstraZeneca Performance Share Plan**

This plan was approved by shareholders in 2005 for a period of 10 years. Generally, awards can be granted at any time, but not during a close period of the Company. The first grant of awards was made in June 2005. The main grant of awards in 2007 under the plan was in March, at the same time as options were granted under the AstraZeneca Share Option Plan, with further smaller grants in August and November. Awards granted under the plan vest after three years depending on the performance of the Company compared to that of a selected peer group of other pharmaceutical companies. The Remuneration Committee has responsibility for agreeing any awards under the plan and for setting the policy for the way in which the plan should be operated, including agreeing performance targets and which employees should be invited to participate. A fuller description of this plan can be found on page 103 in the Directors' Remuneration Report.

**The AstraZeneca Pharmaceuticals LP Restricted Stock Unit Award Plan**

This plan was introduced in 2007 and provides for the grant of restricted stock unit (RSU) awards (Awards) to selected employees (predominantly in the US). The RSU Plan is used in conjunction with the AstraZeneca Share Option Plan to provide a mix of restricted stock units and share options. Awards typically vest on the third anniversary of the date of grant and are contingent on continued employment with the Company. The RSU Plan has also been used in 2007 to make Awards to certain employees within the MedImmune part of the Group.

**Sweden**

In Sweden an all-employee performance bonus plan is in operation, which rewards strong individual performance. Bonuses are paid partly into a fund investing 50% in AstraZeneca equities and partly in cash. The AstraZeneca Executive Annual Bonus Scheme, the AstraZeneca Share Option Plan and the AstraZeneca Performance Share Plan all operate in respect of relevant AstraZeneca employees in Sweden.

**US**

In the US, there are two all-employee performance bonus plans in operation, which reward strong individual performance. Annual bonuses are paid in cash. There are also two senior staff incentive schemes, under which approximately 450 participants may be eligible for awards granted as either AstraZeneca ADSs or stock appreciation rights related to AstraZeneca ADSs. AstraZeneca ADSs necessary to satisfy the awards are purchased in the market. The AstraZeneca Share Option Plan and the AstraZeneca Pharmaceuticals LP Restricted Stock Unit Award Plan both operate in respect of relevant AstraZeneca employees in the US.

**26 EMPLOYEE COSTS AND SHARE OPTION PLANS FOR EMPLOYEES CONTINUED****AstraZeneca Performance Share Plan**

	Shares '000	WAFV* pence
Shares awarded in June 2005	312	1121
Shares awarded in March 2006	280	1486
Shares awarded in May 2006	19	1424
Shares awarded in March 2007	1,611	1372
Shares awarded in August 2007	68	1217
Shares awarded in November 2007	16	1105

**US incentive share schemes**

	Shares '000	WAFV* \$
	1,028	50.86

**Restricted Stock Unit Award Plan**

	Units '000	WAFV* \$
Units awarded in March 2007	755	26.90
Units awarded in November 2007	270	21.56

\* Weighted average fair value.

The fair values were determined using a modified version of the binomial model. This method incorporated expected dividends but no other features into the measurements of fair value.

The charge for share-based payments in respect of the AstraZeneca Performance Share Plan, the US incentive share schemes and restricted stock unit award plan is \$31m (2006 \$14m, 2005 \$15m). The plans are equity-settled.

**Share option plans**

At 31 December 2007, there were options outstanding under the Zeneca 1994 Executive Share Option Scheme, the AstraZeneca Savings-Related Share Option Scheme, the AstraZeneca Savings-Related Share Option Plan and the AstraZeneca Share Option Plan.

**(1) Summary of the AstraZeneca Share Option Plan**

This is a share option plan for employees of participating AstraZeneca Group companies which was approved by shareholders at the Company's AGM in 2000. The first grant of options occurred in August 2000. The main grant of options in 2007 under the plan was in March, with further smaller grants in August and November. The Remuneration Committee sets the policy for the Company's operation of the plan and, in accordance with the rules of the plan, conducted a review of the plan in 2004.

**Eligibility**

Any AstraZeneca employee may be recommended from time to time for the grant of an option. The Remuneration Committee sets the policy for the Company's operation of the plan including as regards which employees will be eligible to participate.

**Grant of options**

Options may be granted at any time other than during a close period. The grant of options is supervised by the Remuneration Committee, which is comprised wholly of Non-Executive Directors. No payment is required for the grant of an option. Options are not transferable. Options may be granted over AstraZeneca Ordinary Shares or ADSs.

**Acquisition price**

The price per Ordinary Share payable upon the exercise of an option will not be less than an amount equal to the average of the middle-market closing price for an Ordinary Share or ADS of the Company on the London or New York Stock Exchange on the three consecutive dealing days immediately before the date of grant (or as otherwise agreed with HM Revenue & Customs). Where the option is an option to subscribe, the price payable upon exercise cannot be less than the nominal value of an Ordinary Share of the Company.

## NOTES TO THE FINANCIAL STATEMENTS CONTINUED

**26 EMPLOYEE COSTS AND SHARE OPTION PLANS FOR EMPLOYEES CONTINUED****Exercise of options**

An option will normally be exercisable between three and 10 years following its grant provided any relevant performance condition has been satisfied. Options may be satisfied by the issue of new Ordinary Shares or by existing Ordinary Shares purchased in the market. The Remuneration Committee sets the policy for the Company's operation of the plan including as regards whether any performance target(s) will apply to the grant and/or exercise of each eligible employee's option. Options normally lapse on cessation of employment. Exercise is, however, permitted for a limited period following cessation of employment either for reasons of injury or disability, redundancy or retirement, or at the discretion of the Remuneration Committee, and on an amalgamation, take-over or winding-up of the Company.

**(2) Summary of the AstraZeneca Savings-Related Share Option Scheme and the AstraZeneca Savings-Related Share Option Plan**

The AstraZeneca Savings-Related Share Option Scheme was approved by shareholders in 1994 for a period of 10 years. The last grant of options under this scheme was made in September 2002. In 2003, shareholders approved the AstraZeneca Savings-Related Share Option Plan for a period of 10 years. The first grant of options under this plan was made in September 2003. The following sections apply to both the AstraZeneca Savings-Related Share Option Scheme and the AstraZeneca Savings-Related Share Option Plan, which have broadly similar rules.

**Eligibility**

UK-resident employees of participating AstraZeneca companies are automatically eligible to participate.

**Grant of options**

Invitations to apply for options may be issued within six weeks after the announcement by the Company of its results for any period and at other times in circumstances considered to be exceptional by the Directors. No invitations may be issued later than 10 years after the approval of the scheme by shareholders. Options may only be granted to employees who enter into HM Revenue & Customs-approved savings contracts with the savings body nominated by the Company, under which monthly savings of a fixed amount (currently not less than £5 nor more than £250) are made over a period of three or five years. The number of Ordinary Shares over which an option is granted will be such that the total amount payable on its exercise will be the proceeds on maturity of the related savings contract. No payment will be required for the grant of an option. Options are not transferable.

**Individual participation**

Monthly savings by an employee under all savings contracts linked to options granted under any Save As You Earn scheme may not exceed £250 or such lower amounts as may be determined by the Directors.

**Acquisition price**

The price per Ordinary Share payable upon the exercise of an option will not normally be less than the higher of:

- (a) 90% of the arithmetical average of the middle-market quotations for an Ordinary Share on the London Stock Exchange on three consecutive dealing days shortly before the date on which invitations to apply for options are issued (provided that no such day may fall before the Company last announced its results for any period) or such other dealing day or days falling within the six week period for the issue of invitations, as the Directors may decide; and
- (b) the nominal value of an Ordinary Share (unless the option is expressed to relate only to existing Ordinary Shares).

**Exercise of options**

An option will normally be exercisable only for six months commencing on the third or fifth anniversary of the commencement of the related savings contract. Options are satisfied by the issue of new Ordinary Shares. Options normally lapse on cessation of employment. Exercise is, however, permitted for a limited period (irrespective of the period during which the option has been held) following cessation of employment in certain compassionate circumstances or where an option has been held for more than three years (except on dismissal for misconduct) and on an amalgamation, take-over or winding-up of the Company.

**(3) Summary of the Zeneca 1994 Executive Share Option Scheme**

The Zeneca 1994 Executive Share Option Scheme was introduced in 1994. The last date for the grant of options was 16 March 2000 and the scheme has been replaced by the AstraZeneca Share Option Plan. Options granted under the 1994 scheme are normally exercisable between three and 10 years following grant, provided the relevant performance condition has been satisfied. Options are satisfied by the issue of new Ordinary Shares. The performance condition applicable to the 1994 scheme was that earnings per share must have grown by at least the increase in the UK Retail Price Index over three years plus 3% per annum. Satisfaction of this condition was tested annually by reference to the audited financial statements. All options granted under the 1994 scheme have become exercisable, the performance conditions having been satisfied.

## NOTES TO THE FINANCIAL STATEMENTS CONTINUED

## 26 EMPLOYEE COSTS AND SHARE OPTION PLANS FOR EMPLOYEES CONTINUED

	AstraZeneca Share Option Plan		1994 Scheme		SAYE Schemes		Shares under option '000	ASVIP WAEP* SEK
	Options '000	WAEP* pence	Options '000	WAEP* pence	Options '000	WAEP* pence		
<b>At 1 January 2005</b>								
Options outstanding	44,136	2790	7,489	2650	4,113	2005	483	431
<b>Movements during 2005</b>								
Options granted	9,621	2133	–	–	606	2257	–	–
Options exercised	(1,053)	2486	(1,259)	2601	(689)	1782	(6)	442
Options forfeited	(2,625)	2800	(272)	2688	(592)	2248	(168)	411
Options lapsed	–	–	–	–	–	–	–	–
Weighted average fair value of options granted during the year		619				700		
<b>At 31 December 2005</b>								
Options outstanding	50,079	2670	5,958	2658	3,438	2053	309	442
<b>Movements during 2006</b>								
Options granted	9,266	2977	–	–	280	3001	–	–
Options exercised	(18,543)	2708	(4,038)	2665	(289)	2278	–	–
Options forfeited	(1,078)	2669	(14)	2862	(218)	2473	(309)	442
Options lapsed	–	–	–	–	–	–	–	–
Weighted average fair value of options granted during the year		857				943		
<b>At 31 December 2006</b>								
Options outstanding	39,724	2428	1,906	2371	3,211	2087	–	–
<b>Movements during 2007</b>								
Options granted	7,312	2737	–	–	1,074	2164	–	–
Options exercised	(2,770)	2648	(321)	2426	(1,327)	1785	–	–
Options forfeited	(1,706)	2745	(95)	2603	(238)	2528	–	–
Options lapsed	–	–	–	–	–	–	–	–
Weighted average fair value of options granted during the year		682				616		
<b>At 31 December 2007</b>								
Options outstanding	42,560	2451	1,490	2364	2,720	2226	–	–
Range of exercise prices		1477p to 3487p		2208p to 2749p		1756p to 3001p		n/a
Weighted average remaining contractual life		2,473 days		751 days		1,109 days		n/a
Options exercisable	19,637	2860	1,490	2689	350	1879	–	n/a

\*Weighted average exercise price.

## NOTES TO THE FINANCIAL STATEMENTS CONTINUED

## 26 EMPLOYEE COSTS AND SHARE OPTION PLANS FOR EMPLOYEES CONTINUED

	2007	2006	2005
Average share price (pence)	2599	3020	2384
Weighted average exercise price (pence)			
AstraZeneca Share Option Plan	2737	2977	2133
SAYE schemes	2164	3001	2257
Weighted average fair value of options granted in the period (pence)			
AstraZeneca Share Option Plan	682	857	619
SAYE schemes	616	943	700
Expected volatility (%)	25.0	30.0	30.0
Dividend yield (%)	2.6	2.3	2.3
Risk-free interest rate (%)	4.8	4.3	4.3
Expected lives: AstraZeneca Share Option Plan (years)	6.0	6.0	6.0
Expected lives: SAYE schemes (years)	4.3	4.1	3.9

The expected volatility is based on the historic volatility (calculated based on the weighted average remaining life of the share options) adjusted for any expected changes to future volatility due to publicly available information.

No other features of options granted were incorporated into the measurement of fair value.

The charge for share-based payments in respect of share options is \$124m (2006 \$125m, 2005 \$128m) which is comprised entirely of equity-settled transactions.

## 27 COMMITMENTS AND CONTINGENT LIABILITIES

	2007 \$m	2006 \$m	2005 \$m
<b>Commitments</b>			
Contracts placed for future capital expenditure not provided for in these accounts	571	383	220

Included in the above total are contracts related to certain product purchase and licence agreements with deferred consideration obligations, the amounts of which are variable depending upon particular 'milestone' achievements. Sales of the products to which these milestones relate could give rise to additional payments, contingent upon the sales levels achieved. Guarantees and contingencies arising in the ordinary course of business, for which no security has been given, are not expected to result in any material financial loss.

