EPO rules on contested gene patent

➜ Kathy Redmond

The European Patent Office (EPO) has decided that the European patent on mutations in breast and ovarian cancer susceptibility (EP 705903) is to be maintained in amended form.

The original patent, one of a number granted to the American company Myriad for the BRCA1 and BRCA2 genes, had been contested by a number of bodies, including European research institutions, who argued that it was too restrictive and that, taken together, the patents gave Myriad a virtual monopoly on genetic testing.

European laboratories have developed their own methods for testing for mutations of the BRCA1 gene but, under the terms of the patent, Myriad would have had sole right to carry out tests, for which they charge around 2000 euros.

The decision to maintain the patent, but in amended form, was reached by a panel following a public hearing involving all parties to opposition proceedings. The patent now relates to a gene probe of a defined composition for the detection of a specific mutation in the breast and ovarian cancer susceptibility gene and no longer includes claims for diagnostic methods. This should mean that other companies and institutions will be free to offer genetic testing for BRCA 1 mutations. The parties to the proceedings are entitled to appeal this decision.

It's bonanza time for cancer drugs

The sales of anti-cancer drugs grew dramatically in 2004, overtaking anti-depressants and mood stabilisers as the third-ranked therapy class. A report from IMS Health showed sales were up 17% on 2003. During the same year global pharmaceutical sales as a whole grew by 7%. Nearly 45% of all global sales were in the US with only 28% in the European Union. Today, seven anti-cancer drugs have achieved blockbuster status, commonly defined as having sales of over US$1 billion (770 million euros) per year. These are MabThera (rituximab), Glivec (imatinib), Eloxatin (oxaliplatin), Gemzar (gemcitabine), Casodex (bicalutamide), Taxotere (docetaxel) and Zometa (zoledronic acid).

Audited world therapy class	2004 Sales (US$bn)	% Global sales (US$)	% Growth year-on-year (constant $)
Cholesterol & triglyceride reducers	$ 30.2	5.8%	11.7%
Antiulcerants	25.5	4.9	1.4
Cytostatics	23.8	4.6	16.9
Antidepressants	20.3	3.9	1.3
Antipsychotics	14.1	2.7	12.1
Antirheumatic non-steroidals	13.1	2.5	3.3
Angiotensin-II inhibitors	12.0	2.3	22.1
Calcium antagonists plain	11.6	2.2	1.6
Erythropoietin products	11.4	2.2	8.9
Anti-epileptics	11.3	2.2	17.7
Total leading therapy classes*	$ 173.3	33.2%	8.9%

*Sales cover direct and indirect pharmaceutical channel purchases in US dollars from pharmaceutical wholesalers and manufacturers. The figures above include prescription and certain over-the-counter data and represent manufacturer prices. Totals may not add due to rounding.

Source: IMS Midas®, MAT Dec 2004.

THE EUROPEAN COMMISSION (EC) has approved Roche's Avastin (bevacizumab, rhuMAb-VEGF), an anti-angiogenesis agent indicated for the treatment of patients with previously untreated metastatic colorectal cancer. Avastin is now approved for the first-line treatment of patients with metastatic carcinoma of the colon or rectum in combination with the chemotherapy regimens of intravenous 5-fluorouracil/folinic acid or intravenous 5-fluorouracil/folinic acid/irinotecan.

THE CHMP, EMEA'S Committee for Medicinal Products for Human Use, has recommended that Aloxi (palonosetron) from Helsinn Birex Pharmaceuticals be approved for the prevention of chemotherapy-induced nausea and vomiting. The EC must now decide whether to award marketing authorisation for the product.

ROCHE'S DRUG TARCEVA (erlotinib) has been approved by the Swissmedic for the treatment of patients with locally advanced or metastatic non-small-cell lung cancer (NSCLC) after failure of at least one prior chemotherapy regimen. Roche filed for approval with the Swissmedic in September 2004 and was granted a fast track procedure. Tarceva was first approved in the US in November 2004. EU approval is still outstanding.

ASTRAZENECA HAS WITHDRAWN its European marketing authorisation application for its EGFR- (epidermal growth factor receptor-) targeted anticancer agent Iressa (gefitinib). The company took this decision after consultation with EMEA, in view of the Iressa Survival Evaluation in Lung cancer (ISEL) results, which do not meet approval requirements for the requested indication. The company will consider a new application for Iressa in the future, after evaluation of the full ISEL dataset and emerging data. AstraZeneca has announced that it will not close the Iressa compassionate use (expanded access) programme to new patients until the full ISEL dataset is reviewed, as it is convinced that Iressa provides some benefit for patients with non-small-cell lung cancer (NSCLC). The status of all ongoing AstraZeneca-sponsored studies in NSCLC is under review. Investigator and co-operative groups have been informed, all trials are open to recruitment and are being reviewed on a case by case basis. Studies in other cancer types are set to continue.

NOVARTIS HAS RECEIVED marketing authorisation via the EU's Mutual Recognition Procedure in Germany for Femara (letrozole) for the treatment of postmenopausal women who have completed five years of standard adjuvant (post-surgery) tamoxifen therapy (extended adjuvant).

NOVARTIS HAS UPDATED its US package insert for Aredia (pamidronate) and Zometa (zoledronic acid) to warn that there have been reports of osteonecrosis of the jaw (ONJ) in patients with cancer receiving bisphosphonates as a component of their treatment. The majority of cases are associated with dental procedures, and while on treatment patients are advised to avoid invasive dental procedures. The Australian Therapeutic Goods Agency has also issued a safety alert warning of the risk of bisphosphonates and ONJ. The European package insert has not changed and EMEA have not issued a safety alert.

EMEA HAVE ISSUED new guidelines on the evaluation of anticancer medicinal products in humans for consultation. The revised guidelines aim to cover the wide spectrum of anti-cancer agents in development in a more comprehensive manner. The deadline for comments is June 30th 2005 and the guideline is available on the EMEA site at www.emea.eu.int.

EXTENDED INDICATIONS

The CHMP has recommended the following extensions to indications for cancer drugs:

- Merck Sharpe & Dohme's Emend (aprepitant), for use in the treatment of moderately emetogenic cancer chemotherapy
- Janssen-Cilag's Velcade (bortezomib) for patients with progressive myeloma who have received at least one prior therapy and who have already undergone or are unsuitable for bone marrow transplantation
- Roche's Xeloda (capecitabine) for use as an adjuvant treatment of patients following surgery for colorectal cancer (Duke's stage C)
- Norton HealthCare's Paxene (paclitaxel) for use in combination with cisplatin for the treatment of advanced ovarian cancer and in the treatment of non-small-cell lung cancer.
- Sanofi-Aventis' Taxotere (docetaxel) for use in combination with doxorubicin and cyclophosphamide in the treatment of patients with operable node-positive breast cancer and in combination with Herceptin (trastuzumab) in patients with metastatic breast cancer whose tumours overexpress HER2.