

# Patents in the public interest

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**The UK High Court has granted an injunction allowing Chiron Corporation a monopoly in selling hepatitis C virus test kits. The decision will be welcomed by the pharmaceutical and biotechnology industries.**

LAST month, the UK High Court rejected applications by Murex Diagnostics Limited and Organon Teknika Limited to end Chiron's monopoly in making and selling hepatitis C virus (HCV) test kits (see *Nature* 372, 485; 487; 8 December 1994). The crux of Murex and Organon's case was that an injunction would be contrary to the public interest: first, it was in the public interest that other test kits should be available, not just Chiron's; and, second, an injunction would impede research and development. This decision follows an earlier judgement in which the High Court found Chiron's patent to be valid and infringed.

Much controversy has surrounded the issue of whether injunctions should be granted in these types of cases. The courts do have discretion to award damages rather than injunctions, either by a lump sum or on a royalty-type basis for the remaining term of the patent. But this discretion is exercised only rarely, and we believe that it was right to award the injunction on this occasion and, indeed, that it can hardly ever be right to refuse injunctions in patent cases.

HCV is widely distributed around the world, with 0.1–2 % people affected in Western Europe and North America, 3% in some Mediterranean countries and up to 6% in some tropical areas. Some estimates suggest 300 million people are affected world-wide. Murex is concerned because it believes that only Chiron and companies that license from Chiron will have access to the UK market for hepatitis-C screening. Hepatitis-C tests cost three to four times more than many other virus tests. Murex has until now supplied the UK's National Health Service with more than a third of its HCV test kits

The companies are also concerned that the injunctions will suppress further research and development on the virus test that would eventually benefit patients. One example is the development by Murex of an assay for serotyping the virus (there are at least six strains of HCV) which Murex believes to be "a unique epidemiological tool". The assay is about to come into use, but would be suppressed by an injunction. (Chiron is also working on its own assay but has not announced when it will be ready.) But in court last month Murex and Chiron sensibly agreed a "stay" on the injunction pending the appeal on this assay only, because there is no alternative currently available.

Although accepting that an injunction gives the patentee a monopoly, thus providing the right to restrict competition and put prices up, the UK patents judge, Mr Justice Aldous, said that this is inherent in any patent system. If an injunction had not been granted here, it would set an unhelpful precedent for arguments that injunctions should not be granted for most pharmaceutical patents, for example antibiotics or anti-inflammatory drugs.

It is true that the injunction means that the HCV test is likely to be more expensive. Nonetheless, there are many advantages of the patent system, mainly in stimulating technical progress: it encourages research and invention; it induces inventors to disclose discoveries; it offers a reward for the expense of developing inventions to the level at which they are commercially practical; and it provides an inducement to invest capital in new lines of production which might not appear profitable if many competing producers embarked on them simultaneously — particularly relevant to medicinal products.

Additionally, patent laws have always contained safeguards to protect the public against abuse by a patentee of monopoly rights: compulsory licenses are available (after 3 years from the date of the patent) if, for example, there were not sufficient HCV test kits available or if the court considered Murex's test kits made a substantial contribution to the art and its working was "prevented or hindered" by Chiron's patent. Further, there are provisions in the UK Patents Act for Crown use, that is for life-saving drugs, medicines and diagnostic kits to be made available publicly in the United Kingdom without the patentee's permission. The Crown has the power to authorize Murex to sell its own test kits.

Injunctions should be refused only in extreme cases: a vital life-saving medicine or an epidemic that requires urgent treatment which could be given only by the infringing product, not merely because the treatment will cost more because of the patentee's monopoly. With safeguards for the public already in place, everything must be done to strengthen the rights of patent owners and the patent system around the world. Otherwise, potentially crucial discoveries can be lost. For example, in countries such as those of Eastern Europe, where researchers rank among the best in the world, inventions cannot be properly exploited because the necessary

infrastructure for obtaining and asserting patents does not exist.

A move in the right direction was the introduction recently of supplementary protection certificates (SPCs) by the European Commission to extend the protection for patents for pharmaceuticals. The term of a European patent is 20 years from the filing of the application, and the patentee cannot bring an action to restrain infringement until the patent is granted. With delays in granting patents, particularly in areas such as biotechnology where there is so much legislative ambiguity and lengthy clinical trials and regulatory approval are often required before a drug can be marketed, the effective monopoly is often as little as 10 years, and can be 3 or 4 years. In contrast, the patent term in the United States is 17 years from grant, so delays in the application procedure have no impact on the length of effective monopoly. The SPC extends the period of protection initially conferred by a patent, once that patent has expired, to compensate to an extent for the patent life lost in obtaining such approval. The duration of the certificate reflects a compromise between the interests of patentees and those of generic producers, and is therefore equal to the patent life lost between the patent filing date and the date of first marketing approval in the community, minus 5 years, subject to a maximum of 5 years.

The judge dismissed Murex's argument that an injunction would impede research and development on the grounds that "there can be no doubt that the Chiron patent monopoly will in the short term deter some companies from carrying out research and development, but that is inherent in the patent system".

For every successful research project, countless others fail miserably. They all require substantial investment. They must all continue if breakthroughs are to be made at the pace they are required. There must be as much incentive as possible for scientists to be encouraged to innovate. In the words of Mr Justice Aldous, "It is in the public interest that patent monopolies be enforced with the resulting restrictions upon competition that are inherent in the patent system". □

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