## Arrangements with Merck

## Introduction

In 1982, Astra AB set up a joint venture with Merck & Co., Inc. for the purposes of selling, marketing and distributing certain Astra products in the US. In 1998, this joint venture was restructured (the "Restructuring"). Under the agreements relating to the Restructuring (the "Agreements"), a US limited partnership was formed, in which Merck is the limited partner and AstraZeneca is the general partner, and AstraZeneca obtained control of the joint venture's business subject to certain limited partner and other rights held by Merck and its affiliates. These rights provide Merck with safeguards over the activities of the partnership and place limitations on AstraZeneca's commercial freedom to operate. The Agreements provide for:

- > Annual contingent payments.
- > A payment to Merck in the event of a business combination between Astra and a third party in order for Merck to relinquish certain claims to that third party's products.
- > Termination arrangements which, if and when triggered, cause Merck to relinquish its interests in AstraZeneca's products and activities.

These elements are discussed in further detail below together with a summary of their accounting treatments.

## Annual contingent payments

AstraZeneca makes ongoing payments to Merck based on sales of certain of its products in the US (the "contingent payments" on the "agreement products"). As a result of the merger of Astra and Zeneca in 1999, these contingent payments (excluding those in respect of *Prilosec* and *Nexium*) cannot be less than annual minimum sums between 2002 and 2007 ranging from \$125m to \$225m. AstraZeneca's payments have exceeded the minimum level in all years.

## Payment in the event of a business combination

On the merger of Astra and Zeneca, a one-time Lump Sum Payment of \$809m was triggered. As a result of this payment, Merck relinquished any claims it may have had to Zeneca products.

## 27 COMMITMENTS AND CONTINGENT LIABILITIES CONTINUED

### Termination arrangements

The Agreements provided for arrangements and payments under which, subject to the exercise of certain options, the rights and interests in AstraZeneca's activities and products held by Merck immediately prior to the merger would be terminated, including details of:

- > The Advance Payment.
- > The Partial Retirement.
- > The First Option and True-Up.
- > The Loan Note Receivable.
- > The Second Option.

### Advance Payment

The merger between Astra and Zeneca triggered the first step in the termination arrangements. Merck relinquished all rights, including contingent payments on future sales, to potential Astra products with no existing or pending US patents at the time of the merger. As a result, AstraZeneca now has rights to such products and is relieved of potential obligations to Merck and restrictions in respect of those products (including annual contingent payments), affording AstraZeneca substantial freedom to exploit the products as it sees fit.

At the time of the merger, the Advance Payment was paid. It was calculated as the then net present value of \$2.8bn discounted from 2008 to the date of merger at a rate of 13% per annum and amounted to \$967m. It is subject to a true-up in 2008, as discussed under "First Option and True-Up" below.

### Partial Retirement

In March 2008, there will be a partial retirement of Merck's limited partnership interest by payment to Merck of an amount calculated as a multiple of the average annual contingent payments from 2005 to 2007 on the relevant products, plus \$750m. See "General" below for the current estimate of the amount of this payment.

Upon the Partial Retirement, Merck's rights in respect of certain of the agreement products will end. The products covered by the Partial Retirement include *Toprol-XL*, *Pulmicort*, *Rhinocort* and *Symbicort*.

### First Option and True-Up

In 2008, a calculation will be made of the Appraised Value, being the net present value of the future contingent payments in respect of all agreement products not covered by the Partial Retirement, other than *Prilosec* and *Nexium*. Payment of the Appraised Value to Merck in March 2008 will take place only if Merck exercises the First Option. Should Merck not exercise this option in 2008, AstraZeneca may exercise it in 2010 for a sum equal to the 2008 Appraised Value. See "General" below for the current estimate of the amount of this payment. Contingent payments will continue from 2008 to 2010 if AstraZeneca exercises in 2010.

Upon exercise of the First Option, Merck will relinquish its rights over the agreement products not covered by the Partial Retirement, other than *Nexium* and *Prilosec*. If neither Merck nor AstraZeneca exercises the option, the contingent payment arrangements in respect of these agreement products will continue (as will AstraZeneca's other obligations and restrictions in respect of these products) and the Appraised Value will not be paid. Products covered by the First Option include *Atacand*, *Plendil*, *Entocort* and certain compounds still in development.

In addition, in 2008 there will be a true-up of the Advance Payment. The true-up amount will be based on a multiple of the average annual contingent payments from 2005 to 2007 in respect of all the agreement products with the exception of *Prilosec* and *Nexium* (subject to a minimum of \$6.6bn), plus other defined amounts (totalling \$912m). It is then reduced by the Appraised Value (whether paid or not), the Partial Retirement and the Advance Payment (at its undiscounted amount of \$2.8bn) to determine the true-up amount. The true-up will be settled in 2008 irrespective of whether the First Option is exercised, and this could result in a further payment by AstraZeneca to Merck or, more likely, a payment by Merck to AstraZeneca. See "General" below for the current estimate of the amount of this payment.

Should Merck exercise the First Option in 2008, AstraZeneca will make payments in respect of the Partial Retirement, the First Option and the true-up totalling a minimum of \$4.7bn. If AstraZeneca exercises the First Option in 2010, the combined effect of the amounts paid to Merck in 2008 and 2010 will total the same amount.

### Loan Note Receivable

Included in the assets and liabilities covered by the Restructuring is a loan note receivable by AstraZeneca from Merck with a face value of \$1.4bn. In 2008, at the same time as the settlement of the Partial Retirement and the true-up, Merck will settle the loan note receivable by paying AstraZeneca \$1.4bn.

### Second Option

A Second Option exists whereby AstraZeneca has the option to repurchase Merck's interests in *Prilosec* and *Nexium* in the US. This option is exercisable by AstraZeneca two years after the exercise of the First Option, whether the First Option is exercised in either 2008 or 2010. Exercise of the Second Option by AstraZeneca at a later date is also provided for in 2017 or if combined annual sales of the two products fall below a minimum amount provided, in each case, that the First Option has been exercised. The exercise price for the Second Option is the net present value of the future annual contingent payments on *Prilosec* and *Nexium* as determined at the time of exercise. If the Second Option is exercised, Merck will then have relinquished all its interests in the partnership and the agreement products including rights to contingent payments.

## NOTES TO THE FINANCIAL STATEMENTS CONTINUED

**27 COMMITMENTS AND CONTINGENT LIABILITIES CONTINUED****General**

The precise timing and amount of settlements with Merck under the Partial Retirement, the First Option and the true-up cannot be determined at this time. For example, the payment of the First Option is contingent upon Merck (or AstraZeneca) exercising the First Option. Similarly, the timing and amount of the Second Option cannot be determined at this time. The amount of the true-up, the Partial Retirement and the Appraised Value, have been estimated, and are subject to finalisation. However, the total payments in respect of the Partial Retirement, the true-up and the First Option will not exceed the minimum of \$4.7bn referred to above should the First Option be exercised. We estimate the amount of the Partial Retirement will be approximately \$4.3bn, the amount of the Appraised Value will be approximately \$0.6bn and the amount of the true-up (a payment from Merck to AstraZeneca) will be approximately \$0.2bn.

If Merck exercises the First Option in 2008, the net minimum payment to be made to Merck, being the combined payments of \$4.7bn less the repayment of the loan note of \$1.4bn, will be \$3.3bn. In accounting for the Restructuring in 1998, the loan note was included in the determination of the fair values of the assets and liabilities to be acquired. At that time, the loan note was ascribed a fair value of zero on acquisition and on the balance sheet because it was estimated that the net minimum payment of \$3.3bn equated to the fair value of the rights to be acquired under the Partial Retirement, true-up and First Option.

AstraZeneca anticipates that the benefits that accrue under all the termination arrangements arise:

- > Currently, from the substantial freedom over products acquired or discovered post-merger.
- > On occurrence of each stage of such arrangements, from enhanced contributions from, and substantial freedom over, those products that have already been launched (for example, *Pulmicort*, *Symbicort*, *Rhinocort* and *Atacand*), and those that are in development.
- > Economic benefits include relief from contingent payments, anticipated cost savings from cessation of manufacturing arrangements and other cost efficiencies, together with the strategic advantages of increased freedom to operate.

**Accounting treatments****Annual contingent payments**

The annual contingent payments on agreement products are expensed as incurred.

**Payment in the event of a business combination**

The Lump Sum Payment was expensed at the point of merger since it caused no incremental benefits over the prior years' aggregate Astra and Zeneca performance to accrue to the merged AstraZeneca entity.

**Termination arrangements**

AstraZeneca considers that the termination arrangements described above represent the acquisition, in stages, of Merck's interests in the partnership and agreement products (including Merck's rights to contingent payments) and depend, in part, on the exercise of the First and Second Options. The effects will only be reflected in the Financial Statements as these stages are reached. If and when all such payments are made, AstraZeneca will have unencumbered discretion in its operations in the US market.

The Advance Payment has been accounted for as an intangible asset and is being amortised over 20 years. This approach reflects the fact that, under the Agreements, AstraZeneca has acquired rights relieving it of potential obligations and restrictions in respect of Astra products with no existing or pending patents at the time of merger. Although these rights apply in perpetuity, the period of amortisation of 20 years has been chosen to reflect the typical timescale of development and marketing of a product.

The net payment expected to be made (\$2.6bn, or \$3.3bn if Merck exercises the First Option) will be capitalised as intangible assets representing acquired product rights.

Ongoing monitoring of the projected payments to Merck and the value to AstraZeneca of the related rights takes full account of changing business circumstances and the range of possible outcomes to ensure that the payments to be made to Merck are covered by the economic benefits expected to be realised, including those attributable to the strategic benefits of being relieved from some or all of the restrictions of the partnership with Merck. Should the monitoring reveal that these payments exceed the economic benefits expected to be realised, a provision for an onerous contract would be recognised.

**Environmental costs and liabilities**

The Group's expenditure on environmental protection, including both capital and revenue items, relates to costs which are necessary for implementing internal systems and programmes and meeting legal and regulatory requirements for processes and products.

They are an integral part of normal ongoing expenditure for carrying out the Group's research, manufacturing and commercial operations and are not separated from overall operating and development costs. There are no known changes in legal, regulatory or other requirements resulting in material changes to the levels of expenditure for 2005, 2006 or 2007.

In addition to expenditure for meeting current and foreseen environmental protection requirements, the Group incurs costs in investigating and cleaning up land and groundwater contamination. In particular, AstraZeneca and/or its affiliates have environmental liabilities at some currently or formerly owned, leased and third party sites.

## 27 COMMITMENTS AND CONTINGENT LIABILITIES CONTINUED

In the US, the AstraZeneca affiliate, Zeneca Inc., and/or its indemnitees, have been named as potentially responsible parties (PRPs) or defendants at approximately 19 sites where Zeneca Inc. is likely to incur future investigation, remediation or operation and maintenance costs under federal or state, statutory or common law environmental liability allocations schemes. Similarly, the AstraZeneca affiliate, Stauffer Management Company LLC (SMC), which was established in 1987 to own and manage certain assets of Stauffer Chemical Company acquired that year, and/or its indemnitees, have been named as PRPs or defendants at approximately 28 sites where SMC is likely to incur future investigation, remediation or operation and maintenance costs under federal or state, statutory or common law environmental liability allocations schemes. In Europe and other parts of the world outside the US, AstraZeneca is likely to incur costs at one currently owned site and has given indemnities to third parties in respect of approximately 45 other sites. These environmental liabilities arise from legacy operations that are not part of the Group's current pharmaceuticals business and, at most of these sites, remediation, where required, is either completed or nearing completion.

AstraZeneca has made provisions for the estimated costs of future environmental investigation, remediation and operation and maintenance activity beyond normal ongoing expenditure for maintaining the Group's R&D and manufacturing capacity and product ranges where a present obligation exists, it is probable that such costs will be incurred, and they can be estimated reliably. With respect to such estimated future costs, there were provisions at 31 December 2007 in the aggregate of \$111m, which mainly relate to the US. These provisions do not include possible additional costs that are not currently probable. Where we are jointly liable or otherwise have cost sharing agreements with third parties we reflect only our share of the obligation. Where the liability is insured in part or in whole by insurance or other arrangements for reimbursement, an asset is recognised to the extent that this recovery is virtually certain.

It is possible that the Company, or its affiliates, could incur future environmental costs beyond the extent of our current provisions. The extent of such possible, additional costs is inherently difficult to estimate due to a number of factors, including, but not limited to: (1) the nature and extent of claims that may be asserted in the future; (2) whether the Company or any of its affiliates has or will have any legal obligation with respect to asserted or unasserted claims; (3) the type of remedial action, if any, that may be selected at sites where the remedy is presently not known; (4) the potential for recoveries from or allocation of liability to third parties; and (5) the length of time that the environmental investigation, remediation and liability allocation process can take. Notwithstanding and subject to the foregoing, it is estimated that potential additional loss for future environmental investigation, remediation and remedial operation and maintenance activity above and beyond our provisions could be, in the aggregate, in the order of \$25-40m of which \$15-30m relates to the US.

