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# Big trouble over tiny enzymes: limits on geographic reach of Patent Act

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A dispute over a tiny enzyme could have a far-reaching impact for patent holders whose covered technology can be assembled in components. In keeping with a decades-long trend, the Supreme Court has again articulated limits on the foreign reach of US patent rights for exported products.

In May 1972 another large dispute, this time concerning a tiny crustacean, made its way before the court. The clash concerned machines for deveining shrimp, and the issue was whether Deepsouth Packing Co had infringed a rival's patents on the machines by making all of the component parts of the infringing machines in the United States, then shipping them overseas in three separate boxes to be assembled and used abroad. Under the then-current version of the Patent Act, the court's answer was no (*Deepsouth Packing Co v Laitram Corp*, 406 US 518 (1972)).

In Congress's view, the *Deepsouth* decision exposed a loophole in the existing Patent Act: suppliers could avoid liability for the unauthorised making or selling of a US-patented product simply by shipping its domestically made component parts out of the country for assembly. To close this loophole, Congress enacted 35 USC §271(f) in 1984. Under Section 271(f)(1), the supplier faces liability where the export comprises "all or a substantial portion of the components of a patented invention".

Relying on the statute's use of the term 'substantial', Promega Corporation sued its sub-licensee, Life Technologies Corporation, over the latter's alleged unlicensed sales of the technology covered by the former's US Reissue Patent No RE 37,984 (the Tautz patent). At trial, a jury determined that Life Technologies had indeed infringed. The dispute in question then arose when Promega produced a damages calculation including damages resulting from foreign sales of the patented technology. Under Section 271(f)(1), such sales fall foul of Promega's US rights in the Tautz patent only if "all or a substantial portion of the components" of the device were supplied from the United States.

Yet only one component of patented device was manufactured by Life Technologies in the United States: an enzyme known as the Taq polymerase. After producing the enzyme stateside, Life Technologies then shipped it to its UK facility, where it was combined with four other components to make a genetic testing toolkit designed for use by law enforcement agencies and clinical and research institutions for forensic identification. In the court's view, this single component was not enough to be considered a "substantial portion" of the patented toolkits, despite expert trial testimony that the Taq polymerase was a "main" and "major" component of the kits (*Life Technologies Corp v Promega Corp*, __ US __ (Feb 22 2017)).

In rendering its decision, the Supreme Court rejected the qualitative test embraced by the Federal Circuit below for determining what aspect(s) of a patented device comprise a "substantial portion". Instead, patent holders (and their licensees and competitors) are left with a bright-line rule: a critical component of an invention under a US patent can nonetheless be manufactured in the United States by a third party with impunity, provided that the component is shipped abroad for assembly with the remaining components and sale. Of course, manufacturers should be mindful that single-component US manufacture could give rise to liability under the second half of Section 271(f) (35 USC §271(f)(2)) if that single component is a specialised piece for use specifically in the patented device – that is, a single component "especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial non-infringing use".

The *Promega* decision should be considered by patent holders and manufacturers or suppliers (and their attorneys) where export of all or a portion of a patented product is likely. *Promega* provides a bright-line rule that exporting a single component part (of even a two-component invention covered by a US patent) places the exporting party outside the reach of the patent holder's US patent rights. For licensors, licensing a third party to make or sell a single component of a patented device could be dangerous as a complete workaround for the licensee could be exporting the component for assembly and sales overseas. There is a potentially wide divide between a single component part and the entirety of a patented invention, and the *Promega* decision provides no insight into where exactly the Supreme Court may draw the line between 'substantial' and 'insubstantial'. That said, bright-line rules articulated by the court are relatively few and far between and, in this case, the court's decision could provide a small island of certainty in an otherwise complex legal landscape.

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