PATENT LAW

Talking of harmony

Washington

1989 ends with patent lawyers hopeful that at long last the holy grail of patenting — the international harmonization of patent laws — lies within their sight, if not yet within their grasp. The reason for this surge of optimism is the unexpected success of the World Intellectual Property Organization (WIPO) set up last year in Geneva under UN sponsorship.

Unlike two earlier organizations that attempted harmonization of patent law, WIPO involves 121 countries, not just the patent offices of Europe, the United States and Japan. WIPO sponsored a successful meeting in Geneva in November at which patent experts examined the details of a draft harmonization treaty. It will sponsor a second meeting next June, with the aim of preparing a treaty for a diplomatic conference in June 1991.

The draft treaty that WIPO discussed in November would bring in some striking changes. The most contentious for the United States is a change from a 'first-to-invent' system to the 'first-to-file' system practised in Japan and Europe in which the patent is granted to whoever wins the race to the patent office. Although proponents of the US system contend that it is fairer, the procedures to determine who was first to invent are time-consuming and expensive.

Many of the clauses in the treaty are hotly disputed by all WIPO members, but one that meets with few obstacles is the plan for a uniform 'grace period' — the time before a patent application is filed during which the disclosure of a competing invention cannot influence the granting of a patent. The United States allows a grace period of one year and Japan six months but Europe has no grace period at all. This difference is one of the most troublesome for those filing for patents in several different countries. Most members agree on a 12-month grace period.

A rule that patent applications must be published no later than 18 months after they are filed is strongly supported, with objections only from the United States and New Zealand. The United States complains that it is unfair to publish a patent application because if the patent is not subsequently granted, valuable secrets may be given away. As the US patent office grants patents, on average, about 18 months after the date of application, the United States argues that there is no need for compulsory early publication, especially as much of the information is disseminated in scientific jurnals. But Japan argues that early publication benefits both everybody because it avoids a long period of insecurity during which the contents of patent applications remain unknown.

Japan's preference for early publication is in part explained by the remarkable length of time it takes to examine patents. Not surprisingly, Japan objects to attempts to put a time limit of 18 months on examination of patents. Opposing the United States, United Kingdom, the Soviet Union and others supporting the limit, Japan argues that strict time limits have no place in an international treaty because many unpredictable factors, such as surges in the number of patent applications or a shortage of patent officers, could block even efforts made in good faith to meet them.

One article in the draft treaty which could reduce the enormous number of patents currently clogging up the Japanese system gains universal support. The article broadens the meaning of 'unity of invention', so that technically related features of an invention are all protected under one patent, rather than under several different ones as is now common.

The question of patent lifetime provokes much argument. The draft WIPO treaty would provide 20 years protection. Uruguay is among those that argue that 20 years is too long, and India argues that the term should vary for different fields of ▶

EPO PATENT DISPUTE

Court battle ends at the start

Washington

ONE of biotechnology's longest-running battles was expected to end last week but now looks set to go into a new round of bargaining and bickering. On Monday 11 December a Boston court ruled that neither of the two protagonists — Genetics Institute of Boston and Amgen Corporation of Thousand Oaks, California — has a clear overall right to produce recombinant erythropoietin (EPO) by genetic engineering. In the short term, the ruling seems to favour Genetics Institute. EPO is a kidney cell protein that stimulates bone marrow red-blood-cell production, and annual worldwide sales are expected to reach between $250 million and $1,000 million.

The ruling, which is complex and runs to 184 pages, validates the central claims of the patents held by the two companies but at the same time doubles the confusion by considering both patents partially invalid and mutally infringing.

The Genetics Institute patent, issued in June 1987 after the company purified EPO from human urine, refers to "homogeneous human EPO", a term that the company claims to include recombinant EPO. The Amgen patent, issued in October 1987, covers the gene, vectors and cells required for production of recombinant EPO, although the patent did not specify the product itself.

Genetics Institute's version of recombinant EPO is called Marogen and is currently only in experimental use in the United States as it has not gained Food and Drug Administration (FDA) approval.

Amgen's recombinant EPO, called Epogen, gained FDA approval in June, 1989 and already has sales of more than $50 million.

The most immediate effect of the court decison may be to make it easier for Genetics Institute to produce Marogen abroad. The Amgen patent has so far prevented Genetics Institute from manufacturing recombinant EPO in the United States. But it has been getting around the restriction by licensing Marogen to Chugai Pharmaceuticals of Japan and importing the product into the United States.

The new ruling found that offshore production of recombinant EPO by Chugai Pharmaceuticals does not infringe the Amgen patent, effectively putting an end to legal action by Amgen designed to prevent the import of Marogen. Even worse for Amgen, the ruling says that Amgen cannot produce Epogen in the United States without infringing the Genetics Institute patent. That puts Amgen in the same boat as Genetics Institute, which cannot produce recombinant EPO without infringing Amgen's patent. Amgen says that the ruling is unlikely to affect the availability of Epogen to patients. The stage looks set for a tussle over some form of cross-licensing agreement.

But Amgen may try to gain an advantage by waiting for the outcome of actions associated with a wider EPO dispute. Amgen has submitted two EPO process patents. If they are granted, Chugai Pharmaceuticals would be prevented from importing recombinant EPO into the United States.

Amgen is also benefiting from 'orphan drug' status for Epogen, granted by FDA for the treatment of anaemia in patients with chronic renal failure. This provides Amgen with a seven-year monopoly in the United States (see *Nature* **339,** 493; 1989). Marogen, which is awaiting FDA approval for sale in the United States, could receive equivalent status if the FDA declares it to be a product distinct from Epogen. If not, an agreement may be negotiated whereby the orphan-drug status of Epogen is shared with Genetics Institute in return for Amgen not paying royalties in a cross-licensing agreement.

Both parties may, however, wish to see a speedy resolution to the dispute as the market for EPO is huge. **Diane Gershon**