### Legal proceedings

AstraZeneca is involved in various legal proceedings considered typical to its businesses, including litigation relating to employment, product liability, commercial disputes, infringement of intellectual property rights, the validity of certain patents, anti-trust, securities laws and governmental investigations. The more significant matters are discussed below.

Most of the claims involve highly complex issues. Often, these issues are subject to substantial uncertainties and therefore the probability of a loss, if any, being sustained and an estimate of the amount of any loss are difficult to ascertain. Consequently, for a majority of these claims, it is not possible to make a reasonable estimate of the expected financial effect, if any, that will result from ultimate resolution of the proceedings. In these cases, AstraZeneca discloses information with respect to the nature and facts of the case.

With respect to each of the legal proceedings described below, other than those which have been disposed of, we are unable to make estimates of the possible loss or range of possible losses at this stage, other than where noted in the case of the European Commission fine and the proposed settlement with class 1 plaintiffs in the Average Wholesale Price litigation. We also do not believe that disclosure of the amount sought by plaintiffs, if that is known, would be meaningful with respect to those legal proceedings. This is due to a number of factors including: the stage of the proceedings (in many cases trial dates have not been set) and the overall length and extent of pre-trial discovery; the entitlement of the parties to an action to appeal a decision; clarity as to theories of liability; damages and governing law; uncertainties in timing of litigation; and the possible need for further legal proceedings to establish the appropriate amount of damages, if any. However, although there can be no assurance regarding the outcome of any of the legal proceedings or investigations referred to in this Note 27 to the Financial Statements, we do not expect them to have a materially adverse effect on our financial position.

In cases that have been settled or adjudicated, or where quantifiable fines and penalties have been assessed or where a loss is probable and we are able to make a reasonable estimate of the loss, we indicate the loss absorbed or the amount of the provision accrued (which includes all related legal costs). No provisions have been made for any such claims and legal costs incurred discussed below other than the European Commission fine which has been paid and the settlement with certain parties under the Average Wholesale Price litigation.

Where it is considered that the Group is more likely than not to prevail, legal costs involved in defending the claim are charged to the income statement as they are incurred.

Where it is considered that the Group has a valid contract which provides the right to reimbursement (from insurance or otherwise) of legal costs and/or all or part of any loss incurred or for which a provision has been established, the best estimate of the amount expected to be received is recognised as an asset.

Assessments as to whether or not to recognise provisions or assets and of the amounts concerned usually involve a series of complex judgements about future events and can rely heavily on estimates and assumptions. AstraZeneca believes that the provisions recorded are adequate based on currently available information and that the insurance recoveries recorded will be received. However, given the inherent uncertainties involved in assessing the outcomes of these cases and in estimating the amount of the potential losses and the associated insurance recoveries, we could in future periods incur judgments or insurance settlements that could have a material adverse effect on our results in any particular period.

## NOTES TO THE FINANCIAL STATEMENTS CONTINUED

**27 COMMITMENTS AND CONTINGENT LIABILITIES CONTINUED**

Intellectual property claims include challenges to the Group's patents on various products or processes and assertions of non-infringement of patents. A loss in any of these cases could result in loss of patent protection on the related product. The consequences of any such loss could be a significant decrease in sales of the product which could materially affect the future results of the Group. The lawsuits pending against companies that have filed abbreviated new drug applications (ANDAs) in the US, seeking to market generic forms of products sold by the Group prior to the expiry of the applicable patents covering these products typically include allegations of non-infringement, invalidity and unenforceability of these patents. In the event that the Group is not successful in these actions or the statutory 30-month stay expires before a ruling is obtained, the companies involved will also have the ability, subject to US Food and Drug Administration (FDA) approval, to introduce generic versions of the product concerned. 30-month stays will not prevent the FDA from approving ANDAs for *Nexium*, *Pulmicort Respules* and *Seroquel* in the year ending 31 December 2008.

**Abraxane® (paclitaxel protein-bound particles for injectable suspension) (albumin-bound)**

In July 2006, Elan Pharma International Limited (Elan) filed a lawsuit in the US District Court for the District of Delaware against Abraxis BioScience, Inc. (Abraxis). Elan essentially alleges that Abraxis infringes two US patents in connection with the marketing, use and sale of Abraxane®. During 2007, the Court held a Markman hearing and issued an opinion on claims construction. Expert and fact discovery are ongoing. No trial date has been set. AstraZeneca is not named as a party in the lawsuit. AstraZeneca is party to an agreement with Abraxis to co-promote Abraxane® in the US.

**Atacand (candesartan cilexetil)**

In April 2007, AstraZeneca (new drug application (NDA) holder) and Takeda (patent holder) received notice from Sandoz Inc. (Sandoz) that Sandoz had filed an ANDA with the FDA, seeking approval to market a generic version of *Atacand* (candesartan cilexetil) in the 4, 8, 16 and 32mg doses, prior to the expiration of US Patent No. 5534534 (the '534 patent), which expires in July 2013. The notification claims that the Sandoz product does not infringe the '534 patent. Sandoz did not challenge the compound patents listed in the FDA Orange Book with reference to *Atacand*, the later of which expires in June 2012. As a result, Sandoz cannot market candesartan cilexetil until the end of the exclusivity period afforded by these patents. AstraZeneca and Takeda have decided not to bring an action for patent infringement at this time.

**Crestor (rosuvastatin)**

From 2004 to present, AstraZeneca Pharmaceuticals LP and/or AstraZeneca LP in the US were served with 15 individual lawsuits in various US jurisdictions, alleging injury in association with the use of *Crestor*. 11 of the cases were dismissed in early stages, and another was dismissed after the court granted AstraZeneca's motion for summary judgment in June 2007. These decisions were not appealed by the plaintiffs. AstraZeneca intends to vigorously defend the remaining cases, all of which are still in preliminary stages. In addition, a motion to institute a class action was filed in Quebec, Canada against AstraZeneca PLC and AstraZeneca Canada Inc. in which the petitioners alleged injury as a result of the use of *Crestor*. In March 2007, the Court granted the named plaintiff's request to discontinue this action.

AstraZeneca lists three patents in the FDA Orange Book: No. RE37,314 covering the active ingredient (the '314 patent); No. 6,316,460 covering formulations (the '460 patent); and No. 6,858,618 covering medical use (the '618 patent). The '314 patent expires in January 2016, the '460 patent expires in August 2020 and the '618 patent expires in December 2021. Between 30 October 2007 and 6 December 2007, AstraZeneca received Paragraph IV certification notice-letters from Apotex, Inc. (Apotex); Aurobindo Pharma Limited (Aurobindo); Cobalt Pharmaceuticals Inc. and Cobalt Laboratories Inc. (together Cobalt); Glenmark Pharmaceuticals Inc. USA (Glenmark); Mylan Pharmaceuticals, Inc. (Mylan); Par Pharmaceutical, Inc. (Par); Sandoz, Inc. (Sandoz); Sun Pharmaceuticals Industries Limited (Sun); and Teva Pharmaceuticals USA, Inc (Teva). Each entity notified AstraZeneca that it had submitted an ANDA to the FDA for approval to market *Crestor* 5, 10, 20 and 40mg rosuvastatin calcium tablets prior to the expiration of one or more of AstraZeneca's three FDA Orange Book-listed patents. The notice-letters notified AstraZeneca that each respective ANDA contained a Paragraph IV certification alleging non-infringement, invalidity or unenforceability of one or more of AstraZeneca's three patents. In December 2007, in response to notice-letters from seven of the nine manufacturers, AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals, Inc., and AstraZeneca's licensor, Shionogi Seiyaku Kabushiki Kaisha (Shionogi), filed separate lawsuits in the US District Court for the District of Delaware, against Apotex, Aurobindo, Cobalt, Mylan, Par, Sandoz and Sun for infringement of the patent covering rosuvastatin calcium, the active ingredient in *Crestor* tablets. AstraZeneca did not file patent infringement actions against Teva and Glenmark because they did not seek approval to market products before the 2016 expiration date of the patent covering the active ingredient. In addition to filing actions in the US District Court for the District of Delaware, for procedural reasons, AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals, Inc. and Shionogi filed three duplicate patent infringement actions against Mylan, Aurobindo and Cobalt respectively in US District Courts in West Virginia, New Jersey and Florida. These cases proceed.

AstraZeneca continues to have full confidence in and will vigorously defend and enforce its intellectual property protecting *Crestor*.

## 27 COMMITMENTS AND CONTINGENT LIABILITIES CONTINUED

### *Exanta* (ximelagatran)

Four putative and essentially similar securities class actions were filed in the US against AstraZeneca PLC, Håkan Mogren (who currently serves as a Director of AstraZeneca PLC), Sir Tom McKillop, Jonathan Symonds and Percy Barnevik (who are former Directors of AstraZeneca PLC) between January and March 2005. These actions were subsequently consolidated into a single action pending in the US District Court for the Southern District of New York. The Consolidated Amended Complaint alleges that the defendants made materially false and misleading statements regarding *Exanta* clinical trials and the status of the *Exanta* new drug application in the US. The plaintiffs purport to assert claims on behalf of purchasers of AstraZeneca publicly traded securities during the period April 2003 to September 2004 under sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and SEC Rule 10b-5.

The defendants deny the allegations made in the lawsuit and will vigorously defend the action. In 2006 they filed a motion to dismiss the action, and that motion is pending before the Court.

### *Iressa* (gefitinib)

During 2004, 2005 and 2006, six claims were filed against AstraZeneca KK in Japan, in the Osaka and Tokyo District Courts. In five of the claims, it is alleged that *Iressa* caused a fatal incidence of interstitial lung disease (ILD) in a Japanese patient. In the sixth claim, it is alleged that *Iressa* caused a non-fatal incidence of ILD. AstraZeneca KK, following consultation with external legal advisers, believes the claims are without merit and is defending all the cases. ILD is a known complication of lung disease, including advanced lung cancer, regardless of treatment.

### *Losec/Prilosec* (omeprazole)

In 2001, AstraZeneca filed a suit in the US against Andrx Pharmaceuticals, Inc. (Andrx) for infringement of a patent number 6,013,281 directed to a process for making an omeprazole formulation (the '281 patent). Andrx filed counterclaims of non-infringement, invalidity and unenforceability for inequitable conduct during prosecution of the '281 patent. Andrx also asserted that in addition to the '281 patent, two other formulation patents, numbered 4,786,505 and 4,853,230 (the '505 and '230 patents) were unenforceable for alleged litigation misconduct by AstraZeneca. Both parties sought attorneys' fees. In May 2004, the US District Court for the Southern District of New York ruled that the '281 patent was infringed, but also ruled that the '281 patent was invalid.

The US District Court for the Southern District of New York dismissed Andrx's litigation misconduct and other counterclaims and affirmative defences, leaving intact the Court's October 2002 decision finding the '230 and '505 patents not invalid and infringed by Andrx. The Court's October 2002 decision was affirmed in all respects on appeal in December 2003. The Court entered final judgment regarding the '281 patent in July 2004, after determining to stay the attorneys' fees claims pending any appeals. Andrx appealed the judgment and AstraZeneca cross-appealed. The appeal was argued to the US Court of Appeals for the Federal Circuit in August 2006. In April 2007, the Federal Circuit affirmed the lower court decision that the asserted claims of the '281 patent are invalid. The Federal Circuit also concluded that AstraZeneca's '505 and '230 formulation patents remained enforceable. As a result of Andrx's infringement of the '505 and '230 patents, AstraZeneca was the prevailing party against Andrx in the lower court. AstraZeneca is pursuing appropriate relief, including damages.

During 2000 and 2001, AstraZeneca had filed suits against Lek Pharmaceutical and Chemical Company d.d. and Lek Services USA, Inc. (together Lek), Impax Laboratories Inc. (Impax), Eon Labs Manufacturing Inc. (Eon), Mylan Pharmaceuticals Inc. (Mylan), Apotex Corp, Apotex, Inc. (together Apotex), Torpharm, Inc. (Torpharm) and Zenith Goldline Pharmaceuticals, Inc. (now known as IVAX Pharmaceuticals, Inc.) (IVAX). These suits followed the filing of ANDAs by these companies with the FDA concerning the companies' intention to market generic omeprazole products in the US. The basis for the proceedings is that the actions of all the companies infringe the '505 and '230 formulation patents relating to omeprazole. The cases are proceeding under the US Hatch-Waxman legislation. The case against IVAX was dismissed without prejudice shortly after it was filed, after IVAX withdrew its application to market generic omeprazole. During 2003, after Mylan commenced commercial sale of its product, AstraZeneca filed suit against Laboratorios Esteve, SA and Esteve Quimica, SA (together Esteve), manufacturers of the omeprazole product to be distributed in the US by Mylan. In 2003 and 2004, Lek, Apotex and Impax all began commercial sales of their generic omeprazole products. In July 2004, Lek filed a motion for summary judgment of non-infringement. In January 2005, AstraZeneca filed suit against Teva Pharmaceutical Industries Ltd and Teva Pharmaceuticals USA, Inc., which are marketing and selling Impax's omeprazole products. The Teva case was stayed in June 2005 until liability issues in the Impax action are resolved. AstraZeneca made claims for damages against each of the selling defendants. Anti-trust and non-infringement counterclaims were filed by Andrx, Apotex/Torpharm, Impax, Eon and Lek. All defendants except Lek have also raised invalidity and unenforceability counterclaims. The anti-trust counterclaims, as well as AstraZeneca's claims for damages, have been stayed pending resolution of the patent liability issues.

