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THE LAST WORD/

FOR EUROPE TO COMPETE

by Gerard Fairtlough

Forecasters predicting which countries are most likely to succeed in the race to incorporate the new biotechnologies into marketable products generally put the U.S. at the top of the list. Japan, they say, likely will catch up in due course, and Europe will be left behind. But this scenario is not inevitable. Enormous strength exists in Europe in basic science, as demonstrated by the U.K. Medical Research Council Laboratory of Molecular Biology at Cambridge and the Institut Pasteur (Paris). Scientific training is excellent. And European pharmaceutical firms, with loads of cash and well-established world-wide marketing and distribution channels, continue to compete quite effectively in the global race.

The fight for market share will be tough, and Europe cannot for one instant relax. High levels of R&D spending will be required, entailing a lot of risk and some very skillful leadership and direction. But the right environment for patenting, product registration, and pricing is vital to justify such R&D spending. Europe would be very foolish to handicap itself in this competition. The wrong procedures for regulatory approval of new drugs and for patents can seriously disadvantage European-based researchers.

By design, the European Commission's drug registration regime has been spearheaded by high technology products—in particular, biopharmaceuticals. The reasons for this are twofold: the expectation that introducing a new system for a new type of product would be easier; and the fact that introducing an important new technology is a stated aim of the European Community (EC). This also dovetails with the EC's goal of achieving a fully integrated market for pharmaceuticals by the end of that magic year, 1992.

The Committee for Proprietary Medicinal Products (CPMP) was formally established in 1976 to enable rapid co-recognition of member states' product approvals. Under this so-called multi-state procedure, a license granted by one state may be recognized by some or all of the other EC member states. The Community also established a separate mechanism for biopharmaceuticals in 1987, called concertation, under which the CPMP itself will consider applications before the member states do.

Experience with the initial multi-state procedure has been mixed. Some 50 or more multi-state applications have gone through. But they often have been delayed considerably relative to the timetable laid down in the EC directives that established the procedure. And even when the process has been followed, not all member states have granted licenses in mutual recognition.

The newer concertation procedure, encompassing products such as erythropoietin and interleukin-2, seems to be operating better. So it may be possible to say that Europe has responded well to the challenge of simpler and more rapid registration, but in ways that do not lower the high standards essential to protect patients.

But there may be problems ahead. First, rivalry between the CPMP and national regulatory agencies (that may fear losing influence and jobs) can cause interagency squabbling that may create delays and extra costs for applicants. The sheer volume of work under CPMP also may slow things down, regardless of good intentions, and recruiting staff, especially in a multi-national context, is not easy. The U.S. and Japan enjoy the advantage of an already established system. The talk in the U.S. about federal-state and interagency conflicts pales by comparison to the task the EC now faces.

What about patent issues? In the U.S. patent priority is decided by reference to the date of invention, which is determined by examining laboratory notebooks and other records. In the European system, the *date of filing* establishes priority. Under the U.S. system inventors do not have to worry much about enablement; initially everything need not be set out in a way that would allow others to replicate the idea as this can be added to the patent specification later on. Under the European system, however, the filing has to be reasonably enabling (but traditionally, it has been possible to add further data during the twelve months after the first filing). Signs are that the European Patent Office is now insisting on much fuller enablement in the initial filing, a trend that would put European researchers at a considerable disadvantage.

The U.S. system therefore gives researchers the earliest possible priority date while the Europeans are insisting on more complete data. Of course fuller data make for a better patent, but if the U.S. courts uphold the patents filed under the U.S. system—which they generally do—then the greater theoretical perfection of the European system is to no avail. What is happening in Europe will be felt more strongly by academia and small companies—the heart of discovery research. A huge industrial laboratory is better able to throw resources at a project in order to produce the data required for fuller enablement at an earlier stage. Academics, by contrast, need to file early to be able to publish their work, as well as protect it commercially. This almost always precludes a fully enabling description at the time of filing, but with the help of an industrial collaborator, it can be fleshed out over the ensuing year.

Ideally, the three major industrial areas should move their patent laws into harmony, preserving the best of each system. The best mixture might be the "date of filing" feature of the European system, plus some ability to provide full enablement at the later stages (as the U.S. allows, although this would have to be done in a manner different from the current U.S. procedure). Another useful feature would be the one-year grace period which the U.S. system provides.

Some of us love the intricate convolutions of the world patent scene, while others wish they would stop interrupting the progress of science. But like it or not the impact of patent systems on research in biological science is enormous. All would do well to understand this impact, and we Europeans would do well to make sure that our patent and regulatory systems are as friendly to our researchers as they are to our international competitors.

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