Immunity from Infringement For Use in Clinical Testing

Does it Cover All Devices Used in Clinical Testing, or Only Devices For Which FDA Approval May be Sought?

By Thomas Carey, Partner

Not for the first time, a federal court has read reason into an illogical provision of the Hatch-Waxman Act in order to arrive at a fair result. In doing so, it ignored the plain language of the statute, which is in great need of repair.

InnovaSystems makes and sells a device that, while not itself the subject of FDA clinical trials, is designed for use in clinical trials of aerosol sprays used as drug delivery devices. The design of the device is covered by a patent owned by Proveris Scientific Corporation. In Proveris Scientific Corporation v. Innovasystems, Inc., the Court of Appeals for the Federal Circuit held that Innova could not make, use or sell the device without a license from Proveris, notwithstanding statutory language that seems to compel the opposite result.

Innova admitted that Proveris's patent read on its device, but claimed immunity from suit under 35 USC 271(e)(1), which provides:

> [I]t shall not be an act of infringement to make, use, offer to sell or sell within the United States … a patented invention … solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

This statute, enacted as part of the Hatch-Waxman Act, contains no express requirement that the patented invention itself be the subject of the regulatory submission. The statute requires only that the use be "reasonably related" to the development of information needed for such a submission. Pharmaceutical companies purchased Innova's device to determine the spray characteristics of nasal sprays that they intended to submit to the FDA for regulatory approval. Under those circumstances, how could Innova not be protected by the statute?

In finding that Innova was not protected, the Federal Circuit relied upon Eli Lilly & Co. v. Medtronic, Inc., 496 US 669 (1990), in which the Supreme Court examined the same statute and held that it protected the testing of medical devices, even though the statute refers expressly only to "drugs or veterinary biological products."

This interpretive *tour de force*, the dissent from which attracted none of the strict constructionists on the Supreme Court, appears to have been motivated by a desire to achieve a sensible result in furtherance of the spirit of the Hatch-Waxman Act: to counteract the distorting effects that the FDA regulatory process can have on a patent term.

These effects are two-fold: the process can shorten a patent term by delaying the introduction of a novel drug; and lengthen it by delaying the introduction of generics at the end of the term. The former effect was addressed in 35 U.S.C 156(a), which allows for the extension of a patent term if the introduction of a product is delayed by the regulatory process.

The latter effect was addressed in section 271(a), which allows a generic drug maker to begin to collect data on a generic drug before the patent term on the pioneer drug has expired. Unfortunately for lovers of symmetry, the former statute expressly includes medical devices in its scope, while the latter does not.

In *Eli Lilly*, the Court held that the phrase "patented invention" in section 271(e) includes all products described in section 156(a) (including medical devices), and that the testing of patented medical devices without a license is therefore not infringing because of section 271(e).

The Court knew that it had stretched the words of the statute. It said: "No interpretation we have been able to imagine can transform 271(e)(1) into an elegant piece of

statutory draftsmanship. To construe it as the Court of Appeals decided, one must posit a good deal of legislative imprecision; but to construe it as petitioner would, one must posit that and an implausible substantive intent as well."

The Federal Circuit followed in the tracks of the Supreme Court by holding that the measurement device at issue in *Proveris* was not a "patented invention" within the meaning of section 271(e) because it is not a product described in section 156(a) as subject to regulatory review.

If the Court of Appeals had ruled differently, patents covering products that constitute research equipment used in FDA clinical trials might have been rendered worthless. Such a result was not the intent of the Hatch-Waxman Act, yet a creative reading of the statute was needed to preserve a fair outcome.

It would be too much to expect legislators to clean up this statutory language to reflect the sensible opinions of the Supreme Court and the Federal Circuit. Thus, one must immerse oneself in the case law to understand that a statute that says one thing actually means something quite different.