The cases were consolidated for discovery before, or are directly assigned to, Judge Jones in the US District Court for the Southern District of New York. All discovery in these cases was completed in February 2005. Briefing on the summary judgment motion filed by Lek and 14 additional motions for summary judgment were completed in July 2005. All of the defendants' motions for summary judgment were denied in January 2006. In February 2006, the Eon suit was dismissed after it announced it would not commence sales until after the '505 and '230 patents expired. In July 2005, AstraZeneca filed suit against Ranbaxy Laboratories Limited, Ranbaxy, Inc. and Ranbaxy Pharmaceuticals, Inc. (together Ranbaxy) for infringement of the '505 and '230 formulation patents. The Ranbaxy case was consolidated with the other omeprazole patent cases for pre-trial purposes. In March 2006, the Ranbaxy case was dismissed when it announced it would not commence sales until after the '505 and '230 patents expired.

## NOTES TO THE FINANCIAL STATEMENTS CONTINUED

**27 COMMITMENTS AND CONTINGENT LIABILITIES CONTINUED**

In January 2006, AstraZeneca withdrew its claims for damages against Impax, and as a result the Court struck Impax's jury demand. Impax appealed this decision on an interlocutory basis to the US Court of Appeals for the Federal Circuit, which denied the appeal, and then to the US Supreme Court, which also denied the appeal. From April to June 2006, Judge Jones conducted a consolidated bench trial on patent liability issues involving the remaining defendants, Mylan/Esteve, Lek, Apotex and Impax. Post-trial briefing was completed in July 2006.

In May 2007, the US District Court for the Southern District of New York upheld both formulation patents covering *Prilosec* (omeprazole), a ruling consistent with the previously disclosed decision in the first wave case in October 2002. The Court found that the generic omeprazole formulations of Impax and Apotex infringed both patents in suit. AstraZeneca is seeking appropriate relief, including damages. The Court also found that the generic omeprazole products sold by Lek and Mylan/Esteve did not infringe. Lek and Mylan/Esteve are pursuing costs, attorney's fees and anti-trust counterclaims. AstraZeneca has appealed the Mylan/Esteve decision to the US Court of Appeals for the Federal Circuit.

In April 2006, AstraZeneca received a notice from Dexcel Pharma Technologies, Ltd (Dexcel) that Dexcel had submitted a new drug application seeking FDA approval to market a 20mg omeprazole tablet for the over-the-counter (OTC) market. Dexcel seeks approval to market a generic omeprazole OTC product before the expiration of the patents listed in the FDA Orange Book in reference to AstraZeneca's *Prilosec* product and the *Prilosec* OTC that is marketed by The Procter & Gamble Co. (Procter & Gamble). In May 2006, AstraZeneca filed suit in the US District Courts for the District of Delaware and the Eastern District of Virginia charging Dexcel with infringement of the '505 and '230 patents and US Patent No. 6,150,380. In September 2007, the parties entered into a settlement agreement, and the cases have been dismissed in their entirety. The terms of the settlement are confidential and are not material to AstraZeneca.

In June 2007, AstraZeneca received a notice from Dr. Reddy's Laboratories, Ltd and from Dr. Reddy's Laboratories, Inc. (together, Dr Reddy's) that Dr. Reddy's had submitted an ANDA seeking FDA approval to market a 20mg delayed release omeprazole magnesium capsule for the OTC market. Dr. Reddy's seeks approval to market a generic omeprazole OTC product before the expiration of the patents listed in the FDA Orange Book in reference to the *Prilosec* OTC product that is marketed by Procter & Gamble. In July 2007, AstraZeneca commenced patent infringement litigation in the US District Court for the Southern District of New York against Dr. Reddy's in response to Dr. Reddy's Paragraph IV certifications regarding *Prilosec* OTC. No trial date has been set.

In June and July 2004, AstraZeneca applied in France for injunctions based on its omeprazole formulation patent against six companies for marketing generic omeprazole. In August 2004, the applications were rejected at first instance. AstraZeneca appealed this decision and in March 2005 the applications were rejected on appeal. In May 2004, AstraZeneca also started legal proceedings against the same companies for infringement of its omeprazole formulation patent in France. These proceedings have been consolidated with a case challenging the validity of the patent, brought by one of the companies against AstraZeneca. No date has yet been set for a hearing.

In 2001, AstraZeneca was granted an interlocutory injunction based on AstraZeneca's omeprazole formulation patents against the generic company A/S Gea Farmaceutiske Fabrik (now Hexal A/S). The parties have now settled this case. The terms of the settlement are confidential and are not material to AstraZeneca.

An interlocutory injunction against Biochemie Novartis Healthcare A/S was granted in Denmark during 2003, based on AstraZeneca's omeprazole formulation patent. The parties have now settled this case. The terms of the settlement are confidential and are not material to AstraZeneca.

In December 2004, an interlocutory injunction against Norneco A/S, a Danish distributor of a generic omeprazole product from ratiopharm, was granted in Denmark based on AstraZeneca's omeprazole formulation patent. The case was heard on appeal in November and December 2005 and, in February 2006, the High Court repealed the interlocutory injunction. The parties have now settled this case. The terms of the settlement are confidential and are not material to AstraZeneca.

During 2003 and 2004, AstraZeneca was denied interlocutory injunctions based on certain of its omeprazole patents against Novartis Sverige AB and ratiopharm AB in Sweden and Novartis Finland Oy and ratiopharm Oy in Finland. In 2002 and 2003, Novartis Sverige AB, ratiopharm AB and Arrow Läkemedel AB initiated cases to invalidate AstraZeneca's omeprazole formulation patent. AstraZeneca initiated infringement cases against Novartis Sverige AB and ratiopharm AB in Sweden, in 2003. The parties have now settled all of these cases. The terms of the settlement are confidential and are not material to AstraZeneca.

In Finland, the separate infringement proceedings against ratiopharm Oy and Novartis Finland Oy based on infringement of AstraZeneca's omeprazole formulation patent had been stayed in 2005, as Novartis Finland Oy had initiated an invalidation action against the formulation patent. In May 2006, AstraZeneca and Novartis Finland Oy settled their disputes, as a result of which the invalidation action against the formulation patent and the infringement action against Novartis Finland Oy were withdrawn. During the autumn of 2006, the infringement action against ratiopharm Oy, which had been stayed pending the outcome of the invalidation action by Novartis Finland Oy, was resumed. The parties have now settled this case. The terms of the settlement are confidential and are not material to AstraZeneca.

Also during 2003, the District Court in Norway found that the generic omeprazole product marketed by ratiopharm AB did not infringe AstraZeneca's omeprazole formulation patent. This judgment was confirmed by the Norwegian Appeal Court in October 2005. In January 2006, the Supreme Court in Norway denied AstraZeneca leave to appeal.

## 27 COMMITMENTS AND CONTINGENT LIABILITIES CONTINUED

AstraZeneca continues to be involved in proceedings in Canada involving various generics and patents, including under the Patented Medicines (Notice of Compliance) Regulations, relating to omeprazole capsules or omeprazole magnesium tablets. Apotex launched a generic omeprazole capsule product in Canada in January 2004. Following this launch, AstraZeneca commenced judicial review proceedings seeking to quash Apotex's Notice of Compliance (marketing approval) and AstraZeneca sued Apotex in July 2004 alleging infringement of its formulation patents by Apotex's omeprazole capsules. In May 2005, the Canadian Federal Court of Appeal quashed Apotex's Notice of Compliance, overruling the first instance decision in September 2004, which went against AstraZeneca. In June 2005, the Canadian Federal Court of Appeal granted Apotex's motion for a stay of the Court's decision to quash the Notice of Compliance, pending an application by Apotex for leave to appeal to the Supreme Court of Canada. The Supreme Court of Canada granted Apotex leave to appeal and also continued the stay granted by the Federal Court of Appeal, thereby allowing Apotex to continue selling its omeprazole capsules pending a decision by the Supreme Court on Apotex's appeal. The appeal was heard in May 2006 and allowed in November 2006, with the result that Apotex can continue to sell omeprazole capsules pending the outcome of the patent infringement action.

In February 2006, the Federal Court of Appeal upheld a lower court decision that prohibited Apotex from obtaining a Notice of Compliance for omeprazole magnesium tablets until the expiry of a relevant formulation patent in December 2008.

In January 2006, AstraZeneca Canada Inc. was served with a claim in the Federal Court of Canada for payment of an undetermined sum based on damages allegedly suffered by Apotex due to the delay from January 2002 to January 2004 in the issuance to Apotex of a Notice of Compliance in Canada for its 20mg omeprazole capsule product. AstraZeneca believes the claim is without merit and intends to defend it and to pursue its already pending patent infringement action against Apotex vigorously.

AstraZeneca initiated proceedings in the Federal Court of Canada against Novopharm Limited in connection with certain patents related to omeprazole magnesium tablets, on the basis that Novopharm was seeking a Notice of Compliance in Canada based on a comparison with AstraZeneca's *Losec* tablets. Two of these proceedings remain pending.

AstraZeneca initiated proceedings in the Federal Court of Canada against Sandoz Canada Inc. ("Sandoz") in connection with certain patents related to omeprazole capsules, on the basis that Sandoz was seeking a Notice of Compliance in Canada based on a comparison with AstraZeneca's *Losec* capsules. The proceedings were discontinued in September 2007 and Sandoz has subsequently started marketing and selling its omeprazole capsule product in Canada.

In January 2007, AstraZeneca discontinued long pending proceedings against Reddy-Chemisor Inc. in respect of patents relating to omeprazole capsules, following Reddy-Chemisor's withdrawal of its allegations.

### European Commission investigation

In February 2000, the European Commission commenced an investigation relating to certain omeprazole intellectual property rights, and associated regulatory and patent infringement litigation. The investigation is pursuant to Article 82 of the EC Treaty, which prohibits an abuse of a dominant position. The investigation was precipitated by a complaint by a party to a number of patent and other proceedings involving AstraZeneca. AstraZeneca has, in accordance with its corporate policy, co-operated with the Commission. In July 2003, the Commission served a Statement of Objections on AstraZeneca, referring to alleged infringements regarding the obtaining of supplementary protection certificates for omeprazole in certain European countries; and regarding AstraZeneca's replacement of omeprazole capsules by omeprazole MUPS (tablets) and withdrawal of capsule marketing authorisations in three European countries. AstraZeneca replied fully to the Commission, explaining why its actions were, in AstraZeneca's view, lawful. An oral hearing took place in February 2004. In June 2005, the Commission notified AstraZeneca PLC and AstraZeneca AB of its Decision to impose fines totalling €60m on the companies for infringement of European competition law (Article 82 of the EC Treaty and Article 54 of the EEA Agreement). The Commission alleges that the companies abused their dominant positions in the periods between 1993 and 2000 by making a pattern of misleading representations before the patent offices and/or courts in Belgium, Denmark, Germany, The Netherlands, Norway and the UK in regard to obtaining supplementary protection certificates for omeprazole; and by requesting the surrender of market authorisations for omeprazole capsules in Denmark, Norway and Sweden, combined with withdrawal from these countries of omeprazole capsules and the launch of omeprazole MUPS (tablets). AstraZeneca does not accept the Commission's Decision and has appealed it to the Court of First Instance. AstraZeneca denies that it had a dominant position or that it was engaged in the behaviours as characterised by the Commission. In the meantime, the fine was fully provided for in the half year results in 2005 through a charge to operating profit of \$75m. Because it is further alleged by the Commission that these activities had the effect of hindering the entry of the generic version of *Losec* and parallel trade, it is possible that third parties could seek damages for alleged losses arising from this matter. Any such claims would be vigorously resisted.

### Nexium (esomeprazole magnesium)

#### Sales and marketing practices

AstraZeneca entities have been sued in various state and federal courts in the US in purported representative class actions involving the marketing of *Nexium* (esomeprazole magnesium). These actions generally allege that AstraZeneca's promotion and advertising of *Nexium* to physicians and consumers is unfair, unlawful and deceptive conduct, particularly as the promotion relates to comparisons of *Nexium* with *Prilosec*. They also allege that AstraZeneca's conduct relating to the pricing of *Nexium* was unfair, unlawful and deceptive. The plaintiffs allege claims under various state consumer protection, unfair practices and false advertising laws. The plaintiffs in these cases seek remedies that include restitution, disgorgement of profits, damages, punitive damages, injunctive relief, attorneys' fees and costs of suit.

