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30 Legal proceedings

The Group is involved in various legal and administrative proceedings, principally product liability, intellectual property, antitrust, and governmental investigations and related private litigation. The most significant of these matters are described below.

Intellectual property

In the USA a number of distributors of generic drugs have filed applications with the FDA to market generic versions of *Paxil/Seroxat* (paroxetine hydrochloride) prior to the expiration in 2006 of the Group's patent on paroxetine hydrochloride hemihydrate. The distributors are looking to bring to market anhydrate or other versions of paroxetine hydrochloride and in one case paroxetine mesylate. The cases are complex but the Group believes that the generic anhydrate and other versions infringe because they contain and/or convert to the hemihydrate form and/or infringe other Group patents. In response the Group has filed actions against all those distributors for infringement of various of the Group's patents.

In July 1998 GlaxoSmithKline filed an action against Apotex in the US District Court for the Northern District of Illinois for infringement of the Group's patent for paroxetine hydrochloride hemihydrate. Apotex had filed an Abbreviated New Drug Application (ANDA) with the FDA seeking approval to introduce a generic form of *Paxil*. Following a trial in February 2003 the judge ruled that GlaxoSmithKline's patent is valid but not infringed by Apotex's product. GlaxoSmithKline is appealing the ruling of non-infringement to the US Court of Appeals for the Federal Circuit (CAFC), which hears all appeals from US District Courts on intellectual property matters.

In June 1999 GlaxoSmithKline filed an action against Geneva Pharmaceuticals, a subsidiary of Novartis Pharmaceuticals, in the US District Court for the Eastern District of Pennsylvania for infringement of the Group's patents for paroxetine hydrochloride following notice of Geneva's ANDA filing. That case has been consolidated with similar infringement actions against other generic companies that subsequently filed ANDAs. Additional infringement actions have been brought based on patents issued subsequent to the original filing against Apotex in the Northern District of Illinois. The Group also filed an action against Apotex relating to those new patents in the Eastern District of Pennsylvania. In December 2002 the judge granted in part and denied in part summary judgement motions filed by Apotex with the result that issues of validity and infringement of three of the four new patents will move toward trial. GlaxoSmithKline has petitioned the District Court to permit an interim appeal to the CAFC. The last to expire Hatch-Waxman stay on FDA approval of the Apotex ANDA expires in September 2003.

In February 2003 the CAFC heard Apotex's appeal from a decision by the US District Court for the District of Columbia denying Apotex's request that the FDA be required to delist certain of the Group's patents for *Paxil* from the Orange Book. The CAFC has not yet ruled on that matter. In addition, Apotex has applied to the court in the litigation in the Eastern District of Pennsylvania for an order that GlaxoSmithKline delist certain patents.

In March 2000 GlaxoSmithKline filed an action against Pentech Pharmaceuticals in the US District Court for the Northern District of Illinois for infringement of the Group's patents for paroxetine hydrochloride. Pentech filed an ANDA for a capsule version of *Paxil*, asserting that its compound and presentation do not infringe the Group's patents or that the patents are invalid.

Even if the FDA were to approve the Pentech ANDA, GlaxoSmithKline believes that the Pentech capsule would not be substitutable for *Paxil* tablets.

In October 2000 GlaxoSmithKline filed an action against Synthon Pharmaceuticals in the US District Court for the Middle District of North Carolina for infringement of the Group's patents for paroxetine hydrochloride and paroxetine mesylate. Synthon had filed a 505(b)(2) application (a 'paper NDA') with the FDA using paroxetine mesylate, a different salt form of paroxetine than that used in the marketed form of *Paxil*. Even if the FDA approves the Synthon application, GlaxoSmithKline believes the Synthon compound would not be substitutable for *Paxil*. Briefing on summary judgement motions filed by the parties has been completed and those motions remain pending. No trial date has been set. The Hatch-Waxman stay on FDA approval of the Synthon application expires in April 2003.

Following the expiration of the data exclusivity period in Europe, a marketing authorisation was issued to Synthon BV/Genthon in October 2000 by regulatory authorities in Denmark for paroxetine mesylate, a different salt form of paroxetine than that used in the marketed form of Seroxat/Paxil. Marketing authorisations have since been granted in nine other European countries, one further national approval and eight approvals under the Mutual Recognition process based on the original Danish approval. Generic products containing paroxetine mesylate have been launched in Denmark, Germany, The Netherlands, Austria, Ireland, Sweden and Italy, although the product in Austria and Denmark has been withdrawn following the award of patent interim injunctions. The Group has initiated litigation challenging the approval by the Danish Medicines Agency on grounds that an authorisation should not have been granted under the abridged procedure as paroxetine mesylate is not essentially similar to *Seroxat*. Marketing authorisations have also been issued in eleven European countries for products containing paroxetine hydrochloride anhydrate, another variant of the Group's product. Generic products containing the anhydrate are now on the market in Germany, Austria, Denmark, the Netherlands, Spain, Sweden and Finland. GlaxoSmithKline believes that marketing of either a paroxetine hydrochloride anhydrate product or a paroxetine mesylate product by third parties in European countries infringes its patents and is litigating its position in actions in many European and other countries outside the USA. In June 2002 the European Patent Office Opposition Division rejected an opposition filed by Synthon against the Group's European patent covering a crystal form of paroxetine mesylate that is used in Synthon's product. That decision is under appeal. In contrast, following an action initiated by Synthon, a UK court revoked the corresponding UK patent relating to paroxetine mesylate in December 2002. An appeal before the Court of Appeal is expected to commence in May 2003. In February 2003 the Dutch court revoked the corresponding Dutch patent which decision will also be appealed.

In response to a challenge by BASF to the Group's UK patent for paroxetine hydrochloride anhydrate in the UK High Court in July 2002 the Judge decided that the patent was partly valid and partly invalid. The claims held valid were asserted against Apotex, Neolab and Waymade Healthcare and an interim injunction preventing sale of their version of the product was granted in November 2002. The decision granting the injunction was affirmed on appeal in early February 2003. A full trial relating to both alleged infringement and alleged invalidity will take place in June 2003.