AN UNSETTLED AREA OF PATENT INFRINGEMENT LAW

Paul Sutton looks at the confusing and unsettled US picture regarding the infringement of manufactured product patents.

There is an unsettled area of US patent law regarding the infringement of patents that include 'product-by-process' and 'product-formed-by-process' types of claims. Many products that are imported into and sold within the US have been manufactured using processes or methods, some of which have been performed abroad. Others have been made through a series of processes by more than a single entity, some performed abroad with the remainder completed in the US. When deciding the issue of infringement, it is not clear how the US courts construe the scope of such product-by-process patent claims. This presents a challenge to those asked to opine regarding patents' scope and the issue of infringement. For the purposes of this article, the terms 'method' and 'process' are used synonymously.

US patent attorneys are routinely asked by clients to provide them with infringement and/or non-infringement opinions. For clients wishing to enter the US market with a product, there will be comfort for those who first obtain a written 'right to use' or non-infringement patent opinion covering their new product prior to its introduction. Similarly, clients that own patents and wish to enforce them against perceived infringers would be wise to first obtain an infringement opinion before rushing to court. The Federal Rules of Civil Procedure provide for district court sanctions against attorneys and parties who, after notice and a reasonable opportunity to respond, submit pleadings containing arguments that are frivolous or that have no evidentiary support.

Many inventions reside in novel industrial processes used to make products that may be indistinguishable from existing products. Product areas where new manufacturing processes have proliferated include composites, metals, plastics and ceramics (see *Composites Manufacturing: Materials, Product, and Process Engineering* by Sanjay Mazumdar). Industries within which these products have become commonplace include aerospace, automotive, dental, sporting goods, marine applications and consumer goods, to name but a few.

A product-by-process patent claim is a product claim that "defines the claimed product in terms of the process by which it is made". Similarly, according to the Manual of Patent Examining Procedure, "[a] claim to a device, apparatus, manufacture or composition of matter may contain a reference to the process in which it is intended to be used without being objectionable under 35 U.S.C. 112, second paragraph, so long as it is clear that the claim is directed to the product and not the process".

There was a time when the US Patent and Trademark Office (USPTO) only permitted the product-by-process patent claim format to be used where the product could not be adequately defined other than by reference to the process steps by which the product was made. The USPTO reversed this view, and this is no longer a requirement.

This presents a challenge for the IP attorney seeking to draft patent claims that will protect such inventive processes and their resulting products. The claim drafter will normally create claims of varying scope, which may include product-by-process claims, where appropriate. There are other IP practitioners who may "…avoid a product-by-process [patent claim] format unless the invention cannot be distinguished from a prior art product in terms of composition and/or structure. This is because a court in the United States could well hold that such claims are limited to a product that is prepared by the specific process steps recited therein (or their equivalent)" (see *Product-By-Process Claims; Patentability and Infringement* by Abraham Rosner *et al* for more information).

The following hypothetical example sums up the main issues:

Company X makes an automotive component made of a composite material. It is formed in a series of four sequential process steps. The first two process steps are performed by Companies A and B in Asia. Thereafter, the article is imported into the US where the third and fourth process steps are completed by Company C, which neither performs nor is familiar with the first two process steps.

After this, the fully processed component is installed by Company D on an assembly line into its automobiles. There is no relationship or control between and among Companies A, B, C and D.

Company X owns a US patent that includes: a method Claim 1, which literally recites all four of the foregoing process steps, and a product-by-process Claim 2, which recites: "An automotive component product formed by the process of Claim 1."

Company X sends Company D a letter, alleging infringement of product-by-process Claim 2 and threatening to commence a patent infringement lawsuit if Company D does not immediately cease and desist from all such sales. Company D promptly seeks an exculpatory opinion from its patent counsel.

A US patent counsel seeking to provide Company D with an exculpatory patent infringement opinion covering the situation outlined will find the US law unclear and unsettled. In two different Federal Circuit decisions, summarised below, the three-judge panels of this patent court, as it is sometimes called, rendered decisions based upon differing reasoning.

> "FOR CLIENTS WISHING TO ENTER THE US MARKET WITH A PRODUCT, THERE WILL BE COMFORT FOR THOSE WHO FIRST OBTAIN A WRITTEN 'RIGHT TO USE' OR NON-INFRINGEMENT PATENT OPINION COVERING THEIR NEW PRODUCT PRIOR TO ITS INTRODUCTION."

In *Scripps Clinic & Research Fdn v. Genentech*, the Federal Circuit held that a product-by-process patent claim is not limited by the process steps recited therein. The panel of judges held that: "In determining patentability, we construe the product as not limited by the process stated in the claims. Since claims must be construed the same way for validity and for infringement, the correct reading of product-by-process claims is that they are not limited to product prepared by the process set forth in the claims."

The following year, in *Atlantic Thermoplastics v. Faytex*, the Federal Circuit in a similar case applied different reasoning. The panel held that product-by-process claims only cover products that are produced by the process steps recited in the claim. It stated that: "The court recognises that product-by-process claims will receive different treatment for administrative [USPTO] patentability determinations than for judicial [court] infringement determinations." A divided court, with four dissenting judges, denied a rehearing of the case.

Despite the uncertainty created by the conflicting reasoning in these decisions, we believe that the Atlantic decision, coupled with the court's historic commitment to the substantial sanctity of patent claim language, remains the most likely basis for continuing support by the Federal Circuit. Accordingly, an exculpatory opinion of non-infringement is both reasonable and sound under the circumstances of the example above.

Since, in the example, no single entity performs all four process steps, which US case law requires in order to establish the infringement of the elements of a product-by-process claim, there is no infringement. A valid argument can be made that, in order to meet the elements of a product-by-process Claim 2 in the example above, the party accused of infringing this claim must have carried out all of the process steps itself, possibly all in the US, which was not the case in the foregoing example.

The concept of the supremacy of patent claim language in determining the issue of infringement has been repeatedly reaffirmed by the US Supreme Court, including recently in *Warner-Jenkinson v. Hilton Davis* and reiterated by the Federal Circuit in *Phillips v. AWH*. Under this clear mandate, the omission of a single element of a patent claim will avoid infringement of that claim. Since, in the example above, the four process steps are embedded within product-by-process Claim 2, the fact that Company D did not perform all four steps means it avoids infringement.

While we await a further clarifying decision from the Federal Circuit directed to product-by-process patent claims or a decision of the US Supreme Court, we believe most district courts will follow the Atlantic decision, requiring infringement of the process steps. Those involved in the prosecution of US patent applications will be wise to avoid circumstances that may be later construed by the courts as estoppel in determining the scope of patent claims containing process elements.

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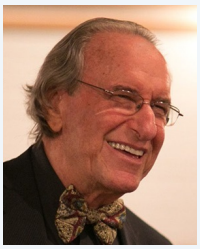

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Paul Sutton is the co-founding partner of Sutton Magidoff. With a Juris Doctor degree and four decades of IP experience, he was selected by *Super Lawyers* magazine in 2006, 2007 and 2008, and is listed in Strathmore's *Who's Who*. He is adjunct professor of law at Polytechnic Institute of New York University.