## NOTES TO THE FINANCIAL STATEMENTS CONTINUED

**27 COMMITMENTS AND CONTINGENT LIABILITIES CONTINUED**

The first action was brought in 2004 in the Superior Court of the State of California for the County of Los Angeles by the AFL-CIO, two unincorporated associations, and an individual on behalf of themselves, the general public and a class of California consumers, third party payers, cash payers and those making a co-payment. A second action was filed in the same court on behalf of a similar putative class of consumers. Actions making substantially similar allegations were filed in 2004 and 2005 on behalf of putative classes of consumers, third party payers, purchasers and labour management trust funds in the Circuit Court of Searcy County, Arkansas; in the Superior Court of the State of Delaware in and for New Castle County; in the Superior Court of Massachusetts in Boston; in the US District Court for the District of Delaware (three consolidated cases); and in the Circuit Court of the 11th Judicial Court in and for Miami-Dade County, Florida.

In September 2005, the Court in California issued a ruling on AstraZeneca's demurrer and motion to strike in the two California actions. The Court granted AstraZeneca's motion with respect to the associational plaintiffs and denied the motion with respect to the individual plaintiffs, allowing the cases of the individuals to proceed. In October 2005, the Court in Massachusetts denied AstraZeneca's motion to dismiss. Discovery in the California and Massachusetts cases is proceeding, and plaintiffs' motions for class certification were filed in October 2007. The California plaintiffs filed an amended class certification motion in January 2008.

In November 2005, the US District Court for the District of Delaware granted AstraZeneca's motion to dismiss the consolidated class action complaint. In September 2007, the US Court of Appeals for the Third Circuit affirmed the dismissal and denied plaintiffs' petition for rehearing *en banc*. On 18 December 2007, plaintiffs filed a petition for *writ of certiorari* with the US Supreme Court. AstraZeneca's response to the petition is due in February 2008. The Delaware state case has been stayed pending the outcome of the Delaware federal cases.

In May 2006, the Arkansas State Court granted AstraZeneca's motion to dismiss the plaintiffs' complaint. The plaintiffs filed additional motions and pleadings, including an amended complaint. AstraZeneca filed a motion to dismiss the amended complaint.

In October 2006, the Florida Court dismissed the plaintiffs' complaint with prejudice and without leave to amend. In June 2007, the Florida Court of Appeal affirmed the dismissal and the Florida Supreme Court denied further review.

**Anti-trust**

In December 2006 and January 2007, several lawsuits against AstraZeneca entities, including putative class actions, were filed in the US District Court for the District of Columbia alleging anti-trust claims of unlawful monopolisation relating to *Prilosec* and *Nexium*. Individual actions were filed in December 2006 by Walgreen Co., Eckerd Corporation, Maxi Drug, Inc. d/b/a Brooks Pharmacy, The Kroger Co., New Albertson's Inc., Safeway, Inc., Hy-Vee, Inc., American Sales Company, Inc., Rite Aid Corporation, and Rite Aid Headquarters Corp. Also, putative class actions brought on behalf of direct purchasers were filed on 18 December 2006 by Meijer, Inc., Meijer Distribution, Inc., Louisiana Wholesale Drug Co., Inc., and in January 2007 by Burlington Drug Co., Inc., Dik Drug Co., Inc. and King Drug Co. of Florence, Inc. The plaintiffs seek treble damages, injunctive relief and attorney fees. All plaintiffs filed amended complaints in February 2007. In April 2007, AstraZeneca filed a motion to dismiss the amended complaints in each of the cases.

**Patent proceedings**

In October 2007, the European Patent Office (EPO) Opposition Division ruled that the European process patent EP 0773940 for *Nexium* is valid in amended form, despite an opposition by the German generic manufacturer, ratiopharm. The patent has been upheld as granted except, with respect to certain claims, minor amendments were made. On 23 January 2008, ratiopharm filed a notice of appeal against this decision.

The EP 0773940 patent for *Nexium* covers a process for the manufacturing of esomeprazole and its salts in Austria, Belgium, Switzerland, Germany, Denmark, Spain, France, UK, Greece, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Monaco, The Netherlands, Portugal, Slovenia and Sweden. This positive decision by the EPO means that this patent, in its amended form, still covers the manufacturing process for *Nexium*. This patent expires in 2015.

This portfolio includes additional patents with expiration dates ranging from 2009 to 2018. In addition to these patents, *Nexium* has data exclusivity valid until March 2010 in most major European markets. AstraZeneca will vigorously defend and enforce its intellectual property rights protecting *Nexium*.

**Patent litigation**

In October 2005, AstraZeneca received a notice from Ranbaxy Pharmaceuticals, Inc. that Ranbaxy Laboratories Limited (together Ranbaxy) had submitted an ANDA to the FDA for esomeprazole magnesium delayed-release capsules, 20mg and 40mg. The ANDA contained Paragraph IV certifications of invalidity and/or non-infringement in respect of certain AstraZeneca US patents listed in the FDA Orange Book with reference to *Nexium*. In November 2005, AstraZeneca commenced wilful infringement patent litigation in the US District Court for the District of New Jersey against Ranbaxy and its affiliates in response to Ranbaxy's Paragraph IV certifications regarding *Nexium*.

In January 2006, AstraZeneca received a notice from IVAX Pharmaceuticals Inc. that IVAX Corporation had submitted an ANDA to the FDA for esomeprazole magnesium delayed-release capsules, 20mg and 40mg. The ANDA contained Paragraph IV certifications of invalidity and/or non-infringement in respect of certain AstraZeneca US patents listed in the FDA Orange Book with reference to *Nexium*. IVAX also certified in respect of certain other AstraZeneca US patents listed in the FDA Orange Book with reference to *Nexium* that IVAX will not launch its product prior to the expiry of those patents, the latter of which expired in October 2007. In March 2006, AstraZeneca commenced wilful patent infringement litigation in the US District Court for the District of New Jersey against IVAX, its parent Teva Pharmaceuticals, and their affiliates. The Ranbaxy and Teva/IVAX matters have been consolidated. No trial date has been set.

## 27 COMMITMENTS AND CONTINGENT LIABILITIES CONTINUED

In August 2006, AstraZeneca received a notice from Dr Reddy's Laboratories Inc. and Dr Reddy's Laboratories Limited (together, Dr Reddy's) that Dr Reddy's had submitted an ANDA to the FDA for esomeprazole magnesium delayed-release capsules, 20mg and 40mg. Dr Reddy's August 2006 notice did not challenge three FDA Orange Book-listed patents claiming esomeprazole magnesium (US Patent Nos. 5,714,504, 5,877,192 and 6,875,872). In December 2007, AstraZeneca received another notice from Dr. Reddy's that Dr. Reddy's had submitted an ANDA to the FDA for esomeprazole magnesium delayed-release capsules, 20mg and 40mg. Dissimilar from the August 2006 notice, Dr. Reddy's December 2007 notice did challenge three FDA Orange Book-listed patents claiming esomeprazole magnesium (US Patent Nos. 5,714,504, 5,877,192 and 6,875,872). AstraZeneca's exclusivity relating to these three patents expires on 3 August 2015, 27 November 2014 and 27 November 2014, respectively. In January 2008, AstraZeneca commenced patent infringement litigation in the US District Court for the District of New Jersey against Dr. Reddy's in response to Dr. Reddy's Paragraph IV certifications regarding *Nexium*. No trial date has been set.

In July and September 2007, AstraZeneca received notice from Matrix Laboratories, Inc. (Matrix) that Matrix had submitted an ANDA to the FDA for esomeprazole magnesium delayed-release capsules, 20mg and 40mg. Matrix was seeking FDA approval to market a generic esomeprazole magnesium product prior to the expiration of some but not all of the patents listed in the FDA Orange Book with reference to *Nexium*. Matrix's notice did not challenge three FDA Orange Book-listed patents claiming esomeprazole magnesium (US Patent Nos. 5,714,504, 5,877,192 and 6,875,872). Because AstraZeneca has not received notice from Matrix as to these three US patents, Matrix cannot market generic esomeprazole magnesium until the end of the exclusivity afforded by these patents. As a result, AstraZeneca did not bring a lawsuit at this time. AstraZeneca reserves the right to enforce all patents related to *Nexium*, including those listed in the FDA Orange Book.

After its expiry, a 30-month stay will not prevent the FDA from approving an ANDA, and an 'at risk' launch by a generic drug manufacturer may occur, of delayed-release esomeprazole magnesium capsules, in the year ending 31 December 2008.

In Canada, AstraZeneca Canada, Inc. received several notices of allegation from Apotex Inc. (Apotex) in late 2007 in respect of patents listed on the Patent Register in Canada for *Nexium*. Apotex has asserted in its notices that it has filed an Abbreviated New Drug Submission in March 2007, for 20mg and 40mg esomeprazole magnesium trihydrate tablets and alleges non-infringement and/or invalidity of numerous patents. AstraZeneca has responded by commencing seven court applications in January 2008 under the Patented Medicines (Notice of Compliance) Regulations. On 17 January 2008, Apotex advised that its product was erroneously described as being a trihydrate in its recent allegations, which allegations Apotex asserted it was withdrawing. Apotex mailed replacement allegations on 17 January 2008, which AstraZeneca is entitled to challenge. Apotex cannot obtain a Notice of Compliance (marketing approval) for its esomeprazole tablets until the earlier of the disposition of all of the court applications in Apotex's favour or 24 months from the date on which the latest court application has been commenced.

AstraZeneca has full confidence in and will vigorously defend and enforce its intellectual property protecting *Nexium*.

### **Nolvadex (tamoxifen)**

AstraZeneca was a co-defendant with Barr Laboratories, Inc. (Barr) in numerous purported class actions filed in federal and state courts throughout the US. All of the state court actions were removed to federal court and were consolidated, along with all of the cases originally filed in the federal courts, in a federal multi-district litigation proceeding pending in the US District Court for the Eastern District of New York. Some of the cases were filed by plaintiffs representing a putative class of consumers who purchased tamoxifen. The other cases were filed on behalf of a putative class of 'third party payers' (including health maintenance organisations, insurers and other managed care providers and health plans) that have reimbursed or otherwise paid for prescriptions of tamoxifen. The plaintiffs alleged that they paid 'supra-competitive and monopolistic prices' for tamoxifen as a result of the settlement of patent litigation between Zeneca and Barr in 1993. The plaintiffs sought injunctive relief, treble damages under the anti-trust laws, disgorgement and restitution. In April 2002, AstraZeneca filed a motion to dismiss the cases for failure to state a cause of action. In May 2003, the US District Court for the Eastern District of New York granted AstraZeneca's motion to dismiss. The plaintiffs appealed the decision.

In November 2005, the US Court of Appeals for the Second Circuit affirmed the District Court's decision. The plaintiffs thereafter moved for re-hearing by the original panel of judges in the case and re-hearing by a panel of all of the judges on the US Court of Appeals for the Second Circuit. The plaintiffs' requests for re-hearing were denied in September 2006. In December 2006, the plaintiffs filed a petition for a *writ of certiorari* to the US Supreme Court seeking to have the Court hear an appeal of the Second Circuit's decision. In June 2007, the US Supreme Court denied the plaintiffs' writ, thus ending the litigation.

### **Pulmicort Respules (budesonide inhalation suspension)**

In September 2005, AstraZeneca received a notice from IVAX Pharmaceuticals Inc. (IVAX) that IVAX had submitted an ANDA to the FDA for a budesonide inhalation suspension containing a Paragraph IV certification and alleging invalidity and non-infringement in respect of certain of AstraZeneca's patents relating to budesonide inhalation suspension. In October 2005, AstraZeneca filed a patent infringement action against IVAX in the US District Court for the District of New Jersey. In December 2005, IVAX responded and filed counterclaims alleging non-infringement and invalidity. In January 2006, AstraZeneca filed an amended complaint, withdrawing averments as to the infringement of one of the patents-in-suit. Discovery in the litigation is ongoing. After its expiry, a 30-month stay will not prevent the FDA from approving an ANDA, and an 'at risk' launch by a generic drug manufacturer may occur, of a budesonide inhalation suspension in the year ending 31 December 2008.

AstraZeneca continues to have full confidence in and will vigorously defend and enforce its intellectual property protecting *Pulmicort Respules*.

## NOTES TO THE FINANCIAL STATEMENTS CONTINUED

**27 COMMITMENTS AND CONTINGENT LIABILITIES CONTINUED****Rhinocort Aqua (budesonide nasal spray)**

In September 2007, AstraZeneca AB received a letter from Apotex Inc. (Apotex) stating that Apotex had submitted an ANDA for a budesonide nasal spray (32mcg spray) and that it intended to engage in the commercial manufacture, use and sale of a generic version of *Rhinocort Aqua* budesonide nasal spray before the expiration of US Patent Nos. 6,291,445, 6,686,346 and 6,986,904 (the '445, '346 and '904 patents). The Apotex notice contained a Paragraph IV certification alleging that the claims of the '445, '346 and '904 patents are 'not infringed and invalid'. The '346 and '904 patents will expire in April 2017. The '445 patent has an additional six months of paediatric exclusivity which ends in October 2017.

After investigating the allegations in Apotex's Paragraph IV letter, AstraZeneca has decided not to file a patent infringement suit against Apotex. AstraZeneca will not maintain or enforce the '445, '346 and '904 patents and has requested their de-listing from the FDA Orange Book.

**Seroquel (quetiapine fumarate)****Product liability**

In August 2003, Susan Zehel-Miller filed a putative class action against AstraZeneca PLC and AstraZeneca Pharmaceuticals LP on behalf of 'all persons in the US who purchased and/or used *Seroquel*'. Among other things, the class action alleged that AstraZeneca failed to provide adequate warnings in connection with an alleged association between *Seroquel* and the onset of diabetes. In 2004, the US District Court for the Middle District of Florida denied class certification and the case was ultimately dismissed. Two additional putative class actions raising similar allegations have likewise been dismissed. There are no other US class actions relating to *Seroquel*; however, four putative class actions raising substantially similar allegations have been filed in Canada.

Additionally, AstraZeneca Pharmaceuticals LP, either alone or in conjunction with one or more affiliates, has been sued in numerous individual personal injury actions involving *Seroquel*. In most of these cases, the nature of the plaintiffs' alleged injuries is not clear from the complaint and in most cases, little or no factual information regarding the alleged injury has been provided in the complaint. However, the plaintiffs generally contend that they developed diabetes and/or other related injuries as a result of taking *Seroquel* and/or other atypical anti-psychotic medications. As of 16 January 2008 AstraZeneca was defending 8,121 served or answered lawsuits involving approximately 12,347 plaintiff groups (24 January 2007: 604 served or answered lawsuits involving approximately 7,450 plaintiff groups). To date, approximately 1,900 additional cases have been dismissed by order or agreement and approximately 1,400 of those cases have been dismissed with prejudice. Approximately 22% of the cases that were or are pending in the federal court multi-district litigation (MDL) have been dismissed. Approximately half of the currently pending *Seroquel* cases are in federal court with clusters of state court activity in Delaware, New Jersey, New York and Missouri. Single cases are pending in a few additional jurisdictions, including one case in Canada. Plaintiffs' discovery of AstraZeneca, as well as AstraZeneca's discovery of specific plaintiffs' cases, is ongoing in most jurisdictions and AstraZeneca intends to vigorously test the merits of those individual cases on factual and legal grounds. Bellwether case systems have been implemented by the courts in Delaware, New Jersey and the federal court MDL due to the larger volume of consolidated cases in those jurisdictions. No trials are expected to begin in any of the *Seroquel* cases until the autumn of 2008. One trial that was scheduled in Minnesota for March 2008 has been dismissed. AstraZeneca is also aware of approximately 70 additional cases that have been filed but not yet served and has not determined how many additional cases, if any, may have been filed. Some of the cases also include claims against other pharmaceutical manufacturers such as Eli Lilly & Co., Janssen Pharmaceutica, Inc. and/or Bristol-Myers Squibb Company. AstraZeneca intends to litigate these cases on the merits and will defend the cases vigorously. As of 31 January 2008, legal defence costs of approximately \$200m have been incurred (of which approximately \$160m was incurred during 2007). AstraZeneca has product liability insurance that is considered to respond to the vast majority of claims brought in these *Seroquel* cases, subject to a retention. This insurance provides coverage for legal defence costs and potential damages that may be incurred up to a specified limit. AstraZeneca currently expects the legal defence costs to be less than the upper limit of the insurance coverage and has recorded an insurance receivable of \$139m (2006 \$nil). However, these cases are at an early stage and there can be no guarantee that the ultimate cost incurred will not exceed any insurance recoveries received.

**Patent litigation**

In September 2005, AstraZeneca received a notice from Teva Pharmaceuticals USA Inc. (Teva) that Teva had submitted an ANDA for quetiapine fumarate 25mg tablets containing a Paragraph IV certification alleging invalidity, unenforceability or non-infringement respecting AstraZeneca's US patent listed in the FDA Orange Book with reference to *Seroquel*. In November 2005, AstraZeneca filed a lawsuit directed to Teva's 25mg tablets ANDA in the US District Court for the District of New Jersey for wilful patent infringement.

In February 2006, AstraZeneca received another notice from Teva that it had amended its previously submitted ANDA for quetiapine fumarate 25mg tablets and added 100, 200 and 300mg tablets to its application to the FDA. The amended ANDA submission contained a similar Paragraph IV certification alleging invalidity, unenforceability or non-infringement in respect of AstraZeneca's US patent listed in the FDA Orange Book with reference to *Seroquel*. In March 2006, in response to Teva's amended ANDA and Teva's intent to market additional strengths of a generic version of *Seroquel* in the US prior to the expiration of AstraZeneca's patent, AstraZeneca filed an additional lawsuit against Teva in the US District Court for the District of New Jersey for patent infringement.

The two Teva lawsuits were consolidated in April 2006. However, in March 2006, the US District Court had granted Teva's motion to strike AstraZeneca's added allegation of wilfulness in its patent infringement claim in the first complaint directed to Teva's 25mg tablets. Therefore, in the consolidated action, in response to AstraZeneca's now combined allegations of patent infringement directed to Teva's 25, 100, 200 and 300mg tablets ANDA, Teva alleges non-infringement and patent invalidity. In January 2007, Teva filed a motion seeking leave to amend its pleadings in the consolidated action to add allegations, defences and counter-claims directed to alleged inequitable conduct in the procurement of AstraZeneca's patent.

## 27 COMMITMENTS AND CONTINGENT LIABILITIES CONTINUED

In March 2007, AstraZeneca received a Paragraph IV certification notice-letter from another generic drug manufacturer, Sandoz Inc. (Sandoz), notifying AstraZeneca that it had submitted an ANDA to the FDA for approval to market a generic version of AstraZeneca's 25mg quetiapine fumarate tablets prior to the expiration of AstraZeneca's listed patent. Sandoz's notice-letter alleged non-infringement and patent invalidity. In April 2007, AstraZeneca filed a lawsuit in the US District Court for the District of New Jersey against Sandoz alleging patent infringement.

In June 2007, AstraZeneca received a third notice from Teva notifying AstraZeneca that it had supplemented its ANDA for quetiapine fumarate tablets again, adding 50, 150 and 400mg tablets to the application. The third notice-letter similarly advised that Teva's supplementation contained a Paragraph IV certification respecting AstraZeneca's listed patent covering *Seroquel*. In June 2007, AstraZeneca filed a third lawsuit in the US District Court for the District of New Jersey against Teva for its supplementation adding the 50, 150 and 400mg dosage strengths.

In October 2007, the Court granted AstraZeneca's partial summary judgment motion based on collateral estoppel, which precludes Teva from re-litigating issues previously resolved against it in another previous patent litigation involving Eli Lilly's anti-psychotic drug, Zyprexa™.

The four pending patent infringement cases against Teva and Sandoz have been consolidated for purposes of discovery, which proceeds. After its expiry, a 30-month stay will not prevent the FDA from approving an ANDA, and an 'at risk' launch by a generic drug manufacturer may occur, of quetiapine fumarate tablets in the year ending 31 December 2008.

We continue to have full confidence in our intellectual property protecting *Seroquel* and will vigorously defend and enforce it.

### Sales and marketing practices

In February 2007, the Commonwealth of Pennsylvania filed suit against AstraZeneca, Eli Lilly & Co. (Lilly), and Janssen Pharmaceutica Inc. (Janssen) claiming damages incurred by the Commonwealth as a result of alleged off-label promotion of atypical anti-psychotics by the three manufacturers. The lawsuit is filed in state court in Philadelphia and seeks to recover the cost to the Pennsylvania Medicaid programme and other state-funded health insurance programmes for prescriptions written as a result of the alleged off-label promotion. In December 2007, the Court granted defendants' motion to sever the claims against AstraZeneca and Janssen from those against Lilly and directed the Commonwealth to file separate complaints against the two severed defendants, which the Commonwealth did in January 2008. Although no similar lawsuits have been brought by states other than Pennsylvania, AstraZeneca has been informed that the Attorney Generals' Offices of multiple other states have investigations into similar *Seroquel* off-label issues. AstraZeneca has signed agreements with 20 states tolling the statutes of limitations on potential claims, and has been approached by additional states for similar tolling agreements. AstraZeneca believes these claims to be without merit and intends to vigorously defend the Pennsylvania lawsuit.

In May 2007, the New Jersey Ironworkers Local Union No. 68 filed a class action suit against AstraZeneca on behalf of all individuals and non-governmental entities that paid for *Seroquel* from January 2000 to date. The lawsuit is filed in the federal District Court in New Jersey and alleges that AstraZeneca promoted *Seroquel* for off-label uses and misled class members into believing that *Seroquel* was superior to other, lower-cost alternative medicines. Two similar class action lawsuits were filed in June 2007 in the New Jersey and Pennsylvania federal courts. In December 2007, the three lawsuits were transferred to the Middle District of Florida by the US Judicial Panel on Multidistrict Litigation. AstraZeneca believes these suits to be without merit and intends to vigorously defend the claims.

### Symbicort (budesonide/formoterol)

In October 2007, following an appeal by a group of generic manufacturers, Norton Healthcare Limited, Miat SpA, Generics (UK) Limited and Licons SA, the European Patent Office (EPO) Technical Board of Appeal revoked the European combination patent for *Symbicort* for use in asthma. Two European patents (EPB1014993 and EPB1210943) claiming *Symbicort* for use in COPD are under appeal and opposition respectively. The hearing date for the COPD appeal at the EPO is now set for 6 May 2008. The proceedings instituted by IVAX Pharmaceuticals (UK) Limited in the UK and Ireland with respect to the *Symbicort* patents will remain stayed until the EPO Technical Board of Appeal decision on the COPD patent.

AstraZeneca will vigorously defend and enforce its remaining intellectual property portfolio protecting *Symbicort*, which has patent expiry dates up to 2019 in Europe.

### Toprol-XL (metoprolol succinate)

In May 2003, AstraZeneca filed a patent infringement action against KV Pharmaceutical Company (KV) in the US District Court for the Eastern District of Missouri in response to KV's notification of its intention to market a generic version of *Toprol-XL* tablets in the 200mg dose prior to the expiration of AstraZeneca's patents covering the substance and its formulation. In response to later similar notices from KV related to the 25, 50 and 100mg doses, AstraZeneca filed further actions. KV responded in each instance and filed counterclaims alleging non-infringement, invalidity and unenforceability of the listed patents.

In February 2004, AstraZeneca filed a patent infringement action against Andrx Pharmaceuticals LLC (Andrx) in the US District Court for the District of Delaware in response to Andrx's notification of its intention to market a generic version of *Toprol-XL* tablets in the 50mg dose prior to the expiration of AstraZeneca's patents. In response to two later similar notices from Andrx related to the 25, 100 and 200mg doses, AstraZeneca filed two additional patent infringement actions in the same court. In each instance, Andrx claimed that each of the listed patents is invalid, not infringed and unenforceable.

## NOTES TO THE FINANCIAL STATEMENTS CONTINUED

**27 COMMITMENTS AND CONTINGENT LIABILITIES CONTINUED**

In April 2004, AstraZeneca filed a patent infringement action against Eon Labs Manufacturing Inc. (Eon) in the US District Court for the District of Delaware in response to Eon's notification of its intention to market generic versions of *Toprol-XL* tablets in the 25, 50, 100 and 200mg doses prior to the expiration of AstraZeneca's patents. In its response, Eon alleged that each of the listed patents is invalid, not infringed and unenforceable. Eon also alleged that the filing of the infringement complaints, as well as other actions by AstraZeneca, constitutes anti-competitive conduct in violation of US anti-trust laws. Pursuant to a joint motion of AstraZeneca and Eon these anti-trust counts were severed from the case and stayed, for possible consideration depending on the outcome of the trial of the patent claims.

All of the patent litigation relating to *Toprol-XL* against KV, Andrx and Eon was consolidated for pre-trial discovery purposes and motion practice in the US District Court for the Eastern District of Missouri. The defendants filed a motion for summary judgment in December 2004 alleging that the *Toprol-XL* patents are invalid due to double patenting. A summary judgment motion of unenforceability was filed by the defendants in 2005 and AstraZeneca filed summary judgment motions on infringement and validity in 2005. In January 2006, the US District Court for the Eastern District of Missouri issued a ruling finding that the two patents-in-suit are unenforceable (based on AstraZeneca's inequitable conduct in the prosecution of these patents in the US Patent and Trademark Office) and invalid. AstraZeneca appealed the District Court decision to the US Court of Appeals for the Federal Circuit. In July 2007, a three-judge panel of the Federal Circuit unanimously ruled that the inequitable conduct determination by the District Court was improper on summary judgment because there were material facts in dispute and therefore the issue of inequitable conduct was remanded to the District Court. The panel upheld, however, in a divided (2-1) decision, the finding that the *Toprol-XL* patents were invalid due to double patenting. In August 2007, AstraZeneca petitioned the Federal Circuit for reconsideration of the invalidity determination. Reconsideration was denied in October 2007.

In August 2006, Sandoz (formerly Eon) received final approval from the FDA on the 25mg dose of metoprolol succinate and tentative approval on the 50, 100 and 200mg doses. On 21 November 2006, Sandoz launched its 25mg metoprolol succinate product, which was followed by Par Pharmaceuticals' (Par) launch of a 25mg generic metoprolol succinate product under a distribution agreement with AstraZeneca. In May 2007, the FDA issued final approval to KV for the 100 and 200mg doses of generic metoprolol succinate. KV launched these products in July 2007, followed by a launch of an authorised generic by Par under its distribution agreement with AstraZeneca. In May 2007, the FDA issued final approval to Sandoz for a 50mg generic metoprolol succinate product after Andrx waived its right to 180 days exclusivity on the 50mg product. In August 2007, Sandoz launched its 50mg product, followed immediately by the launch of a 50mg authorised generic by Par, pursuant to its distribution agreement with AstraZeneca.

In the first quarter of 2006, AstraZeneca was served with 14 complaints filed in the US District Courts in Delaware, Massachusetts and Florida against AstraZeneca Pharmaceuticals LP, AstraZeneca LP, AstraZeneca AB and Aktiebolaget Hässle. The complaints were putative class actions filed on behalf of both direct purchasers and indirect purchasers that allege that the AstraZeneca defendants attempted to illegally maintain monopoly power in the US over *Toprol-XL* in violation of the Sherman Act through the listing of invalid and unenforceable patents in the FDA Orange Book and the enforcement of such patents through litigation against generic manufacturers seeking to market metoprolol succinate. The complaints seek treble damages based on alleged overcharges to the putative classes of plaintiffs. These 14 complaints were consolidated into two amended complaints in the US District Court in Delaware, one on behalf of direct purchasers, and one on behalf of indirect purchasers. The lawsuits are based upon the 2006 ruling described above by the US District Court for the Eastern District of Missouri in the consolidated patent litigation against KV, Andrx and Eon, that the AstraZeneca patents relating to *Toprol-XL* are invalid and unenforceable. In 2006 AstraZeneca filed a motion seeking to dismiss or in the alternative stay the consolidated complaint in both anti-trust cases. As noted above, AstraZeneca appealed the District Court decision, which resulted in a reversal and remand on the issue of inequitable conduct and an affirmation that the *Toprol-XL* patents were invalid. AstraZeneca's motion to dismiss the complaints is still pending. AstraZeneca denies the allegations of the anti-trust complaints and will vigorously defend the lawsuits.

In June 2007, AstraZeneca received notification from Dr. Reddy's Laboratories Inc that it had filed an ANDA for the 100 and 200mg doses of metoprolol succinate and that sale of its generic products would not infringe AstraZeneca's US Patent Nos. 4,957,745 and 5,246,714. AstraZeneca did not file suit in response to this notification.

**Zestril (lisinopril)**

In 1996, two of AstraZeneca's predecessor companies, Zeneca Limited and Zeneca Pharma Inc. (as licensees), Merck & Co., Inc. and Merck Frosst Canada Inc. commenced a patent infringement action in the Federal Court of Canada against Apotex, Inc. (Apotex), alleging infringement of Merck's lisinopril patent. Apotex sold a generic version of AstraZeneca's *Zestril* and Merck's Prinivil™ tablets. Apotex admitted infringement but raised positive defences to infringement, including that it acquired certain quantities of lisinopril prior to issuance of the patent and that certain quantities were licensed under a compulsory licence. Apotex also alleged invalidity of the patent. Following a trial in early 2006, in April 2006 the Federal Court of Canada ruled in favour of AstraZeneca and Merck on the key issues and Apotex stopped selling lisinopril in May 2006. In October 2006, the Federal Court of Appeal in Canada upheld the lower court's decision and dismissed Apotex's appeal. In December 2006, Apotex sought leave to appeal to the Supreme Court of Canada. The Supreme Court of Canada dismissed Apotex's leave to appeal in May 2007. AstraZeneca intends to pursue a reference proceeding in the Federal Court to quantify the damages related to the infringement by Apotex. Apotex commenced the sale of lisinopril in October 2007 after expiry of the relevant patent.

## 27 COMMITMENTS AND CONTINGENT LIABILITIES CONTINUED

### Average wholesale price class action litigation

In January 2002, AstraZeneca was named as a defendant along with 24 other pharmaceutical manufacturers in a class action suit in Massachusetts, brought on behalf of a putative class of plaintiffs alleged to have overpaid for prescription drugs as a result of inflated wholesale list prices. Following the Massachusetts complaint, nearly identical class action suits were filed against AstraZeneca and various other pharmaceutical manufacturers in four other states. AstraZeneca and other manufacturers have since been sued in similar lawsuits filed by the state Attorneys General of Pennsylvania, Nevada, Montana, Wisconsin, Illinois, Alabama, Kentucky, Arizona, Mississippi, Hawaii, Alaska, Idaho and Utah as well as by multiple individual counties in the state of New York. The Attorney General lawsuits seek to recover alleged overpayments under Medicaid and other state-funded healthcare programmes. In several cases, the states are also suing to recover alleged overpayments by state residents. Several of these suits have been consolidated with the Massachusetts action for pre-trial purposes, pursuant to federal multi-district litigation procedures.

In January 2006, the District Court in Boston certified three classes of plaintiffs against the 'Track 1' manufacturer defendants, AstraZeneca, GlaxoSmithKline, Bristol-Myers Squibb, Schering-Plough and Johnson & Johnson. The three certified classes are: (Class 1) a nationwide class of consumers who made co-payments for certain physician-administered drugs reimbursed under the Medicare Part B programme (Part B drugs); (Class 2) a Massachusetts-only class of third-party payers, including insurance companies, union health and welfare benefit plans, and self-insured employers, who covered consumer co-payments for Part B drugs; and (Class 3) a Massachusetts-only class of third-party payers and consumers who paid for Part B drugs outside of the Medicare programme. For all classes, the only AstraZeneca drug at issue is *Zoladex* (goserelin acetate implant).

A bench trial against four of the Track 1 defendants, including AstraZeneca, by Classes 2 and 3 began in November 2006 and concluded in January 2007. A separate jury trial against AstraZeneca only, involving the Class 1 claims, was scheduled to begin in June 2007.

In May 2007, the parties reached a proposed settlement agreement resolving the Class 1 claims. The settlement, if ultimately approved by the Court, will involve payments of up to \$24m, not including attorneys' fees, to reimburse individual class members submitting claims. AstraZeneca has agreed that \$10m of any unclaimed amounts will be donated to charitable organisations funding cancer patient care and research. Notice of the proposed settlement was mailed to potential class members in December 2007, and the Court has scheduled a hearing for final approval of the settlement in May 2008. A provision of \$27m was established in 2007.

In June 2007 and November 2007, the Court issued decisions on liability and damages on Classes 2 and 3. The Court found AstraZeneca liable under the Massachusetts consumer protection statute for engaging in unfair and deceptive conduct in connection with the pricing of *Zoladex* during the period 1998 to 2003. The Court awarded double damages (with pre-judgment interest) of \$5.5m for Class 2, and single damages (with pre-judgment interest) of \$7.4m for Class 3. AstraZeneca believes the decision to be in error and has filed an appeal in which it is confident that it will prevail and so no provision has been made for these awards.

The Court's award on Classes 2 and 3, if it survives appeal, relates to damages incurred by payers within the Commonwealth of Massachusetts only. Plaintiffs have filed a motion seeking certification of multi-state classes of third-party payers in an effort to pursue similar claims for damages under the consumer protection statutes of other states. The Court has scheduled a hearing on plaintiffs' motion in May 2008.

The decision on Classes 2 and 3 and the settlement of Class 1 relate to *Zoladex* only. The multiple Attorney General lawsuits pending against AstraZeneca and other manufacturers nationwide, which involve numerous drugs in addition to *Zoladex*, remain pending against AstraZeneca. The first of these cases scheduled for trial is the case filed by the Alabama Attorney General in state court in Montgomery, Alabama. That case is scheduled for a jury trial against AstraZeneca beginning February 2008.

Separately, MedImmune is involved in various lawsuits brought by various states and counties in the US alleging manipulation of average wholesale prices by several defendants, including MedImmune. The lawsuits were filed between 2003 and 2007 by Alabama, Mississippi, Iowa, New York City, and by various New York counties. The status of the various lawsuits by various states and counties alleging manipulation of average wholesale price by several defendants, including MedImmune, did not change materially during the financial year ended 31 December 2007, except that in April 2007, Orange County, New York filed suit in the Southern District of New York against a number of defendants, including MedImmune and in October 2007, the State of Iowa filed a lawsuit against a number of defendants, including MedImmune, in the US District Court for the Southern District of Iowa.

The allegations made in respect of the average wholesale price lawsuits described in this section are denied and will be vigorously defended.

### 340B class action litigation

In August 2004, AstraZeneca was named as a defendant, along with multiple other pharmaceutical manufacturers, in a class action suit filed by the County of Santa Clara in California state court on behalf of similarly situated California counties and cities that allegedly overpaid for drugs covered by the federal '340B' programme. The 340B programme entitles hospitals and clinics that treat a substantial portion of uninsured patients to preferential drug pricing for outpatient drugs. According to the complaint, the genesis of the suit was an audit report by the US Department of Health and Human Services Office of Inspector General (OIG) in June 2004. The OIG later withdrew the audit report and in 2006, re-issued a revised audit report that substantially modified the previous audit findings.

The case was removed to federal court, the US District Court for the Northern District of California. In 2006, the US District Court dismissed each of the allegations in the County's complaint. The County appealed the dismissal to the US Court of Appeals for the Ninth Circuit, and the parties briefed the matter. A date for oral argument has not yet been set. AstraZeneca denies the allegations in the County's complaint and intends to continue to defend them vigorously.

## NOTES TO THE FINANCIAL STATEMENTS CONTINUED

**27 COMMITMENTS AND CONTINGENT LIABILITIES CONTINUED****Drug importation anti-trust litigation**

In May 2004, plaintiffs in a purported class action filed complaints in the US District Court for Minnesota and for New Jersey, alleging that AstraZeneca Pharmaceuticals LP and eight other pharmaceutical manufacturer defendants conspired to prevent American consumers from purchasing prescription drugs from Canada, 'depriving consumers of the ability to purchase' drugs at competitive prices. The New Jersey case was voluntarily dismissed in July 2004. In August 2005, the Minnesota District Court dismissed with prejudice the plaintiffs' federal anti-trust claims and declined to exercise supplemental jurisdiction in relation to the state statutory and common law claims, which claims were dismissed without prejudice. The plaintiffs appealed the District Court's decision to the US Court of Appeals for the Eighth Circuit. In November 2006, the US Court of Appeals for the Eighth Circuit affirmed the District Court's decision. This matter is now concluded.

In August 2004, Californian retail pharmacy plaintiffs filed an action in the Superior Court of California making similar allegations to the Minnesota action and also alleging a conspiracy by approximately 15 pharmaceutical manufacturer defendants to set the price of drugs sold in California at or above the Canadian sales price for those same drugs. In July 2005, the Court overruled in part and sustained in part, without leave to amend, the defendants' motion to dismiss the plaintiffs' third amended complaint in these proceedings. The Court overruled the defendants' motion in respect of conspiracy claims but sustained the motion in respect of the California Unfair Competition Law claims. In December 2006, the Court granted the defendants' motion for summary judgment and the case was subsequently dismissed. In January 2007, plaintiffs filed a Notice of Appeal with the Court of Appeal of the State of California. Briefing on the appeal is now complete.

AstraZeneca denies the material allegations in the California action and is vigorously defending this matter.

**Anti-trust**

In July 2006, AstraZeneca Pharmaceuticals LP was named as a defendant, along with a number of other pharmaceutical manufacturers and wholesalers, in a complaint filed by RxUSA Wholesale, Inc. (RxUSA) in the US District Court for the Eastern District of New York. The complaint alleges that the defendants violated federal and state anti-trust laws by, amongst other things, allegedly refusing to deal with RxUSA and other 'secondary wholesalers' in the wholesale pharmaceutical industry. The plaintiff alleges a conspiracy among the manufacturers and seeks an injunction and treble damages. AstraZeneca vigorously denies the allegations and in November 2006 filed a motion to dismiss the complaint.

For a description of other anti-trust-related litigation involving AstraZeneca, see the subsections entitled *Nexium* (esomeprazole), *Losec/Prilosec* (omeprazole), *Nolvadex* (tamoxifen) and *Toprol-XL* (metoprolol succinate) in this Note 27 to the Financial Statements.

AstraZeneca is part of a sectoral inquiry by the European Commission into the pharmaceutical industry and was the subject of an unannounced inspection in January 2008. The inquiry relates to the introduction of innovative and generic medicines and it will cover commercial practices, including the use of patents and generics. We understand that several companies have been similarly approached.

The Commission has stated that this inquiry is not aimed at investigating practices where there have been any indications of wrongdoing although it could address any competition law breaches found by means of separate proceedings. The Commission has also stated that it plans to issue an interim report in autumn 2008 and envisages that the final results of its inquiry will be available in spring 2009.

AstraZeneca is cooperating fully with the Commission in relation to its inquiry.

**Employment-wage/hour litigation**

In September 2006, Marc Brody filed a putative class action lawsuit against AstraZeneca LP on behalf of himself and a class of approximately 844 pharmaceutical sales specialists employed by the Group in California during the period 19 September 2002 to the present. The plaintiff alleges he and the proposed class members were unlawfully classified as exempt employees and denied overtime compensation and meal breaks in violation of the California Labour Code. AstraZeneca removed this action to the US District Court for the Central District of California in October 2006. The Plaintiff filed a first amended complaint on or about 20 March 2007, for failure to provide meal and rest periods, failure to pay all wages earned each pay period, failure to provide accurate wage statements, failure to pay wages timely upon termination, unfair competition and civil penalties. AstraZeneca denies the allegations made by the plaintiff, asserting that the sales specialists are properly classified under various exemptions to the wage laws. Discovery is ongoing. (The plaintiff's lawyers are also pursuing similar claims in lawsuits against most of the major pharmaceutical companies.)

In separate lawsuits against AstraZeneca, the firms representing Brody filed additional state wage-and-hour class actions, the first under Pennsylvania Minimum Wage Act and Wage Payment Collection Law in the US District Court for the Western District of Pennsylvania on behalf of two plaintiffs and a putative class of approximately 473 sales specialists working in Pennsylvania during the period March 2004 to the present; and the second in the US District Court for the Southern District of New York on behalf of one plaintiff and a putative class of approximately 890 sales specialists working in the state of New York during the period June 2001 to the present, claiming the sales specialists were misclassified as exempt from overtime pay under New York labour law.

Additionally, in June 2007, the firms representing Brody filed a nationwide collective action based on federal wage-and-hour law (FLSA) in the US District Court for the District of Delaware, seeking unpaid overtime compensation and liquidated damages. The lawsuit has a potential class size of 8,300 current and former sales specialists employed by the Group in the US during the period June 2004 to the present. The parties have negotiated a stipulation of dismissal of this lawsuit, and the action has been dismissed with prejudice. Plaintiff's counsel is expected to file a new FLSA action with a different named plaintiff in the near future.

## 27 COMMITMENTS AND CONTINGENT LIABILITIES CONTINUED

### Additional government investigations into drug marketing practices

As is true for most, if not all, major prescription pharmaceutical companies operating in the US, AstraZeneca is currently involved in multiple US federal and state investigations into drug marketing and pricing practices. The US Attorney's Office in Philadelphia is directing four active investigations involving AstraZeneca. The first two involve requests for documents and information relating to contracting and disease management programmes with two of the leading national Pharmacy Benefits Managers. The third involves a review of sales and marketing practices relating to *Seroquel*, including allegations that AstraZeneca promoted *Seroquel* for non-indicated (off-label) uses. The fourth investigation relates to selected physicians who participated in clinical trials involving *Seroquel*. The US Attorney's Office in Boston is conducting an additional investigation into sales and marketing interactions with a leading provider of pharmacy services to long-term care facilities. AstraZeneca understands that all of these investigations may be the subjects of sealed *qui tam* lawsuits filed under the False Claims Act.

There are also a number of additional active investigations led by state Attorneys General. These include multiple investigations relating to *Seroquel* off-label issues, discussed above, along with an investigation by the Delaware Attorney General's Office into marketing and sale activities within the state of Delaware.

It is not possible to predict the outcome of any of these investigations, which could include the payment of damages and the imposition of fines, penalties and administrative remedies.

### Congressional investigations

AstraZeneca, along with several other manufacturers, has received a letter from the Committee on Oversight and Government Reform of the US House of Representatives as part of the Committee's ongoing oversight of the pharmaceutical industry's research and marketing practices. The Committee has requested that AstraZeneca provide clinical and marketing information relating to *Seroquel*.

AstraZeneca also received letters from the Finance Committee of the US Senate requesting information regarding AstraZeneca's payments to certain identified physicians and their prescribing information related to *Seroquel*. In addition, the Finance Committee has requested sales and marketing information regarding the use of *Seroquel* in nursing homes.

AstraZeneca is co-operating with both Committees.

### Federal Trade Commission (FTC) study on authorised generics

In October 2007, AstraZeneca received a Special Order from the FTC, requesting certain information in connection with the FTC's industry-wide study of the short- and long-term competitive effects of authorised generics in the prescription drug marketplace. AstraZeneca has begun to collect the requested information and plans to respond to the Special Order.

### Informal US Securities and Exchange Commission (SEC) inquiry

In October 2006, AstraZeneca received from the SEC a letter requesting documents related to its business activities in Italy, Croatia, Russia and Slovakia for the period '1 October 2003 to the present'. The SEC's request generally seeks documents concerning any payments to doctors or government officials and related internal accounting controls. The request also seeks policies, correspondence, audits and other documents concerning compliance with the Foreign Corrupt Practices Act, as well as any allegations or communications with prosecutors' offices relating to corruption or bribery of doctors or government officials. AstraZeneca has produced documents in response to this request. It is not currently possible to predict the outcome of this inquiry.

### Serious Fraud Office (SFO) inquiry

In 2007, AstraZeneca received from the SFO in the UK a request for documentation about its involvement in the UN Oil for Food programme in Iraq. AstraZeneca denies any allegation of illegal or unethical behaviour in its trading relationships with Iraq. AstraZeneca will comply with the SFO's request for documentation.

### Other government investigations

From time to time, AstraZeneca receives enquiries and requests for information from a number of governmental and/or other regulatory bodies relating to a range of issues (some, but not all, of which relate directly to the business of AstraZeneca) and some of which are confidential in nature. AstraZeneca seeks to comply with these requests in an appropriate and timely manner and generally on the basis of legal advice received. The nature and scope of the investigation in relation to which such enquiries and requests for information have been received is not always known to AstraZeneca. Consequently, it is not always possible to determine whether such enquiries and investigations relate specifically to AstraZeneca or are merely a means of gathering factual information in the context of an unrelated third-party issue.

## NOTES TO THE FINANCIAL STATEMENTS CONTINUED

**27 COMMITMENTS AND CONTINGENT LIABILITIES CONTINUED****Taxation**

Where tax exposures can be quantified, an accrual is made based on best estimates and management's judgement. Details of the movements in relation to material tax exposures are discussed below.

AstraZeneca faces a number of transfer pricing audits in jurisdictions around the world and, in some cases, is in dispute with the tax authorities. The issues under discussion are often complex and can require many years to resolve. Accruals for tax contingencies require management to make estimates and judgements with respect to the ultimate outcome of a tax audit, and actual results could vary from these estimates. The international tax environment presents increasingly challenging dynamics for the resolution of transfer pricing disputes. These disputes usually result in taxable profits being increased in one territory and correspondingly decreased in another. Our balance sheet positions for these matters reflect appropriate corresponding relief in the territories affected. Management considers that at present such corresponding relief will be available but given the challenges in the international tax environment will keep this aspect under careful review. The total net accrual included in the Financial Statements to cover the worldwide exposure to transfer pricing audits is \$1,322m, an increase of \$327m due to a number of new audits, revisions of estimates relating to existing audits, offset by a number of negotiated settlements. For transfer pricing audits where AstraZeneca and the tax authorities are in dispute, AstraZeneca estimates the potential for reasonably possible additional losses above and beyond the amount provided to be up to \$400m; however, management believes that it is unlikely that these additional losses will arise. Of the remaining tax exposures, AstraZeneca does not expect material additional losses. It is not possible to estimate the timing of tax cash flows in relation to each outcome, however, it is anticipated that a number of significant disputes may be resolved over the next one to two years. Included in the provision is an amount of interest of \$234m. Interest is accrued as a tax expense.

**28 LEASES**

Total rentals under operating leases charged to the income statement were as follows:

	2007 \$m	2006 \$m	2005 \$m
	<b>210</b>	197	155

The future minimum lease payments under operating leases that have initial or remaining terms in excess of one year at 31 December 2007 were as follows:

	2007 \$m	2006 \$m	2005 \$m
<b>Obligations under leases comprise</b>			
Rentals due within one year	<b>103</b>	108	83
Rentals due after more than one year:			
After five years	<b>184</b>	161	90
From four to five years	<b>34</b>	30	18
From three to four years	<b>43</b>	38	26
From two to three years	<b>51</b>	51	41
From one to two years	<b>67</b>	63	52
	<b>379</b>	343	227
	<b>482</b>	451	310

## NOTES TO THE FINANCIAL STATEMENTS CONTINUED

**29 STATUTORY AND OTHER INFORMATION**

	2007 \$m	2006 \$m	2005 \$m
Fees payable to KPMG Audit Plc and its associates:			
Group audit fee	3.6	3.1	2.5
Fees payable to KPMG Audit Plc and its associates for other services:			
The audit of subsidiaries pursuant to legislation	6.1	5.4	5.0
Other services pursuant to legislation	3.6	4.1	0.8
Taxation	1.1	1.2	1.0
All other services	0.7	1.0	2.2
Fees payable to KPMG Audit Plc in respect of the Group's pension schemes:			
The audit of subsidiaries' pension schemes	0.6	0.5	0.5
	<b>15.7</b>	<b>15.3</b>	<b>12.0</b>

Other services pursuant to legislation includes fees of \$2.7m (2006 \$3.2m, 2005 \$nil) in respect of section 404 of the Sarbanes-Oxley Act. All other services includes \$nil (2006 \$nil, 2005 \$1.8m) in respect of section 404 of the Sarbanes-Oxley Act.

Included within the Group audit fee is an amount of \$0.1m (2006 \$0.1m) in respect of the audit of the Company.

Taxation services consist of tax compliance services and tax advice.

**Related party transactions**

The Group had no material related party transactions which might reasonably be expected to influence decisions made by the users of these Financial Statements.

**Key management personnel compensation**

	2007 \$'000	2006 \$'000	2005 \$'000
Short-term employee benefits	31,525	21,321	19,334
Post-employment benefits	2,072	3,191	1,731
Share-based payments	11,515	8,417	5,663
	<b>45,112</b>	<b>32,929</b>	<b>26,728</b>

Short-term employee benefits in 2007 include one-off employee costs of \$11m in relation to the acquisition of MedImmune.

Total remuneration is included within employee costs (Note 26).

**Subsequent events**

There were no material subsequent events.

## NOTES TO THE FINANCIAL STATEMENTS CONTINUED

## 30 SHARE CAPITAL OF PARENT COMPANY

	Authorised	Allotted, called-up and fully paid		
	2007 \$m	2007 \$m	2006 \$m	2005 \$m
Issued Ordinary Shares (\$0.25 each)	364	364	383	395
Unissued Ordinary Shares (\$0.25 each)	236	–	–	–
Redeemable Preference Shares (£1 each – £50,000)	–	–	–	–
	<b>600</b>	<b>364</b>	<b>383</b>	<b>395</b>

The total authorised number of Ordinary Shares at 31 December 2007 was 2,400,000,000, of which 1,457,000,853 Ordinary Shares were in issue.

The Redeemable Preference Shares carry limited class voting rights and no dividend rights. This class of shares is capable of redemption at par at the option of the Company on the giving of seven days' written notice to the registered holder of the shares.

The movements in share capital during the year can be summarised as follows:

	No. of shares (million)	\$m
At 1 January 2007	1,532	383
Issues of shares	5	1
Re-purchase of shares	(80)	(20)
<b>At 31 December 2007</b>	<b>1,457</b>	<b>364</b>

**Share re-purchases**

During the year the Company re-purchased, and subsequently cancelled, 79,927,377 Ordinary Shares at an average price of 2593 pence per share. The total consideration, including expenses, was \$4,170m. The consideration has been charged against retained earnings.

**Share schemes**

A total of 4,682,622 Ordinary Shares were issued during the year in respect of share schemes. Details of movements in the number of Ordinary Shares under option are shown in Note 26; details of options granted to Directors are shown in the Directors' Remuneration Report.

**Shares held by subsidiaries**

No shares in the Company were held by subsidiaries in any year.